Promotion and Support of Implementation of Directive 2010/32/EU on the prevention of sharps injuries in the hospital and health care sector

Report of second regional workshop

Rome, 7 March 2013

Contents

With the support of the European Commission

1 Introduction

This document provides the report from the second regional workshop of the joint EPSU-HOSPEEM project on the Implementation of Directive 2010/32/EU on the prevention of sharps injuries in the hospital and healthcare sector (see http://www.epsu.org/r/629), which was held in Rome on 7th March 2013 (see http://www.epsu.org/a/9117 and http://www.epsu.org/a/9393).

1.1 Background of the project

A framework agreement on the prevention from sharp injuries in the hospital and healthcare sector was signed in July 2009 by the European sectoral social partner organisations – the European Public Services Union (EPSU) and the European Hospital and Healthcare Employers' Association (HOSPEEM). The social partners requested the Commission to submit the agreement to Council for a decision, in accordance with Article 155(2) TFEU. In 26 October 2009, the European Commission issued a proposal for a Council Directive containing the full social partner agreement as an annex. On 11 February 2010 the European Parliament supported the proposed Directive in a resolution and on 8 March the Council reached political agreement on its adoption. The Directive was published in the Official Journal as Council Directive 2010/32/EU of 1st June 2010 (L134/66). Member States have to implement the Directive by the 11th May 2013.

The Directive aims to achieve the safest possible working environment for employees in the sector and protect workers at risk, as well as patients, including prevention of injuries to workers caused by all types of sharp medical objects (including needle sticks). The Directive proposes the setting up of an integrated approach to assessing and preventing risks as well as to training and informing workers.

Clause 11 of the agreement concerning its implementation stipulates that the interpretation of the framework agreement could be referred by the Commission to the signatory parties, i.e. EPSU and HOSPEEM, for them to give their opinion. The European sectoral social partners also included the possibility to review its application five years after the date of the Council decision if requested by one of the parties to the agreement, an option which also supports the idea of an early and timely follow-up to allow for an informed decision making at a later stage. There is finally a formal obligation by the European and national sectoral partners to engage in and stay involved in appropriate follow-up activities including awareness-raising, monitoring and assessing the implementation process, participation in relevant committees and bodies responsible for the transposition.

Having in mind that the deadline of implementation approaches shortly, the aim of the project is:

a) To gather information on the transposition and implementation of the Directive at the national level;

b) To gather and exchange information about existing guidance and toolkits at the national and local level to help with the implementation of the agreement at the organisational level:

c) To learn about the practical issues being raised at the organisational level in the implementation of the agreement; how to deal with these issues and to learn from good practice.

1.2 Participating countries

The second regional workshop was held in Rome on 7th March 2013 with the participation of about 80 representatives of sectoral social partner organisations from Belgium (French speaking), Cyprus, France, Italy, Malta, Norway, the UK, and Spain. Further information on the event, including a full set of presentations can be found on http://www.epsu.org/a/9393.

1.3 Purpose of the report

The goal of this report is to summarise the discussions of the workshop.

2 Sharps injuries: a significant risk in the health care sector

There are 21 million workers active in the hospital and healthcare sector in Europe[1]. It is estimated that 1 million needle-stick injuries occur annually.[2] The number of other accidents with medical sharps is not known because they are even less likely to be recorded. It is not just medical professionals who are at risk. While hospital nurses and doctors working in acute medical situations are identified as being at the highest risk, many other workers have the potential to sustain these injuries such as nurses working in the elderly care sector, social workers (working with drug addicts for example) and auxiliary staff, for example cleaners, waste managers or laundry staff.

Both Italy and Spain report just under 100,000 sharps injuries in the health care sector per year. When looking at these figures it must be borne in mind that it is estimated that around 70% of such injuries go unreported for a variety of reasons, including workers blaming themselves, bureaucratic reporting procedures and a feeling that nothing is being done to address risks, even where incidents are reported.

With rising rates of HIV, Hepatitis B and C infections in the patient population, the risk of infection among health care staff is increasing. A positive development in the last decade in this regard has been the significantly improved regime of HIV prophylaxis and the higher rates of vaccination against the risk of Hep. B infection among health care staff. However, risk of Hep. C infection remains high and in Italy alone 30 cases of occupational Hep. C infection resulting from sharps injuries are reported by annum.

Detailed research has been carried out in Italy and Spain in relation to the risk factors and risk categories of workers most likely to suffer from exposure and indeed high risk exposure to infection as a result of sharps injuries. These studies show the general risk of exposure to be greatest among nurses, doctors and housekeepers in general surgery and surgical specialities, whereas the incidence of high risk exposure is most significant in general medicine and medical specialities (particularly among nurses). The risk factors for housekeepers are significant, given that such exposures are largely related to inadequate disposal of needles and sharp instruments.

Even where a serious blood borne infection is not acquired, nurses and healthcare workers can be subjected to many months of mental anguish and uncertainty as they await the results of their follow-up tests.

Independent studies show that the majority of these potentially fatal injuries can be avoided using a combination of training, safer working practices and medical technology incorporating safety features, e.g. needles with automatic protective sheaths.[3]

[1] Data from the Eurofound Report, 'Employment and industrial relations in the healthcare sector, February 2011, Dublin, accessed at: http://www.eurofound.europa.eu/eiro/studies/tn1008022s/index.htm

[2] Estimate comes from the European Agency for Health and Safety at Work (EU-OSHA), https://osha.europa.eu/en.

[3] For example Van der Molen et al (2012) Interventions to prevent needle stick injuries among health care workers, Work ; 2012, Vol. 41, p1969-1971, 3p

3 State of Play of Transposition

As part of the project, ICF GHK is carrying out a survey among social partner organisations. Among the answers received to date (end of February 2013), only three Member States have transposed Directive 2010/32/EU already, namely Austria, The Netherlands and Sweden. Denmark and Latvia are likely to implement the Directive prior the 11th of May 2013, while Italy, Ireland, the UK and Finland are most likely to implement it by the deadline. The competent government administration in countries such as Spain, Cyprus and Estonia are not aware of an implementation date.

Social partner involvement for the transposition was ensured in most of the countries that responded to the survey – as of end of February 2013. Most of the Member States chose to implement the Directive via legislation and supplement it with specific guidelines (or collective agreement). The Netherlands is an exception, as a national Guideline for the prevention of sharps injuries is in place since 2007; the transposition of the Directive was done via this Guideline. It is now up to the hospitals and health care sector to implement these guidelines at organisational level.

The survey has been carried out in connection with the organisation of the workshops (20 respondents from 12 EU Member States, 1 from Belarus and one from the Ukraine as of 6 March 2013, with the enquiry on-going) and more answers from social partners are expected in the coming months and this information will be updated for each regional seminar.

In 8 of the 12 Member States where responses are so far available, the level of change required to existing legislation is considered to be either moderate or significant, with the main alterations to existing legislative texts revolving around issues such as the ban on recapping, requirements for more specific risk assessment and the provision of preventative vaccination.

The majority of countries already have existing guidance on the prevention of sharps injuries and most countries where such guidance is not yet available, plan to issue it as part of the transposition and implementation of the Directive.

4 Good Practice and Challenges for Transposition and Implementation

The workshop mainly discussed progress in the transposition of the Directive, outstanding issues and relevant practice in the implementation of the provisions of the legislation at organisational level.

4.1 Key elements of good transposition

The following elements below are at the centre of good transposition (as developed also in the implementation guidelines by the European Biosafety Network, cf. http://europeanbiosafetynetwork.eu/) which was presented and acknowledged by participants of the workshop:

- Setting up of a monitoring body/ data surveillance body at national level – to ensure standardised reporting of injuries and control compliance of legislation
- Setting up of a health and safety committee at organisational level that represents management and workers to work on risk assessment, reporting procedures, choosing of safety devices, follow – up of use of new products, training of staff, procedures after injuries
- Standardised vocational training for all types of health care workers regarding knowledge of sharps injury prevention and reporting
- Banning of recapping on the basis of risk assessment
- Free vaccination of affected workers
- Standardised minimum requirements for safety devices (should be developed on the long term) and policy for safe working procedures
- Creation of a national working group including social partners, health and safety bodies, healthcare and social work representatives, producers of safety devices, training providers, researchers – working groups could as well be created at local/municipal level – to work on guidelines for risk assessment, safety products and safe working procedures, best practice exchange.

4.2 Transposition experiences

The following presentations held at the workshop highlighted current challenges of transposition of the Directive and experiences with the reporting and prevention of sharps injuries.

4.2.1 Italy

In Italy, many of the provisions of the Directive are already covered by existing legislative decrees. However, some amendments are required to fill some gaps highlighted by the EU framework agreement and subsequent Directive.

Legislative Decree 81 provides for the elimination of risk in line with risk assessment. It includes provision for the use of safety engineered devices.

New provisions will be added to chapter 10 of legislative degree 81 to ensure that its provisions also cover medical students. Furthermore, Article 286 on risk assessment will be amended to ensure that the risk of exposure to blood borne infections is taken into account.

The new draft legislation is complete, but the current political situation arising from the lack of an overall majority to form a new government (as a result of the general election that took place at the end of February 2013) brings an inevitable delay in the debate and passage of the amended law through parliament.

In practice, the implementation of safer work processes and equipment has been ongoing since the 1980s, with increasing awareness of the risk of HIV and Hep B and C infection (as the rate of such infections has grown in the patient population). Over the years, there has been a ban on recapping, the mandatory introduction of sharps containers, the introduction of personal protective equipment, enhanced awareness raising and training, and from the mid-to late 1990s, the increasing introduction of safety engineered devices.

Guidelines have been developed for risk assessment and procedures for recording have been improved and in some cases simplified.

Faster testing for exposure and better prophylaxis and treatment for affected workers has also helped to reduce significant health risks posed to workers suffering sharps injuries.

Since all these measures have been introduced there has been a significant reduction in the rate of injuries suffered, particularly where safety engineered devices have been used and safe containers for sharps collection have been made readily available.

The Italian experience shows that an integrated approach is to most effective way to work towards a sustainable reduction of sharps injuries. It was argued that the Directive has brought an important step forward towards ensuring the implementation of such an integrated approach.

4.2.2 France

In France, transposition of the Directive is foreseen by May 2013 and the law will cover 1.2 million employees in the health care sector, both in public and private sector institutions. Trade unions in the sector would be keen to see the application of the law expanded to cover not only hospitals but also clinics and health care workers working in patients' homes.

France already has a wide range of legislative measures relevant to the principles covered by the Directive. These include the Labour Code, the Public Health Code and various regulations applying to the hospital sector[4]. This also covers the issue of prevention (for example in relation to the vaccination of health care staff and the disposal of sharps).

The monitoring of the incidence of sharps injuries with blood exposure is the responsibility of a National Surveillance Institute established in 1998 (e.g. monitoring of risk of HIV, Hep B or C infection).

A committee has been established with the goal of reducing the risk of sharps injuries (*Réseau RAISIN*). This body was responsible for a 5 year action plan 2009-2013 with the goal of achieving a 25% reduction in exposures per 100 beds. Around 16,000 incidents with a risk of exposure to blood borne infections are reported per day, and this is bearing in mind that approximately 70% of such incidents are not reported.

In order to address the situation of under-reporting, it is suggested by the trade union representative presenting the case of France that reporting should be made mandatory.

In practice, hospital managers are responsible for establishing a prevention strategy and trade unions play an important role here in influencing and ensuring the implementation and monitoring of such strategies. Such strategies include steps towards prevention (including the introduction of safety engineered devices in high risk areas), steps for reporting, treatment, and – where necessary – compensation of affected staff.

The trade unions have particularly supported the use of a single document (in French: *document unique*) at organisational level which includes the initial risk assessment, the prevention plan and strategy for reducing and managing risks, as well as reporting and follow up actions. This process also includes a regular process of assessment of the level of

[4] E.g. Décret No 94-353 of 1994 on the protection of workers from exposure to biological agents; Circulate DGS/SH/DRT No 98/228 of 1998 on recommendations on anti-retroviral treatments following exposure to risk of transmission of HIV; Circulaire DGS/DH No 98/249 of 1998 on the prevention of the transmission infectious agents through blood or other biological liquids in a health care establishment; Circulaire DH/SL20DGS/VS3 No 554 of 1998 on the collection of sharps etc.

reduction achieved in sharps injuries and the next steps required to improve the existing prevention policy.

4.2.3 Spain

In Spain the Directive is set to be implemented in line with the deadline of May 2013 via amending existing legislation.

Current legislation allows for the prioritisation of intervention and in particularly the introduction of safety engineered devices in areas where risk factors are greatest. Detailed research has been done to demonstrate in which areas of work, among which staff and qualification levels the risk of exposure is currently greatest.

The importance of involving professionals in the design of safety-engineered devices was underlined, as well as the fact that it should be a requirement for companies marketing such devices to offer training in their safe use. Without such training, it is often found that the risk of injury initially increases as health care workers are unaware how to use the new devices.

The Spanish experience shows that with use of safety engineered devices in high risk areas, it has been possible to reduce percutaneous injuries suffered by 41%.

4.2.4 Norway

Norway faces a rather specific situation as all blood samples are taken by bio-medical scientists. There is a risk of the issue being overlooked as the prevalence of such injuries is not very high. According to the most recent data, there were 200 reported cases of sharps injuries in 2011, with an estimated 150 cases not reported.

According to a recent study, 50% of these accidents were caused by inattentiveness, but safety engineered devices could have prevented the injury. Currently such devices are primarily used in blood sampling (90% of such procedures use these devices), but in other procedures, safety engineered devices are only used in 5% of cases.

Norway will transpose the EU Directive in full, and public hearing is currently being organised by the Norwegian Labour Inspection Authority, with responses requested by 28th April.

Changes suggested to existing legislation are relatively limited and mainly relate to:

- Strengthening the duty to perform risk assessment
- Training of staff to include information on the risk from sharps injuries
- Safe containers to be made available to collect sharps
- Ban on recapping

The Norwegian transposing legislation is currently not proposed to go as far as the Swedish text. In cases where risks factors are identified the Swedish legislation requires the use of safety-engineered devices. In Norway, the legislation does not currently foreseen requiring the use of such devices.

4.2.5 Belgium

As in most countries, in Belgium there is some pre-existing legislation relevant to the provisions of the Directive and implementation of its provisions is likely to be done via an amendment of the Royal Decree on exposure to biological agents. A draft text for this amendment has been proposed by the cross-industry social partners on their own initiative, not involving the sectoral social partners signatories of the HOSPEEM-EPSU Framework Agreement on the prevention from sharp injuries in the hospital and healthcare sector of July 2009 transposed into Directive 201/32/EU. This is being questioned by the sectoral social partners in Belgium as the cross-industry social partners are not signatories to the European Framework Agreement. Furthermore the sectoral social partners were not involved in the transposition of the Directive, which only the cross-sectoral social partners participated in.

However, in principle the changes proposed are relatively minor and primarily serve to cover not only directly employed health care sector workers, but also workers of sub-contractors at risk of exposure to sharps injuries. Greater responsibility for workers to take care of their

health and safety (according to the individual level of training/qualification and pursuant the instructions given at a specific workplace by the employer) and to pursue relevant training, as well as the notification of sharps injuries at central level is also foreseen by the amended legislation. The use of safety-engineered instruments is not an absolute obligation, but where they are available, they have to be used.

4.2.6 Cyprus

A bill to transpose the Directive has been submitted to parliament. This would amend existing legislation.

Guidance on the prevention of sharps injuries already exists. It has been uploaded to the webpage (http://www.epsu.org/a/9157) showcasing available guidance, training material, films, etc, as for a range of other countries.

4.2.7 Malta

The Ministry of Health in Malta will be responsible for the implementation of the Directive.

One of the concerns expressed by the trade unions is over the coverage of the Directive which could be widened in order not only to cover the health care sector. The example of postal workers was given, as there have been incidents of injuries resulting from drug users disposing of needles into letterboxes.

4.2.8 UK and the work of the EBN

In the UK, UNISON has been involved in the setting up of the European Biosafety Network (EBN; cf. http://europeanbiosafetynetwork.eu/) as a response to the perceived reluctance by the Courts and by the government to recognise needlestick injuries as an occupational injury and to institute national legislation on the issue.

The EBN lobbied in a broader campaign to protect all occupations at risk from medical sharps injuries. The objective of the EBN in this regard is to work towards the prevention of sharps injuries by lobbying for legislation, sharing good practice and providing practical guidance for the workplace level.

The EBN brings together national and European professional institutions, representative associations, unions and other interested parties to develop guidance and share good practice in order to ensure that the Directive is fully transposed and then implemented at organisational level.

Trade union involvement in risk assessment is strongly encouraged and unions are considered to have an important role in encouraging workers to take part in training, comply with prevention provisions and to report any incidents of sharps injuries.

The EBN Toolkit has been designed around the requirements of the Directive.

In the UK, the Directive will be implemented through an amendment of existing health and safety legislation. As a statutory instrument, this can be approved through acceptance by a parliamentary Committee (see also report from the Dublin seminar, accessible via webpage http://www.epsu.org/a/9264).

The EBN is also keen to speak to other European employers such as CEEP and cross-industry trade unions such as ETUC to suggest that the principles of the Directive are also taken up in other sectors where there are risks from sharps injuries.

4.3 Challenges of Transposition

In the afternoon a discussion was held in plenary to address the following questions:

1. Are reliable data gathered at national/organisational level on the number of sharps injuries per annum (will this allow for a monitoring of a potential reduction of such injuries post-implementation)?

2. Are there any concerns about the transposition and subsequent implementation of the

Directive at national and organisational level, and if so, what are they?

3. How will practice at organisational level change as a result?

Please find below a summary of these discussions.

4.3.1 Data gathering

- Social partners share the concern that injuries are under-reported – certainly for sharps injuries – it is also a question of procedure and which deadlines for reporting need to be respected.
- Clinicians are also concerned about this because prophylaxis in a case of (potential) exposure must start within one hour of the injury occurring in order to be most effective.
- Processes for reporting must be robust, but not so bureaucratic and multi-faceted as to put workers off from reporting injuries.
- Individuals must feel that something is done with their report on how and why the injury occurred in order to reduce risk in future. Otherwise the impetus to report is reduced.
- Often injured persons blame themselves and do not want to report “their mistake” – this type of ‘blame culture’ must be effectively addressed.
- Simply making reporting mandatory is insufficient, as this is already the case in some countries, but has not helped to increase the extent to which injuries are reported.
- Examples at the hospital level were presented of an anonymous reporting procedure which could still feed into process improvements.
- Training on reporting should be already in the initial training – in order to create awareness.

4.3.2 Challenges of transposition

- Small Member States in particular face difficulties in covering the higher purchasing cost of safety engineered devices. Although greater use can lead to lower costs, order sizes (often going hand in hand with more centralised procedures of public purchase or procurement, on the various levels) can have a significant impact.
- It was emphasised that when looking at costs it is important not only to bear in mind the cost of implementing the requirements of the Directive, but also the cost of injuries occurring.
- The importance of training for the use of safety-engineered devices was emphasised. It was considered that this should be the responsibility of the manufacturer.
- Several participants, representing the trade union side, considered that the application of the Directive should be wider than the health care sector alone, to cover other workers potentially exposed to sharps injuries, e.g. those working in elderly care, social work and prison services.

4.3.3 Implementation in practice

- It is really up to the organisational level to implement the necessary procedures and measures of control. Committees for health and safety, or responsible managers, need to be in place in order to process and follow-up on organisational change and risk assessment;
- When standardisation of equipment occurs concerned workers should be consulted.
- Purchase departments and procurement should take into account the experiences of workers and devices should always be available and not change too often.

- Good practices regarding personal attitudes of workers to deal with sharps and needle sticks require also leadership from hospital managers – it is often a cultural change to adapt behaviour and attitudes – cannot be influenced by legislation alone.
- Awareness raising and information campaigns should be organised and easy to access material be provided – such materials have been developed by trade unions in Spain and in other countries.

5 Forthcoming Events

Further regional seminars will be held in Vienna on 16th of April with participants from Austria, Bulgaria, Czech Republic, Estonia, Germany, Hungary, Latvia, Luxemburg (German speaking), Poland, Romania, Slovakia, and Slovenia, as well as Switzerland (German speaking), Bosnia & Herzegovina, Croatia, Kosovo, Macedonia (FYROM), Montenegro, Serbia, Belarus, Russia, and Ukraine. A closing conference will take place in Barcelona on the 20th of June 2013.

A report will be prepared following each event.