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 first regional workshop

Dublin, 31 January 2013

Contents

With the support of the European Commission

1 Introduction

This document provides the report from the first 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 Dublin on 31st January 2013 (see http://www.epsu.org/a/9118 and http://www.epsu.org/a/9264).

1.1 Background of the project

A framework agreement on 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 first regional workshop was held in Dublin on 31st January 2013 under the participation of about 90 representatives of sectoral social partner organisations from Belgium (Dutch speaking), Denmark, Finland, Ireland, Latvia, Lithuania, the Netherlands, Sweden, the UK, and Iceland. Further information on the event, including a full set of presentations can be found on http://www.epsu.org/a/9264.

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.

In the UK, 5822 occupational exposures to blood or other high-risk body fluids were reported since 1997 in England, Wales and Northern Ireland. From 2002 to 2011, 4381 incidents have been reported from 172 centres (increasing from 276 in 2002 to 541 in 2011), nearly three-quarters (72%, 3140/4381) of reported injuries between 2002 and 2011 were percutaneous injuries. In suffering an injury from a contaminated needle, the risk of transmission of infections is 1 in 3 healthcare workers for hepatitis B, 1 in 30 for hepatitis C, and 1 in 300 for HIV.[3] Yet, data are gathered in different manners or at different levels and can vary significantly from 68 reported incidents in Sweden in 2010 to between 13,000–15,000 in the Netherlands for example. It should also be kept in mind that data seem to be gathered separately for needle-sticks and sharps.

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.[4]

[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] Data retrieved from the Health Protection Agency (2012) Eye of the Needle Report.

[4] 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 January 2013), only two Member States have transposed Directive 2010/32/EU already, namely The Netherlands and Sweden. Denmark and Latvia are likely to implement the Directive prior the 11th of May 2013, while 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. In Ireland, the goal is to implement by the deadline of May 2013, but negotiations are still ongoing and outstanding issues remain to be resolved.

Social partner involvement for the transposition was ensured in most of the countries that responded to the survey - as of end of January 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 (15 respondents from 6 EU Member States, 1 from Belarus as of 24 January 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.

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/) 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 Ireland

Early in 2012, the Irish Health and Safety Authority (HSA) launched a stakeholder consultation on its draft Safety, Health and Welfare at Work (Prevention from Sharps Injuries in the Hospital and Healthcare Sector) Regulations. The impact assessment of the Irish HSA states the following: *The impact of transposing the Directive through the proposed new Regulations is expected to be minimal given that many of the obligations already exist in principles expounded in the Safety Health and Welfare at Work Act 2005 and the Safety Health and Welfare at Work (Biological Agents) Regulations 1994 and amended Regulations. The proposed new Regulations apply the same principles specifically to the issue of sharps injuries but are more explicit with regard to certain obligations such as the preparation of a risk assessment for sharps, switching to safety engineered devices, information and training on new devices and a ban on the practice of recapping sharps. The analysis concludes as many of the obligations are already in existence most healthcare employers will only need to extend existing practices to those areas where changes have not yet been implemented*.

The scope of the draft refers to all employees working in the hospital and health care sector. This includes self-employed and unpaid interns. The risk assessment should be carried out

by the employer in consultation with the employees. The employer should take into account in the assessment available technologies reducing risks, work organisation in place and the experience of the employees. If risks are assessed the employer has the duty to eliminate or reduce them by preventive procedures, prohibition of recapping, training, awareness raising, procedures if injuries occur, provision of safety devices and provide for safe transportation of sharps devices at the workplace.

The employer would have a general duty to provide training. Employees need to report any incident to the employer, while the employer has the duty to report incidences that result in employee absences of more than 3 days and those that present a high risk of contamination to the national Authority.

Free vaccination should be provided to workers that are exposed to high risks.

In case an accident occurs employers have to ensure counselling.

At this stage the draft has not turned into legislation and further steps need to be taken. The Irish Congress of Trade Union (ICTU) has been quite satisfied with the draft, finding that the provision of free vaccination for workers is a step forward, as well as the risk assessment in consultation with employees. There are concerns regarding current interpretations on the provisions on recapping, having in mind the clinical reality and the practicability of the procedure and rules spelled out in the directive. Furthermore, trade unions are more generally worried about the impact of budget cuts in the health care sector on the implementation of the provisions of the legislation.

The presentation by a Health and Safety Expert from a local Irish hospital demonstrated that hospitals keep reports on sharps injuries and already apply prevention measures and procedures. Internal research showed that even if great health and safety standards are in place, injuries still occur simply because of human factors. For example, not applying training or resistance to new technologies or methods can be a factor. Similarly, purchase and procurement departments are sometimes bound by contracts that would not allow for a change of product, or sometimes stock is not replaced and new products are not always displayed and stored where they are most likely to be used. It was remarked that safety devices are not always proven to be “safest” as accidents occurred by using them indicating that further research and development is needed by the providers side. Finally, even if the injury as such presents a low risk but it is mainly the psychological stress created for the worker that causes longer term impacts.

4.2.2 The Netherlands

As mentioned above the Netherlands has already implemented the Directive by amending the national Health and Safety Law (Arbo) through two new articles: obliging hospitals to switch to safety needle systems and by the ban of recapping.[5] In addition to legislation the Guidelines for the prevention of needle stick injuries apply. However the scope of the Guidelines is more restrictive as the Directive since it applies only to the hospital sector. It is left to the hospitals to implement the necessary procedures and the spirit of the Directive. The national Labour Inspectorate will carry out controls from 2014 onwards. The main elements of the Guidelines state that employers have to provide for safe working conditions, need to introduce safety devices wherever possible without costs playing a predominant role.

A report published 2008 by the National Hepatitis Centre recommended that hospitals should focus on information and training to reduce costs for new purchases and use available devices as much and for as long as possible as reconversion of needle sticks does represent quite an important cost. Furthermore it was recommended to establish a health and safety committee at hospital level involving management, workers and their representatives in order to establish a safe environment in which workers would feel as well safe. This has the benefit that working environments will cause less insecurity and stressful situations.

[5] Besluit 399 van 22 augustus 2011, houdende wijziging van het Arbeidsomstandighedenbesluit in verband met opname van regels uit de Beleidsregels Arbeidsomstandighedenwetgeving

4.2.3 Sweden

The Directive has been implemented in Sweden already via amending existing legislation. The country has started initiatives already in the late 90s to promote health and safe work environments, creation of Safe Communities, which included risk assessments also with regard to exposure of blood borne viruses. Nevertheless, the number of needle stick injuries has not significantly dropped (difficult to assess, as no national data is available and information is only gathered at organisational level). Therefore research is currently carried out to assess what needs to be done in practice to reduce the number of injuries.

A project was undertaken in Sweden to speak to employees that had reported a needle stick injury in order to find out when accidents occur, what kind of training was received and information was available prior the accident and what kind of steps were taken as follow-up of the accident. The outcome of the interviews was that most of the workers blamed themselves for the accident; had a rather poor knowledge on ban of recapping; the use of safety devices and safe working procedures existed; but incidents were poorly followed up by managers and were not discussed though often incidents lead to long term anxiety and fear.

The project furthermore organised workshops with national stakeholders to determine best practices and develop measures that should be included in a strategy. The main challenges that were identified: environment – how to reduce plastic waste from safety devices; how to use safe waste bins correctly; how to balance costs for products and safe work procedures; how does patient react to safety procedures – should be as well good for the patient; finally how to implement organisational responsibilities for procurement of safety devices, reporting and follow- up. In order to answer these questions staff working routines, organisational structures and education aspects will further be studied and researched.

The project will be finalised end of 2013.

4.2.4 Finland

The Finnish tripartite Advisory Committee in the Ministry of Social Affairs and Health decided to set up a sub-committee in early 2011 to work on the implementation of the Directive and to assess which national regulations would need to be amended in order to propose amendments. The sub-committee was composed of various stakeholders such as social partners, municipal authorities, and safety device producer organization. The task was quite complex as in Finland there are already 17 regulations that address parts of the principles of the Directive. In the beginning of the assessment it seemed that most of the principles were already applied in Finland and no substantial amendment needed to be made. When the chair of the committee provided the first draft of a decree to the committee the employers remained opposed to the proposal. Consequently, negotiations were prolonged until early 2013 and no final agreement has been reached so far.

The most debated issues were: 1/ risk assessment and elimination of risk of sharps injuries, providing for safe working procedures – here it was discussed what are safe devices and safe working standards at this moment not much experience exists; 2/ place technically safe waste bins for sharps, 3/ vaccination free of charge for affected workers; 4/ and finally reporting and follow-up after injuries occurred. The debate concerned also the scope of the Directive on how to practically implement standards for the health care sector, nursing homes and social work sector – as it was not clear what can be also considered as a sharp instrument (for example acupuncture needles) and what is a safe waste bin for example in home care.

4.2.5 UK

Many of the underlying principles of the Framework Agreement are already included in current UK legislation and practice. The UK has national working groups that promote safe working policies with regard to needlestick injuries such as the Safer Needle Network. Reporting is in place in most of the hospitals, ensured via specific software (EPInet) that is to guarantee in the future standardised reporting. The UK Health Protection Agency publishes every 2 to 4 years the “Eye of a needle” report on surveillance of significant occupational

exposures to blood-borne viruses for healthcare workers. Nevertheless, most of the rules in place are more of a generic nature. For example, employers are already required to undertake risk assessments to assess the risks to the health and safety of their employees. However, the Directive goes further and requires a risk assessment specifically for sharps injuries and requiring certain elements to be considered in that risk assessment. The Directive will have a similar impact in relation to safe practices, information sharing, training and reporting.

The starkest change in UK law will be the immediate banning of the practice of recapping or re-sheathing needles. Whilst this is a practice that is frowned upon in the healthcare sector, it is not, yet, specifically outlawed. It is anticipated that national guidance, including the NHS Handbook and Department of Health Guidance, will be updated to reflect the more specific standards set out in the Directive.

End of the year 2012 the Health and Safety Executive (HSE, body that regulates health and safety at the workplace) launched a stakeholder consultation on the proposed draft to implement the Directive. The draft had been developed after an inspection campaign by the HSE in 21 hospitals and an evaluation of safety devices. The inspection report concluded that in the majority of hospitals policies were in place to reduce employee's exposure to blood borne viruses however in a minority of hospitals all staff were aware of risks and their responsibilities. The HSE has inspection powers and has in October 2010 prosecuted an NHS trust after a healthcare worker contracted the Hepatitis C virus after injuring herself on a needle used to take blood from an infected patient. The trust was fined £12,500 plus £9,000 costs. The evaluation of safety devices concluded that their use reduces incidents when combined with training and safe workplace policies.

Trade Unions found that the current draft is not yet satisfactory with regard to the scope – the current draft regulation would only apply to healthcare workers and not to auxiliary staff such as cleaners – and also not to those working in social care, a sector not covered by the health sector according to UK legislation and administrative practice (as confirmed by the NHS representative participating in the seminar, see also 4.3.2); furthermore recapping is not yet banned for all sharps devices; no broad working group to establish accompanying code of practice and guidelines involving social partners; finally reporting responsibilities seem to be imposed on employees only in the draft which does not reflect the spirit of the Directive.

4.3 Challenges of Transposition

In an afternoon workshop participants were split up into mixed national groups to discuss 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
- Often injured persons blame themselves and do not want to report "their mistake"

- NL suggested anonymous reporting via a hotline – which would take necessary steps afterwards regarding investigation and follow-up;
- Social partners expressed their concern that the wording of the Directive might leave to much room for interpretation and implementations might not be as intended by the spirit of the text, for example as regards recapping and its ban with immediate effect;
- Hospitals in the UK, IE, SE, FI, NL have procedures for reporting already in place – the question is rather what happens afterwards to the data that was gathered – if it is not used at a central level it does not make sense to precisely monitor incidents; data should be gathered in a standardised manner at national and European level to allow for comparability;
- Questions were raised regarding what needs to be reported – what type of injury – to whom to be reported, which formalities would need to be complied with – reporting should not be too time consuming, reflections about how to create a "no blame" culture;
- Central data – monitoring and follow-up can be costly for some countries especially in times of austerity
- Training on reporting should be already in the initial training – in order to create awareness.

4.3.2 Challenges of transposition

- Eastern European Member States find that reporting and training obligations can be too costly – public budgets are limited and cuts in the public health sector are announced, safer products could be too costly; also social partners from other Member States expressed their concerns over the costs of implementation and tight public budgets – cost-efficient solutions need to be promoted and found;
- If no investments on health and safety devices will be made at national or organisational level – risk assessments need to take this into account and more prevention measures might need to be applied which can be as costly as buying the products;
- More standardisation of training is needed so that all types of nurses and medical assistants receive appropriate training;
- Question about sanctions if organisations are not complying with legislation – who will oversee and control implementation, what are appropriate sanctions;
- Tendering procedures for health and safety devices should not just take into account the price but also what is the safest device for workers and patients – intuitive and passive devices often reduce the need for training;
- Some workers are still excluded from the scope of the Directive – such as those dealing with waste management – how can protection be provided;
- Implementation regarding social work sector or nursing homes or elderly care in out-patient services can be difficult as health sector and social work sector are governed separately – difficult to standardise procedures and devices for both sectors – especially for nurses working in home care there are no immediate solutions available – each doctor prescribes the type of insulin pens for example she/he prefers – use of a special waste bin can be difficult in practice;
- What is a safety device – incidents occur also because of safety devices – the Directive is not specific what this should mean, what are standardised criteria;
- What is a correct risk assessment – setting up procedures might be again costly for organisations;

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 voice of workers and devices should always be available and not change too often;
- Reporting need is already high among health care workers if reporting is further to be increased – will reach a transparency paradox leading to over reporting;
- 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 – short films on safe working standards could be helpful – is also not very costly.

5 Forthcoming Events

Further regional seminars will be held in Rome on 7th of March with participants from Belgium (French speaking), Cyprus, Greece, Italy, Luxemburg (French speaking), Malta, Norway, Portugal, and Spain as well as Switzerland (French speaking) and Turkey; and on 16th of April in Vienna with participants from Austria, Bulgaria, Czech Republic, Estonia, Germany, Hungary, Latvia, Luxemburg (French 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.