BIOSAFETY IMPLEMENTATION GUIDEBOOK

DRAFT

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1. - INTRODUCTION

Sharps and needlestick injuries represent one of the most common serious risks for healthcare professionals throughout Europe, as well as a high cost for healthcare systems and society in general.

Healthcare personnel (nurses, physicians, surgeons, etc.), especially those involved in some specific departments and activities (emergency care, intensive care, surgical interventions, etc.) and non-healthcare personnel linked to this sector are often forced to face the risk of infection due to injuries caused by needlesticks and other sharps injuries (scalpels, suture equipment, etc.). The ensuing consequences can be serious and provoke dangerous diseases such as viral hepatitis or aids.

According to research, the number of needlestick injuries amounts to 1,200,000 cases per year in Europe.

In the community strategy for health and safety at work (2007-2012), the Commission announced its intention to continue its work to improve risk prevention, among other things, relative to needlestick infections, by consulting European social partners pursuant to Article 139 of the EC Treaty.

The European Parliament has expressed on several occasions its concerns for the health of healthcare personnel who manipulates contaminated needles.

The European Parliament resolution of 24 February 2005 on the promotion of health and safety at the workplace requests a review of Directive 2000/54/EC with a view to tackling risks stemming from the manipulation of needles and other medical sharp instruments.

On 6 July 2006, the European Parliament adopted a Resolution on the protection of European healthcare workers from blood-borne infections due to needlestick injuries. In this Resolution the Commission was urged to table –

pursuant to Articles 137 and 251 of the EC Treaty – a proposal for a legislative directive to amend Directive 2000/54/EC on biological agents at work.

According to Article 138, Part 1, of the EC Treaty the Commission shall promote the consultation of social partners at community level and adopt all the relevant measures to facilitate dialogue and monitor that both parties receive a balanced support. To this end, before tabling social policy proposals, the Commission shall consult employers and workers (i.e. European social partners) on the possible orientation of EU action and the content of the proposal under discussion. On the other hand Article 138, Part 4, of the EC Treaty establishes that social partners shall be able to inform the Commission about their will to start the process enshrined in Art. 139 of the EC Treaty which involves setting up a dialogue at community level that could lead to conventions and agreements.

On 21 December 2006, the Commission launched the first consultation phase with the European social partners. The second phase was launched on 20 December 2007.

In the consultation document social partners were asked to: 1) provide their opinion on the objectives and the content of the legislative and non-legislative initiatives foreseen; 2) notify the Commission, if it is the case, their will to engage in negotiations pursuant to Article 138, Part 4, and Article 139 of the EC Treaty.

In a joint letter of 17 November 2008, EPSU (European Federation of Public Service Unions) and HOSPEEM (European Hospital and Healthcare Employers Association) informed the Commission about their intention to negotiate a framework agreement for the prevention of sharps injuries in the healthcare field.

Since the Commission fully acknowledges the autonomy of European social partners to negotiate issues that fall within their sphere of competence, the drafting of a legislative proposal for a directive aimed at amending Directive

2000/54/EC on biological agents at work was suspended while awaiting the outcome of the negotiations between the social partners.

On 2 June 2009, the social partners reached an Agreement.

On 17 July 2009, EPSU and HOSPEEM signed the text of a Framework Agreement for the Prevention of Sharps Injuries in the Healthcare Sector and informed the Commission about their will to submit it to the Council for decision pursuant to Article 139, Part 2, of the EC Treaty.

The actions undertaken are consistent with the EU public healthcare policy. The white paper «Together for health: a strategic approach for the EU (2008-2013) » highlights that patient safety is an important issue of concern. All measures aimed at protecting the health and safety of workers in the healthcare sector contribute to enhance the quality of the services rendered to patients and reduce the possibility of adverse effects derived from the healthcare received.

2. - DEFINITION OF CONCEPTS

2.1. - Biosafety: set of rules or attitudes aimed at preventing accidents in the workplace and reducing potential occupational risks. It can also be defined as the set of preventive measures to be adopted by healthcare staff to avoid the transmission of occupational illnesses.

2.2. - Occupational risk

2.2.1. - Risk: the likelihood of an individual to suffer an injury, a disease or a related complication, or die as a consequence of the exposure to a risk factor.

2.2.2. - Occupational risk: the risk a worker is exposed to in his working facilities while performing his job.

The frequency of accidental exposures of healthcare workers and other related staff to infectious agents such as the Human Immunodeficiency Virus

(HIV), Hepatitis B and C virus (HBV and HCV) and other blood-borne illnesses or diseases transmitted through infected liquids depends on their activity, their attitude towards biosafety and the specific conditions of their work or the risk factors they are exposed to or their information or the education and training received in this field. The risk of transmission implies the presence of an infectious agent which is transmittable and triggers an organic response.

Therefore a third of the accidents reported occur when individuals try to reintroduce needles in a syringe or when they try to put them in the protective sheath. The other two thirds are caused by cuts, other types of injuries or mucocutaneous exposure.

2.3. - Risk factors: all the human elements, substances, procedures and actions relative to the working setting that some way or another put workers at risk of suffering an injury. These risk factors can be found at the source, the environment or in individuals themselves. Their main feature is that they can be brought under control.

2.4. - Biological risk: any accidental inoculation or contact of the skin or mucosa with blood, tissue or any other body fluid potentially infected with biological agents that workers could suffer while performing their work.

2.5. - Preventive actions in the field of biological accidents: action procedures established with a view to curbing or, given the case, eliminating biological accidents within the set of activities or measures that should be adopted and foreseen in all the activities of the company to avoid or reduce risks at work.

2.6. - Safety products: healthcare safety-engineered protection devices designed to eliminate or minimize biological accidents. Safety products have to comply with specific criteria.

2.7. - Biological agent: microorganisms, including those genetically modified, cell cultures and human endoparasites, capable of causing any type of infection, allergy or toxicity.

2.8. - Surveillance system for biological accidents: a standardized, systematic and continuous register of data on biological accidents as well as its analysis, interpretation and use in order to plan, implement and assess programmes to prevent occupational risks.

3. - OBJECTIVES OF THE EUROPEAN PROPOSAL

3.1. - MAIN OBJECTIVE

To have the safest possible working environment as well as to prevent injuries caused by medical sharps including needlesticks to both healthcare and non-healthcare personnel, to protect the staff at risk in the healthcare sector and to curb, as a result, the economic cost derived from the occupational health and safety problems. This should also help to achieve the general objectives of the Lisbon Strategy on Growth and Employment, especially as regards economic growth and employment.

3.2. - SPECIFIC OBJECTIVES

- To set up an Observatory on sharps injuries;
- To develop a biosafety best practices guidebook relative to the legislative implementation of the Council Directive on the Prevention of Sharps Injuries;
- To provide guidance and assistance to Member States with a view to adopting the most appropriate method and legislative text for the implementation of the Directive;
- To try to ensure that the guidelines linked to the Directive are phrased so as to ensure the biggest impact on the largest possible number of workers and sectors;
- To ensure that best practices regarding sharps injuries, in the interest of the health and safety of all workers, are expanded beyond the healthcare system whenever possible;

- To devise programmes involving mentors for EU emerging States on the development of best practices for the implementation of the Directive;

-To create the European Biosafety Day to be celebrated every year.

4. - FIELD OF APPLICATION

The biosafety best practices guidebook is aimed at those healthcare professionals, students, teachers, auxiliary staff, etc. who work in healthcare centres facing occupational risks directly or indirectly.

5. - REGULATION IN FORCE IN THE FIELD OF BIOSAFETY

5.1. - EU REGULATION

89/391/EEC Council Directive, of 12 June 1989, relative to the implementation of measures aimed at promoting the improvement of workers' health and safety at work establishes general preventive measures for the protection of their health and safety. It lays down the minimum requirements as regards, among other things, risk assessment and information, as well as training and consultation. In particular, Article 6 of the Directive establishes the general prevention principles which are mainly: «to avoid risks», «to combat risks at source» and «to replace what is dangerous with what entails little or no danger». Apart from Directive 89/391/EEC, some specific directives are also applicable to the prevention of infection risks of healthcare personnel as well.

Directive 2000/54/EC of the European Parliament and of the Council, of 18 September 2000, on the protection of workers against the risks of exposure to biological agents at work (seventh specific Directive pursuant to Part 1 of Article 16 of Directive 89/391/EEC) includes provisions aimed at preventing such risks and establishes the minimum specific requirements in this field. It also lays down the duties of employers as regards risk prevention. More specifically, in any activity entailing a risk of exposure to biological agents, the characteristics, the degree and the duration of the exposure of workers shall be

established with a view to assessing the risks posed to their health and safety and identifying the adequate measures to be adopted.

Directive 89/655/EEC of the Council, of 30 November 1989, concerning the minimum health and safety requirements for the use of work equipments by workers at work (second specific Directive pursuant to Part 1 of Article 16 of Directive 89/391/EEC) (amended by Directives 95/63/EC8 y 2001/45/EC9) is aimed at improving the safety of workers who use work equipment, such as hospital medical equipment. Employers should use work equipment on the basis of the working conditions and the risk posed to workers with a view to eliminating or minimising such risks.

Directive 89/656/EEC of the Council, of 30 November 1989, concerning the minimum health and safety requirements for the use by workers of personal protective equipment (third specific Directive pursuant to Section 1 of Article 16 of Directive 89/391/EEC) establishes that personal protective equipment shall be used when risks cannot be avoided or sufficiently limited by technical means of collective protection or by measures, methods or procedures of work organization. All personal protective equipment shall be appropriate for the risks involved, without itself leading to any increased risk.

In addition, they must be appropriate to the existent conditions at the workplace and fit the user correctly.

It should also be highlighted that Annex I, Part II of Directive 93/42/EEC of the Council, of 14 June 1993, concerning medical devices, lays down that «the devices and manufacturing process must be designed in such a way as to eliminate or reduce, as much as possible, the risk of infection to the patient, the user and third parties. The design shall allow easy handling and, where necessary, minimise contamination of the device by the patient or vice versa during use» (point 8.1).

Any marketed product must have previously obtained the EC label certifying its compliance with the essential requirements of this Directive.

5.2. STATE OR REGIONAL REGULATION

There exists regulation at regional level laying down and implementing the relevant safety procedures and a surveillance system for biological accidents in different Regions of the Kingdom of Spain.

This is the case of the Autonomous Region of Madrid, the Autonomous Region of the Balearic Islands, the Autonomous Region of Navarra, the Autonomous Region of the Canary Islands, the Autonomous Region of Castile La Mancha, the Autonomous Region of Galicia, the Autonomous Region of Catalonia and the Autonomous Region of Andalusia.

6. – LEGAL BASIS FOR THE EUROPEAN PROPOSAL

The proposal is based on Article 139, Part 2, of the EC Treaty.
Article 139, Part 2 establishes that the agreements reached by social partners at community level in the fields pursuant to Article 137 of the EC Treaty shall be applied, «at the joint request of the signing parties on the basis of a decision adopted by the Council following a proposal made by the Commission». It also lays down that «the Council shall decide by qualified majority except if the agreement under discussion has one or more provisions concerning some of the fields enshrined in Part 3 of Article 137, in which case the decision shall be taken by unanimity».

The aim of the Agreement reached by HOSPEEM and EPSU is to have the safest possible workplaces by avoiding medical sharps injuries (including needlesticks) to workers and protecting them at risk. Therefore it aims at ensuring «a concrete improvement in workplaces to protect the health and safety of workers», i.e. a field that abides by Article 137 of the EC Treaty and thus the Council can take a decision by qualified majority. Therefore Article 139, Part 2, of the EC Treaty is the appropriate legal basis for the proposal of the Commission.

This Article does not foresee the involvement of the Parliament in the legislative procedure. However, on the basis of previous commitments, the Commission shall inform the Parliament about its proposal so that the latter can - if it wishes to – submit an opinion to the Commission and to the Council. The same applies to the European Economic and Social Committee.

7. – ANALYSIS OF RISK FACTORS

Risk factors are represented by all the elements, substances, procedures or human actions present in the working environment with the capacity to, one way or another, provoke injuries to individuals or material damages to the workplace. Such risks can be found at the source, the environment or the individuals, and their main feature is that they are easy to bring under control.

Biological factors are the ones that pose a higher risk to healthcare personnel though ergonomic and psychosocial risks can also affect the development of work.

7.1. – ERGONOMIC RISKS

Some examples of such risks could be poor illumination or poor design of the workplace and its furniture, as well as body postures and positions while performing tasks because they lead to errors as a result of lumbagos, inflammations, circulatory disorders, etc.

7.2. - PSYCHOSOCIAL RISKS

These risks are due to unexpected changes experienced by an individual in his/her working environment leading to health damage.

7.3. - BIOLOGICAL RISKS

However, biological risks are the most important ones among all the existent risk factors in the healthcare field due to the variety and great

aggressiveness of the microorganisms involved (bacteria, virus and fungus), which cause occupational accidents or diseases.

Among the variable dangerous risks healthcare personnel face – which are potentially lethal – the following can be highlighted: the risk of contracting infections due to the presence of pathogens at work or other non suspicious agents present in the samples received at labs. These agents pose a primary risk to the worker and sometimes to the community as well.

Biological risks lead to acute and chronic infections, to parasitism and to toxic and allergic reactions.

The following are considered to be among the most frequent causes of infection in healthcare personnel:

- Occupational accidents while manipulating devices;

- Negligence or incompliance with the relevant rules and procedures while manipulating devices;

- Unavailability of appropriate protection means;

- Personnel lacking adequate education and training;

- Time pressure / high working pace;

- Undertaking procedures or tasks in uncomfortable postures;

- Having to perform several tasks at the same time;

- The presence of colleagues sharing the same space while working;

- Lack of space at the workplace.

The following is the breakdown of these factors into the areas of work (medical, surgical, primary healthcare and general services) according to a

research study carried out in the Autonomous Region of Madrid (Spain) during the years 2007, 2008 y 2009:

As for medical specialties, the most recurring factor contributing to accidents is time pressure. As regards the frequency, this factor was followed by: having to perform the task in uncomfortable postures, having to carry out many tasks at the same time, patients moving during the task, stress and lack of enough space at work.

As for surgical specialties, the most frequently mentioned factor was time pressure. This factor was followed by: having to perform the task in uncomfortable postures, the presence of colleagues sharing the same space at work, having to perform many tasks at the same time, stress and tiredness.

As for primary healthcare, the most frequently mentioned factor was having to perform the task in uncomfortable postures. The subsequent factors were: the patient moving while performing the task, lack of cooperation of the patient, time pressure and lack of safety garments / devices.

It should be highlighted that time pressure / high working pace is a widely notified factor in all areas of specialised healthcare (medical and surgical specialities as well as in other services) and in primary healthcare.

And concerning **healthcare personnel, nursing staff** together with nursing auxiliary personnel suffered 60% of sharps injuries. Medical personnel suffered 25% of such accidents and specialised lab technicians suffered 3% of them. The rest - 12% - was suffered by other healthcare professionals and non-healthcare personnel working in the different centres.

83.7% of sharps injuries occurred in hands or fingers.

8. – BIOSAFETY PROGRAMME

8.1. – PREVENTIVE ACTIONS IN BIOLOGICAL ACCIDENTS

Those in charge of healthcare centres shall adopt the necessary provisions to implement effectively the relevant actions aimed at reducing or eliminating the impact and seriousness of accidents involving biological agents.

To this end, the Services responsible for the Prevention of Occupational Risks shall implement actions considering the following activities:

To draft a protocol and plan all processes and actions relative to biological accidents;

To disseminate this action protocol to managers, services, workers and their representatives ensuring it is known throughout the hierarchical line;

To implement safety-engineered devices to prevent biological accidents;

Education, training and information of workers on the prevention of biological accidents putting special emphasis on the importance of complying with the universal precautionary measures;

To implement a surveillance system for biological accidents that enables a systematic and continuing assessment of such risks and of the preventive measures adopted;

To plan the necessary preventive measures for biological accidents including the relevant technique, work organization and conditions, as well as the impact of environmental factors on the workplace.

8.2. Implementation of safety-engineered devices to prevent biological accidents

Those responsible for healthcare centres shall adopt the relevant preventive measures concerning biological accidents in accordance with the following general principles: avoid risks, assess unavoidable risks, take into

account the evolution of techniques and replace what is dangerous with what poses little danger or no danger at all.

Those responsible for healthcare centres shall consult workers in due time before taking decisions on the introduction of new technologies. This consultation shall embrace all aspects concerning the potential consequences for the health and safety of workers relative to the choice of new equipment.

Those responsible for healthcare centres shall plan the introduction of such material gradually so that these new costs can be assumed according to the implementation timeline established.

This gradual implementation and replacement shall be carried out considering simultaneously the following two criteria:

- The impact of traditional devices in terms of frequency of inoculations attributed to them;

- The impact of traditional devices in terms of the potential seriousness of the inoculation. According to this criterion, in the first implementation phase, priority will be given to those devices that act directly on veins or arteries.

A list of safety-engineered products to be gradually implemented is included in **Annex 1**. This list is an orientation and shall be continuously updated in accordance with future technological developments.

Safety-engineered devices shall comply with the minimum requirements listed in **Annex 2.**

8.3. - Education, training and information

The epidemiology of occupational accidents due to accidental inoculations shall be known as well as the relevant costs.

The main national and international initiatives on the prevention of occupational risks due to accidental inoculations shall be known.

The key procedures and strategies to improve practice and safety in the working environment shall be known and acknowledged as well as the main features that safety-engineered devices should have in order to be eligible in calls for tenders.

Workers shall know how to use the main safety-engineered devices safely.

Workers shall know the normalized action protocol in force in case of biological accidents due to an inoculation.

Services responsible for the prevention of occupational risks in healthcare centres shall promote adequate measures to educate and train healthcare personnel in the use of safety devices and products, as well as to implement safer working practices.

In addition, such services shall promote educational programmes aimed at healthcare personnel with a view to identifying the risks associated with blood-borne pathogens, among others, and periodically remind the existing occupational risks. These programmes shall stress safe practices as regards safety and hygiene, as well as cleaning and decontamination of working places.

All this shall be developed in the framework of an education and training programme following at least the following indications:

- Key notions on biological risks. European regulation and State regulation if it exists;
- Best practices. Precautions. Active and passive protection measures;
- Action protocols for biological accidents. Study of costs;
- Descriptive study on biological accidents;

- Actions by hospital centres, healthcare centres and others, as well as by the Ministry of Health, with a view to avoiding accidental inoculations;
- Waste management;
- Analysis of safety-engineered devices. Education and training workshop;

All professionals at risk of exposure to biological agents shall receive all the relevant information on the prevention of occupational risks as required by the applicable legislation.

Professionals' representatives shall participate in this education and training process through their associative, corporate and representative organizations.

8.4. – Surveillance system for biological accidents in healthcare centres

Healthcare centres, through the Services responsible for the Prevention of Occupational Risks, shall implement a register of biological accidents according to the indications provided by the competent authorities. This standardized register shall include the time and space variables of the accident, the material agent, the injury mechanism and the contributing or concurring factors.

The Services responsible for the prevention of occupational risks shall keep this information, send it to the European Observatory on Sharps Injuries, undertake an epidemiological analysis and disseminate the outcome ensuring the following principles:

- Do not apply or use the data for any other aim than for epidemiological surveillance purposes;

- Do not distribute copies of individual data to third parties, either completely or partially;

- Adopt the high level safety measures implemented in their healthcare centre;

- Do not identify individually workers who have suffered an injury;

- Adopt the necessary technical and organizational measures to ensure data security and prevent data alteration, loss, treatment or unauthorised access;

- Always publish the data in an aggregated manner.

8.5. – Actions in case of biological accident

8.6. – Actions in case of infected material spillages

When infected or potentially infected material is spilled, the professional shall put on gloves and cover the spilled fluid with absorbent paper, put decontaminating solution around it and conclude the process by putting decontaminating solution on the paper and letting it work for 10 minutes.

Use dry and clean absorbent paper to lift the material and throw it into the contaminated waste container for its subsequent elimination. The surface shall be rinsed with decontaminating solution.

The use of alcohol is not recommended since it evaporates quickly and coagulates superficial organic rests without penetrating into them.

Gloves should be worn during the whole disinfection process and contact with the spilled and disinfected material should be avoided.

Sharps injuries and contaminated skin due to splashes of infected material shall be washed with plenty of water and disinfecting soap. Bleeding of the wound shall be favoured.

If a worker suffers a parenteral infection or his/her the mucous membranes get infected by blood or body fluids, the material in question shall be identified and the presence of virus or antibodies shall be determined if

possible. The worker in question shall notify any acute fever disease that occurs within twelve weeks of the exposure.

8.7. – Proper use of protective elements

Latex gloves shall be worn in all procedures involving the manipulation of biological materials or were the risk of exposure to blood or fluid exists. Gloves shall also be worn in the processes for the decontamination and disposal of contaminated rests.

Once contaminated, gloves shall be properly disposed of and replaced by another pair. Contact with eyes, nose or skin should always be avoided.

Masks should be used in procedures involving the risk of biological material splashing to mouth and nose mucus.

8.8. - Management and disposal of contaminated waste

All the equipment used (needles, cannulas, tubes, etc.) shall be put in a sharps resistant metal or plastic container. Wide containers with rigid or semi-rigid walls and safety lid for their subsequent destruction and with decontaminating liquid shall be preferred. In addition, containers shall be put in the working place. Material shall be disinfected with chemicals before cleaning it and putting it in the autoclave.

10. - CONCLUSIONS

Around 75% of accidental inoculations can be avoided through several simultaneous preventive strategies.

On the other hand, replacing traditional sharps by safety-engineered devices would prevent part of these accidents.

In addition to this principle of preventive action consisting in replacing what is dangerous by what is little dangerous, best practices should be

promoted systematically and continuously, as well as education, training and the provision of information; workers should be involved in the preventive strategies; safe working methods should be implemented and working settings should be improved

It is unlikely that an isolated action has a clear impact on decreasing the accidents toll and therefore this issue should be tackled in a fully comprehensive way.

Finally, including preventive measures and a systematic notification and analysis of accidental inoculations allows to: know the magnitude of the problem, analyse trends, assess concrete measures and actions and implement preventive policies aimed at improving working conditions as well as the health and safety of workers.

11. - BIBLIOGRAPHY

ANNEX I

INDICATIVE TABLE OF SAFETY PRODUCTS

Safety-engineered devices

- Safety needles adaptable to blood extraction systems with vacuum tubes
- Covers for vacuum extraction
- Adaptors for multiple extraction vacuum systems
- Safety peripheral catheters.
- Simple and bifurcated safety valves for catheters
- Hypodermic safety needles
- Syringes with safety needle for gasometry purposes
- Needles with extraction flaps
- Needles with safety flaps for peripheral cannulas
- Safety needles for arteriovenous fistulas
- Safety needles for reservoirs
- Blunt needles
- Insulin syringe with a safety needle embedded

- Automatic safety lancet for adults
- Automatic safety lancet for paediatric use
- Safety devices for capillary incisions
- Needle counter
- Disposable containers
- Preloaded sterilized syringe in single blister to wash intravenous tubes

ANNEX II

MINIMUM CONDITIONS FOR SAFETY-ENGINEERED DEVICES

- The structure of safety-engineered devices shall always be aimed primarily towards eliminating sharps;

- Safety-engineered devices shall never compromise the health of the patient;

- The safety mechanism shall be embedded in the device in all cases;

- When the safety-engineered device is turned on the user shall receive an audible, tactile or visual sign;

- It shall not be possible to turn off the device. And the protection mechanism will be effective till the device is put in a sharps container;

- Whenever it is possible, devices shall be turned on by healthcare professionals using just one hand;

- Safety-engineered devices shall be compatible with other accessories that might be used;

- The safety-engineered devices shall be easy to use, practical, reliable and efficient to achieve their purpose.