The EU Directive: what it is, and what are its implications

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The European Federation of Nurses Associations (EFN) was established in 1971 and is the independent voice of the profession. The EFN consists of National Nurses Associations from 34 EU Member States, working for the benefit of 6 million nurses throughout the European Union and Europe. The mission of EFN is to strengthen the status and practice of the profession of nursing for the benefit of the health of the citizens and the interests of nurses in the EU & Europe

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On World AIDS Day, in December 2004, thirty nurses from nine member states, who had been victims of needlestick injury, visited the European Parliament for a series of meetings with Members of the Parliament and with the European Commission. The Parliament heard some very moving stories about life-changing injuries, all of which could have been avoided. This work prepared the EFN's lobby work in 2005-2006 on the amendments to the Biological Agent Directive 2000/54/EC leading to the adoption in July 2006 of the Stephen Hughes own-initiative report and the Parliament Resolution 2006/2015 in which MEP Liz Lynne became the champion for change. In 2008, the EFN provided input to the public consultation on the revision of the Medical Devices Directive, to the second stage consultation on needlestick injuries, and wrote a letter to the EU Commissioner for Employment, Social Affairs and Equal Opportunities, to express the EFN's concerns about the delay of more than two years in the publication of an amendment to Directive 2000/54/EC, on the protection of workers from risks related to exposure to biological agents at work. In July 2009, EFN welcomed the binding agreement signed by the European Social Partners, the designated EU representatives of healthcare workers (European Public Service Union, EPSU) and healthcare employers (European Hospital and Healthcare Employers' Association, HOSPEEM) on the prevention of sharps injuries in the hospital and healthcare sector. This was central to the June 2010 adoption of the new European Directive 2010/32/EU to be incorporated into national law in all EU member states by 11 May 2013. So, on May 12th 2013, on the International Nurses Day, we should wake up to go to work with the implementation and effects of the directive established.

The Directive covers eliminating the re-capping of needles, the provision of safety devices, disposal of devices, involving health care staff in selecting safety devices, rapid post-event activities and the recording of sharps injuries. One key area to build your business case on is the Risk Assessment (Clause 5) carried out by trained clinical staff with expertise in occupational health. It is within this context that national governments can support by offering expertise on the methodology of risk assessment. There is no need to re-invent the wheel.

The Directive Clause 6 relates to elimination, prevention and protection which are the core organs of the Directive. Based on the risk assessment report all risks must be eliminated by the consistent introduction of safety devices, sharps bins and safe procedures for using and disposing of sharp medical instruments and contaminated waste. Nurses, in all working settings, need the equipment at their disposal to protect themselves. Public procurements are an essential part to implementing this clause.

Furthermore, healthcare professionals and workers need to be trained about risk assessment and controls and the proper procedure for using the medical devices and disposal equipment (Clause 8 Training). Continuous professional development sessions and developing the occupation of a 'sharps injury link nurse' will be important developments within the health safety strategy designed and implemented by nurses. Additionally, as the impact is not restricted to healthcare workers the involvement of patient representatives and input is essential to the training packages. Through the sharp injury directive, nursing IT skills can be explored further by developing e-learning tools. The Spanish General Council of Nursing, an EFN member, has already shown great leadership in developing a model of biosafety education and training programme which aims to equip healthcare workers with competencies on biosafety and the necessary competencies to act correctly in case of an accident or an emergency. The model also focuses on using e-health tools to teach teachers and inform 'link nurses', bringing to the forefront innovative and cost-effective solutions. As a result, this e-learning tool is paving the way for other EFN members to develop similar models at national level.

In addition to the employer taking appropriate measures to raise awareness amongst workers and their managers, coalition building at national level is essential (Clause 7 Information and Awareness Raising). It is important to establish a coalition of stakeholders to engage in policy design and implementation. The Coalition can disseminate information and raise awareness about sharps injuries and the preventative measures in the Directive 32. Bringing together governments, regulators, nurses organisations, employers and manufacturers and politicians, in addition to strengthening the employer-worker social partnership in each working environment is an effective way to target and focus resources where they are most needed to achieve change so EU law becomes 'fit for practice'. A national/regional/local media campaign will need to raise awareness of the issue amongst the public as well as healthcare workers although e-health application tools are way more important to create contact with the public.

Finally, it is important to report. Most member states have reporting systems but the culture to register varies between member states. While some voices say that 'you need to be obliged and punished if you do not report', evidence shows this does not make sense. It is important to install a culture of 'no blame, no shame'. As complacency is one of the major challenges for implementing change, it is important that the nursing workforce engages to be open, transparent and challenging the 'no blame, no shame' established culture will be the antidote for complacency. The International Council of Nurses also understands that early identification of risk is key to preventing patient harm and so a system-wide approach is strongly supported, based on a philosophy of transparency and reporting - not on blaming and shaming the individual care provider – and incorporating measures that address human and system factors in adverse events (EuNetPas, 2008). Building on the workforce views and experiences, it leads

the Professional Nurses Associations to keep on lobbying their Minister of Health and the Minister of Employment to monitor implementation. When doing this, national representatives are shocked to find that governmental civil servants lack the knowledge of Directive 32, its purpose and the key components. The Minister, health, employment or finance, is apparently taking the view that the majority of the requirements of the Directive are already present in national law, so their intention is to make only minor changes to existing law. One of the reasons for us now having the important benefit of this Directive is because the European Parliament and the Commission agreed that the general worker safety national legislation in the Member States, that is linked to existing Directives on worker safety, work equipment and workers exposed to biological agents, has proved to be largely ineffective in protecting health care workers from potentially fatal injuries from contaminated needles and other medical sharps. For this reason, the European Parliament requested a specific Directive to address this problem. After many years of advocacy and lobbying, it becomes a new challenge to ensure that the Directive is fully and consistently implemented in all Member States by 11 May 2013, requiring that national law includes significant penalties for non-compliance with the requirements.

The EFN has always urged the EU to assist Member States in the effective implementation of the Directive and Member States should make use of the Social Cohesion Funds to facilitate this process. Social Cohesion Funds can provide the financial backing necessary for Member States to transpose the directive into national legislation, and to monitor its implementation and the effects thereof. The Social Cohesion Funds for the period 2014-2020 will be crucial in ensuring this and EFN members will, as always, be pro-active and engaged in ensuring that they have the necessary funding to successfully apply tools and methods to sustain the implementation of the Directive. Based on the designed business case for implementation, financial considerations are not an excuse for Member States not fully implementing the Directive, and there are legal precedents (e.g. in Scotland in 2004) that state that cost alone cannot be used as a reason for not adopting engineering controls or changing work practices to comply with European health and safety directives. Nevertheless, it is time to build capacity to 'start following the money' to access EU funding. 'The Social Cohesion Funds are rarely used for health - only 3% was spent on health. Local authorities often lack the capacity to access the necessary financial support to bring about a positive change that will benefit not only nurses but the whole public health system.

Each Member State, together with the Commission, agrees on one or more Operational Programmes for European Social Fund (ESF). EFN has followed the political discussion in the European institutions in preparing the 2014-2020 budget (EU Multiannual Financial Framework 2014-2020). Nevertheless, funds can still be allocated in 2013 to the Educational Development for Quality Nursing Care and Patient Safety and, in particular, continuous professional development for Patient Safety, in addition to developing new skills within the EU agenda for growth, competitiveness, and employment. Stakeholders should contact the ESF Managing Authority - usually a department of employment or technical agency of government to explore preparing a concrete file. If there is still available funding in the Member State budget for the current period, then beneficiary organisations can apply for funding now in order to prepare for the implementation of the Sharps Directive. Although it is anticipated that the implementation of the Directive and its transposition into national legislation of the Member States

should be cost-neutral, any change in practice towards safer systems or work implies investment. But as we all know; “investment in health is wealth” (David Buyrn, 2005)