Conclusions

What might the conclusion be, if these several strands are considered together? EU legislation is now irreversibly in train, in less than three years or so, all healthcare organisations throughout Europe will be legally obliged to comply with the new Directive, which specifically mentions “providing medical devices incorporating safety-engineered protection mechanisms.”

It is also a fact that some healthcare organisations – in both public and private sectors – have recognised a compelling business case for conversion to safety devices straight away. They reasoning usually contains, in order of importance, the factors: they understand the NHS costs can be substantial, when treatment, lost working time, and staff turnover are taken into account. They have constructed a business case for conversion to safety devices which is at least cost-neutral, if not delivering actual savings. They also wish to send damaging legal action, costly compensation claims, and adverse publicity, all of which is far better avoided from day one.

Finally, those heading healthcare organisations need to create an environment for staff and clinicians which provides proper protection against injuries. At all at best following, and at worst can create carnage.

You can also obtain further copies of this Manifesto for Safety, or an electronic version for distribution to colleagues, by contacting: safety@europe.bd.com

References

1. Examples include, Medisch Centrum Haaglanden, Atrium Medisch Centrum Heerlen, Laboratoires GEN-BIO, Matérial de prélèvement,尖刺, sharp or breakable devices should be replaced by safer engineered devices designed to help prevent injuries and infections to healthcare workers. Infection Control and Hospital Epidemiology 2007;28:1352-60.


A Manifesto for Safety

A New Directive has been published by the EU, specifically designed to help prevent injuries to healthcare workers from sharp objects such as needles and intravenous catheters. Estimated by the EU to “cause more than one million injuries each year”, the prevention of needlestick injury has become an issue that all healthcare organisations throughout Europe have to address. The new Directive, which must be transposed into national law in each Member State by May 2013 at the latest, specifically talks about “providing medical devices incorporating safety-engineered protection mechanisms”, since numerous studies have demonstrated their key role in reducing needlestick injuries.

In order to help European healthcare organisations build the ethical and business case for conversion to safety-engineered devices, this short document lays out the key issues around needlestick injury, including:

• More than one million injuries each year
• A review of current local legislation
• Achieving cost neutrality or even cost savings through conversion to safety devices
• Samples of compensation claims and court awards resulting from needlestick injuries
• Best practice in converting to safety devices, along with a selection of what constitutes a safety-engineered device

The basic reasoning of the Directive is to protect their employees from sharp injuries, and compliance will be mandatory. Despite health budgets being under pressure across Europe, many healthcare organisations have been able to construct a robust financial case for conversion to safety devices. Some healthcare organisations have already converted, in order to provide a safer working environment for staff, to improve the quality of their institutions, to eliminate the cost of treatment and staff absence, and to send damaging and expensive legal action.

“more than one million injuries each year”

“A Manifesto for Safety

European Regulatory and Adoption Overview

Across Europe, the use of safety-engineered needles and catheters is very uneven, as it is applied and implementation of existing laws and regulations. The European Directive will significantly increase harmonisation across Member States on the needlestick issue and will go a long way towards creating a safer working environment for healthcare workers. In Germany, usage of safety devices in hospitals varies widely, despite the assertion in various studies that needlestick injury incidence may be as high as 500,000 per year. In Germany primary care, where most biological samples are drawn, safety device usage is also low. The exceptions are where pioneering laboratories have taken the initiative to provide general practitioners with blood sample collection kits, incorporating safety devices.

In Germany, the use of safety-engineered sharp is mandated by the Technical Rule 250-13 in cases where it can be guaranteed that the patient being treated does not carry a bloodborne pathogen, “Biological Agents in Health Care and Welfare Facilities” (TB 355, 1993). TRB 255 was developed by the Committee on Biological Agents (Schweizerische Arbeitsgemeinschaft für Arzneimittel, SAGA), an initiative of the German Federal Ministry of Economics and Labour. In paragraph 4.14 of TRB 255, it is demanded that, sharp, spike or breakable devices should be replaced by suitable devices or methods which have no risk at all of causing needlestick injuries. Nonetheless, the use of safety devices in general practice has remained low, due to the fact that treatment, lost working time, and staff turnover are taken into account.

Despite health budgets being under pressure across Europe, many healthcare organisations have been able to construct a robust financial case for conversion to safety devices. Some healthcare organisations have already converted, in order to provide a safer working environment for staff, to improve the quality of their institutions, to eliminate the cost of treatment and staff absence, and to send damaging and expensive legal action.

The European Directive will go a long way towards creating a safer working environment for healthcare workers.”

Accruals


Die Welt, A needlestick decides, 5th July 2005, quoting Andreas Wittmann, Department of Occupational Medicine and Infection Protection, University of Tübingen.

Ordonnance No 2010-49 du 13 Janvier 2010 relative à la biologie médicale

Boletin Oficial de la Comunidad de Madrid., Orden 827-2005

ISPESL – Istituto Superiore per la Prevenzione e la Sicurezza sul Lavoro LINEE GUIDA SUGLI STANDARD DI SICUREZZA E DI IGIENE DEL LAVORO NEL REPARTO OPERATORIO, December 2009

“NSI costs can be substantial, when treatment, lost working time, and staff turnover are taken into account.”
In Spain, five of the autonomous regions have now made the use of safety-engineered devices a legal requirement. Evidence from the Madrid region shows that the original legislative initiative in the Madrid region has been adopted by the majority of healthcare institutions.

The regulatory governing medical laboratories in both the public and private sector have recently changed, allowing consolidations between laboratories. Moreover, laboratories will have to meet stringent quality control (ISO 15189). In this new environment, a number of medical biology laboratories in the private sector have implemented safety-engineered medical devices as part of their quality system compliance with ISO 15189 guidelines and to provide safe working conditions for their staff and patients.

In Italy, recommendations to eliminate the risk of needlestick injuries and infections resulting in potentially expensive hospital stays, as well as some organisations have come purely ethically. This varied approach to healthcare workers wanting to work for reputable institutions with safer working conditions has been adopted by a number of leading Trusts that have converted to safety device policies on the basis of measured business case, for example, safer working practices and the use of medical devices is both affordable and cost effective.

Every Spanish study also found that “savings in injuries and infections have much higher value than additional costs of a possible profit-making” (safety-engineered sharps injury prevention devices). A Spanish study reported that “the expected life in a hospital for a Spanish sharps injury in the workplace is about €40 million, with a further €130 million costs because of increased staff churn.”

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