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### The Cost-Effectiveness of Protection Systems for Sharps

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Figure 1: Blood collection system with a retractable needle guard (Bioscan Dichtsystem)

Uniform European rules are in place to regulate the key elements of occupational health and safety, with Article 118a of the European Treaty underpinning European minimum standards for health and safety in the workplace. The Federal Republic of Germany transposed European law in this area by means of the Occupational Safety Law, which has since been amended and complemented by a series of further regulations. It also introduced a Biological Agents Regulation to implement the requirements set down in EU Directive 2000/54/EC for the protection of employees from biological agents. This regulation explicitly refers to the danger posed by biological agents in human samples and the risk of injury arising from procedures of this nature.

The medical device industry now offers an array of products for percutaneous interventions which significantly reduce the risk of needlestick injury. Known as safety engineered devices, these products offer a range of safety features for sharps, including simple needle guards (Figure 1), sophisticated retraction systems in which used needles are pulled into a sheath using a spring mechanism and assistive devices that render sharps harmless immediately after use.

In 2003, the European Agency for Safety and Health at Work formally called for these types of safety systems to be introduced in the healthcare sector. Partly as a result of this statement, the European Parliament adopted a resolution in June 2006 calling on the Commission to make the use of safety engineered instruments mandatory at the earliest possible date. One of the reasons for the parliamentary resolution was the consistently positive results to have emerged from the United States since a law was introduced in 2000 obliging healthcare providers to use safety engineered sharp systems.

In Germany, paragraph 4.2.4 of Technical Rule 250 - Biological Agents in Healthcare and Welfare Facilities - requires that safety devices be used where the risk of infection or accidents is high (prisons, accident and emergency departments, the ambulance service and in the treatment of safety patients with life-threatening infectious diseases or at risk of causing harm to others). They are also prescribed where procedures are likely to result in the transmission of a quantity of blood or other bodily fluid sufficient to cause infection. The paragraph specifically refers to drawing blood and all percutaneous procedures for the collection of bodily fluids.

#### Additional Costs Arising from the Use of Safety Designed Devices

It subsequently transpired that the principal obstacle to the introduction of these modern safety products was their significantly higher cost when compared to conventional devices.

We calculated these costs by posing a set of questions to ten manufacturers using a hypothetical maximum care hospital with 1,000 beds. It was estimated that for 2003 the additional cost of switching to safety products would be  $\text{€}156,000$ . The corresponding figure for the same hospital for 2006 was  $\text{€}116,000$  or  $\text{€}116$  per bed. Using these figures, the anticipated additional cost of introducing safety devices across Germany, where the hospital sector has 530,000 beds, would be roughly  $\text{€}61$  million.

#### The Costs of Needlestick Injuries

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There is a tendency to overlook the high costs associated with needlestick injuries, contingent on the prevalence of key infectious agents, hepatitis B immunisation rates among staff and the possibility of testing the source patients. Our working group at the Bergische University of Wuppertal in Germany calculated the individual cost of a needlestick injury to be €487 per reported incident, of which the hospital must bear a cost of €147. When the administrative costs incurred as a result of a reported NSI are taken into account, the costs to the hospital are significantly higher. A recent German study identified the cost to one hospital per reported NSI to be €1,601, of which €754 was recouped from the accident insurance company.

International studies cite broadly comparable figures. For example, a Swiss author has produced figures in the range of €356 to €3,465, while an American research team put the cost of each reported NSI at between €630 and €785 (figures are based on prevailing exchange rates at the time of publication). Using a mathematical model developed at the University of Wuppertal and the Niederrhein University of Applied Sciences, it is possible, for the first time, to calculate the estimated costs of unreported needlestick injuries. The economically relevant costs of an unreported NSI are €79 (undiscounted) and around €52 when discounted over 30 years. These can largely be attributed to the high treatment costs associated with long-term illnesses.

Number of Reported NSI	Number of NSI after Introduction of Safety Devices	Hospital Savings	Insurance Company Savings	Savings Hospital + Insurance Company	Savings Insurance Co. Additional Costs for Hospital
400	60	50.000 €	166.000 €	216.000 €	166.000 € 66.000 €
300	45	38.000 €	124.000 €	162.000 €	124.000 € 78.000 €
200	30	25.000 €	83.000 €	108.000 €	83.000 € 91.000 €
166	25	21.000 €	69.000 €	90.000 €	69.000 € 95.000 €
100	15	13.000 €	42.000 €	54.000 €	42.000 € 103.000 €

*Table 1: Economic cost-benefit analysis for the introduction of safety devices in a 100-bed hospital with 166 reported needlestick injuries per annum; costs per NSI of €487, of which €147 are direct costs for the hospital. The additional costs for safety products of approx. €116,000 will only be recouped if all savings arising from a reduction in the number of needlestick injuries (i.e. savings for both the hospital and the insurance provider) are treated in combination.*

#### Cost-Effectiveness of Safety Devices

Recent studies demonstrate that the use of safety engineered devices reduces needlestick injuries by around 85%. The costs of a NSI are closely correlated with immunisation rates among staff, where as to the prevalence of dangerous pathogens among patients is less significant. Cost benefit calculations were carried out for the hospital in question based on the known figures on the prevalence of dangerous pathogens and staff immunisation rates.

The figures show that the introduction of safety engineered devices would not be cost-effective in the hospital. Even if the level of needlestick injury reporting were to increase significantly, the hospital's accident insurance provider would stand to benefit from any savings accruing (Table 1).

Only about one tenth of the estimated 500,000 needlestick injuries in Germany are reported each year. The total cost of NSI to the country is approximately €47 million per annum (€23 million in unreported NSI and €24 million in reported injuries).

#### Discussion

Safety products designed to prevent needlestick injuries reduce the number of expensive injuries. The costs of NSI are largely borne by the statutory health insurance providers, although it should be noted that their expenditure and income are financed by employers. When further potential savings associated with the use of safety products are taken into account, for example, the option of allowing pregnant women to perform tasks from which they have generally been precluded due to the high risks of infection (taking blood and giving injections), the change-over to safety products could, in some cases, already make economic sense.

The economic cost of NSI in Germany only slightly outweighs the anticipated additional cost of introducing safety devices nationwide. Moreover, given that the price of these products has already fallen by more than 25% over the past three years, rising demand will probably mean that the introduction of safety engineered devices will be cost neutral in the foreseeable future.

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