

Health and Safety Executive Board		Paper No: HSE/08/60	
Meeting Date:	25 th September 2008	Fol Status	Fully Open
Type of Paper:	Above the Line	Exemptions	None
European Commission measures for protecting healthcare workers from infections due to needlestick injuries			

Purpose of the paper

1. The European Commission is considering a legislative proposal on infections arising from needlestick injuries in healthcare workers.
2. The Board is asked to endorse the proposed UK line and influencing strategy set out in paragraph 16.

Background

3. The European Commission (EC) has consulted the social partners on the potential exposure of European healthcare workers to blood-borne infections from needlestick injuries¹. The EC has quoted studies estimating the number of needlestick injuries at around one million per year in Europe, and is considering a possible amendment to the Biological Agents Directive (2000/54/EC). Most of the recommendations the EC is considering, such as education and training, are already reflected in British law and good practice (Annex 1). Needles, cannulae and sharps are not only used in treatment of people, but for animals, and there may be implications in possible extension of legislative measures to workers exposed to needlestick injuries while working with infected animals.
4. The EC has also commissioned an EU wide impact assessment which should be completed in the summer of 2008; initial findings indicate a voluntary agreement between employers and employees to tackle this issue is appropriate (a non-legislative approach). Such an initiative is still possible as the social partner dialogue has been extended to allow for further discussions, although the EC has recently written to employer representatives indicating a preference for a legislative approach. If a draft proposal amending the Biological Agents Directive is taken forward this is likely to appear in October 2008.
5. Broadly, employers' representatives question the need for any new Community legislation, and have proposed that such a move is not necessary as existing legislation already affords appropriate protection. They would rather the emphasis be placed on the more effective application of the current legislation, information and awareness-raising activities and the promotion of best practice in this area. On the whole, employees' organisations (Royal College of Nursing (RCN), UNISON, and the Safer Needles Network) have been in favour of a Community initiative in the form of legislation, taking the view that, while the existing legislation covers the risk in general terms, more specific legislation would reinforce worker protection. There is an appetite for safer medical devices from all perspectives, though this is already required by existing law.

¹ Information on the EC Social Dialogue process and papers on the EC needlestick injuries consultation can be found at http://ec.europa.eu/employment_social/social_dialogue/consultations_en.htm.

Argument

Scale of the problem

6. Injuries from needles and other sharp instruments contaminated with patients' blood can transmit more than 20 infectious diseases; for those liable to cause very serious illnesses such as hepatitis B or C, or AIDS the consequences can, of course, be grave. There are no effective vaccines for Hepatitis C or HIV.
7. Needlestick and sharps injuries, where there is a known exposure to an infectious agent/blood-borne virus, are recorded statutorily through RIDDOR and voluntarily via the Health Protection Agency's surveillance of significant occupational exposure to blood-borne viruses in healthcare workers database². The data from both indicate that incident reports are rising - figures for 2005/06 are 91 and 232³ respectively. This rise may be as a result of increases in exposure or greater reporting of incidents as underreporting is significant.
8. National Health Service (NHS) employers report approximately 40,000 needlestick injuries a year, and recognise that the true figure could be as much as double this. The RCN estimate 100,000 needlestick injuries a year. The number of formally documented instances of occupational disease from needlestick injuries are shown in the table below:

Year	Number of needle related occupationally acquired diseases (RIDDOR)
2002/03	0
2003/04	0
2004/05	1
2005/06	1
2006/07	3
2007/08	0

9. Antiviral post-exposure treatment, given as a prophylactic, can have significant side effects, and employee representative organisations highlight the psychological distress and trauma which can be caused by a needlestick injury.

The Legislative Framework

10. The relevant existing legislation⁴ is largely EU based. The Biological Agents Directive requires that risks from exposure to biological agents, including those associated with needlestick injuries, be effectively managed. Employers are required to assess and manage the risk to their workers from needlestick injuries. They must properly consider worker health and safety when designing work processes and by providing suitable equipment, such as safer needle

² Database covers England, Wales and Northern Ireland.

³ Percutaneous injuries include those sustained through needles, other sharp instruments, human bites and human scratches.

⁴ The Health and Safety at Work etc Act 1974, the Control of Substances Hazardous to Health Regulations 2002 (COSHH) and the Management of Health, Safety and Welfare Regulations 1999 cover control of infection measures.

devices, finger shields and sharps bins. Additionally PUWER⁵ requires employers to ensure work equipment is suitable for the work to be carried out. In deciding what is suitable the employer must consider the hazards which exist in the particular workplace. Analysis of each of the proposed measures being discussed indicate that the majority are covered by the European legislative framework at a general level (Annex 1). Two specific measures currently not provided for in the legislation are the prohibiting of recapping needles and provision of post-exposure prophylaxis. These measures are in GB's NHS guidance but this may not be the case for other Member States.

Impact of the proposed measures.

11. In general, the measures under consideration by the Commission are all covered by GB law, guidance and good practice. However, the introduction of safer needle technology has been slow and accounts for only 5% of all relevant instruments used in the NHS (England). Safer needles technology is more costly and resource is required to introduce, monitor and evaluate the effectiveness of the new instruments. This resource commitment should reduce with greater experience of their use and potentially lower costs from more orders. Studies in Europe and the USA indicate that safer needle technologies can significantly reduce injuries. This has been shown in both voluntary initiatives, and those before and after the introduction of relevant legislation in the USA (Needlestick Safety and Prevention Act 2001). However, it should be noted that safer needle technology can fail, and can also cause needlestick injuries when not backed up by appropriate training and education.
12. NHS employers (England) recognise needlestick injuries as an issue. They distributed 4000 guidance leaflets on prevention of needlestick injuries in 2005 to support their published guidance (chapter 19 of the NHS 'Blue book'). This guidance advocates among other measures the use of safer needle technology. However, needlestick injuries have not been a priority for NHS employers. Instead, they have been working actively with HSE to tackle NHS and national health and safety priorities of stress, musculoskeletal disorders, slip trips and falls, and violence and aggression. HSE has served a number of improvement notices on needlestick injuries in the past, with one prosecution case in 2003 (involving a child). Over the last few years HSE has targeted its activities on areas of greater risk, reflecting its strategic aims.

UK line and influencing strategy

13. Needlestick injuries are an ongoing issue. HSE staff believe that employers need to do more to reduce the incidence of needlestick injuries. Increased use of suitable equipment (i.e. safer needle technology), improved education and training and higher levels of awareness of the risks and preventive measures are needed. HSE Field Operations Division is considering fresh enforcement initiatives, which could provide impetus to reduce risks in this area, but this action needs to be balanced against other priorities.
14. Given that the existing legislation has not yet been effective in reducing the incidence of needlestick injuries, HSE staff are sceptical that yet more law will be effective in stimulating the behavioural change necessary. Moreover, legislation will take some years to be negotiated and implemented, while nothing is done in

⁵ The Provision and Use of Work Equipment Regulations 1998

practical terms in the meantime to reduce the injuries. Finally, the impact assessment (annex 2) indicates that the costs and benefits of both a legislative and a non-legislative are roughly equal. Staff therefore believe that the initial UK influencing strategy should be to oppose any Commission legislative proposal. Instead, the UK should argue for a vigorous Europe-wide campaign to encourage employers and workers to work in partnership to secure the better implementation of the existing legislation.

15. Nevertheless, we also need to be realistic. Staff sense that there may be an appetite amongst some other member states for more legislation and we need to start thinking ahead on the UK's possible negotiating strategy. As a fall-back position, the UK should argue for minimal changes to the European legislation, that changes should not duplicate other provisions in law, and should reflect our existing risk-based goal-setting approach to legislation.
16. While we recognise that needlestick injuries are an important issue, we believe a non-binding initiative to improve the implementation of the existing framework would be a more proportionate, effective and quicker approach to addressing the issue. We recommend seeking to influence the EC, the European Parliament and other Member States on this basis.

Consultation

17. The Department of Health, the Medicines and Healthcare Products Regulatory Agency support HSE's approach. The administrations in Scotland, Wales, Northern Ireland and Gibraltar have also been consulted on the proposed approach. The Advisory Committee on Dangerous Pathogens has been informed.

Resource Implications for HSE and Costs and Benefits Analysis

18. If the EC takes a formal proposal forward there would be resource implications for HSE as part of the usual EC negotiating procedures, amending GB legislation and providing guidance – assuming a 4-5 year EC negotiation and GB implementation period this may exceed £250,000. The impact assessment for both legislative and non-legislative proposals is at Annex 2. Broadly, the costs and benefits are the same for both because the action required is essentially the same. However, the non-legislative approach should deliver its benefits earlier.

Action

19. That the Board considers the approach proposed in paragraph 16. If a proposal is published, officials will then seek the Board's and Ministers' approval for a negotiating strategy, based on the agreed approach.

Paper Clearance

20. This revised paper was produced by Delyth Dyne (Specific Interventions Division Tel: 020 7717 6234 email: delyth.dyne@hse.gsi.gov.uk) and Sarah Senior (Specific Interventions Division Tel: 020 7717 6266 email: sarah.senior@hse.gsi.gov.uk) and was cleared by Giles Denham.

Analysis of the existing legislation in relation to the EC's proposed measures on protecting EU healthcare workers from blood-borne infections resulting from needlestick injuries

1. **the use of instruments - such as syringes and needles - with safety devices** European (Directive 89/655/EEC) and GB legislation (PUWER) already requires work equipment to be suitable taking into account the sort of risks to which the worker is exposed. The fact that safer, albeit more expensive equipment, is available may mean less safe equipment is held to be unsuitable.
2. **the use of safe and effective systems to minimise the use of cannulae;** The Framework Directive already requires employers to avoid risks and the Biological Agents Directive to prevent exposure to hazardous substances, and where this is not technically practicable to require a risk assessment to adequately protect human health. In Great Britain, these requirements are reflected in regulations 6 and 7 of COSHH, which require an employer to prevent exposure or where it is not reasonably practicable to adequately control the risks. These requirements therefore already mean employers should be considering minimising the use of cannulae where possible.
3. **the modification of work practices which pose a risk of needle injury in order to make them safer;** The Framework Directive and the Biological Agents Directive already require employers to carry out risk assessments of work practices to reduce the risk of foreseeable injuries, such as needle stick injuries. This includes specific requirements for the safe handling, storage and disposal of equipment.
4. **a complete end to the recapping of needles;** There is no specific requirement to end this practice, unless such needles are not suitable equipment within the meaning of PUWER or unless it is contrary to the safe disposal of needles requirement in the Biological Agents Directive (see below).
5. **the training of workers in the safe use and disposal of needles and other medical sharps in special containers intended for this purpose, and in the correct handling of these containers;** Safe disposal of equipment infected with biological agents is already required by the Biological Agents Directive (article 6) and COSHH (regulation 7). Training of workers is also required by the Framework Directive (article 9) and COSHH (regulation 12). This sort of training should already be happening.

6. **the general provision of written instructions and notices indicating the procedures to be followed in the event of an accident or incident involving needles or other medical sharps;** There is no specific provision for written instructions or notices following a needle-stick injury. However, article 10 of the Biological Agents Directive does provide a requirement for the **notification of any** accident or incident involving a biological agent and for written instructions in the case of a **serious** accident and notices if appropriate (article 10).
7. **immediate and effective response and follow-up to any accidental exposure, including rapid post-exposure prophylaxis;** The Biological Agents Directive (article 14) provides that measures shall be introduced at a national level for health surveillance appropriate to the health and safety risks that workers may be exposed to, and COSHH regulation 11 makes detailed provision for such surveillance. However, the current proposal seems to go beyond that.
8. It is questionable how far it would be appropriate to make it an employer's responsibility to provide medical treatment where there is a National Health Service in the Member State.
9. **the offer of vaccination against hepatitis B to all workers who may come into contact with needles and other medical sharps;** This is a requirement of article 14(3) of the Biological Agents Directive.

PRELIMINARY IMPACT ASSESSMENT

<p>Description of the intervention</p> <p>Legislative and/or non-legislative European Commission initiative to reduce the number of needle stick injuries in healthcare workers.</p>
<p>Objectives</p> <p>This initiative from the EC aims to reduce the number of needle stick injuries to health care professionals across the European Union, with the objective of protecting these workers from contracting blood-borne infections in the workplace. The UK's policy objective is to ensure, as far as possible, that the initiative emerging from Europe is proportionate to the risks to workers.</p>
<p>Calculation of costs</p> <p>The main risk posed by a needle stick (NS) injury is exposure to a blood-borne virus (BBV), eg HIV, which is usually difficult to treat, and treatment cannot be guaranteed to be successful. Most needle stick injuries occur in a health care setting, which is the focus of this EC initiative, although other professions come into contact with used needles, eg veterinarians, researchers working with animals, refuse collectors.</p> <p>The EC is currently considering how to address the risk from NS injuries, and is looking to include the following measures in particular:</p> <ul style="list-style-type: none"> ▪ the use of instruments - such as syringes and needles – with safety devices; ▪ the use of safe and effective systems to minimise the use of cannulae; ▪ the modification of work practices which pose a risk of needle injury, including a complete end to the recapping of needles; ▪ the training of workers in the safe use and disposal of needles and other medical sharps in special containers intended for this purpose, and in the correct handling of these containers; ▪ the general provision of written instructions and notices indicating the procedures to be followed in the event of an accident or incident involving needles or other medical sharps; ▪ the recording in a special register of all injuries caused by needles or other medical sharps. <p>The EC is consulting on two possible approaches - firstly through amending existing European legislation to include these measures, and secondly a possible non-legislative initiative through a social partner agreement. The options available are :</p> <ol style="list-style-type: none"> a. amend an existing directive (the Biological Agents Directive 2000/54/EC) and/or b. to adopt non-legislative initiatives (such as a guide to good practice, awareness raising activities, establishing policy frameworks etc). <p><u>Main organisations affected</u></p> <p>The costs arising from either option are likely to be incurred predominantly by NHS organisations. Although GP/dental practices and Ambulance Trusts (and other healthcare professions that come into contact with used needles) fall into the reach of the proposals, due to their low level of risk of exposure to NS injuries, they have not been included in the calculations.</p>

Number of injuries/affected workers

Elder and Paterson (2006) suggest that underreporting maybe as high as 10ldⁱ. Further, According to the NHS (2005)ⁱⁱ 40,000 NS injury incidents are reported a year and 'least as many unreported'. On this basis, a rate of 85,000 NS injuries per year is assumed in this analysis.

Total cost and benefit estimates

Where the costs (and benefits) are assumed to be recurring, a ten year appraisal period has been applied. However, for option a., apart from costs that maybe incurred by the HSE, costs are unlikely to be realised until after three years reflecting the time taken for negotiation and national implementation of an amendment to a directive. A non-legislative route, on the other hand, could be actioned immediately. This is reflected in the calculations. Costs have been discounted by applying a 3.5%ⁱⁱⁱ discount rate. Health and safety benefits have been discounted at a rate of 1.5%. All cost estimates have been rounded.

The final estimates of the costs and benefits, in present value terms, are summarised in Table 1 and Table 2 (detailed explanations on assumptions and method that underpin these estimates follow). These estimates are based on assumptions derived from the available evidence and are, therefore, only indicative of the scale of potential costs and benefits. It should be noted that the total costs for option a. are lower than those of option b., only because they are incurred from year four onwards, over a seven year period. The total costs for option b. are incurred over a ten year period: please refer to Annex A for details of the costs and benefits had the options been appraised over the same period.

Table 1 : Estimated costs

	Option a. Legislative	Option b. Non-legislative
Familiarisation costs	£32,000	£14,000 to £17,000
Risk assessment costs	£44,000 to £52,000	£54,000 to £64,000
Training costs	£14 million to £17 million	£17 million to £20 million
Information costs	£5 million to £6 million	£6 million to £7million
Safety device costs	£17 million to £21 million	£16.7 million to £21 million
Surveillance costs	£2 million to £2 million	£2 million to £3 million
Total costs	£38 million to £46 million Annual costs of : £5 million to £7 million	£42 million to £51 million Annual costs of: £4 million to £5million

Table 2 : Estimated benefits

	Option a. Legislative	Option b. Non-legislative
Total benefits	£63 million to £70 million Annual benefits of : £9 million to £10 million	£61 million to £71 million Annual benefits of: £6 million to £7 million

Familiarisation costs

As of September 2007^{iv}, there were 170 Acute Trusts, 59 Mental Health Trusts and 152 Primary Care Trusts in the UK. This equates to a total number of 381 NHS Trusts that are considered in this analysis.

A National Audit Office survey of the number of NS injury accidents reported by all NHS Trusts in 2001-02 indicates that 70% - 80% occurred in Acute Trusts (AT), 10%-15% in Mental Health Trusts (MHT), and around 10% in Primary Care Trusts (PCT).^v This suggests that NS injuries occur mainly in Acute Trusts, which is reflected in the assumptions that follow.

The following number of Trusts are assumed to familiarise/read the guidance/regulations :

For Option a: It is assumed that all AT, MHT and PCT (a total of 381 NHS Trusts) will incur familiarisation costs.

For Option b: It is assumed that 70% to 80% of AT (119 to 136), 20% to 30% of MHT (12 to 18), and 20% to 30% of PCT (30 to 46) will incur familiarisation costs.

The new guidelines are assumed to take three senior NHS managers per AT, MHT and PCT one hour each to read. The hourly wage of a NHS manager, uprated by 30% to account for non-wage costs, is estimated at £28^{vi}. This gives one-off familiarisation costs, incurred in the fourth year of the appraisal period, of £32,300 for option a.; and £13,700 to £16,900 for option b.

Risk assessment costs

Of the AT, MHT and PCT that read the guidance, for both options, it is assumed that :

70-80%^{vii} of AT (119 to 126), PCT (21 to 36) and MHT (8 to 14), proceed to carry out a risk assessment. The risk assessment is estimated to take one hour. In order to reflect the relative size of the category of Trust, it is assumed to involve five doctors, five nurses, one health care assistant and two managers per AT; two doctors, two nurses, one health care assistant and one manager per MHT; and one doctor, one nurse, one health care assistant and one manager per PCT. The risk assessment is assumed to take one manager per AT, MHT and PCT one hour to record the findings.

Applying the appropriate wage costs^{viii} to the above assumptions yields a total one-off risk assessment cost for option a. of £43,900 to £52,300, incurred in year four of the appraisal period; and approximately £53,900 to £64,200 for option b., incurred in year one of the appraisal period.

Training costs

Feedback from NHS employers indicates that there is a strong inclination for the provision of increased training. The risk assessment may therefore have identified the need for training in the appropriate use of needle devices. On this basis, it assumed for both options that all Trusts undertaking a risk assessment will invest in a training programme.

The training programme is assumed to incorporate the following:

1. Induction design. Table 3 displays the total number of Trusts and the number and category of worker per trust that are assumed to be involved in the induction design. This assumed to take one hour per worker.

Table 3

No. of Trusts	Doctors	Nurses	Manager
AT :119-126	2 x 1hour	2 x 1hour	1 x 1hour

PCT: 21-36	1 x 1hour	1 x 1hour	1 x 1hour
MHT:8-14	1 x 1hour	1 x 1hour	1 x 1hour

Applying the appropriate wage costs^{ix} yields a cost estimate for induction design in year one of approximately £20,600 to £24,900. Note that all year one cost estimates presented in this Impact Assessment correspond to the values for option b. The estimates for option a. differ as the costs are incurred in year four of the appraisal period.

2. Attend/Deliver induction: According to Health Protection Agency and EPINet data^x, NS injuries are incurred by the following main groups of workers: 45% are incurred by nurses, 25% incurred by doctors and 10% incurred by Health Care Assistants. These percentages have been applied to the average number of workers per AT/MHT/PCT in each of these work categories^{xi}, in order to arrive at an estimate of the average number of workers per trust that attend the induction. This is assumed to take 45 minutes per worker. This information is presented in Table 4.

Table 4

No. of Trusts	Doctors	Nurses	HCA
AT :119-126	40 x 45 mins	644 x 45 min	67 x 45 min
PCT: 21-36	14 x 45 mins	396 x 45 min	76 x 45 min
MHT:8-14	2 x 45 mins	231 x 45 min	26 x 45 min

Applying the appropriate wage costs^{xii} yields a cost estimate of attending and delivering the induction in year one of approximately £1,500,000 to £1,700,000.

3. Set up induction: Table 5 displays the average number of administrative workers per trust (number of Trusts as per Tables 1 and 2) that are assumed to set up the induction, and the time taken.

Table 5

	AT : 119-126	PCT:21-36	MHT:8-14
Admin Asst.	2 x 30 min	2 x 30 min	1 x 30 min

Applying the appropriate wage costs^{xiii} yields a cost estimate for set up of the induction in year one of approximately £1,600 to £2,000.

Training costs are assumed to be incurred on an annual basis. Combining the above training programme costs yields the following cost estimates:

For option a., over the appraisal period, incurred from year four onwards, gives estimated training costs of approximately £13.8 million to £16.6 million in present value terms. This corresponds to annual costs of £2 million to £2.4 million.

For option b., over the appraisal period, gives estimated training costs of approximately £16.7 million to £20 million in present value terms. This corresponds to annual costs of £1.7 million to £2 million.

Information costs

Both options include a requirement to provide workers information on good practice, and raise awareness of risk. This is most likely to be achieved by issuing leaflets and putting up notices in areas where NS injuries are most likely to occur.

NHS employers acknowledge the need for improved communication of risk to workers. Further, information provision is likely to be invested in as it is perceived to be a low-cost activity. It is thus assumed (as with training costs), for both options, that all AT, MHT and PCT that carry out a risk assessment go on to invest in the provision of information.

Information costs are assumed to comprise of the following:

1. Design costs : Table 6 displays the total number of Trusts^{xiv} and the number and category of workers per trust that are assumed to be involved in the induction design. This assumed to take one hour per worker.

Table 6

No. of Trusts	Doctors	Nurses	Manager
AT :119-126	2 x 1hour	2 x 1hour	1 x 1hour
PCT: 21-36	1 x 1hour	1 x 1hour	1 x 1hour
MHT:8-14	1 x 1hour	1 x 1hour	1 x 1hour

Applying the appropriate wage costs^{xv} yields a cost estimate for information design in year one of approximately £20,600 to £24,900.

2. Distribution of leaflets/notices : It is assumed to take an administrative worker, on average, fifteen minutes to distribute leaflets and put up notices. Table 7 displays the average number of leaflets/ notices that are assumed to be distributed per trust^{xvi}

Table 7

No. of Trusts	No. of leaflets
AT :119-126	70
PCT: 21-36	50
MHT:8-14	25

Applying the appropriate wage costs^{xvii} yields a cost estimate for leaflet/notice distribution in year one of approximately £27,000 to £35,500.

3. Read information/notices. This is assumed to take an average of fifteen minutes per worker. The assumptions applied in order to estimate the average number/type of workers per each category of Trust expected to read the information is identical to the figures presented in Table 2.

Applying the appropriate wage costs^{xviii} yields a cost estimate for reading leaflets/notices in year one of approximately £490,000 to £580,000.

Information costs are assumed to be recurring on an annual basis. Combining the above costs of information provision yields costs of:

For option a., over the appraisal period, incurred from year four onwards, estimated costs of information of approximately £5 million to £5.9 million in present value terms. This corresponds to annual costs of £700,000 to £800,000.

For option b., over the appraisal period, estimated costs of information of approximately £6 million to £7.1 million in present value terms. This corresponds to annual costs of £600,000 to £700,000.

Purchase of safety- engineered devices

A key requirement of the proposals is for NHS Trusts to switch to the use of instruments with safety-engineered devices. Sales data^{xix} indicates that there was an increase in the purchase of safer devices in 2006 of 40% compared to 2005 (2006 is the year following the release of NHS guidance; but note that the rate of increase fell to 15% in 2007). This data suggests that the total number of devices sold that are categorised as those with safety mechanisms, as per the requirements of existing regulations, constitute only 5% of all instruments sold. Also, within the NHS, the costs of safer devices are perceived to be high. The outcome of the risk assessment may therefore lead to the decision that this may be an unnecessary expenditure, particularly since most cases of NS injuries generally lead to only very minor injuries^{xx}. To reflect this evidence, it is

assumed that:

Of the Trusts that undertake a risk assessment, for option a., 40% to 50% are assumed to switch to the use of safety-engineered devices. For option b., this percentage is assumed to be lower at 20% to 30%. Table 8 displays the estimated number of Trusts that are assumed to purchase safety-engineered devices for each option.^{xxi}

Table 8

Category of Trust	Option A : 40 -50% of Trusts	Option B : 20-30% of Trusts
A T	77-88	42-48
MHT	5-9	3-5
PCT	14-24	7-13

To arrive at a cost estimate, the number of Trusts (as in Table 8) have been multiplied by the average number of devices purchased per trust (assumed to be 1 million^{xxii}). This gives an estimate of the total number of safety devices purchased, which has been multiplied by the average cost difference between a 'safe' and 'normal' device, which is estimated at 5 pence.^{xxiii}

Safety-engineered device costs are assumed to be recurring. The estimate of the number purchased per year is held constant at the rate assumed in the first year. Applying these assumptions and method yields the following cost estimate :

For option a., over the appraisal period, incurred from year four onwards, gives estimated costs of approximately £17 million to £21.4 million in present value terms. This corresponds to annual costs of £2.4 million to £3.1 million.

For option b., over the appraisal period, gives estimated costs of approximately £16.7 million to £21 million in present value terms. This corresponds to annual costs of £1.7 million to £2.1 million.

Surveillance costs

Existing levels of the reporting of NS injuries are very low: underreporting may be as high as 80%. Both options propose requirements to improve the reporting of NS injuries.

As with training and information costs, it is assumed for both options that all Trusts that undertake a risk assessment will identify the need to improve reporting, and then go onto implement a NS injury recording system.

In order to arrive at a surveillance cost estimate, a rate of 85,000 NS injuries per year is assumed. The following assumptions^{xxiv} : 70% of injuries occur in AT, 15% in MHT and 10% in PCT; have been applied to the assumed rate of NS injuries per year. This gives the estimated total number of injuries in the trust categories, presented in Table 9.

Table 9

No. of Trusts	Total number of injuries
AT :119-126	41,650 – 47,600
PCT: 21-36	1785 - 3060
MHT:8-14	1190 - 2040

It is assumed to take an administrative assistant fifteen minutes to record an injury. Applying the wage cost of an administrative assistant^{xxv} to the number of NS injuries as above, yields the following total cost of surveillance:

For option a., over the appraisal period, incurred from year four onwards, gives estimated costs of

£1.9 million to £2.3 million in present value terms, corresponding to annual costs of £273,000 to £322,600.

For option b., over the appraisal period, gives estimated costs of £2.3 million to £2.7 million in present value terms over the appraisal period. This corresponds to annual costs of £231,300 to £273,200.

Overall costs

Option a.

The total costs to Trusts over a ten year appraisal period, incurred from year four onwards, using 2008 as a base year, are estimated at approximately **£38 million to £46.1 million** in present value terms. Of this total, the recurring cost portion (training, information, safety device and surveillance costs) corresponds to an annual cost of approximately £5.4 million to £6.6 million per annum.

Option b.

The total costs to Trusts over a ten year appraisal period, using 2008 as a base year, are estimated at approximately **£41.8 million to £51 million** in present value terms. Of this total, the recurring cost portion (training, information, safety device and surveillance costs) corresponds to an annual cost of approximately £4.2 million to £5.1 million per annum.

It should be noted that the total costs for option a. are lower than those of option b., only because they are incurred from year four onwards, over a seven year period. The total costs for option b. are incurred over a ten year period.

Impact on industry (including any effect on the Admin Burdens Baseline):

The costs outlined above would mainly fall on the health care sector, although other sectors working with used needles could be affected by a legislative approach. A legislative approach would add to HSE's Admin Burden exercise. The main administrative costs associated with option a., arise from information provision, incurred from year four onwards, of approximately £5 million to £5.9 million in present value terms, corresponding to annual costs of £700,000 to £800,000. For option b., information provision, incurred over the appraisal period of approximately £6 million to £7.1 million in present value terms, corresponding to annual costs of £600,000 to £700,000 Other administrative costs, arising from familiarisation, risk assessment and training costs, are also generated. However, these costs are negligible.

Benefits (quantified where possible):

The estimated benefits presented below are based on the assumed rate of 85 000 NS injuries per year. The following assumptions have been applied in order to arrive at an estimate of the benefits :

1. 25 %: 21,250 NS injuries are not preventable.^{xxvi}

2. 50%: 31, 875 NS injuries may be preventable through the use of safety-engineered devices.^{xxvii}

Of this total, for option a., it is estimated that between 40 % (12,750) to 50% (15,938) may be prevented. This assumption reflects the number of Trusts assumed to purchase safer devices for this option in the costs section. For option a., it is estimated that between 20% (6,375) to 30% (9,562) may be prevented – again, this is consistent with number of Trusts estimated to purchase safer devices.

3. 25%: 15,938 may be preventable by a combination of training and provision of information^{xxviii}. It has been assumed in the costs section for both options that all Trusts undertaking a risk assessment invest in training/information provision. Therefore for both options, it is estimated that 15,938 NS injuries may be prevented.

The majority of NS injuries lead to only very minor injuries. The cost of a typical NS injury has therefore been based on the 2005 (Q3) HSE Economic Analysis Unit appraisal values estimate for the unit cost of an average minor injury to society.^{xxix} A reduction in NS injuries would equate to a benefit to the value of this amount.

Applying the above assumptions and method yields the following estimated total benefits :

For Option a.: Over the appraisal period, incurred from year four onwards, in present value terms of **£62.5 million to £69.5 million** in present value terms. This corresponds to an annual value of £8.9 million to £9.9 million per annum.

For Option b.: Over the appraisal period, in present value terms of **£62 million to £70.8 million** in present value terms. This corresponds to an annual value of £6.2 million to £7.1 million per annum.

This approach has been discussed with HSE's Chief Economist and the Better Regulation Team.

ⁱ Sharps injuries in UK health care: a review of injury rates, viral transmission and potential efficacy of safety devices, Occupational Medicine, 2006.

ⁱⁱ The management of health, safety and welfare issues for NHS staff, 2005. Note that there is no mention of a specific year on which this estimate is based (or whether this figure is an average of several years).

ⁱⁱⁱ HMT Green Book – 3.5% is the social time preference rate.

^{iv} Data provided by the NHS Information Centre, www.ic.nhs.uk.

^v 5% of NS injuries were found to occur in Ambulance Trusts, a number deemed too small for Ambulance Trusts to be considered in this analysis.

^{vi} Source: Office of National Statistics, Annual Survey of Hours and Earnings, 2007.

^{vii} The level of non-compliance, for all NHS Trusts, is estimated at between 70% to 80%. This estimate reflects in particular that only 5% of all instruments in use can be classified as 'safe'. Further, evidence indicates that up to 80% of needlestick injuries could be prevented through a combination of increased training and the use of safer instruments, highlighting the scope for improved compliance.

^{viii} Source: Office of National Statistics, Annual Survey of Hours and Earnings, 2007. Hourly wage (uprated by 1.3 to account for non wage costs) of a Doctor: £43.93; Nurse/HCA: £18.38; Senior NHS Manager £28.26.

^{ix} Wage costs applied as per footnote 8.

^x EPINet results are based on a Royal College of Nursing surveillance project carried out between 2000-2003.

^{xi} Source NHS Information Centre, NHS Hospital and Community Health Services and General Practice workforce as of 30 September 2007. Average number of workers in the following categories of NHS Trusts : Acute Trusts : 158 doctors, 1,435 nurses and 681 HCA. Mental Health Trusts: 58 doctors, 882 nurses and 773 HCA. Primary Care Trusts: 9 Doctors, 516 nurses and 269 HCA.

^{xii} As per footnote 8

^{xiii} Wage cost source as per footnote 6. Based on hourly wage of an administrative officer (uprated by 1.3 to account for non wage costs): £11.74.

^{xiv} Note that the number of Trusts in each category is identical to those assumed to undertake a risk assessment and invest in a training programme.

^{xv} Refer to footnote 8 for details on wage costs applied.

^{xvi} The number of leaflets/notices assumed to be distributed reflects the risk profile of each category of trust. For example, it is likely that a greater number of leaflets and notices are put up in Acute Trusts, where NS injuries are more common.

^{xvii} As per footnote 8.

^{xviii} Refer to footnote 8 for details on wage costs applied.

^{xix} Information related to the sales on instruments/devices was provided by NHS Supply Chain www.supplychain.nhs.uk.

^{xx} Although NS injuries are common, confirmed viral transmission is rare – only 15 cases have been confirmed over the past ten years. However, the psychological impact may in some cases be lasting, but there is limited evidence to support this.

^{xxi} Note that the figures presented in Table 6 are based on an average of the lower and /upper bounds of the number of Trusts assumed to undertake a risk assessment.

^{xxii} As per NHS Supply Chain, a total of 405.8 million devices were sold in 2007. 5% of these were classified as 'safe' devices, leaving 385.5 million 'non-safe' devices sold/in circulation. Dividing 385.5 million by 381 - the total number of AT, MHT and PCT as of September 2007- gives an estimated average of 1 million devices purchased per trust.

^{xxiii} This estimate is based on information provided by NHS Supply Chain.

^{xxiv} These assumptions are identical to those stated in the familiarisation costs section.

^{xxv} Refer to footnote 13.

^{xxvi} The management of health, safety and welfare issues for NHS staff (2005) indicates that a combination of training and the use of safety-engineered devices could reduce NS injuries by 80%, implying that 20% of NS injuries are non-preventable. Also, feedback from NHS staff suggests that up to 25% of NS injuries occur during use at time-critical moments, and are thus non-preventable. On this basis a rate of 25% has been assumed.

^{xxvii} Elder& Paterson (2003) cite evidence from a study carried by Sohan *et al* suggesting that safety-engineered devices are likely to be effective in reducing NS injuries by 58.2%. Also, a National Audit Office survey of Trusts (2003) presents a case study example of a 42% reduction in the rate of NS injuries after the trust purchased a tray incorporating a sharp bin. An average of these rates (58.2% + 42%/2) of 50% has therefore been assumed in this analysis.

^{xxviii} This assumption reflects that 25% of NS injuries have been assumed to be non-preventable, and 50% preventable through the use of safety-engineered devices. Hence the remaining 25% have been assumed to be preventable through a combination of training and information provision.

^{xxix} The average cost to society of a minor injury has been estimated at £350. Note that this cost includes human costs (pain and grief), resource costs, and costs of lost output. Further details can be found at <http://www.hse.gov.uk/economics/eauappraisal.htm>.

Annex A

Tables 1 and 2 present the costs and benefits in present value terms for both options, appraised over a ten year period, for illustrative purposes only.

Table 1 : Estimated costs applying identical appraisal period

	Option a. Legislative	Option b. Non-legislative
Familiarisation costs	£32,000	£14,000 to £17,000
Risk assessment costs	£55,000 to £64,000	£55,00 to £64,000
Training costs	£17 million to £20 million	£17 million to £20 million
Information costs	£5 million to £6 million	£5 million to £6 million
Safety device costs	£31 million to £39 million	£17 million to £21 million
Surveillance costs	£2 million to £3 million	£2 million to £3 million
Total costs	£56 million to £69 million	£42 million to £51 million

Table 2 :Estimated benefits applying identical appraisal period

	Option a. Legislative	Option b. Non-legislative
Total benefits	£89 million to £101 million	£62 million to £71million