Title: The Health and Safety (Sharp Instruments in Healthcare) Regulations 2013 PIR	Post Implementation Review
PIR No: HSE-PIR2023_002	**Date:** 10/05/2023
Original IA/RPC No: RPC12-HSE-1335(2).	**Type of regulation:** Domestic
Lead department or agency: HSE	**Type of review:** Statutory
Other departments or agencies: N/A	**Date measure came into force:** 11/05/2013
Contact for enquiries: Martin.McMahon@hse.gov.uk	**Recommendation:** Keep
	RPC Opinion: N/A

1. What were the policy objectives of the measure? (Maximum 5 lines)

To ensure effective implementation of Council Directive 2010/32/EU by introducing measures specified in the Directive not already specified in UK Law; to minimise burdens on public, independent and third sector employers and ensure businesses in UK are not placed at competitive disadvantage relative to EU counterparts; to offer good standards of protection to healthcare workers from risk of sharps injury at work and that sharps injury numbers fall.

2. What evidence has informed the PIR? (Maximum 5 lines)

Reflecting government guidance, a proportionate low resource approach was agreed to collecting evidence. Stakeholder engagement was undertaken with relevant representative groups, both directly and through online questionnaire. Existing research was reviewed including a significant Royal College of Nursing (RCN) report on blood and body fluid exposures. Findings from HSE inspections assessing sharps risk in NHS also contributed.

3. To what extent have the policy objectives been achieved? (Maximum 5 lines)

Stakeholder consultation provides evidence of the increasing use of safer sharps across all healthcare sectors. Evidence from RCN research and HSE inspections indicates that risks to healthcare workers from sharps injuries remains high. The policy conclusion from this evidence is that the Regulations are still required, and that the Regulations' objectives cannot be met with a system that imposes less burden to business.

Sign-off for Post Implementation Review: Chief economist

I have read the PIR and I am satisfied that it represents a fair and proportionate assessment of the impact of the measure.

Signed: E. Woolley Edward Woolley Date: *03/03/2023*

Further information sheet

Please provide additional evidence in subsequent sheets, as required.

4. What were the original assumptions? (Maximum 5 lines)

The initial impact assessment estimated the equivalent annual net cost to business of approximately £0.5m in 2013 prices, well below the £5m *de minimis* threshold. This included estimates made on time required to review risk assessments and implement new controls, and assuming 36% of healthcare was provided by private providers (based on share of private hospitals versus NHS). These costs have been re-estimated to reflect latest information.

5. Were there any unintended consequences? (Maximum 5 lines)

The stakeholder consultation highlighted the environmental impact and cost of waste disposal associated with the safer sharps as an unintended consequence of the Regulations. This was a particular issue in the dental sector, and in part is caused by the increased bulk of safer sharps in comparison with traditional needles.

6. Has the evidence identified any opportunities for reducing the burden on business? (Maximum 5 lines)

Few stakeholders were aware of ways for reducing the burden on business. Some respondents from the dental sector suggested relaxation of the Regulations and the use of existing control processes and risk assessments. This approach could however provide undue latitude and drive protection down. The Regulations do allow for use of traditional needles if it can be demonstrated it is not reasonably practicable to use a safer device, or one is not available.

7. How does the UK approach compare with the implementation of similar measures internationally, including how EU member states implemented EU requirements that are comparable or now form part of retained EU law, or how other countries have implemented international agreements? (Maximum 5 lines)

It is considered that any comparison activity would be irrelevant and represent a disproportionate use of time and resource. The EU Withdrawal Act 2018 repealed requirements for statutory reviews to consider how an EU obligation has been implemented across member states and therefore there is no intention to include a comparison as originally required by the review clause.

Title: The Health and Safety (Sharp Instruments in Healthcare) Regulations 2013 PIR **Lead department or agency:** Health and Safety Executive **Other departments or agencies:** None **Contact for enquiries:** Martin McMahon (Tel 07785 248185) Martin.Mcmahon@hse.gov.uk	Post Implementation Review (HSEPIR013) **Source of intervention:** **Type of regulation:** Domestic **Type of review:** Statutory Review **Date of implementation: 11 May 2013** **Date review due (if applicable):** **10 May 2023**

Introduction

Injuries from needles and other sharp instruments (often referred to as needlestick injuries or sharps injuries) are a known risk in the healthcare sector. Sharps injuries to healthcare workers from instruments contaminated with a patient's blood have the potential to transmit more than twenty infectious diseases including blood-borne viruses which can have a serious impact on their health. In addition, the anxiety caused from, and side-effects of, sharps injuries can have a significant personal impact on healthcare workers and their mental health.

The Health and Safety (Sharp Instruments in Healthcare) Regulations 2013 (the Sharps Regulations) came into force on 11th May 2013. The Regulations implement aspects of the European Council Directive 2010/32/EU (the Sharps Directive) that are not specifically addressed in existing GB health and safety legislation. They are concerned with the control of risks to healthcare workers of injury and infection from needles, scalpels and other medical sharps (commonly referred to as 'sharps'). They are specifically focused on healthcare provision and apply exclusively to healthcare employers and their contractors. The Regulations cover Scotland, England and Wales; The Northern Ireland Government enacted its own Regulations to give effect to the Sharps Directive that apply in Northern Ireland.

It is a statutory requirement to undertake a Post Implementation Review (PIR) of the Regulations within 5 years of them coming into force, and then each subsequent 5 years. The purpose of the PIR is to set out the objectives of the Regulations, assess the extent to which these objectives have been achieved, consider whether they remain appropriate and if so, whether they could be achieved with a system that imposes less regulation.

This is the second PIR carried out since the Regulations were implemented in 2013. The previous PIR process in 2018 sought the views and experiences of healthcare managers and employees who need to comply with the Regulations during the

course of their work. A series of interviews, focus groups, and an online survey were carried out with healthcare managers and employees. The research found that overall, the Regulations were considered by managers and employers to be:

- clear and practical to implement.
- effective in reducing injury risks from sharps, raising awareness, promoting safer work practices, and encouraging organisations to review how they manage sharps risks.

The previous PIR in 2018 found that overall, the Sharps Regulations provide a sound contribution to the existing legal framework protecting healthcare workers and reducing the risks associated with the use of sharps.

For this review, a low resource PIR has been considered proportionate and has been agreed based on the policy background as laid out above, the initial impact assessment, the larger scale of the previous 2018 PIR and that the estimated cost to business is less than the *de minimis*[1] of £5m.

1. What were the policy objectives of the measure?

The main policy objectives of the Regulations were:

- To ensure effective implementation of the Sharps Directive by introducing the measures in addition to existing general requirements that must be taken by employers in the healthcare sector;
- To minimise burdens on public, independent and third sector employers and ensure that businesses in the UK are not placed at a competitive disadvantage relative to their EU counterparts.

The general intention of the Regulations is that healthcare workers are offered a good standard of protection and that the number of sharps injuries fall.

2. What evidence informed the PIR?

The evidence review resources were in line with a proportionate approach to PIRs. This decision was based upon several factors.

- The impact on businesses was estimated to be low: the equivalent annual net direct cost to business (EANDCB) in the Impact Assessment (IA) was £0.5m (well below the £5m de minimis threshold).
- The findings of the 2018 PIR attributed a positive impact achieved by the Sharps Regulations in relation to protecting healthcare workers.

[1] Where the equivalent annual net direct cost to business (EANDCB) is estimated to be below £5 million threshold a low resource PIR is recommended as per the Magenta Book Guidance 2020

- Existing evidence is available which supports some of the objectives for this PIR.

The evidence review for this PIR considered the following questions:

- To what extent have the policy objectives been achieved?
- Were there any unintended consequences?
- Are there any opportunities for reducing the burden on business?
- What have been the actual costs and benefits of the regulation?
- How do these compare with the estimated costs and benefits?
- Is the existing form of regulation still the most appropriate approach?

Research Methods

This evidence review has been designed to answer the key PIR questions in a proportionate manner, in recognition of its low burden on businesses.

As the Regulations apply only to the healthcare sector the evidence review focuses only on this sector.

The evidence base was compiled in-house and consists of the following elements:

- Stakeholder consultation

  Direct engagement was undertaken with stakeholder representative groups at meetings and a presentation by policy colleagues at a webinar. Stakeholders were directed to an online questionnaire used to collect opinions on the PIR questions. The questionnaire was also distributed to individual contacts considered missing from group engagement. Selected semi-structured interviews were conducted to follow-up on themes emerging from the consultation.

- Review of existing research

  In 2021 the Royal College of Nursing (RCN) published a major report on blood and body fluid exposures (BBFE). This analysis was based on survey responses from 7,500 RCN members. Key information and lessons from this research have been identified to inform the PIR evidence base.

- Pre-planned inspection activity

  HSE occupational health inspectors conducted a series of eleven inspections of NHS trusts/boards in Great Britain during the second half of 2022.

Inspection reports have been reviewed to assess the management of risk from sharps injuries and inspectors have been interviewed for comment on how effectively the Regulations are implemented in the sector.

3. To what extent have the policy objectives been achieved?

The principal objective of the Regulations was to ensure that all measures specified in the Council Directive 2010/32/EU were implemented into UK law, with the intended effect that healthcare workers are offered a good standard of protection and the number of sharps injuries fall.

Data acquired from NHS Supply Chain provides evidence of increasing use of safer sharps in healthcare:

- In the 12 months up to July 2014, 45% of sharps purchased were safer devices. By the same period up to July 2022, this share had risen to 85%.

- In terms of units of safer devices purchased, this represented an increase from 125 million devices in 2014 to almost 304 million in 2022.

Despite an increase in the purchase and use of safer devices, sharps injuries continue to be an issue that impacts on the health and wellbeing of healthcare workers. A major research report from the Royal College of Nursing (RCN) highlights high incidence rates of sharps injury amongst their members and also the importance of training in reducing the incidence of sharps injury. The latest available data from NHS Resolution shows, over a 5-year period between 2014 and 2018, a total of 1088 claims for sharps injuries to healthcare workers were settled at an overall cost of £2,645,878.

The first PIR for the Regulations in 2018 identified the usability of safer sharps as a factor that had the potential to hinder the implementation of the Regulations. This remains a concern for some respondents from the dental sector. However, stakeholders from other healthcare sectors do not view usability of safer sharps as a hindrance to the implementation of the Regulations.

Stakeholder engagement indicated that, when the Regulations were first introduced there was some misunderstanding around the requirements within the dental sector. This was borne from uncertainty that the Regulations applied in this sector, which in turn led to slow adoption of the requirements. The sector is now clear that the Regulations do apply to them, and while some resistance remains, in general this sector is moving towards greater implementation of the Regulations (as evidenced though the stakeholder engagement process).

Between June and December 2022 HSE Occupational Health Inspectors carried out a programme of eleven inspections at NHS Organisations, to assess their management of sharps risk. Analysis of the findings indicate that compliance gaps remain in respect of duties under health and safety legislation:

- Inspectors identified contraventions to health and safety legislation in all eleven organisations inspected.

- Contraventions in seven (64%) of the inspections were so significant that formal improvement notices were served (in total 11 notices served across 7 organisations).

- Nine (82%) of the inspections identified specific contraventions to the Sharps Regulations. These included: 5 breaches of Regulation 5 (avoid unnecessary use of sharps); 5 of Regulation 6 (provide information and training on use of sharps); and 4 of Regulation 7 (record and investigate sharps incident).

- Other contraventions found were in relation to Regulations 3 and 5 of The Management of Health and Safety at Work Regulations 1999, regulation 7 of the Reporting of Injuries, Diseases and Dangerous Occurrences Regulations 2013 (RIDDOR) and regulation 6 of the Control of Substances Hazardous to Health Regulations 2002

The findings overall suggest that work remains to raise levels of compliance in respect of managing sharps risk. They also indicate that, while other legislation does apply, referring to the specific requirements of the Regulations provides a clear and practical focus on what needs to be done to enhance control of risk from sharps injuries.

4. What were the original assumptions? What have been the actual costs and benefits of the regulation and its effects on business?

The 2013 IA estimated a total cost (in 2013 prices) of the Sharps Regulations of around £13m, with one-off costs estimated to be £11m. The total costs included a one-off cost of providing information of £2.2m; one-off costs of familiarisation of around £3m and one-off costs of updating risk assessments, estimated to be around £6m. On-going costs of reporting, recording and investigating all sharps injuries were estimated at £1.4m.

The 2018 PIR provided an in-depth re-estimate of these costs using the best available information on the impact of the Regulations. It found that the one-off costs were around £31m (in 2013 prices) and that the ongoing costs were nil. The expected ongoing costs of reporting requirements had not been realised as duty holders confirmed existing mechanisms were already in place to report, record and investigate sharps injuries prior to the implementation of the Regulations.

Since the 2018 PIR found that the costs incurred were entirely due to the one-off costs around the time of the introduction of the Regulations in 2013, and amounted to an EANDCB well below the £5m threshold, it was not thought proportionate to provide a full update of the estimates presented in the 2018 PIR here. Instead we have used GDP deflators to update the estimates contained in the 2018 PIR and have tested the assumptions about ongoing costs. A full description of the costs and benefits can be found in Appendix 3 below.

Summary of cost estimates

One-off Costs

Cost Impact	2013 Impact Assessment costs (£m)	2018 PIR estimated cost in 2013 prices (£m)	Estimated cost in 2022 prices (£m)*
Documentation	6	8.5	9.9
Familiarisation	3.1	3.3	3.8
Training and information	1.4	19	22.1
TOTAL ONE- OFF COSTS	**11**	**31**	**36.1**

* Note - since these one-off costs occurred around the time of the Regulations being introduced, we have not updated the estimates for this PIR, but have used GDP deflators to calculate the previous estimates in 2022 prices for illustrative purposes

Ongoing costs (10 year present value)

Cost Impact	2013 Impact Assessment costs (£m)	2018 PIR estimated cost in 2013 prices (£m)	Estimated cost in 2022 prices (£m)*
Reporting, recording and investigating	1.4	Nil	Nil
TOTAL ONGOING COSTS	1.4	Nil	Nil

* Note: The 2013 IA assumed ongoing costs for reporting sharps injuries that posed no risk. However, from the data collected for the 2018 PIR it was evident that before the Sharps Regulations came into force, duty holders confirmed that they were already reporting, recording and investigating all sharps injuries in any case, so this cannot be included as an additional ongoing cost directly attributable to the Regulations.

There are no ongoing costs of the Regulations that have been quantified. Therefore, the cost estimate is solely comprised of one-off costs that occurred when the Regulations came into force in 2013. This is estimated as £36.1m in current prices, and £31m in 2013 prices.

The equivalent annual cost to business (private healthcare employers) is estimated to be £0.4m in current prices, and £0.38m in 2013 prices.

Consideration was given to any cost impact that the Regulations may have had on the COVID-19 response, specifically in relation to sharps use during the vaccination rollout. It was found that, as the vaccination rollout was entirely delivered through the public sector, this had no impact on the EANDCB. Therefore, for the purposes of this

PIR, COVID-19 has had no impact on cost estimates or the proportionality of the Regulations.

5. Were there any unintended consequences?

The stakeholder consultation highlighted the hitherto not acknowledged environmental impact and cost of waste disposal associated with safer devices as an unintended consequence of the Regulations. This was a particular issue in the dental sector, and in part is caused by the increased bulk of safer devices in comparison with traditional needles.

However, evidence provided by Terry Grimmond - consultant microbiologist, researcher and expert on blood and body fluid exposures (BBFE) - indicated that there are fully automated safety devices, considered the highest level of safety provision due to their ability to automatically shroud the needle without need for manual application, available that are significantly smaller and lighter than other safer devices. This suggests that increased waste costs incurred due to using safer devices could be mitigated by using devices considered the safest available.

6. Has the evidence identified any opportunities for reducing the burden on business?

The Regulations were devised to minimise burdens on public, independent and third sector employers and to ensure that businesses in the UK were not placed at a competitive disadvantage relative to their EU counterparts. Very few stakeholders from healthcare sectors other than dental were aware of ways in which the burden of the Sharps Regulations on businesses could be reduced.

The overwhelming majority of stakeholder respondents supported the Regulations. This included the majority of respondents from the dental sector.

A minority of respondents from the dental sector did suggest proposed relaxation of the Regulations and the use of existing control processes and risk assessments to reduce the likelihood of sharps injury. This approach however could provide undue latitude for those responsible for controlling risk, with the potential effect of increasing sharps injuries and reducing protections for those at risk. The Regulations as written do allow use of traditional needles in certain circumstances, if it can be demonstrated it is not reasonably practical to use a safer device, or one is not available.

7. How does the UK approach compare with the implementation of similar measures internationally, including how EU member states implemented EU requirements that are comparable or now form part of retained EU law, or how other countries have implemented international agreements?

It is considered any comparison activity would not be relevant and would represent a disproportionate use of time and resource. The EU Withdrawal Act 2018 repealed requirements for statutory reviews to consider how an EU obligation has been implemented across member states. There is therefore no intention to include a comparison as originally required by the review clause as the 2018 Act now renders this unnecessary.

With respect to international obligations, the International Labour Organisation (ILO)'s ILO's Declaration on Fundamental Principles and Rights at Work requires *'a safe and healthy working environment'*. The International Covenant on Economic, Social and Cultural Rights speaks of '*Safe and healthy working conditions '*. The Regulations are an important contributor to healthcare worker protections and as such are consistent with the objectives of both these obligations.

PIR Conclusion.

Across all stakeholders there remains strong support for the Regulations, with only one respondent from healthcare sectors other than dental, saying that the Regulations are not required. Levels of support for the Regulations were not as high amongst stakeholders from the dental sector; however, most of these respondents still thought that the Regulations are required. The hesitancy amongst some in this group reflects issues around the suitability of safer sharps for specific clinical procedures and the increased cost and waste associated with disposing of safer sharps.

It is estimated that safer devices exist for 90 percent of sharps work. However, the RCN research shows that only 45 percent of members who responded to the survey (in 2020) stated that they have excellent access to safer sharps. Staff who had "Excellent" access to safer sharps had a significantly lower incidence of sharps injury than staff who had "Nil to Poor" access. The Regulations also require sharps training and the research findings highlighted the value of effective training in reducing the incidence of sharps injury.

Inspections of healthcare organisations' management of sharps risk indicate that there is still work to do to increase compliance levels to health and safety legislation, including the Regulations. The Regulations provide a focus and a clear direction on what needs to be done to improve management of risk and to ensure compliance with duties.

Expert consensus view, gathered though the consultation exercise, is that the Regulations are a vital tool in protecting the health and wellbeing of healthcare workers, and without them the situation is likely to revert to where it was prior to their introduction. Indeed, this expert opinion gathered goes further to suggest that more reductions in sharps injuries could be achieved if the Regulations specifically called for the use of the safest sharps device available, for example passive devices that do not require manual application of the safety mechanism, rather than simply safer devices. This means that the potential impact that passive devices could have on reducing the rate of sharps injury is not being fully realised.

It is therefore proposed that the Regulations are retained, to continue to give effect to their objectives and to maintain these important protections for healthcare workers in Great Britain.

The Regulations will be reviewed again in 5 years to check they continue to be relevant and deliver their intended objectives.

Annex 1: Evidence Review for the Health and Safety (Sharp Instruments in Healthcare) Regulations 2013 Post Implementation Review

Contents

Summary

- 87 stakeholders participated in the consultation that informed this evidence review. These participants come from a variety of healthcare settings, with dental practices being particularly well represented.
- The stakeholder consultation was supplemented with a review of published research, feedback from inspections and analysis of other relevant data sources.
- Stakeholders confirmed that there is an increasing use of safer sharps across healthcare sectors and there is clear evidence of support for the main policy objectives of the Regulations, with a majority of stakeholders stating that the Regulations are still required.
- The 2018 PIR identified some resistance to the use of safer sharps. This remains an issue for some stakeholders from the dental sector who voiced concerns about the suitability and effectiveness of safer sharps devices for specific procedures.
- There is no evidence of significant unforeseen costs to business arising from the Regulations. Although some stakeholders from the dental sector raised issues of increased disposal costs due to the increased volume of safer devices when compared with traditional sharps.
- HSE Inspections of healthcare settings identified ongoing compliance issues and demonstrate the continued need for the Regulations to support and encourage best practice in relation to using safer sharps.
- Evidence from research conducted on behalf of the Royal College of Nursing shows that Needle Stick Injuries (NSI) continue to be experienced by healthcare workers, who are at risk of infection from more than 20 different Blood Borne Viruses (BBV).

Introduction

This evidence review has been undertaken by the Health and Safety Executive (HSE) to accompany and support the Post-Implementation Review of The Health and Safety (Sharp Instruments in Healthcare) Regulations 2013 ("Regulations") (S.I 2013/645). These regulations came into force on 11 May 2013 and were introduced to transpose those requirements of the Council Directive 2010/32/EU not already specified in UK law.

The Regulations are concerned with the control of risks to healthcare workers of injury and infection from needles, scalpels and other medical sharps (commonly referred to as 'sharps'). They are specifically focused on healthcare provision and apply specifically to healthcare employers and their contractors.

The principal objectives of the Regulations were to:

- ensure effective implementation of Council Directive 2010/32/EU by introducing the measures specified in the Directive (not already in UK law) that must be taken by employers in the healthcare sector;
- minimise burdens on public, independent and third sector employers and ensure that businesses in the UK were not placed at a competitive disadvantage relative to their EU counterparts.

Provision 10 of the Regulations requires that a post-implementation review (PIR) is carried out every 5 years to review their effectiveness, to assess whether the objectives remain appropriate and, if so, the extent to which they could be achieved with a system that imposes less regulation.

This is the second PIR since the Regulations were implemented in 2013. The previous PIR (2018) sought the views and experiences of healthcare managers and employees who need to comply with the Regulations during the course of their work. A series of interviews, focus groups, and an online survey were carried out with healthcare managers and employees. The research found that overall, the Regulations were considered by managers and employees to be:

- clear and practical to implement.
- effective in reducing injury risks from sharps, raising awareness, promoting safer work practices, and encouraging organisations to review how they manage sharps risks.

The 2018 PIR found that, overall, the Regulations provide a sound contribution to the existing legal framework, protecting healthcare workers and reducing the risks associated with the use of sharps.

Proportionality of approach

The level of resourcing put into the evidence review was low, in line with a proportionate approach to PIRs. This decision was based upon the following factors:

- The impact on businesses was estimated to be low: the equivalent annual net direct cost to business (EANDCB) in the Impact Assessment (IA) was £0.5m (well below the £5m de minimis threshold).
- The findings of the 2018 PIR, attributed a positive impact achieved by the Regulations in relation to protecting healthcare workers.
- Existing evidence is available which supports some of the objectives for this PIR.

Key Questions for the PIR
This report builds on the evidence base developed to inform the 2018 PIR and sets out to answer the following questions:

- To what extent have the policy objectives been achieved?
- Were there any unintended consequences?
- Are there any opportunities for reducing the burden on business?
- What have been the actual costs and benefits of the regulation?
- How do these compare with the estimated costs and benefits?
- Is the existing form of regulation still the most appropriate approach?

Research Methods

This evidence review has been designed to answer the key PIR questions in a proportionate manner with a low burden on businesses.

As the Regulations apply only to the healthcare sector the evidence review focuses only on this sector.

The evidence base was compiled in-house and consists of the following elements:

- Stakeholder consultation
  Direct engagement was undertaken with stakeholder representative groups at meetings and a presentation by policy colleagues at a webinar. Stakeholders were directed to a questionnaire used to collect opinions on the PIR questions. The questionnaire was also distributed to individual contacts considered missing from group engagement. Semi-structured interviews were conducted to follow-up on themes emerging from the consultation.
- Review of existing research
  In 2021 the Royal College of Nursing (RCN) published a major report on blood and body fluid exposures (BBFE). This analysis was based on survey responses from 7,500 RCN members. Key information and lessons from this research have been identified to inform the PIR evidence base.
- Pre-planned inspection activity
  HSE occupational health inspectors conducted a series of ten inspections of NHS trusts/boards in Great Britain during Autumn 2022. Inspection reports have been reviewed to assess the management of risk from sharps injuries and inspectors have been interviewed to explore the perspective of those responsible for the enforcement of the Regulations.

Stakeholder consultation

Methodology

The consultation was designed to enable a wide range of stakeholders to contribute to this PIR. A web-based questionnaire was identified as an appropriate tool for collecting stakeholder responses.

The questionnaire was devised with the objective of securing an insight into the views and opinions of those who are implementing the Regulations across the healthcare sector and to provide an update to the core PIR questions from the first PIR in 2018.

The questionnaire (see Appendix 1) was designed to be quick and simple to complete, stakeholders took an average of eight minutes to complete the form. Time for follow-up was built into the research schedule, enabling any responses that raised further substantial questions to be further investigated.

There is no comprehensive list of stakeholders covered by the Regulations from which to draw a random sample. Instead, the questionnaire was circulated to contacts who had been previously engaged via the Safer Healthcare and Biosafety Network, NHS Health Safety and Wellbeing Partnership Group, and National Association for Safety and Health in Care Services (NASHiCS). This enabled stakeholders from across the healthcare sector to contribute. The survey was open from 1st September to 14th October 2022.

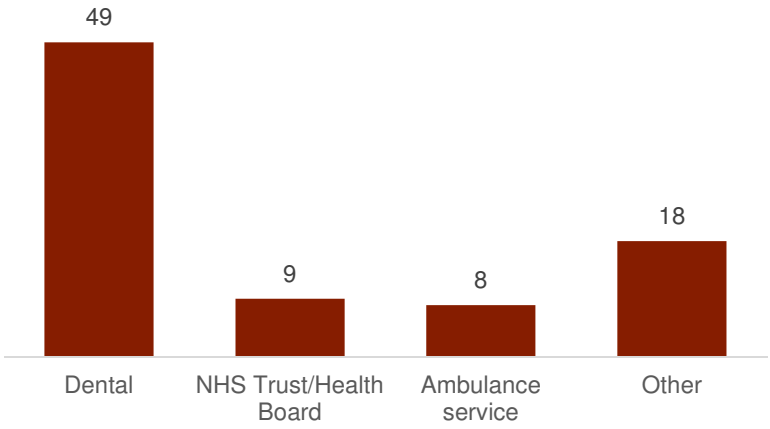
There are limitations with this approach as the non-random approach limits the interpretation of the results to being representative of the consultation participants only. It is encouraging that responses were sufficiently broad to have captured a range of views from across sectors and business sizes.

Characteristics of respondents

In total, 85 stakeholders returned completed questionnaires. These respondents came from a range of different organisations within the healthcare sector, including NHS hospital trusts, ambulance services, professional bodies, unions, private health care providers, occupational health, charity health services and dental practices.

The dental sector was particularly well represented in the consultation, accounting for more than half of all completed questionnaires (49 stakeholders), see Figure 1. Organisations covered by the ‘other’ category included unions and professional bodies, universities, private health care and charity care along with other NHS providers.

Figure 1: Number of respondents by indicative sector



Data from the Labour Force Survey shows that dental practices (SIC 86230) account for approximately 4.3 percent of all employment in the healthcare sector (SIC 86) in Great Britain[2]. To account for the overrepresentation of the dental sector in this consultation, all data presented has been analysed to explore any differences between those working in the dental sector and other stakeholders.

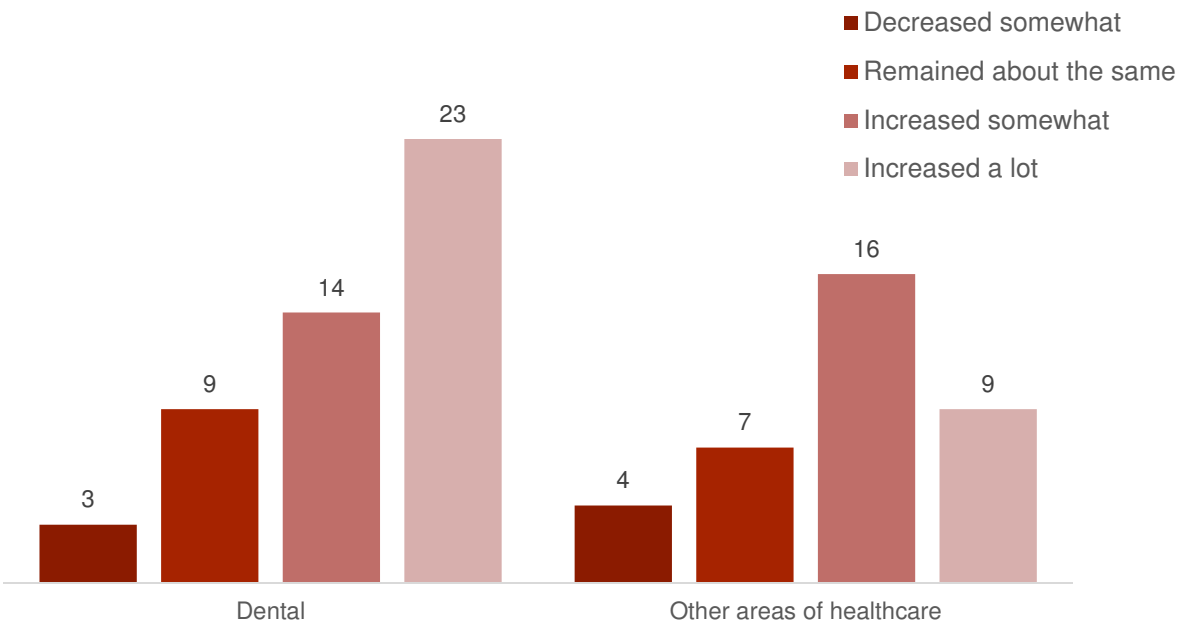
Findings

Change in use of safer sharps over the last 5 years

Stakeholders from both dental and other healthcare sectors stated that there has been an increase in the use of safer sharps over the past five years. With three-quarters of those in the dental sector (37 respondents) and seven out of ten stakeholders from other healthcare sectors (25 respondents) saying that use had increased either a lot or somewhat. It is interesting to note that four stakeholders from other areas of healthcare said that there has been a decrease in use of safer sharps during this time period.

[2]https://www.ons.gov.uk/employmentandlabourmarket/peopleinwork/employmentandemployeetypes/bulletins/employeesintheukbyindustry/2018 table 2 Dental practices (SIC 86230) Health sector (SIC 86)

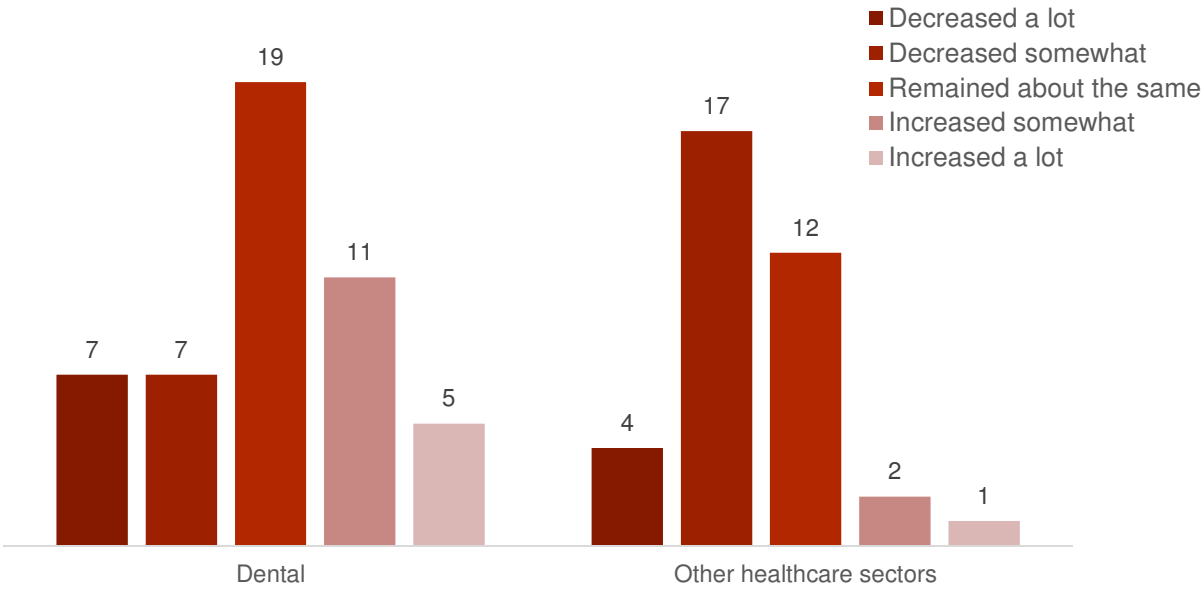
Figure 2: In your opinion, in the last 5 years, has the use of 'safer sharps'...



Workforce resistance to safer sharps

This consultation provides a mixed picture on the extent to which workforce resistance to the use of safer sharps has changed over the last five years. Almost a third of those from dental sectors (16 respondents) said there had been an increase in resistance, a further fourteen said that resistance had decreased with nineteen saying there had been no change. There is a different picture amongst stakeholders from other healthcare sectors; fewer than one in ten of these stakeholders said that resistance had increased (3 respondents) a further third said that levels of workforce resistance had remained the same (12 respondents) with the majority of these stakeholders saying that resistance had decreased a lot or somewhat (21 respondents).

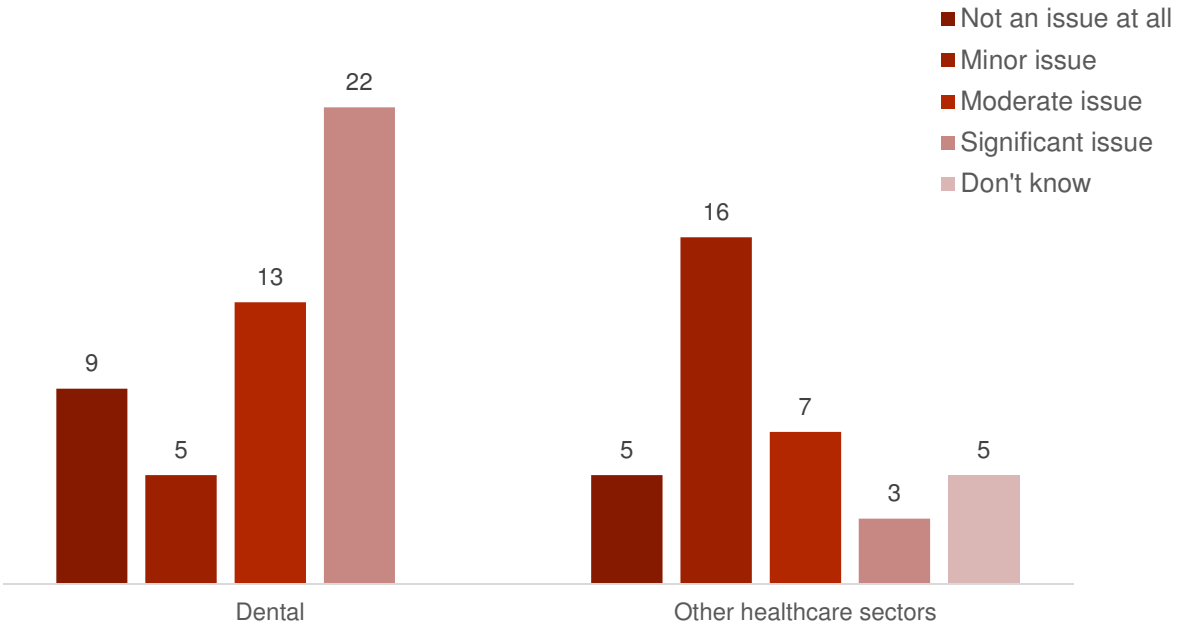
Figure 3: **The post-implementation review carried out in 2018 found that some sections of the workforce were resistant to using 'safer sharps'. In your opinion, over the past 5 years, has resistance to safer sharps . . .**



Usability issues with safer sharps

The 2018 Post-Implementation Review found that some practitioners identified usability issues with 'safer sharps'. This continues to be a particular issue for those stakeholders from the dental sector, with 22 of these stakeholders saying it was a significant issue compared with three respondents from other healthcare sectors. Usability issues remain a minor issue or moderate issue for stakeholders from other healthcare sectors (23 respondents).

Figure 4: The post-implementation review carried out in 2018 found that some practitioners identified usability issues with 'safer sharps' relative to traditional devices. In your opinion, to what extent is this . . .

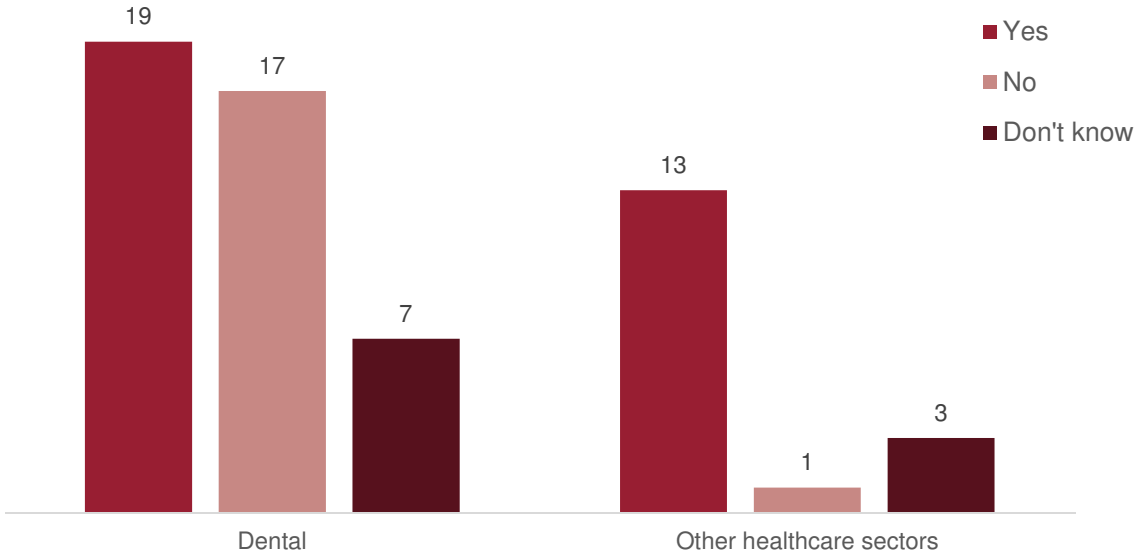


Are the Regulations still required?

Due to a technical error with the web-based survey which temporarily removed this question, fewer than half of respondents answered this question.

Overall, stakeholders working in both dental and other areas of healthcare thought that the Regulations are still required. However, support for these regulations was much higher amongst stakeholders working in other areas of healthcare than stakeholders from the dental sector, with only one stakeholder from the non-dental sector said that the Regulations are **not** still required, whilst 17 stakeholders from the dental sector said this was the case.

Figure 5: In your opinion, are the Health and Safety (Sharp Instruments in Healthcare) Regulations 2013 still required?

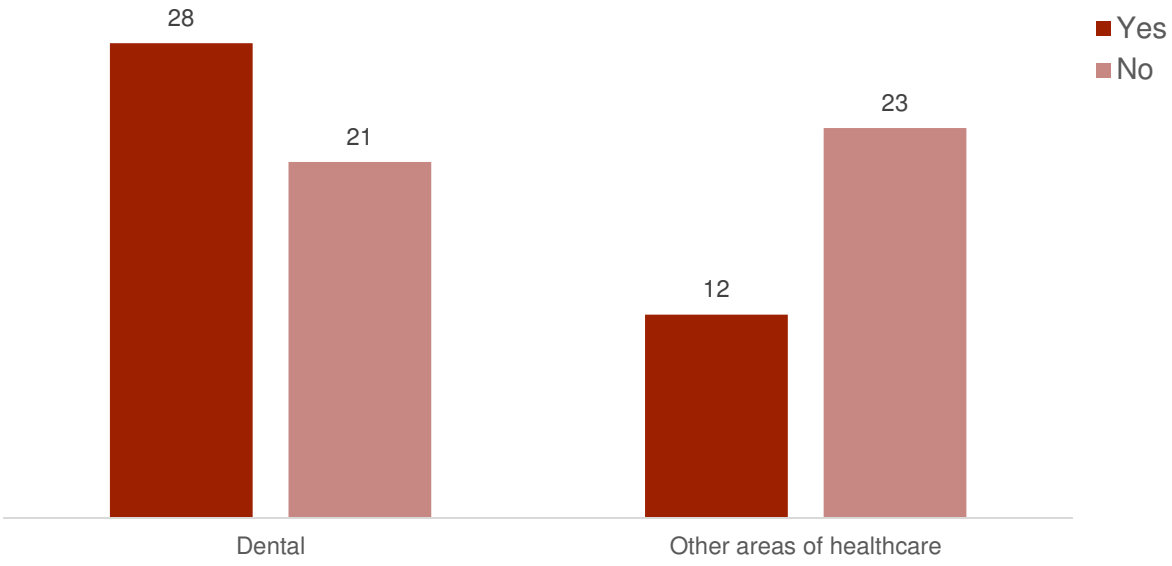


Sixteen of these stakeholders took the opportunity to expand on their reasons for stating that the Regulations are not still required. Several of these mentioned how existing risk management or Management of Health and Safety Regulations could be used to reduce the risk of using traditional needles and that needle-stick injuries are, in their experience, uncommon and that appropriate training can reduce the risk of sharps injuries. Full responses are given in Appendix 2 Table 1.

Unintended consequences

Stakeholders were asked if they were aware of any unintended consequences, positive or negative, of the Regulations. Almost half of all respondents (40 stakeholders) said that there had been unintended consequences. Those from the dental sector were more likely than others to say that there had been unintended consequences.

Figure 6: Are you aware of any unintended consequences (positive or negative) arising from the Health and Safety (Sharp Instruments in Healthcare) Regulations 2013?



Stakeholders were asked to specify the nature of the unintended consequences they had experienced. Their responses fell into the following general categories:

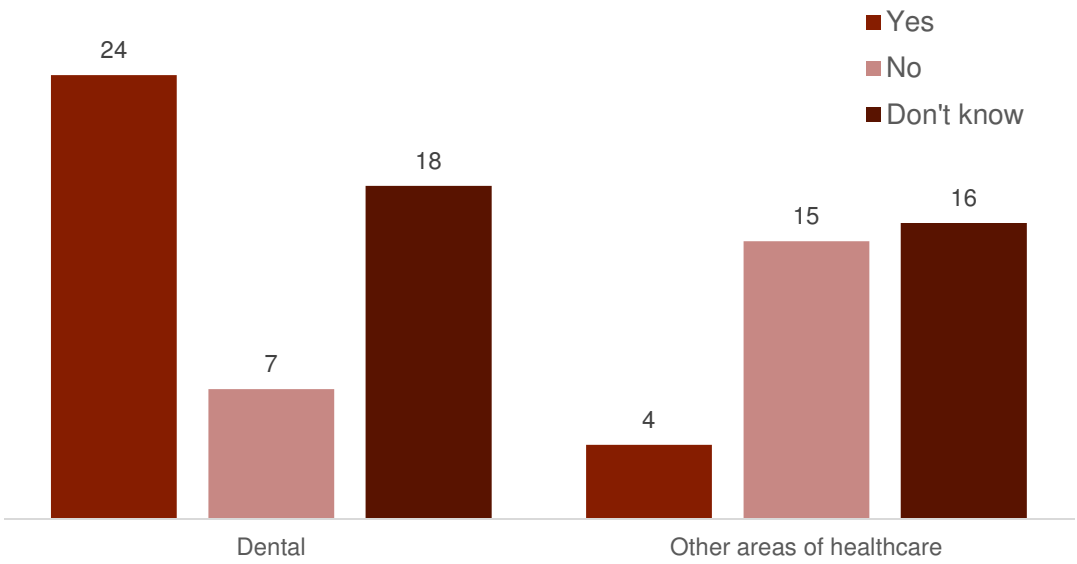
- Issues relating to the introduction of new processes and equipment.
- Waste and environmental impact.
- Issues around the appropriateness and design of safer sharps.

Very few respondents referred to cost as an unintended consequence, however the Regulations require the use of safety-engineered devices (SEDs) so far is reasonably practicable and concern was expressed by one respondent that Trusts may purchase cheaper and less safe sharps to enable them to remain in budget as this would be 'reasonably practicable.'

Stakeholders from the dental sector were particularly concerned with issues arising from the move to new, and for some, unfamiliar products which could possibly increase the risk of sharps injury. There were concerns about appropriateness of the safer sharps for application in the dental sector, and the quality of this equipment, specifically in relation to delivering local anaesthetic, with the sharps described as 'flimsy', 'fragile', 'clumsy' and 'crude'. The environmental impact of the increased waste associated with safer sharps was also raised by stakeholders from the dental sector. For some there appears to be some confusion about how the Regulations should be implemented. Answers from all respondents are given in full in Appendix 2 Table 2 and 3.

Could the aims of the Regulations be achieved with less burden on businesses
Four out of every ten stakeholders consulted (34 respondents) answered 'don't know' to this question. However, there was notable variation by sector. Almost half of those from the dental sector (24 stakeholders) stated that the aims of the Regulations could be achieved with less burden on businesses compared with just over one in ten stakeholders from other areas of healthcare (4 stakeholders).

Figure 7: In your opinion, could the aims of the Health and Safety (Sharp Instruments in Healthcare) Regulations 2013 be achieved with a system that imposes less burden on business?



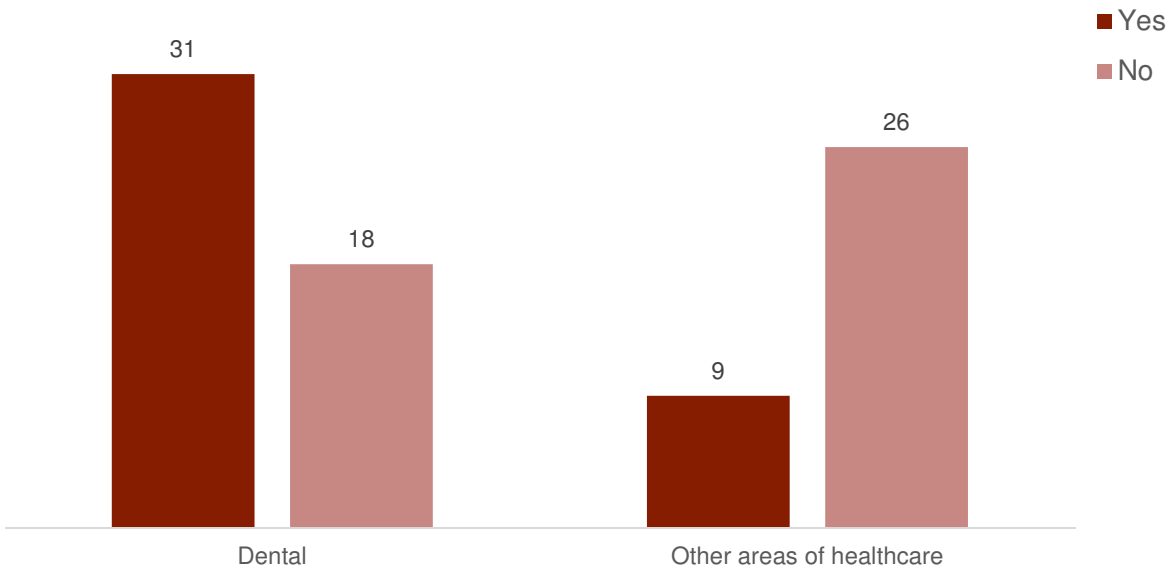
When asked how the aims of the Regulations could be achieved with a system that imposes less burden on business several respondents suggested relaxing or removing the Regulations, however, these respondents did not specify how this action would help achieve the aims of the Regulations. In the dental sector a move to safer sharps has resulted in an increased use of disposable equipment and several respondents suggested how the previous reusable metal syringes could or should be used to reduce the burden on businesses. Some respondents highlighted issues around the disposal of sharps and the need for reduced waste.

A full list of suggestions by stakeholders of how he aims of the Regulations could be achieved with a system that imposes less burden on businesses are given in Appendix 2 Table 4

Unintended costs

Stakeholders from the dental sector (31 of 49 respondents) were far more likely to suggest there were unintended costs arising from the Regulations than stakeholders from other areas of healthcare (9 of 35 respondents).

Figure 8: Are you aware of any unintended costs arising directly from the Health and Safety (Sharp Instruments in Healthcare) Regulations 2013?



In terms of unintended costs, stakeholders from the dental sector were particularly concerned with two issues: the cost of clinical waste arising from the use of disposable syringes and the cost of purchasing safer sharps. The cost of purchasing safer sharps formed part of the initial impact assessment, as so is not 'unintended'. Additional waste costs were not previously considered, though very few respondents provided any detail. One respondent suggested "The disposal costs are the problem and the safety syringes occupy a higher volume, Disposal for 100 normal needles is around £2, disposal of 100 safety syringes is about £30". Other respondents mentioned the cost of training, and additional costs caused by supply chain issues when stock of safer sharps is not readily available.

The cost of the safer sharps was also mentioned by one stakeholder from other areas of healthcare. A further issue was the staff time required to "update documentation, undertake validation activities and conduct risk assessments" this was identified as a particular cost when the move to safer sharps was first made, however it continues to be a potential cost as and when new safer sharp devices become available. Stakeholders from non-dental areas of healthcare also highlighted reduced costs as a result of the Regulations because of the reduced cost of claims in relation to sharps injuries and how in some cases, for example needle free infusion bags, the amount of time to prepare aseptic products has been reduced, although the cost for needle free versions is higher.

For a full list of responses to this question see Appendix 2 Tables 5 and 6

Other observations and comments about the Regulations

Stakeholders who returned a questionnaire were given the opportunity to make further comments or observations about the Regulations. Many made considered and careful comments covering a range of issues. Key comments by stakeholders from other healthcare sectors include:

- The dramatic effect that the Regulations have had on protecting healthcare workers.
- The importance of the Regulations in supporting behavioural change.
- The benefit of the Regulations and resulting use of safety devices in reducing the injuries to ancillary staff who were often injured through poorly disposed of sharps.
- How the Regulations have acted as a 'catalyst for better practice in healthcare'.
- The importance of education in relation to BBFE and competency-based training to reduce BBFE.
- Behavioural change to address and prevent sharps injuries had started before the Regulations were implemented, however, this accelerated after the Regulations came into force.
- There are potential dangers faced by healthcare workers from patients' own sharps, for prescribed medicines or illicit drugs which are not safer sharps.
- Issues around the 'inferior workability' of some safer sharps.
- How 'personal preference, custom and practice may be used as a reason not to implement new devices'.
- How the Regulations serve as a reminder of employer duties in managing risk and provide a specific requirement for compliance in relation to sharps.

Comments from stakeholders operating in the dental sector tended to repeat points already made in relation to cost, waste and functionality. In relation to the efficacy of the Regulations stakeholders also mentioned:

- How safer sharps have minimised needlestick injuries and given staff the knowledge they need to handle them.
- How the Regulations were much needed but also need to be enforced and monitored.
- The importance of training in using safer sharps.

All responses to this question are given in full in Appendix 2 Table 7.

Evidence from interviews with industry experts

Terry Grimmond[3] is an expert in BBFE, NSI and safer sharps, he has completed major research in this area and is a member of several international committees concerned with

[3] Terry Grimmond is a microbiologist who specialises in the prevention of BBFE, he has more than 53 years of experience working in university hospitals industry and consultancy, he is an international speaker on Sharps Injury Prevention and Hospital waste

reducing BBFE and related topics. He was interviewed to explore the issues covered by the stakeholder consultation in more depth and to provide an understanding of the wider context in relation to safer sharps and sharps injuries. Key points raised by the interviewee include:

- Legal regulation is vital, take that away and you will revert to where we were before.
- If anything the regulation doesn't go far enough. Flexibility within the Regulations allows UK trusts to use cost as a reason for not putting in best and safest devices. The Regulations adoption of 'so far as is reasonably practicable' as a qualifier to using safer devices potentially allows duty holders to be able to use cost as a sole reason not to use safer devices, in comparison to other countries where cost specifically cannot be used as a sole reason for not using safer sharps.
- Costs associated with safer sharps should not be viewed as just financial, they also include the physical personal and psychological impacts suffered by those who incur needle injury and especially those that suffer a BBV. The higher initial costs of safer devices are offset by reduced injury costs.
- The importance of healthcare workers having access to the safest devices, as many needlestick injuries occur with safety devices. It is important healthcare workers have access to the 'safest' device rather than just a 'safer' device and the need for a move towards auto and semi-auto devices that deploy safety features without the need for a healthcare worker to activate them. There is evidence that passive safety devices, now called automatic/ semi-automatic, have reduced injury rates.
- Training is essential to ensure devices are used safely and this needs to be competency based and thorough; "See one, do one, teach one" is an inadequate approach to training. Trim and Elliot[4] established the role of competency-based training in preventing NSI.
- Whilst not all procedures have a suitable safety device available, estimates that around 90% of sharps work in healthcare will have a safer device available.
- A wide range of healthcare professionals are at risk of sharps injuries including porters and other non-clinical staff who can be exposed if contaminated needles are not disposed of properly. This is potentially worse for non-clinical staff as they are often far downstream of the patient, and it may be impossible to trace the patient to do blood tests on.
- Really need better data on incident rates, to monitor the incidence of NSI and the impact of safer sharps effectively, annual incident rates should be published by UK trusts.
- Staff safety and patient safety are intertwined, and needle safety is intrinsic to high patient outcomes.
- Costs of waste disposal are higher as safety devices are 15-20 percent bulkier, making them larger in volume. Although the automatic devices are often smaller than other safer sharps and so may generate less waste. There are increasing opportunities to reuse/recycle rather than incinerate.

Analysis of the stakeholder consultation identified some differences in the responses from those working in the dental care compared with those based in other sectors of healthcare. To provide a better understanding of comments made by respondents from the dental sector

[4] Trim, J.C., & Elliott, T.S. (2003). A review of sharps injuries and preventative strategies. *The Journal of hospital infection, 53 4*, 237-42

and to explore related contextual issues an interview was conducted with Harriet Patel (BDS), health safety and compliance adviser to the British Dental Association.

During the interview the importance and value of the Regulations for dentists as for other healthcare sectors was highlighted, along with the fact that the Regulations are generally well accepted and positively adopted into practice compliance.

The key issues that had been identified through the stakeholder consultation were the issues that Ms Patel had expected those in dental practice to raise, namely:

- The appropriateness/design of safer devices.
- Low level of injuries from traditional needles.
- The amount and type of waste generated by safer sharps devices.
- Cost of safer sharps devices, systems and associated waste.

Key points raised by the interviewee include:

- The appropriateness and quality of safer devices is a major issue, with safer sharps considered not as robust as traditional devices. The 'flimsiness' of some safer sharps has, on occasion, resulted in needle stick injuries due to breakages. The design of the safer sharps is a particular issue in relation to inferior dental block (IDB), a procedure frequently used in dentistry. The biggest barrier to the use of safer sharps in respect of IDB is that the safer sharps devices are not as effective as traditional equipment, they are bulkier and this makes the procedure more challenging with the potential of impacting negatively on patients. These issues relate to the quality and appropriateness of the devices rather than any training in the use of these devices.

- Dentists, hygienists and dental nurses are at risk from sharps injuries from a range of implements including matrix bands, wedges and files. This means there is often a reduced perception of risk from needles, and a view that the safer devices that are available are not necessarily for the equipment that poses the greatest risk.

- When devices are labelled 'safer' there is also the potential for them to be considered less risky. A concern was expressed that if a device is viewed as 'safer' then it could be regarded as safe for dental nurses to dispose of. There have been incidents where dental nurses have received NSI when safer sharps have been left for them to clear away without the safety features being fully engaged by the clinician. This highlights the importance of process when dealing with sharps and the benefit of requiring the clinician to be responsible for disposing the sharps they have been using. Clarity in the guidance on clinician-nurse roles around sharps handling with a focus on clinician responsibility for disposal would reduce these incidents.

- Access to occupational health support for those who have received a NSI can be patchy for those working in the dental sector. The Regulations are an important reminder of the importance of mindfulness when dealing with sharps and the negative impact that busyness and rushing can have.

- Waste is a concern to the dental sector both in relation to the environmental impact of plastics and the cost of disposal. Safer sharps are 4 to 5 times bulkier than traditional devices, consequently the cost of disposal is 4 to 5 times higher, this is at a time when general waste disposal costs are increasing.

- When the Regulations were first introduced there was some confusion within the sector as to whether they applied to dental practices or not. As sharps injuries through needles were relatively rare compared with injuries from other sharps there was some questioning of the need for the use of safer sharps, particularly if onehanded recapping was being used effectively.

- To some extent it was thought that the stakeholders opinions of safer sharps is a generational issue, with dentists who have been through training more recently only ever using safer sharps.

- It remains the case that the dental sector can still use non-safety devices as long as they have assessed the risks and established appropriate processes through risk assessment.

Review of existing research

In 2021 the Royal College of Nursing (RCN) published a major research report into the incidence of Blood and Body Fluid Exposure (BBFE)[5]. This was a large-scale survey with an electronic questionnaire sent to all members of RCN, achieving 7,571 responses from members. This report provides a snapshot of RCN members experience of sharps injuries and experience of BBFE. Key findings from this research that are relevant to the PIR include:

- Almost two thirds of respondents (63 percent) had experienced a sharps injury during their career with 15 percent experiencing a sharps injury in the previous 12 months.
- The level of sharps injuries reported in this survey was higher than in the 2008 RCN[6] survey when 10 percent of respondents had experienced a sharps injury in the previous 12 months.
- A quarter of respondents (25 percent) had no training on safer sharps use and a fifth (21 percent) had no education on reporting sharps injuries.
- Whilst three quarters of respondents (75 percent) received training on safer sharps, a smaller proportion (62 percent) had received training on each safer sharp that they need to use.
- Staff who received training on all safer sharps they used had a significantly lower incidence of sharps injury (21.4/100FTE) than staff who did not (26.6/100FTE)
- The top three contributing factors to sharps injuries were identified as “fatigue/tiredness” (27 percent), “lack of safety equipment” (25 percent) and “non-co-operative patient” (25 percent).

[5] *Blood and Body Fluid Exposures in 2020. Results from a survey of RCN members* (2021) Royal College of Nursing London available from https://www.rcn.org.uk/professional-development/publications/rcn-blood-and-bodily-fluid-exposures-uk-pub-009-687

[6] Needlestick Injury in 2008. Results from a survey of RCN members. Royal College of Nursing, 20 Cavendish Square, London, W1G 0RN; RCN Publication Code 003 304

- This survey was conducted late in 2020 when fatigue associated with working during COVID-19 was extreme and supply chains were, on occasion, unreliable, meaning that safer sharps were not always available. Almost one in 10 respondents (9 percent) stated that wearing Personal Protective Equipment was a contributary factor to their most recent sharps injury.
- 85 percent of respondents reported that they had good or excellent access to safer devices, however 15 percent said they had low or nil access.
- Staff who had "excellent" access to safer sharps had a significantly lower incidence of sharps injuries (16.7/100FTE) than staff who had "Nil to Poor" access (35.0/100FTE).
- 71 percent of those experiencing a sharps injury reported it officially, a further 12 percent reported it to a manager or colleague with 17 percent not reporting it to anyone.
- Reasons given for not reporting sharps injuries officially included that the injury was low risk (39 percent) that the respondent had reported it to a manager instead (19 percent) or that they saw no benefit in reporting the injury (15 percent).

The RCN report identified a high incidence of sharps related injuries in 2020, however "it is likely related to COVID-19 workloads, fatigue and stress".

The survey found that not all respondents had access to 'safer sharps, device training and BBFE education' and this could be a 'contributing factor the high incidence' of sharps injuries. However, further research is required to establish if this is due to employees lack of take up or employers lack of provision.

Evidence from other research

Terry Grimmond identified several academic papers relevant to this evidence review, key points are detailed below.

Research from Robert Wood Johnson University Hospital (RWJUH) in New Brunswick NJ demonstrates how the use of appropriate safer sharps can reduce needlestick injuries (NSI) and result in cost savings[7]. In 2008 an employee at RWJUH acquired Hepatitis C following a NSI, this incident resulted in the hospital refocusing efforts on reducing overall sharps injuries and adopting a new style of safety winged blood collection set. Introduction of the new device resulted in a 64% reduction in rate of sharps injuries. Reductions in the number of NSI had immediate cost savings. The research also highlighted the importance of a systematic approach to training on the new devices rather than depending on peer-to-peer training as the hospital worked towards a goal of zero NSI.

The importance of appropriate safer sharps is demonstrated in a study by Hotaling (2009)[8]. This research documented how a retractable winged steel (butterfly) device reduced phlebotomy needle stick injuries at a 500+ bed hospital by 88%, with zero injuries in the last 21 months of the study.

[7] Dicristina, Doris L. "Successfully Reducing Wingset-related Needlestick Injuries: A combination of institutional culture, staff commitment and semi-passive safety device." (2014).
Available from https://www.bd.com/resource.aspx?IDX=31023

[8] Hotaling M. (2009). A retractable winged steel (butterfly) needle performance improvement project. *Joint Commission journal on quality and patient safety*, *35*(2), https://doi.org/10.1016/s1553-7250(09)35013-8

In terms of reducing the number of sharps injuries the type of safer sharp used matters. Research by Black[9] et al showed higher rate of sharps injuries when healthcare workers were using active devices where the user has to activate the safety feature compared to passive safer sharps, where the devices activate automatically. They also highlighted the importance of training and good working practices when using both passive and active sharps. Based on their research they estimated that approximately 23 to 32 percent of injuries could have been prevented had an available safety feature been activated after use. This mirrored the findings of Tosini et al (2010)[10], who conducted a major review of NSI across 61 hospitals in France, concluding that passive safer sharp devices resulted in fewer NSI than active devices.

Evidence from NHS Supply Chain

NHS Supply Chain manages the sourcing, delivery and supply of healthcare products for NHS trusts and healthcare organisations across England and Wales. In July 2022 NHS Supply Chain presented data relating to the sales of sharps to the Safer Healthcare Biosafety Network[11]. This data provides an overview of the sales of different categories of sharps. In the year to July 2022 sales of safer sharps via NHS Supply Chain accounted for 85% of all sharps devices purchased, up from 45 percent in 2014, demonstrating a year on year increase in the purchase of safer sharps since the introduction of the Regulations in 2013.

Table 1: Sales of safe and conventional devices via NHS Supply Chain

	Number of safer devices (million)	Number of conventional devices (million)	Total sales (million)	Safer sharps as % of sales
12 months to July **2014**	125.2	155.0	280.3	45%
12 months to July **2015**	154.1	133.7	287.8	54%
12 months to July **2016**	180.4	109.3	289.7	62%
12 months to July **2017**	205.4	93.3	298.7	69%
12 months to July **2018**	217.9	77.0	294.8	74%
12 months to July **2019**	229.8	74.3	304.1	76%
12 months to July **2020**	230.5	60.7	291.1	79%
12 months to July **2021**	245.8	51.2	297.0	83%
12 months to July **2022**	303.9	53.7	357.6	85%

(Figures may not sum due to rounding) Data: NHS Supply Chain

Evidence from inspections

Health and Safety Executive Occupational Health Inspectors conducted 11 inspections of NHS Organisations between June and December 2022, focusing specifically on the

[9] Black, L., Parker, G., & Jagger, J. (2012). Chinks in the armor: activation patterns of hollow-bore safety-engineered sharp devices. *Infection control and hospital epidemiology*, *33*(8), 842–844. https://doi.org/10.1086/666630

[10] Tosini, W., Ciotti, C., Goyer, F., Lolom, I., L'Hériteau, F., Abiteboul, D., Pellissier, G., & Bouvet, E. (2010). Needlestick injury rates according to different types of safety-engineered devices: results of a French multicenter study. *Infection control and hospital epidemiology*, *31*(4), 402–407. https://doi.org/10.1086/651301

[11] https://www.pslhub.org/learn/commissioning-service-provision-and-innovation-in-health-and-care/safer-sharps-%E2%80%93-nhs-supply-chain-update-to-the-safer-needles-network-22-june-2022h-2021-r4296/

management of sharps. Inspectors identified contraventions to health and safety legislation in all organisations inspected, as a result a total of 11 formal improvement notices served across seven organisations. Contraventions to the Regulations included:

- 5 breaches of Regulation 5 (avoid unnecessary use of sharps).
- 5 breaches of Regulation 6 (provide information and training on use of sharps).
- 4 breaches of Regulation 7 (record and investigate sharps incidents).

A discussion with the inspectors who completed the inspections identified a number of characteristics of a good sharps risk management system. These included:

- A clear policy on managing sharps risk.
- Close liaison between occupational health providers, health and safety, infection prevention and control (IPC) and procurement departments.
- Establishment of 'steering groups' including clinicians and members of the above departments.
- Strong and visible IPC teams.
- Effective training including face to face element.
- Strong organisational leadership at Director level.

The absence of one or more of these characteristics are, in the opinion of the HSE inspectors involved, a key factor in the lack of compliance seen.

Conclusions

The feedback and opinions of stakeholders, industry experts and inspectors along with a review of existing research has been collated in this evidence base to address the key questions for the PIR.

To what extent have the policy objectives been achieved?
The principal objective of the Regulations was to ensure that all measures specified in the Council Directive 2010/32/EU were implemented into UK law. With the intended effect that healthcare workers are offered a good standard of protection and the number of sharps injuries fall.

The stakeholder consultation provides evidence of an increasing use of safer sharps across all healthcare sectors. With data from NHS Supply Chain providing further confirmation of an increase in use of safer sharps, with 85% of all sharps purchased in the year to July 2022 being safer sharps, up from 45% of all applicable sharps sales by NHS Supply Chain in 2014[12] – the year immediately after the introduction of the Regulations.

Despite an increase in the use of safer devices, sharps injuries continue to impact on the health and wellbeing of healthcare workers. Research from the RCN highlights high rates of NSI amongst their members and demonstrates the importance of training in reducing the incidence of NSI. Data from NHS resolutions shows how NSI cost £2.6 million in terms of the compensation awards paid to 1,088 healthcare workers between 2014/15 and 2018/19[13].

[12] https://www.pslhub.org/learn/commissioning-service-provision-and-innovation-in-health-and-care/safer-sharps-%E2%80%93-nhs-supply-chain-update-to-the-safer-needles-network-22-june-2022h-2021-r4296/
[13] https://resolution.nhs.uk/wp-content/uploads/2020/11/FOI_4155_Sharps-Injury.pdf

HSE Occupational Health Inspectors report that compliance in relation to the Regulations remains a concern. With contraventions to health and safety legislation in relation to the management of sharps risks at all NHS organisations inspected between June and December 2022.

The first PIR for the Regulations (2018) identified the usability of safer sharps as a factor that had the potential to hinder the implementation of the Regulations. This remains a concern for some respondents from the dental sector. However, stakeholders from other healthcare sectors do not view usability of safer sharps as a hindrance to the implementation of the Regulations.

Were there any unintended consequences?
The stakeholder consultation highlighted the environmental impact and cost of waste disposal associated with the safer sharps as an unintended consequence of the Regulations. This was a particular issue in the dental sector, and in part is caused by the increased bulk of safer sharps in comparison with traditional needles.

Are there any opportunities for reducing the burden on business?
Very few stakeholders from healthcare sectors other than dental were aware of ways in which the burden of the Regulations on businesses could be reduced. A small minority of respondents from the dental sector wanted to see a relaxation of the Regulations and the use of existing control processes and risk assessments to reduce the likelihood of NSI. In contrast, one expert consulted was clear that such an approach would, in their view, lead to worse health and safety outcomes.

Is the existing form of regulation still the most appropriate approach?
Across stakeholders there remains strong support for the Regulations. Levels of support for the Regulations were not as high amongst stakeholders from the dental sector, however, the majority of these respondents still thought that the Regulations are required. The hesitancy amongst some in this group reflects issues around the suitability of safer sharps for specific clinical procedures and the increased cost and waste associated with disposing of safer sharps.

It is estimated that safer devices exist for 90 percent of sharps work. However, the RCN research shows that only 45 percent of members who responded to the survey (in 2020) stated that they have excellent access to safer sharps. Staff who had “Excellent” access to safer sharps had a significantly lower incidence of NSI than staff who had “Nil to Poor” access. The Regulations also make provision for sharps training, the research findings highlighted the with value of effective training in reducing the incidence of NSI.

The expert view is that the Regulations are a vital tool in protecting the health and wellbeing of healthcare workers, and without the Regulations the situation is likely to revert to where it was prior to their introduction. NSI would be reduced further if the Regulations called for the use of safest sharps rather than just safer sharps, given the potential impact that passive devices have on reducing the rate of NSI.

Appendix 1: Stakeholder Questionnaire

The questionnaire below is reproduced from the original format in the web-based platform Microsoft Forms.

Health and Safety (Sharp Instruments in Healthcare) Regulations 2013 - Policy Review

Background

The Sharps Regulations (the Health and Safety (Sharp Instruments in Healthcare) Regulations 2013) are being reviewed now by the Health and Safety Executive (HSE). We want to hear your views about how the Regulations are working.

This short questionnaire takes about 5-10 minutes to complete and is an opportunity to ensure your views are heard.

Confidentiality:
Your individual responses are for HSE's internal use, they will not be provided to third parties, and will not be used for regulatory inspection purposes. The data you provide will be securely stored and deleted upon publication of the final post-implementation review (PIR). All data is processed in line with HSE's privacy policy (https://www.hse.gov.uk/privacy.htm). You can contact us to have the information you provide changed or deleted if you choose to provide contact details.

Any problems or questions, please contact X

To review the Regulations in full go to: https://www.legislation.gov.uk/uksi/2013/645/made, otherwise **please continue to question 1**.

Section 1. About you

Please complete the following questions so that we can understand your responses in the context of your role and organisation.

1.What is the name of the organisation you work for?

2.What is your job role?

Section 2. The Regulations

3.Are you aware of any unintended costs arising directly from the Health and Safety (Sharp Instruments in Healthcare) Regulations 2013?

Yes		*Carry on to question 4*
No		*Go to question 5*

4.Please provide a brief description, and estimated cost, for those other cost areas.

5.Are you aware of any unintended consequences (positive or negative) arising from the Health and Safety (Sharp Instruments in Healthcare) Regulations 2013?

Yes		*Carry on to question 6*
No		*Go to question 7*

6.Please provide a brief description.

7.In your opinion, are the Health and Safety (Sharp Instruments in Healthcare) Regulations 2013 still required?

Yes		*Go to question 9*
No		*Carry on to question 8*
Don't know		*Go to question 9*

8.Please explain why you do not think the Regulations are required.

9.In your opinion, could the aims of the Health and Safety (Sharp Instruments in Healthcare) Regulations 2013 be achieved with a system that imposes less burden on business?

Yes		*Carry on to question 10*
No		*Go to question 11*
Don't know		*Go to question 11*

10.Please explain how you think the aims of the Regulations could be achieved with a system that imposes less burden on business.

3. Use of 'safer sharps'

The term 'safer sharps' describes medical sharps that incorporate features or mechanisms to prevent or minimise the risk of accidental injury.

11.In your opinion, **in the last 5 years**, has the use of 'safer sharps'...

Increased a lot	
Increased somewhat	
Remained about the same	
Decreased somewhat	
Decreased a lot	

12.The post-implementation review carried out in 2018 found that some sections of the workforce were resistant to using 'safer sharps'.

In your opinion, over the past 5 years, has resistance to safer sharps increased or decreased?

Increased a lot	
Increased somewhat	
Remained about the same	
Decreased somewhat	
Decreased a lot	

13.The post-implementation review carried out in 2018 found that some practitioners identified usability issues with 'safer sharps' relative to traditional devices.

In your opinion, to what extent is usability **currently** an issue for 'safer sharps'?

Significant issue	
Moderate issue	
Minor issue	
Not an issue at all	
Don't know	

And finally...

14.If you have any further observations or comments about the Health and Safety (Sharp Instruments in Healthcare) Regulations 2013, please enter these below:

15.As part of this research, the Health and Safety Executive may want to contact you again to clarify, or get further information, on the responses you provided.

If you are happy for the Health and Safety Executive to re-contact you, **please provide your email address**:

Thank you for completing this questionnaire.

Appendix 2: Tables containing full open text answers from respondents

Table 1: Reasons why Regulations are NOT required

Response from stakeholders from other healthcare sectors

The requirement to risk assess activities is already covered by the Management of Health and Safety Regulations. More appropriate than legislation would be a best practice guide.

Responses from stakeholders from the dental sector

The use of needles within dental practices already is covered by their normal workplace risk assessments
With good procedures you can reduce the risk by using conventional syringes, I really question the benefit.
Because the clinician can judge the most effective way to use local anaesthetics without compromising patient care
They can still be there, with the option of using something traditional when a risk assessment has been completed.
Practitioners and staff can function well without change, as long they are trained.
Common sense and proper care, time and attention completely eliminates most risk
Dentists are well trained in using traditional methods and should not be forced upon them to use safer sharps
In dentistry in general practice sharps are not moved around the surgery but disposed of directly into a sharps bin next to the practitioner after use.
Needle stick injuries incredibly rare with proper training.
Needlestick injuries extremely rare pre regulation Extra environmental cost excessive
Not noticed any reduction in needle stick injuries in the practice.
Was only a very rare issue in dental practices with well trained staff and clinicians. Many of the sharps injuries can come from other types of instruments not covered by the legislation anyhow (such as polishing instruments and scaling instruments).
Regulation has made working in dentistry far more dangerous.
Too costly and not a flexible regulation.
Costs of compliance are too high and the environmental cost is hugely disproportionate compared to the perceived advantages, which in my opinion do not exist anyhow.
We have not seen any direct impact from the regulations. Audit shows that more injuries occur from other issues than a reduction in sharps injuries from the use of safe sharp devices.

Table 2: Unintended consequences - responses from stakeholders from the dental sector

Process/implementation issues	Design/equipment issues
Having to use products we are unfamiliar with, therefore possibly increasing the risk of sharps injury	Clumsy and crude instruments increasing the risk of problems when treating patients (like instrument/syringe failures)
Dentists not used to using them, don't feel as in control	I have found the chances of needles stick injuries are higher with the newer "safer" types of syringes most especially with trainees. Your hands are more involved. Older fashioned metal syringes and re-sheathing devices keep hands much further away from used needles
In dentistry in general practice sharps are not moved around the surgery but disposed of directly into a sharps bin next to the practitioner after use	I've yet to find a "safer sharp" that doesn't have massive clinical disadvantages
Increased GDP time to deal with sharps, so decreased patient contact time. 1-2 mins per patient, but with 10-15 treatment apps a day 15-30 mins.	Rubber holders were brought in to recap needles. I know more dentists who had needlestick injuries with this device, compared to the previous "put the cap down and slide the needle in"
On initial conversion to, for example, Ultra Safety Plus: increase in sharps injuries due to lack of familiarity with new system.	Just because something is assumed safer, doesn't mean it's safer.
New "regulations" should be audited to see if it IS safer than before	Some so-called safe sharp local anaesthetic delivery systems are very fragile
In dentistry the suppliers of safety plus devices lied to profession stating unless we were using their products we were noncompliance. The only sharp injury in recent years in our practice was from a safety plus device!	The safe sharp can dis assemble from the syringe especially if extra pressure used
Increased pressure from sales representatives regarding the use of their products citing HSE and implying it was illegal to use the normal syringe and needle systems already in place in dentistry.	There [sic] efficiency is poor and ultimately the improvement or lessening of risk is debatable.
Many dentists dispute the legal need to adopt safety needle systems.	Ultra-safe needles are lethal as they collapse, fly off and fall apart regularly
Needle stick injuries remain covered by indemnity policies, according to many clinicians. This is offered as a reason not to adopt safe devices. CQC clarification has improved but advice seems to differ depending upon the individual inspector.	Using safety needles and syringes-they are flimsy and do not help in the delivery of local anaesthetic
	In dentistry you often have to give multiple injections in the same patient, often separated in time (if anaesthesia doesn't take) and safer sharps systems make this impossible or more dangerous than conventional sharps
	Various devices/procedures intended to reduce needle stick injuries, actually end up increasing the risk of them.
	More dangerous working environment: The rubber bungs to put on the ends are too heavy and make the needle unsheathing more of a risk.
	Lack of robustness of product
	The plastic type needles make it very difficult to do a gentle local anaesthetic which makes people feel more anxious and potentially less able to have

	treatment without sedation for example. This is especially important for the children at the practice.

Environment	**Positive**
A big increase in sharps waste Huge Environmental impact due to the huge amount of plastics involved. Hugely increased sharps disposal costs there is a vast increase in sharps waste and massive increase in single use plastics Increased use of plastic waste from the disposable syringes we use Increased waste worse for the environment Massive increase in the amount of single use plastic Huge increase in plastic usage/ disposal Need more sharps bins in dental surgeries as they fill so rapidly.	Positive only Personnel safety at all times **Cost** Raised costs, time cost impacting patient care opportunity

Table 3: Unintended consequences non-dental sector

Process/implementation issues	**Positive**
Sharps may be put into waste bins not designed for sharps. There is the risk of running out of sharps boxes. More storage space needed for the Safety plus syringes, and sharps bins fill up quicker- with more cost and more storage space again. There is a learning curve with new equipment, so staff are possibly more at risk of sharps injuries to begin with. Need for sheathed needles, requirement for sheathing devices "The Wand" pain-free computer controlled anaesthetic delivery, does not have safer sharps. Staff have developed habits of activating devices and are then more inclined to leave sharps in kidney dishes rather than immediately disposing of them into a sharps container. Sometimes staff forget to activate the device leaving sharps exposed. Immediate disposal needs to be the prime message as the majority of devices used are active and not passive.	Decrease of sharps injuries Gives guidance which is necessary Staff need additional training, which is an educational benefit and staff see this as a positive step to maintain their health and safety at work Reduction in number of sharps and needlestick injuries While needle stock injuries do still occur (even with needle sheath blocks) we believe there are far less than pre-regulation.
Environment	**Cost**
Environmental issues [not specified]	Higher cost can be seen as a potential issue for care homes The 2013 Sharps regs required trusts to purchase SED, “so far as is reasonably Practicable”. This is a flaw in the law as it enabled cash-strapped trusts to purchase cheaper (less safe) SED to enable them to remain within budget – as to do otherwise would not be “reasonably practical”. There is always cost to safety. I know of no other country whose BBFE law allows facilities to use their fiscal shortfall as a reason for not purchasing safer SED

Table 4: How you think the aims of the Regulations could be achieved with a system that imposes less burden on business?

Responses from stakeholders from the dental sector

Businesses need to have systems in place to safely deal with used sharps. We said only the person using the sharp should place it in the bin thus removing the nurses from the hazard.
By relying on the removal and disposal of used sharps by one operator. Using process control rather than specifically designed systems. More sharps injuries in dentistry come from cleaning instruments than needlesticks
Encourage use of appliances which minimise clinical waste
Simply by requiring sharps to be disposed of directly after use into a sharps bin by the practitioner without having to move around the surgery.
Training and use of correct risk assessments.
Using traditional syringes with enhanced training
Use metal aspiration syringes that have far less waste, better for the environment and safer
Reusable handles and disposable needles like we always used to have.
With good procedures you can reduce the risk by using conventional syringes, I really question the benefit.
Exemptions
Give it more options and flexibility
Trust professionals to be professional. Single operator procedures with simple equipment.
Don't fix what's perceived by paper pushers as broken.
Any changes that reduce the burden on business without compromising safety are welcome
Be less prescriptive and encourage common sense and flexibility
Don't make us use safety needles and syringes - they are useless
let the dentists decide what they wish to use, that way they have options over costings and preference.
More freedom of choice and a better look at sustainable systems would be good.
Only essential staff (health care professionals) should assemble and dissemble sharp devices
Introducing cost effective community need specific measures

Table 5: Are you aware of any unintended costs arising directly from the Health and Safety (Sharp Instruments in Healthcare) Regulations 2013?

Responses from stakeholders from the dental sector

Waste related issues
Clinical waste disposal
Costs of disposal much higher as fill sharps bins very quickly
Extra cost of disposal as fill sharps bin quicker. the handles need replacing a lot more often than metal ones
Increase in disposable of plastic waste
Sharps bins filled more quickly with safer sharps than older style - they are considerably larger - leading to increased cost for clinical waste disposal
increased costs of disposal (fewer fit in disposal containers)
Increased cost of disposal of safe sharps
More clinical waste disposal, increased costs by £2000 per year
Safer sharps are Bulkier items that fill up sharps bins inefficiently at a far greater cost. Less durable and safe to use on patients (without risk of sharp injury) resulting in more wastage and again bulkier disposal as a result.
Waste is more so collection of waste costs have increased considerably
Sharps bins fill up very rapidly due to the bulky nature of the safer sharps needles and single use scalpels. I would say sharps bins fill up at least twice as fast.
The waste clinical cost along with the environmental cost
Increased disposal costs by a factor of 10
The disposal costs are the problem and the safety syringes occupy a higher volume, Disposal for 100 normal needles is around £2, disposal of 100 safety syringes is about £30.
Syringe systems such as ultra-safety plus twist produce a huge amount of plastic waste which means sharps bins become full quicker.
Cost of equipment
Disposable syringe
Increased costs of safer sharps devices compared to previous
Equipment costs, time costs, waste costs.
Increase cost of safety plus syringes are 3.5 times the cost of the alternative. They are much larger, so they take up more space in the sharps bins, increasing the cost of disposal. The environmental cost of producing these is also high as they contain a lot more single use plastic
Having to use ultra-safety plus needles. Massive compared to aspiration metal syringes of old
Increase in cost as instead of LA cartridges and needles, single use needle/syringe combos are used with LA cartridges. This massively increased costs

Cost of equipment (continued)

Increased cost in providing safer sharps products for use compared to older type sharps especially dental needles

Increased cost of purchase of safe sharps

Increased costs of use - often more devices used per patient than for example reusable LA cartridge holders (syringes) with disposable needles.

Massive increase in the amount of single use instruments

Safer sharps are hugely more expensive

Safety plus system is much more expensive than simple needles.

The number of syringes needed

Use of specialist to buy safer sharps has increased our sharps costs for purchase by a factor of 10

The cost of safer sharps syringes is extremely high, normal needles £10 per 100, Safety plus syringes £40 per 100.

we moved to using fully disposable syringes- which had an impact on cost but now nearly 10 years down the line that cost is just part of our day to day equipment budget

Syringe systems (ultra-safety plus twist) are very expensive.

Cost of the safety lid syringes is higher

Training

costs of developing training and lost time costs from taking HCW from patient care in order to undergo training.

staff training cost

Other

Rising cost due to economic instability

extra storage costs as take up more space

Increased cost unknown

Logistic cost from acquiring to disposal

Additional staff cost and administrative cost for procedure and management

Short term solution cost when out of stock item or no availability ,

Completely separating the sharps and having to send a sharps / toxin container back in based on time and not need of required, is a waste of money

Table 6: Are you aware of any unintended costs arising directly from the Health and Safety (Sharp Instruments in Healthcare) Regulations 2013?

Response from stakeholders from other healthcare sectors

Cost of instrumentation increased. Staff time for additional training/awareness.
Equipment for re-sheathing needles, needle free devices and infusion bags can cost significantly more than standard needles (anecdotally three times the cost). There is some procurement activity within the NHS that mitigates costs and as well as reducing the risk of injury, in some cases (needle free infusion bags) has reduced the time to prepare aseptic products. That said, in order to use new equipment within an NHS aseptic unit, time was required to update documentation, undertake validation activities and conduct risk assessments. It is difficult to estimate the cost of this but we have received feedback this took months and for some products a failure to meet quality assurance requirements to ensure the integrity of aseptic compounded products. Extra storage capacity has been required for the new equipment/needle free devices (being larger than standard needles); we expect this to have had a minimal impact in terms of costs.
I am not a UK employer of HCW however my research indicates trusts need purchase safer safety engineered devices (SED) than what the 2013 regs proposed. Whether the extra costs of safer devices would be offset by savings in sharps injury reduction remains to be studied in UK.
Need for sheathed needles, requirement for sheathing devices.
On average up to £2-6K per year on sharps related claims
Perceived increase in cost because the product is more complex than a plain needle, however these costs are offset due to decrease in incidents
Safety-plus syringes cost more than a use-once needle and reusable syringe.
The cost of safer sharps to teach nursing students with were more expensive initially than the conventional ones

Table 7: Other observations and comments

Comments from stakeholders from non-dental sector
A recent (2020) survey of members by the RCN suggested that training in the use of safer sharps was still lacking for many health care workers; also that the need for additional PPE use during the pandemic period has made the use of sharps generally more risky, presumably due to physical difficulties linked to additional PPE.
A review of incident data pre and post Regulation implementation from the NHS through a Freedom of Information request would allow good comparisons on whether incidents have reduced, remained the same or increased. Surely the success of a Regulation is to reduce or eliminate incidents or accidents.
Consideration should be given to the environment in which sharps are being used. In pharmacy aseptic units, it is imperative the clean room environment and product being prepared is not contaminated hence the practice of re-sheathing needles will continue (with due cognisance of the regulation requirements).
Cost and process changes should not be underestimated to ensure healthcare providers uptake use of needle free devices.
Important to balance the views that safety engineered devices affect the quality of clinical care. and safety performance. Users must be integrated into the selection of suitable devices but occasionally personal preference, custom and practice may be used as a reason not to implement new devices.
Noted what appears to be enhanced duty to effectively investigate incidents and to support staff. This is good.
Issues still occur. This is dependent on the type of safer sharps device being used. Implementation needs to be supported by education and training because newly qualified staff do not find the devices intuitive because they have little experience to base their intuition on for these to be intuitive devices.
Larger & group practices tend to be more compliant, due to more staff and better HR awareness.
Many independents continue to do and use what they have always done, despite occasional needlestick injuries, which they often deny.
My own research indicates UK trusts have a high level of adoption of SED. However, The RCN 2020 BBFE study showed that members who responded had a significantly higher BBFE incidence (seven-fold) than do other developed countries. Trusts need adopt safer SED. Only proven-safe SED plus continued and repeated BBFE education and competency-based training can reduce BBFE.
Patients sharps pose a significant risk. At difficult scene crews are not always aware of the patients' own sharps which results in injuries to staff. These can be from prescribed medication such as diabetic medication or illicit drugs. When using safer sharps provided by the Trust there are still injuries. One of the issues is the supply chain. We teach crews how to use the device and then they are unavailable and more training is needed on a new device. This is really difficult to achieve when there is little or no notice in a mobile workforce. When we see stability in supplies the injuries reduce.

Comments from stakeholders from non-dental sector (continued)

Since 2013, the Regulations have had a dramatic impact on protecting healthcare and social care workers both through greater awareness of sharps injuries and the implementation of prevention measures used, including the greater use of safer sharps. For example, dentistry has adopted new practices and technology which would never have happened without the Regulations. Behavioural change in the NHS to address and prevent sharps injuries started well before the Regulations, with campaigns like the Safer Needles Network (precursor to the SHBN) and those by the trades unions, in the late 1990s/2000s but accelerated and really took off after the Regulations came into force.

However, the problem and risk of sharps injuries persists which is why the Regulations are needed as much today as they were in 2013. For example, during COVID when normal practices and procedures were abandoned quite legitimately to deal with a crisis it is reported that the number of sharps injuries increased in the UK (and Europe). The Regulations continue to act as the catalyst for better practice in healthcare and social care in the prevention of sharps injuries and without them it is likely that complacency would gain an upper hand and workers would be at greater harm from sharps injuries.

Some 'safer sharps' products have inferior workability for example plastic matrix bands- they lead to inferior shaped restorations which has clinical liability issues to the operator. In addition, some 'safer sharps' are no safer than the traditional options and can still result in needlestick injury (such as the 'safer' plastic local anaesthetic carriers).

The Regulations serve as a reminder of employer duties with regard to the management of risk providing specific requirement for compliance in relation to Sharps

hasn't carried out a recent survey but our comments come from intelligence from our health and safety reps. As well as users of the devices - the Regulations and use of safety devices have benefitted ancillary/support staff who are often the injured party through poorly disposed sharps.

Whilst the 5 year data at out Trust Shows a downward trend. I have taken that cautiously in that we had 2 years of Covid related service reduction. Having said that the sharps used for Covid vaccine administration were not safety sharps due to supply chain issues and to meet the demand. So at best data could be good and encouraging.

Comments from dental sector

Clinical sharps waste disposal costs are a huge burden to Practices which adopt the use of safer sharps, this is completely disregarded in all literature and guidance. In clinical use we have found them more difficult and less effective in clinical use and if not put together properly, a significantly greater risk of causing a needlestick injury than the regular needles. Dentistry is littered with all sorts of sharp pointy instruments and in reality very few injuries relate to needles and syringes,

clinicians should be allowed to decide what they prefer to use, without penalty. many clinicians use traditional methods despite the regulation because they feel more competent using traditional methods.

Don't fix what's perceived by paper pushers as broken. Basics have never failed me. Still use the metal syringes with no issues.

I have used safer LA syringe and needles and have never been successful or safe when giving a palatal infiltration. These syringes can't take the pressure and 'pop' leading to separation of hub and needle. Also the cost associated with the additional costs, and plastic waste is unacceptable when a there is a safe alternative if staff are trained correctly.

Increased costs of safer sharps (etc) can be borne in private practice, however NHS fees do not reflect the increased costs. We have ceased NHS treatment to remain viable and allow best practice

No reason not to use safer sharps - simply a brief adaptation time - although Septodont Ultrasafe switch to "twisty" without making packaging look more different for computability certainty has not helped gain co-operation form some clinicians

Overall, the regulations are good in principal, but "safer sharps" can be an oxymoron and also, we need to be making significant changes to our huge amount of single use plastic going forward as a profession.

Please weigh up not being able to give a gentle, comfortable local anaesthetic properly. This has massive impacts on patient experience, and especially for children.

Received my first ever needle stick injury this year using a safer sharp after 30 years of using traditional needles safely

Safe sharps regulations has minimised needlestick injuries and given members of staff the knowledge they need to handle them.

Safer sharps easy to get used to and we have used routinely for years without issues. Negative factor is with the high cost of the safety plus syringes and the higher disposal costs as fill sharps bins much more rapidly.

Safer sharps in this environment has had a positive impact only.

The regulations are much needed but need to be enforced and monitored. Training in use of safer sharps is paramount when resistance is occurring in practices. Some clinicians not trained to dismantle so are at risk

they are a significant extra financial burden

Translating the information into regional languages for better dissemination of information

the significant increased costs of safer sharps systems over conventional needles/syringes may lead to them being misused

Appendix 3 – Analysis of costs and benefits

Introduction

This analysis describes the process undertaken to quantify and monetise the costs and benefits of the Health and Safety (Sharps Instruments in Healthcare) Regulations 2013 ('the Regulations' hereafter). With reference to the Better Regulation Framework Manual (BRFM), a low resource PIR has been considered proportionate and has been agreed by the Health and Safety Executive's (HSE) Regulation Committee.

Background: Specific duties required by the Sharps Regulations

Before the Sharps Regulations came into force, existing general requirements in health and safety legislation required employers to protect employees against the risk of sharps injuries at work. Relevant legislation includes the Health and Safety at Work Act 1974, the Control of Substances Hazardous to Health Regulations 2002(COSHH) and the Management of Health and Safety at Work Regulations 1999. The Sharps Regulations introduce specific duties on healthcare employers to control the risks to healthcare workers of injury and infection from sharps; and also specific duties on workers who suffer a sharps injury.

The Regulations follow the principles of the hierarchy of preventative control measures set out in COSHH. The specific duties in the Sharps Regulations are as follows, (see also section in the Command paper, 'Background to the Sharps Instruments in Healthcare Regulations'):

1. To avoid the unnecessary use of sharps. The employer is required to substitute traditional sharps with a 'safer sharp' alternative where it is reasonably practicable to do so. A 'safer sharp' is one which has features or mechanisms to prevent or minimise the risk of accidental injury.
2. Prevent the re-capping of needles unless the employer's risk assessment has identified that recapping itself is required to prevent a risk (e.g. to reduce the risk of contamination of sterile preparations). In these cases, appropriate equipment must be provided, for example needle blocks.
3. Containers and instructions for disposal of sharps must be placed close to the work area. Some healthcare workers do not operate in controlled premises for example paramedics or healthcare workers working in a patient's home. If this is the case, then the employer should select appropriate sharps, specify safe working procedures, and provide suitable portable sharp containers and means for collection and replacement of those.
4. Information and training. Information must be provided to employees. There is no specific prescription about the form it must take, although it must include details of the risks from injuries involving medical sharps; relevant legal duties on employers and workers; good practice in the event of an injury; the benefits and drawbacks of vaccination; and the support available to an injured person from their employer. Training should be in an appropriate form and must cover: the correct use of safer sharps; the safe use and disposal of medical sharps; what to do in the event of an injury; the employer's arrangements for health surveillance and other procedures.

5. Arrangements in the event of an injury – employers are required to take specific actions in the event of a sharps injury.
6. The injured employee has a duty to notify their employer of a sharps accident.
7. Recording and investigating the incident – employers must make a record of the sharps injury, including the circumstances and the causes of the incident. They must investigate the circumstances and causes of the incident and take any action required as a result.
8. The employer must ensure that there is treatment and follow-up of a sharps injury. This includes providing immediate access to medical advice, post-exposure prophylaxis and consideration of whether counselling is appropriate.

Cost Benefit Analysis as part of the PIR

Baseline

As part of the PIR for the Sharps Regulations, we aim to estimate the actual costs and benefits of the Sharps Regulations, meaning those that have actually been experienced by duty holders and employees. At the time the Sharps Regulations came into force, healthcare employers already had duties around sharps under the existing legislation at the time (see section above).

The 2013 IA and 2018 PIR both assumed that there was full compliance with those existing duties and so only the costs of the additional requirements in the Sharps Regulations were counted. The baseline position is the same in this CBA, i.e. that duty holders should have been complying with the existing legislation at the time the Sharps Regulations came into force, and therefore additional costs are those which are a direct consequence of the Sharps Regulations only.

It is important to note that by not counting the costs that arise due to an increase in compliance as an additional cost in this PIR, it ensures no potential double counting in the future if ever there were to be a PIR of COSHH or other existing legislation.

Costs

When analysing the costs, there are some that should have only been incurred in the first year of implementation, such as familiarisation and updating policies, procedures and risk assessments; we refer to these costs as one-off costs.

There are also some costs associated with the Regulations that will be incurred on an ongoing basis, such as the cost of purchasing safer sharps; we refer to these costs as ongoing annual costs.

Since by the time of the 2018 PIR the Regulations had already been in effect for 5 years, the one-off costs as a result of the legislation can be considered to have already been borne by that point, and are only considered here where they are additional to those already estimated in the 2018 PIR cost benefit analysis.

Key risks and assumptions

Time Horizon, discounting and rounding

The costs presented in the original impact assessment and 2018 PIR included the total NPV over 10 years (from the implementation date of 2013), the equivalent annual net cost to duty holders, separate reporting of the one-off costs and the annual costs thereafter. The appraisal period for the purposes of this PIR is therefore set at 10 years. This is the standard appraisal period suggested by HM Treasury guidance for when there is no more appropriate time period to use.

For ongoing costs, which are discounted, we apply a discount rate of 3.5% per annum, consistent with HM Treasury's (HMT) Green Book.

Any cost or savings presented in the analysis have been rounded to two significant figures, unless otherwise stated. As such, some of the tables and totals may not appear to sum.

Assumptions about costs

The assumptions in the following analysis have been informed by a combination of the survey results, interview findings and HSE experience. The costs for the public sector have also been reported separately to the costs to the private sector. It has been assumed that, unless otherwise stated, assumptions for both public and private differ in terms of the type of healthcare provider it is ('hospital' versus 'other healthcare provider') but the costs do not differ in terms of whether the provider is a publicly funded or privately funded enterprise. So, for example, we might assume that costs would differ between, say, a dental practice and a hospital; but we would not assume that costs would differ between different dental practices if one were private and the other public.

Monetised Costs

One-off costs: The analysis will begin with describing, quantifying and monetising the one-off costs that occurred when the Sharps Regulations were introduced. In terms of decision making going forwards, these can also be described as 'sunk' costs because they are no longer relevant to the decision-making process. In other words, they have already been incurred by duty holders, and any changes to the Sharps Regulations now will not be able to change these costs. These costs are converted to 2013 prices, being the financial year in which the Regulations came into force to enable comparison with the 2013 IA.

Ongoing costs: These are costs which the existing and new duty holders continue to experience on an ongoing basis as they comply with the Sharps Regulations. These ongoing costs will be used to estimate the present value costs of the Regulations from 2013 over a 10-year period, for comparison with the original IA, using 2013 prices.

Present value costs: This is the sum of the discounted one-off and ongoing costs over a certain time period, which we are defining here as 10 years. Discounting is a technique used to compare costs and benefits that occur in different time periods. It is based on the principle that, generally, people prefer to receive goods and services now rather than later, a concept known as time preference. A discount rate of 3.5% is used for a 10-year appraisal period, consistent with Green Book guidance.

Equivalent annual net cost to duty holders: This is the average discounted annual cost of the Regulations per annum. It facilitates comparison between different appraisal options over different time periods because it converts present values which might occur over different time periods to an equivalent annual discounted cost.

One-Off Costs

Documentation - updating risk assessments, policies and procedures

From the survey data combined with interview questions, we understand that policies, procedures and risk assessments would have all required updating when the Sharps Regulations came into force to address the specific requirements of the Sharps Regulations, but under existing legislation these documents should have already been in place. So, the relevant costs here are just the updating costs.

Familiarisation

When the Sharps Regulations were introduced it was assumed that all healthcare employers would have had to spend some time understanding the new requirements that the Regulations would place on them.

The 2018 PIR found that the total cost of familiarisation was between around £2.3m and £4.6m with a best estimate of £3.4m. Of this total, the costs to the public sector ranged between £2.0m and £4.1m with a best estimate of £3.1m. The costs to the private sector ranged between £0.25m and £0.50m with a best estimate of £0.37m.

In order to compare the costs of familiarisation in the 2018 PIR, the estimates were converted to 2013 prices and it was found that the total costs of familiarisation can be re-stated in 2013 prices as between £2.2m and £4.4m with a best estimate of £3.3m. The difference to the 2013 IA ranges between a decrease of £0.19m and an increase of £0.7m, with the best estimate being an increase of £0.26m or 9% higher than expected at implementation.

For this PIR it was not considered proportionate to re-estimate these costs again, with the Regulations already having been in place for 5 years at the time of the previous PIR the one-off familiarisation costs from the Regulations had already been borne. We have updated the 2018 estimates to current prices for illustrative purposes.

Training and information

When the Sharps Regulations were introduced, the specific requirements of the Regulations required that training and information provided to workers should specifically refer to the Sharps Regulations and the specific requirements, in addition to the general training requirements on infection control that were already required under COSHH.

The total one-off costs of training and information

The 2018 PIR found that the total cost of training and information associated with the Sharps Regulations was estimated at between £16m and £24m with a best estimate of £20m. The

total falling to the public sector was estimated to be between £14m and £21m with a best estimate of £18m. The total falling to the private sector was estimated to be between £1.7m and £2.6m with a best estimate of £2.2m. (all in 2018 prices).

There is also a cost of manufacturer training. If there was 100% compliance with the Sharps Regulations and all clinical staff had to be trained in the use of new safer sharps for the first time then the maximum cost of the manufacturer training would be between £3.2m and £4.8m with a best estimate of £4.0m.

However, as noted this is the maximum because it is likely that some clinical staff would have already been using some or all of the safer sharps they could and so would not need all of the training. This maximum cost of manufacturer training is a cost that employers might have experienced, but is not included in our total cost estimates here because it should have been happening under the existing legislation.

For this PIR we have updated the 2018 estimates to current prices for illustrative purposes in the summary table below.

Containers and instructions for disposal of sharps

The Sharps Regulations specifically require that containers and instructions for disposal of sharps must be placed close to the work area (see above). However, under COSHH, specifically regulation 7 (3) (a) employers are required to design and use appropriate work processes, systems and engineering controls and the provision of suitable work equipment and materials. Therefore, duty holders should have been providing containers for sharps and instructions for disposal as close to the work environment as possible, in order to control risk. It is likely, however, that the Sharps Regulations with their specific requirement to ensure disposal bins are located close to areas where sharps are used at work might focus attention and increase compliance with this existing requirement.

The three main costs that might arise from this requirement to employers are as follows:

- Updating their risk assessment around the placement of containers. Although they should have had sufficient and suitable sharps disposal containers under COSHH, they may not have made this specific in their risk assessment. Therefore, there could be some requirement to update risk assessments in specific relation to the placement of containers. However, this will be included in the cost of updating risk assessments, which is already covered above.
- Updating information about how to dispose of sharps. Although general training about infection control would have taken place under COSHH, it may not have been specific to sharps. Therefore, it is possible that some duty holders may have had to update their training and information to explain about the safer disposal of sharps. The costs of updating training and information are quantified above and these costs will include any updates about disposal.
- Moving containers or purchasing new containers to be close to the point of work. Under COSHH duty holders should have had sufficient containers in close proximity to the work area. However, from the interview analysis it has been observed that the Sharps Regulations have focussed attention on sharps. Thus, there may well have been an increase in compliance with COSHH and duty holders could have moved containers around or purchased new ones.

HSE operational experience

HSE operational experience is that the duties around providing sharps bins in close proximity to the work area should already have been taking place under COSHH. The Sharps Regulations specifically mention that some healthcare workers do not operate in controlled premises, for example paramedics or healthcare workers working in a patient's home. If this is the case, then the employer should select appropriate sharps, specify safe working procedures and provide suitable portable sharp containers and means for collection and replacement of those. HSE advisors explained that this would have been seen as a duty under COSHH and therefore, although some duty holders may have seen an increase in costs due to the Sharps Regulations focusing their attention on sharps and improving their compliance with the existing legislative framework, these are not direct and additional costs of the Sharps Regulations.

All healthcare duty holders

The 2018 PIR survey found that for the vast majority (more than 90%) of duty holders, sharps bins were a business as usual cost. For a small minority there has been an effect on increasing compliance. This means that some duty holders may have had to physically move containers. The physical moving of the bins would be a minimal cost, taking merely seconds, most likely when the duty holder was moving around the workplace anyway. As already explained, this is something they should have done under COSHH anyway and no costs of compliance have been calculated.

It is possible that some duty holders may have purchased new sharps containers following the introduction of the Regulations. Under COSHH they should have had these, so these costs are not considered as direct costs.

Total one-off costs

The total one-off costs were estimated in the 2018 PIR as ranging between £26m and £39m with a best estimate of £32m in 2018 prices. These have been updated to current prices for illustrative purposes in the summary table below.

Ongoing costs

Ongoing costs are those which will continue to be incurred each year that the Sharps Regulations are in force. Analysis of these costs follows:

Safer sharps

Existing general requirements in health and safety legislation already put a duty on healthcare employers to protect employers against the risk of sharps injuries at work, however, the Sharps Regulations placed specific duties on employers.

Safer sharps are alternatives to standard sharps with an in-built safety device which reduces the risk of a sharps injury occurring. Under COSHH, these safer sharps should have been considered by healthcare employers to reduce the risk to their employees. However, the fact the Sharps Regulations mentioned safer sharps specifically would suggest that there would

be an increase in uptake of safer sharps compared to the baseline under COSHH. Therefore, the cost of purchasing safer sharps is not viewed as a direct cost of the Sharps Regulations, although an attempt is made below to understand what impact the Sharps Regulations might have had on improving compliance with COSHH around sharps, the uptake of safer sharps by healthcare employers, and any associated cost impacts.

It is clear from the data that since the Sharps Regulations came into force, the percentage of safer sharps compared to total sharps purchased has continued to increase per annum.

Sales of safe and conventional devices via NHS Supply Chain:

	Number of safer devices (million)	Number of conventional devices (million)	Total sales (million)	Safer sharps as % of sales
12 months to July **2014**	125.2	155.0	280.3	45%
12 months to July **2015**	154.1	133.7	287.8	54%
12 months to July **2016**	180.4	109.3	289.7	62%
12 months to July **2017**	205.4	93.3	298.7	69%
12 months to July **2018**	217.9	77.0	294.8	74%
12 months to July **2019**	229.8	74.3	304.1	76%
12 months to July **2020**	230.5	60.7	291.1	79%
12 months to July **2021**	245.8	51.2	297.0	83%

It is not possible to conclude on how much of this increase in the share of total devices sold and the increase in absolute quantity, respectively, is due to the Sharps Regulations and how much an increase there would have also been under the existing legislative framework. Over time the unit price of some safer sharps has decreased and also the availability of improved safer sharps has increased.

There is not a standard cost uplift of a safer sharp compared to a non-safer or standard version. The cost varies depending on the type of sharp and has varied over time. Also, one might expect the additional cost of safer sharps to decrease over time as their manufacture and usage becomes more widespread. This has been observed for some of the equipment, but not all.

In our survey, one of the dental sector respondents put a figure on the additional cost of safter sharps in their practice, saying:

" The cost of safer sharps syringes is extremely high, normal needles £10 per 100, Safety plus syringes £40 per 100”

This anecdotal figure of roughly four times the cost of standard sharps would appear to be on the high side looking at figures quoted elsewhere[14], though it is no doubt true that in some cases the adoption of safer sharps has led to an increase in unit costs. However, as already explained above, the cost of safer sharps cannot be considered a direct cost of the Sharps Regulations and so is not included in our total cost estimates. To the extent that the Sharps Regulations have led to increased costs in this respect it is due to them focusing minds on sharps and increasing compliance with existing requirements.

Both in the 2018 PIR and in our survey, a recurrent theme was that safer sharps take up more room in the waste disposal bins. Thus, the bins are getting full much quicker and so the costs of disposing of this waste are higher than with standard sharps. Again, this would not be a cost of the Sharps Regulations directly, as they should already be using safer sharps under COSHH, but the Sharps Regulations are likely to have increased compliance with safer sharps and therefore the disposal of the products. However, there is evidence that some fully automated safety devices, considered the highest level of safety provision due to their ability to automatically shroud the needle without need for manual application, are significantly smaller and lighter than other safer devices. This suggests that increased waste costs incurred due to using safer devices could be mitigated by using devices considered the safest available.

Reporting, recording and investigating

The Sharps Regulations put specific duties on healthcare employees to report every sharps injury, including those from clean sharps, and the employer is required to investigate each incident and take the necessary actions. The reporting of all injuries, including those where no risk is posed is a new requirement under the Sharps Regulations.

It was therefore thought ex-ante that duty holders would have to do more around reporting, based on evidence gathered prior to the introduction of the Regulations. However, research undertaken for the 2018 PIR revealed that the vast majority of respondents did not feel anything had changed since the introduction of the Sharps Regulations and they had not had to do anything differently, so it was judged to be more appropriate not to allocate this as a cost of the Regulations.

Training of new staff

In the original IA, it was assumed that the additional training provided to existing staff when the Sharps Regulations were introduced might have taken up around 20 – 30 minutes of each member of staff's time, including non-clinical staff.

However, new starters would have to have an induction before starting work in the absence of the Sharps Regulations. So although the Sharps Regulations mean that this induction will have to mention the control procedures to reduce risk from sharps injury, it is reasonable to assume that the general principles of infection control will be conveyed, including making specific reference to sharps. Unlike for existing staff, who would have needed to have a dedicated section of their training on sharps rather than another general infection control section, new starters will not need to be told what is new or what the Sharps Regulations

[14] E.g. http://www.medidex.com/research/792-the-economics-of-using-sharp-safety-engineered-devices.html

clarify, because they will not see them as a new requirement, just one of many pieces of legislation that keep them safe at work. Therefore, it is assumed that there is no additional cost to new starters around training.

This assumption is consistent with both the 2013 IA and the 2018 PIR. Both of which assumed there are no costs of ongoing training for new staff directly attributable to the Regulations.

Re-capping of needles

As explained above, the Regulations require that recapping of needles should not take place unless there is more risk associated with not doing so. HSE understands that re-capping might prove necessary for certain pharmacy procedures where aseptic-techniques are required. However, the re-capping of needles would be subject to COSHH and existing legislation and so this is not a new requirement under the Sharps Regulations.

Familiarisation

There will be new entrants to the healthcare sector. Under existing legislation before the Sharps Regulations came into force these new duty holders would have to spend time understanding what COSHH meant in terms of the managing the risk from sharps. However, the Sharps Regulations, although an extra set of regulations on the statute books, provide specifics for dealing with the risk from sharps. Therefore, although new entrants to the market will spend time understanding the Sharps Regulations; this will be offset by the saving they make from not having to spend quite as long determining how COSHH should specifically apply to the use of sharps in their organisation. Therefore, as with the 2018 PIR, it is assumed here that there will be no additional cost of familiarisation for new entrants to the healthcare sector.

Containers and instructions for disposal of sharps

As explained above, placing containers for the safe disposal of sharps close to the place of work is something that would have been a requirement under COSHH. Therefore, as with the 2018 PIR, it is assumed here that there will be no additional ongoing cost resulting from this requirement of the Regulations.

Total ongoing costs

For the reasons discussed above, it is estimated that there are no ongoing costs that are a direct consequence of the Sharps Regulations. It has been explained above that for both safer sharps and re-capping of needles, there is a possible effect whereby the existence of the Sharps Regulations improves compliance with the existing legislative requirements. Illustrations of the potential cost of this increase in compliance are provided, but the costs are not included in the total estimate in this CBA.

Summary of costs

The total Net Present Value of the Sharps Regulations is estimated by adding together the one-off costs when the Sharps Regulations came into force plus the ongoing costs over the

appraisal period (10 years). As explained above there are no ongoing costs and so the present value is the costs of the one-off costs.

Since these costs were incurred around the time of the introduction of the Regulations in 2013, it was not thought proportionate to provide a full update of the estimates presented in the 2018 PIR. Instead we have used GDP deflators to update the estimates contained in the 2018 PIR. In doing so this CBA has estimated the one-off costs to be around £36.1m in current prices. The total cost to the public sector in current prices has a best estimate of around £32.6m and the total cost to the private sector in current prices has a best estimate of £3.7m.

The Sharps Regulations came into force in 2013 and so re-stating these costs in 2013 prices gives an estimate of around £31m. Of this total, the estimated total cost to the public sector in 2013 prices was around £28m and the total cost to the private sector in 2013 prices was around £3.2m.

The following table summarises the cost impacts associated with the Sharps Regulations.

Summary of additional regulatory costs (Note table uses best estimates only)

One-off Costs

Cost Impact	**2013 Impact Assessment costs (£m)**	**2018 PIR estimated cost in 2013 prices (£m)**	**Estimated cost in 2022 prices (£m)***
Documentation	6	8.5	9.9
Familiarisation	3.1	3.3	3.8
Training and information	1.4	19	22.1
TOTAL ONE- OFF COSTS	**11**	**31**	**36.1**

* Note - since these one-off costs occurred around the time of the Regulations being introduced, we have not updated the estimates for this PIR, but have used GDP deflators to calculate the previous estimates in 2022 prices for illustrative purposes

Ongoing costs (10 year present value)

Cost Impact	**2013 Impact Assessment costs (£m)**	**2018 PIR estimated cost in 2013 prices (£m)**	**Estimated cost in 2022 prices (£m)***
Reporting, recording and investigating	1.4	Nil	Nil

TOTAL ONGOING COSTS	1.4	Nil	Nil

* Note: The 2013 IA assumed ongoing costs for reporting sharps injuries that posed no risk. However, from the data collected for the 2018 PIR it was evident that before the Sharps Regulations came into force, duty holders confirmed that they were already reporting, recording and investigating all sharps injuries in any case, so this cannot be included as an additional ongoing cost directly attributable to the Regulations.

Equivalent Annual net cost

The estimated equivalent annual net cost is a useful measure of cost that presents the net present value as the equivalent discounted cost per annum.

There are no ongoing costs of the Regulations that have been quantified. Therefore, the estimate of net present value is solely comprised of one-off costs that occurred when the Regulations came into force in 2013. The equivalent annual net cost of the Sharps Regulations to all duty holders, in current prices, is therefore estimated to be around £4.2m and £3.6m in 2013 prices.

The equivalent annual cost to business (private healthcare employers) is estimated to be £0.4m in current prices, and £0.38m in 2013 prices.

Benefits

Any reduction in the number of sharps injuries (or in fact any avoided increase that might have otherwise occurred in the absence of the Regulations) will lead to reduced costs in treatment and other associated costs. Due to the lack of data on sharps injuries in aggregate, it has not been possible to identify whether a reduction in sharps injuries has occurred, and so a benefit figure has not been provided however it is possible to illustrate some of the benefits likely to accrue as a result of the Regulations.

Blood-Borne Viruses

The main risk from a sharps injury is contracting a blood-borne virus (BBV). The viruses of major concern are HIV, (which causes Acquired Immune Deficiency Syndrome or AIDS); and the causative agents of causes of acute and chronic viral hepatitis (hepatitis B and C). These viruses persist in the blood and are known to be endemic in the UK population.

Very low-risk sharps injuries will not incur any costs to the individual beyond the pain and discomfort from the injury itself. Such an injury might result from a clean sharp and could range from a small pin-prick type of injury to a more substantial injury from the likes of a scalpel. So the range of physical pain and suffering will vary depending on the type of sharp involved. For clean sharps, there cannot be a risk of contracting a blood borne virus, by definition, and so there should not be any anxiety for the individual around contracting a disease following the injury.

For sharps injuries that are low risk or high risk, the individual will undergo some level of anxiety. It is likely that this anxiety will be greater for those who have been exposed to blood / body fluids from a source with significant risk factors for a BBV.

Some examples of the main costs incurred are as follows:

1. The cost to the individual of the loss in quality of life associated with anxiety during the period in which tests are undertaken to confirm whether they have seroconverted or not. It is not possible to monetise the effects of this specific anxiety.
2. Counselling services to assist recovery from the anxiety which will have a cost to the NHS in terms of provision of the service and to the individual in terms of time taken to attend appointments. There could also possibly be a cost to their employer in terms of time taken to attend appointments if they continue to work and time off work due to the anxiety. An estimate of the cost of counselling in the 2018 PIR was given as £3,121 to £12,808 per case.
3. Working days lost as a result of the sharps injury. According to W.C Lee (see footnote[15]) the average time off work for a sharps injury is 0.45 days. This was based on a sample of 168 who had post-exposure treatment. This is a cost to the healthcare employer. Obviously, this is an average and for cases where there is a high risk of a seroconversion and / or where there has been a level of anxiety caused, the time off work could be much greater.
4. The cost of time spent attending appointments for blood tests and check-ups. The cost will fall to the individual in terms of their time to attend appointments, to the NHS in terms of providing the check-ups and blood tests and potentially time to the individual's employer if the individual needs to take time off work to attend. This will be specific to the individual and their circumstances and it is not proportionate to attempt to model the different costs that could be incurred here.
5. The cost of vaccination or booster injections to deal with the risk of HBV. There will be a cost to the individual in terms of the time to attend the appointments for these appointments and also in terms of the pain / anxiety that the vaccinations might cause the individual. There will also be a cost to the NHS of providing these vaccinations. Data from the NHS shows that an individual can purchase the HBV vaccine if they are not in one of the at-risk groups for around £50. This is the best proxy for what it would cost the NHS to administer this vaccine to a healthcare worker following a potential exposure to HBV. Again, it is not possible to quantify the cost of time to attend the vaccination appointment on the grounds of proportionality.

There will also be further costs for any individual who does go on to seroconvert. Some indicative costs of the treatment options are outlined below, but it is not possible to give a monetised cost for each particular virus because there are so many uncertainties that determine the costs for a particular individual, such as any other underlying health conditions which might determine the type of drug they can take, the period for which they will need to take the drugs, their age when they contract the virus and so on. As well as these drug costs which are illustrated below, there are also the costs of the individual going to medical appointments and the cost to the NHS of those appointments plus any administration

[15] Won Chan Lee, Lars Nicklasson, David Cobden, Er Chen, Donald Conway & Chris L. Pashos "Short-term economic impact associated with occupational needlestick injuries among acute care nurses" - Current Medical Research and Opinion Vol 1(12) (2005)

associated with the patient which have not been quantified due to the large variability by patient and the disproportionate amount of time this would take to model.

In some circumstances, HSE might prosecute the healthcare employer following a sharps injury if they have not been compliant with the Regulations. There are unlimited fines for prosecutions. This is a transfer of funds from the employer to the government as a result of the breach of regulation.

So there are a large number of cost impacts that result from a sharps injury, including for very low risk, low risk and high risk injuries. The costs fall to the individual, to the healthcare provider (the NHS or private), to government (via the NHS). It is not possible to predict a robust cost for an 'average sharps injury' because of the wide variety in the possible circumstances of the injury and the victim's health and then whether they seroconvert or not. However, the cost illustrations give some indication of the sorts of cost that may result from a sharps injury.

Wider benefits of the Sharps Regulations

From the qualitative research work undertaken for the 2018 PIR the following additional benefits of the Sharps Regulations were mentioned by stakeholders.

1. Psychological impacts – people feel safer before an accident due to the presence of the Regulations and the safer equipment being used. The Sharps Regulations were even referred to as having wellbeing impacts. Such effects cannot be monetised or quantified but are important to the performance of workers in the work place.
2. Regulations allow the healthcare providers to focus on the area and prioritise. This is seen in some of the cost areas discussed in the previous text, that the presence of the Sharps Regulations allows the healthcare employer to prioritise sharps and therefore compliance with existing legislation has improved.
3. The Regulations have made a positive contribution to the culture of openness and no blame.
4. More priority afforded to Sharps could improve the way that lessons are being learned and therefore reduce incidents in the future.

Comparison of costs to Benefits

The total one-off costs of the Sharps Regulations are estimated to have been about £36.1m in current prices, and £31m in 2013 prices when the Regulations came into force. There are no additional costs of the Sharps Regulations on an ongoing basis, because the two main requirements of safer sharps and the ban on re-capping are not additional costs under the Sharps Regulations as they would have been required under COSHH.

The cost of a sharps injury can be considerable. Other benefits include that sharps injuries have been brought into clearer focus since the introduction of the Sharps Regulations and there has been an increase in staff training to manage the specific risks from Sharps. Staff have been trained in how to manage the specific risks from sharps. Whilst the data picture is unclear on how sharps injuries have changed since the Sharps Regulations came into force, the other benefits, such as feelings of wellbeing and lessons learned will continue on an ongoing basis.

Additional consideration – COVID-19

While the evidence for this PIR was being gathered, the UK was still in the booster stage of the COVID-19 vaccination programme, with over 150m vaccinations having now been delivered throughout the country.

It was therefore natural to consider the impact of the Regulations on the vaccine rollout. For the purposes of the costs estimates in this PIR, COVID-19 does not have an impact on the cost estimates or proportionality because a) as we have identified above, the additional costs of safer sharps themselves are not directly attributable to the Regulations, and b) even if they were the vaccine rollout in the UK was entirely delivered through the public sector and so the EANDCB would not be affected.

In the UK the initial vaccine doses were administered through the use of sharps that did not have safety features, as the Government purchased needles that would minimise wastage of what was then a very scarce vaccine supply. It was estimated that in a 50 million dose single-shot campaign, the dose-saving devices could enable 9.5 million more people to be vaccinated.

As the vaccination programme has progressed to the current steady-state/booster period, safer sharps are now being used as a matter of routine. This perhaps provides some useful context of how the “reasonably practicable” instruction in the Regulations has been interpreted under extremely testing circumstances.