GLOBAL PRODUCT STEWARDSHIP COUNCIL

Stewardship for Sharps and Reusable Sharps Containers

Business Case Considerations
December 2020

CONTENTS

GLOSSARY

Background Paper	Stewardship for Sharps and Reusable Sharps Containers – Background and Issues Paper
DASTRI	(France) EPR system for home-generated sharps
DfE	Design for Environment
DSC	Disposable Sharps Container
EPR	Extended Producer Responsibility
GHG	Greenhouse Gas
GlobalPSC	Global Product Stewardship Council
IPR	Inevitable Policy Response
OECD	Organisation for Economic Co-operation and Development
RSC	Reusable Sharps Container
WHO	World Health Organization

EXECUTIVE SUMMARY

THIS REPORT IS INTENDED TO ASSESS CURRENT BUSINESS CASE CONSIDERATIONS FOR REUSABLE SHARPS STEWARDSHIP MODELS FOR THE HOME HEALTHCARE INDUSTRY, AND BUILDS UPON THE ACCOMPANYING GLOBAL PRODUCT STEWARDSHIP COUNCIL (GLOBALPSC) REPORT, STEWARDSHIP FOR SHARPS AND REUSABLE SHARPS CONTAINERS – BACKGROUND AND ISSUES PAPER (BACKGROUND PAPER). THE BACKGROUND PAPER COMPARES REUSABLE SHARPS CONTAINERS (RSCS) TO DISPOSABLE SHARPS CONTAINERS (DSCS) FOR HOME HEALTHCARE USE, AND HIGHLIGHTS OPPORTUNITIES TO INTEGRATE RSCS IN PRODUCT STEWARDSHIP AND EXTENDED PRODUCER RESPONSIBILITY (EPR) APPROACHES.

FOR BOTH REPORTS, HEALTHBEACON COMMISSIONED THIS GLOBALPSC RESEARCH TO UPDATE THE GLOBALPSC's 2016 REPORT FOR THE US HEALTHCARE INDUSTRY ON PRODUCT STEWARDSHIP AND EPR PROGRAMS FOR SHARPS.

SHARPS PROGRAM OVERVIEW

Increased demand for home healthcare, underscored by the COVID-19 pandemic, will continue to drive the increased generation of household-generated sharps such as used needles, lancets and similar devices, with the resultant need for the safe collection and management of sharps.

RSCs are used in Australia, USA, UK, New Zealand, South Africa, Canada, South America, and by the World Health Organization (WHO) and Medecins Sans Frontieres. However, current RSC usage is predominantly in hospital and clinical settings; examples of the use of RSCs in the home and residential care settings have not been identified outside of those being initiated by HealthBeacon.

All existing programs for home healthcare sharps focus on ensuring proper management and disposal through autoclaving (steam sterilization), incineration or landfilling in the interests of consumer safety and the environment.

Redesign, reuse and recycling are not viable options for sharps themselves at this stage, given specific medical and regulatory requirements, but represent significant potential opportunities for growth in these areas as part of reducing risks while meeting growing demand. Regulatory frameworks, including product stewardship / EPR programs, should allow for flexibility as technology and program design evolve. Although this is an area for further development, EPR programs should consider the use of RSCs more closely as a viable option to reducing the waste associated with sharps disposal and its carbon impact.

RISKS OF SHARPS WASTE

Perceived risks to waste management and recycling workers are often cited for introducing sharps product stewardship / EPR. However, as detailed in the Background Paper, research shows that actual risks to these workers of infectious disease transmission are quite low. The greater risks, however appear to lie with family members of sharps users. An approach specifically addressing household sharps users and their caretakers could therefore provide greater safety if made convenient and accessible.

EXECUTIVE SUMMARY

LIFE-CYCLE BENEFITS OF RSCs

Both DSCs and RSCs are essential in healthcare. Although life-cycle data on home healthcare for RSCs is not currently available, peer-reviewed studies on RSC use in hospitals show that RSCs may help to eliminate almost all sharps plastic that is currently landfilled, greatly reduce greenhouse gas emissions, significantly reduce sharps injuries and reduce labour.

These benefits are possible while still keeping risks to public health and safety low, as both DSCs and RSCs are designed, manufactured and tested to the same high standards. Expanding use of RSCs into home healthcare would therefore be consistent with circular economy and sustainability principles if part of robust, managed collection, processing and reuse initiatives coupled with appropriate education and outreach to patients and carers. Indeed, patient management of sharps is highly dependent on the level of education they receive.

Sharps users lacking appropriate education frequently dispose of sharps loosely in the household trash or into toilets.

Where they exist, product stewardship and EPR approaches for sharps in home healthcare do not fully consider the potential roles of RSCs. However, viable reuse systems should be rolled out in cooperation with the introduction of products onto the market, as part of individual producers' responsibility under these approaches.

To date, waste in the medical industry has typically been incinerated, but as carbon budgets tighten and the clear effects of climate change force action, this will no longer be considered a long-term viable solution. A move to reuse and recycling will become of paramount importance.

INTRODUCTION

This report is intended to highlight business case considerations for reusable sharps stewardship models for the home healthcare industry, and builds upon the accompanying Global Product Stewardship Council (GlobalPSC) report Stewardship for Sharps and Reusable Sharps Containers – Background and Issues Paper (Background Paper).

HealthBeacon[1] has funded this report to update the GlobalPSC's 2016 background research (2016 Report or GlobalPSC 2016) on global product stewardship and Extended Producer Responsibility (EPR) programs for sharps and unwanted or out-of-date, medicines. The 2016 Report was funded by Eli Lilly and Company in support of facilitated discussions between the US pharmaceutical industry and key stakeholders.

The Background Paper addresses adoption and significance of public health and safety concerns, the circular economy and reuse for sharps.

Comparison of reusable sharps containers (RSCs) against disposable sharps containers (DSCs) and opportunities to integrate RSCs into product stewardship and EPR approaches are specific areas of focus for the Background Paper.

ABOUT THE GLOBALPSC

The GlobalPSC is an independent, not-for-profit organization dedicated to facilitating the development of effective product stewardship and EPR schemes globally. The GlobalPSC has members operating worldwide that span producers, product recovery organizations, reprocessors, NGOs, universities and governments at federal, state and local levels.

ABOUT HEALTHBEACON AND THE HB GREEN LABS

HealthBeacon is a medication adherence technology company which develops smart tools for managing medication.

HealthBeacon's FDA-cleared Smart Sharps Bin tracks patient injection history, provides personalized interactive reminders and safely stores used injections. With the intervention of HealthBeacon's Smart Sharps Technology, patients' persistence and adherence increased by 25-30% within twelve months of initiating therapy. HealthBeacon's integrated model connects a patient's routine and the prescribing clinician's workflow. This technology has been adopted across 13 countries with >400,000 injections tracked since launch in 2014, and a patient acceptance rate of 80-90%.

HealthBeacon follows the EPR model as a part of its fundamental business model, embracing end to end product stewardship. Earlier this year, HealthBeacon launched its innovative Green Labs initiative for sustainable waste management. The labs which HealthBeacon have built will allow for the sterilisation and reuse of sharps bins and recovery of injection waste for more sustainable processing.

[1]Disclosure: HealthBeacon (www.healthbeacon.com) is a GlobalPSC Corporate member.

PRODUCT STEWARDSHIP AND EPR

PRODUCT STEWARDSHIP IS AN ENVIRONMENTAL MANAGEMENT STRATEGY TO PROMOTE INCREASED RESPONSIBILITY FOR THOSE WHO DESIGN, PRODUCE, SELL OR USE A PRODUCT, TO MINIMIZE THAT PRODUCT'S ENVIRONMENTAL IMPACT. MOST MODELS AIM TO SHIFT SOME PHYSICAL AND/OR FINANCIAL RESPONSIBILITY FROM STATE AND LOCAL GOVERNMENTS TO PRODUCERS AND CONSUMERS OF SPECIFIC PRODUCTS (TRADITIONALLY FOR PACKAGING AND E-WASTE BUT INCREASINGLY APPLIED TO A WIDE RANGE OF PRODUCTS).

The Organisation for Economic Co-operation and Development (OECD) defines EPR as (OECD 2014):

> "...an environmental policy approach in which a producer's responsibility for a product is extended to the post-consumer stage of a product's life cycle."

Shifting responsibility through EPR is intended to drive improvements in design for environment (DfE), an approach that attempts to reduce a product's overall impacts on human health and the environment.

Responsibility is invariably shared across a range of stakeholders, including consumers. Program costs, however, are generally incorporated into purchase prices so that consumers are not charged when they return items at end-of-life.

IMPACTS ON DFE AND SUPPLY CHAINS

While EPR has delivered a variety of benefits across product types, its direct impact on a primary objective, DfE, has been quite limited overall and focused mainly on packaging design considerations. Design for environment is also more viable in consumer products with more rapid design turnover, such as packaging and e-waste. (OECD 2016)

Various product stewardship and EPR programs are working to integrate more of a circular economy approach in which the value of products, materials and resources is maintained in the economy for as long as possible, and the generation of waste is minimized. Broader circular economy approaches, such as the EU action plan for the circular economy and the French Roadmap for the Circular Economy, increasingly integrate stewardship and EPR. (European Commission 2015) (OECD 2016) (Republic of France 2018)

The home healthcare industry has opportunities to develop circular economy models that provide both significant life-cycle and circular economy benefits overall, while potentially reducing supply chain risks, and disruptions, and addressing potential resource scarcity through resource management and control.

THE NEED FOR SHARPS STEWARDSHIP

With sharps used in the treatment and management of various conditions, including one of the leading causes of morbidity worldwide, diabetes, there is significant need for enhanced sharps stewardship. Against the background of the COVID-19 pandemic, with remote care in the home setting growing, such stewardship is becoming increasingly necessary.

SIGNIFICANCE OF DIABETES

According to the World Health Organization (WHO), globally around 422 million adults were living with diabetes in 2014, a significant increase from the 108 million living with diabetes in 1980. The age-standardized global prevalence of diabetes has nearly doubled in adults, rising from 4.7% in 1980 to 8.5% in 2014. Over the past decade, diabetes prevalence has risen faster in low- and middle-income countries than in high-income countries. (WHO 2016)

The WHO estimates that diabetes caused 1.5 million deaths in 2012, with higher-than-optimal blood glucose causing an additional 2.2 million deaths, with 43% of these 3.7 million deaths occurring before 70 years of age. (WHO 2016)

This high burden of disease comes with a high demand for treatment, resulting in significant use of insulin needles. Diabetes however is not the only disease for which patients take injectable therapy in the home setting. Indeed, an estimated 9 million people in the US use sharps at home, resulting in more than 3 billion disposable needles and syringes and 900 million lancets each year being disposed (safeneedledisposal.org, 2020).

Although 'needle-free' insulin delivery methods are under development, such approaches are not likely to be available for the foreseeable future (Diabetes.co.uk, 2020). Diabetes-related products account for 80-90% of the materials recovered through the French sharps EPR program, DASTRI[2].

IMPACTS OF THE COVID-19 PANDEMIC

As the full impact of the COVID-19 pandemic comes to light, it is clear that its impact on the home healthcare industry will be significant. Factors such as increased home isolation and minimization of travel and exposure at medical facilities may have lasting effects on healthcare as we know it, and increase the burden on remote patient care. The collection, transport and handling of sharps from home healthcare will also likely be impacted as a result. However, these conditions could also generate commercial opportunities.

HealthBeacon's Smart Sharps Bin has been implemented across 13 markets including the USA, Canada, Germany, Italy, Belgium, Netherlands, Ireland, Portugal, Israel, South Africa, Luxembourg, Latvia and Lithuania. With thousands of active users across different continents, many of these patients on injectable medications are considered high-risk if they contract the COVID-19 virus. From their digital-enabled Sharps Bin, HealthBeacon has been able to detect a trend towards higher rates of non-adherence in some injectable medications in 2020 compared to previous years. The reasons for this are varied and may include delays to treatment start dates, postponed hospital appointments, challenges accessing medications and healthcare providers. Some patients deemed 'high-risk', taking medications which suppress their immune system, may have been instructed to pause their treatment during this pandemic, with the resultant impact on their adherence. The extremely valuable data that HealthBeacon provides enables targeted intervention programs and an additional level of support for these high-risk patients.

SHARPS MANAGEMENT AND DISPOSAL PRACTICES

Most references show high rates of direct sharps disposal into household trash, although information on whether the sharps were contained prior to this disposal is limited.

Four US states (California, Massachusetts, Oregon and Wisconsin) and the Canadian province of Ontario allow medical waste generators such as hospitals and other institutions to dispose of sharps as general solid waste in landfills if treated to be non-infectious/non-hazardous (autoclaving is common practice); this provides for no additional risk of exposure. Apart from Oregon allowing a de minimus 50 pounds per month exemption from prior treatment requirements, these jurisdictions do not allow for landfilling of sharps containers without prior treatment. This raises the question as to the need for treatment of home-generated sharps where infectious disease transmission is different, as discussed further in the Background Report.

[2]DASTRI-related information is based on personal communication with Laurence Bouret, Déléguée Générale for DASTRI from 2016 to 2020, unless otherwise indicated.

ADDITIONAL ISSUES FOR SHARPS STEWARDSHIP

REUSABLE VS DISPOSABLE SHARPS CONTAINERS

ALTHOUGH RSCS ARE A MORE SUSTAINABLE OPTION COMPARED TO DSCS, THEIR USE INVOLVES A NUMBER OF KEY CONSIDERATIONS, IN PARTICULAR RELATING TO POTENTIAL PUBLIC HEALTH RISKS.

IN RESEARCH AND CONSULTATIONS FOR THIS REPORT, THE GLOBALPSC COULD NOT CONFIRM THE ADOPTION OF RSCS FOR HOME HEALTHCARE USE OUTSIDE OF THE SYSTEM BEING IMPLEMENTED BY HEALTHBEACON. EVEN DATA ON RSC USAGE WITHIN HEALTHCARE FACILITIES IS QUITE LIMITED. ADDITIONAL RESEARCH WILL THEREFORE BE NECESSARY TO DETERMINE ATTRIBUTES SPECIFIC TO HOME HEALTHCARE USE. NOTE, ALL LIFE-CYCLE INFORMATION ON RSCS THAT FOLLOWS IS BASED IN HOSPITAL OR SIMILAR HEALTHCARE SETTINGS INSTEAD OF HOME HEALTHCARE, DUE TO THE LIMITED INDEPENDENT, PEER-REVIEWED DATA AVAILABLE.

USE OF REUSABLE SHARPS CONTAINERS

Commercial RSCs were first used in US and Australian hospitals in 1986, and now represent approximately 50% and 75%, respectively, of the sharps containers used in these countries. Since 1999, RSCs have been increasingly used in Canada, UK, Ireland, New Zealand, South Africa and South America. RSCs are also used by the WHO and Medecins Sans Frontieres. (Grimmond, 2019) (McPherson et al, 2019)

TESTING OF RSCS

RSCs can be reused many times per year and may be in use for several decades with appropriate manufacture, usage and maintenance. The US FDA requires both RSCs and DSCs to pass identical performance tests and design requirements under relevant standards. Prior to this testing, the US FDA also requires ‘‘lifespan simulation’’ of RSCs, which includes filling and processing for the number of lifespan uses stated by the manufacturer (e.g., 500 times) and transport vibration tests such as the US Department of Transport Packaging Vibration Standard to ensure robustness during transit. The Canadian sharps container standard involves similar requirements. (McPherson et al, 2019)

ENVIRONMENTAL IMPACT OF RSCS

Both DSCs and RSCs are essential in healthcare. Although life-cycle data on home healthcare for RSCs is not currently available, peer-reviewed studies on RSC use in hospitals show that RSCs may (Grimmond, 2019):

99%

Eliminate 99% of sharps plastic landfilled;

65-84%

Eliminate 65-84% of Greenhouse Gas (GHG) emissions;

Significantly reduce sharps injuries;

Reduce labour.

These benefits are possible while still keeping risks to public health and safety low.

FIT WITHIN CIRCULAR ECONOMY PRINCIPLES

While various healthcare facilities adopted RSCs for sustainability reasons, quantitative studies for this are rare. While limited quantitative data is available, recent life-cycle analysis comparing RSCs and DSCs in a US hospital (McPherson et al, 2019) found that:

- RSCs achieved significant GHG reductions over DSCs, even where large RSC transport distances lessen the GHG differential between the two systems

- Transport and electricity cleanliness (e.g., renewables vs coal) are key factors in GHG emissions for RSC systems

- The lifespan of RSCs has minimal effect when comparing carbon footprint between the two systems

- Purchasing decisions can significantly contribute to GHG reduction strategies.

- Institution-wide adoption of RSCs can reduce GHG with minimal staff behavior-change.

Annual GHG emissions by life stage (with DSCs normalized to Adjusted Patient Days) are shown in Figure 1.

A previous study had found that converting from DSCs to RSCs reduced sharps waste stream GHG by 84%. However, the 2019 study confirmed that transport distances impacted significantly on GHG outcomes.

The 2019 study examined the impact on GHG of nation-wide transport distances when a large US teaching hospital system converted from DSCs to RSCs. The RSCs in the study were certified for 500 uses and reused an average of 12 times/year, for a theoretical ''end-of-life'' lifespan of 41.7 years. However, a ''worst-case'' lifespan scenario of 26.4 years based on the most frequently used RSC still in service in the US was assumed for the study. The study confirmed that large transport distances between polymer manufacturer, container manufacturer, user and processing facilities, can significantly impact the carbon footprint of sharps containment systems. (McPherson et al, 2019)

Converting to RSCs, the hospital system examined reduced its annual GHG by 162.4 tonnes $CO_{2\text{-eq}}$, a 65.3% reduction. They also had an annual elimination of 50.2 tonnes of plastic DSC and 8.1 tonnes of cardboard from the sharps waste stream. Of the DSC plastic eliminated, 31.8 tonnes were diverted from landfill and 18.4 tonnes were diverted from incineration. (McPherson et al, 2019)

Under circular economy principles, the value of products, materials and resources is maintained in the economy for as long as possible, the generation of waste is minimized and landfilling is avoided, where possible. Higher-value uses are regularly sought, rather than downcycling and disposal. Rather than an end-of-life perspective and a focus on material recovery, circular economy takes a life-cycle perspective and spans entire supply and recovery chains. Many newer circular economy initiatives also seek to minimize the manufacture of, or maximize the reuse of, plastics and integrate product stewardship and EPR. (European Commission 2015) (OECD 2016) (Republic of France 2018)

Given the benefits of RSCs shown earlier, expanding the use of RSCs into home healthcare would therefore be consistent with circular economy and sustainability principles if part of robust, managed collection, processing and reuse initiatives coupled with appropriate education and outreach to patients and carers.

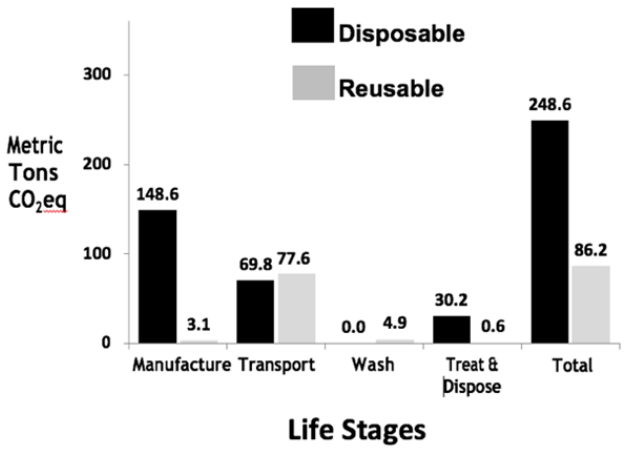

Figure 1: Annual GHG emissions by life stage (McPherson et al, 2019)

ADDITIONAL ISSUES FOR SHARPS STEWARDSHIP

PUBLIC HEALTH AND SAFETY

Most of the public health and safety considerations around sharps containers revolve around increasing the appropriate use and management of approved sharps containers through access, convenience and education, regardless of whether the sharps containers are disposable or reusable. Both RCSs and DSCs are made to perform to the same high standards, and reuse systems are designed to minimize human contact. Various studies have confirmed that RSCs represent no greater risk than DSCs. (Grimmond, 2019)

INTEGRATION WITH PRODUCT STEWARDSHIP AND EPR

Where they exist, product stewardship and EPR approaches for sharps from home healthcare do not fully consider the potential roles of RSCs. However, viable reuse systems should be considered and rolled out in cooperation with product manufacturers as individual producer responsibility under these approaches.

Determining collection data for sharps can pose difficulties, as highlighted for Ontario and DASTRI in the Background Paper. While material collections from a given jurisdiction can ultimately be determined, the amount of product sales into a given jurisdiction (especially at a state or local level) can be difficult to determine given existing distribution networks. The durability and tracking possible for RSCs should help avoid many of these problems experienced by product stewardship and EPR programs, as long as the process and tracking are explained clearly.

OTHER CONSIDERATIONS – THE INEVITABLE POLICY RESPONSE

The landscape for stewardship of sharps and sharps containers is chaotic and fragmented at the moment, but governments around the world are coming to the realization that waste will need to be tackled and legislated in a more cohesive and globalized manner.

The medical industry is not escaping scrutiny, and as it becomes clear that the pandemic has greatly increased single use plastics and medical waste, the risk of a strong policy response is becoming inevitable.

In financial circles, this phenomenon, known as the inevitable policy response (IPR), predicts a sharp and disruptive government response to the climate crisis the closer we get to 2025.

Waste in the medical industry has typically been incinerated, but as carbon budgets tighten and the clear effects of climate change force action, this will no longer be considered a long-term viable solution. A move to reuse and recycling will become of paramount importance.

Along with the tightening of financial regulations will come the scrutiny of supply chains and the inevitable tightening of regulations around waste. It is therefore advantageous for those who are aware of these coming changes to get ahead of the curve, make the necessary changes in an orderly fashion, and position themselves as leaders in the new circular and sustainable economy.

> "Government action to tackle climate change has so far been highly insufficient to achieve the commitments made under the Paris Agreement, and the market's default assumption appears to be that no further climate-related policies are coming in the near-term. Yet as the realities of climate change become increasingly apparent, it is inevitable that governments will be forced to act more decisively than they have so far.
>
> The question for investors now is not if governments will act, but when they will do so, what policies they will use and where the impact will be felt. The IPR project forecasts a response by 2025 that will be forceful, abrupt, and disorderly because of the delay." (UNPRI 2020)

ADDITIONAL ISSUES FOR SHARPS STEWARDSHIP

AREAS FOR FURTHER EXPLORATION

GIVEN THE SCARCITY OF DATA ON REUSABLE SHARPS SYSTEMS FOR HOME HEALTHCARE, THE GLOBALPSC RECOMMENDS THAT THE FOLLOWING AREAS BE EXAMINED TO BETTER DEFINE THE BUSINESS CASE FOR THESE SYSTEMS:

1. Define collection and transport models for RSCs used in home healthcare, including ground and air transport, and including mailback options specifically.

2. Life-cycle analysis of processing and decontamination systems such as HealthBeacon's Green Labs, factoring in specific collection and transport models.

3. Extent to which collection and transport methods affect classification of sharps and RSCs (e.g., Dangerous Goods, Clinical and Sharps Waste and Special Waste) and resulting transport, storage and management costs.

4. Opportunities for further reuse and recycling initiatives, including of the sharps themselves.

5. Benchmarking and verified public reporting to provide transparency and increase government and public trust in the sector.

6. The healthcare sector is heavily regulated and scrutinized by governments at all levels. Therefore, the development of a government relationship road map plan would inform a better understanding of government departments that influence the sector. From this, a sphere of influence and targeted relationship-building exercise between the home healthcare sector and government departments can begin e.g. Dept. Health and Human Services, EPAs, Local Government Associations and Departments of Environment, Social Services Commission etc.

7. Support the Business Case with a high-level financial assessment that scopes out the cost / benefit analysis and return on investment period for RSCs versus DSCs.

8. Scope and map current home RSC disposal options for specific and strategic geographical locations identified by key stakeholders.

9. Develop an RSC marketing and communications plan to support the Business Case and test the marcomm plan with key stakeholders in specific and strategic geographical locations e.g. pharmacies, medical centres and doctors' surgeries.

CONCLUSIONS

This report, building upon previous GlobalPSC research, highlights the key considerations for reusable sharps stewardship. Compared to DSCs, RSCs provide a viable option to tackle several of the main challenges facing medical waste in the home setting today, while integrating product stewardship and EPR approaches for producers.

As redesign, reuse and recycling are not yet viable options for sharps themselves, an innovative approach to the challenge of sharps waste is needed and regulatory frameworks, including product stewardship and EPR programs, should allow for flexibility to meet the safety, storage and sustainability needs in the home healthcare sharps domain.

This report has demonstrated that expanding the use of RSCs into home healthcare would be consistent with circular economy models and sustainability principles. Indeed, with an ever-increasing importance on environmentally friendly practices and as carbon budgets tighten with the effects of climate change becoming more obvious, mass incineration of sharps waste will likely no longer be acceptable.

A shift towards reuse and recycling will be of greater importance. On the back of the COVID-19 pandemic, and with the move towards increasingly remote patient care and its associated challenges, the use of RSCs in the home setting can become part of the solution.

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