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Review

Regulating Environmental Impact of Medical Devices in the United Kingdom—A Scoping Review

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Abstract: Medical devices are highly regulated to ensure safety and efficacy of the products and minimize the risk of harm to users and patients. However, the broader impacts of these devices on the environment have scarcely been questioned until recently. The United Kingdom National Health Service intends to achieve a "net zero" emissions service by 2040 and has identified specific targets to achieve through this process. However, medical device manufacturers do not see sufficient incentives to invest in reducing greenhouse gas emissions unless enforced by legislation. Furthermore, there is little evidence on the legislation required to reduce emissions from medical devices. This study addresses the relationship of medical device regulations and the environmental impact of the devices throughout their lifecycle. A scoping review was conducted on academic literature on the topic, followed by a critical review of the current medical device regulations and associated guidelines in the United Kingdom. The challenges to regulating environmental impact of medical devices were identified under seven themes. These challenges were contextualized with the National Health Service target of achieving zero emissions by 2040. The review indicates that current guidelines support single-use disposal of devices and equipment as the best approach to prevent pathogen transmission and landfilling and incineration are the most used waste management strategies. Manufacturers need to be guided and educated on reducing their emissions while ensuring the development of safe and effective devices.

Keywords: medical device; regulations; ecodesign; environmental impact

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1. Introduction

Brexit has ushered in a new era for medical device regulations in the United Kingdom (UK), establishing an independent UK certification system and initiating the phasing out of European certified devices through the Medicines and Medical Devices Act 2021 [1]. As the UK prepares to host the 26th United Nations Climate Change Summit (COP26) [2], there is global attention on how the UK upholds the targets for the reduction of greenhouse gas (GHG) emissions. At the same time, the COVID-19 pandemic has put tremendous pressures on the National Health Service (NHS) to meet the requirements of waves of infections, morbidities and deaths due to the virus and its variants. The UK waste management systems have faced much of the strain due to exponential increases in disposal of medical devices and personal protective equipment (PPE), leading to an increase in the environmental impact of medical equipment [3–5].

Medical devices have significantly contributed to greenhouse gas (GHG) emissions even before the pandemic. In 2019, the GHG emissions from medical equipment procured by the NHS was estimated as 2.52 $MtCO_2e$, accounting for about 10% of the total emissions from the NHS [6]. Among many reasons for these emissions is the increasing adoption of single-use medical devices, primarily disposed of through incineration or landfilling. The result of this cradle-to-grave lifecycle is not just the emissions generated but also the air, water and soil pollution, damage to biodiversity and contribution to climate change [5,7]. It has been evidenced that climate change has direct implications on human health, and

so, it becomes important to mitigate the environmental impacts of this industry to reduce further pressures on healthcare infrastructure.

While medical devices generate GHG emissions throughout their lifecycle, many of these environmental impacts are determined at the early stages of the lifecycle, namely the design and development process [8,9]. There are various barriers to the ecodesign of medical devices, including lack of a regulatory push for ecodesign, high regulatory conformity requirements, lack of knowledge on ecodesign for medical devices and a lack of awareness or education on implementing ecodesign in practice [10–13]. Surveys with designers on this issue indicate that unless there is a regulatory push for environmentally conscious design of medical devices, there is a low probability of ecodesign being considered in the design process [10], but what is not clear is the regulatory push required, how it can be implemented and what are the challenges to enforcing environmentally conscious design of medical devices through regulations. There is little evidence to ascertain how current regulations have affected the environmental impact from medical devices.

This study explores the existing literature on the relationship between medical device regulations and the environmental impact from medical devices in the UK. The study uses academic literature, existing medical device regulations in the UK and the associated guidance provided by the Government of UK to scope the relationship between regulations and the environmental impact of medical devices. The following sections detail the methods used for the scoping review, an assessment of the challenges to regulating environmental impact of this industry and opportunities for further research and ways in which the government can promote the ecodesign of medical devices.

2. Methodology

A literature review was conducted on the state of the art of the role of medical device regulations in environmental implications of medical devices throughout their lifecycles. Keywords included ("environmental legislation" AND "medical device regulations") OR ("medical waste" AND "medical device regulations") OR ("carbon emissions" AND "medical device regulations"). The first 200 results on Google Scholar were considered for each set of keywords. Google Scholar was used as the preferred database due to the wide-ranging subject matter being considered and the scarce data found through previous studies in select databases [11,13]. A further search was conducted on The Web of Science database with the keywords ((ALL = (medical device)) AND ALL = (regulation)) AND ALL = (environmental impact) OR ((ALL = (medical device)) AND ALL = (legislation)) AND ALL = (environmental impact). Fifty-nine results were found. Relevant articles were identified through the title and the contents of the abstract. The inclusion criteria were literature considering environmental impact of medical devices and healthcare infrastructure, medical device regulations and associated legislation. The exclusion criteria were literature discussing safety of healthcare infrastructure not pertaining to environmental impacts, such as regulatory conformity requirements, and pharmacological studies. Papers discussing current practices were also studied to see how regulations and legislation impacted practice.

A second review was conducted on existing regulations for medical devices throughout their lifecycles in the UK. The gov.uk website, which is the UK's public sector information website, was used to conduct a search on the term "medical device". The search was refined, specifying the topic as "health and social care" with a sub-topic of "medicines, medical devices". The content types selected were "guidance and regulation" and "policy papers and consultations". The search resulted in 127 items. The exclusion criteria were documents on legislation for PPE, medicinal products, non-device related care and treatment, medicinal research, medical consultations, competitions, adverse event reports and Northern Ireland related documents. Thirty-eight documents were obtained and studied.

The documents studied helped identify current legislation and regulation on medical devices in the UK, which were validated through the website legislation.gov.uk, the official website for access to all UK legislation. Further searches on gov.uk helped identify

guidelines and best practice documents for the various phases of the lifecycle of medical devices. These documents were critically reviewed to identify insights on the current progress in reducing the environmental impact from medical devices and opportunities for further research. In this study, medical devices for which the entire lifecycle of the product is regulated in the United Kingdom were considered. Thus, products that have been manufactured, distributed, purchased, used and disposed of within the UK, not including Northern Ireland, were considered. Devices manufactured or supplied from outside of the UK have not been considered, as different legislations apply to lifecycles beyond those in the United Kingdom. The material extraction stage was not considered in this study because material extraction and synthesis fall under diverse legal acts ranging from the mining of ores, to agriculture, to production of chemicals and polymers, some of which overlap with manufacturing processes and are hence not always bound by any specific legal act. Thus, this process is context dependent and cannot be defined under any specific regulations.

The environmental aspects considered to determine the impact of medical devices on the environment was based on categories provided in the ISO Standard No. 14001:2015, Annex A, including emissions to air, releases to water, waste management, contamination of land, consumption of natural resources and raw materials, chemical releases, toxic substances and other community issues such as noise pollution and release of foul odours [14].

3. Current Regulatory Framework for Medical Devices in the UK

Medical devices are regulated through various regulations throughout their lifecycle in the UK [15–17]. The UK Medical Device Regulations 2002, the main regulatory guidance on medical devices, transposes the European Union (EU) directives on medical devices (Directive 93/42/EEC), active implantable devices (Directive 90/385/EEC) and in-vitro diagnostics (Directive 98/79/EC) regarding the regulatory conformity required to market and sell a device in the UK [18]. These directives should not be confused with the EU regulations for medical devices (EU 2017/745) and in-vitro diagnostic devices (EU 2017/246). While the EU has repealed the directives in favour of new medical device regulations, the UK continues to transpose the earlier European directives, while developing its own regulations and a dedicated UK conformity assessment, independent of European regulatory structures and in line with the Medicines and Medical Devices Act 2021 [1,18–20]. Medical devices must also conform to the General Product Safety Regulations 2005 [21]. While the MDR 2002 regulates manufacture and use of devices, the health technical memoranda (HTM) issued by the Department of Health and Social Care (DHSC) provide specific guidance on the management, decontamination and disposal of devices for healthcare providers, based on a broad range of regulations. The Health Technical Memoranda reviewed in this study include HTM 01-01, 01-05, 01-06 (guidelines on management and decontamination of medical equipment, linen, dental care practice and flexible endoscopes) and 07-01 (guidelines on management of healthcare waste) along with the guidance on reprocessing and re-manufacturing of medical devices [22–38]. For the purpose of this review, it is assumed that the best-practice guidelines meet the requirements of all associated regulations, and reviewing these guidelines along with relevant literature should help scope the challenges based on secondary sources, similar to inferences by Martin et al. for dental care devices [39].

4. Challenges to Regulating Environmental Impact of Medical Devices

Based on the literature reviewed, challenges to regulating environmental impact were identified and structured in seven themes. These challenges were compared with the NHS "net zero" emissions target report and compared with the current research on identified emissions and ways to mitigate these emissions [5]. Specific clauses, their relevance to environmental impact of medical device and associated research opportunities have been provided in Appendix A for further details.

4.1. Psychological Challenges

There are broad psychological explanations to the inertia against environmentally conscious interventions in healthcare. The individual psychological explanations include the paradoxes of preventing harm to the individual while harming the environment, safe management of waste while making the environment unsafe and the use of advanced technology with high energy requirements to treat minor ailments and aesthetic corrections. Topf [40] suggests that the values of profit making and environmentalism are inherently at odds, as profits are driven by consumption. Much of the psychological hindrances in adopting green strategies are also propounded by myths such as greening is costly, a passing fad, not aesthetic or not well supported by the right materials. Then there are forms of denial which limit the greening of hospitals, including a direct denial of contribution to emissions through hospital activities, a procrastination of addressing the problem or resorting to distorting the facts and avoiding relevant information. Beyond the individual psychological explanations to the indifference towards greening hospitals, Topf also suggests group psychological explanations, such as individuals regarding greening as not their responsibility (diffusion of responsibility), disregarding the strides towards greening of other members of a community (pleuritic group ignorance) and the influence of a charismatic leader clouding the individual's judgement, leading to a herd mindset, often resulting in no action (Groupthink) [40].

This need to upskill healthcare workers, and not just sensitize them, has been recognized by the NHS, where 98% of the staff surveyed agree to the need for more sustainable practices in healthcare in the UK. It is well understood that sensitization must be accompanied with education programmes and staff protocol to minimize emissions and maximize value for resources. While various organizations such as the Nursing and Midwifery Council and the General Medical Council have introduced sustainability and climate change into the education system, more evidence is needed for developing protocol for healthcare providers in practice [5].

4.2. Evaluating Emissions and Creating Policy

The NHS quantifies its emissions as per scopes 1, 2 and 3 of the Greenhouse Gas Protocol, based on which they identified medical and non-medical equipment accounting for 18% of the total emission generated by the NHS in 2019 [5,6]. The gold standard for determining environmental impacts of medical devices is to use a Life Cycle Assessment (LCA) [7]. Various competing products can be compared on their impacts, associated costs and value for the healthcare provider to identify the best option. However, the existing literature on comparative assessment of environmental impact of medical devices uses diverse metrics, at various scales of device use and in varied contexts of healthcare settings, state regulations and policy on medical devices. While the quantity of single-use devices used may cause higher emissions than an equivalent reusable version, sterilization processes sometimes are more environmentally damaging as compared to disposing of single-use devices [11,41]. Thus, the results from these LCAs are not easily generalized to suggest policy-level interventions beyond that of the setting in which it has been studied [42–51].

Beyond the concerns of individual, tangible devices, there is limited regulatory oversight for connected health, particularly software as medical devices (SaMD). Data-driven and data-oriented healthcare creates new challenges for the medical device industry, in terms of regulation and the risks involved. The NHS estimates emissions of 456 $ktCO_2e$ from information and communication technology and continued growth in the adoption of digital services [5]. As of now, the understanding of the environmental impacts of SaMD are yet to be determined, even though the role and impact of SaMD in the medical device industry continues to grow [52].

Manufacturers have little incentive in encouraging the regulation of environmental impact of medical devices, unless it is profitable or helps improve the brand image among their consumers [53]. Considering the high conformity requirements to place medical devices on the market, risks of reinfection and cross-contamination and expensive legal

action thereafter, manufacturers remain averse to considering environmental impact at the cost of safety and efficacy of devices [10]. This has led to an increasing reliance on single-use disposable medical devices, leading to higher inventory costs at hospitals, higher waste management costs and higher production of medical waste [54,55].

4.3. Lack of Education and Awareness

One factor that has been found to affect the limited involvement of stakeholders on this subject is the lack of awareness and education, both on environmental impact as well as regulatory structures governing medical devices and environmental impact [10]. Kumar and Wang [12] found limited exposure and education of design for environment principles in medical device design and engineering courses around the world. A survey by Moultrie et al. [10] further suggests that designers find current regulations discourage designing for the environment and that manufacturers need to be educated about the opportunities to save expenses in developing sustainable medical devices. Under the theme of knowledge exchange, Martin et al. [39] suggest that there is a lack of encouragement in curricula for sustainable practices in dentistry. Furthermore, while many universities encourage the design and development of medical devices, and provide a platform for research and development in this field, there is very little evidence of education of regulatory structures governing medical devices in the United States of America (USA) and UK academic programmes, as found in a study by Hendricusdottir et al. [56].

4.4. Single-Use, Reusable and Reprocessed Devices

The NHS has found that over 1.4% of all emissions generated are due to single-use devices, some of which can be refurbished and reused to save emissions as well as money. They intend to reduce their reliance on single-use plastics in order to save on waste management costs and almost 224 ktCO_2e in emissions [5]. However, the current regulations suggest otherwise in some cases. Martin et al. note that a significant increase in the generation of biomedical waste in dental practices in the UK over the past few decades can be attributed to increased use of single-use devices and regulation that is confusing staff on best practice and segregation of wastes for sustainable management, among other things [39]. The increasing use of plastics, although providing inexpensive and wide-ranging uses in the medical device industry, is unattractive economically for recycling, thus being relegated to disposal in landfills. The guidelines on decontamination of medical equipment allow healthcare organizations to operate using only single-use devices if they do not have relevant decontamination services [23]. To reduce the risks of prion transmission, certain devices such as endodontic reamers and files which are designated as reusable should be treated as single-use [22,31]. Certain PPE worn during decontamination processes such as aprons, gloves, face masks and gowns must be single-use disposable [22]. Manual cleaning equipment such as brushes and sponges for cleaning endoscopes must be single-use [31]. All accessories with endoscopes must also be single-use. It is also advised that disposable liners be used for decontamination trays [31]. Where the guidelines suggest disposal as the safest form of practice to prevent transmission of pathogens, it is difficult to expect clinicians to identify alternative practices such as treatment or reuse of products.

4.5. Waste Management and the NHS Long Term Plan

The guidelines for safe management of healthcare waste are currently skewed towards landfilling and incineration as the safest options for most of the waste types generated. Table 1 provides an overview of the prescribed disposal strategies for the waste categories provided in HTM 07-01.

Table 1. Disposal options for various waste categories (as prescribed in HTM 07-01 [36]).

Waste Type	Waste Subtypes	Landfill	Municipal Incineration	Energy from Waste	Other Authorised Disposal	Clinical Waste Incineration	Alternative Treatment	Recovery
Domestic type waste		x	x	x	x			x
Offensive waste	Healthcare waste	x	x	x	x			x
	Municipal waste	x	x	x	x			x
Anatomical waste	Chemically preserved					x		
	Not chemically preserved					x		
Infectious waste	Contaminated with chemicals					x		
	Not containing contaminated chemicals or medicinal contamination					x	x	
Sharps	Non-medicinally contaminated					x	x	
	Medicinally contaminated other than cytotoic and cytostatic waste					x		
	Contaminated with cytotoxic and cytostatic waste					x		
Other infectious waste contaminated with cytotoxic and cytostatic waste						x		
Cytotoxic and cytostatic medicines	(in original packaging)					x		
	(not in original packaging)					x		
Other medicines	(in original packaging)					x		
	(not in original packaging)					x		
Dental amalgam								x

Table 1. *Cont.*

Waste Type	Waste Subtypes	Landfill	Municipal Incinera-tion	Energy from Waste	Other Authorised Disposal	Clinical Waste Incineration	Alternative Treatment	Recovery
Photographic (X-ray) waste	X-ray fixer						x	x
	X-ray developer						x	x
	Lead foil							x
	X-ray film							x
Gypsum and plaster-cast waste		x (special-ist landfill)						x
Radioactive waste						x		

Out of the 22 waste types, 16 are advised for incineration (in red) as one of the strategies for waste management. 4 of the 22 waste types are advised for landfilling (in yellow). Thus, a combined total of 20 of the 22 waste types are advised for a cradle-to-grave lifecycle (either incineration or landfilling). Nine out of the 22 waste types can be potentially recovered in some form (in green). Out of the nine, only three waste types are necessary to be recovered (dental amalgam, lead foil and X-ray film). The other three may still be disposed of without any recovery strategy. Thus, there is a predominant leaning towards cradle-to-grave lifecycles with few recovery options prescribed for various waste categories.

Healthcare waste management also faces new challenges which have currently not been addressed by the prescribed guidelines. The NHS has embarked on a long-term redesign of the care pathways it offers to the UK, specifically towards reducing in-person visits for patients through digital care consultations and reducing the burden on critical care infrastructure through preventive and public health investments [57]. This also indicates the increasing reliance on home healthcare. However, the current guidelines do not address the appropriate management of hazardous waste generated through home healthcare. Waste that contains hazardous substances such as cytotoxic or cytostatic medication or offensive waste that is infectious in nature is deemed as healthcare waste [36]. However, when these substances are disposed of through municipal waste streams, they are treated as municipal waste. There is also a broader acceptance and uptake of implants by society, both functional and aesthetic. However, these implants are not treated as healthcare waste, unless they are identified through a post-mortem or registered for donation upon the death of the current user [36]. The cremation or burial of these implants poses further environmental challenges which have not been studied or addressed within the current waste management policies.

4.6. Lack of Environmentally Conscious Standards for Medical Device Design

Another factor that has to be considered is the designated standards for medical devices, in-vitro diagnostic devices and active implantable devices. The DHSC does not include the ISO 14000 series on environmental management [58] or the IEC 62430 on environmentally conscious design (ECD) [59] as designated standards, thus excluding any standards on environmental impact of medical devices [60–62]. ISO 14006 builds on the existing quality management system of an organization (ISO 9001) [63] and while the UK designates a standard for quality management for medical devices (EN ISO 13485:2016) it does not mandate adherence to ecodesign or ECD standards. In fact, none of the standards for ecodesign endorsed or prescribed by the British standards institution have been designated for medical devices by the DHSC [64] nor has the ecodesign directive (The

Ecodesign for Energy-Related Products Regulations 2010) [65] been referenced in the MDR 2002 [18,66].

4.7. Limitations to Legislation Motivating Environmentally Conscious Practices

Assuming the above-mentioned challenges can be addressed, there is still the question of whether regulations and legislation can reduce the environmental impact of medical devices. Martin et al. identified that in the UK, the implementation of HTM 01-05 [22] led to an increase in waste management costs due to the instruction of disposing PPEs and single-use devices to prevent reinfection and cross-infection cases. The interpretation of HTM 01-05 has also frustrated users, leading to confusion in sustainable practices while trying to avoid litigation. Martin et al. [39] find that the legislation and regulation of safe disposal of dental amalgam is varied and inconsistent across the world, leading to the risk of higher contribution of mercury toxicity in the environment. Technology, in the form of dental separators, exists to ensure safe disposal of mercury, but this technology is not used all over the world, and there continues to be resistance from the dental profession to mandate dental separators in legislation. Along with metals, X-ray waste, gypsum and composite waste, there is a lack of harmonized regulations for the safe management and disposal of these materials from the dental industry. Wagner [67] argues that environmental legislation incentivizes actors to conceal relevant information of the harm that their products may cause to the environment, despite government subsidies on research on factors affecting environmental damage. Wagner also proposes that regulatory bodies cannot wait for the research to emerge regarding harmful substances (as has been the modus operandi), and instead they must penalize the concealment of information regarding the harmful impacts of substances being used or produced by various organizations. It has become evident over the last two decades that the pace of scientific progress has been accelerated in comparison with the legislation to control its adverse effects. While scientific progress cannot be slowed down, new approaches are required to increase the pace of legislation to ensure safe and effective use of new technology [68]. Musazzi et al. [69] argue that the current European regulatory framework does not effectively assess the human health and environmental risks of nanomaterials in medical devices, thus posing risks to users and patients. Ren et al. [70] studied the effect of environmental regulations on eco-efficiency gains in different regions of China. They classified regulations under three categories: command-and-control regulations (legislation discouraging environmentally damaging practices), market-based regulations (incentivizing eco-efficiency through tax-rebates, taxes and emission subsidies) and voluntary regulation (guidelines and protocols that are encouraged through public participation but not imposed as legislation). Their study indicates that different types of regulations have shown to influence eco-efficiency differently in different regions of China. Based on their study, they were able to propose suitable policy interventions to specific regions of China based on public participation, role of incentives and role of regulatory discouragement of environmentally damaging practices. The current research indicates that there is no consensus on how climate change policies can be implemented to reduce the environmental impact from healthcare systems. Yet, the NHS continues to be one of the few healthcare systems in the world with a meticulous record of environmental impacts and a long term plan for achieving net zero emissions through its services [5,6].

The review of literature on the relationship between medical device regulations and environmental impact, although insightful in terms of the challenges to regulating environmental impact, provided little evidence of how environmental legislation works to curb environmental impact and how such legislation can be developed. Fragmented literature indicated that research is required to structure the process and methods for translating knowledge of environmental implications of medical devices to policy for more transformative change.

5. Opportunities for Future Research and Policy Development

This review has helped identify various gaps in the current literature for regulating environmental impact in the medical device industry. The results indicate that more research is required to understand how the environmental impact of medical devices can be regulated without compromising the safety and efficacy of the devices. Through the findings, a few suggestions for research directions have been proposed which may encourage medical device stakeholders to embrace environmentally conscious approaches to their trade.

While many studies exist on the impact assessment of individual medical devices within their defined contexts, it is not clear how the evolution of the regulatory framework affects the environmental impacts of medical devices. It is also not clear how this can be studied. Yet it is important to develop systematic assessment methods so that future regulations can be developed with clear evidence of associated environmental impact. The NHS expects an increase in emissions of 1734 $ktCO_2e$ from vehicle use [5]. However, some of these emissions can be reduced through supply chain initiatives [5]. The adoption of industry 4.0 strategies provides pathways to reduce transport requirements by encouraging in-house manufacture and reprocessing of devices [13]. As the current regulations allow both of these processes, research can help develop complete cradle-to-cradle device lifecycles and product-service systems within healthcare institutions, reducing transport emissions of supply chain requirements. The MDR 2002 also provides conformity requirements for in-house manufacture of medical devices by healthcare facilities, for which the overall conformity requirements are lower than those for externally manufactured devices [18,71]. This also contributes to the envisioned reduction of emissions by the NHS from metal instrument reprocessing (157 $ktCO_2e$) and device reuse and refurbishment (202 $ktCO_2e$) [5].

The NHS intends to reduce reliance on single-use plastics and increase reuse and refurbishment of medical devices [5]. However, these targets are dependent on appropriate procurement and supply chain transformations. Currently, these impacts are being assessed through a limited number of suppliers volunteering to share their plans on carbon reduction [5], but more policy level decisions are required to achieve the goal of net zero emissions within the stipulated timeline. From a manufacturer's perspective, there are three approaches to encourage sustainability in the medical device ecosystem. The first is to encourage the recycling of materials after the use of a product as well as increase the use of recycled materials for the production of new devices. The second is to adopt more sustainable practices in manufacturing, such as reducing the waste of material in production processes and use local production facilities and local supply chains. The third approach is to design sustainability into the entire lifecycle of the product. This would enable considering the materials used, the logistics involved in cradle-to-cradle design and ensure that the product is easy to disassemble [11,53]. As the government of the UK already provides guidance on conforming to the various regulations, and also on the design of medical devices [72], guidance can be developed for manufacturers on environmentally conscious design of medical devices, based on established standards as well as through research by field experts [59,63]. The government also provides guidance for patients and users on the use and management of medical devices [73], particularly for home use and devices prescribed by clinicians. Thus, users can also be educated on the environmental impacts of medical devices through reports, documents and leaflets at the local healthcare facility, generating an informed demand for more environmentally conscious practices in the design of medical devices.

Through the investments in a digital care pathway redesign, the NHS expects to reduce travel-related emissions by 159 $ktCO_2e$ [5]. However, the NHS also estimates emissions of 456 $ktCO_2e$ from information and communication technology [5]. Currently there is very little research on assessing the environmental impact of SaMD. Considering the rising dependence on digital health records, and information engineering approaches to healthcare, it will be important to identify critical factors influencing the environmental

impacts of SaMD and address them through regulatory oversight, particularly if the NHS strives to build a net zero digital maturity framework [5].

6. Conclusions

The increasing global focus on climate change begs the question of environmental sustainability of healthcare systems. The growing evidence of rising GHG emissions from the medical device industry, and the paradox of harm to the individual versus harm to the environment of the population questions which strategies will tackle the inertia against ecodesign of medical devices. The existing research suggests that regulating environmental impacts of medical devices is necessary for compliance of the industry as a whole, but the evidence on how to regulate environmental impacts is limited.

This study identified the various challenges to regulating environmental impact of medical devices and how the current regulations can affect environmental sustainability of this industry. Lower emissions cannot be promoted at the cost of safety and efficacy of devices, and manufacturers will not voluntarily consider environmental sustainability at the cost of economic profit. There is also limited evidence to suggest that regulation will help limit environmental impacts, and it may lead to manufacturers hiding the dangerous environmental impacts of their trade. While it is clear that the industry has significant environmental impacts and the NHS strives to work towards becoming a net-zero emissions organization, the appropriate strategies for the medical device industry are continuing to evolve.

Current guidelines on management and decontamination of devices actively promote disposal of devices after a single use to prevent reinfection and cross-contamination, particularly from prion transmission. The regulations on disposal of devices indicate incineration and landfilling as the best practice, with very few opportunities for waste recovery. Despite the existence of recognized ecodesign and environmentally conscious design standards, these have not yet been designated to medical device regulations.

By educating stakeholders such as manufacturers and patients, more awareness can be generated on environmentally conscious approaches to the management of medical devices throughout their lifecycle. The government can support ecodesign of devices through appropriate guidance and eventually regulate the impacts based on developed criteria for evaluation of environmental impacts.

The regulation of environmental impacts of medical devices is a complex issue, with many factors working at cross-purposes with each other. More research is required to understand how this industry can accommodate environmentally conscious practices which are safe, effective and economically sustainable. While this is an opportune moment for the UK to consider ways to improve their medical device regulations, the literature reviewed indicates a lack of attention to environmental impact of medical devices around the world and a lack of appropriate legislation to curb these impacts. Climate change and healthcare are global challenges with global implications, as has been seen through the COVID-19 pandemic and the impact of climate change on destructive weather patterns. These challenges are also closely interlinked, suggesting that curbing environmental impacts from the medical device industry can go a long way in ensuring sustainability of healthcare systems.

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Appendix A

Table A1. Critical review of regulatory clauses and research opportunities.

Legal Act	Statement	Relevance to Environmental Impact	Research Opportunities
HTM 01-01, Part-A (pg 10)	"Section 3 Guidance for commissioners, regulators and providers, point 3.2: Responsibility for achieving acceptable standards of decontamination rests with commissioning organisations, individual trusts and provider organisations. Reprocessing units in healthcare establishments responsible for the decontamination of medical devices fall into two distinct categories when considering compliance with the MDD: • Devices transferred between legal entities (for example—reprocessing by one entity followed by use in another). • Devices remaining within one legal entity (for example—reprocessing and use by the same entity or organisation)." [23]	Reprocessing medical devices has been evidenced to incur reduced environmental impacts as compared with the equivalent disposable options for certain devices [48,74]. However, research does not indicate the environmental implications of on-site and off-site reprocessing.	Research on the environmental and cost implications of on-site and off-site reprocessing of medical devices can help healthcare centres consider investment strategies in reprocessing of devices.
HTM 01-01, Part-A (pg 15)	"Section 4 Regulatory framework, Outsourcing 4.23 The options for those healthcare organisations that do not undertake decontamination services include: • Using a decontamination service that is registered with the MHRA, that is compliant with the MDR, and that uses a notified body as its third-party auditor. • Using CE-marked single-use medical devices." [23]	There are varied reports on the environmental and cost implications of reusable vs. single-use devices [49,75]. This clause of the memorandum indicates that health systems are allowed to run completely on single-use devices if no decontamination facility is available. There is limited literature to indicate the environmental and cost implications of health systems of a similar scale running on purely single-use devices or having access to decontamination/ reprocessing facilities.	Evaluating the environmental and cost implications of running a healthcare facility purely on single-use devices as compared to investing in decontamination and reprocessing systems.
HTM 01-01, Part-A (pg 22)	"6 Management of surgical instruments, Loan sets 6.11 Instrument sets that are supplied from an external source, used for that procedure only and then returned are known as loan sets. This practice increases the risks associated with the decontamination and reprocessing of such instruments, because the organisation may not be familiar with them. Organisations have also expressed concern over the decontamination status of such instruments and the lack of track and traceability, including potential for instrument migration. It is a requirement of the Code of Practice that reusable medical devices should be decontaminated in accordance with manufacturers' instructions. Therefore, loan sets should be provided with decontamination instructions so that staff can ensure their compatibility with local decontamination processes. It should be ensured that when equipment is supplied to a healthcare provider, adequate time is allowed for cleaning, sterilization and return of the equipment to the theatres, both prior to and after use (see the AfPP's (2010) guidance 'Loan set management principles between suppliers/manufacturers, theatres & sterile service departments' and MHRA's 'Managing medical devices')." [23]	Loaning of medical devices allows sharing of resources, reducing the reliance on procuring new devices for each healthcare setting. It is well established that a sharing economy promotes sustainable outcomes and reduces environmental impacts in various industries such as mobility, digital economies and consumer appliances [76]. However, studies do not indicate the environmental and cost impacts of a sharing economy in healthcare, particularly the case of loaning medical devices vs. procuring devices.	Evaluating the environmental and cost implications of loaning medical devices vs. procuring medical devices for the same purpose.

Table A1. *Cont.*

Legal Act	Statement	Relevance to Environmental Impact	Research Opportunities
HTM 01-05 (pg 14)	"2 Essential quality requirements and best practice, Segregating instruments 2.17 Where instruments are difficult to clean, consideration should be given to replacing them with single-use instruments where possible. In dentistry this will include, but is not limited to, instruments such as matrix bands, saliva ejectors, aspirator tips and three-in-one tips. 2.18 Where endodontic reamers and files are designated reusable, they should be treated as single patient use or single use—regardless of the manufacturer's designation—to reduce the risk of prion transmission. Practices must have effective procedures in place to exclude errors in identifying the instrument(s) and associating them with the correct patient." [22]	When reusable devices are replaced with single-use devices due to difficulties in cleaning them, it is a design failure leading to the adoption of more wasteful alternatives. However, research does not indicate these design failures and the resultant transition to single-use devices.	Identify devices that are difficult to decontaminate effectively and study the design failures leading to a replacement with single-use devices.
HTM 01-05 (pg 34)	"6 General hygiene principles, Personal protective equipment for decontamination processes 6.14 Appropriate PPE should be worn during decontamination procedures. PPE includes disposable clinical gloves, household gloves, plastic disposable aprons, face masks, eye protection and adequate footwear. PPE should be stored in accordance with manufacturers' instructions. 6.21 Gloves other than domestic household types are single use only. They should be discarded as clinical waste. 6.25 Aprons should be used as a single-use item and disposed of as clinical waste. Plastic aprons should be changed at the completion of each procedure. 6.27 Face masks are single-use items and should be disposed of as clinical waste. 6.29 Eye protection may be reusable but is often difficult to clean. It may be reused if cleaned according to manufacturers' instructions. This should take place when it becomes visibly dirty and/or at the end of each session. Disposable visors are available and may be used. 6.33 Short sleeves allow the forearms to be washed as part of the hand hygiene routine. Dental staff need to be aware of the hazards that may be encountered in the decontamination process and may wish to wear long-cuffed gloves or disposable long-sleeved gowns to protect their arms." [22]	Personal protective equipment has been a major cause of excess waste and environmental impact through the COVID-19 pandemic, and the current guidance also endorses disposal of various PPE after a single use. However, the guidance does not necessitate the disposal of all PPE, and there is no argument provided for single use or reuse of equipment.	Research is needed to evaluate the risks of cross-contamination from various PPE, and appropriate design criteria is required to ensure that equipment is designed appropriately for minimum waste.

Table A1. *Cont.*

Legal Act	Statement	Relevance to Environmental Impact	Research Opportunities
HTM 01-06 (pg 3)	"2 Flexible endoscopes and decontamination, 2.7 The process of decontaminating flexible endoscopes with lumens has three components: a. Manual cleaning: this includes brushing with a specific single-use cleaning device, rinsing and exposure of all external and accessible internal components to a lowfoaming detergent known to be compatible with the endoscope. This procedure is uncontrolled and relies on the training of the operator for success." [31]	Point 2.7a specifies the use of a single-use cleaning brush; however, research does not indicate the associated value over reusable brushes. Furthermore, research does not indicate environmental or cost advantages over reusable brushes.	Compare the environmental and cost implications of single-use versus reusable channel port cleaning brushes and determine the risk versus benefits of the two.
HTM 01-06 (pg 12)	"5 Human prion diseases (including variant CJD and other forms of CJD) 5.17 The guidance below is based on that from the ACDP-TSE Subgroup's Annex F (last revised in October 2015). Users should check for updates on the ACDP-TSE Subgroup's website. a. Channel cleaning brushes and, if biopsy forceps or other accessories have been passed, the valve on the endoscope biopsy/instrument channel port should be disposed of as healthcare waste after each use. Single-use biopsy forceps should be used in all patients. Endoscope accessories should be single use wherever possible. It is essential to have systems in place that enable endoscopes, together with all their detachable components and any reused accessories, to be traced to the patients on whom they have been used. f. Following use in patients at risk of vCJD endoscopic accessories (including normally reusable devices such as heater probes) and cleaning aids such as brushes should be disposed of as healthcare waste." [31]	To reduce the risk of prion transmission, this point indicates disposal of cleaning equipment, which would either lead to landfilling or incineration. However, literature does not indicate whether alternative options supporting a cradle-to-cradle lifecycle exist for these products.	To explore alternative recovery and treatment strategies for disposable cleaning equipment for medical devices
HTM 01-06, Part B (pg 4)	"1 Design of an endoscope reprocessing unit, Layout of the unit, Single-room decontamination area 1.13 In addition to endoscope decontamination, the decontamination of trays or use of disposable liners is recommended. In addition, transport trolleys should be considered for decontamination as necessary. This should be considered as part of operational risk assessment." [31]	Packaging plastics are extensively used in healthcare settings for pre-sterilized as well as non-sterile products to ensure safe handling of equipment by healthcare workers and reduce the risks of cross-contamination. However, the environmental impact of these liners has not been evidenced, considering most of the packaging is disposed of after a single use. It has been evidenced that packaging in other industries is one of the leading producers of landfill waste.	Identify, develop and comparatively evaluate suitable alternatives to disposable liners for medical devices

Table A1. *Cont.*

Legal Act	Statement	Relevance to Environmental Impact	Research Opportunities
HTM 07-01 (pg 23)	4 Healthcare waste definitions and classifications Healthcare waste classification and assessment framework [36]	Waste having medicinal properties (e.g., expired medicines, devices containing medicinal products) produced from households is treated as municipal waste, despite being assessed by the guidelines as healthcare waste. The environmental impacts of home healthcare waste have scarcely been studied, despite having risks of leaching hazardous substances into municipal landfills, soil, air and water tables. The safe management of home healthcare waste has not been addressed in these guidelines.	Evaluate the quantities and environmental impacts of home healthcare waste.
HTM 07-01 (pg 46)	"Implants 4.154 Special care should be taken when removing an implant, particularly if it has electronic components such as an implantable cardioverter defibrillator or other implanted cardiac aid. For example: • there may be a risk of electric shock to a person removing and subsequently handling them; • cremation or disposal by incineration might cause batteries to explode, leaking toxic gas. 4.155 Such implants should be deactivated, removed with consent, decontaminated, and disposed of in a safe manner in the hazardous waste stream. Note Removed items are waste produced by the healthcare organisation. Where the patient has asked to retain the item, it is not considered waste, since it has not been discarded. 4.156 Protocols for the removal of implants should be determined locally. Local cardiac units, manufacturers/suppliers and funeral directors should be consulted. Helpful guidance has been published by the Association of British Healthcare Industries, the National Association of Funeral Directors, the Institute of Cemetery and Crematorium Management, and the Medicines and Healthcare products Regulatory Agency (MHRA) in its circular MDA SN 2008/068). 4.157 Disposal may include return to the manufacturer or cardiac unit to access stored data (see also Chapter 5, 'Waste minimisation, segregation, colour-coding and storage'). The receiving authority needs to be aware of duty-of-care implications. Reference to decontamination procedures and appropriate protocols for returning equipment should be provided by the receiving authority." [36]	Current research on implants from deceased persons only relates to organ donation, person identification through implants and material recovery from post-mortems [77–80]. However, research does not address the environmental impact of implants which are not safely disposed of by healthcare facilities. The increasing access and affordability of implants, both functional and aesthetic, make it an important aspect of study from an environmental impact perspective.	Evaluating the environmental impact of body implants throughout their lifecycle and developing suitable recovery strategies and device designs to reduce associated waste.

Table A1. *Cont.*

Legal Act	Statement	Relevance to Environmental Impact	Research Opportunities
HTM 07-01 (pg 53–57)	"Figure 11. Waste segregation chart" [36]	The waste segregation chart not only delineates the segregation process but also provides the disposal options. The disposal options for each waste type have been provided in Table 1. Majority of the disposal strategies suggest cradle-to-grave lifecycles, with very few recovery strategies offered for different types of waste streams.	Explore novel waste recovery and value addition strategies for waste types currently designated for a cradle-to-grave lifecycle.

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