

POLICY BRIEF

Reducing the environmental impact of medical devices adopted for use in the NHS

APRIL 2024

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This report was prepared by Brighton & Sussex Medical School and funded by a University of Sussex Knowledge Exchange Policy Fellowship to lead author Dr Rizan, with co-funding from Greener NHS. The views expressed in this report are those of the authors and not necessarily of the Greener NHS.

Method and acknowledgements

This report was based on review of literature and semi-structured interviews. We thank individuals who contributed to this process, including representatives from NHS policymakers, industry, approved bodies, NHS Supply Chain, organisations involved in developing national guidelines, NHS Trust procurement teams, departmental procurement leads, and clinicians. We are particularly grateful for support from Tsanko Dimov, Agnes Henson, Sarah Ouanhnon and Nicole Fletcher (all NHS England).

Cite this as “Rizan C, Bhutta MF. Policy Brief: Reducing the environmental impact of medical devices adopted for use in the NHS. Brighton and Sussex Medical School, 2024. doi 10.13140/RG.2.2.26977.93283”

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Acronyms

ATACH	Alliance for Transformative Action on Climate Change and Health
BSI	British Standards Institute
CPP	Collaborative Procurement Partnership
CTSP	Category Tower Service Provider
DALYs	Disability Adjusted Life Years
EU	European Union
ISO	International Organization for Standardization
LCA	Life Cycle Assessment
MDR	Medical Device Regulation
MHRA	Medicines and Healthcare products Regulatory Agency
NHS	National Health System
NICE	National Institute for Health and Care Excellence
PCR	Public Contracts Regulations
PIN	Prior information Notice
PPN	Procurement Policy Notice
QALYs	Quality Adjusted Life Years (QALYs)
SCCL	Supply Chain Coordination Limited
SHIPP	Sustainable Health in Procurement Project
UKCA	UK Conformity Assessment
WHO	World Health Organization

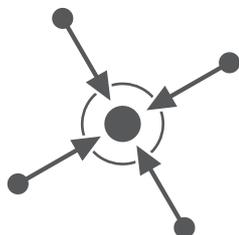
Executive summary

In this paper we explore challenges and opportunities for integrating environmental impact considerations into key decisions and processes for medical devices in their journey from regulatory approval to adoption in England's National Health Service (NHS).

We outline a journey map for medical devices from approval for the UK market to adoption, identifying key stakeholders (including regulatory, commissioning, procurement and adoption stakeholder groups), and stages and processes along that route. We find large variation in the product (and performance) considerations that stakeholders prioritise, and in the approach to identifying and tackling environmental impact targets or criteria. We find many existing and emerging initiatives across the healthcare ecosystem that demonstrate appetite and momentum for improved environmental performance, although such initiatives are disjointed and tend to focus either at supplier level, or only on pharmaceuticals. We find absence of a widely accepted or standardised methodology for evaluation of environmental impact specific to medical devices, making comparison between products challenging and unreliable.

We analyse existing academic literature to identify environmental impact hotspots of medical devices and approaches to improving resource efficiency of medical devices. A substantial area of focus has been on considering reusable versus single-use medical devices, identifying that reusable products deliver average carbon savings of 38-56% across the product life cycle,¹ and may offer cost savings through more efficient resource use. We identify the contributing processes to the environmental impact of both single-use and reusable medical devices, and approaches to reduce environmental impact of those processes.

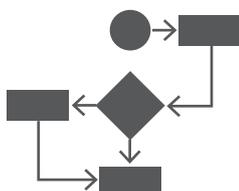
We conclude with three recommendations for reducing the environmental impact of medical devices adopted for use in the NHS, as follows:



1. Development of a centralised, consistent, and broadly communicated national medical device circularity strategy, to prevent disjointed (and often inexpert) assessment.



2. National support for the prioritisation of reduce and reuse initiatives across NHS organisations.



3. Evaluation of medical product categories in the NHS with high environmental impact, identifying the key drivers of their environmental impact to facilitate evidenced-based product decision-making, preferential procurement (and so incentivise change in the industry), and progress monitoring.

Introduction

In 2020 the national health service (NHS) in England became the first healthcare system to develop a strategy towards meeting net zero carbon emissions, spearheaded by the Greener NHS, with a year 2045 target.² This was subsequently supported by the 2022 amendment of the UK Health and Care Act, which now specifies how healthcare providers must comply with the Climate Change Act and the Environment Act.³ Meeting this net zero ambition must include alignment of the NHS supply chain, representing around 80,000 suppliers who provide medical equipment, pharmaceuticals, and other goods and services to the NHS;² collectively responsible for two-thirds of the NHS England carbon footprint. Of this, medical equipment is responsible for 10% of total NHS and 15% of hospital care emissions.⁴ There is growing academic literature evidencing ways to reduce the environmental impact of medical devices,⁵ but translation into change in practice remains a challenge. There are also a growing number of initiatives that consider environmental impact in the medical devices journey to adoption, but these are often disjointed and lack consistency in approach and implementation.

This report explores the challenges and opportunities for integrating environmental impact into decision-making around medical device adoption, including products used to diagnose, monitor, treat or manage a medical condition,⁶ focusing on those used in both primary and secondary care in NHS England (pharmaceuticals, and non-clinical equipment are outside of scope). Here we define environmental impact as the net effect on the natural world associated with the production, use, and disposal of medical devices, including wider environmental impacts beyond greenhouse gas emissions.

Opportunities for reducing environmental impact may include the adoption of circular economy principles. In this report, circularity is defined as approaches to product design, use and end-of-life treatment that maximises the useful life of the product and its constituent materials. Broadly this aligns with the principles of waste hierarchy application, in which the material value retention is approached first through the strategies of reduction, reuse, repair, refurbishment and remanufacture, only resorting to materials recovery for alternative purposes via recycling or other reclamation methods where alternative strategies have been exhausted.

For innovative or leading suppliers, most opportunities to make a product more sustainable exist in the research and development stage of the products lifecycle, and this paper focuses on how commissioning and procurement processes could be shaped and coordinated to encourage more environmentally conscious design and selection.

This report is divided into three sections.

In Section One we identify end-to-end processes and key stakeholders in the journey from regulatory approval to adoption of medical devices, and challenges and opportunities for integrating environmental impacts considerations into the current processes.

In Section Two we critically evaluate existing and emerging initiatives which may support, or be built upon to inform commissioning and procurement of medical products with lower environmental impact.

In Section Three, we evaluate evidence for approaches to reducing environmental impact associated with the design or use of medical devices.

Finally, and building on analysis presented in Sections One to Three, we explore solutions and policy recommendations for integrating environmental impact into the commissioning and procurement of medical devices.

Section 1

The medical product journey to adoption

In this section, we explore processes and stakeholders involved in the adoption of medical devices, and identify the challenges and opportunities that this system presents for integrating environmental impact considerations into commissioning and procurement decisions.

Processes and stakeholders involved in adoption of medical devices

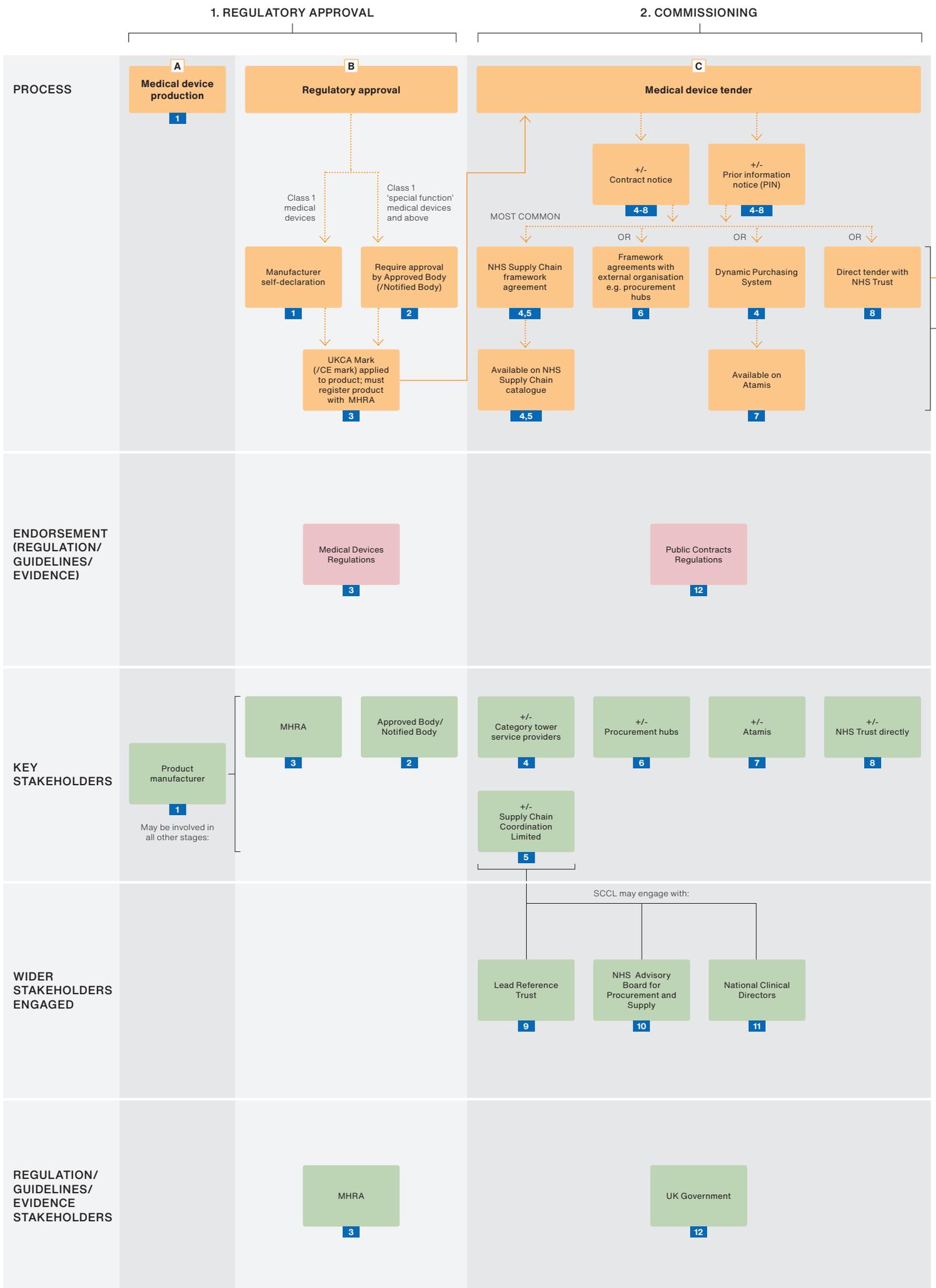
Figure 1 outlines a journey map of the key stages, processes, stakeholders, and supporting regulations and guidelines typically relevant to adoption of medical devices in the NHS, informed by semi-structured interviews and correspondence with key stakeholders. The journey map identifies points at which environmental impact could be considered, and stakeholder groups with potential influence.

Summarising this journey:

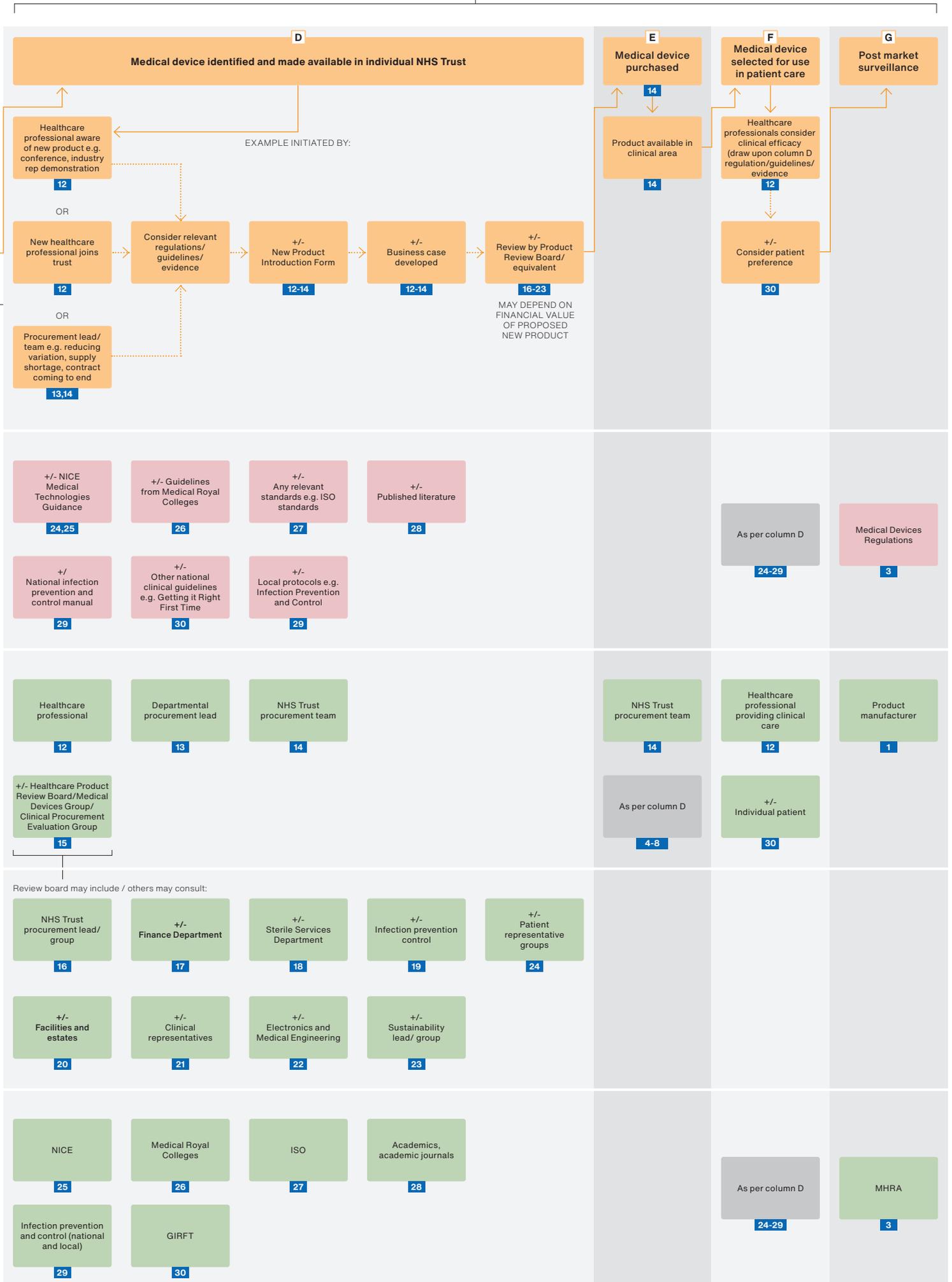
1. Once a medical device has been developed (A) it must undergo regulatory approval (B) enabling a UK Conformity Assessed (UKCA) mark to be applied, and be registered with the Medicines and Healthcare products Regulatory Agency (MHRA).
2. There are several main commissioning routes in the NHS (C), most commonly through NHS Supply Chain (approximately 60% of all products supplied to the NHS). Alternatives include other framework providers, dynamic purchasing systems (quicker and simpler), or (less commonly outside of primary care) directly through an NHS organisation.
3. The introduction of a new product at a given NHS Trust (D) is typically initiated by healthcare professionals (for example when becoming aware of a new product at a conference or following demonstration by an industry representative, or due to a new healthcare professional joining a department), or by procurement leads at departmental or trust level (for example seeking to rationalise equipment, responding to supply chain shortages, or review at point of contract renewal). There is variation between NHS Trusts in the process for introduction of a new product. Once a product has been purchased and available in a clinical area (E), selection for use (F) is principally driven by healthcare professionals, who may draw upon relevant guidelines and evidence. This is followed by a period of post market surveillance (G).

Key considerations typically considered throughout these product decisions are perception or evidence of: patient safety, clinical effectiveness, functionality or convenience, familiarity with product and supplier, financial cost, cost-effectiveness, and added value to the patient pathway (or other clinical benefit).

Figure 1: Journey map for adoption of medical devices



3. PROCUREMENT & ADOPTION



Challenges and opportunities for integrating environmental impact into the current medical product journey

The current medical product journey to adoption (Figure 1) poses several challenges to reducing the environmental impact of medical devices:

Scale

- 30 stakeholder groups were identified.
- Each group may have many sub-organisations e.g. around 80,000 suppliers, 229 NHS Trusts.
- Approximately 592,000 different medical products available on the NHS Supply Chain Catalogue.

Time and expertise

- Perceived lack of time to consider environmental impact amongst the stretched NHS workforce (including procurement and clinical staff).
- Limited relevant expertise to consider information in relation to environmental impact amongst those involved in medical product procurement and selection for clinical use.

Incentivisation

- Suppliers are not currently incentivised (either in guidance, approvals processes, or purchasing patterns) to move away from single-use devices.

Variation

- Lack of standardisation in products used between clinicians/ departments/ hospitals for the same procedure.
- Variation in the route from commissioning to procurement and surrounding governance between NHS Trusts (for example, some but not all trusts have a product review group to appraise new products, of varying constitution).
- Variation between trusts in the financial threshold of a contract at which greater scrutiny is applied. This often results in single-use products requiring a less rigorous approval process and experiencing fewer delays than reusable products (for example reusable products are more likely to require consideration by product review boards, and further clinical evaluation of products, which can take months).

Process considerations

- Framework agreements are typically four years in duration, and so opportunities to make a product with lower environmental impact widely available to the system will depend on the framework cycle.
- Framework and contract specifications sometimes specify that products must be single-use, rather than specifying the function they serve, preventing suppliers from proposing circular solutions that meet the clinical need.
- Regulatory approval and commissioning processes are considered slow and costly, which can stifle the introduction of innovative sustainable products or ongoing product design improvements.

Infrastructure

- Lack of infrastructure to support widescale circular product solutions, including sterilisation, laundry capacity, waste segregation, reverse logistics and storage space in NHS sites.

Supply chain externalities

- Supply chain resilience/ continuity issues result in products frequently becoming unavailable or discontinued, limiting the ability to standardise products (whether sustainable or not). This may be due to shortages in raw materials, manufactured components (e.g. micro-chips), logistics, or regulatory changes.
- The globalised nature of supply chains limits the potential of a single purchasing group to influence demand, and reduces the impact that single-state regulatory changes may have (compared to international co-ordination).
- Tension between rationalisation (reduce supplier base, longer-term agreements), versus supply chain resilience.

There are also several opportunities for improving environmental impact arising from the current system:

- Healthcare professionals will typically opt for products they have used within their training and are familiar with, but many are open to trialling new products, and to reconsidering the way existing products are used.
- There are examples where innovation achieves clinical and/ or cost benefit in addition to environmental benefit. Decisions on medical product selection are primarily driven by clinical safety and efficacy, and where win-wins can be demonstrated (to both environment and patient) these are not always communicated.
- At the population level, the environmental impact of a given product can be used to model subsequent effects on human health, which may align with measures regulatory bodies have experience of (such as Disability Adjusted Life Years).

Section 2

Existing and emerging initiatives and approaches for integrating environmental impact assessments into medical product decisions

In this section, we explore current (and emerging) initiatives, approaches and tools that could be adapted and leveraged for integrating environmental impact into medical product purchasing decisions, and discuss their strengths and limitations. Such initiatives are summarised in Table 1. There are wider emerging initiatives seeking to harmonise the approach to evaluating and reporting environmental impact (Supplementary Table 3), which could be adapted or extended to medical devices, but are focused largely at supplier level, and are either generic (to healthcare or broader sectors) or targeted at pharmaceuticals, and so may not be applicable here.

In Table 2 we summarise key approaches to undertaking an environmental impact assessment of medical devices, and consider their pros and cons.

Table 1: Current and emerging initiatives applying sustainability principles to medical product adoption in NHS England

Initiative/commitment (year initiated)	Stakeholders	Detail
Net Zero Supplier Roadmap (2021) ⁷	Suppliers, commissioners and purchasers	<ul style="list-style-type: none"> • Minimum 10% net zero and social value weighting applied to all NHS procurements from April 2022, mandatory for directly awarded contracts, and integrates Procurement Policy Note (PPN) 06/20 • Suppliers must publish a Carbon Reduction Plan for Scope 1, 2 and a subset of Scope 3 emissions (for contract >£5 million per year from April 2023, proportionately to all contracts from April 2024) • All suppliers to publicly report targets, emissions, and publish a Carbon Reduction Plan for all Scope 1, 2 and 3 emissions by April 2027 • Carbon footprinting of individual products by April 2028 (scope and methodology to be determined) • Suppliers only eligible for NHS contracts if can demonstrate progress and continued emission reporting from 2030 <ul style="list-style-type: none"> – Evergreen Sustainable Supplier Assessment (2023)⁸ developed as a tool to support this roadmap – Piloted in 2022, launched 2023 – Suppliers on existing NHS Supply Chain Frameworks required to submit Evergreen Assessment by 1 February 2024. Suppliers bidding to be on any new NHS Supply Chain Frameworks will be required to submit an Evergreen Assessment as part of the tendering process. – Online self-assessment and reporting by suppliers, hosted on 'Atamis' platform – Single point for suppliers to report progress against emissions reductions, modern slavery, and other sustainability criteria – Assesses supplier against four maturity levels, with highest available for suppliers with '2045 net zero targets, independently validated, across the global organisation, while actively taking steps to map supply chain or investigate and mitigate supplier risks of modern slavery'
Procurement Policy Note PPN 06/21 (2021) ⁹	Contracting authorities	<ul style="list-style-type: none"> • UK Government requirement to consider Carbon Reduction Plans in procurement of all major government contracts (contracts > £5 million per year)
NICE commitment to include environmental impact (2021) ¹⁰	NICE guidelines	<ul style="list-style-type: none"> • NICE indicate that they are "examining how environmental sustainability considerations should be included in a new framework for prioritising topics across NICE"
Medicines and Healthcare Products Regulatory Agency Corporate Plan: 2023 to 2026 (2023) ¹¹	Medical device suppliers, commissioners	<ul style="list-style-type: none"> • The MHRA has committed to "deliver a sustainability strategy for medical products in conjunction with international regulators, which contributes to addressing the climate change emergency"
Varying individual NHS trust-led initiatives for Scope 3 emissions	Individual trust procurement teams, departmental procurement leads	<p>Each NHS Trust now has a Green Plan, and individual trusts are developing varying frameworks and questions to evaluate environmental impact. For example:</p> <ul style="list-style-type: none"> • Discrete category indicators (traffic light system), with subjective weighting applied to different environmental impact areas • Questions integrated into new product introduction forms
Varying individual clinician-led initiatives	Individual clinicians	<p>Individual clinicians may consider environmental impact. For example:</p> <ul style="list-style-type: none"> • From published literature, e.g. available via the online repository HealthcareLCA (although studies included are not quality assessed)¹² • Accessing industry reports • Directly asking industry representatives about environmental impact

Table 2: Approaches to evaluate the environmental impact of medical devices

Initiative	Detail	Pros	Cons
Full life cycle assessment (LCA)	Evaluation of broad environmental impacts associated with a given product e.g. may include eutrophication, freshwater ecotoxicity, ozone depletion potential, particulate matter formation	<ul style="list-style-type: none"> Evaluates factors beyond greenhouse gas emissions Possible to define Product Category Rules (see Supplementary Table 3) enabling comparison between products Possible to model human health impacts of environmental impact Can take cradle-to-grave approach (looking at all process from raw material extraction, manufacture, distribution, use, to final disposal) 	<ul style="list-style-type: none"> Resource intensive (time, expensive databases) for data collection and analysis Not advisable to compare between products (in absence of Product Category Rules)- results subject to manipulation e.g. dependent on system boundary, assumptions, allocation methods, sources of characterisation factors Greater expertise required for interpretation of results
Carbon footprint	Evaluation of greenhouse gas emissions associated with a given product	<ul style="list-style-type: none"> Similar to full LCA but focused only on greenhouse gas emissions Single measure of evaluation 	<ul style="list-style-type: none"> Limited to greenhouse gas emissions, lacking consideration for other environmental impacts Similar cons to full LCA, although less resource intensive, and less expertise required for interpretation (provides a single result)
Discrete category indicators	Specific areas of environmental impact defined (e.g. energy source, mode of transportation, volume of water consumed) and scoring system (such as traffic light) applied	<ul style="list-style-type: none"> Can be helpful for highlighting areas of real-world change May capture primary data related to product life cycle hotspots, without risking inaccuracies/inconsistencies from assumptions implicit in carbon factors Data collection less resource intensive Simple to communicate results 	<ul style="list-style-type: none"> Current lack of consistency in indicators included If equal weighting applied to different categories, implies equal importance Not one size fits all- different products will have different hotspot sources of emissions
Green tick	Various certification schemes available to endorse environmental credentials	<ul style="list-style-type: none"> Simple label 	<ul style="list-style-type: none"> Simplistic, lack of robustness Does not incentivise further innovation once green tick awarded Concerns re-greenwashing
White space questions	Free text responses to questions E.g. suppliers asked to demonstrate reduced greenhouse emissions	<ul style="list-style-type: none"> Easily implemented 	<ul style="list-style-type: none"> Lack of consistency in questions posed Lack of consistency in quality of responses Concern about how these are being evaluated

Initiatives to integrate environmental impact assessment into healthcare (or other) products have developed relatively rapidly, signalling enthusiasm for change, but data from our semi-structured interviews with stakeholders highlight several concerns:

Lack of consistency in approach

There is inconsistency in the way environmental impact of medical devices is considered, for example:

- Some individual procurement teams (and individual clinicians) define their own system for evaluating environmental impact, including questions on strategy (with varying depth or granularity, for example some simply asking ‘what is your company doing to move towards carbon neutral operations’), and questions on evaluation of products (with a variety of criteria, and variable or informal weighting given to these criteria, often based on subjective judgement).
- There is variation in the way in which net zero and social value questions are posed to industry. Responses to these questions are also open to subjective interpretation.

This lack of consistency is associated with risk. Where there is variation in the methods used to evaluate environmental impact of the same products, the conclusions drawn from approaches may differ, and may not accurately reflect real-world environmental impact. Where similar questions are asked in different ways it creates extra work for suppliers, in particular creating disproportionate and disadvantageous burden on small and medium size enterprises. This duplicates work, wasting time, effort, and resources, dilutes messaging to industry, and reduces confidence in the commercial benefit of investment into improving performance on specified environmental measures.

Concerns about costs and scope of reporting

In terms of generating reports of environmental impact, concerns were expressed about:

- The time, resources, and financial cost of evaluating environmental impact and who pays for this.
- A perception that evaluating/ reporting environmental impact takes away from initiatives to drive real-world change, representing opportunity cost.
- Risks of disclosure of commercially sensitive data.
- Concerns about extended producer responsibility, given that suppliers do not have direct control over how items are used (including how many times they are re-used or reprocessed, and how they are disposed of).

We also acknowledge issues with data availability. Whilst product suppliers often have access to data on manufacturing, this is not always the case. They may not have oversight of upstream or downstream processes, may be reliant upon their own set of suppliers, and may be unaware of variation in material and energy consumption associated with use and disposal phases.

Concerns about how reported information is valued and used

We found scepticism from multiple parties on how reported information could be used, for example:

- Concerns that evaluating environmental impact could be a 'tick box' exercise.
- Concerns from industry about whether information put forward relating to environmental impact is read (and if it is, the expertise of individuals evaluating this).
- Concerns whether the clinical benefits of using products would be taken into account when evaluating environmental impact (however we are cognisant that claims of clinical benefit may not be evidenced or may be over-stated).
- Scepticism amongst procurement teams and healthcare professionals about industry self-reported, unverified evidence about environmental impact, including concerns of 'greenwashing'.
- Scepticism about auditing processes, and validity of results if funded by industry (even when using a third-party auditor, in line with the European Council of the European Union and European Parliament Corporate Sustainability Directive).¹³

This sentiment is reflected in wider concerns about the use of environmental performance certification schemes within industry such as ISO 14001, including cost associated with maintaining such certification,¹⁴ evidence for tokenistic focus on criteria used in such certification by some companies, and poor correlation between measured improved performance and real-world net impact.¹⁵

We note concerns that focusing solely on carbon footprint risks other environmental impacts beyond greenhouse gas emissions being overlooked, as captured in more comprehensive approaches such as life cycle assessment.

Principles of an 'ideal' environmental impact assessment of medical devices

We now explore what may be the principles of an ideal environmental impact assessment of medical devices (Table 3). This would involve undertaking assessment using a full life cycle approach for all products, using consistent methodology. There are concerns that focusing solely on carbon footprint risks other environmental impacts beyond greenhouse gas emissions being overlooked, and so broader impact categories should be considered. Converting results of environmental impact into health impacts may ease integration into existing clinical guidelines. Drawing on stakeholder concerns, transparency is important to improve confidence in evaluations, and any assumptions, limitations and dependencies of findings should be clearly stated. Results would ideally be presented in a single database of full life cycle assessments of all medical devices, and reported in a way that enables procurement teams to interpret and integrate results into evaluation, comparison, and purchasing decisions (at the level of individual clinician, department, hospital or primary care facility, or procurement hub). Such initiatives would ideally require minimal additional training, analysis or personnel, and allow products to be compared in a fair manner, applying sensitivity and scenario analysis where relevant.

Table 3: Principles of an ideal environmental impact assessment of medical devices

Principles	Independent evaluation	<ul style="list-style-type: none"> • Evaluation undertaken by independent, impartial and expert third party • In line with principles of Environmental Product Declarations (ISO 14025:2006)¹⁶ • Need confidence robust evaluation
	Transparent	<ul style="list-style-type: none"> • Full transparency, at least at point of independent review (not necessary for full inventory data to be disclosed publicly) • Must be clear about assumptions made and characterisation factors used
	Standardised and internationally utilised assessment	<ul style="list-style-type: none"> • Enable stakeholders across the value chain to draw upon the same environmental impact assessment • Ensure consistency in decisions being made • Reduce duplication and impact on suppliers
Methodological approach	Full life cycle assessment	<ul style="list-style-type: none"> • In line with ISO 14040:2006 and ISO 14044:2006
	Life cycle approach	<ul style="list-style-type: none"> • Consider cradle-to-grave emissions
	Include broad environmental impact categories	<ul style="list-style-type: none"> • Consider environmental impacts beyond greenhouse gas emissions
	Enable comparison	<p>Define standard for evaluating LCA (for each product type) in line with Product Category Rules, allowing comparison, including ensuring consistency in</p> <ul style="list-style-type: none"> • System boundaries • Allocation methods • Sources of characterisation factors • Method to estimate number of uses of reusable equipment
	Consider variation in product use	<ul style="list-style-type: none"> • Use of scenario analysis to model differences in product use, e.g. accounting for differences in number of uses, energy supply (e.g. for energy devices), reprocessing facilities, waste disposal methods
	System boundary	<ul style="list-style-type: none"> • Consider expanding system boundary where necessary and evidenced, for example where change in product would have impact on length of hospital stay, complication rate, etc
Reporting	Report data on different environmental impacts	<ul style="list-style-type: none"> • Report on broad environmental impacts, beyond carbon footprint
	Evaluate impact of environmental harm on human health	<ul style="list-style-type: none"> • Convert results of environmental impact into health impacts e.g. Disability Adjusted Life Years (DALYs), or Quality Adjusted Life Years (QALYs)
	Limitations stated explicitly	<ul style="list-style-type: none"> • Clearly state assumptions, limitations, and dependencies of results • Include estimate of uncertainty in environmental impact assessment
	Appropriate communication of environmental impact results	<ul style="list-style-type: none"> • Results communicated to stakeholders in ways that are clear and easy to access, interpret and action • Require minimal additional training or extra personnel • May be different for different stakeholder groups e.g. procurement teams may want to understand more detail
	Integration into hospital level environmental impact assessments	<ul style="list-style-type: none"> • Enable hospital to integrate results into hospital or primary care facility environmental impact assessments • Enable healthcare commissioners, procurers, and providers to understand the role that the decision about an individual medical product will play in Net Zero targets

Section 3

Evidence for approaches to reducing environmental impact of medical devices

In Section Two we identified principles underpinning an ‘ideal’ environmental impact assessment of medical devices, but we recognise that time, expertise, and resource constraints mean undertaking such assessments would not be feasible across even a fraction of the thousands of medical devices currently used within the NHS. In this section we therefore consider the evidence for more pragmatic strategies to reducing the environmental impact of medical devices.

We explored published literature to answer three questions on how the environmental impact of medical devices could be minimised.

Environmental impact of single-use versus reusable medical devices

On first principles, reuse of medical devices causes less environmental harm. However, in healthcare many devices will need decontamination or sterilisation prior to reuse. A systematic review found average reductions in carbon footprint of 38-56% across the product life cycle through switching from single-use to reusable products, depending on the product group, with wider reductions typically observed in other environmental impact categories aside from water use.¹ Given that this review evaluated 27 medical product life cycle assessments across different geographical settings, it is likely that the direction of these findings would apply to medical devices used in the NHS, England. We have not here explored the safety of reuse of medical devices, but recognise this as an important question, and one where the answer will be specific to the product type and its use.

Contributing processes to the carbon footprint of medical devices

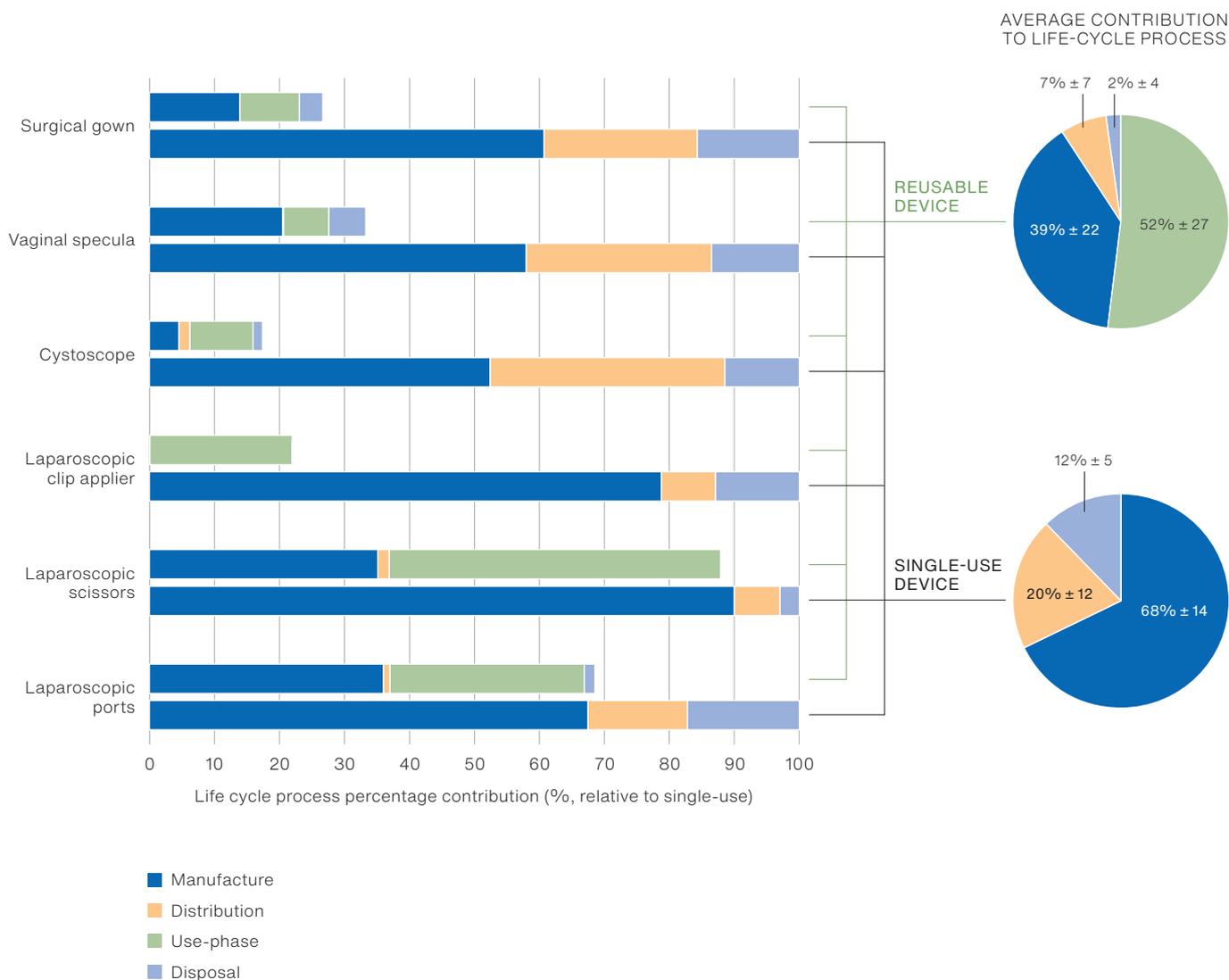
Beyond general principles of circularity, the evidence base of LCAs helps to reveal which life cycle stages might be best candidates for optimisation to further improve sustainability performance. We sought evidence on the relative contribution of different life cycle stages to the carbon footprint of both single-use and reusable medical devices, extracting data from studies in recent systematic reviews.^{1,5} We found many published LCA studies were non-informative, because they did not report the breakdown at life cycle stage,¹⁷ incompletely reported it (such as focusing on largest contributing processes),¹⁸ or failed to disaggregate stages (for example combining manufacture and distribution phases,¹⁹ or distribution and packaging phases²⁰).

Finally, we selected data from informative studies of six medical devices which included both reusable and single-use alternatives (which collectively include textiles, metalware, plastics, and electrosurgical devices). Figure 2 summarises the relative contribution of life cycle stages to the carbon footprint.

- For single-use devices, the life cycle stage with greatest proportional contribution to carbon footprint was manufacturing (mean average 68%, standard deviation [SD]= 14%), followed by distribution (mean 20%, SD=12%), and disposal (mean 12%, SD=5%).
- For reusable equivalents, the life cycle stage with greatest proportional contribution to carbon footprint was the use-phase (mean 52%, SD=27%), followed by manufacturing (mean 39%, SD=22%), and disposal (mean 7%, SD=7%).

Figure 2: Relative contribution of life cycle stages to carbon footprint of six medical devices

Bar graph shows contribution of life cycle processes for reusable devices relative to single-use equivalents (100%) for each of six devices. Pie chart shows contributions of life cycle processes averaged across all reusable (top) and single-use (bottom) devices, with figures representing mean percentage contribution +/- one standard deviation. Data sources: surgical gown = Burguburu et al. (2022),²¹ vaginal speculum = Donahue et al. (2020),²² cystoscope = Kemble et al. (2023),²³ laparoscopic clip applicator / scissors / ports = Rizan et al. (2022)²⁴. * = hybrid (predominantly reusable, small single-use component).



Approaches to reduce environmental impact of each life cycle phase of medical devices

We reviewed literature for evidence on how to optimise each life-cycle phase of medical devices using circular economy principles (Table 4), and note that many of these approaches also apply to capital equipment.

We acknowledge that not all approaches outlined in Table 4 will be applicable to every medical device, and further research is required to identify exceptions and further opportunities for mitigations where these approaches do not result in reduced environmental impact for a particular device. Manufacturers and suppliers may choose to integrate these principles into their product design processes or operational processes. Ideally, regulators can shape policies and processes to prepare the market and incentivise suppliers to align with such approaches. However, given existing constraints, commissioning and procurement guidance may have to develop awareness of which levers are currently at a manufacturer's disposal.

There are important considerations not included in Table 4. Phases including manufacture and cleaning / sterilisation should avoid environmental toxins where possible, for example endocrine disruptors such as perfluoroalkyl substances, phthalates and bisphenols.²⁵ Material choice in manufacture is also important, for example using recycled materials where possible, and designing devices for ease of recycling at end of life. Medical devices that are reusable should be designed for longevity: it is noteworthy that remanufacture of cardiac catheters is successful in only half of cases due to material failure (such devices are discarded and do not re-enter the health system).²⁶

Table 4: Approaches to reducing the environmental impact of life cycle phases of medical devices

Product life cycle stage	Approach	Illustration of environmental impact
Manufacture	Use renewable energy and maximise energy efficiency	Solar and wind powered electricity has 94-96% lower carbon footprint compared with coal powered electricity ²⁷
	Avoid wastage (materials, water, energy)	Reduction in the weight of material in a product correlates with a proportional reduction in the environmental impact of that material, but should be considered against impact on durability
Distribution	Avoid air freight, use zero emission vehicles where possible	Transporting medical product by electric van has 89% lower carbon compared to a short haul flight to/from UK ²⁸
Use-phase (for single-use products)	Avoid waste	One study found that 2.5% of all goods (by financial value) were unused and discarded in neurointerventional procedures ²⁹ Opportunities to increase number of uses should be considered. For example, moving from single-use to single-patient use where appropriate.
	Remanufacture to enable reuse of a device labelled as single-use	Remanufacture of electrophysiology catheters is associated with 50-60% carbon reduction compared to a virgin catheter ²⁶
Use-phase (for reusable products)	Maximise number of uses	Increasing the number of uses of a laryngeal mask airway from 10 to 40 reduces carbon footprint by 35% ¹⁸
	Optimise loading of reprocessing machines (decontamination, laundering) and use renewable energy	At one site, typical loading of steam sterilisation machines was associated with 60% reduction in carbon footprint compared with lowest observed loading ³⁰
	Repair	Repair of surgical scissors (rather than replacement with a new reusable pair) is associated with carbon savings of 20% ³¹
Disposal	Recycle materials, maintaining highest functionality	100% recyclability of packaging was modelled to reduce carbon footprint of the resulting packaging by 38% ³² in one (non-healthcare) study. However, recycling of medical devices themselves may be more difficult if they are contaminated or made of multiple material types.
	Recover energy from waste	For items undergoing low and high temperature incineration, recovery of energy from waste is associated with 42% ³³ and 50% ³⁴ reductions in carbon footprint respectively

Policy recommendations

Recommendation 1

Develop a centralised, consistent and broadly communicated national medical device circularity strategy

Our analysis in Sections One and Two identified fragmented and complex structures and approaches to integrating environmental impact across the medical product journey to adoption in the NHS, risking duplication of work, inexpert assessment, inconsistency in data analysis and strategic approach, and fatigue from industry as well as procurers. Considerable improvements in the resource efficiency of NHS organisations could be achieved through a centralised, consistent, national approach for evaluating and targeting environmental impact of medical devices. Broad communication to individual commissioners and procurement teams, and discipline specific resources for healthcare professionals should enable consistent uptake and approach.

It is critical that the strategy aligns across government policies, regulators, notified bodies and public sector buyers, including NHS Supply Chain, MHRA, and procurement hubs. We acknowledge that many suppliers of medical devices are international, and so co-ordination across other international agencies and healthcare systems would be prudent. Environmental impact should be considered at early stages of the product journey to adoption, ensuring that minimum environmental standards are incorporated into specifications and tender weightings, that preferred medical device types (e.g., reusable alternatives to single-use) are widely available on frameworks, and sustainable alternatives are prioritised for inclusion on NHS Supply Chain Catalogue. This would shift the burden away from local procurement teams and clinicians.

Recommendation 2

Provide national support for the prioritisation of reduce and reuse initiatives throughout the NHS

Reducing use of medical devices will typically save 100% of their environmental impact. Whilst reduction strategies are important, this paper is also concerned with strategic approaches to assessing the relative environmental impacts of other approaches. In Section Three of this report we found the principle of opting for reuse of medical devices instead of single-use equivalents was associated with average reductions in carbon footprint of 38-56% across the product life cycle (based upon review of life cycle assessments in peer reviewed literature).¹ Reduce and reuse should therefore be prioritised in national strategy, given no other strategies we identified on phases in the life cycle (Section Three, Table 5) can reduce emissions at this scale. Remanufacture appears to achieve similar carbon savings to reuse,³⁵ and so should be supported, but remains sub-optimal because devices frequently fail during this process (and are then discarded by the remanufacturer), because these products were not originally designed for the remanufacturing process.

To achieve more efficient use of resources at a national or systematic level, there should be clear policy developed and communicated to preference reduce and reuse of medical devices, supported by central purchasing mechanisms. For instance, catalogues might highlight reusable alternatives to buyers, and guidance could be provided for framework providers to develop specifications that support or preference reusable medical devices.

The transition to greater reuse will need to be supported with infection control policy to ensure clinical safety, and encourage innovation in, and expansion of regional and national infrastructure for decontamination. The use-phase is the largest contributor to environmental impact for reusable items (dominated by decontamination and laundering processes), and so this should be optimised. Solutions for minimising environmental impact across reusable product design, material choice, and method of decontamination and laundering should be explored collaboratively across academia, public and private sectors.

Whilst this recommendation outlines strategic prioritisation of reduce and reuse across the commissioning and procurement of all medical devices, there will be further specific dimensions on which product design, use and disposal could be optimised (for reducing environmental impact), depending on the class of medical device under consideration. The following final recommendation reflects a need for further research to explore the nature of these dimensions, which could, over time, be incorporated further into buying guides to provide greater insight into sustainable procurement strategies.

Recommendation 3

Identify high impact categories of products, and identify and target key drivers of their environmental impact

Our analysis (Section Two) indicates that undertaking detailed environmental impact assessments of all medical devices across NHS England is unfeasible given time and resource constraints. Instead, a targeted approach should be taken to identify categories of products likely to have largest collective environmental impact (often this means the products bought in greatest quantity, but could also include large/complex products), enabling these product categories to be prioritised. Of relevance, our analysis of the five most common surgical operations in England found a relatively small proportion (23%) of products were responsible for the majority (80%) of the carbon footprint.³⁶

For prioritised product categories, we suggest an environmental impact assessment is undertaken of exemplar medical devices (aligning with principles outlined in Section Three, Table 4) enabling the identification of product-specific life cycle processes with the largest environmental impact (i.e. the key drivers). This could be followed by sensitivity analysis of variation beyond the exemplar device (modelling variation across all life cycle stages which impact on material and energy flows), informed by data on alternative devices currently available on the market, and alternative approaches to the 'use' and disposal phases. This would avoid the need to undertake new environmental impact assessments of all iterations and settings for substantially similar devices.

Given inconsistency and scepticism surrounding industry generated environmental impact assessments (Section Two), it seems appropriate for an independent body to undertake such assessment, and whilst responsibility for the commissioning and co-ordination of this research activity is to be determined, the outputs of such research could be leveraged by the NHS.

This assessment could then be used to:

- Develop evidence-based discrete category indicators, informed by identified key contributors to environmental impact of a medical device, weighted according to relative contribution. These insights could be incorporated into disclosure requirements at tender; for instance, presence of high emissions intensity materials where material inputs are known to be a life cycle hotspot, alongside other questions relating to product specific determinants of environmental impact, weighted by importance. The information gathered through such an exercise could also be used to inform product level buying guides, and help define best-practice benchmarks. A standardised indicator-style approach would be simpler and provide more reliable data than asking industry to undertake their own environmental impact assessments.
- Enable transparent and standardised comparisons between similar medical devices and preferential purchasing on the basis of environmental impact reduction, incentivising industry innovation towards this.
- Evaluate and temporally monitor environmental impact reduction for the medical device type, with periodic reassessment.
- Such data may be representative and valid for analyses of other medical devices within the product category, meaning that detailed environmental impact assessment may not need to be repeated for all devices (but this concept needs academic validation). As such, these outputs would not only provide substantial additional information on specific, high impact device solutions, but may offer a route to identifying generalisable principles for similar medical devices.

Through this process, life cycle assessments could be leveraged on exemplar medical devices to provide generalisable principles at category level. The benefit of such approach is not only because undertaking environmental impact assessments on thousands of products is impractical, but it is also crucial to take away any interpretive burden on commissioners and procurement teams.

Appendix

Supplementary Table 1: Definitions to support Figure 1 (listed alphabetically)

Atamis ³⁷	UK procurement software provider
Approved body ³⁸	Designated by MHRA, to undertake conformity assessment evaluating whether medical device fulfils requirements of UK MDR 2002, enabling product to be placed on Great Britain market Currently four Approved Bodies Formerly EU 'Notified Bodies'
Category Tower Service Provider (CTSP) ³⁹	Organisations contracted to buy goods, equipment, and services on behalf of NHS Supply Chain Include Akeso & Company Ltd, Collaborative Procurement Partnership, Crown Commercial Services, DHL Supply Chain Ltd, Foodbuy, Health Solutions Team, NHS North of England Commercial Procurement Collaborative
CE mark ³⁸	Product marking indicating conformity with European Union (EU) regulations, required for medical devices to be marketed in EU CE marks currently accepted on Great Britain market, but due to be superseded by UKCA mark in UK by 2030 CE certificates issued before January 2021 remain valid
Collaborative Procurement Partnership ⁴⁰	Partnership of four NHS procurement hubs: NHS Commercial Solutions, NHS London Procurement Partnership, NHS East of England Collaborative Procurement Hub, NHS North of England Commercial Procurement Collaborative Owns three out of eleven CTSPs
Contract Notice or Prior information Notice (PIN) ⁴¹	A notice of preliminary market consultation, that signals that the buyer has a specific upcoming commercial need
Dynamic purchasing System ⁴²	Electronic 'open market' system ('Atamis')- public sector buyers can access a pool of pre-qualified suppliers Quicker and simpler than traditional frameworks Improves accessibility for small to medium size enterprises Managed by CTSPs
Framework agreements ⁴³	An agreement establishing the terms governing procurement contracts to be awarded during a given period between contracting authority and one or more suppliers. Includes awarding contract length (typically four years), price and quality, quantity
Getting it Right First Time ⁴⁴	National NHS England programme seeking to reduce unwarranted variation and standardise patient pathways Activities including development of best practice guidance
International Organization for Standardization (ISO) ⁴⁵	Independent non-governmental organisation develops international standards for member national standard bodies, across 168 countries (including United Kingdom) E.g. includes standards for medical device quality management systems, sterilisation, medical device labelling
Lead Reference Trust ⁴⁶	NHS Trust coordinating wider feedback from Reference Trusts (engage and contribute towards procurement strategies) to CTSP Sign off procurement

Atamis ³⁷	UK procurement software provider
Medical device ⁶	Product used to diagnose, monitor, treat, or manage a medical condition (other than pharmaceuticals)
Medical Devices Regulations ⁴⁷	<p>EU:</p> <ul style="list-style-type: none"> • Medical Devices Regulations 2017/745 (MDR); In Vitro Diagnostic Medical devices 2017/746 (IVDR) <ul style="list-style-type: none"> – Introduced May 2021, replacing Medical Devices Directive (MDD); with aim of improving consistency across EU member states – Compliance by May 2024 – More rigorous than MDD, including requirement for unique device identification, and post-market surveillance • Directive 93/42/EEC on Medical Devices (EU MDD); Directive 90/385/EED on Active Implantable Medical Devices Directive (EU AIMDD); Directive 98/79/EC on In Vitro Diagnostic Medical Devices (EU IVDD) <ul style="list-style-type: none"> – Given effect in UK law through UK MDR 2002 – Being superseded in EU by MDR <p>UK:</p> <ul style="list-style-type: none"> • Medical Devices Regulations 2002 (UK MDR 2002): SI 2002 No 618, as amended <ul style="list-style-type: none"> – Amended in 2021 (prior to UK departure from EU) to give effect in UK law the following directives derived from EU legislation: EU AIMDD, EU MDD, EU IVDD
Medical and Nursing Royal Colleges ⁴⁸	<p>Specialty specific national professional bodies</p> <p>Functions include setting standards and training</p>
Medicines and Healthcare products Regulatory Agency (MHRA) ⁴⁹	<p>Regulator of medical devices in the UK, executive agency of Department of Health and Social Care</p> <p>All products must be registered with MHRA before placed on Great Britain Market</p>
National infection prevention and control manual ⁵⁰	Evidence-based manual on infection prevention and control, seeking consistent approach across UK
National Institute for Health and Care Excellence (NICE) ⁵¹	<p>Provides evidence- based recommendations, seeking to improve quality care and best-value health and social care in England</p> <p>Includes clinical and cost effectiveness review of new medical devices for adoption in NHS</p>
NHS Advisory Board for Procurement and Supply ⁵²	<p>Comprises National Advisory Board, and four Regional Advisory Board Forums</p> <p>Influence and lead procurement strategy</p>
NHS Supply Chain ⁵³	<p>Launched in 2019, manages sourcing, delivery and supply of healthcare products to the NHS</p> <p>11 specialist buying functions called 'Category Tower Service Providers', including six medical consumable categories and two capital medical equipment and services</p> <p>Currently undergoing transformation to in-house model</p> <p>Releases tenders, successful products listed on a Framework Agreement under respective CTSP</p>
Notified Body ³⁸	<p>Designated by an EU country to undertake conformity assessment to evaluate whether medical device fulfils requirements of EU regulations, enabling product to be placed on EU market.</p> <p>The EU no longer recognises UK Notified Bodies (see Approved Bodies)</p>

Atamis ³⁷	UK procurement software provider
Post-market surveillance and vigilance ⁴⁷	<p>Medical device supplier required to submit vigilance reports to MHRA if any adverse incidents, including corrective actions</p> <p>Must ensure safety and performance of product device throughout its use</p>
Public Contracts Regulations ⁵⁴	<p>Public Contracts Regulations (PCR 2015)</p> <p>Applies to all spend over threshold, includes regulation on advertising tender opportunities</p> <p>Informed by World Trade Organisation General Procurement Agreement and EU Procurement Directives</p>
Supply Chain Coordination Limited (SCCL) ⁵⁵	<p>Management function of NHS Supply Chain</p>
UK Conformity Assessment (UKCA) mark ³⁸	<p>Product marking indicating conformity with UK regulations, required for medical devices to be sold on Great Britain Market</p> <p>Available since January 2021, and will supersede CE mark, with deadline of 30 June 2030</p>

Supplementary Table 2: Medical Devices Classification⁵⁶

Class	Sub-class	Devices included	Example products	
Class I (low risk)	Class I	Non-invasive devices that do not come in direct contact with patient, or only contact intact skin (except devices intended as mechanical barrier, for compression or absorption of exudates), not meeting other criteria	Face mask, wheelchairs, stethoscope, wound dressing	
	Special function	Class Is	Sterile non-invasive products (either delivered sterile, or sterilised on receipt)	Sterile surgical gown, sterile gauze
		Class Im	Device with a measurement function	Syringe, thermometer, weighing scales
		Class Ir	Reprocessed or reusable product, including invasive devices intended for transient use (<60 minutes)	Reusable surgical instruments and endoscopes
Class II (medium risk)	IIa	Non-invasive device intended for storing, channelling, or treating bodily fluids (including blood), cells, tissues, or other liquids or gases returned or infused, into the body (except blood bags) Active therapeutic or diagnostic devices used to administer/ exchange energy with patient Surgically invasive devices for transient or short-term use, generally limited to natural orifices	Devices for infusion, transfusion, delivery of anaesthetic gases and oxygen, surgical clamps, tracheotomy tubes, indwelling urinary catheters, needles for suturing, single-use scalpel blades	
	Class IIb	Devices intended to modify biological/ chemical composition of human tissues, cells, blood, or bodily liquids Active therapeutic devices used to administer/ exchange energy with patient in potentially hazardous way, or emit ionizing radiation for therapeutic purposes Most surgically invasive devices of long-term use (>30 days)/ devices implantable in the body (unless fulfilling class III)	Blood bags, lung ventilators, bone fixation plate, urethral stents, surgical lasers	
Class III (high risk)	Class III	Include machinery important to patient health, or sustaining life of patient Devices presenting potential, unreasonable risk of illness or injury Device that connects directly with the central nervous system, circulatory system, heart, or contains a medicinal product	Pacemakers, heart valves, implanted cerebral simulators, spinal needles	

*This table is illustrative and not exhaustive – there are exceptions and rules available in Annex VIII of the Medical Devices Regulations.⁵⁶

Supplementary Table 3: Examples of wider emerging initiatives / guidelines related to environmental impact which may be applied or extended to medical devices used in England or their suppliers

Initiative	Detail	Level	Sector	Reach
British Standards Institution (BSI) Medicines Environment Standardization Programme	<p>Seeking to create medicine- specific environment footprinting measurement methodology standards</p> <p>Build consensus for defining product environment categories rules for medicines</p> <p>Draws upon PEF methodology and ISO 14067</p> <p>BSI proposing to take a convening role, as independent and non-competitive party</p> <p>Standards development due 2024, followed by development of metrics and assurance mechanism to verify compliance</p>	Product (Pharmaceutical)	Pharmaceuticals	Global
Carbon Disclosure Project ⁵⁷	<p>Global disclosure system which companies may use to report environmental data</p> <p>Currently piloting an approach for reporting on product level lifecycle footprints</p>	Supplier	Any company, any sector, any product (pilot)	Global
Corporate Sustainability Reporting Directive ¹³	<p>Agreement between European Council of the European Union and European Parliament</p> <p>Any reporting on sustainability issues to be certified by an accredited independent auditor or certifier</p> <p>To be introduced 2024-2026</p>	Supplier	Any company, any sector	Companies with ≥1 subsidiary or branch in EU
Cradle to Cradle Products Innovation Institute ⁵⁸	Provide certification of sustainability performance (material health, product circularity, social fairness, water and soil stewardship, clean air and climate protection)	Supplier	Any company, any sector	Global
Ecovadis ⁵⁹	Provide independent sustainability assessments, providing sustainability and carbon scorecards	Supplier	Any company, any sector	Global
Environmental Product Declaration ¹⁶	<p>Labels reporting life cycle environmental performance of products</p> <p>Determined in line with Product Category Rules</p> <p>Conforms with ISO 14025:2006 requirements</p> <p>Enables comparison between products fulfilling the same function</p> <p>Verified by independent third party</p>	Product	Any product, any sector	ISO member countries
EQUATOR Network Publication Standards Development ⁶⁰	<p>Undergoing Delphi process to create a set of standards for conduct and reporting of healthcare life cycle assessments</p> <p>Aimed towards those undertaking and seeking to publish academic studies, journal editors, and peer reviewers</p>	All levels of healthcare activity	Healthcare	Global
European Commission Circular Economy Action Plan ⁶¹	<p>Part of European Green Deal</p> <p>Sustainable Product Policy legislation proposed an action plan for products entering EU market, including requirements to encourage circularity (for example encouraging durability, reusability, reparability, recyclability). Includes development of Digital Product Passports for regulated products, aiding tracking (medical devices currently out of scope)</p>	Product	Any product, any sector	European Union
ISO standards carbon footprint of products and life cycle assessment ⁶²⁻⁶⁴	Provides requirements and guidelines for quantification and reporting of carbon footprint of products (ISO 14067:2018), and life cycle assessment principles and framework, (ISO 14040:2006) requirements and guidelines (ISO 14044:2006)	Products	Any product, any sector	ISO member countries

Initiative	Detail	Level	Sector	Reach
Lancet Commission on Sustainable Healthcare	Includes working group on standardisation and harmonisation of methods and measures of environmental impact of healthcare activities	All levels of healthcare activity	Healthcare	Global
Partnership for Carbon Transparency (PACT) ⁶⁵	World Business Council for Sustainable Development initiative Enables exchange of primary data-based product carbon footprint across value change Seeks to address challenge of companies evaluating scope 3 emissions Provides guidance for calculating and reporting product carbon footprints	Products	Any product, any sector	Global
Procuring for Greener Pharma ⁶⁶	Report by <i>Health Care Without Harm</i> highlighting case studies from Europe assessing environmental impacts for pharmaceuticals e.g. by Norwegian Hospital Procurement Trust; National Agency for Public Procurement of Sweden; French Ministry of Health; and (for antibiotics) by Stockholm International Water Institute	Product (Pharmaceutical)	Pharmaceuticals	Europe
Product Environmental Footprint (PEF) ⁶⁷	Proposed by European Commission Provides common framework, including steps and specific rules ('Product Category Rules') for evaluation of environmental performance via life cycle assessment Enabling robust, verifiable and impartial evaluation Enabled comparison between products, and benchmarking of products within the same category group Piloted in 2021 for specific sectors	Product	Piloted in other non-healthcare sectors	EU
Science Based Targets ⁶⁸	Partnership between CDP, the United Nations Global Compact, World Resources Institute, and the World Wide Fund for Nature Voluntary scheme whereby companies can set a target for greenhouse gas emission reductions, in line with goals of the Paris Agreement	Supplier	Any company, any sector	Global
Sustainable Procurement Index for Health (SHIPP) ⁶⁹	Sustainable Health in Procurement Project (SHiPP)- collaboration between United Nations Development Programme and Health Care Without Harm, funded by Swedish International Development and Cooperation Agency Developed Sustainable Procurement Index for Health Set criteria relating to greenhouse gas emissions, resource depletion, chemicals and toxicology, gender, human and labour rights (provides score out of 3 for each)	Product	Healthcare (including products and pharmaceuticals)	Global
Sustainable Markets Initiative Health Systems Task Force ⁷⁰	Public-private partnership brings together CEOs and leaders from AstraZeneca, GlaxoSmithKline, Merck KgaA, Novo Nordisk, Roche, Samsung Biologics, Sanofi, Karolinska Institutet, NHS England, the Sustainable Healthcare Coalition, UNICEF, the University of Pavia, and World Health Organization (WHO) Set joint minimum supplier targets for climate and sustainability Includes commitment to cascade targets upstream, setting standards for own suppliers	Supplier	Predominantly pharmaceuticals	Global
B Corp Certification ⁷¹	Provide certification for "high standards of social and environmental performance, transparency, and accountability"	Supplier	Any company, any sector	Global
WHO Alliance for Transformative Action on Climate Change and Health (ATACH) ⁷²	Voluntary network of government and intergovernmental entities Includes supply chain working group, with sub-objective to strengthen evidence for measuring supply chain carbon emissions, life cycle assessment of products, and sustainability standards	Product	Healthcare	Global

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