

Policy paper

Design for life roadmap

Contents

Ministerial foreword	2
Summary	4
Introduction	13
Vision and case for change	20
The structure of the roadmap	27
Leadership and alignment	29
Behavioural change	33
Commercial incentivisation	36
Regulations and standards	40
Physical and digital infrastructure	44
Transformative innovation	48
Next steps	52
Annex A: areas of research interest	54
Annex B: collaborative members	60

Ministerial foreword

To maintain excellent patient care in our increasingly volatile world, the NHS and the health sector will need not only resilience, but sustainable growth that maximises our resources, skills and investment. Medical technology (medtech) is crucial to this and that is why I am so excited to publish the 'Design for Life' roadmap. We need to end our over-reliance on vulnerable supply chains and wasteful practices and embed a more circular approach to medical products that protects continuity of care, gets the best value for money and creates jobs and opportunities that boost the UK economy.

With the scale and excellence of the NHS and our world-leading life science sector, the UK is uniquely well-placed to meet these challenges.

Every single medtech product purchased by the NHS is bought because we prioritise and always will prioritise patient care and safety. But the volume of products thrown away after a single use - from tourniquets and scissors to high-tech electronics - should concern all of us. We can no longer accept this as normal practice.

Reliance on high-volume products imported from overseas can make patient care vulnerable to global supply shocks which are becoming all too frequent. By shifting to circular methods of reuse, remanufacture and recycling, we can keep our resources as close as possible to where they are needed and generate substantial opportunities for UK business and infrastructure in the process. This is just one way that this government will deliver on our manifesto commitment to move towards a circular economy, alongside the work of a new circular economy taskforce that is being convened and supported by my colleagues across government.

Smarter and more innovative use of medical products can save the NHS millions of pounds of taxpayers' money that could be better spent on priorities such as cutting waiting lists or speeding up diagnostic tests. Supporting our path to a world-leading net zero NHS and responding to the growing threat to health posed by climate change, these sustainable solutions will also reduce excess pollution from incineration, single-use plastics and wasted resources.

This government is committed to driving a medtech and life sciences revolution and this roadmap will play an important role in delivering this. By ensuring several of our strongest industries come together - for example, life sciences, green technology and artificial intelligence (AI) - we will drive development of new solutions to help grow national and local industries.

We will use the regional anchors of the NHS as engines for new markets and opportunities: from development of data-driven business models in Exeter to robotic reprocessing technologies in Loughborough. I also look forward to working together with my devolved colleagues in Scotland, Wales and Northern Ireland to ensure we all learn from the excellent work they are already pioneering.

In launching this more than 20-year ambition, I would like to extend my thanks to colleagues across the health and care system, medtech industry, academia and devolved governments (listed in annex B) whose work has been integral to developing this roadmap.



Baroness Merron Parliamentary Under-Secretary of State for Patient Safety, Women's Health and Mental Health I am very pleased to endorse this vision on behalf of the Scottish Government and NHS Scotland - moving medtech to a circular economy model can have major benefits for the economy and the environment. To achieve those benefits we will all need to work together - governments, health service, academia and industry - both in the UK and internationally. This vision builds on our shared commitments made at COP26 to create sustainable, low-carbon and climate resilient health services across the UK.

Neil Gray Cabinet Secretary for Health and Social Care (Scotland)

I welcome the Department of Health and Social Care's (DHSC) plan which aligns with our own ambitions.

In Wales, we are developing strategic infrastructure and support for our health, social care and business sectors to become more efficient, to reduce emissions and embrace sustainability. Our circular and foundational economy programmes set out how adopting circular economy principles can strengthen local supply chains, reduce dependency on imports, and build more resilient and ethical supply practices.

By embracing the circular economy priorities for medtech, in line with the Wellbeing of Future Generations (Wales) Act, we will contribute to a stronger, fairer and greener healthcare sector. This in turn will translate into long-term benefits for the environment and for people in Wales and across the UK.

Jeremy Miles Cabinet Secretary for Health and Social Care (Wales)

I very much welcome this programme led by DHSC for improving the sustainability of medical technology by developing an approach to develop circularity in its use. I am pleased that this approach for the health sector also aligns with the ongoing work of the Department for the Economy in Northern Ireland which is leading on the development of a circular economy strategy for Northern Ireland, with key principles including designing out waste and keeping products and materials in use for as long as possible at their highest value.

The UK health sector is very much interlinked and the medtech industry encompasses all of the UK. This programme, supported by the 4 health administrations in the UK, highlights the need for the change that is so needed to protect health service delivery, the environment and the scarce natural resources upon which we all depend.

Mike Nesbitt Minister of Health for Northern Ireland

Summary

The Design for Life programme is an initiative of the medical technologies and innovation directorate in DHSC dedicated to delivery of a circular approach to medtech.

Circularity in medtech means designing, procuring and processing medical products in a way that enables them to be reused, remanufactured or recycled, preserving their value for as long as possible. The benefits of a circular economy in the health sector are vast and increasingly well-understood, but are rarely put into practice and are difficult to scale. Unlocking these benefits across the UK health sector will bring many opportunities for innovation and growth, while improving patient care and value for money and supporting the transition to a net zero NHS.

The programme has been developed by a collaborative of more than 80 stakeholders from the UK medtech industry, the health family and academia with wide support across the sector.

This roadmap divides the programme into 6 problem statements which will be addressed by a suite of 30 actions to deliver our 2045 vision below. DHSC will work with the UK health services and other partners to agree action leads and governance mechanisms to underpin delivery, supported by a costed delivery plan.

Our vision

By 2045 the UK will have transitioned away from all avoidable single-use medtech products towards a functioning circular system, safely transforming the sector to deliver enhanced resilience, increased economic growth, better value for patients and the NHS, and minimised environmental impacts.

Problem statements

The 6 problem statements set out the fundamental challenges we will address to develop and embed a circular system. By addressing these challenges, the programme will aim to deliver a circular system by 2045.

Leadership and alignment

Statement 1: unclear direction and misaligned strategies across the value chain lead to inconsistencies, inefficiencies and inertia, hindering meaningful, coordinated progress.

Behavioural change

Statement 2: the medtech landscape is one in which linear products are the default choice, maintained by a lack of value placed on circular systems and limited support for change.

Commercial incentivisation

Statement 3: stakeholders are insufficiently incentivised, or in some instances are disincentivised to choose and deliver circular solutions.

Regulations and standards

Statement 4: UK regulatory regimes and technical standards predate circularity and have potential to further enable the medtech sector to recognise opportunities and align internationally.

Physical and digital infrastructure

Statement 5: the existing physical and digital infrastructure and supporting services hold back the scaling of circular solutions, both locally and nationally.

Transformative innovation

Statement 6: the innovation ecosystem is not tailored to circular objectives, impeding development of solutions.

Objectives

In tackling the above problem statements, the programme seeks to achieve 4 primary objectives.

Boost UK growth

Introducing a circular approach to medical technologies will create skilled jobs and growth opportunities in supporting industries such as decontamination and materials recovery. A functioning circular system will mean that more of the £10 billion the NHS spends on medical devices could be spent in the UK, boosting our life sciences sector. To illustrate this, the Waste and Resources Action Programme (WRAP), in their report How a circular economy can help us build back better, have estimated that if an economy-wide shift to a circular economy was realised it could bring £75 billion to the economy and create 500,000 new jobs by 2030.

Improve NHS resilience

By reducing reliance on volatile supply chains and growing local capacity to meet demand, circularity will protect health systems from global supply shocks. For example, 66% of Belgian companies using circular techniques experienced significantly less disruption during the COVID-19 pandemic (see the Ellen MacArthur Foundation article, <u>Building</u> resilience: the impact of the circular economy on global trade and supply chains).

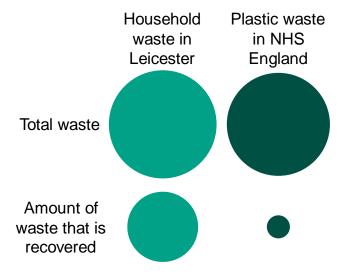
¹ DHSC Estimate, 2021, based on multiple data sources

Reduce waste and emissions

Circular approaches to medtech will reduce waste and carbon emissions. To put this in context, the NHS throws away 133,000 tonnes of plastic each year (see the NHS Providers' blog, Not so fantastic plastic), roughly the same weight as all the household waste generated in Leicester, yet it is recovered 9 times less often.²

Furthermore, reuse of medical devices is associated with an average of 38% to 56% decarbonisation compared to single-use (see Brighton and Sussex Medical School's (BSMS) policy brief, Reducing the environmental impact of medical devices adopted for use in the NHS).

Figure 1: visualisation comparing household waste in Leicester and plastic waste in NHS England



Generate substantial cost savings

Circular devices are often more cost-effective than single-use. In several case studies, savings of more than 50% can be realised compared to conventional single-use equivalents. However, in one case study where circular alternatives were available and could create significant cost savings, they only occurred in 2% of eligible cases.³

Roadmap actions

We propose 30 actions to address the challenges raised in the problem statements. Some of these actions can begin immediately, whereas others require significant research activity before they can commence. Therefore, this roadmap's actions can also be viewed on how 'mature' they are, where indicatively high-maturity actions could be completed in

² Calculated using Local authority collected waste management - annual results 2022/23, Local Authority Profile, Leicester City Council (2023), Waste Rates, Open Leicester

³ Calculated using data from the Medtech spotlight report.

2024 to 2027, medium-maturity actions in 2027 to 2029 and low-maturity actions in 2029 to 2031.

In each problem statement one action is labelled as the 'priority action'.

Figure 2: summary of the design for life roadmap's 30 actions

High maturity (2024 to 2027)	Medium maturity (2027 to 2029)	Low maturity (2029 to 2031)
Leadership and alignment		
Collaborate with other policymaking bodies to ensure strategy alignment	Priority action: develop circular KPIs and standardised metrics	Understand and define data requirements for the programme
Present a full ecosystem roadmap to the Design for Life vision	Establish clear governance and responsibilities for the whole ecosystem	
Behavioural change		
	Priority action: develop a training and skills framework	9. Develop a behavioural change plan
	7. Deliver targeted resources to support self-care	
	8. Establish a support framework as a central hub for industry queries and assistance	
Commercial incentivisation		
10. Circularity of medtech embedded in communications, engagements and strategies	Identify opportunities and barriers for incentivisation of circularity	15. Embed circularity in the commercial ecosystem
	12. Establish a feedback loop for stakeholders	
	13. Conduct market research to identify gaps and opportunities	
	14. Priority action: deliver value-based procurement for circularity of medtech products	
Regulation and standards		
		16. Develop and maintain circular standards (including vocabulary)
		Priority action: align regulatory environment for circular medtech with global counterparts
		18. Establish medtech as a core sector with UK circular economy work
Physical and digital infrastructu	ıre	
	19. Priority action: survey existing systems and model future demand	20. Develop a decontamination infrastructure framework
		21. Establish a materials recovery and recycling framework
		22. Develop a strategy for digital enablement
		23. Explore collaborative data sharing initiatives
		24. Identify and connect material purchasing partners
Transformative innovation		
	25. Identify opportunities for innovation across the system	30. Identify areas where circular design research is needed
	26. Research standardised methodology for supply resilience and sustainability assessments	
	27. Embed inter-industry collaboration as a core component of delivering circularity	
	28. Priority action: establish a medtech innovation centre	
	29. Streamline innovation pathways	

Leadership and alignment

From 2024 to 2027 (high maturity):

- 1. Collaborate with other policymaking bodies to ensure strategic alignment.
- 2. Present a full ecosystem roadmap to the Design for Life vision.

From 2027 to 2029 (medium maturity):

- 3. Develop circular key performance indicators (KPIs) and standardised metrics (priority action).
- 4. Establish clear governance and responsibilities for the whole ecosystem.

From 2029 to 2031 (low maturity):

5. Understand and define data requirements for the programme.

Behavioural change

From 2027 to 2029 (medium maturity):

- 6. Develop a training and skills framework (priority action).
- 7. Deliver targeted resources to support self-care.
- 8. Establish a support framework as a central hub for industry queries and assistance.

From 2029 to 2031 (low maturity):

9. Develop a behavioural change plan.

Commercial incentivisation

From 2024 to 2027 (high maturity):

10. Circularity of medtech embedded in engagements and strategies.

From 2027 to 2029 (medium maturity):

- 11. Identify opportunities and barriers for incentivisation of circularity.
- 12. Establish a feedback loop for stakeholders.
- 13. Conduct market research to identify gaps and opportunities.
- 14. Deliver value-based procurement for circularity of medtech products (priority action).

From 2029 to 2031 (low maturity):

15. Embed circularity in the commercial ecosystem.

Regulations and standards

From 2029 to 2031 (low maturity):

- 16. Develop and maintain circular standards (including vocabulary).
- 17. Align regulatory environment for circular medtech with global counterparts (priority action).
- 18. Establish medtech as a core sector within UK circular economy work.

Physical and digital infrastructure

From 2027 to 2029 (medium maturity):

19. Survey existing systems and model future demand (priority action).

From 2029 to 2031 (low maturity):

- 20. Develop a decontamination infrastructure framework.
- 21. Establish a materials recovery and recycling framework.
- 22. Develop a strategy for digital enablement.
- 23. Explore collaborative data sharing initiatives.
- 24. Identify and connect material purchasing partners.

Transformative innovation

From 2027 to 2029 (medium maturity):

- 25. Identify opportunities for innovation across the system.
- 26. Research standardised methodology for supply resilience and sustainability assessments.
- 27. Embed inter-industry collaboration as a core component of delivering circularity.
- 28. Establish a medtech innovation centre (priority action).
- 29. Streamline innovation pathways.

From 2029 to 2031 (low maturity):

30. Identify areas where circular design research is needed.

Stakeholder navigation

Clinicians and patients

Clinicians and patients have a core role in the shift to a circular model. Often they will know the best ways to make positive change as they are using these devices in practice. They may also, completely understandably, have concerns about what a move towards a circular system may entail. The most relevant problem statement for these groups is behavioural change. We would benefit from clinicians' lived experience and thoughts for actions 6 and 9, and we believe patients will be most enabled by action 7.

Academia

Academics across the UK have contributed to the understanding of embedding circularity in medtech and form a part of our collaborative. Problem statements such as behavioural change, physical and digital infrastructure and transformative innovation will greatly benefit from the knowledge of academics. For instance, engineering specialists could provide their insight on actions 20 and 21, based on their experience in the field, data scientists can share their expertise for action 22 and both parties could contribute their skills and knowledge to action 28.

Industry

The programme will bring great opportunity to the medtech industry, due to the scale of proposals addressing product design, supply chains and business models. Therefore, aspects of all the problem statements will be relevant, although leadership and alignment, commercial incentivisation, regulations and standards and transformative innovation are particularly relevant. For instance, innovation teams within companies can share their knowledge and expertise to help us with actions 22, 25 and 26, whereas their commercial teams could provide us with examples for actions 5 and 11.

Healthcare and institutions

Circularity could greatly improve how trusts and other healthcare institutions use medtech products, and therefore we value the opportunity to work with them. Particularly important problem statements for healthcare providers include leadership and alignment, behavioural change, commercial incentivisation and physical and digital infrastructure. NHS healthcare providers and community providers could collaborate with us on actions such as 3, 9, 15 and 23.

Supporting sectors

Design for Life will require the assistance of many adjacent industries including decontamination, material processing and logistics to embed circularity of medtech in the UK. For organisations and individuals working in these industries, the most relevant

problem statement will be physical and digital infrastructure. For instance, for those in sterile services we would benefit from your expertise for action 20, while those in recycling services could share their knowledge for action 21.

Standards bodies

Design for Life will involve development of new and updated circular standards for circularity of medtech. For organisations whose work relates to these topics, an important problem statement will be regulations and standards.

Introduction

Shifting to a model of medtech use that is fit for the future

Medtech is integral for tackling our major health challenges, with the ability to transform care and improve both productivity and patient outcomes. The Medical technology strategy, published in February 2023, identified resilience and continuity of supply of medical equipment, devices and consumables as essential for the consistent delivery of safe, high-quality patient care. The strategy attributes part of current resilience risks to the prevalence of single-use devices and how they create a heavy reliance on a permanent flow of predominantly imported materials and products.

The programme is dedicated to the exploration and delivery of one of the most promising solutions for better medtech supply - 'circularity'. This is where products are designed to be maintained in their highest value state for as long as possible - for example, by being highly reusable.

Reliance on continuous extraction of virgin materials to create products that are destined to be permanently disposed of after use, known as 'linear supply', has become a significant trait of the UK health system. Even among devices containing electronic components, a recent European study found that approximately 73% of devices are single-use, of which a large proportion will be incinerated (as cited in the Medtech spotlight report: accelerating circular economy adoption). This has exacerbated our dependence on volatile supply chains, which are still feeling the effect of COVID-19 and global conflicts.

In recent years, UK health systems have seen disruptions caused by factors such as the volatility in the supply of raw materials, turbulence in energy supply and price, trade embargoes and tariffs, transport constraints and sudden spikes in global demand. All of these are playing a greater role in decisions relating to patient care.

This reliance on linear supply also raises questions of sustainability. The NHS clinical waste strategy notes that medical devices are contributing to tens of thousands of tonnes of waste produced by UK health services each year. Many thrown-away devices are single-use plastics but others are sophisticated, composite devices that can contain rare minerals such as titanium, palladium and platinum and can be valued in the £1,000s. Most of these products are disposed of regardless of the fact many of these materials are increasingly scarce, have high economic value and could be recovered for sale to cut NHS costs.

With the NHS in England committed to net zero by 2045 and the UK government committed to halving residual waste by 2042, medtech has a role to play in realising these targets. For example, the weight of electrophysiology catheters disposed of each year is equal to 9 London taxis. This is despite their combined sales value of almost £5 million if they were recovered rather than discarded. These devices represent just a few among the 100,000s of product lines in regular use in the UK (see Medtech spotlight report - these calculations are based on their data).

Beyond resilience, sustainability and cost savings, there is a vast opportunity to generate growth in the UK economy and jobs market if we were to find a more domestic solution. With approximately £10 billion spent annually on medtech in the UK,⁴ we foresee new innovative methods ensuring more and more of that spend being invested in domestic, high-skill markets fit for the future.

For the reasons above, the government is committed to delivering change, moving away from linear supply towards a robust solution known as 'circular supply', for UK medtech. Circular medtech is:

- known to make systems more resilient: 66% of Belgian companies who employed circular techniques experienced considerably less disruption during the COVID-19 pandemic than those that didn't
- known to make systems more sustainable: reuse of medical devices as opposed to single use is associated with an average decarbonisation of 38% to 56% within their whole lifecycle
- known to make systems more cost effective: over 50% cost savings have been realised for customers when buying circular products (see <u>Accelerating the transition towards a net zero NHS: Delivering a sustainable and resilient UK healthcare sector</u>, University of Exeter) and then selling them after use (as opposed to paying for disposal) (see the <u>Medtech spotlight report: accelerating economy adoption</u>)
- expected to grow the UK economy: WRAP have estimated that if an economy-wide shift to a circular economy was realised it could bring £75 billion to the economy and <u>create 500,000 new jobs by 2030</u>

Accordingly, this roadmap sets out a clear vision and plan towards circularity becoming the model of choice for UK systems by 2045. The development and subsequent delivery of this roadmap and its vision is known as the Design for Life programme.

At a time when resources are finite, we will continue working closely with the 80 plus stakeholders that make up our collaborative to identify new ways of working together and implementing system-wide change that does not depend entirely on finding new resources. Specific areas of programme delivery that do require new funding will be subject to identifying additional resource.

This roadmap puts forward a UK-wide position, where the overarching vision and much of the ambition and purpose is shared by all 4 health administrations in the UK (as described in the ministerial foreword). However, operational health policy is devolved in the UK, so the journey and implementation towards this vision may differ based on devolved nations' health systems and other devolved policy requirements. For this reason, when this roadmap uses the terms 'the NHS' it will be indicating the relevant NHS or equivalent providers in England, Scotland, Wales, Northern Ireland, or all of these, depending on the context (NHS England, NHS Scotland, NHS Wales or Health and Social Care Northern Ireland).

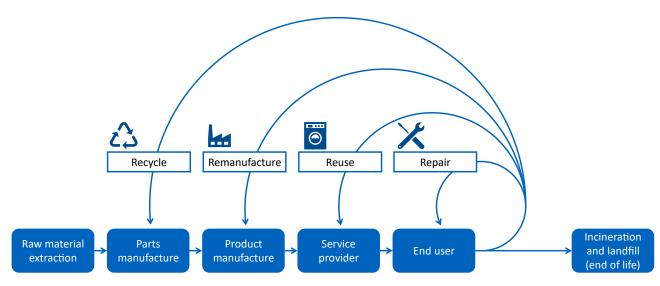
⁴ DHSC Estimate, 2021, based on multiple data sources.

Defining circularity for medtech

A circular economy is one where materials are delayed from becoming waste for as long as possible, by ensuring products and the materials they are made from are maintained at their highest value for as long as possible. This is achieved by a multi-layered approach which ranges from processes such as repair, reuse, remanufacture and recycling of products, to fundamentally re-designing the product to be more sustainable at the point of manufacture, use and disposal.

In this type of model, the products and materials will have 'value' at all points through their lifetime and as they undergo some form of change - for example, being recycled into a different product. As such, in circular models, we tend to refer to 'value chains' rather than 'supply chains'. Markets and systems will be described as more or less 'circular' or achieving greater or less 'circularity' depending on how close they are to maximising products and materials usage.

Figure 3: circular economy system



In the medtech sector, opportunities for circularity span a huge variety of products. This ranges from simple items, such as tourniquets, to tools like scissors to high-tech electronic devices such as electrophysiology (EP) catheters. In Northampton Hospitals NHS Trust, a single ophthalmology department was able to save 1,000 pairs of single-use scissors and £12,000 in costs by switching to reusable pairs that can be decontaminated along with other surgical instruments (see the case study A paradigm change: from disposable to reusable instruments usage in the Ophthalmology Department). NHS procurement data for England and Wales suggests that several million pairs of single-use scissors were used and thrown away in the 2022 to 2023 financial year.⁵ A more complex device is harmonic shears - electrical surgical instruments used to handle multiple surgical jobs such as dissecting, cauterising and sealing. The vast majority of these products are supplied as single-use despite their potential to be remanufactured and returned to use. Recent studies, cited in the Medtech spotlight report, have shown that use of remanufactured

⁵ NHS Supply Chain procurement data, Dec 2022 to Nov 2023.

harmonic shears could save an average of 50% on the sales price and save the NHS millions of pounds in procurement costs.

Circularity in a global context and other sector examples

In recent years many nations and cities have begun developing plans to shift towards a circular economy model to ensure they maintain their resource security (their control and ease of access to critical products and materials), while taking economic advantage of the opportunities a circular economy will provide.

Examples of geographies who have developed strategies, roadmaps and/or initiatives for shifting towards a circular economy include:

- Chile: see Enel Americas publication, Roadmap for a Circular Chile by 2040
- Spain: see the Spanish government's Strategy for a Circular Economy in Spain
- Singapore: see the <u>resources from the Ministry of Sustainability and the Environment</u>
- Amsterdam: see City of Amsterdam's <u>Circular economy policy</u>

In the UK, Wales published its <u>Beyond recycling</u> strategy to build on its already world-leading recycling rates, and London Waste and Recycling Board has published a <u>circular economy roadmap</u> targeting high-potential sectors within the city. The UK government has set out their ambition to work with stakeholders to create a circular economy strategy for England, aligning where possible with the devolved governments, to realise benefits for industry and other stakeholders. The circular economy strategy will aim to support economic growth, deliver green jobs, promote efficient and productive use of resources, minimise negative environmental impacts and accelerate net zero. Likewise, Northern Ireland is developing a <u>circular economy strategy</u> that the Design for Life programme will align and collaborate with.

Consumer electronics and ICT sectors have also begun employing circular techniques. For instance, using Al-powered robotics for material separation to recover valuable minerals. Apple developed a robot called Daisy which can disassemble 23 different iPhone models, allowing Apple to recover valuable materials within, such as rare earth magnets, tungsten and steel.

This type of clear policy vision is crucial to delivering change. Initiatives have highlighted the common challenges involved - for instance, reassessing regulatory regimes, improving technical capabilities or establishing supporting infrastructure. We have aimed to incorporate these learnings into this roadmap and in our approach to the programme as a whole.

Circularity and medtech in a UK context

The <u>Circularity gap report, UK</u>, an indication of how close the UK economy is to a circular economy, highlights that the UK's current circularity metric sits at 7.5%, leaving a circularity gap of 92.5%. In other words, the report argues the UK is not yet 10% into the journey of shifting from linear to circular. In part, this is because over 90% of the UK's material inputs come from virgin sources (over 1 billion tonnes), 80% of which are

imported from abroad. While this indicates low resource security and high reliance on international supply chains to fulfil demand, it also indicates a big opportunity to begin capitalising on the benefits across relevant sectors.

The health sector is one where there is a known circularity research and innovation gap compared with adjacent sectors (for example, automotives and textiles). This is due to its unique challenges, which include safety considerations, lack of existing system infrastructure (for example, hospital waste collection and recovery options) and, importantly, the sheer diversity of medtech products in the market. Medtech comprises everything from urine bottles to magnetic resonance imaging (MRI) machines, with over 3 million products registered for use in the UK.

In the UK, according to <u>Driving innovation in medtech</u> research from EY, approximately 90% of medical device waste results from single-use devices, while NHS England reports that <u>156,000 tonnes of clinical waste is disposed of per year in England</u> alone, roughly the equivalent of 34 double-decker buses every day. According to NHS England, <u>approximately a third of that clinical waste is incinerated</u> at an approximate cost of £617 per tonne.

The NHS in England has committed to reaching net zero by 2045 for the emissions it influences through the goods and services it buys from its partners and suppliers. It has published the world-leading NHS Net zero supplier roadmap to help suppliers align with the NHS net zero ambition, supported by the Evergreen Sustainable Supplier Assessment. The UK government has a statutory commitment to halve residual waste per capita by 2042 in England, alongside other targets set out in the Environmental Improvement Plan. Indicative figures show a circular UK economy (all sectors) could cut national emissions by up to 43% according to the Circularity gap report. The case for moving towards a circular UK medtech sector is clear. This landscape shows there is much room for improvement in medtech and that an assessment of the opportunities to be gained from a shift to medtech circularity, and a plan for how to deliver it, is urgently needed for the sector.

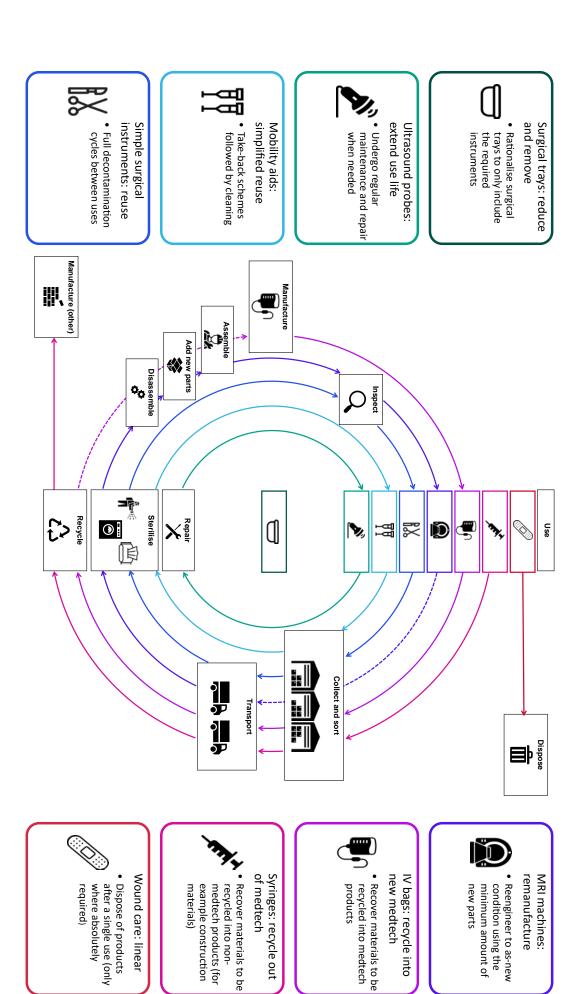
To make the medtech sector more circular will require a variety of effective circular options such as the following conceptual examples:

- reduce and/or remove use: surgical trays could be rationalised to only include the required instruments
- extend use life: ultrasound probes could undergo regular maintenance and repair where needed
- simplified reuse: mobility aids could undergo take-back schemes and be refurbished
- reuse: simple surgical instruments could be fully decontaminated between uses
- remanufacture: MRI machines could be reengineered to as-new condition using the minimum amount of new parts
- recycle into new medtech: intravenous (IV) bags could be collected after use for recycling into new medtech products
- recycle out of medtech: plastic syringes could be collected after use for recycling into new non-medtech products, such as construction materials

These all provide alternatives to the traditional linear option where wound care products are disposed of after a single use.

All of these pathways have differing steps from one another and can look very different. For example, where simplified reuse may only require sterilising wipes before a product can be used again, remanufacture may require intensive decontamination, disassembly, the addition of new parts, reassembly and then sophisticated inspection before being used again.

Figure 4 (overleaf): the potential circular pathways that can be taken by medtech products. This image has been designed using resources from flaticon.com.



Vision and case for change

To confront the challenges of our current systems and realise the benefits of circularity, the Design for Life programme was launched in March 2023 to explore how the UK can bring about a circular medtech sector, and now includes a collaborative of over 80 stakeholders. The programme has a vision that emphasises our ambition to achieve significant and safe improvements in how medtech is supplied, used and used again in the UK.

Our vision

By 2045 the UK will have transitioned away from all avoidable single-use medtech products towards a functioning circular system, safely transforming the sector to have enhanced resilience, increased economic growth, better value for patients and the NHS, and minimised environmental impacts.

This vision is not just an ambition but a strategic direction that requires a comprehensive and collective effort across all stakeholders in the medtech ecosystem.

Achieving the vision demands a future where:

- all stakeholders, including manufacturers, healthcare providers, policymakers and consumers, fully understand, are committed to and are fully enabled to capitalise on the benefits of circularity. This means fostering a culture of knowledge sharing, where clinicians are aware of and can advocate for sustainable medtech solutions, patients accept and support the use of circular products, and procurement professionals understand the value of circularity when assessing product options. For this to materialise, education and awareness-raising efforts are crucial, alongside demonstrating the practical benefits and safety of circular medtech products, as well as their role in bolstering resilience and driving cost savings within the NHS
- circularity, where safe to do so, is enabled by all medical device regulations, standards, policies and strategies. This means creating an environment where the device's value chain is considered at the design stage and carried throughout its lifecycle, encouraging the use of sustainable materials and ensuring that devices can be easily repaired, reused or recycled. Regulatory frameworks and newly developed standards support the highest levels of safety while incentivising innovative circular practices and there is also international harmonisation and partnership where global regimes apply
- the innovation potential within medtech is fully exploited, driving investment in the sector, creating jobs and developing better products for patients. This involves not only innovating in product design and materials but also in business models that support product-as-a-service offerings or recycling, thereby reducing waste and extending product lifecycles. It also means medtech must be fully integrated into the wider transition to circularity, identifying and leveraging opportunities for crosssector collaboration - for example, on utilisation of recovered materials

progress in the medtech sector contributes significantly to broader government
goals of environmental sustainability, economic growth, the UK as a technology
superpower and social wellbeing. The transition to a circular economy in medtech
presents a profound opportunity to rethink how healthcare technologies are
produced, used and disposed of, setting a global standard for sustainable and highvalue healthcare

Objectives

Given the opportunities highlighted in earlier sections, we have focused our objectives for the programme around the following areas:

- improving resilience: strengthening the resilience of care provision by minimising reliance on volatile sources of supply and ensuring a more self-sustaining system for patients and clinicians
- driving UK growth: fostering growth and creating employment opportunities by supporting a domestic market for local reuse, remanufacturing and recycling activities
- reducing environmental impact: significantly reducing carbon emissions and waste generation through promoting more sustainable approaches
- creating NHS savings: generating cost savings through reduced purchasing and disposal costs and standing up new revenue streams based on post-use product sales

Examples of how these opportunities can be realised are set out below. Each action within this roadmap will be evaluated for its contribution to these overarching objectives, ensuring a coherent, optimised and impactful progression towards our vision.

Improving resilience

Having widescale availability and usage of products that are resource efficient improves the resilience of medtech supply. For example, using a product several times before disposal rather than once gives flexibility in times of disruption and can drastically reduce the flow of new products required to maintain a functioning health service. There is a clear link between circular practices and protection from negative outcomes during global shocks. For example, one study of Belgian businesses in 2020 showed that 66% of companies employing circular practices suffered considerably less supply chain disruptions during COVID-19 compared to those that didn't. Therefore, at a time of rising tensions and risks around the world, such as increasing disruption from wars and vulnerable supply chains in semiconductors and critical minerals, it is integral that the UK has a long-term strategy for the resource security of its medical devices.

Driving UK growth

The medtech sector represents a large proportion of NHS spend: approximately £10 billion a year in England.⁶ Large proportions of this will be spent on devices manufactured overseas that are then disposed of after a single use, with no further value recovered.

⁶ DHSC Estimate, 2021, based on multiple data sources.

Even fractional shifts to domestic markets such as sterile services, engineers for remanufacturing and recycled material sales have the potential to generate significant local growth opportunities across the UK. Analysis by WRAP identified a potential opportunity to add £75 billion to the UK economy and create half a million new jobs by 2030 from a wholesale shift to circularity across all sectors. Therefore, the plans within this roadmap will be optimised to enable the UK's world class life sciences base to foster valuable innovation and create new, local growth opportunities.

Creating NHS savings

Medtech costs UK health systems in several ways - for instance, procuring the devices themselves, paying waste handling companies for incineration, and warehousing costs when storing inventory and stocks. However, circular practices provide widescale opportunities to reduce costs through better value products, less waste and turning materials recovered into resource streams. For example, cited in the Medtech spotlight report, Leeds Teaching Hospitals Trust has cut down their EP catheter costs by not only buying remanufactured products at a reduced price, but also selling their used catheters to the same remanufacturing company after they can no longer be used. In 2021 they purchased 604 remanufactured catheters, saving £76,610 in costs, and generated a further £22,923 for selling used devices for collection. If the same approach were to be scaled up across the UK, the NHS could save millions of pounds per year on EP catheters alone, just a few product lines among hundreds of thousands.

Reducing environmental impact

Using 10 products once and then incinerating them consumes significantly more raw materials than using one product 10 times and then recycling it. Given the government and the NHS have numerous commitments the medtech sector must work towards in order to protect our planet, circular practices are certain to have a significant role in achieving these targets - shown, for example, by the carbon footprint reduction of 38% to 56% that can be realised through a switch from single-use to reusable. In 2020, the NHS in England became the world's first health system to commit to reaching net zero emissions in response to the growing threat to health posed by climate change, with a clear roadmap to help its suppliers align with this ambition. Furthermore, government has a statutory commitment to halve residual waste per capita by 2042, as set out in the 'Environmental Improvement Plan'. It is clear that circularity will be crucial to achieving maximum decarbonisation and minimised waste to landfill for the whole health system.

Scope of the programme

Medtech encompasses a staggering variety of different products, from urine bottles to MRI machines, from dialysis filters to defibrillators. It also comes with a variety of additional materials to support its supply and use, such as packaging and instruction booklets. Circular practices are similarly broad, covering recycling, to remanufacture, to reducing the need for the product entirely. In order to create a manageable plan, this roadmap has defined some areas of focus.

This roadmap will focus on medtech products themselves and their value chains. Primarily, this is because innovations in topics such as packaging appear to be already emerging (for

example, see the Association of the British Pharmaceutical Industry regarding <u>blister pack</u> <u>recycling</u>), whereas innovation in circular products and system design is still a low-maturity area requiring longer-term commitments.

Therefore, this roadmap will focus on 3 circular practices in particular:

- reuse
- remanufacture
- recycling

This is because these can be seen as the lowest maturity and least utilised practices in medtech and because they will remain the most relevant in times of crisis. For example, it would have been impossible to eliminate syringe usage during the COVID-19 vaccination programme, but it may have been possible to reuse and/or recycle them.

Therefore, of the examples discussed in the 'Circularity and medtech in a UK context' section, only the following will be within scope of the programme:

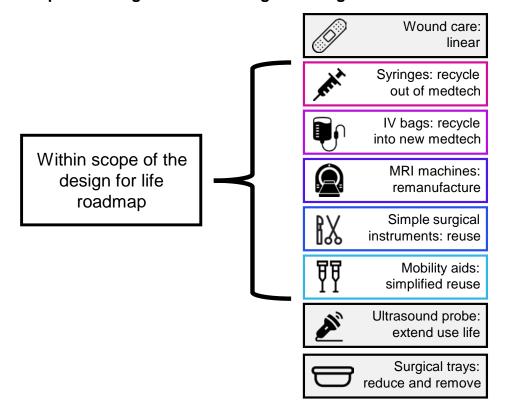
- recycling out of medtech
- · recycling into new medtech
- remanufacture
- reuse
- simplified reuse

Alongside new types of linear pathways, the following will not be within scope of the programme (although they will be supported):

- extending use life
- reducing and/or removing use

While it is necessary to define a scope, we will seek to support all other ongoing initiatives related to circularity and medtech. The focus will be on areas of low maturity where there is a lack of existing initiatives and there is a clear role for this programme and our stakeholders to add value.

Figure 5: visualisation of the circular pathways that are within scope of the Design for life roadmap. This image has been designed using resources from flaticon.com.



Programme approach and phases

This roadmap sets out a vision for the whole medtech sector based on feedback that a clear central direction was needed to enable change. This mirrors one of the recommendations given in BSMS's report on Reducing the environmental impact of medical devices adopted for use in the NHS (see under 'Our reports'). The roadmap is the product of over a year's work with over 80 collaborators from industry, government, the health and care system and academia, which not only created our vision but also the core actions and priorities to be taken forward. As a consequence, the intention is that ownership of those actions and priorities will be spread across the system and will continue to require a collaborative approach to delivery.

This roadmap puts forward a UK-wide position, where the overarching vision and much of the ambition and purpose is shared by all 4 health administrations in the UK (as described in the ministerial foreword). However, operational health policy is devolved in the UK, so the journey and implementation towards this vision will differ based on devolved nations' health systems and other devolved policy requirements. As such for the actions specified within the next section it should be assumed that these apply only to England, but that similar programmes are likely to be ongoing in Scotland, Wales and Northern Ireland. For example, all 4 nations will work together to scope action 3 (development of KPIs and standard metrics for the setting and monitoring of circularity targets). As there is close cooperation and synergies between UK health systems, those actions that influence and

drive industry and the market will have widespread impact, or, in other words, actions in one region will provide benefits across the whole UK.

The phases of the programme can be seen below. Publication of this roadmap marks the end of the design phase, where we have identified and communicated the actions that can begin immediately - for example, research, policymaking and new expert groups and collaborations. New funding will be required in future to implement the next steps that follow these actions - for example, where research concludes that new types of infrastructure need to be created. Therefore, as we move into the development phase, the programme and collaborative will seek to coordinate the necessary resource at a time where the evidence base can advise on the highest-impact and highest-value ways to spend it.

Finally, the intention is that the Design for Life collaborative will continue on far beyond the publication of this roadmap, through the development and delivery of all relevant actions.

Phase 1: discovery

Bring together the actors and their ideas. The objectives are to:

- bring together all actors and experts within the relevant systems and technical domains
- agree a vision and scope for the desired change
- collate available evidence
- make early observations and generate ideas

Phase 2: design

Build evidence to validate and plan the best ideas. The objectives are to:

- refine and complete the evidence base
- develop a strategy built on high-impact actions (this roadmap)
- set out projects and agree associated governance

Phase 3: development

Coordinate resource, people and support systems. The objectives are to:

- coordinate activity around existing initiatives
- coordinate resources around funding opportunities
- form the networks and consortia that can deliver actions
- prepare actors with systems of support

Phase 4: delivery

Deliver the plan, monitor and refine. The objectives are to:

- see the roadmap implemented through a series of enabled activity
 ensure findings are utilised and translated within health system and across government
- monitor activity to ensure direction is maintained

The structure of the roadmap

From problem statements to actions

In order to determine the tangible actions required to deliver our vision, we first identified the core problems experienced by the system when seeking to improve circularity in medtech. Through expanding to the specific challenges that drive the problems (the subissues) and the tangible solutions to overcoming them (the outputs), we were able to determine a suite of 30 actions that start to resolve our 6 core problems and therefore chart a course to achieving our vision.

We used the following queries to drive this process:

- problem statement: what is an overarching issue that is preventing programme objectives?
- sub-issues: what are the specific challenges within the broader problem statement?
- outputs: what is needed to overcome the sub-issues?
- actions: what are the main initiatives needed to develop and implement the outputs?

The 30 actions are not an exhaustive list. There will be other activity happening across the system and internationally that supports medtech circularity. However, we see these as the core enablers that articulate how we will coordinate and deliver the backbone of widescale improvement (subject to obtaining any new funding required and coordinating this when the best implementation options are known).

The main body of this roadmap will look at each of these problem statements in detail. Each problem statement has been assigned a 'priority action', a crucial enabling action within its section of the roadmap that will be set out in some more detail to exemplify how we and our collaborative foresee delivering this roadmap.

For a summary of the problem statements and actions see 'Roadmap actions'.

Levels of maturity

Maturity cannot be a surefire way of determining when an action will be delivered, but indicative timeframes for each are:

- high-maturity actions should be delivered within 1 to 3 years
- medium-maturity actions should be delivered within 3 to 5 years
- low-maturity actions should be delivered in 5 to 7 years

High maturity: actions are ready for implementation planning. Generally, they involve emerged technologies, systems or processes, there is good evidence of value and there is a high appetite to deliver within the network of actors.

Medium maturity: actions require some designing or researching before their implementation can be planned. They may have some of the aspects of a high-maturity area, but not all.

Low maturity: actions will require significant designing or research as new evidence is produced. There may be no understanding of how feasible some of the implementation options are, or some of the core stakeholders may not have been brought into the programme to date.

The majority of actions identified are medium to low maturity. This reflects the scale of the challenge in shifting medtech towards a more circular system and the need for a long-term system change to deliver on our vision.

Including our areas of research interest

The skew to low-maturity actions creates a significant research requirement across the whole programme. While this isn't unexpected, as circular medtech systems have not fully matured anywhere in the world, it does mean there are several evidence gaps that create bottlenecks to the UK taking action.

One example is within the action 'survey existing systems and model future demand'. In order to model demand, there needs to be a framework to understand what type of decontamination models are available and where health providers would want to apply them.

For example:

- centralised models of mass collection and decontamination of products in a single 'hub' work effectively for dense urban geographies such as London, but could be completely ineffective for rural settings
- trusts that have preferences for therapies conducted by clinicians in an acute setting will require a very different circular model to those that optimise selftreatment by patients in their own homes

However, the UK health and care system lacks awareness of what different models are available, as well as their advantages, disadvantages, applicability, average costs and other implications. Therefore to complete our action we must first conduct research to remediate this evidence gap, or in other words this is an area of research interest.

While there are several programmes that are already looking to address evidence gaps similar to ours, including the Scottish Government's <u>CivTech Challenge 10.9</u> on 'How can technology increase circularity in the NHS Scotland Supply Chain', it is unlikely that these alone can remediate the whole of the Design for Life programme's research needs.

In this roadmap, we have collated our known areas of research interest at the end of each problem statement section, though we expect these to evolve as the programme develops. For a single, centralised list see annex A.

Leadership and alignment

Context

By setting specific targets and priorities, our 'Leadership and alignment' actions intend to provide direction for policymakers, regulators and industry leaders, ensuring that actions align with an overarching vision that encourages collaboration and consensus, drives effective change and creates an enabling environment conducive to sustainable practices.

Problem statement

Unclear direction and misaligned strategies across the value chain lead to inconsistencies, inefficiencies and inertia, hindering meaningful, coordinated progress.

This problem statement exists due to the complexities and diverse stakeholder priorities within the healthcare ecosystem. Without aligned policies and strategies that guide stakeholders towards a common goal, meaningful and coordinated progress remains challenging. Fragmentation and disconnection across the value chain not only impedes efficiency but also undermines efforts to implement circular practices at scale. As a result, the sector's ability to transition is limited, maintaining existing challenges and limiting innovation.

This problem is wide-ranging but can be better understood in the way it manifests in the following 3 sub-issues.

Sub-issues

Poor alignment on objectives across the value chain

Circular strategies often lack clear and consistent objectives with respect to medtech, impacting effective planning and delivery. This results in misaligned efforts among stakeholders, leading to duplicated initiatives, resource inefficiencies and a missed opportunity in addressing common challenges systemically. For example, the sale of single-use plastic straws and single-use cotton buds are banned in England, but the use of these products for medical devices or medical purposes is exempt from this ban. While this exemption was decided based on close engagement with relevant groups, policy moving forward must continue to look at different treatment for the medtech sector based on the merits of each case, and not create assumptions that exemptions are always a valid choice.

Lack of clear research priorities

The lack of defined and prioritised research translates into an inefficient approach to addressing policy challenges once identified. Disjointed research, where efforts may overlap or diverge from the needs of the system, undermines the ability of the medtech sector to contribute meaningfully to broader research agendas and therefore transition to more valuable models.

New types of oversight and performance monitoring

Updated data gathering techniques are needed to improve visibility for critical safety and assurances processes. Through these, highest-standard patient safety can be maintained and new policy can progress. For example, if data on the detailed usage of medtech products was to be continuously gathered, tracing them would be faster and simpler, which could, for example, prevent an infection event from spreading further as the source of the infection could be investigated and addressed efficiently and with clear evidence.

The healthcare system in the UK has become predominantly based on a 'linear supply model', whereby supply relies on continuous extraction of virgin materials that are destined to be permanently disposed after use.

Outputs and actions

To address this problem statement we propose that 3 outputs are required with 5 relevant actions to develop and implement them. A collated summary of our actions for all problem statements with indicative timelines and maturity levels can be found in the 'Roadmap actions' section of the summary.

Aligned policies with clear leadership

With a comprehensive roadmap, scope and vision, this initiative aims to establish a framework that unifies UK policymakers, regulators and industry stakeholders behind common objectives. This strategic alignment encourages collaboration across the value chain, mitigating inefficiencies and streamlining efforts towards achieving sustainable outcomes. This was the foremost recommendation of the BSMS's recent report on the environmental impact of NHS devices.

This work will enable collaboration between medtech policymaking bodies, such as the Medicines and Healthcare products Regulatory Agency (MHRA), NHS services, NHS Supply Chain and the National Institute for Health and Care Excellence (NICE), with circular economy policymaking bodies soon to be coordinated through the circular economy taskforce, such as the Department for Environment, Food and Rural Affairs (Defra), the Department for Energy Security and Net Zero (DESNZ), the Department for Business and Trade (DBT), the Department for Transport (DfT) and HM Treasury. For example, this programme of work will seek to explore with Defra what medtech's role is within their 2042 target to halve residual waste and how medtech related publications, such as MHRA's commitment to deliver a sustainability strategy, which is due in 2025, (see the MHRA Corporate Plan 2023 to 2026) can and should support our vision.

Finally, we will work with international partners to ensure UK direction is aligned and that the UK is playing a leading role in defining the direction of travel for medtech circularity for example, harmonising and building on policy such as the EU ecodesign directive and the Food and Drug Administration's (FDA's) recommendations for the Remanufacturing of medical devices (note: the UK and USA define the word 'remanufacture' differently meaning this guidance will have varying applicability for UK system insight).

Our core actions for delivering this output are to:

- develop circular KPIs and standardised metrics
- · collaborate with other policymaking bodies to ensure strategy alignment
- present a full ecosystem roadmap to the Design for Life vision

Clarified roles and governance

By establishing transparent and accountable governance structures, the programme aims to overcome challenges related to lack of leadership, fragmented efforts and conflicting priorities. It will provide a framework for coordination between all relevant stakeholders such as clinicians, governmental bodies, regulators and manufacturers, enabling clear decision-making processes, points of escalation and action owners to ensure change is operationalised.

This involves consulting on and defining roles and responsibilities for core stakeholders, ensuring that each stakeholder group is empowered to contribute towards the programme's objectives (in a similar manner to the National Interdisciplinary Circular Economy Research programme's recent Medtech spotlight report). Decision-making processes will be developed to consider input from diverse perspectives, encouraging collaboration and ensuring that decisions align with the programme vision. Transparency and accountability will be prioritised within the governance structure, enabling stakeholders to track progress and hold each other to account.

Our core action for delivering this output is to:

establish clear governance and responsibilities for the whole ecosystem

Minimum-level data collection

By defining data requirements and aligning digital infrastructure, the programme looks to establish the core data necessary to ensure the safest and correct processes are being followed.

Principles to standardise data across the value chain will take inspiration from initiatives such as the Catena-X initiative in the automotive industry, which focuses on capturing essential information like remanufacturing processes, compliance standards, material composition and computer-aided design (CAD) files throughout the supply chain (see the blog Networks and Data Ecosystems Essential for the Medtech Industry's Circular Future published by Siemens). Furthermore, digital product passports (systems that collect and share a product's data throughout its lifetime) play a crucial role by offering detailed product sustainability information, previous use locations and settings and number of reprocessing cycles, all incredibly helpful information for ensuring a product is traceable and reprocessed the recommended number of times.

Our core action for delivering this output is to:

understand and define data requirements for the programme

Priority action

Develop circular KPIs and standardised metrics

Developing circular, industry-aligned KPIs to be used across the system plays a critical role in driving progress towards adopting more resilient practices. By establishing clear and measurable KPIs, the programme can effectively track and monitor the sector's transition towards circularity, providing a structured framework for evaluating success and identifying areas for improvement. It ensures that circularity objectives are integrated into the core operations of medtech organisations, setting a minimum standard for performance and supporting a culture of accountability, collaboration towards shared benefit and continuous improvement. This also requires the setting of standardised metrics to measure circularity in medtech. While this has developed a lot in relation to environmental metrics such as measures of CO₂ impacts, there are a much broader set of metrics that will need to be defined in order to set KPIs.

Further benefits to these metrics include prioritisation, described in the BSMS report on the environmental impact of NHS devices, where the third recommendation was to undergo assessments to understand the products of greatest impact. For example, the report's analysis concluded 23% of surgical products make up 80% of the carbon footprint of the 5 most common operations.

Areas of research interest

Most of our areas of research interest for this problem statement are based on determining value chain blueprints (a series of simulated value chains for different product types), finding case studies from other countries and sectors and data requirements for robust and traceable circular systems.

These are described in detail in the relevant section of annex A.

Core stakeholders

The following organisations will be our core stakeholders for this problem statement:

- Defra
- devolved governments and health services
- medtech trade associations
- MHRA
- NHS England
- NHS Supply Chain
- NICE
- Office for Life Sciences (OLS)

Behavioural change

Context

By promoting awareness, instilling skills and inspiring action among all actors within the value chain, 'behavioural change' aims to accelerate a fundamental shift towards achieving the programme's vision. This involves driving meaningful changes in attitudes, habits and practices throughout the industry and our systems of care.

Problem statement

The medtech landscape is one in which linear products are the default choice, maintained by a lack of value placed on circular systems and limited support for change.

Overcoming this challenge is integral as, without a shift in the culture around this 'default choice' and supporting skillsets to allow for the change, no amount of new circular offerings will generate benefits - they simply won't be adopted or used to their full potential. Whether it's understanding the motivation of NHS clinical decisions or manufacturers' investment profiles in circular technology, promoting and educating on the value of circular behaviours stimulates both supply and demand, creating positive impact across the value chain.

This problem is wide-ranging but can be better understood in the way it manifests in the following 2 sub-issues.

Sub-issues

Lack of opportunity to improve circularity awareness and skills

Core stakeholders, including clinicians, patients, product designers, service managers, procurement specialists and more, all often lack accessible information and guidance about the benefits of circular products and services, which stymies availability and adoption. For example, in January 2024, the General Medical Council updated its <u>Good medical practice</u> guidance stating that all registered doctors are required to manage resources effectively and sustainably. Progress is being made - for example, the <u>green theatre checklist</u>, published by the Royal College of Surgeons - but change will need to happen across the whole system.

No mechanism for providing ongoing support to stakeholders

Without clear guidance or expert networks regarding circular medtech usage, stakeholders struggle to address bespoke queries regarding, for example, the use of circular solutions in particular patient-related situations. This not only impacts the adoption of circular practices, but also limits stakeholders' ability to refine and optimise approaches over time and propagate new knowledge from hotspots of activity.

Outputs and actions

To address this problem statement we propose that 2 outputs are required with 4 relevant actions to develop and implement them. A collated summary of our actions for all problem statements with indicative timelines and maturity levels can be found in the 'Roadmap actions' section of the summary.

Training and behaviour change plan

A behaviour change plan would address the need to improve motivations and opportunities to make circular options the safe and easy default option. The plan would expand on existing initiatives such as NHS England's programme Getting It Right First Time and their infection prevention and control education framework, which utilised the COM-B model (Capability, Opportunity and Motivation) (see appendix 2).

With regards to capabilities, the programme would need to establish a training and skills framework in collaboration with expert training institutions including the royal colleges. Our intention, dependent on the ambition and funding that can be coordinated within the network, is to take inspiration from successful initiatives like the green public procurement training toolkit, published by the European Commission, who have embedded circular economy principles into core training programmes for multiple professions; or from Philips's sustainability training programme and Practice Greenhealth's sustainability initiatives, who have developed educational resources and training for hospitals interested in building deep local expertise and specialisms.

Finally, to support patients to change their behaviours they will need to have the confidence instilled by clear and accessible guidance on how reusables can work for them. Working with primary and community care services will be crucial for supporting this.

Our core actions for delivering this output are to:

- develop a training and skills framework
- develop a behavioural change plan
- deliver targeted resources to support self-care

Industry and system support framework

Establishing a support framework as a central hub for queries and assistance could ensure more efficient and collaborative problem solving through multiple routes of bespoke advice. Therefore, we will engage with stakeholders on how clinical networks, royal colleges, trade associations and other relevant stakeholders could compile guidance resources (such as standardised operating procedures) and signpost active, expert networks who can be engaged with queries and foster a culture of shared experience.

Our core action for delivering this output is to:

establish a support framework as a central hub for queries and assistance

Priority action

Develop a training and skills framework

To achieve this primary action, several steps have been outlined to identify, understand and change behaviours.

First, segmenting stakeholder cohorts will enable targeted interventions tailored to the specific needs of different groups within the healthcare ecosystem, including clinicians, procurement specialists, industry research and development specialists and patients.

Second, conducting workshops, surveys and interviews will serve as invaluable tools for gathering insights into existing educational needs and potential solutions - be they embedding into core training or nominated, expert-level programmes.

Third, the establishment of a structured framework for training and skills development will provide a strategy for how the sector will design and deliver education geared towards promoting circularity in healthcare. Through national bodies such as DHSC and NHS services enabling expert bodies such as the royal colleges, efforts can be made to implement targeted training to drive a culture of circularity and sustainability within all professions.

Areas of research interest

Most of our areas of research interest for this problem statement are based on creating effective training programmes and behavioural science.

These are described in detail in the relevant section of annex A.

Core stakeholders

The following organisations will be our core stakeholders for this problem statement:

- devolved governments and health services
- medtech trade associations
- NHS England
- NHS Confederation
- royal colleges

Commercial incentivisation

Context

Various sectors have demonstrated that aligning economic incentives with sustainability goals can drive innovation, improve operational efficiency and create new commercial opportunities. Transitioning to circular commercial models can reduce costs associated with resource consumption, waste disposal and regulatory compliance, leading to long-term savings and improved profitability. By incentivising stakeholders to choose and deliver circular solutions, the programme can unlock economic value, drive sustainability and growth and, ultimately, progress towards the programme's vision.

Problem statement

Stakeholders are insufficiently incentivised, or in some instances are disincentivised to choose and deliver circular solutions.

The 'Commercial incentivisation' problem statement confronts the present situation where stakeholders lack incentives (financial or otherwise) or face disincentives in a way that maintains traditional linear approaches to product design, manufacturing and consumption. This inhibits progress towards the programme vision.

This problem is wide-ranging but can be better understood in the way it manifests in the following 3 sub-issues.

Sub-issues

Linear demand signalling

Suppliers in the medtech industry are responding to existing market demands and regulatory frameworks by offering linear solutions. As a result this prevents the adoption of circular innovation and entrenches linear models within the system. For instance, while NHS organisations are content with selling their used medtech for remanufacture, they continue to purchase brand new devices rather than remanufactured alternatives, which maintains the linear status quo and does not promote circularity in the system. This does not promote long-term sustainability or cost savings as most of the potential carbon and financial savings come from purchasing remanufactured devices rather than the creation of new ones.

Counterproductive incentivisation

Buyers are currently incentivised to procure single-use products or services due to various factors such as budget constraints, procurement processes, or perceived short-term cost savings. For example, in managing multi-year capital budgets, healthcare institutions may prioritise linear products over circular alternatives due to perceived lower upfront costs rather than considering the lifetime value of a product.

Value of circular products and services is not recognised commercially

Circular products and services may not receive adequate attention or investment due to a lack of emphasis on their economic feasibility, and so they struggle to gain traction in the market, introducing scaling and adoption barriers despite their potential benefits. Without recognising the value of circular products and services, stakeholders are less incentivised to invest in research, development and implementation of circular solutions. For example, during the 2022 to 2023 financial year, the NHS purchased £16.2 million worth of single-use harmonic shears, of which 71% were eligible for remanufacture. Despite the average sales price of remanufactured shears offering a 50% saving compared to the single-use product, only 1.7% of the total shears purchased were remanufactured. In a positive trend, however, this figure had increased to 6.9% the following year and through the actions in this roadmap we hope the rates for these shears and many other devices will increase.

Outputs and actions

To address this problem statement we propose that 3 outputs are required with 6 relevant actions to develop and implement them. A collated summary of our actions for all problem statements with indicative timelines and maturity levels can be found in the 'Roadmap actions' section of the summary.

Strategic demand signalling and communications

Within the medtech strategy, we describe the value of demand signalling as industry being given the clarity to offer products and innovation that most closely reflect clinical needs. To do this, we will be aiming to ensure relevant procurement and sustainability strategies align with our programme vision and promote circular products. For example, we will ensure we create links to recommendations from the National Audit Office for the NHS Supply Chain, emphasising the economic and environmental advantages of circular procurement practices and how they are integral to a resilient system. We will also look to explore detailed communications on particular product categories or clinical areas, similar to the Accelerated Access Collaborative's demand signalling reports (see under 'Research prioritisation'). NICE have also recently consulted on plans to make topic selection and prioritisation more integrated, effective and timely.

Our core action for delivering this output:

circularity of medtech embedded in engagements and strategies

Updated commercial mechanisms

By updating commercial mechanisms, the programme aims to create an enabling environment for all circular solutions. The programme will first identify opportunities and barriers for incentivising circularity within the commercial landscape, including a review of existing challenges that prevent adoption and the development of targeted strategies to mitigate. Examples our collaborative has raised include guarantees of longer tender periods on category frameworks and new shared value models where a supplier is still rewarded for creating new sources of value mid-framework-agreement (such as take-back

schemes). We will link with the <u>various commercial playbooks</u> produced by the Cabinet Office and development in NHS England's Evergreen Sustainable Supplier Assessment.

The establishment of a continuous or periodic feedback loop from stakeholders is also important for gathering insights on the effectiveness of commercial incentivisation interventions, allowing the programme to be refined and optimised.

Our core actions for delivering this output are to:

- identify opportunities and barriers for incentivisation of circularity
- · establish a feedback loop for stakeholders
- · embed circularity into the commercial ecosystem

Value-based procurement

Through value-based procurement, challenges related to linear demand signalling and the undervaluing of circular products and services can be overcome. Stakeholders can evaluate the benefits of circularity, including increased resilience, reduced environmental impact, extended product lifespan and long-term cost savings, therefore increasing recognition of circular offerings and incentivising procurement of circular solutions. Design for Life will collaborate with the value-based procurement initiative, part of the wider medtech strategy, to develop and embed new assessment models into procurement guidance.

To complement this, market research will need to be conducted to identify gaps and opportunities where customers see value in particular products and services emerging but are yet to see them arise. For example, many clinical groups are keen to improve the circular offerings in procedure packs and surgical instruments, yet options are not emerging at the same pace as other areas such as walking aids. In the study by Stockert and Langerman, Assessing the magnitude and costs of intraoperative inefficiencies attributable to surgical instrument trays, over 75% of instruments included within standard trays remain unused, adding to operating costs and increasing carbon impact. Where market research shows a gap, we hope to explore with our collaborative how to use these insights to streamline new market entries.

Our core actions for delivering this output are to:

- conduct market research to identify gaps and opportunities
- deliver a value-based procurement methodology for medtech products

Priority action

Deliver value-based procurement for circularity of medtech products

To achieve this primary action, we will work to ensure that the value of medtech products to the wider system will be assessed according to the principles of a circular economy. This assessment will be delivered through work to establish a methodology for value-based procurement to be applied at a national and local level. This methodology is being developed in collaboration with core stakeholders including NHS England, NHS Supply

Chain, procurement professionals and industry (see <u>The medical technology strategy: one year on</u>). It aims to introduce consistency in how value-based procurement decisions are made and support the shift away from a focus on upfront cost.

Several case studies demonstrate the significant impact of strategic and value-based procurement strategies on driving innovation. The Erasmus Medical Center's innovative value-based procurement strategy in the Netherlands, focused on digitally connected hospital beds, led to substantial financial savings (35% reduction in total cost of ownership), improved patient care and environmental benefits through reduced CO₂ emissions and energy use (65% reduction in footprint). NHS Wales' adoption of value-based procurement for wound management resulted in enhanced patient quality of life and reduced hospital visits, while Europe's shift towards outcome-and-value-based contracts showcased the industry's transition towards value-based procurement, leading to improved patient care and cost reductions.

Areas of research interest

Most of our areas of research interest for this problem statement are based on case studies from other countries and sectors and measuring systems for resilience.

These are described in detail in the relevant section of annex A.

Core stakeholders

The following organisations will be our core stakeholders for this problem statement:

- Crown Commercial Service
- DBT
- Defra
- Department for Science, Innovation and Technology
- devolved governments and health services
- · medtech trade associations
- NHS England
- NHS Supply Chain
- NICE
- OLS
- UK Research and Innovation (UKRI)

Regulations and standards

Context

'Regulations and standards' are fundamental for safe and effective design, use and disposal of all medtech, be it linear or circular. By updating and aligning existing regulations and standards, an environment conducive to the adoption of circular medtech can be created, accelerating programme benefits.

Problem statement

UK regulatory regimes and technical standards predate circularity and have potential to further enable the medtech sector to recognise opportunities and align internationally.

Current regulatory frameworks and technical standards largely predate the drive towards a circular economy and so may in many cases overlook the specific requirements for practices such as reuse, remanufacture, recycling and use of recycled materials. This problem statement highlights the importance of reviewing and, where needed, updating these frameworks to ensure that the medtech sector can fully embrace sustainable approaches and remain competitive on the international stage.

Furthermore, many different regulatory regimes apply to a circular medtech system - for example, in England the MHRA-enforced Medical Devices Regulations 2002 (now being updated), Hazardous Waste (England and Wales) Regulations 2005 and Waste Framework Directive 2008 (both enforced by the Environment Agency) could apply with a reuse cycle of a medtech product. This differs in Scotland, Wales and Northern Ireland who will have their own devolved waste regulations, and so cross-border systems will have many legal considerations before delivery.

This problem is wide-ranging, but can be better understood in the way it manifests in the following 3 sub-issues.

Sub-issues

Regulations and standards predate circularity

Current standards and regulations predate the drive to understand the unique requirements of circular products and practices, creating misalignment within the ambitions of the circular economy. This disconnect can lead to compliance uncertainties and hamper the transition to circular models in healthcare. Adding to the complexity, there is a crucial need for trust and confidence in recycling efforts, ensuring that materials sorted and sterilised are recycled, and to address hospital infection controls that may veto recycling based on now incorrect assumptions. These factors combined could discourage investment and innovation in circular medtech solutions, highlighting the need for circularity to form a crucial part of regulatory and standards evolution.

Lack of international consensus

The absence of international consensus for regulations and standards complicates the regulatory landscape for medtech products. Varying requirements across different regions can lead to inefficiencies, increased compliance burdens and barriers to market. Without a consensus at the international level, most circular systems face the challenge of navigating contrasting regulatory frameworks, which may require costly and time-consuming adjustments to meet different standards for each market.

UK regime is federated between many regulators

Regulatory oversight of medtech products is distributed across multiple agencies, such as MHRA, the Environment Agency, the Health and Safety Executive and others, each with their own requirements and processes. As a consequence, navigating this diverse regulatory environment can be challenging for industry stakeholders, leading to inefficiencies, delays for suppliers and missed opportunities for scaling change and driving innovation. Furthermore, local infection controls are not always consistent between healthcare providers, which adds further difficulties for stakeholders looking to bring new products and services to the whole market. By promoting greater alignment and consistency in regulatory requirements, stakeholders can overcome barriers to innovation, drive efficiencies and advance the adoption of circular and sustainable practices.

Outputs and actions

To address this problem statement we propose that 3 outputs are required with 3 relevant actions to develop and implement them. A collated summary of our actions for all problem statements with indicative timelines and maturity levels can be found in the 'Roadmap actions' section of the summary.

Circular standards to support a more diverse system

By enhancing existing standards and developing new ones tailored to circularity, this output aims to promote evidence-based consistency within circular practice to ensure safety and effectiveness. This is expected to include the formation of committees to both create new standards to support circular medtech policy and review existing standards to see whether new considerations need to be included. One example is the development of a new technical vocabulary to support consistent understanding when commissioning, regulating and delivering new circular systems. We envision that much of this output will be led by the British Standards Institution, who will oversee new standards development and ensure appropriate technical representation.

Our core action for delivering this output is to:

develop and maintain circular standards (including vocabulary)

Positions on international consensus

This output addresses the challenges associated with differing regulatory frameworks and standards. Through collaboration and dialogue, the programme will work to develop

consensus on options for international alignment and influence the direction of thought leadership in regulatory matters, leveraging collective expertise and resources to drive meaningful change. To achieve this, the programme will consider collaboration with global regulatory sector leaders via existing global fora to develop joint proposals for research and pilot schemes.

Furthermore, changes related to regulatory development such as the EU <u>Ecodesign for sustainable products regulation</u>, and FDA's guidance for the <u>Remanufacturing of medical devices</u> will be tracked and learned from where they emerge before any equivalent UK change (note that the UK and USA define the word 'remanufacture' differently meaning this guidance will have varying applicability for UK system insight).

Our core action for delivering this output is to:

align regulatory environment with global counterparts

Establish medtech as a core sector within UK circular economy work

By elevating the importance of medtech within industrial and research strategies, this initiative aims to ensure medtech receives adequate attention and support within broader regulatory frameworks and that regulatory frameworks can be tailored to the unique needs and challenges of the industry.

To achieve this output, medtech circularity should be integrated as a core objective within UK circular economy work, ensuring alignment and collaboration across regulatory bodies. This includes advocating for medtech representation in various working groups, embedding medtech vocabulary and metrics into wider circular economy strategies and setting up governance mechanisms to align sustainability objectives set by MHRA with other regulatory bodies such as the Environment Agency and Defra. Additionally, the programme will evaluate existing wider circular UK regulations to identify any misalignments with circular objectives and opportunities for optimisation.

Our core action for delivering this output is to:

• establish medtech as a core sector within UK circular economy work

Priority action

Align regulatory environment with global counterparts

In aligning to global best practice and taking a role as a thought leader in this area, the UK medtech industry can enhance its competitiveness and leverage global partnerships to deliver sophisticated circular systems.

This action includes the UK partnering with other countries to submit proposals to global fora. Currently, we believe systems of recycling and recyclate usage (that is, how medtech can be sold as a recycled resource and how recycled material can be purchased to use as feedstocks for manufacture) has particular potential for collaboration and may form the

basis of initial proposals. This is subject to discussions with any potential partner countries who go on to co-own our proposal, and the global fora the UK will be submitting to.

We are also planning a UK survey of potential and perceived regulatory barriers and local infection controls and guidance to be conducted with medtech industry and healthcare providers to understand reasons given for why circular systems may not have been able to emerge in the past. We hope this will highlight the areas with greatest need of clarification or reform.

Areas of research interest

Most of our areas of research interest for this problem statement are related to innovation horizon scanning and market economics.

These are described in detail in the relevant section of annex A.

Core stakeholders

The following organisations will be our core stakeholders for this problem statement:

- British Standards Institution
- devolved governments and health services
- Environment Agency
- Foreign, Commonwealth and Development Office
- Health and Safety Executive
- medtech trade associations
- MHRA
- NHS England
- royal colleges

Physical and digital infrastructure

Context

'Physical and digital infrastructure' plays a pivotal role in facilitating the transition towards a circular healthcare ecosystem. Strategic, nationwide enhancements in physical infrastructure will be paramount to enabling any ambitions for improved circularity and advanced digital solutions present some of the best opportunities to optimise operations for safety, cost-effectiveness and flexibility.

Problem statement

The existing physical and digital infrastructure and supporting services hold back the scaling of circular solutions, both locally and nationally.

This problem statement highlights the need to re-evaluate and potentially restructure existing infrastructure to accommodate and support the transition towards circular healthcare practices. Inadequate infrastructure originates from various factors. Outdated physical facilities may lack the necessary design features or technological capabilities to facilitate the adoption of circular solutions, such as efficient waste management systems or space for remanufacturing centres. Similarly, outdated or incompatible digital systems may impede the integration of circular processes, hindering data collection, analysis and communication needed for implementing effective, modern systems.

This problem is wide-ranging, but can be better understood in the way it manifests in the following 2 sub-issues.

Sub-issues

Inflexible and/or misaligned legacy infrastructure

Current physical infrastructure, tailored for linear products and services, lacks the capabilities to accommodate the demands of circular practices like decontamination, recycling and remanufacturing. This not only impedes the adoption and scaling of circular solutions within healthcare settings but also undermines broader sustainability efforts. Without the required infrastructure to drive circular practices, healthcare facilities remain tied to linear consumption practices with potential for regional disparities in ability to capture value from circular systems (for example, in cities where multiple hospitals may be geographically close and so can more easily share decontamination or material processing facilities).

Lack of available digital enablement

This challenge highlights the limited utilisation of suitable digital systems. Healthcare facilities do not fully leverage digital technologies to enhance their operations in line with circular principles: improving visibility, traceability, product distribution, efficient waste management, maintenance tracking and circular procurement. Without adequate digital

infrastructure, healthcare providers will struggle to transition to circular models and will be unable to meet regulatory requirements as easily, leading to continued reliance on linear approaches.

Outputs and actions

To address this problem statement we propose that 3 outputs are required with 6 relevant actions to develop and implement them. A collated summary of our actions for all problem statements with indicative timelines and maturity levels can be found in the 'Roadmap actions' section of the summary.

Clear views of volume capacity requirements

A clear view of volume capacity requirements and product prioritisation is crucial for aligning physical infrastructure with the expected demands of circular healthcare practices. It involves understanding the gap between the long-term needs of the healthcare system, such as funding and facility types, and the capabilities of existing NHS-owned and third-party services. This is essential for determining the level of scale-up required to effectively support circular solutions. For a detailed case study of the research required for this output see the section 'Including our areas of research interest'.

Our core action for delivering this output is to:

survey existing systems and models of future demand

Optimised implementation plan

Once we know the gap between required and current infrastructure, we will need a plan to close it. To deliver this output, both a decontamination infrastructure framework and a materials recovery and recycling framework will need to be established. The former involves defining best practices for setting up and operating decontamination facilities, exploring various models such as centralised and federated options to enhance nationwide availability. It also involves developing best practice blueprints (for example, guidance for facilities that are in-hospital, out-of-hospital, or owned by a third party) offering advice on policy considerations and approximate costs.

The materials recovery and recycling framework would draw inspiration from initiatives such as the <u>Nederland Circular</u> by the Dutch Ministry of Infrastructure, which sought to rationalise down to a single plastic type rather than a large variety. It aims to standardise processes, enable transparency in the market for recovered devices and establish mechanisms for brokering asset owners with purchasers.

Our core actions for delivering this output are to:

- develop a decontamination infrastructure framework
- establish a materials recovery and recycling framework

Consensus on areas of digital enablement

By identifying and prioritising areas where digital solutions can enhance circularity and collaborating with core institutions such as the University of Exeter (who lead the Digitally Enabled Circular Healthcare Initiative – DECHI, funded by the Engineering and Physical Science Research Council), NICE, the Digital Catapult and Heath Data Research UK, this initiative aims to fully capitalise on intelligent, digitally enabled systems.

Consensus will be driven by the development of a strategy for digital enablement that identifies and addresses all the valuable and feasible areas for digital integration and advocating for national initiatives to bring them about, such as securing cross-UK support and funding. This action will be delivered in close collaboration with DECHI, where DHSC and other core Design for Life stakeholders will be members of their steering group.

Our core actions for delivering this output are to:

- develop a strategy for digital enablement
- explore collaborative data sharing initiatives
- · identify and connect material purchasing partners

Priority action

Survey existing systems and model future demand

In England, there is currently no survey that describes all available decontamination infrastructure with metrics such as location, ownership, specialisms and spare capacity (if any). A transition away from all unnecessary linear products is entirely contingent on a larger and healthier decontamination sector, so this overview of the current baseline is critical to any planning efforts.

To plug this gap, English authorities will collaborate with devolved nation authorities who have a significantly better picture of their decontamination capacity. Through workstreams such as mapping existing infrastructure and how health providers prefer to run it (do they own it 'in-house', or prefer to contract an external provider?), priority product analysis (which products make up the biggest proportion of those that require decontamination? What about in the future?) and undergoing technical reviews of sterilisation techniques (for example, plastic saline bags and implanted devices are likely to need very different treatments), this programme anticipates we will greatly improve our insight for not only England, but the whole UK. We will also explore whether similar processes will be undertaken for remanufacturing and recycling infrastructure.

Areas of research interest

Most of our areas of research interest for this problem statement are related to material flow analysis, decontamination techniques and assessment models for selecting digital solutions.

These are described in detail in the relevant section of annex A.

Core stakeholders

The following organisations will be our core stakeholders for this problem statement:

- Catapult Network
- Crown Commercial Service
- Defra
- devolved governments and health administrations
- medtech trade associations
- NHS England
- NHS Supply Chain
- OLS
- UKRI

Transformative innovation

Context

'Transformative innovation' focuses on developing an enabling innovation ecosystem that aligns with circular objectives and sees circularity as a valuable mode of innovation in its own right. Embracing circular innovation could increase competitiveness, drive market differentiation and improve resilience.

Problem statement

The innovation ecosystem is not tailored to circular objectives, impeding development of solutions.

The problem statement highlights the current misalignment between innovation and circular objectives, which is caused by various factors, including traditional linear approaches to product development, limited consideration of lifecycle impacts and the fact that sustainable innovations are traditionally less valued in healthcare than other sectors. Without an innovation ecosystem that supports circular objectives, innovation may inadvertently continue to support unsustainable practices or fail to take advantage of opportunities.

This problem is wide-ranging, but can be better understood in the way it manifests in the following 3 sub-issues.

Sub-issues

Limited market collaboration on innovation

A lack of established forums for pre-competition collaboration within the medtech industry often restricts the sharing of knowledge, technologies and resources within the market. As a result, companies develop innovation in isolation rather than leveraging collective expertise to address common challenges or advance shared goals. This not only slows the pace of innovation but also results in redundant research and missed opportunities. An example of effective technological collaboration involves HERU Technologies, who were supported by Siemens to create a greentech solution that transforms everyday items that were destined for landfill into energy, with healthcare being one of the best suited settings.

Risk of being first movers deters innovation

There is reluctance among medtech innovators to implement innovation due to the uncertainties and risks involved. Without a clear circular medtech innovation strategy, innovators face challenges related to market acceptance, regulatory compliance, return on investment, clinical efficacy, safety concerns and uncertain value propositions. As a result, innovators may not invest resources in developing solutions due to the potential negative outcomes or increased regulations and other requirements associated with being early adopters in an uncertain landscape.

Slow market innovation adoption

There are delays in embracing innovative products and services despite their potential benefits. This delay is primarily due to a lack of support and promotion for circular solutions, due to misaligned regulations and standards, inadequate waste infrastructure and business models that incentivise linear purchasing. The lack of support for circular solutions results in limited visibility and awareness among stakeholders, leading to delayed widespread acceptance and integration. This compounds with existing barriers to adoption for innovative devices in general. As a result, the industry continues to rely on conventional, linear practices, despite the growing recognition of the need to accelerate the uptake of circularity.

Outputs and actions

To address this problem statement we propose that 3 outputs are required with 6 relevant actions to develop and implement them. A collated summary of our actions for all problem statements with indicative timelines and maturity levels can be found in the 'Roadmap actions' section of the summary.

Clear leadership and strategy

Circular innovation could come from a number of domains: materials science such as development of new, more easily recovered and biocompatible polymers, chemical engineering such as more efficient and sustainable chemical recycling techniques, or robotics with Al-enabled sorting machinery.

By establishing a clear, evidence-based circular innovation strategy, the programme aims to support the targeted development of the most transformative innovation aligned with patient needs. To achieve this, the programme will identify areas where circular design research is needed, informing prioritisation and guiding investment towards innovations that have the greatest potential to drive meaningful change.

This links to DHSC's leadership on innovation classification as described in the <u>Medical</u> technology innovation classification framework, where we have established clear criteria for a device being described as innovative to support prioritisation and rapid adoption of the most impactful technologies.

Our core actions for delivering this output are to:

- identify opportunities for innovation across the system
- identify areas where circular product design research is needed
- research standardised methodology for supply resilience and sustainability assessments

Industry collaboration and alignment

The programme will establish working groups around core innovation areas to enable precommercial collaboration, involving stakeholders from the medtech industry, supporting sectors such as sustainable science and the health system who have the best knowledge of patient and clinician needs. The establishment of a dedicated medtech innovation centre could also play a role in supporting collaboration, advancing circular economy design, developing an environment that encourages experimentation and knowledge exchange and supporting businesses to overcome the risks associated with being first movers in the market.

Novo Nordisk's <u>Circular for Zero</u> (see under 'Novo Nordisk case study') initiative demonstrates how collaboration between industry leaders and startups can lead to innovative solutions, in this case improving recyclability. Through programmes like PenCycle, Novo Nordisk in Denmark aims to repurpose used insulin pens into office furniture, significantly reducing plastic waste.

Our core actions for delivering this output are to:

- embed inter-industry collaboration as a core component of delivering circularity
- establish a medtech innovation centre

Innovation pathways, adoption and scaling

Linking closely with 'commercial incentivisation', this output aligns with the <u>rules-based</u> <u>medtech pathway</u> programme being led by DHSC, NHS England and NICE, with a consultation that closed in August 2024. Where possible we will integrate with this system to streamline innovation under a single pathway, including understanding how innovation required in supporting services, such as decontamination techniques, may be able to be incorporated into the pathway's development.

Our core action for delivering this output is to:

streamline innovation pathways

Priority action

Establish a medtech innovation centre

Should suitable funding opportunities be found, establishing an innovation centre could accelerate breakthroughs in circular economy innovation within the medtech industry. Creating a dedicated environment could allow organisations to collaborate and experiment through a physical space that also facilitates the establishment of processes and governance structures necessary for developing innovations. An innovation centre would serve as a space for providing innovators with testbeds, enabling safe trialling and accelerating the progression of ideas through technology readiness levels 5 to 7, increasing the likelihood that scalable solutions emerge.

Areas of research interest

Most of our areas of research interest for this problem statement are related to horizon scanning emerging technologies.

These are described in detail in the relevant section of annex A.

Core stakeholders

The following organisations will be our core stakeholders for this problem statement:

- Accelerated Access Collaborative
- British Standards Institute
- Catapult Network
- Crown Commercial Service
- Department for Science, Innovation and Technology
- devolved governments and health services
- Health Innovation Networks
- medtech trade associations
- NHS England
- NHS Supply Chain
- OLS
- royal colleges
- UKRI

Next steps

Having set out our roadmap to a circular system for medtech, Design for Life will now accelerate delivery of the programme with partners across government, the health and care sector, industry and academia. While some actions set out above require further funding and partnership arrangements to be put in place, many actions can be started immediately. Below is a summary of where some of this work will start in the coming months.

Governance

Drawing on the expertise of our advisory group of members from across the health sector, we will establish a governance structure to support coordination and ensure progress is made against our shared objectives.

We will keep membership of our advisory group under review and ensure that each stakeholder group is appropriately represented and empowered to contribute.

Developing key performance indicators and metrics for circularity in healthcare, we will establish data-driven oversight of maturity and progress across the sector.

Engagement

We will review and engage with relevant strategies across government, the health sector and beyond, including value-based procurement, to ensure that medtech is well integrated wherever appropriate with all efforts in support of a circular economy.

We will learn from our partners in devolved governments who have implemented advantageous approaches that support circularity, such as NHS Scotland's detailed mapping of sterile services capacity.

We will explore opportunities for precommercial collaboration with industry to support codesign of circular approaches and facilitate linkup between industries and sectors.

We will survey industry and other stakeholders to identify any changes to guidance that could help circular innovators to navigate existing regulations and debunk perceived barriers, as well as identifying any real regulatory barriers.

We will engage international forums to seek alignment and collaboration on issues such as standards and regulatory barriers.

We will explore opportunities to establish a medtech innovation centre, building strong links with industry and academia to accelerate circular innovations in medtech and showcase excellent local initiatives at a much wider scale.

Priority research

Among our first research priorities will be:

- exploring the potential performance indicators that can be used to govern targets in increasing effective provision of circular medtech and how can they be delivered
- understanding the different decontamination service models (existing and potential), the pros and cons of each and approximate costs involved
- identifying specific processes within existing regulations and standards that could be improved and/or have acted as barriers in the past by surveying industry and healthcare providers
- identifying a small number of demonstrator products and services to scope rapid pilot projects

Annex A: areas of research interest

This annex collates all the areas of research interest that are described within their relevant problem statement chapter.

Leadership and alignment

Output: aligned policies with clear leadership

Core evidence and knowledge gap: where policy interventions are likely to have the greatest impact on improving rates of circularity.

Our relevant research question is:

how can a series of 'value-chain blueprints' of medtech products be produced? Can
we utilise this to determine the points where policy intervention would have the
greatest impact?

Core evidence and knowledge gap: the attributes of effective circularity KPIs and their handling thereof.

Our relevant research questions are:

- what are the potential performance indicators that can be used to govern targets in increasing effective provision of circular medtech and how can they be delivered?
- how should these indicators be deployed for different product types for example, for those where reuse until eventual remanufacture is the standard pathway compared to those that are immediately recycled after use?

Output: clarified roles and governance

Core evidence and knowledge gap: effective ways to build accountability.

- in other sectors that are looking to upscale circularity, how is accountability federated between core actors?
- how could core actors of the medtech value chain be given this accountability to resilience and sustainability that embeds it within their business as usual?

Output: minimum level data collection

Core evidence and knowledge gap: minimum viable systems that ensure safety and what is required to build them.

Our relevant research questions are:

- will existing reporting requirements be sufficient for potential performance indicators? If not, what are the systems that could collect the missing data and how could they be delivered?
- how can digital product passports support a minimum viable solution for ensuring safety?

Behavioural change

Output: training and behaviour change plan

Core evidence and knowledge gap: the most effective ways to deliver circularity training.

Our relevant research questions are:

- what are the knowledge and skills gaps that could drive new opportunities for different stakeholder groups?
- what are the key drivers for different stakeholder groups to upskill in circularity?
- are net zero and circularity training programmes better delivered together or separately?

Core evidence and knowledge gap: drivers of current behaviours and how can we seek to change the culture.

Our relevant research questions are:

- what drives both resistance to and slow rates of change, and what drives championing and high rates of change for different stakeholder groups?
- what are the case study methods regarding changing a culture to address the drivers for and against circularity (once identified)?

Output: industry and system support framework

Core evidence and knowledge gap: the role of bespoke advice when driving greater circularity and in our 2045 scenario.

Our relevant research question is:

• will there always be a need for a centralised source of bespoke advice, or can expert networks serve that role?

Commercial incentivisation

Output: strategic demand signalling and communications

Core evidence and knowledge gap: effective means of demand signalling.

Our relevant research questions are:

- how does industry currently perceive and respond to existing demand signals that are based on resilience and sustainability objectives?
- which levers of demand signalling (for example, white paper strategies, research grants, framework tender launches) have greatest sway on incentivising new business offerings?

Output: updated commercial mechanisms

Core evidence and knowledge gap: the mechanisms that provide the greatest barriers or greatest opportunities.

Our relevant research questions are:

- what are the greatest procedural barriers to circularity in procurements, and what are the options for reform?
- based on other sectors, what are the best potential levers of incentivisation (for example, tax breaks, longer framework tender periods)?
- would a set, nationwide system, or a series of flexible, locally determined systems
 of incentives be more effective?

Core evidence and knowledge gap: monitoring and adjustment protocols for systems of incentives.

Our relevant research questions are:

- what would an effective system of continuous monitoring and adjustments look like?
- what data would be needed to power decisions, and what would be an effective way of collecting it?

Output: value-based procurement

Core evidence and knowledge gap: the most effective role for value-based procurement in incentivising circularity.

- how do you quantify the value of circularity for the purpose of a value-based procurement system?
- how do you quantify indirect savings (for example, lower warehousing costs or lower rates of product failure) for the purpose of a value-based system?

Regulations and standards

Output: circular standards to support a more diverse system

Core evidence and knowledge gap: the key standards that are either missing or require reform.

Our relevant research questions are:

- what are the standards gaps that would safely enable better and more diverse circular medtech?
- what are the key emerging technologies that are currently poorly enabled by regulations, standards and/or guidance?

Output: positions on international consensus

Core evidence and knowledge gap: the tangible benefits of global alignment and where it could have the greatest impact.

Our relevant research questions are:

- what are the overall effects of international regulatory dissonance?
- what are the key areas of global consensus where the UK can drive harmonisation, and how?

Physical and digital infrastructure

Output: clear view of volume capacity requirements

Core evidence and knowledge gap: existing and required systems of decontamination.

Our relevant research questions are:

- what is the current proportion of in-hospital, out-of-hospital and third-party decontamination?
- what are all the different decontamination service models (existing and potential), the pros and cons of each and the approximate costs involved?

Core evidence and knowledge gap: existing and required systems of material recovery.

- what are the current material flows within medtech as a whole and within key product categories?
- what are all the different material recovery service models (existing and potential), the pros and cons of each and the approximate costs involved?

Core evidence and knowledge gap: existing and required systems of remanufacture.

Our relevant research question is:

• what is the potential size of a remanufacturing market in our 2045 scenario?

Output: optimised implementation plan

Core evidence and knowledge gap: the effective systems of decontamination.

Our relevant research questions are:

- what are all the different decontamination service models (existing and potential), the pros and cons of each and the approximate costs involved?
- based on the UK's health services, what are the best options for different regions and/or service types and the best practices for each?

Core evidence and knowledge gap: the effective systems of material sales.

Our relevant research questions are:

- which materials are the most cost-effective for health services to recover and sell?
- what are the reverse logistics requirements in a future scenario where our vision is achieved?
- what are the potential permanent arrangements that could be stood up between a health service and a material buyer?

Output: consensus on areas for digital enablement

Core evidence and knowledge gap: where digital enablement is required or most valuable.

- based on the value-chain blueprints (see leadership and alignment areas of research interest) what are the potentially valuable areas of digital enablement for medtech systems?
- what assessment models allow for prioritisation of the most feasible and highest impact options?

Transformative innovation

Output: clear leadership and strategy

Core evidence and knowledge gap: emerging technologies that could transform circular medtech offerings.

Our relevant research questions are:

- what are the emerging innovations that will transform circular offerings across the whole economy, and how do they relate to medtech?
- is there scope in the pipeline of transformative innovation areas (for example, robotics may be one) to ensure circularity is a core part of the design process?

Core evidence and knowledge gap: the bottleneck areas of the value chain that could benefit from innovation most.

Our relevant research question is:

 based on the value-chain blueprints (see leadership and alignment areas of research interest) what are the areas of greatest friction and/or opportunity for innovation - for example, where there is the most outdated technology and systems, lack of digital enablement and so on?

Annex B: collaborative members

We have endeavoured to include everyone who we collaborated with or who has contributed to our discovery phase, but we will inevitably miss certain stakeholders, for which we apologise.

- Association of British HealthTech Industries
- Association of Healthcare Technology Providers for Imaging, Radiotherapy and Care
- Association of Medical Device Reprocessors
- B Braun Medical
- Baxter Healthcare
- Becton Dickinson
- Birmingham and Solihull Integrated Care System
- Boston Scientific
- British In Vitro Diagnostic Association
- British Standards Institution
- Centre for Process Innovation
- CE Hub, National Interdisciplinary Circular Economy Research Programme
- Circular Economy for Small Medical Devices: REMED
- Coloplast
- Cook Medical
- DBT
- Deloitte LLP
- DESNZ
- Defra
- Denroy Limited
- Department of Health (Northern Ireland)
- East Suffolk and North Essex NHS Foundation Trust
- Engineering and Physical Sciences Research Council
- Health and Social Care Northern Ireland
- Health Innovation Network East
- Health Innovation Network London
- Inspiration Healthcare Limited
- Institute of Decontamination Sciences
- Johnson and Johnson
- Kimal
- Knowledge Transfer Network
- Leeds Teaching Hospitals NHS Trust
- Lord O'Shaughnessy, previous Parliamentary Under-Secretary at DHSC
- Manchester University NHS Foundation Trust
- Medequip
- MHRA
- Medtronic
- NHS England
- NHS Scotland
- NHS Supply Chain
- NHS Wales
- OLS

- Patients Association
- PD-M International
- Pennine Healthcare
- Pentax
- Philips
- Protomax Plastics
- Revolution-ZERO
- Ricoh UK
- Roche Healthcare
- Rocialle
- · Royal College of Nursing
- Scottish Government
- Surgical Holdings
- Teleflex
- University of Cambridge
- University of Glasgow
- University of Huddersfield
- UK Critical Minerals Intelligence Centre
- UK Trade Association for Instrumentation, Control, Automation and Laboratory Technology
- Vanguard

© Crown copyright 2024

www.gov.uk/dhsc

This publication is licensed under the terms of the Open Government Licence v3.0 except where otherwise stated. To view this licence, visit nationalarchives.gov.uk/doc/open-government-licence/version/3.

Where we have identified any third party copyright information you will need to obtain permission from the copyright holders concerned.

