SUSTAINABLE SOLUTIONS FOR RESPIRATORY AND AIRWAY BIOMEDICAL DEVICES

A Thesis Submitted for the

Degree of Doctor of Philosophy

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16/02/2024

Abstract

The detrimental impact human activity has on the environment is undeniable with unsustainable practices and consumerist mentality of great concern. Due to the precautionary nature around the safety of medical equipment, the medical industry has been one of the slowest to incorporate sustainability into their design considerations. The research in this field is scarce thus requiring extensive communication between numerous stakeholders to ensure the proposed solutions are attainable across the entirety of the products' life cycles.

This PhD project aims to generate evidence for improving sustainability, in particularly environmental aspects, of medical devices and practices using a life cycle approach incorporating the views of key stakeholders. Life cycle assessment (LCA) and Life cycle costing (LCC) methodologies are used to assess respiratory and airway devices following ISO standards 14040/44:2006. Evaluation of environmental impacts from each life cycle stage are provided to identify improvement opportunities. Mechanical testing is also used to explore the mechanical properties of an environmentally sustainable alternative to polypropylene; calcium carbonate filled polypropylene composites.

Diverse scenarios were explored throughout, including: investigation of more environmentally sustainable materials as alternatives to currently used medical polymers (Chapters 4, 5, and 6); the potential to use disinfection to allow for reusing and/or recycling of plastic medical devices (Chapters 6 and 7); the environmental and economic impact of reusable versus single-use devices (Chapter 7), and qualitative exploration of barriers faced when segregating and recycling used devices (Chapter 8).

It is shown that environmental and economic impacts can be reduced by using alternative materials such as reducing the use of phthalate-based plasticisers, replacing polyvinyl chloride with thermoplastic elastomer, and using calcium carbonate filled polypropylene. To reduce the environmental impact of the end-of-life stage, respiratory devices can be reused but the electricity demands during reprocessing requires reduction before being environmentally and economically favourable to single-use devices. Some environmental impacts can be reduced by disinfecting and recycling breathing systems instead of incinerating. The volume of incinerated medical waste can be reduced significantly by addressing poor waste segregation within hospitals by providing additional training and increasing availability of various coloured waste streams.

Dedication

This thesis is dedicated to my dear mum, Suzanne Webb. Throughout the ups and downs, she was always there to lend a compassionate ear; no matter for how long or what time of day. Her encouragement and wisdom helped me through the toughest of times and I am forever grateful.

Acknowledgements

Despite a PhD primarily being an individual journey of knowledge expansion and exploration, that does not necessitate that it must be a solidary one. There are many whose mere presence enhanced my whole experience and whose support kept me going even when I felt lost.

Primarily, I would like to express my deepest gratitude toward my supervisor Dr Ximena Schmidt. Her guidance not only in my professional life but also through the personal interferences has shaped me into the researcher I am today. There is no doubt that I could not have accomplished all I did without her kindness and unfaltering drive and vision. Thank you.

A special thank you to my secondary supervisor and research development advisor; Lorna Anguilano and Kun Qi. Your contributions to the operations and editing of my research has allowed for this thesis to be created to the standard at which it can currently be found. Your expertise and scientific proficiency is admirable and allowed me to grow great confidence in the work I was producing.

I am forever grateful for the people I have met and the friendships I have developed over the course of my PhD. In particular, I would like to thank Samuel East. Throughout the long hours of studying and endless rambling about my work, you were always there to listen even if you had heard it a thousand times before. I am lucky to have met you; not just for your kind spirit but also your intelligence and ability to make any situation brighter.

Furthermore, thank you Jessica Taylor, Yasmine Qudsiyeh, Claire Lines, and the chemical engineering research group for providing well needed support and for keeping my spirits high. You created a community where I felt valued and have given me memories I will always treasure.

Finally, I am incredibly appreciative to all the work conducted by members of the English National Health Service. Despite your busy schedules, you somehow found the time to go above and beyond and are credits to your organisation. Thank you in particular: Gareth Thompson, Charmaine Wareham-Voyce, the waste management and sustainability team at Hillingdon hospital, and the Greener NHS team.

Thank you.

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List of Abbreviations

The following table is used to describe the various abbreviations used throughout this thesis.

Abbreviation	Meaning
ADPe	Abiotic depletion of elements
ADPf	Abiotic depletion of fossil fuels
AP	Acidification Potential
Au	Gold
Ba	Barium
Be	Beryllium
$CaCO_3$	Calcium carbonate
CM	Cypermethrin
CO	Carbon Monoxide
CO_2	Carbon Dioxide
DEHP	Di(2-ethylhexyl) phthalate
EP	Eutrophication Potential
Eq	Equivalent
EtO	Ethylene Oxide
EU	European Union
FU	Functional Unit
FWAEP	Fresh water aquatic ecotoxicity potential
GHG	Greenhouse Gas
GWP	Global Warming potential
HDPE	High Density Polyethylene
HF	Hydrogen Fluoride
Hg	Mercury
HTM	Health technical memoranda
HTP	Human toxicity potential
ISO	International Organization for Standardization
LCA	Life Cycle Assessment
LCC	Life Cycle Costing
LCI	Life Cycle Inventory
LDPE	Low Density Polyethylene
MAEP	Marine aquatic ecotoxicity potential

MDD	Medical Device Directive
MDR	Medical Device Regulation
MHRA	Medicines and Healthcare products Regulatory Agency
MOM	Medical oxygen mask
NHS	National Health Service
NO	Nitrogen Oxide
PO_4^{3-}	Phosphate
PP	Polypropylene
RER	Region of Europe
RMEP	Raw material extraction and pre-processing stage
Sb	Antimony
SEBS	Styrene-Ethylene-Butylene-Styrene
SO_2	Sulphur Dioxide
SuD	Single-use Device
TETP	Terrestrial ecotoxicity potential
TPE-S	Styrene-Ethylene-Butylene-Styrene based Thermoplastic elastomer
ODP	Ozone depletion potential
PHT	Phthalate
PLA	Polylactic Acid
POCP	Photochemical ozone creation potential
PPE	Personal protection equipment
PVC	Polyvinyl Chloride
UK	United Kingdom
WHO	World Health Organisation

CHAPTER 1

1: INTRODUCTION

The impact of human activity on the environment has generated a significant amount of discussion over the last few decades with rising issues such as global warming, the plastic pollution crisis, and climate change regularly in the public eye (Venghaus et al., 2022). Rapid expansion of mass production to keep up with demand generated by a growing global population (Ingrao, 2023) has resulted in an alarming rate of depletion of natural resources and a large volume of waste entering the global ecosystem (Mittal and Gupta, 2015). Industrial manufacture of materials has boomed since the golden age of capitalism in the 1950s attributed to the availability of cheaper mass production methods; in particular production of synthetic materials, such as plastics (Ostle et al., 2019). The environmental implications of over-consumption has raised serious concerns over the sustainability of current practices particularly in regard to material procurement and disposal (Swearengen and Woodhouse, 2003).

The need for quick action is vital as projections presented during the 2019 United Nations General assembly high level meeting showed that environmental damage at current rate will be irreversible if not tackled within the next decade (UNCC, 2019). The medical industry poses a particular challenge due to the need to prioritise patient health over sustainability, with the COVID-19 pandemic further bringing light to these issues. One of the many ways the medical industry impacts the environment is through the need for a large quantity of medical devices (TechnoFunc, 2013). The UK is the third biggest medical device market in Europe (MedTech, 2022) selling around 600,000 different types of medical devices (GOV.UK, 2021). The medical technology sector within the UK was valued at around £24.5 billion pounds sterling in 2021 with £14 billion originating from medical devices (Statista, 2022). Due to the pandemic, respiratory medical devices experienced increased market need (Saini et al., 2022) with the demand for respirators and surgical masks (e.g., N95 and KN95) rising 140x during COVID-19's peak (Premier Data, 2021). The enforced isolation reduced the general public's exposure to viruses leading to decreased immunity to respiratory diseases and resulting in a surge of respiratory-based illnesses (in terms of frequency and level of harm) (Lancet, 2022).

The global market for respiratory and airway devices is currently valued at £39.5 billion and covers devices such as anaesthetic equipment, oxygen delivery devices, ventilators, infraglottic Devices, supraglottic devices, laryngoscopes, and resuscitators (GVR, 2022; Allied, 2022). The COVID-19 pandemic has resulted in a dramatic increase in the use of single-use medical devices of which most are incinerated due to concerns of cross contamination (Billingsley, 2019). In the UK, any medical devices deemed potentially infectious will be incinerated as outlined in the hazardous waste (England and Wales) regulations 2005 (CWIM, 2014). Despite a need for sustainable medical devices, very few studies have been published demonstrating environmentally friendly options displaying an overall general lack of knowledge on how to design sustainable medical devices (Sousa et al., 2021).

The ability to investigate the environmental impact at each stage of a product's life is essential in order to optimise sustainability. One well-established approach to analyse environmental impact is through life cycle assessment (LCA) methodology (Sousa et al., 2021). An LCA involves the acquisition and analysis of input data, such as materials and energy, as well as emissions and waste produced during a product's life. Similarly, the studies require the definition of the goal and scope, a functional unit, system boundaries, among others. The stages of a product's life cycle, considering a cradle to grave approach, are: raw material extraction, transportation, processing and manufacturing, use, and end-of-life. Other factors and steps which contribute to the overall environmental impact of the

devices should also be considered. In the case of medical devices, this may include: the sterilisation of the product before use and disinfection prior to disposal.

The availability of research within this area is growing but still lacks studies on sustainable design improvement of medical devices, comparison of improvements quantitatively using LCA methodology, the development of sustainable medical devices utilising sustainable materials, and exploration of the feasibility of reusing and recycling used devices. Throughout this thesis, specific respiratory and airway devices will be explored for their environmental impact; all of which were carefully chosen for particular reasons. The primary reason is that alongside this thesis, the author worked with a sponsor company (a large international medical device manufacturer). Real time data was used to determine which medical devices were required in large quantities by consumers and those with high demand were chosen to be explored. The possibility of evaluating a vast number of medical devices was considered but deemed unattainable in respect to the time and resources available during this project.

A further reason for the choice of these particular devices is that they were found to best allow certain life cycle stages and relevant design attributes to be explored in further detail within each chapter. For example, the breathing systems in chapter 6 were chosen as they demonstrated the possibility of manual disinfection and recycling of used medical devices. Choosing to evaluate other medical devices may have added additional complexities and reduced the available literature on the subject which would have distracted from the intended objective of the chapter.

Finally, it was ensured that the devices included throughout this thesis contained materials that were common within medical devices available on the market so that, if required, comparisons can be made between devices which contain similar materials. A good example of this is with the oxygen mask in chapter 4 which is comprised of polyvinyl chloride (a material which is found in over 25% of all single-use medical devices). Evaluating the environmental impact of the most utilised materials within medical devices will allow future researchers to better translate the findings to their own products.

1.1. Aim and Objectives

The aim of this research is to generate evidence which can be used to improve the sustainable production and management of respiratory and airway medical devices during their complete life cycle (raw material extraction, manufacture, transport, packaging, end-of-life) in order to influence policies and practices. The specific objectives set out to facilitate achievement of the aim are:

Objective 1

Evaluation of the life cycle environmental impacts of respiratory and airway medical devices to identify improvement opportunities along their life cycle.

Objective 2

Environmental and mechanical evaluation of new materials to be used within respiratory and airway devices.

Objective 3

Exploration of alternative end-of-life options of respiratory and airway devices and their environmental and economic impacts.

Objective 4

Identify barriers to improving management and utilisation of sustainable alternative methods of disposal of medical devices within UK hospitals involving stakeholder engagement.

The structure of this thesis follows an alternative format – thesis by publication. Each publication/chapter still follows a clearly linked narrative throughout and individual publications/chapters will respond to the specific objectives detailed above.

1.2. Thesis structure

This thesis consists of nine chapters. Chapter 1 is the introduction. Chapter 2 covers a literature review detailing various aspects which influence the sustainable design of medical devices and previous work within this area. Chapter 3 describes the methodologies used throughout this thesis. A mixed-method approach has been used, where both qualitative and quantitative methods are employed to fulfil the objectives.

Chapters 4, 5, 6, 7, and 8 are then studies which explore various aspects across the life cycles of numerous respiratory and airway medical devices. Some chapters address more than one objective.

Objective 1 is covered in chapters 4, 6, and 7. These will be exploring the use of Life Cycle Assessment methodology to assess the environmental impacts of currently available respiratory and airway medical devices to determine their impacts and to help identify key areas for improvement. Changes are then suggested followed by further environmental assessments to validate impact reductions.

Objective 2 is addressed in chapters 4, 5, and 6. Chapter 4 includes environmental evaluation of an environmentally sustainable material alternative to polyvinyl chloride called thermoplastic elastomer. Chapter 5 investigates a sustainable solution to virgin polypropylene by using mechanical experiments to test calcium carbonate ($CaCO_3$) as a filler. Chapter 6 includes environmental assessment of replacing polypropylene with $CaCO_3$ composite and Polylactic acid.

Objective 3 is tackled in chapters 6 and 7. Chapter 6 proposes an alternative to the incineration of used breathing systems by exploring the possibility for cleaning and subsequent recycling. Chapter 7 is a case study within a UK based hospital on the environmental and economic impact of reusable versus single-use respiratory medical devices. Life Cycle Costing methodology is used to explore the economic impacts.

Objective 4 is explored in chapter 8 where barriers and potential interventions within a hospital setting are discussed which explore sustainable end-of-life waste management of medical waste with a particular focus on waste segregation, reducing quantity of incinerated waste, and increasing recycling.

This thesis is then concluded with the conclusion chapter (chapter 9) where the findings are summarised, recommendations provided for healthcare providers, and suggestions for future work are proposed.

1.3. Novelty and intended audience

Due to the lack of research currently available in the field of sustainable healthcare, there is a range of novel findings that have originated from this work. In the bullet points below, the key areas of novelty have been provided.

- Life cycle assessments and the subsequent environmental evaluation of a variety of medical devices have been generated to add to the limited number of assessments currently available. These LCAs extensively cover the life cycle stages of the medical devices in detail and provide all impact categories per the CML-IA impact assessment methodology; something that is often missing in current literature.

- New material life cycle inventory data has been generated for commonly used materials within medical devices, particularly plasticised polyvinyl chloride and calcium carbonate filled polypropylene.
- There are only a handful of studies which explore the possibility of disinfecting and recycling medical devices instead of incineration, none of which evaluate the environmental impact of doing so. Chapter 6 fills in this gap in knowledge by using LCAs to assess manual and mechanical methods of disinfection and the overall environmental impact of then recycling.
- No studies are present within literature which use LCAs to assess the environmental impact of single-use medical devices by life cycle stage and then evaluate improvements to determine potential environmental impact savings. This thesis helps demonstrate the importance of taking a life cycle thinking approach when designing medical devices more sustainably.
- Chapter 7 is the first study of its kind to detail the exact steps required to reprocess medical devices, especially including quite impactful factors such as the sterilisation packaging used.
- Chapter 8 is the only study to have been conducted within the United Kingdom which identifies barriers to sustainable waste management within NHS facilities taking into consideration the views of the healthcare staff.

When considering the impact that this research could have, it is important to contemplate the extensive nature of sustainable healthcare and it's wide-reaching influence on not just the stakeholders directly involved but also on the general public.

Therefore, the studies conducted within this thesis have been written in a way to not solely target policy makers within the United Kingdom's National Health Service or the direct manufacturers of medical devices but also the healthcare staff that are required to partake in the generation of the environmental and economic issues as a result of their work and the general public for whom these issues impact in terms of global environmental health and taxpayer funding. By incorporating this inclusive approach, the intention is to generate the most change through the engagement of individuals and organisations across each life cycle stage of the medical devices resulting in a universal alignment towards the proposed solutions.

CHAPTER 2

2: LITERATURE REVIEW

The medical industry (also known as the healthcare industry) has been recognised as highly environmentally damaging (Pinzone et al., 2015) and shown to contribute between 4% to 5% of overall global greenhouse gas emissions (Tennison et al., 2021). Healthcare covers a wide range of public health-related services with the main sectors identified as medical devices and equipment, medical insurance, services and facilities, and pharmaceuticals (TechnoFunc, 2013).

The COVID-19 pandemic had a dramatic influence on the environmental impact of the healthcare sector (P. Jiang et al., 2021). As of February 2024, there have been over 774 million confirmed cases of COVID-19 and 7 million deaths (232,000 within the UK) (WHO, 2024). During the peak of the pandemic, an estimate of 2.6 million tonnes of medical waste was being produced globally every day (Andeobu et al., 2022). This increase in waste is largely attributed to the surge in demand of respiratory devices and personal protective equipment (PPE) with estimations that from February 2020 to July 2020, 2.3 billion pieces of PPE were distributed within England alone (GOV.UK, 2020). An estimated 89 million medical masks were required globally for the COVID-19 response each month (WHO, 2020) resulting in a worldwide shortage of medical masks and respirators (Burki, 2020) with no country able to keep up with demand in a sustainable manner (OECD, 2020).

It has been recorded that healthcare is becoming increasingly reliant on single-use devices (Macneill et al., 2020) with a large quantity of environmental impacts attributed to the material design, manufacturing, and disposal stages of these devices (Sherman et al., 2020). The World Health Organisation (WHO) has stated that most PPE is disposed of as unrecovered waste which is reported to be mainly due to hospitals incorrectly identifying all COVID-related waste as hazardous and therefore incinerating it (Wise, 2022). Adding onto this issue, disposable PPE such as masks, gloves, and gowns are made mostly from single-use plastics (SUPs) (Haque et al., 2021) with the majority disposed of via incineration or landfill (Z. Wang et al., 2021).

2.1. The Environmental problem

Irrespective of the COVID-19 pandemic, the current level of global environmental degradation has been widely attributed to the sudden growth of industrialisation (Yadav et al., 2021) correlated with an exponentially rising population, increased consumer demands in line with growing affluence and development of technology, and vast utilisation of rapidly depleting fossil fuels (Prior et al., 2012). Global recognition of the severity of the damage did not begin until the late 1940's with the United Nations (UN) starting to address the worrisome rate of the earth's ever decreasing natural resources in 1949, accounting this primarily to unsustainable demand for resources (Keong, 2021).

Sustainability efforts within the medical industry tends to focus on the mitigation of three key issues: resource depletion (Idso, 2022), climate change (Anåker et al., 2015), and pollution (Eckelman & Sherman, 2016; Lenzen et al., 2020).

Resource depletion: The current level of global resource depletion has been predicted to leave irreversible damage to the natural environment if not addressed immediately (Steer, 2014). The depletion of non-renewable resources (e.g., coal, oil, and gas) is particularly worrying as these are not quickly replenished. Exploitation of natural resources is linked to a variety of related environmental issues such as deforestation (Kaplan et al., 2009), pollution of air and water (Gutti & Aji, 2012), deterioration of nutrient rich soil (Wassie, 2020), and the decline of economic growth as

resources become scarce (Krautkraemer et al., 1998). Dwindling natural resources are predicted to have a severe impact on the ability to provide adequate quantities of medical devices (Schroeder, 2013).

Climate change: Climate change refers to the change to a weather pattern or temperature recorded to be typical for a certain area over a long period of time. Rapid change in climates (e.g., deforestation, destruction of natural habitats, pollution in water and air systems, and soil degradation) across the world has been recorded since the 19th century with 99.9% of scientific studies released between 2012-2021 agreeing this to be the result of human activity (Lynas et al., 2021). The burning of fossil fuels has been demonstrated to be the main contributing source to this shift (Perera & Nadeau, 2022). Climate change has been identified as one of the greatest challenges currently inflicted on humanity due to its wide-reaching impact, unpredictability, and potentially disastrous consequences for human and animal health such as increased risk of cancer (Henriksen *et al.*, 1990), immune deficiency disorders (Anwar et al., 2016), and biochemical changes within aquatic ecosystems (Williamson et al., 2019).

A well-studied example of climate change is global warming. Since 1901, average global temperature has risen by 1.26 degree Celsius (Z. Li et al., 2024) which is mostly credited to the atmospheric emission of numerous harmful gases (e.g., greenhouse gases (GHG), exhaust particles, hydrocarbons, and ozone-depleting substances) (Owen et al., 2006). The medical industry is currently the fifth greatest cause of GHG emissions globally (Van-Norman & Jackson, 2020).

Pollution: Pollution refers to any damaging substance which is released into the environment (Shafi, 2005). Some pollution has natural causes such as acidic water resulting from volcanic gases (Löhr et al., 2004) or smoke from forest fires (Lazaridis et al., 2008) but other pollution is man-made (Pandey S, 2006; Reddy et al., 2017). Although pollution is found more heavily in densely populated and urbanised areas, it can spread globally (Lin et al., 2014). Industrial production is the main cause of pollutants which have been linked to various cancers (Esposito et al., 2010) and respiratory and cardiovascular diseases (Kim et al., 2018). Pollution mitigation in the context of medical devices focuses largely around the generation of medical waste (Macneill et al., 2020) and reducing toxic emissions to air during manufacturing, maintenance, and disposal; particularly GHG emissions (Sherman et al., 2019).

Addressing these issues of sustainability within the medical industry comes with its own unique set of challenges. The primary goal of healthcare is to prioritise the health of the patient posing a particular problem for sustainability as addressing environmental issues are routinely side-lined (DoH, 2013). A big issue is the deficiency of available data with most healthcare services and products lacking studies of their environmental impact (Kandasamy et al., 2022).

2.2. State of the art – Environmental Life Cycle Assessment of Medical Devices

Life Cycle Assessment (LCA) methodology has been suggested by the International Organization for Standardization (ISO) as the best way to determine environmental impact (Kumar et al., 2020). LCA analyses the environmental impact across the life cycle of a product or service, accounting for the materials and energy inputted and the emissions and waste given off when producing a product or service (Finnveden et al., 2009). The lifecycle of a product consists of its life cycle stages e.g., raw materials, manufacture, transportation, use, and end-of-life. Other factors may also be included depending on the individual requirements of the assessment such as packaging and extra processing steps (e.g., sterilisation and reprocessing). Environmental impacts can then be separated by each life cycle stage to identify the most impactful areas for improvement. LCAs also help weigh the severity of each impact in accordance with scientific literature (Curran, 2006). Utilisation of LCA methodology

for medical devices is a growing tool but is still fairly limited. The extent of knowledge around the environmental impact of medical devices is unknown but with the lack of studies being available, it is safe to assume to be an insufficiently studied topic (Svensson, 2017).

Currently there are 20 studies available on the environmental impacts of medical devices using LCA methodology. Three studies compare medical devices that have the same function but are made of varying materials to identify the least environmentally impactful: surgical masks (Schmutz et al., 2020), hysterectomy equipment (Unger et al., 2017), and custom procedure packs (Campion et al., 2015). One study focuses on providing baseline environmental impact data for hospital gowns in order to provide figures on impact generated within hospitals (Rizan, Reed, et al., 2021).

The majority of the literature (16 studies) explores the environmental impact of medical devices by assessing single-use and reusable devices. These include: anaesthetic equipment (McGain et al., 2017), drug trays (McGain et al., 2010), laryngeal masks (Eckelman et al., 2012), laryngoscopes (Sherman et al., 2018), blood pressure cuffs (Sanchez et al., 2020), central venous catheters (McGain, McAlister, et al., 2012), spinal fusion equipment (Leiden et al., 2020), dental burs (Unger & Landis, 2014), ureteroscopes (Davis et al., 2018), vaginal specula (Donahue et al., 2020; Rodriguez Morris & Hicks, 2022), hospital gowns (Hicks et al., 2016), drapes (Dettenkofer et al., 1999), surgical scissors (Ibbotson et al., 2013), and sharps containers (Grimmond & Reiner, 2012; McPherson et al., 2019).

All of these studies took the form of comparative LCAs where the total impact from the use of one type of single-use device was compared to the total impact of switching to using reusable versions. This meant that for many of these studies, specific impacts across the lifecycles of the single-use devices was not broken down and assessed. Five of the studies used a functional unit that covered a whole facility or procedure performed without specifically mentioning the number of devices that were calculated. The remaining 11 studies compared the impact of one reusable device and its equivalent number of single-use replacements.

Out of these 20 studies, 14 were conducted using the LCA software Simapro. One used Umberto NXT, and the remaining five collected environmental data on the materials and processes from independent sources of data then compiled these impacts together without the use of a specific LCA software. 10 of the studies which used Simapro provided up to 10 impact categories for assessment including: Global warming potential, eutrophication, ozone depletion, photochemical ozone formation (smog), acidification, carcinogenic and non-carcinogenic effects, respiratory effects, ecotoxicity potential, and depletion of abiotic resources. The remaining studies only provided global warming potential (kg CO_2 eq.) and water usage. Even in the studies which included all 10 impact categories, global warming potential was emphasised as the most important. If figures were included within the study but not for every category, GWP was always one of the figures shown. Additionally, all of the studies which did not use an LCA software and instead collected independent sources of data did not provide more than the global warming potential or water usage as metrics for comparison. This demonstrates the relationship between using an LCA software and being able to produce additional impact categories for assessment.

Once the environmental impact per life cycle stage has been identified, very little research then alters medical devices in order to provide sustainable variations. All of the previous papers evaluate medical devices which are already in use but do not propose design alternations and then assess these further. The few sustainable versions of medical devices currently available include a sustainably designed dialyser (Hanson & Hitchcock, 2009) and a sustainable syringe by Cambridge

Consultants Limited called 'Syreen' (Moultrie et al., 2015). This highlights a need for environmental evaluations of medical devices and subsequent alterations to produce sustainable alternatives.

There is a gap in literature of studies providing extensive investigation pinpointing what input or emissions in each life cycle stage is causing the greatest impact. Five of the 20 aforementioned LCA papers did not include a breakdown of how each life cycle stage contributed to the overall environmental impact; even though all studies included every stage in their calculations and had a cradle-to-grave system boundary. Of the remaining 15, one paper found manufacturing to be highest, and the final 14 papers found that the raw materials stage was the most impactful.

Despite many of the studies including detailed life cycle inventories of the materials present within the devices, there was little investigation into which of the materials were providing the majority of the impacts. Only four of all studies available discussed the contributions the different materials had on the overall environmental impact with the remaining 16 having no mention of this. This hinders the possibility for manufacturers to identify which materials they should be mitigating during sustainable design considerations.

2.3. Materials and energy use

Each material has its own unique environmental impact. Some materials are environmentally harmful due to their extraction and manufacturing processes; for example, mining coal and gold has been attributed to air pollution and toxic metal leakage into local waterways (Scott et al., 2004). Some materials may be environmentally impactful by being energy intensive. Embodied energy is the term used to describe the amount of energy a material requires throughout its lifecycle (Serranti & Bonifazi, 2019). A material with high energy and electricity requirements will also have increased manufacturing emissions and costs (Cabeza et al., 2013). As of 2016, around 75% of energy used by European countries still originates from non-renewable sources (Asiedu et al., 2021). Many materials also require additives in order to become processable (Hahladakis et al., 2018), some of which are harmful to the environment and human health. For example phthalates, which are regularly used within many medical devices, are now increasingly regulated due to being hormone disrupting and causing neurological harm to foetuses during pregnancy (Clayton et al., 2021). Ideally, materials which do not require the use of harmful additives should be used but manufacturers may be reluctant to change their machinery and practices due to cost and logistics (Anastas & Eghbali, 2009).

Polymers have gained particular attention by environmentalists due to their use of petrochemical feedstocks and accumulating volume of waste. Polymers can be found in nature, such as cellulose or chitin, or be made synthetically using crude oils or natural gas (Brydson, 1999). Plastics are a popular subset of polymers with more than 99% of plastics being made using fossil fuels (Momani, 2009). Plastics are favoured due to their desirable mechanical properties and as an attractive low energy intensive alternative to metal and glass. By 2021, global plastic production reached over 390.7 million metric tons per year (Statista, 2022). In 2019, 860 million tonnes of CO_2 were released in order to produce and incinerate global plastic consumption (compared to total global CO_2 emission of 36 billion tonnes). It has been predicted that this will triple by 2050 (Arkin et al., 2019).

Despite many plastics being recyclable, only 9% of plastic is recycled globally (Geyer et al., 2017) with the rest mostly landfilled or incinerated (Shen & Worrell, 2014). Plastic pollution is accumulating at a frightening rate with, as of 2021, over 14 million tons of plastic being discarded into the ocean each year and currently constituting 80 percent of the total marine debris (Schmaltz et al., 2020).

Almost half of all plastics are known as single use plastics (SUPs) due to being disposed of after one use (Varkey et al., 2021). SUPs allow for hygienic and safe protection from potential disease-causing germs which is particularly important for the medical industry when reducing cross contamination (Das et al., 2021). The main issues with SUPs are based around the overconsumption of petrochemical feedstocks and accumulating waste pollution end-of-life (Leissner & Ryan-Fogarty, 2019). A lot of oil-derived plastics do not biodegrade resulting in inevitable accumulation (Kortei & Quansah, 2016). There is also a growing concern over 'microplastics' which are small pieces of plastics with a diameter between 1 and 5 millimetres. High concentrations of microplastics can lead to a range of negative effects such as altering the biophysical properties of soil (Narancic & O'Connor, 2019) and harming sea life by decreasing reproduction performance, disrupting metabolic functions, and changing physiology (Anbumani & Kakkar, 2018). Due to their size, it is extremely difficult to retrieve microplastic pollutants so are therefore left to accumulate within the environment (Clayton et al., 2021). The best way to avoid future generation of microplastics is to reduce the consumption of plastics in the first place (Prata, 2018).

The most commonly produced fossil fuel derived plastics used within medical devices are Polypropylene (PP), High-Density Polyethylene (HDPE), Low-Density Polyethylene (LDPE), and Polyvinyl Chloride (PVC) (Czuba, 2014). PP, HDPE, and LDPE are overall fairly safe plastics with low embodied energies and are recyclable (Alsabri et al., 2022; Muthusubramanian et al., 2023). The main environmental conflict around PP, HDPE, and LDPE revolves around the depletion of fossil fuels, the need for natural gas, and slow degradation rate leading to accumulation of plastic-based waste (Pelegrini et al., 2019; Tähkämö et al., 2022). These three materials have GWPs of 1.93 to 1.98 kg CO_2 eq. per one kg of material (Alsabri et al., 2022; Bordón et al., 2022) as can be seen in Table 1.

Just over a quarter of all single-use plastic medical devices are made from PVC (Bernard et al., 2014). The main environmental issues when discussing PVC is the use of plasticisers and the release of chlorides when incinerated (EU, 2000). The majority of PVC-based medical devices contain plasticised PVC with phthalates being the most commonly used plasticiser (Nagorka et al., 2022). Phthalates have been increasingly restricted due to concerns around leaching of plasticisers (Wei et al., 2019), risk of infertility and birth defects (Niermann et al., 2015), and being potentially carcinogenic (Caldwell, 2012). This has increased pressure on manufacturers to find material replacements with the same properties as PVC.

Sustainable alternative materials to fossil fuel derived plastics are already in production. Some of these materials are sustainably sourced; e.g., renewably sourced feedstock, bio-based (made from biological matter), have low embodied energy, or made from recycled materials. Others are sustainable due to their end-of-life practices such as being recyclable, biodegradable, or compostable. Currently, landfill is the most popular method of waste disposal for plastics (including medical and non-medical) (Krook et al., 2012) but since most plastics take a long time to decompose, this leads to accumulation of plastic waste and environmental pollution (Visvanathan, 1996). Any potentially usable materials within a discarded product can no longer be introduced back into industrial processes negating any further attempts to conserve valuable material. Another popular form of waste disposal is incineration. The benefits of incineration include reduction of waste volume, energy recovery, and the destruction of any potentially harmful contaminants on the surface of the plastic (WIPH, 2000). However, incineration has been reported to negatively impact human health and the environment through the harmful pollutants emitted when heating certain types of plastics (Sharma et al., 2013).

In order to reduce reliance on landfill and incineration, recycling has become increasingly popular. Many plastics can already be recycled but problems arise such as the logistics around the collection

of plastic waste, the identification and separation of different types of plastics, and issues of contamination. Repeat recycling can also affect the mechanical properties of the material raising concerns around performance (Mele et al., 2023).

Some materials can be disposed of via use of biological processes (e.g., biodegradation and composting) where materials are broken down into environmentally acceptable products such as carbon dioxide, water, oxygen, or biomass through the use of biological species (Narancic & O'Connor, 2019). Composting requires specific environmental conditions in order to break down, whereas biodegradation will occur naturally. Blending of different biodegradable plastics can cause issues due to the difficulty of separating biodegradable from potentially recyclable polymers. It is also important to consider whether a biodegradable material will maintain its strength over its expected life span.

Below is an exploration of sustainable alternatives to traditional polymers that are available on the market; some are already being used for medical applications whilst others are being trialled. Life cycle assessments have been conducted previously on each of these materials, the results of which will be included within the section for each material below. A summary of the key issues is shown in Table 1 and a visual colour-coded table of different properties of each material is summarised in Figure 1.

Table 1: Summary of the key environmental issues, including sustainability data, availability, and mechanical issues of the four popular plastics used within medical devices (PP, LDPE, HDPE, PVC) and the sustainable material alternatives available on the market.

Material	**Main issues**	**GWP** ***(kg CO_2 eq./ per 1 kg)***	**EoL waste management**	**Availability**	**Specific mechanical properties issues**
PP	Fossil fuel depletion, Plastic pollution	1.95	Recyclable	High	No major issues
LDPE	Fossil fuel depletion, Plastic pollution	1.98	Recyclable	High	No major issues
HDPE	Fossil fuel depletion, Plastic pollution	1.93	Recyclable	High	No major issues
PVC	Toxic waste fumes, additives	2.51	Recyclable	High	No major issues
PLA	Cost, some poor mechanical properties	0.6	Recyclable, compostable, and biodegradable	Too high demand for supply	Poor plasticity at low temps (~60°C), low toughness, low ductility
PHA	Cost, lack of production facilities	-2.3 to -1.4	Recyclable, compostable, and biodegradable	Poor	No major issues
Starch	Poor mechanical properties, very sensitive to moisture	1.9	Recyclable, compostable, and biodegradable	High	High water vapour permeability and high viscosity
Chitin	Cost, water insolubility, time consuming production	7	Recyclable, compostable, and biodegradable	High	Insoluble in water, limited processing ability
Cellulose	Cost, Poor mechanical properties	0.75 to 1	Recyclable, compostable, and biodegradable	High	Insoluble in water, limited processing ability
Bio-PP	Poor production capacity	-0.3	Recyclable	Very poor	No major issues
Bio-PE	Poor production capacity	1.6 to 2.1	Recyclable	Too high demand for supply	No major issues

PCL	Cost	1.02	Compostable and biodegradable	Poor	Restricted use in high temps
PBAT	Cost, low thermo-mechanical properties	4.2	Recyclable, compostable, and biodegradable	High	Low thermo-mechanical properties
PBS	High cost, low availability	6.6	Compostable and biodegradable	Poor	Poor strength when blended with cheap materials
PEF	Poor production capacity	1.17	Recyclable	Very poor	No major issues
Recyclate	Contamination, diminished mechanical properties, availability	Depends (e.g., rPP 0.53, rPET 0.91, rHDPE 0.56)	Recyclable	Too high demand for supply	Unpredictable depending on source
Fillers	Poorer mechanical properties at higher filler percentages	Depends (e.g., $CaCO_3$ 0.04, Jute 0.57, Kenaf 0.45)	Recyclable	High	Unknown properties at high filler %

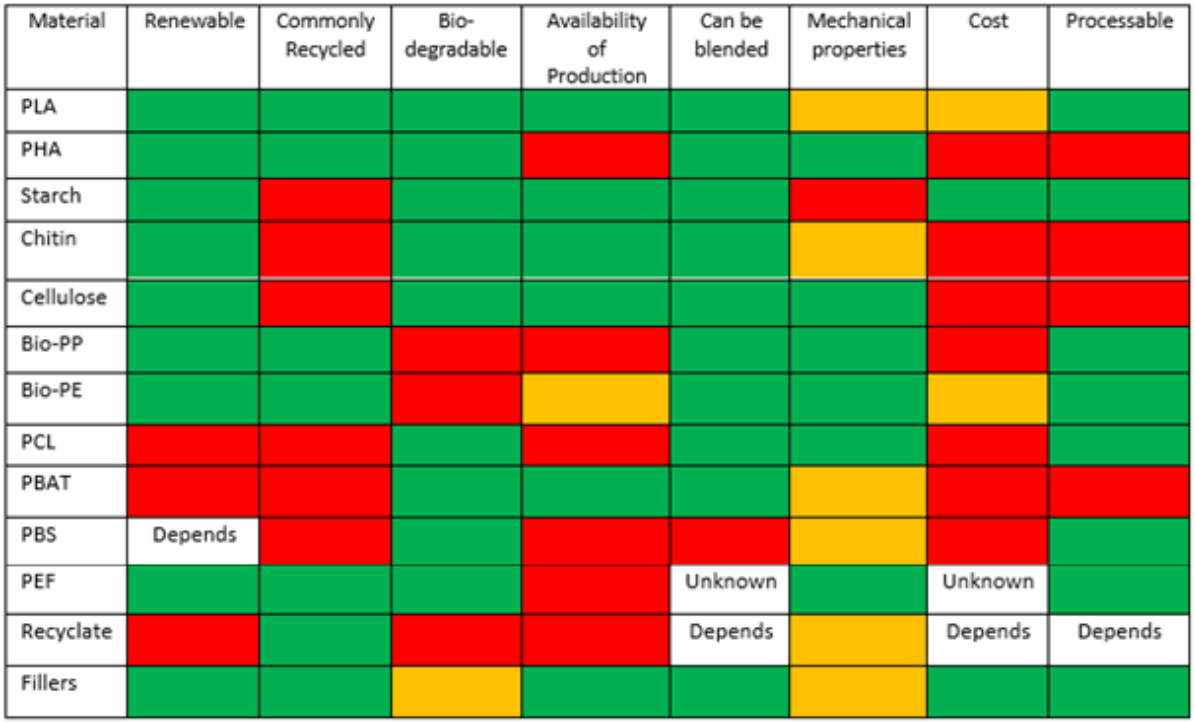

Figure 1: Visual representation of properties found within sustainable materials available on the market. Colour scale use: Red – Poor, Yellow – Average, Green – Good.

Polylactic Acid (PLA)

Polylactic acid (PLA) is a biopolymer derived through the fermentation of renewable resources (e.g., corn and wheat) (Jamshidian et al., 2010) popular due to its recyclable, compostable, and biodegradable properties (Dubey et al., 2017) as well as its absorption of CO_2 from the atmosphere during the growing phase of its renewable agricultural sources. Its mechanical and thermoformable properties are similar to typical synthetic polymers (Madival et al., 2009), but its higher cost means it is typically reserved for higher value films, containers, and paper coatings. Increased customer demand for PLA is projected to increase affordability. Its non-toxic nature also makes PLA a popular choice for biomedical devices such as implants (Carvalho et al., 2020), face masks (Soo et al., 2022),

ventilators (DeStefano et al., 2020), and respirators (Papavasiliou & Chatzimichail, 2021). Previous LCAs on PLA have found that it has lower fossil energy use and greenhouse gas emissions than petrochemically-based polymers but higher eutrophication and water acidification due to the growth and conversion of the biobased resources into plastic (Rezvani Ghomi et al., 2021). PLA has some undesirable mechanical properties such as plasticity at relatively low temperatures (~60°C), low toughness, and low ductility. The effect of these characteristics can be minimised e.g., through copolymerization, plasticization modification, the addition of reinforcing phases (Elsawy et al., 2017), or blending (Carvalho et al., 2020).

Polyhydroxyalkanoates (PHA)

Polyhydroxyalkanoate (PHA) is a natural polyester produced via bacterially fermented lipids and sugar. Its mechanical properties resemble traditional plastics (e.g., PP) and is recyclable, compostable, biodegradable, and non-toxic (Mukherjee & Koller, 2023). PHA is commonly blended with conventional plastics to make bottles, containers, packaging films, and medical applications (e.g., sutures, bone marrow scaffolds, and bone plates (Madison & Huisman, 1999)). PHAs are biocompatible making them a potential choice for use within the body (Kalia et al., 2023) but lack of production facilities, strict requirements for sterile fermentation conditions, and high production costs (Anjum et al., 2016) has limited large-scale commercialisation (Kovalcik et al., 2017). If a PHA strain that has a less strict fermentation process is ever developed, PHA could one day be produced affordably (Y. Wang et al., 2014). Previous LCAs on PHA are currently inconclusive due to the many ways PHA can be synthesised which affects its environmental impact (Narodoslawsky et al., 2015). Studies show that whether PHA is less environmentally impactful than petrochemical-based polymers depends heavily on the manufacturing methods used (Asunis et al., 2021; Koch et al., 2023; Saavedra del Oso et al., 2023).

Polycaprolactone (PCL)

Polycaprolactone (PCL) is a fossil fuel based aliphatic polyester currently used for biodegradable packaging (Bartnikowski et al., 2019), biomedical implants, and prolonged drug release carriers (Sisson et al., 2013) due to its biocompatibility and high degradation rate (Manivasagam et al., 2019; Narayanan et al., 2016). PCL has a low melting point providing low viscosity and ease when processing (Al Hosni, 2019) but restricts use in elevated temperatures (McKeen, 2012). PCL is unlikely to be used as a replacement for traditional plastics due to its extremely high cost but has been prototyped for face masks (Ferreira et al., 2022) and radiotherapy masks (Aoyama et al., 2021). Very few environmental studies have been conducted on PCL but current research shows that the environmental impacts vary greatly depending on the method of synthesis used and so overall conclusions on impact cannot yet be made (Ang et al., 2021).

Polybutylene adipate terephthalate (PBAT)

PBAT is a fossil-fuel derived biodegradable biopolymer with desirable mechanical properties similar to those of LDPE and particularly high elongation at break (over 600%) (Bordes et al., 2009; Nagarajan et al., 2013). Despite the attractiveness of this biodegradable polymer, high cost and low thermo-mechanical properties limits its use on a large scale. As combinations of polymer blends are further explored to improve mechanical properties and reduce cost, PBAT may become increasingly available (Ferreira et al., 2019). A further life cycle assessment of unblended PBAT has not yet to be conducted but previous studies have shown that the global warming potential of PBAT is much higher than other polymers (Choi et al., 2018). Within the medical sector, PBAT is primarily used for tissue engineering (Fukushima et al., 2012) and medical packaging (Kantor-Malujdy et al., 2022). PBAT has been studied as a potential material for medical devices due to its biodegradability but so

far has faced issues such as being unsuitable for certain types of sterilisation (Zhao et al., 2019) and unsatisfactory mechanical properties (Pinheiro et al., 2017).

Chitin

Chitin is the second most abundantly found naturally occurring bio-based polymer sourced from the exoskeleton of invertebrates, yeast, and fungi cell walls. Chitin is biocompatible, biodegradable, nontoxic, non-polluting, and has strong mechanical properties making it a popular choice for biomedical applications such as for artificial skin, bones, and drug carriers (Ravi-Kumar, 2000). Practical applications of chitin are extremely limited due to its water insolubility which also limits its reactivity and processability (Agarwal, 2020). Further research is required to improve the chitin's ability to block moisture and find ways to produce it economically at scale. There is no indication of long-term accumulation of chitin in nature meaning the process of isolating chitin from the exoskeletons is hands-on, time-consuming (Elieh-Ali-Komi & Hamblin, 2016), and expensive (Rao et al., 2014). LCAs have shown that the location of chitin production is an important factor on its overall environmental impact. Due to the need to harvest large quantities of exoskeletons, typically from aquatic animals, water requirements are high and result in greenhouse gas and ammonia emissions from the need for fertiliser (Muñoz et al., 2017).

Starch

Starch accounts for around 20% of global bioplastic production (European Bioplastics, 2020). Starch is a natural polymer with a low carbon footprint derived from renewable polysaccharide-based sources such as corn, wheat, and rice. It is favoured for its biodegradability, biocompatibility, and non-toxicity (Marques et al., 2002). Starch is low cost but has high water vapour permeability (Ribba et al., 2017) and high viscosity (T. Jiang et al., 2020) resulting in poor flow properties (Xie et al., 2009). Plastics made from starch have been shown to reduce greenhouse gas emissions and energy usage but increase eutrophication and land usage compared to traditional plastics (Broeren et al., 2017). Starch is favoured for applications such as drug carriers but displays lower tensile strength under higher moisture conditions. Furthermore, pure starch is known to be brittle (Ghanbarzadeh et al., 2011). Creating starch-based composites or adding plasticisers can decrease the moisture sensitivity and increase the ease of thermal processing (Jiang et al., 2020). These blends can be used in applications such as compostable bags, food containers, packaging, films, and foams, (Jiang et al., 2020). Early-stage research is being conducted on starch as a potential wound dressing (Poehnert et al., 2015) and for tissue engineering (Beilvert et al., 2014) but nothing yet for medical devices.

Cellulose

Cellulose is the most abundant natural-polymer and is extracted from renewable sources such as cotton, bamboo, wheat, and bagasse. It is biocompatible, biodegradable, chemically stable, light weight, and exhibits superior flexural and tensile properties as well (Kumari et al., 2007). Cellulose, however, is insoluble due to its crystallinity and thus unable to be processed in traditional machinery. To allow cellulose to become processable it can be reacted to produce esters or ethers which are then modified with plasticisers. Processable cellulose can be used as films or fibres (Gilbert, 2017) but due to the added expense, is rarely used for commercial applications (Averous & Pollet, 2014). Cellulose has been shown to have a lower global warming potential and fossil fuel use to petrochemical plastics but the processing method used can greatly affect water and energy requirements (Foroughi et al., 2021). Like starch, Cellulose has promising use within tissue engineering and as a wound dressing (Petersen & Gatenholm, 2011) but most likely not within medical devices due to its lack of processability (Chandel et al., 2023).

Bio based bioplastic: Bio-Polyethylene

Bio-Polyethylene (Bio-PE) has chemical, physical, and mechanical properties identical to its petrochemical counterpart but its monomer, ethylene, is derived from glucose obtained from biological feedstocks (e.g., sugar beet, sugarcane, maize, and wheat) which is fermented and distilled to form bioethanol then dehydrated to ethylene and polymerised to bio-polyethylene (Kang & Lee, 2015). The degree of branching of the resulting Bio-PE can be controlled during polymerisation to create bio-HDPE and bio-LDPE. Bio-PE can be used in the same processing equipment and in the same applications as traditional PE such as for films (bags, pouches, packaging), blow moulded and injection moulded parts (e.g., containers), tubing, and any medical devices that currently use PE. Originally Bio-PE was considered too expensive for industrial use but starting from 2008 the price of sugar derived ethanol became competitive with the price of crude oil (Gotro, 2014). As demand for bio-based plastics grows, increase in production volume capacity can be expected as acquiring the material is currently a major struggle. It is hoped that a bio-based alternative to polypropylene may also one day become viable but, as of yet, the commercial production of Bio-PP has accrued limited results (Siracusa & Blanco, 2020). No peer-reviewed LCAs have been conducted on Bio-PE due to its lack of availability. However, the Bio-PE manufacturer 'Braskem' released an LCA which found that all impact categories except global warming potential and ecotoxicity potential increase when using bio-PE compared to petrochemical-based polyethylene (Braskem, 2016).

Biodegradable polyester (PBS)

Poly (butylene succinate) (PBS) is a fossil fuel derived polyester with mechanical properties comparable to PP and PE (Abdelghafour et al., 2021). PBS displays many favourable properties such as melt processability, thermal and chemical resistance, flexibility, gas barrier properties, and biodegradability (Al Hosni, 2019). PBS is also biocompatible and non-toxic making it a potential alternative material for use within biomedical applications (Mtibe et al., 2023). PBS is used in many applications such as films, containers, injection moulded items, and disposable medical devices (Rafiqah et al., 2021). One of PBS' constituents, succinic acid, is produced through electrolysis (Luyt & Malik, 2018) but recently can be synthesised via the fermentation of sugars. The main downsides of PBS are its cost and limited availability resulting in it rarely being used commercially (Rafiqah et al., 2021). The greenhouse gas emissions of PBS have been shown to be very high compared to traditional polymers (Rajendran & Han, 2023) but is overall environmentally non-toxic (Rafiqah et al., 2021). PBS can be blended with cheap material bases to lower cost but issues can occur within the bonding between the fillers and the PBS matrix (Mochane et al., 2021).

Polyethylene Furanoate (PEF)

Polyethylene Furanoate (PEF) is a thermoplastic polyester chemically analogous of polyethylene terephthalate (PET) and has high strength, high toughness, good heat resistance, and desirable gas barrier properties. It also has attractive thermal properties due to its lower melting point and higher glass transition temperature than PET (Polymerdatabase, 2018). It is non-toxic, easily recycled (Werpy et al., 2001), and has promising applications as a replacement for traditional PET packaging such as bottles, films, and trays (CROW, 2018). Once commercial production is established and is cost effective, PEF will become a very promising polymer. Currently no studies explore PEF as a potential material for medical devices mainly due to its lack of production and availability on the market.

Recyclates

Recycled polymers (recyclates) can be mixed with virgin material to reduce virgin resource usage, lower greenhouse gas emissions, and extend the life cycle of used products (Asdrubali et al., 2012). The maximum percentage of recycled material that can be present before performance and

appearance is compromised varies between materials (e.g., in rHDPE <45%) (BPF, 2020). In general, polymers can be recycled around three times before the quality (e.g., appearance, flexibility, and strength) becomes too poor (Baffour-Awuah et al., 2020). Sorting and collecting recyclable materials is also an issue, for example, PET and HDPE are regularly collected whereas PP and PE are less so. PP is often recycled into non-food-packaging applications, such as crates and bins, or ends up in landfills or incinerators. This is due to a number of factors such as not being cost effective compared to virgin material, a lack of processing plants, and difficulty separating food-grade PP from non-food-grade PP (i.e., contamination) (Kosior, 2020). Few medical devices consist of recycled plastic due to issues of contamination (Undas et al., 2023) from previous uses disallowing recycled plastics of medical grades and the risk to patient of potential diminished mechanical properties (Rosli & Ahmad, 2021).

Fillers

Polymers can be mixed with sustainable fillers (e.g., Calcium carbonate, Mica, and Talc) to create blends with lower fossil fuel content, lower carbon footprint, and lower cost (Chang et al., 2021). Polymers blended with fillers typically have inferior mechanical and thermal properties compared to the original polymer (De Luca Bossa et al., 2020) but the extent to which the properties differ is yet to be fully explored. Filled polymer blends are not yet common within the medical device manufacturing industry but has shown promise in non-healthcare sectors (Myllytie et al., 2016; Mohanty et al., 2018).

2.4. Medical device material standards

The materials that respiratory and airway medical devices consist of has changed significantly over time. Very early-day devices were quite rudimentary in design and materials used. Some examples include the first anaesthetic mask (the Schimmelbusch mask) which was made of a metal wire frame covered in gauze fabric (Ball, 1995), oxygen masks which utilised rubber for an air-tight fit to the patient face (Leigh, 1974), and glass IV bottles (Czuba, 2014). These types of materials were used until the 1970s, however, the widespread development of plastics in the mid-20th century revolutionised the design of medical devices (Czuba, 2014). Plastics were shown to have very desirable mechanical properties competitive to those of metal, glass, and rubber whilst being cheap to produce (Andrady & Neal, 2009). Metal frames covered in fabric were replaced with polyolefins and PVC was used to replace rubber and glass IV bottles (Czuba, 2014).

When medical devices are approved for sale, legal regulations place emphasis on the device meeting operational standards (e.g., being non-toxic and biocompatible in order to be classed as medical grade as dictated by ISO 10993 standards (ISO, 2018)) instead of focusing on the specific materials being used. Therefore, if sustainable materials can be shown to meet these operational standards, there is the possibility that alternatives could be used in place of traditional plastics.

For some medical applications, less environmentally harmful materials are already being used. For example, biodegradable materials such as PLA, chitosan, and PCL can be used in implantable monitoring devices (Hosseini et al., 2021) and PHA and PBS in tissue engineering (Narancic et al., 2020). However, when it comes to external devices (e.g., masks and tubing), bioplastics are a lot less common place due to numerous concerns such as low mechanical strength, high water permeability, low thermal stability, and high brittleness (Kong et al., 2023). Some sustainable materials may be more challenging than others to become acceptable for use within medical devices. For example, biodegradable polymers tend to have lower lifetime durability (Moshood et al., 2022), be negatively affected by sterilisation (Zhao et al., 2019), and require segregation from non-biodegradable waste (Song et al., 2009).

With the need for sustainability within healthcare becoming more urgent, a growing acceptance of sustainable material alternatives to petrochemical based plastics can be expected. More studies being released exploring the mechanical properties of environmentally friendly materials will help drive the utilisation of appropriate replacements within medical devices. This will help ensure there is a balance between the mechanical and environmental demands of the medical industry.

2.5. Regulations and Policies

This section discusses the legal regulations at play when designing medical devices. An overview of environmental considerations are detailed followed by the legal requirements during design of medical devices which may affect how sustainable design can be implemented. The specific regulations required within the United Kingdom are also provided.

2.5.1. Overview of Environmental Regulations

An increasing number of businesses attempt to exaggerate the environmental benefits of their product or services in order to increase sales in what has been termed 'Greenwashing' (Marciniak, 2009). This illustrates the importance of guidance, regular data measurement, and imposed regulations when declaring if something is sustainable (Delmas & Burbano, 2011). Most international environmental regulations have been formed over the last 120 years with very few existing before the 20th century (*Environmental Law*, 1981). The first substantial law protecting the environment was the 1969 National Environmental Policy Act which spurred the formation of the Environmental Protection Agency (EPA) in 1970. In 1995, the UK established the Environment Agency (EA). Arguably the largest international organisation is the United Nations (UN). There are 193-member states which meet every 2 to 3 years at 'Conference of the Parties' (COPs). Some of the biggest and most recognisable international laws have been passed via action by the United Nations. For example, the Kyoto Protocol was signed in 1997 which required participating countries to limit their emission of greenhouse gases to agreed targets. This was originally aimed at developed nations but was extended to developing nations via the Paris agreement in 2015. In September 2015, The UN released a list of 17 Sustainable Development Goals (SDGs) which specify the actions countries should take to encourage sustainable development by 2030 (Güney, 2019).

Another major player in the global regulation of environmental protection is the European Union (EU). The EU regularly releases and amends environmental policies and legislation such as the 2003 Directive on the Restriction of use of certain Hazardous Substances (RoHS) and The Waste Framework Directive which ensures waste is disposed of safely.

Outside of these International organisations, each country may have their own environmental laws. Below is an example of laws currently in effect within the United Kingdom:

Regulation	**Date**	**Description**
Control of Pollution Act	1974	Covers issues such as Air, Noise, Water, and Land pollution/waste.
Energy Act	1976	Requires energy providers to meet set energy efficiency requirements including reducing CO_2 emissions.
Environmental Protection Act	1990	large legislation (164 sections) covering topics including: Pollution Control, Land waste, Statutory Nuisances, and Clean Air control.
Environment Act	1995	Air quality, water quality, contaminated Land, and waste.
WEEE Directive	2007	Decrease production of electrical waste and encourages reusing, recycling, and recovering.
Climate Change Act	2008	A long-term framework aiming to bring down UK's carbon emissions to net zero by 2050.
Environmental Permitting Regulations	2010	Regulate storage, transport, and disposal, and treatment of hazardous waste.
The Environment Act	2021	The United Kingdom's framework for environmental protection and environmental targets after leaving the EU.

2.5.2. Medical Devices Regulations

One of the main reasons for an absence of sustainably designed medical devices is a lack of knowledge around lower environmentally impactful design options due to insufficient previous research as well as inadequate pressure from regulatory agencies to require manufacturers to reduce the environmental impact of their medical devices (Kumar, 2021). The slow adaptation of sustainable manufacturing practices by the medical industry is also in part due to the highly regulated nature of medical devices and concerns of safety. In order to minimise risk of contamination and potential harm to patients, current governmental guidelines tend to encourage the use of single-use medical devices and incineration end-of-life despite environmental concerns around accumulating waste and environmental impact of incinerators compared to recycling or reuse (Kumar, 2021).

Within Europe, the main governmental body enforcing the legal regulations of medical products is the European Commission (EC). The EC introduces regulations in the form of European Directives. Most respiratory and airway masks are regulated under specific EU directives namely the Medical Devices Directive (MDD) 93/42/EEC. In 2021, this directive was updated by the EU Medical Devices Regulation (MDR) 2017/745. Some masks are considered PPE and therefore also come under the EU Regulation 2016/425 (PPER). During the product design phase, The Eco-design Directive 2009/125/EC may also be consulted as to optimise the energy requirements of the device (Svensson, 2017).

Some more generalised regulations are the International Organization for Standardization (ISO) standards. The most common standards for medical devices are ISO 10993, 14971, and 62304. When designing medical devices, focus is placed on the safety of the device for its intended purpose instead of focusing on specific design or material choices. ISO 10993 is used to evaluate the biocompatibility of the devices in order to minimise risk to biological organisms (ISO, 2018). ISO 14971 is a standard for risk management during the use of the medical devices in the context of the specific medical procedure it is intended for (ISO, 2019c). Finally, ISO 62304 is used to regulate the software used to produce medical devices or embedded within them (IEC, 2015). The UK's Department of Health and Social Care (DHSC) also provides the ISO standard EN ISO 13485:2016 as a quality management standard for medical devices but does not require environmental consideration during the medical device design phase (Kumar, 2021). The ISO 14000 series may be applicable for the management of environmental design and monitoring but is not strictly required, only advised.

Devices may also be required to adhere to specific requirements set by individual countries. For example, respirators within the United States are required to be evaluated by the US quality standards and approved by National Institute for Occupational Safety and Health (NIOSH) Federal agency. Devices within the EU which fall under the guidance of the MDD and MDR must perform to certain safety and performance standards and appropriately CE-marked to demonstrate conformity with EU health, safety, and environmental protection standards along with a declaration of conformity provided by the manufacturer (French-Mowat, 2012).

UK Medical device Regulations

Within the UK, the Health and Safety Executive (HSE) governmental agency enforces the UK Medical Device Regulations 2002 as its primary medical device regulations and to transpose the EU MDD and MDR. The UK develops its regulations according to the 2021 Medicines and Medical Devices Act (Kumar, 2021). The approval of medical devices onto the UK market is overseen by the Medicines and Healthcare products Regulatory Agency (MHRA) which is an executive agency of the DHSC

(Moultrie et al., 2015). The DHSC also issues the Health Technical Memoranda (HTM) which covers safety, device reprocessing, and safe management within the healthcare sector. The Environment Agency (EA) is the main regulatory entity overseeing environmental and waste regulations within England. The key concepts covered within the regulations for clinical waste are the segregation of waste depending on defined classifications, correct storage and disposal routes, and ensuring thorough documentation of transferring waste between organisations.

2.5.3. UK National Health Service

Healthcare within the United Kingdom is provided by the UK National Health Service (NHS). The main supplier of products and logistical services to the NHS is the NHS Supply Chain. It is currently estimated that the NHS has a yearly CO_2 footprint of 21 million Tonnes CO_2e (Pinzone et al., 2015) and accounts for 4% of the UK's total carbon footprint (Wilkinson, 2021). In 2020, the NHS set a target of becoming carbon net zero by 2040, the first healthcare service in the world to do so.

In 2008, the NHS formed the Sustainable Development Unit (SDU) which is responsible for the implementation of sustainable initiatives (Pencheon, 2015). A primary goal of the SDU is to increase monitoring of environmental impact and encourage engagement and collaboration from NHS trusts. In 2009, they released their first report on Greenhouse gas emissions across the NHS. It was found that 72% of the NHS' carbon footprint originates from procurement, 15% from building energy, and 13% from travelling (NHS, 2020). As of 2019, NHS carbon emissions have reduced by 26% since 1990 (Tennison et al., 2021).

Waste prevention is a priority for many major environmental policies and governmental schemes, especially within the EU; as demonstrated by the Waste framework Directive. This directive provides clear guidance requiring EU countries to carefully record, evaluate, and reduce the waste they are producing (Zorpas & Lasaridi, 2013). Preventing waste is also the most ideal first step in reducing environmental impact according to the waste hierarchy model (Gharfalkar et al., 2015). Great efforts have already been made by the NHS over the last one to two decades addressing a variety of environmental issues throughout the life cycle of medical devices and services. Despite this progress, specific guidelines on sustainable development are still unclear and further studies are required to identify where the best changes can be made (Pencheon, 2015). Sustainability initiatives are becoming increasingly popular within UK hospitals with attention being directed on the end-of-life treatment of medical devices with a large focus on prevention of waste as this is the area hospitals have most control over.

2.6. Medical Waste management

Waste is often a mix of different types of materials which must be separated and sorted to decipher what materials are present before processing. A large proportion of waste leaving a medical facility is classified as 'regulated medical waste (RMW)' (also called clinical waste) due to its potential exposure to harmful or infectious substances and ability to transmit infection (Kandasamy et al., 2022). The treatment of medical waste differs from waste originating from other businesses and residences (which is often referred to as municipal waste) due to the risks involved with contamination and spreading of disease.

The UK Department of Health and Social care released an updated version of the HTM 07-01 in 2011 called 'Safe Management of Healthcare Waste Version 2.0'. These documents define different classifications of clinical waste and how they should be stored, packaged, and transported for disposal. A colour coding system is provided for NHS hospitals to follow to ensure certain types of waste are put in specifically coloured waste containers. Clinical Waste destined for incineration or landfilling will be sealed within their bags and containers with ties or clips and labelled. This waste

will be kept in their bag/box until it is disposed of and will not be reopened at any point. It is therefore key that the healthcare workers correctly place the waste in the correct container before it is sealed in order to ensure it will be disposed of in the correct manner.

The European Waste Catalogue (EWC) provides definitions for different types of waste and assigns each a colour for disposal; shown in Figure 2. Hospital waste is primarily split into hazardous and non-hazardous waste. The non-hazardous waste includes domestic (black bins), recycling (clear bins), and non-hazardous offensive waste (i.e., displeasing substances such as body fluids, excretions, human hygiene waste, uncontaminated dressings etc. which are placed in yellow and black striped tiger bags).

The hazardous waste regulations 2005 defines hazardous waste as waste that is dangerous to either humans or the environment (GOV.UK, 2005). Hazardous waste will enter either the yellow or orange waste stream. The yellow waste stream is for infectious waste which is also anatomical waste, samples contaminated by chemicals or medical substances, or category A pathogens, whereas orange is infectious waste that does not fall under any of these categories e.g., used PPE. Sharp objects (e.g., needles, blades, and broken glass) are also classed under hazardous waste and placed in yellow or orange rigid containers depending on whether the waste is infectious or not (Manager, 2016).

Colour of waste bag		Waste type	Disposal
	Yellow	Hazardous and contaminated infectious waste	Incinerated
	Orange	Potentially infectious waste	Rendered safe through alternative treatment or incinerated
	Black and Yellow stripes	Offensive and hygiene waste	Landfill
	Purple	Cytotoxic waste	Incinerated
	Black	Domestic	Landfill
	Clear	Recycling	Recycled

Figure 2: Colour codes for waste segregation within the United Kingdom's National health service (HTM, 2022).

Across Europe, incineration is currently the primary method of clinical waste disposal (Kumar, 2021) despite this being the most expensive and least environmentally friendly waste stream (Windfeld & Brooks, 2015). Around 15% of waste generated by hospitals meets the criteria of being hazardous; the remaining 85% being non-hazardous with a likeness akin to domestic waste (WHO, 2017). The issue lies where non-hazardous waste is incorrectly placed in waste streams designed for hazardous waste and is therefore incinerated needlessly (Harding et al., 2021). Regulatory guidelines state that

once waste enters the hazardous waste stream it is classified and treated as hazardous (HTM, 2022). A study from six operating suites in Australia discovered 60% of the general waste was actually recyclable (McGain et al., 2009). Less than 10% of the waste generated by the UK NHS is currently recycled (Hutchins & White, 2009).

Lee et al. found correct identification of contaminated devices to be the greatest obstacle to establishing recycling within hospitals (B.K. Lee et al., 2002). (Leissner & Ryan-Fogarty, 2019) identified that poorly labelling of materials made recycling difficult and suggested a clear material labelling system to be developed. (Anåker et al., 2015) and (Shivalli & Sanklapur, 2014) discovered nurses are aware of the need for sustainability but face many challenges such as lack of clear instructions, training, and feedback (Vogt & Nunes, 2014; Sürme & Maraş, 2022). Similarly, (McGain, White, et al., 2012b) found anaesthesiologists supported recycling within operating rooms but felt there were inadequate facilities and guiding information to do so.

Some studies identified knowledge around the correct disposal of waste by healthcare workers to be poor (Oroei et al., 2014; Mugabi et al., 2019). Easy access to the correct waste stream bin required was crucial for effective waste segregation (Sahiledengle, 2019; Cowie et al., 2020) but when these bins were accessible by the general public, incorrect segregation commonly occurred (Shivalli & Sanklapur, 2014). Regardless if devices are made recyclable, biodegradable, or compostable, if they are being incorrectly placed into waste streams destined for incinerated, then they will be incinerated.

2.6.1. Disposal - Landfill and incineration

The most environmentally impactful end-of-life option is disposal where waste is discarded with no intention of recovering any materials or energy (Kumar et al., 2022). The NHS currently creates over 538,600 tonnes of waste each year across the UK (Rizan, Bhutta, et al., 2021). As of March 2023, 156,000 tonnes of this waste is classified as clinical waste and disposed of via high temperature incineration or for alternative treatment (where waste is disinfected prior to disposal often via landfill) (NHS, 2023). Using landfills for waste disposal is known to have a variety of negative environmental impacts such as contamination of nearby water or soil (Kiddee et al., 2020), attraction of disease vectors increasing risk of illness to nearby organisms, and generation of methane emissions due to the decomposition of organic waste (Warith, 2003).

In terms of greenhouse gas emissions, high heat incineration (required for hazardous and contaminated medical waste) produces 1074 kg CO_2e per tonne of waste compared to only 172 to 249 kg CO_2e/t for low heat incineration and 21 to 65 kg CO_2e/t for recycling. These figures were determined by measuring the energy required and emissions given off by a waste disposal facility for waste generated within a south England NHS hospital (Rizan, Bhutta, et al., 2021). The GHG emissions for high heat incineration were determined for treatment of one tonne of hazardous medical waste, the low heat incineration for one tonne of offensive waste, and the recycling for one tonne of recyclable domestic waste; all of which were taken directly from the hospital.

A key method to reducing the impact of disposal is by aiming to avoid it completely. By following the waste hierarchy, products should be designed for re-use, recycling, or recovery before being disposed (Vergara & Tchobanoglous, 2012).

One way to reduce waste intended for landfill is via incineration with energy recovery. This is where waste is burned to produce heat in order to generate electricity within industrial incineration plants called waste-to-energy facilities. Not only is heat produced but also ash and flue gas. Ash is a type of residue and is mainly composed of the inorganic parts of the waste left over after incineration (Knox,

2005). The Flue gas carries the gaseous by-products such as CO_2, SO_2, NOx, CO, Particulate matter, dioxins, and furans (Vergara & Tchobanoglous, 2012). Despite incineration being advantageous by reducing landfill and producing electricity, the air pollutants emitted can cause a variety of environmental issues. It releases chemicals, heavy metals, and greenhouse gases into the atmosphere resulting in air pollution, global warming, and contributing to acid rain (Sharma et al., 2013). Another environmental concern is that incinerators take waste that could have potentially been reused or recycled which wastes resources (Rajadesingu et al., 2021).

2.6.2. Recycling

Recycling allows waste to be diverted from incineration or landfill and provides a reduction in virgin materials where recycled materials can be used in its place (Woolridge et al., 2006). Recycling is regularly found to be more environmentally friendly than landfill and incineration (Björklund & Finnveden, 2005; Morris, 2004; Hou et al., 2018; Rizan, Bhutta, et al., 2021). The NHS currently generates 133,000 tonnes of plastic waste each year with only 5% of this being recycled (Trimedika, 2023). There are different methods of recycling such as: chemical recycling (degraded into chemical components), mechanical and thermal recycling (waste is melted to produce typically lower quality products), closed-loop recycling (recycled multiple times without reducing material quality), and open-loop recycling (transformed into often lower-grade products). Previous research has found the greatest barriers to recycling within hospitals are lack of information about what is recyclable (Azouz et al., 2019) and incorrect placement of non-hazardous potentially recyclable waste within the waste stream for hazardous waste (Wyssusek et al., 2016).

2.6.3. Reuse

Reusing a product helps keep materials and energy circulating within a life cycle for longer, reducing the need for new products which saves time, resources, and money. Within hospitals, reusing is much more challenging due to regulations around decontamination and risk of harm to patients (Spencer et al., 2001). There is an on-going debate comparing single-use to reusable medical devices. Single-use devices (SUDs) have become popular (even encouraged by legal regulations) to reduce healthcare-associated infections (HAIs) despite the lack of studies comparing infection rates of single-use versus reusable devices (Macneill et al., 2020). In terms of financial requirements, studies (using methodologies such as life cycle costing) have found reusable medical devices to have an overall lower cost than single-use (Apelgren et al., 1994; McGain et al., 2010; McGain et al., 2017; Sherman et al., 2018). Only one was found to show single-use to be cheaper (Voigt et al., 2021).

SUDs provide an attractive option for easy-to-dispose devices as well as minimal risk for cross-contamination and are manufactured from cheap materials. Reprocessing devices after use in order to be reintroduced into a circular style economy has been shown to reduce waste volume and cost associated with disposing of waste identified as contaminated within hospitals (Kandasamy et al., 2022). However, issues arise when looking at the feasibility of sterilisation after use and the cost and environmental impact associated with it.

The first concern when designing a device to be reusable is ensuring the properties of the material do not deteriorate during sterilisation in order to meet the standards required to be reused. Polymers such as polypropylene and polyethylene have been shown to be unaffected by lower-level cleaning methods such as hydrogen peroxide disinfection (Laurence et al., 1995) or via use of a washer-disinfector (Bryce et al., 2011). High-level sterilisation, that is required before a device can be reused, has been shown to degrade certain types of plastics such as PP and PE (Rogers, 2012b).

Reusable medical devices already on the market typically require the use of more environmentally impactful materials in order to withstand the harsh conditions of sterilisation such as various

elastomers e.g., polychloroprene and polyisoprene (Rogers, 2012b). Furthermore, the sterilisation process requires extensive energy and chemicals (McGain et al., 2017) as well as requiring PPE for the sterilisation workers (I'ons, 2020) and single-use decontamination tray liners (Kumar, 2021); the full environmental effects of which are yet to be investigated.

Legislation does not allow hospitals without certified decontamination services to decontaminate medical devices. Hospital culture is built around single-use disposal with potential cross-contamination one of the biggest concerns (Kumar, 2021). (Cole et al., 2018) and (Ordway et al., 2020) conducted focus groups to explore the opportunities for reuse of medical devices (hearing aids and durable medical equipment respectively). Both studies found that there was potential for greater reuse but that more understanding around the logistics and quality control of returned devices as well as the need for better communication of information between the healthcare providers and the patients was needed. It was found that the provider of the device has the greatest influence over the rules regarding end-of-life treatment (Cole et al., 2018). An alternative solution to avoid single-use plastics while also removing contamination is via the use of sterilisation. The following section describes the various sterilisation methods that can be used on medical devices.

2.6.4. Types of sterilisation

To ensure a reusable or recyclable device is safe, it can be sterilised. Sterilisation is the process of making something free from microorganisms and bacteria. The most popular methods of sterilisation are:

FDA approved methods

Ethylene Oxide (EtO) - EtO gas denatures the protein inside cells resulting in the cell's death. This process does not cause discoloration and embrittlement of the material but causes a lot of stress and reduction in seal integrity (Boyd, 2002).

Ionising Radiation (gamma and electron beam) – Ionising radiation sterilisation is quick and effective and works by destroying a microorganism's DNA to reduce multiplication. Gamma radiation can be known to discolour or embrittle some polymers, so it is important to assess the effect of radiation on the specific material (Albano et al., 2010).

Heat sterilisation (e.g., high pressure steam, autoclave, microwave, and dry heat from an oven) – High heat causes cell proteins to coagulate resulting in the death of the cell. High pressure steam is effective, the required equipment is widely available, and no hazardous by-products are produced. Using a porous material that vapor can penetrate is required. A disadvantage with heat sterilisation is that plastics such as PS, PE, and PVC can become deformed from the high temperature so more heat resistant materials are required (Coleman et al., 2018). Most medical devices can undergo heat sterilisation with steam being a popular choice (CDC, 2008). If the materials are moisture sensitive, autoclaves and ovens can be used instead. Microwaves are currently only used on a small scale due to a lack of research and greater inconvenience compared to other methods (Gartshore et al., 2021).

Not FDA approved methods

Infrared, ultraviolet, and ozone – Some other options for sterilisation that are less common include infrared radiation (IR), ultraviolet (UV) radiation, and ozone. IR and UV are both non-ionising radiation with IR having wavelengths between 780 nm and 1 mm (Tsai et al., 2017) and UV (the wavelengths specifically used for sterilisation) from 200nm to 280nm (Yin et al., 2013). IR sterilises by creating heat when absorbed resulting in the destruction of the microorganism's cells (Mata-Portuguez et al., 2002). UV sterilises by being absorbed by a cell's nucleic acids causing defects in the

replication of the cell which deactivates the microorganisms (Yin et al., 2013). Both IR and UV, however, can only be used for surface sterilisation. IR radiation has not been FDA approved for use in hospitals (CDC, 2008) and UV radiation is only in its early stages of testing (Ramos et al., 2020). Ozone sterilisation works by energising oxygen molecules which then oxidise surrounding microorganism. This method is highly unstable and still being tested for its use on a wider scale (CDC, 2008).

Sterilisation of single-use medical devices

Single-use devices that are destined for incineration due to contamination could potentially be sterilised to allow it to be disposed of via alternative methods. Some countries are already employing this technique (Goldberg et al., 1996; Carter, 2006; Collier, 2011a; Collier, 2011b) but more research is required into sterilisation and subsequent disposal of originally single-use devices before it will be allowed within the UK due to strict governmental legislation (Oturu et al., 2022).

2.6.5. Biodegradation and Composting

Biodegradable and compostable medical devices are scarce within literature. Studies addressing biodegradability are mainly focusing on discarded drugs within hospital wastewater (Kümmerer et al., 1997; Kajitvichyanukul & Suntronvipart, 2006; Álvarez-Torrellas et al., 2017) or implantable devices which are intended for long term use within the patient's body (Migneco et al., 2009; Zhang et al., 2014; Bao et al., 2022) etc.)

Biodegradable or compostable single-use medical devices are generally not considered due to a variety of reasons. The first is a concern for safety and durability of devices made from biodegradable or compostable materials as these materials tend to have short lifespans (Yaradoddi et al., 2019) or low performing mechanical properties (Babaahmadi et al., 2021). There is also an issue of devices which degrade and negatively interact with the patient's body (Liu et al., 2017). Outside of hospital cafeterias (Galvan et al., 2018; Plevris et al., 2021; Thiel et al., 2021), waste facilities to allow the disposal of biodegradable or compostable medical devices are rarely available. Furthermore, devices which come in contact with infectious material will be discarded in the infectious waste stream negating any benefits of being able to biodegrade or compose. The breakdown of these devices alongside non-degradable waste would need to be further studied as this may cause a cross contamination and segregation issue for the waste management team. Biodegradable or compostable materials may also not have the required mechanical properties to undergo sterilisation (Zhao et al., 2019) causing concerns of safety for the patients and raising the risk of HAIs.

2.7. Need for research

The widespread repercussions from the COVID-19 pandemic has shown that current practices within healthcare are unsustainable. When faced with high levels of stress, the medical industry simply cannot keep up. From depleting resources to an increasing volume of waste, procedures as they are now will not sustain future generations of healthcare provision and will struggle again during the next global crisis. The lack of current data and environmental analysis of medical devices across many stages of their life cycles is a clear problem which must be addressed before sustainable mitigations can be employed.

The research for environmental impact of current medical devices shows gaps within life cycle inventory data disallowing for key problems within the products' life cycles to be identified and addressed. The use of medical devices made from less environmentally harmful materials is also very scarce. The area of end-of-life treatment of used medical devices is often not fully addressed due to the complexities of the medical industry, safety regulations, and stakeholder approval. Similarly, barriers faced when disposing of waste sustainably are currently unknown within the United Kingdom and must be explored. This will help identify the best courses of action in terms of end-of-life treatment of medical waste and to aid regulatory guidance for future waste segregation.

The discussion surrounding sustainable medical devices is evolving rapidly and is likely to produce conflicts between medical device manufacturers (who aim to sell their single-use products) and healthcare facilities (that wish to cut costs as safely as possible while maintaining patient confidence). The whole system must be addressed and not just the medical devices in isolation as stakeholder engagement is key to ensure harmonised solutions can be found (Moultrie, Sutcliffe and Maier, 2015). The work conducted within this project aims not only to identify implementable environmental improvements but also to bring forth collaboration between various parties allowing for sustainable changes moving forward.

Due to the expansive and complex nature of sustainability within healthcare, the scope of this project has been limited to only include respiratory and airway devices. The impact of the COVID-19 pandemic and the effect it has had on the increase of respiratory diseases, deemed this area the most vital. The hope is that future researchers will recognise the possibility for sustainable improvements from work conducted within this thesis and expand these practices to other medical devices in the future.

CHAPTER 3

3: METHODOLOGY

This section details the scientific approaches taken within this research project in order to achieve the desired aim and objectives. An introduction and justification to the choices made in regard to the research methods are described first, followed by an analysis of the quantitative methods and then the qualitative method. A concluding summary is provided at the end.

3.1. Introduction

As of recent years, an increasingly amount of research conducted by doctoral students has employed the use of mixed methods research (MMR), particularly in the field of healthcare-related studies (McKenna et al., 2021). This has been widely accredited due the need for a varied scientific approach when dealing with the complexities of the medical industry that cannot be encapsulated by a singular scientific framework (Curry et al., 2013). Researchers have found that by combining both quantitative methods used for objective numerical analysis and qualitative methods for a deeper understanding of humanistic factors, the strengths of each integrate to yield more comprehensive findings and the ability to explore large and complicated issues (Wasti et al., 2022).

During the creation of this research project, it was found that to address sustainability within healthcare, a multi-disciplinary approach was deemed necessary. This was particularly apparent when examining the multitude of interested stakeholders involved and their own preference for what would be deemed worthwhile and pragmatic solutions. Fixation on a singular scientific method was considered inadequate to address the variety of issues which hinder the sustainable development of medical devices. Chapter 2 can be referred to for a descriptions of such complex issues (e.g., lack of environmental data, lack of exploration into suitable sustainable materials, lack of research on alternative disposal scenarios outside of incineration etc.).

There are six main types of designs used to carry out mixed methods research: convergent parallel, explanatory sequential, exploratory sequential, transformative, embedded, and multiphase (Hafsa, 2019). Since the chapters within this dissertation are not reliant on the findings of other chapters and instead all contribute complimentary information to the overarching theme, the convergent parallel mixed methods approach will be used. With this method, studies using different methodologies can be conducted simultaneously and their results combined provide holistic solutions to a problem. A diagram of this mixed method approach as well as how it will be employed for each objective during this thesis is provided in Figure 3.

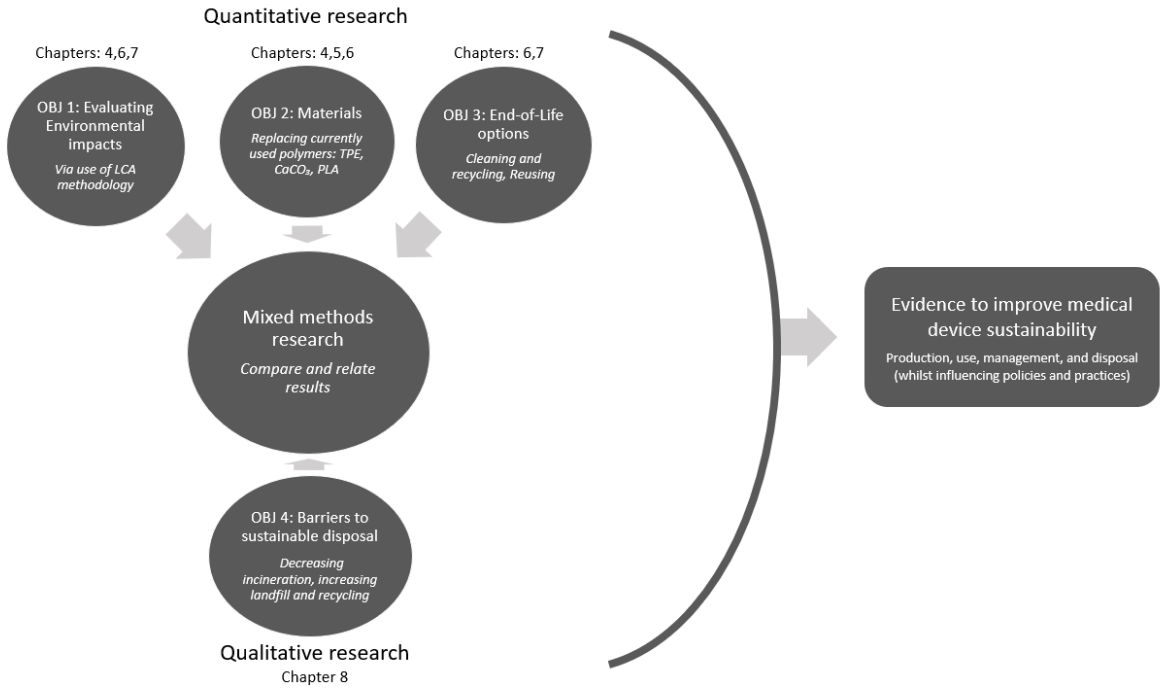

Figure 3: Convergent parallel mixed methods research model, adapted from (Rmn, 2016)*, with signposting to specific objectives and chapters included.*

The conclusions from each objective help contribute to improving the sustainability of specific problems found within medical devices. By schematically addressing each objective in turn, this creates evidence to allow medical device manufacturers, healthcare facilities, and future researchers to implement sustainable changes across the life cycles of their devices.

Figure 3 helps visually illustrate how the objectives will be researched throughout this thesis. Each of the objectives will be covered in various publications/chapters with each generating their results which contribute to the understanding of opportunities to address the problems explored. Each objective will be explored across numerous chapters for different devices or situations in order to provide thorough investigation into various inflicting factors.

The first three objectives require the generation of numerical data in order to determine what the environmental impacts currently are and how the materials and disposal alternatives compare to currently used options. As can be seen in Figure 3, this, therefore, requires a quantitative approach. The quantitative approaches used are life cycle assessments, life cycle costing, and mechanical testing; which are described first. The fourth objective relies on exploration of the humanistic factors involved so therefore a qualitative approach is used. The phenomenological approach is used and described.

3.2. Quantitative methods

This project uses three quantitative methods - life cycle assessments (LCAs) for the environmental impact assessment, life cycle costing for the economic assessment, and analytical mechanical testing to assess the materials' mechanical properties. Life cycle assessments (LCAs) are advised by the International Organization for Standardization (ISO) as the best method to assess environmental impact (Kumar et al., 2020). LCAs also allow for comparison of impacts when changing materials used or the end-of-life disposal option. Life cycle costings (LCCs) can also be explored using a life cycle thinking approach. As is similar to the LCA methodology, the LCC methodology assesses a product or service across its life cycle considering individual life cycle stages and their contribution to

the overall impact. for the LCA methodology, environmental data is used for inputs and outputs whereas economic data (e.g., the intrinsic value of materials or electricity) is used for the LCC methodology.

The mechanical properties considered in this study are tensile, flexural, and impact. These properties were chosen as they allow for testing of the most commonly considered properties when deciding whether a material is suitable for a chosen application, i.e., tensile strength (which allows for yield strength and young's modulus calculations), flexural strength, and impact strength. Furthermore, the mechanical testing methods used within this thesis were specifically conducted on calcium carbonate filled polypropylene composites. For this material, some mechanical properties had already been explored in previous studies (e.g., thermal resistance, elasticity, volume strain, and rheological behaviour), meaning conducting these experiments again was unnecessary.

The three aforementioned methodologies (LCAs, LCCs, and mechanical testing) are now described in further detail below.

3.2.1. Life Cycle Assessment (LCA)

Life cycle assessment (LCA) is a tool to calculate the total environmental impact of a product or service by analysing the materials and energy inputted and the emissions and waste over a life cycle (Finnveden et al., 2009).

One particular advantage of LCAs is that variations across the life cycle of the product can be considered in order to compare alternative options. For example, the change in impact can be observed when replacing certain materials within the product allowing for analysis of more sustainable material choices. Different energy sources and location as well transportation can also be replaced to study the various choices that can be made during the product's life cycle. Furthermore, the end-of-life scenarios can also be altered to determine whether changing from incineration to disposal or reuse etc. would be more environmentally favourable.

Methodology

The lifecycle of a product consists of life cycle stages (e.g., raw materials, manufacture, transportation, use, and end-of-life). Other factors may also be included depending on the individual requirements of the assessment such as packaging and extra processing steps (e.g., sterilisation and reprocessing). Environmental impacts can then be separated by each life cycle stage to identify the most impactful areas for improvement. LCAs also help weigh the severity of each impact in accordance with scientific literature (Curran, 2006). For this research, the LCA software 'SimaPro' was used as it was found to be the most widely used (Teixeira et al., 2011), provided a large array of background data and was flexible when adding in new data (Iswara et al., 2020).

There are four main structural elements of an LCA as currently defined by ISO:

1) Goal and scope definition
2) Life cycle inventory analysis (LCI)
3) Life cycle impact assessment (LCIA)
4) Interpretation

Guidelines to help follow this structure are given in detail by the Environmental Protection Agency, SETAC, and in the form of ISO standards (specifically ISO 14040 and ISO 14044).

Goal and Scope definition

The first step of an LCA is to define the goal and scope. Here is where the aim of the study is stated and parameters such as depth of research or area of investigation are established (Curran, 2017). The goal and scope help define the functional unit and system boundaries. The functional unit is a set unit of measurement in relation to either a physical or functional property of the product. This provides vital context around the quantity of data that needs to be collected and allows comparison of equivalent products with the same functional unit. System boundaries specifies what information should be included or excluded from the study (Curran, 2006).

Inventory analysis and data acquisition

After the goal and scope phase, data must be collected on the input flows (e.g., raw materials, intermediate products, and energy) and output flows (e.g., solid waste, wasted heat, and emissions to land, air, and water) involved in the life cycle of the product being studied (Klöpffer, 1997). This collection of data constitutes what is called the life cycle inventory (Rimos et al., 2014). Data can either be primary or secondary sourced data. Collecting primary data may require an extensive use of time or resources and sometimes would not be available at all (Saavedra-Rubio et al., 2022). Therefore, commercially available LCA databases have been compiled in order to assist a LCA practitioner in accessing the data they required (Laca et al., 2011). A database will collect data from multiple sources such as research organisations, governmental datasets, industrial companies, and literature (Ecoinvent, 2024). This data may be provided as applicable for a specific area or timeframe or may be more generalised and available as aggregated data such as a representation for a country or region (Dai et al., 2020).

Currently, the three largest life cycle inventory databases available are Ecoinvent, GaBi, and the Product Environmental Footprint (PEF) (Ecochain, 2024). Different databases can be found on different LCA softwares but some softwares will include a particular database built in when you purchase access to the software. For example, Simapro incorporates the Ecoinvent database whereas the GaBi software priorities the GaBi database (although Ecoinvent can also be included if required). Currently the three most popular LCA softwares are: Simapro, GaBi, and OpenLCA (Lopes-Silva et al., 2019). LCA software will all have the same core function of providing a life cycle inventory data allowing the user to form their LCA study and calculate impacts, however, different software will offer additional varying features. For example, GaBi uses a sequential calculation algorithm which allows for the user to receive impact feedback from each individual modelling step within the LCA, Simapro has the largest dataset available and can calculate a great quantity of unit processes at once, and OpenLCA is free to use (Curran, 2012).

A noted issue within literature is the lack of consistently followed guidance when it comes to how data collection should be pursued. Currently, LCI data collection is primarily guided by the ISO standards and supported by documents such as book chapters, scientific reports, and LCA textbooks (Saavedra-Rubio et al., 2022). Some impact categories are calculated with more rigidity than others; for example, Global Warming Potential is calculated from the infrared absorption from the greenhouse gases emitted and how long these emissions stay within the atmosphere given a 100-year time horizon. These calculations are derived from original studies conducted by the intergovernmental Panel on Climate Change (IPCC) and so the results are far more standardised and allow comparison across studies and impact assessment methodologies (Shine et al., 2005). For other impact categories, the lack of standardised data collection procedures may result in inconsistencies within data generation and therefore it is important to ensure the data used is reliable and accurate. The data collection stage is the primary determinant of the quality of the resulting study and also of the level of uncertainty of the results (Saavedra-Rubio et al., 2022).

One term used when assessing the quality of LCA data is representativeness which refers to the data's ability to accurately represent the population being sampled considering the context of the study (Henriksen et al., 2020). Representativeness covers temporal attributes (when the data was collected), geographical attributes (where the data was collected), and technological attributes (whether the data is for specific technology or a technology mix) (Fraval et al., 2019). Tools such as uncertainty analysis and sensitivity analysis can help assess the representativeness of LCI data. An uncertainty analysis uses the variability of the data collected (e.g., variance in the sample population, knowledge gaps, assumptions) to quantify the probability of the results given (Loucks, 2005). Confidence intervals can then be determined by calculating the likeliness of this specific result occurring and demonstrates the reliability of the data (Barahmand and Eikeland, 2022). A sensitivity analysis assesses data by demonstrating how significantly the results would vary when data or assumptions are differed. The extent in which the results change then indicates the importance for data accuracy of certain parameters and provides error ranges to indicate to the reader the degree in which the data is reliable for conclusions to be made (Guo, 2012).

Impact assessment (LCIA)

To turn the inventory data into environmental impacts, there are four steps that are followed: classification, characterisation, normalization, and weighting. An environmental impact during a product's life cycle will affect more than just one area of the environment so the classification step allows each input to be assigned separate impacts for each impact category (Klöpffer, 1997). These impacts are then aggregated for the whole life cycle and converted into a 'reference unit' (also called the characterisation factor) allowing comparison of LCAs where different types of emissions are produced.

When conducting an LCA, the LCA practitioner has the choice to assess the impacts via different impact assessment methodologies. Impact categories are used as a way to demonstrate the impact a product or service has on specific aspects within the environment (Mu et al., 2020). How the extent of these impacts are qualified or which impact categories are displayed will be dependent on how the organisations of the impact assessment methodologies have calculated the impact according to their chosen methodologies and data sources (Acero et al., 2016). Currently, the most popular impact assessment methodologies are Recipe, EDIP, CML, TRACI, and ILCD (Dong et al., 2021).

Impact assessment methodologies will differ by the number of impact categories they provide and whether these are midpoint or endpoint indicators (Finnveden and Potting, 2014). Midpoint indicators are described as 'links' in the cause-effect chain meaning that these impact categories assess the impact to specific aspects of the environment by calculating the direct emissions or depletion of resources the inputs and outputs are generating (Bare et al., 2000). Some common examples of midpoint impact categories are Global warming potential (GWP), Ozone depletion Potential (ODP), and Human toxicity potential (HTP). Alternatively, endpoint indicators assess the overall resulting impact at the end of the cause-effect chain. The impacts from a collection of impact categories are aggregated into three endpoint categories: damage to human health, damage to ecosystems, and damage to resource availability (Hardaker et al., 2022). These endpoint indicators demonstrate the overall resulting environmental impact whereas midpoint indicators display the generation of harmful substances which will lead to these overall impacts (Sala et al., 2014). The choice of which impact assessment methodology should be used is dependent on which impact categories are required to be explored, which methodologies are being used by other researchers in the field in order to ease comparability, and the ability of the study's target audience to correctly interpret the results (Yi et al., 2014; Dong et al., 2021).

After the impacts have been generated, the results can be normalised in relation to reference values to understand their significance in a larger context. Subsequent weighting of results allows for some impacts to be deemed more relevant than others within the context of the study and for this to be reflected in the overall assessment (Finnveden et al., 2009). Normalisation and weighting are not required steps due to different goals set within studies but are encouraged by ISO 14044 when it is beneficial for interpretation of overall results (Sala et al., 2017).

Interpretation of the results

Interpretation is more commonly being included as a required step of an LCA. This is the critical evaluation stage where the results are examined in relation to other information provided around the study or in conjunction with mathematical modelling or statistical analysis. The potential for error is taken into consideration and final judgements about the importance of the study outcomes are expressed. This may also be the step where some operators involve expert reviewers to look over the findings to ensure accuracy (Klöpffer, 1997).

Limitations

There are some limitations of using LCAs, some of which are related to the questionable quality of the results produced (Ross et al., 2002). When low quality data is used as an input, the outcome of the study will be limited. Poor quality data can include: not having all the inputs (e.g., materials) you require thus excluding some data from your study, not having data specific for your geographical location, only having data produced a long time ago and may be inaccurate to current impacts, and lacking data on the specific manufacturing process undergone within your study thus requiring a close substitute to be used (Curran, 2006). It can also be challenging when data is not available for a required input or output adding to concerns of poor-quality research (Finnveden et al., 2009). In order to mitigate these concerns, new data collection can be used to replace low quality data or to fill gaps in knowledge. This data collection can be conducted through collaborations with industry partners, especially medical device manufacturers, who work with the data required for the operation of their business. Although, it is important to note that this is not easy. Industry partners may be sceptical to share data and require the use of non-disclosure agreements which makes publishing of generated data difficult and time consuming. Scientific research can also be published on the manufacturing stages of missing inputs can also be adapted to be used within the LCA software. This is another reason why the LCA software SimaPro is advantageous as it is known to be particularly user friendly in respects to adding new data sets. Although not exclusive to Simapro, background data on a variety of base chemicals and manufacturing processes are available and can be used to form new materials once the manufacturing stage is determined. The Ecoinvent database available via the Simapro software has a particularly large database of base chemical and processes which makes creating new materials more accessible.

By ensuring even small steps of a product's life cycle is included within the LCA as well as accurate data is used as possible, the limitation of unreliable results can be minimised as confidence in data quality grows. In situations where primary data collection cannot be achieved when required, the system boundaries of the LCAs can be altered to ensure the accuracy of the assessment is not compromised. Studies with the same system boundaries can still be compared especially in cases where changes are made to a singular product or service and direct comparisons can be made (i.e. a comparative LCA). Comparing the findings of LCAs conducted with LCAs already published also adds an extra layer of security as similar findings will indicate the results are accurate and reproduceable.

3.2.2. Life Cycle Costing (LCC)

Per the International Organisation for Standardisation (ISO), Life Cycle Costing (LCC) methodology is a valuable tool used to assess, and in some cases predict, the cost of assets which have undergone construction or manufacturing (ISO, 2017). An alternative and expanded definition can be found from the 'National Institute of Standards and Technology (NIST) Handbook 135, 1996 edition' where LCC is defined as "the total discounted dollar cost of owning, operating, maintaining, and disposing of a built system" over a given specified time period (Mearig et al., 2018). LCCs are conducted for two primary reasons: to predict cost in order to construct a budget or to decide on preferable courses of action in terms of design options (Bourke. 2016).

The results of an LCC can be useful for multiple reasons. An LCC provides identification of 'hotspots' which are areas of high economic cost. Identifying where these hotspots lie allows for mitigation opportunities to arise ideally resulting in less costly products or services. An LCC can also be used as a decision-making tool when comparing various products or services in order to assist the financial decision of pursuing a particular design choice or recognising one as more advantageous to the other (Kambanou, 2020). Furthermore, LCC methodology can be used to support legislation and policy making; for example, governmental organisations may wish to optimise their region's economic sustainability by minimising total lifetime costs resulting from specific product procurement or service utilisation (Atia et al., 2020). LCCs are particularly useful if the end-of-life stage of the product or service is expected to contribute a relatively large proportion to the overall cost. Other costing methodologies, e.g., Total Cost of Ownership (TCO), primarily focus on the cost to a specific stakeholder within the lifecycle chain; particularly centred on purchase price. Whereas the LCC methodology takes a lifecycle thinking approach and is better suited for considering multiple stages of a product or service's lifecycle (IPB, 2017).

There are three types of life cycle costing methodologies to choose from: conventional LCC, societal LCC, and environmental LCC. The conventional LCC method is often linked closely to the 'Total Cost of Ownership' method in that it is favoured by companies as a method to conduct economic analysis on the cost of their product mainly focused on the direct costs that is occurred from their prospective. Within a conventional LCC, external analysis of the wider reaching effects during the product's lifecycle are often excluded and is primarily used as a decision-making tool typically only available internally within an organisation. A conventional LCC generally does not include end-of-life costs. Societal LCCs include the impact to external societies during the product or service's lifecycle alongside the economic analysis. Examples such as communal wellbeing and quality of job prospects are intertwined into the evaluation which makes this a popular LCC method for governmental organisations and policy makers (Ingemarsdotter, 2022).

The final methodology and the one which will be used within this thesis is the environmental LCC. An environmental LCC is very closely aligned to the LCA methodology in that they contain similar methodological steps and are often used alongside one another utilising the same system boundaries and functional units (Falcone et al., 2016). In the same way as the LCA methodology, the environmental LCC will involve acquisition of input and output economic flows through defined life cycle stages of a product or service which allows the identification of hotspots and potential areas for mitigation (Ingemarsdotter, 2022). The economic flows throughout an environmental LCC includes the costs that are directly incurred with no value added by the companies. This method of LCC does not have the primary intention of assessing the financial cost between businesses (i.e. the purchase value) but instead accounts for financial flow throughout the life cycle stages in order to identify the intrinsic cost of the product or service (Hunkeler et al., 2008).

Methodology

As mentioned previously, when it comes to methodology, environmental LCC is very much similar to the LCA methodology. Both LCC and LCA focus on flows of impacts throughout the lifecycle of a product or service considering individual lifecycle stages. The goal of an LCC is to generate an evaluation of the 'true cost' of a product, which is often neglected when only considering purchase price. When used alongside an LCA framework, LCCs are able to link the environmental impact per lifecycle stage with their corresponding economic impact (Falcone et al., 2016). The LCA methodology is standardised using the ISO standards 14040:2006 and 14044:2006 (ISO, 2006a; ISO, 2006b) whereas the LCC methodology is standardised by the standard ISO 15686:2017 which covers the main definitions and principles of life cycle costing (ISO, 2017). Despite these methodologies have separate standards, the LCC methodology is built around common elements of the LCA methodology.

In the previous section, the four keys elements were described for LCAs: goal and scope definition, data collection, impact assessment, and interpretation. These elements can also be applied for LCCs. The only difference is that for LCCs, the impact assessment is much more simplified as the results are comprised of only a single unit (cost) and therefore there is no requirement for weighting or characterisation factors (Swarr et al., 2011). When running an LCA alongside an LCC congruently, it is beneficial to apply the same system boundaries and functional unit in order to aid consistency and comparison (Swarr et al., 2011). This also applies when choosing which life cycle stages to include and whether the study is cradle-to-grave, cradle-to-gate, cradle to cradle etc. Which lifecycle stages are included will be influenced by the goal and scope of the study and the context of the product or service (IPB, 2017; Ingemarsdotter, 2022). When deciding which economic flows will be required to be included within the LCC, The life cycle stages can be split up into their elementary components (Falcone et al., 2016).

For this thesis, the lifecycle stages included are the same as are used within the LCAs. These stages are: Raw materials and pre-processing, Transport, Manufacturing, Packaging, and End-of-life. The use phase is excluded as it is associated with the medical equipment and not the medical devices and so is outside the scope of this thesis. For an LCC of reusable devices, the cost of reprocessing may also be included.

The LCC has been modelled according the following equation which was constructed with reference to the LCA ISO standards (ISO, 2006a; ISO, 2006b), the LCC ISO standard (ISO, 2017), and the steps detailed by Swarr et al. (Swarr et al., 2011).

$$LCC = CC_{RMEP} + C_T + C_M + C_P + C_{EoL}$$

LCC = Total life cycle cost

C_{RMEP} = Cost of the raw materials and their pre-processing

C_T = Cost of transportation

C_M = Cost of manufacturing

C_P = Cost of packaging

C_{EoL} = Cost of End-of-Life disposal

For each stage, the economic flows will require data collection to form a life cycle inventory. For the raw material and preprocessing stage (C_{RMEP}), the cost of purchasing the raw materials in a pre-processed state from market average data is used. The transportation stage (C_T) includes the cost of petrol (specified to the country of operation and the respective weight of transported product) to transport from the manufacturing site to the hospital and from the hospital to the end-of-life treatment facility. The manufacturing stage (C_M) includes the cost of electricity to process the materials. The packaging stage (C_P) includes the cost of raw materials, cost of electricity to manufacture the packaging, and cost of petrol to transport the packaging to the manufacturer. The End-of-Life stage (C_{EoL}) includes the cost paid to the required end-of-life facility.

Limitations

Some of the limitations of LCCs are similar to those encountered with the LCA methodology. The first is that collecting data on economic impact flows can be challenging and time-consuming. Unlike LCAs, there is a limited amount of secondary data available on LCC input flows and so a heavier reliance on primary sourced data or available industry datasets is required. This may require collaboration with industry partners but this then creates the additional problems of confidentiality within industry. To minimise this limitation, the LCC practitioner may need to be aware of what datasets are available prior to commencement of their study and if missing data is identified, establish early communication with industry partners. Assumptions can also be made if the decision to do so is presented transparently and with justified reasoning.

An additional problem is that the price of goods or services is more unstable in comparison to environmental impacts. Economic flow data that is collected at different timeframes may be subject to change (Swarr et al., 2011). This is why it is important to contextualise the economic flow data within average market value changes and aim to collect data from a similar time period. For data which is highly volatile, sensitivity and uncertainty analyses can be conducted to demonstrate reliability of the data and allow the reader to make informed conclusions (Pernetti et al., 2021). Despite the difficulties that unpredictable economic changes can provide, a credible LCC study can be conducted as long as the data used is transparently disclosed and decision-making is well documented (Mearig et al., 2018).

A final limitation of the life cycle costing methodology is that the results of LCCs can be perceived as absolute values particularly due to the sense of familiarity the general public has was common currency (Ciroth, 2009). It is therefore important to emphasise within the study that the data used is not a direct representation of purchase value of products but instead is an approximate value to identify trends within data and recognise economic hotspots.

3.2.3. Mechanical testing

Once the initial environmental impacts have been determined via use of LCAs, new materials can be assessed for their potential use as a replacement to currently used materials, looking at improving environmental profile of final products. These replacements will be required to be tested experimentally to ensure their mechanical properties meet the same standards. A variety of mechanical tests can be conducted in order to determine a material's strength, toughness, plasticity, ductility, stiffness, and deformation under strain. The main methods employed during mechanical testing (i.e., tensile testing, flexural testing, and impact testing) are provided below.

Methodology

Tensile testing

A tensile test is used to determine a range of mechanical properties such as yield and ultimate tensile strength, ductile properties, and strain hardening characteristics. Further calculations can

also be applied to compute Young's modulus and Poisson's ratio (ASM, 2004). During this test, two opposing ends of a tensile test piece are clamped into a tensile test system which is then pulled apart by an applied load until the materials yields and may eventually fracture. The load is then the calculated stress value and the displacement by the material is converted into the corresponding strain value. A graph can be produced using the stress and strain values generated over the course of the experiment and can be plotted to produce a stress strain graph using software such as excel.

Using different values generated by the graph, mechanical properties can be determined. For example, by dividing stress over strain, the young's modulus can be calculated, the greatest tensile stress within the tensile stress-strain curve data is the yield stress etc. During this study, tensile tests are carried out according to standard ISO 527-1:2019 (ISO, 2019b) using an Instron 5967 tensile test system. All data was recorded by the Instron test system with no need for an extensometer.

Flexural (3-point bend) testing

Flexural properties can be measured using a 3-point bend test according to standard ISO 178:2019 (ISO, 2019a). To determine bending properties, a test piece is secured at each end on supporting pins and then a load is applied to the middle of the sample. The displacement of the curvature of the test piece can be used alongside the applied load to calculate properties such as flexural strength and flexural modulus. To calculate these, the following equations can be used:

Flexural strength: $$\sigma_f = \frac{3F_{max}\mathrm{L}}{2WT^2}$$

Flexural modulus : $$E_f = \frac{L^3 m}{4WT^3}$$

- L (span)
- T (thickness)
- W (width)
- F (force applied)
- m = gradient of the initial straight-line section of the load deflection curve

During this study, an Instron 5967 test system was used and software such as excel can be used to calculate the deflection curve and any data points that need identifying.

Impact testing

For impact testing, a sample piece of material is placed in an impact testing system where a pendulum is able to be released and swing into the sample. The energy (in joules) required to rupture the sample upon impact (calculated by measuring the potential energy of the pendulum prior to and after hitting the sample) is used to determine the materials impact strength.

For this research, Charpy impact testing is conducted using an Instron CEAST impact tester according to standard ISO 179-1:2023 (ISO, 2023). A pendulum of 2 J impact energy was used to measure the specimens over a cross sectional area of 70 mm x 10 mm x 4 mm. In order to calculate Charpy impact strength, the following equation can be used:

$$\text{Impact strength} = \frac{\text{Impact energy}}{\text{Specimen thickness} * \text{Specimen width}}$$

Limitations

A limitation of mechanical testing is related to the potential for human error. In order to ensure the reliability of results and minimise any room for inaccuracies, it is essential that multiple trials are conducted and that standard deviation of data ranges are provided. As per scientific norm, a minimum of three repetitions of any test will be conducted and any anomalies or outliers will be clearly stated in the results and discussion. Minimising potential disruptions to data prior to and during the operation of the tests is also important. Ensuring conditions such as room temperature, sample quality, handling of samples etc. are maintained through the experiments will help minimise any inconsistencies.

3.3. Qualitative method

The final theme identified to achieve the aim of this dissertation is the determination of barriers to the successful integration of more sustainable practices and solutions. Once quantitative methods have been used to identify and mitigate unsustainable designs and disposal options of medical devices, it is then imperative that the proposed alternatives are viable for real-world application. In order to achieve this, an understanding of the obstacles that individuals face when attempting to enact sustainable change is essential. The qualitative method chosen to best explore these barriers is the phenomenological approach. The rationale behind this decision as well as the methodology and limitations are described.

3.3.1. The Phenomenological method

There are four main types of qualitative research methods: Phenomenological, Grounded Theory, Ethnography, and Historical (Whitehead et al., 2018). There are a few reasons why the phenomenological method was deemed the best approach for this research. Phenomenology involves the use of observation and questioning of participants to gain a greater understanding of why decisions (whether sustainable or not) are made the way they are. Focus groups and interviews are examples of study types that can be used within phenomenology. Focus groups are discussions within a group of people whereas interviews are targeted to one individual and allows for a more in-depth investigation. For this dissertation, a mixture of a focus group and individual interviews were selected to allow data collection from a larger audience, where interaction between the participants is allowed to facilitate free flowing conversation, as well as more in-depth analysis through one-on-one discussions.

Upon investigation of the other qualitative research methods, it was found that the other options would be less suitable in comparison to the phenomenological method. Grounded theory relies on provision of a data set to participants and allow emerging theories to be developed of why this behaviour occurs (Breckenridge, 2014). This is not applicable to this dissertation as previous data sets generated are explored using quantitative means. Ethnography involves watching participants' actions in certain scenarios (Goodson & Vassar, 2011). This was considered but deemed an unattainable approach due to the issues around observation within a busy clinical setting, and lack of skills and experience of the researcher. This approach is extremely time-consuming and relies heavily on the cooperation of various healthcare staff (Roberts, 2013). Additionally, the majority of this research was conducted during or shortly after the COVID-19 pandemic making observation particularly challenging due to the added regulations in effect. Finally, the historical method makes use of previous events to make predictions for future action (Whitehead et al., 2018). The issue with this approach is that sustainability within healthcare on the level it is today is unprecedented and there are no previous events that can help with the scale of the problem as it currently presents. This overall leaves the phenomenological method as the primary suitable approach for this thesis.

Methodology

For this study, a semi-structured focus group and a series of interviews were conducted with healthcare workers within the United Kingdom. The focus group and interviews all took place virtually via the use of MS Teams. The goal of the study was to explore how hazardous waste is segregated within the United kingdom and identify why waste may be disposed of in unsustainable manners. Additionally, suggestions were made on how to reduce the quantity of waste which is unnecessarily incinerated focusing on ways to remove the barriers identified during the study. The research was designed as a pilot study to enable emulation by future researchers within their own medical facilities.

Ethical considerations were taken very seriously prior to conduct of the study. Approval was sought from the Brunel University London research ethics committee (ethical approval number 41309) and regular contact with staff higher up in the healthcare organisations was prioritised to receive their support in operating the study. All participants were over the age of 18 and informed consent was received prior to commencement. The participants were provided written details (via a participant information sheet) about the nature of the study as well as any information about what the study would entail and how it would be used. Participation was completely voluntary and the participants were allowed to withdraw at any point with no need for explanation. Information about the participants such as their names, job description, and location of employment were collected but only made available to the principal researcher. After the analysis was concluded, all participant data was anonymised so that no identifiable information is provided.

Participants were identified as potential candidates to partake within the study as well as initially contacted through communication leads within various National Health Service trusts across England. A total of six healthcare workers participated; three as individual interviews and three within the focus group. Of the healthcare workers who contributed, one is a medical doctor, three are nurses, and two were previously nurses who then switched their primary job responsibilities to become head providers of nurse training. Participants were sought that held a range of professional job roles in order to enhance the breadth of investigation that was conducted.

To analyse the responses, the focus group and interviews were recorded and transcribed via use of the MS Teams which were then manually checked by the primary researcher to ensure accuracy to the provided responses. These transcriptions were then transferred to the qualitative analysis software NVivo (Dhakal, 2022) where they were coded and a thematic analysis conducted. The steps of a thematic analysis (as outlined within (Braun & Clarke, 2006)) are as follows:

1. Familiarisation with the data (i.e. transcription, comprehension of the data, general noting of initial identifiable themes)
2. Generating codes by identifying common themes whilst systematically reading through the data
3. Collate all data associated with each theme and identify repetition
4. Review themes in relation to the generated codes
5. Define the features of the themes and the research outcome they suggest
6. Analyse the themes including use of relevant quotes to produce meaningful findings

From these steps, it is possible to identify themes within participant response data, collate the themes with the biggest impact, and identify barriers within the healthcare industry that impede sustainable choices from being made.

Limitations

Time and resource constraints meant that a limited sample of participants were able to take part in the study. The attempt to mitigate this was done by having healthcare workers that have a variety of job roles in order to provide a varied sample of viewpoints. Ideally, future research will be able to conduct similar studies but with a larger representation of the population to enhance the range of investigation. Another limitation of the phenomenological method is the potential for personal bias within the questions provided. To avoid this, the questions were created then reviewed by numerous academic and non-academic peers to ensure no bias remained. The questions were also provided to the Brunel University London research ethics committee for approval.

3.4. Concluding summary

By the end of this thesis, it is this researcher's intention to provide evidence throughout each life cycle stage of various medical devices so that stakeholders (e.g., manufacturers, healthcare facilities, policy makers etc.) have scientific backing for the sustainable changes they can make to their own medical devices and within their own specific environmental context.

As each objective is addressed throughout the chapters, their conclusions can be used collectively to guide suitable options for the development of future medical devices. Key areas of the products' life cycles will be highlighted to help determine which areas should be focused on, new sustainable materials will be tested, and alternative sustainable end-of-life options will be explored. By addressing all aspects of the products' life cycles, the changes can be introduced to reduce the environmental impact across various areas to create overall more sustainable medical devices.

CHAPTER 4

4: LIFE CYCLE ENVIRONMENTAL EVALUATION OF MEDICAL OXYGEN MASKS IN THE UK

This chapter addresses objectives 1 and 2.

A publishable article version of this chapter was submitted to the 'Journal of Cleaner Production' on 10th January 2024. Reviewer comments were received on 1st April 2024 with resubmission occurring on 27th April 2024. As of 21st May 2024, A response to the resubmission is pending.

Statement of contribution:
As multiple authors are listed to have contributed to this chapter, a statement is provided to demonstrate the roles each author had during its construction and a respective overall percentage to the work as a whole.

In order to facilitate fair assignment of author contribution percentages to each of the respective authors, the following division of work contribution has been allocated:

- 20% will be allocated to chapter conceptualisation and planning.
- 20% will be allocated to the running of any required software or alternative methods to obtain the results.
- 20% will be allocated to the interpretation of the results and any further analysis required.
- 25% will be allocated to the writing and editing of the chapter.
- The final 15% of the work is allocated to supervision. This percentage will be split amongst the supervisors according to their respective involvement.

Christina Webb (Percentage contribution: 80%)
Fulfilled roles: Chapter conceptualisation, Methodology, Data curation, Formal analysis, Software, Project administration, Validation, Writing- Original draft preparation, Review and editing.

Lorna Anguilano (Percentage contribution: 2.5%)
Fulfilled roles: Supervision, final read of the finished chapter before submission.

Gera Troisi (Percentage contribution: 2.5%)
Fulfilled roles: Funding acquisition, final read of the finished chapter before submission.

Ximena Schmidt Rivera: (Percentage contribution: 15%)
Fulfilled roles: Supervision, Writing (Review and Editing of all drafts)

Life cycle environmental evaluation of medical oxygen masks in the UK

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Abstract

This study explores the environmental impacts of three (low-flow) MOMs using a life cycle assessment approach from cradle to grave with a functional unit defined as 'one single-use low-flow medical oxygen mask for adult use in the UK'. In a clinical setting, medical oxygen masks (MOMs) are made using lightweight and transparent materials with Polyvinyl Chloride (PVC) being a popular choice. Environmental concerns around the use of PVC have arisen due to the toxicity of plasticisers required; in particular the use of increasingly regulated phthalate (Pht) based plasticisers. Non-Pht plasticisers and alternative materials to PVC are being sought as potential replacements in order to keep MOMs in line with current and expected regulations. PVC is the main component of two MOMs: mask A using a non-Pht based plasticiser and mask C (a hypothetical mask) using Pht-based plasticiser DEHP. For Mask B, styrene-ethylene-butadiene-styrene based thermoplastic elastomer (TPE-S) and polypropylene is used instead of PVC.

The results account for all 11 impact categories as provided by the CML-IA baseline v3.03 methodology. Mask B shows the lowest environmental impact across all impact categories. For six out of 11 impact categories (including global warming potential and ozone depletion), mask C has the highest impact, whereas mask A is highest for the other five categories (with large impacts in human toxicity and ecotoxicities). A scenario analysis shows the importance of supply chain logistics (i.e., the location of the manufacturing site) on overall environmental impact. The results of this study intend to provide evidence to policy makers, healthcare professionals, and manufacturers of MOMs to improve the overall environmental impacts of these products, as they contribute around 4,437 tonnes of CO_2 eq. yearly in the UK alone. The results show that switching from plasticised PVC to TPE-S would reduce the impacts of the use of MOMS within the UK by 2,700 tonnes of CO_2 eq. per year.

Keywords: Plasticisers, LCA, medical devices, phthalates, Sustainable polymers

4.1. Introduction

Medical Oxygen Masks (MOMs) are masks which cover a patient's nose and mouth and transfer oxygen from a gas storage tank to the respiratory system. MOMs can be used within a clinical setting to regulate oxygen concentration a patient receives and is vital for oxygen therapy. MOMs can also be used at the patient's home or in care-homes. Despite the extensive use of medical oxygen masks in hospitals and at home, no environmental assessments have been conducted investigating the environmental impacts during their lifecycles. Furthermore, no studies have explored the hotspots and improvement opportunities in order to mitigate the environmental impact of medical oxygen masks. In order to assess the environmental impact of products, Life Cycle Assessment (LCA) methodology has been suggested as the best method by the International Organization for Standardization (ISO) (Kumar et al., 2020). A benefit of using LCAs is that the environmental impact of a product can be separated by its life cycle stages in order to more effectively identify where the major environmental impacts lie and quantitatively suggest the best areas for improvement. Before

conducting a life cycle assessment, it is important to understand what is required in order to manufacture medical oxygen masks.

MOMs tend to be made of plastic, silicone, or rubber with plastic being popular as it is lightweight, inexpensive, and transparent. Plastic is favoured over heavier, more energy-intensive materials (i.e., silicone and rubber) as MOMs are usually incinerated after first use per the HTM-01-07 regulations (HTM, 2022). This is done to reduce risk of contamination (Unger & Landis, 2016) and costs associated with cleaning and reprocessing. In 2015, the global market for oxygen therapy was estimated at £5.98 billion (Allied, 2022). The demand for disposable oxygen masks heavily increased during the COVID-19 pandemic due to the prevalence of respiratory infections (Allied, 2022). Each year within the UK, over 14.5 million surgeries are performed (Abbott et al., 2017). If each surgery required the use of a single-use oxygen mask, the volume of materials used would exceed 487 tonnes. It is important to note that this figure is only used a guide to imagine the scale of surgeries performed and in many cases an oxygen mask is used in situations outside of surgery. Technavio estimates the global disposable MOMs market will grow by £0.924 billion from 2019 to the end of 2023 due to the rising need for oxygen therapy related services (Technavio, 2020). This demand has sparked concerns over the environmental impact of single-use medical devices, particularly due to the volume of waste and current management practices.

Previous studies have explored the sustainability of reusable medical devices as an alternative to single-use. Reusable masks can be more impactful due to the materials and energy required for manufacture and reprocessing (ISON and MILLER, 2011; Unger and Landis, 2014; Leiden et al., 2020), but single-use masks may be more impactful due to the wasteful nature of single-use plastics and impacts associated with incineration (Unger and Landis, 2016). Some studies conclude that the advantages and disadvantages of both, results in no overall better choice (Dettenkofer et al., 1999; McGain et al., 2017). The dependency on case-by-case studies makes it hard to conclusively show reusable or single-use devices to be evidently less impactful making it difficult for legislators to decide on overseeing policy and therefore single-use devices are expected to stay in high demand for the foreseeable future. One of the biggest concerns with single-use devices is with the materials used.

Polyvinyl Chloride (PVC) is the most widely used plastic within medical devices (around 25% of all plastic medical devices use PVC) (McKeen, 2012), due to its ease to manufacture, low-cost, strong mechanical properties, inertness, and non-toxicity (Chiellini et al., 2013). PVC is considered a highly environmentally damaging plastic (Thornton, 2002) with issues arising during its end-of-life treatment and with the plasticisers added after PVC production. Incinerated PVC creates hazardous flue gas residues and releases toxic dioxins (Buekens and Cen, 2011; Bidoki and Wittlinger, 2010) and chlorinated by-products (Aracil, Font and Conesa, 2005). Environmental concerns have been raised around the potential leaching of plasticisers from between the PVC fibres into solutions in contact with patients (Wei et al., 2019). Phthalates, such as the most popular DEHP (Rowdhwal & Chen, 2018), are used within some plasticisers. These are known to cause infertility and birth defects (Niermann et al., 2015), be endocrine disrupting (Hung et al., 2021), and are potentially carcinogenic (Caldwell, 2012) at certain doses. Regulatory bodies such as the Medicines & Healthcare products Regulatory Agency (MHRA), The European Commission (EC), and the European Union (EU) have released legislation restricting the use of six main phthalates (BBP, DBP, DEHP, DIDP, DINP, and DNOP). DEHP, in particular, is named on the REACH restricted substances list and classed as a substance of very high concern by the European chemicals agency. Medical device companies have been searching for suitable alternatives to using phthalate-based plasticisers with one option being the use of non-phthalate-based plasticisers.

Styrene-ethylene-butylene-styrene (SEBS) based Thermoplastic elastomer (TPE-S) displays similar performance to PVC in medical applications without the need for plasticisers (Râpă et al., 2016). SEBS contains hard end-blocks of polystyrene and a rubbery midblock of ethylene-butylene which provides the mechanical properties similar to rubber at ambient temperature, but thermoplastic

properties once heated. SEBS is used in combination with modifying additives such as polypropylene, oil, and antioxidants to form TPE-S (X. Cheng et al., 2019). Medical devices containing TPE-S as an alternative to PVC are already available on the market. No studies are available within literature which assess the environmental impacts of plasticised PVC compared with SEBS-based TPE. This is also true in the context of medical oxygen masks where no studies have explored the potential changes in environmental impact when manufacturing MOMs with SEBS-based TPE instead of PVC (despite SEBS-based TPE being advertised as an environmentally sustainable alternative to PVC).

There is a lack of studies which investigate the environmental sustainability of materials used within medical devices in general. Studies which are available either focus on end-of-life treatment of healthcare waste without addressing the contribution to environmental impact from the specific materials being used (Wu and Cerceo, 2021; McGain et al., 2020; Xiao et al., 2021; Tyler, 2018) or explore sustainable materials but not specifically materials viable for use in medical devices (Asdrubali, Schiavoni and Horoshenkov, 2012; Ljungberg, 2007; Park and Lakes, 2007; Ramesh and Vinodh, 2020). Some studies investigate sustainable design changes for medical devices, but none address MOMs (Hanson and Hitchcock, 2009; Marshall et al., 2009; Unger, 2015; Cheng et al., 2022; Barbero, Pereno and Tamborrini, 2017; Arif et al., 2022). There has been an increase in studies focusing on the sustainability of face masks since the start of COVID-19 (Rowan and Moral, 2021; Soo et al., 2022; Rodríguez et al., 2021; Luo et al., 2023) but it is important to note that studies that refer to 'face masks' are not describing MOMs but instead face coverings which include examples such as N95 respirators and blue disposable 3-ply masks (i.e., surgical masks). These typically use different materials and abide to less rigorous manufacturing and operational standards than the MOMs used for oxygen therapy, so are unsuitable comparisons.

This study aims to fill the gap in environmental sustainability assessment data of current and improved designs of MOMS used in the UK, including the development of life cycle inventory data on new materials for medical devices.

4.2. Methodology

The environmental impact assessments are performed using the Life Cycle Assessment methodology according to the ISO standards 14040/44:2006 (ISO, 2006a; 2006b), and conducted using the SimaPro software (v8.3.1) (PRé, 2008).

4.2.1 Goal and Scope

The goal of this study is to calculate and compare the environmental impact of three single-use MOMs to identify improvement opportunities. A further goal is to determine the environmental performance of new materials utilised in medical devices to provide information and aid sustainable design and manufacturing in the sector. All three masks are produced within a country based in South Asia and are used and disposed of within the United Kingdom. The outcomes of this study will provide evidence to policy makers, healthcare professionals and providers, and mask manufacturers, in order to improve the environmental sustainability of these devices across their life cycles.

The functional unit is defined as 'one single use low-flow medical oxygen mask for adult use in the UK'. The scope of this study is from 'cradle to grave', including raw material extraction and pre-processing stage, transportation to the processing plant, device manufacturing and assembly, packaging, transportation to and from the hospital, and end of life disposal. The use phase is considered; however, it does not require materials or energy inputs. The oxygen and the machinery required for the oxygen delivery is outside the scope of this study. The full system boundary is provided in Figure 4. The RMEP, manufacturing, and packaging stages all take place within the Asian country. The transportation stage involves transporting the masks to the United Kingdom and then the Use and End-of-life disposal stages take place within the United Kingdom.

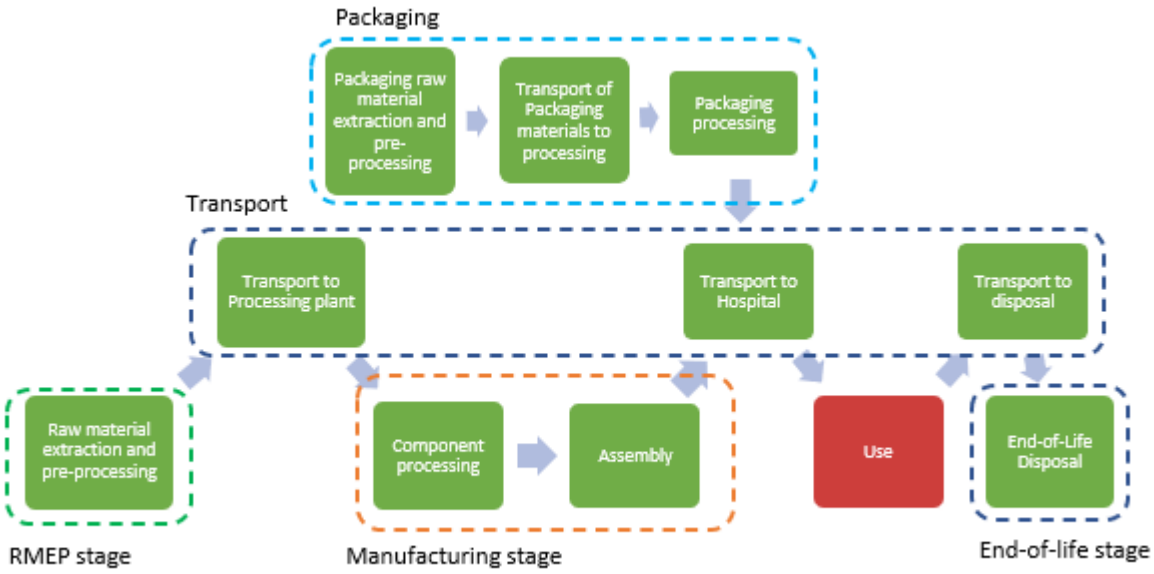


Figure 4: Diagram showing the full life cycle of the MOMs studied (use stage is in red as it does not include any material or energy input). The coloured dotted lines define the individual life cycle stage, which are raw materials (green), packaging (light blue), transport (dark blue), manufacturing (orange), and end-of-life (pink) life cycle stages.

4.2.2. Medical Oxygen Masks (MOMs)

This study assesses three MOMs (mask A, B and C) made of different material compositions (PVC with a non-phthalate-based plasticiser vs TPE-S vs PVC with DEHP); shown in Figure 5. The non-phthalate-based plasticiser used within mask A is known and used for the calculations during this study but due to confidentiality reasons shall be referred to as NonPht. The masks are medium concentration (i.e., low-flow) oxygen masks used to administer oxygen to adult patients. A low-flow mask is capable of providing a patient approximately 30% to 50% oxygen concentration at flows of 5 to 8 litres per minute. These masks are designed to be single-use (designed for use by one patient whether that is a few hours for surgery or many days for oxygen therapy) and are disposed of via incineration. They are all produced in an Asian country (not disclosed for confidentiality). The mask designs consist of a rigid mask shell, a mask connector, and an elastic band to secure the mask to the patient's face (see Figure 5). The two PVC masks require metal nose clips to aid mask rigidity. All masks perform the same function, and any can be substituted in for use without adjustments required by the healthcare provider.

Mask A is comprised of PVC plasticised with an estimated 30-40% (the exact percentage is known and used for the calculations but not provided here for confidentiality) NonPht plasticiser and weighs 33.62 g. Mask B, is made of TPE-S and PP, weighs 15.79g, and is advertised as an environmentally-friendly version of mask A; mask B was redesigned to require less material whilst maintaining the same mechanical performance as mask A. The rigidity of TPE-S allows the successful mask redesign requiring less material.

Due to phthalate regulations in Europe, The use of non-phthalate-based plasticisers replaced most of the previously used DEHP plasticiser in the 2010's. As a theoretical comparison, mask C has been included within this study but is not available for purchase or use. Mask C has been modelled to have the same design and weight (33.62 g) as mask A but uses DEHP as a plasticiser instead of NonPht. Except from change in plasticiser, all other material requirements are the same for these two masks. Figure 5 summarises the masks selected for this study.

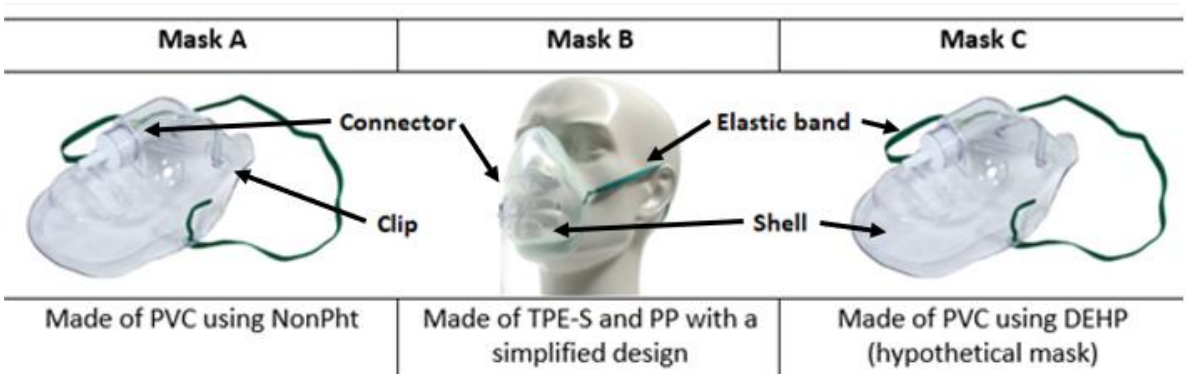


Figure 5: Images and descriptions of the three masks investigated within this study. The images for masks A and B were received from the manufacturer. As mask C is a theoretical mask based on the current design of mask A, the image of mask A has again been used here.

4.2.3. Life Cycle Inventory

The following sections provide details of the inventory developed for each life cycle stage - raw materials, manufacturing, packaging, transport, and end-of-life.

Raw material extraction and pre-processing stage (RMEP)

The RMEP stage involves the extraction of raw materials of the masks and their pre-processing, which includes converting extracted raw material into a form which is mouldable by manufacturing equipment. Ecoinvent 3.2 database (Wernet, 2016) has been used for the background data. The materials requirements were obtained via material datasheets from a manufacturer. Table 2 summarises the material composition of each mask.

Table 2: Life cycle inventory of the raw material and pre-processing stage (RMEP) of the three MOMs; data are presented per functional unit.

		Mask[a]		
Component	**Material**	**A** Mass (g)	**B** Mass (g)	**C** Mass (g)
Mask Shell	Plasticised PVC[b]	28.05	-	28.05
	TPE-S[c]	-	7.53	-
	Polypropylene	-	7.09	
	Colourant (LDPE[d])	-	0.08	
Mask Connector	Polypropylene	2.98	-	2.98
	Colourant (LDPE[d])	0.03	-	0.03
Nose Clip	Aluminium	1.47	-	1.47
Elastic Band	PET[e] Polyester	0.73	0.73	0.73
	Elastane	0.36	0.36	0.36
	Total Weight	**33.62g**	**15.79g**	**33.62g**

[a] Description of masks in figure 5
[b] PVC: Polyvinyl Chloride
[c] TPE-S: SEBS-based Thermoplastic Elastomer, SEBS: Styrene Ethylene Butadiene Styrene
[d] LDPE: Low Density Polyethylene
[e] PET: Polyethylene Terephthalate

In the case of SEBS, DEHP, and NonPht, background information was modelled from patents, literature, and consultations with industry. SEBS was modelled from private consultation and

deemed confidential information (data retrieved from SEBS produced in Germany). The LCI data for DEHP was taken from a life cycle assessment conducted of DEHP from the University of Pittsburgh (Li, 2013) where the average of European data was used as production location. This data is shown in Table 3 and displayed per one kg of plasticiser production. Background information for product flows sourced from Ecoinvent 3.2 database (Wernet, 2016). NonPht was modelled from the patent CN104072365A - Google Patents (2013) alongside confirmation with a plasticiser manufacturer and NonPht's reaction ratio (modelled off production data from Turkey).

Table 3: Inventory data to produce one kg of DEHP (Li, 2013).

1 kg DEHP		
Quantity	**Product flows**	**Background database source**
0.0205 kg	Hydrogen, liquid, at plant/RER U	Ecoinvent3.2
0.287 kg	Carbon monoxide CO, at plant/RER U	Ecoinvent3.2
0.431 kg	Propylene, at plant/RER U	Ecoinvent3.2
0.379 kg	Phthalic anhydride, at plant/RER U	Ecoinvent3.2
25.82 MJ	Energy, Market for/RER U	Ecoinvent3.2

Manufacturing stage (Processing and assembly)

The processing machinery are all present within the same European manufacturing plant and owned by the manufacturer. Processing stages were provided in the form of product data sheets by the manufacturer and via consultations with the machine operators. The environmental impact data for the machines are sourced from the Ecoinvent 3.2 database (Wernet, 2016) and is specified to operate using electricity from the national grid of the specific country of manufacture. Ecoinvent 3.2 uses data valid for the year 2012. It is important to note that as this data is from over 10 years ago that the changes in environmental impact data, particularly for the electricity, would change if conducted again with up-to-date datasets. The key change that would occur would be within the global warming potential (GWP) category due to decarbonisation efforts over the last decade; specifically as a result of the net zero goals set by the 2015 Paris Agreement (Tvinnereim and Mehling, 2018). To ensure accuracy of the data used within this study, the GWP of the electricity used from 2012 has been compared to the current GWP from the same South Asian country modelled. Data from the Ember and Energy Institute shows that the GWP has decreased by 3.8% from 2012 to 2023 (OWID, 2024). This is not a substantial decrease so helps demonstrates reliability of the results but also allows the reader to consider that the overall GWP for each masks would be reduced slightly if this study were to be repeated. It is also of relevance to note that the overall share of fossil fuels used within average electricity mixes has decreased by 0.8% since 2010 to 2020 and has been replaced by renewably sourced electricity (Eurostat, 2021). This may indicate that the abiotic depletion of fossil fuels would decrease slightly for all masks if this study were to be repeated. The changes that would result from using more up-to-date data would occur for all masks studied so would maintain the overall trends found when comparing the masks.

Assembly has no additional environmental impact as the masks are designed to allow the nose clip punching and elastic band to be attached to notches and gaps in the shell by a human operator. Once assembled, the masks are packaged and dispatched for delivery.

Table 4: Input data for the manufacturing stage. Data is presented per functional unit.

	Mask [a]		
Processing inputs	**A**	**B**	**C**
Injection moulding (g)	31.06	14.7	31.06
Sheet Rolling (g)	1.47	-	1.47
Elastic band sewing (g)	1.09	1.09	1.09

[a] Description of mask in Figure 5

Packaging stage

The packaging required for each mask is identical. Table 5 provides the weight and processing steps for each packaging material. This stage includes the extraction and pre-processing of the packaging materials (paper, cardboard, and LDPE film), transport (to the manufacturer and from the hospital to the end-of-life disposal site), and end-of-life disposal. All the materials are virgin material. The paper and cardboard are recycled at a rate of 69% within the UK and the rest is landfilled (Wrap, 2020). The LDPE film is landfilled as is typical destination within an UK hospital setting.

Table 5: Inventory data of packaging stage per functional unit. The packaging is the same for all three type of masks.

Component	**Material**	**Weight (g)**	**Extra processing required after pre-processing**	**Transport to processing centre (km)** *(Vehicle: 7.5-16 mton Euro6 lorry)*	**Transport From hospital to end-of-life (km)** *(Vehicle: 21mton lorry)*
Pack insert	Paper	0.85	None	100	10
Polybag	Low density Polyethylene	2.29	Extrusion plastic film	200	10
Carton	Corrugated Board box	5.71	None	100	10
	Total weight (g)	8.85			

Transportation stage

This stage accounts for all the transportation during the MOMs' life cycles, including transport of raw materials to the device manufacturer, transport from the manufacturing facilities to the hospital, and transport from the hospital to the final end-of-life disposal. The location of raw material extraction plant for each material was received through product data sheets from the manufacturer and the distance travelled from material extraction site to manufacturer (based in South Asia) was calculated using Google maps. For this study, a London-based hospital was used. The type of vehicles used to transport the masks to the hospital were acquired from consultation with the manufacturer and the hospital, and the distance travelled was calculated using Google Maps. After use, the masks are disposed of separate from their original packaging and taken to a nearby incineration site. The disposal site is 10km away from the hospital and information on the type of vehicle used was acquired from consultation with the hospital waste-management team. This data is shown in Table 6.

Table 6: Inventory data use for the transportation stage. Data is presented per functional unit.

Transport Stage	Transport data	Mask[a] A (g)	Mask[a] B (g)	Mask[a] C (g)	Distance by Lorry [km]	Distance by Boat [km]
Raw material to Asian manufacturer ***Vehicle:*** *7.5-16 mton Euro 6 lorry*	Plasticised PVC[b]	28.05	-	28.05	1700	-
	TPE-S[c]	-	7.53	-	100	-
	Polypropylene	2.98	7.09	2.98	100	-
	LDPE[d]	0.03	0.08	0.03	2050	-
	Aluminium	1.47	-	1.47	12	-
	Elastic band	1.09	1.09	1.09	140	-
From Asian manufacturer to UK hospital ***Vehicle:*** *7.5-16 mton Euro 6 lorry, Transoceanic Ship*	Mask + packaging	42.47	24.64	42.47	190	22000
From UK hospital to UK-based end-of-life ***Vehicle:*** *21mton lorry*	Mask	33.62	15.79	33.62	10	-

[a] Description of mask in Figure 5
[b] PVC: Polyvinyl Chloride
[c] TPE-S: SEBS-based Thermoplastic Elastomer, SEBS: Styrene Ethylene Butadiene Styrene
[d] LDPE: Low Density Polyethylene

4.2.4. End of life stage

All the oxygen masks studied are single-use devices and after contact with the patient are placed directly into a waste stream for disposal. The end-of-life scenario modelled for this study is 100% incineration with energy recovery (Great Britain based) which is NHS best practice for contaminated medical devices. It is against best practice (NHS waste disposal regulation HTM 07-01) for used single-use medical devices to be reused or recycled and so neither of these scenarios are modelled within this assessment (HTM, 2022).

4.2.5. Impact Assessment

The Life Cycle Impact assessment results were calculated using the CML-IA Baseline version 3.03 EU25 methodology. A recent study (Rejane-Rigon et al., 2019) found CML to be the most widely used LCA methodology which is why it was chosen. All 11 environmental impact categories that are calculated will be presented in the results to ensure a comprehensive comparison.

4.3. Results and discussion

This section presents the environmental impact results for the three masks studied for the 11 impact categories calculated: abiotic depletion potential of elements (ADP_e), abiotic depletion potential of fossil resources (ADP_f), acidification potential (AP), eutrophication potential (EP), global warming potential (GWP), human toxicity potential (HTP), marine aquatic ecotoxicity potential (MAEP), freshwater aquatic ecotoxicity potential (FAETP), ozone depletion potential (ODP), photochemical oxidants creation potential (POCP) and terrestrial ecotoxicity potential (TETP).

The overall results are discussed in section 4.3.1. where comparisons between masks as well as between life cycle stages will be examined. An in-depth analysis of the materials used within the masks is provided in section 4.3.2. A sensitivity analysis of the material data is provided in section 4.3.3. and a scenario analysis is discussed in section 4.3.4. Validation of the results is shown in section 4.4.

4.3.1. Environmental impacts of oxygen masks

Figure 6 shows mask B (TPE-based) to be the lowest in all impact categories compared to masks A&C. Regardless of impact category, mask B has a reduced environmental impact of at least 40%. For six of the 11 impacts, including ODP and GWP, mask C (DEHP-based PVC) has the highest impact. For the remaining five categories (particularly the toxicity potentials HTP, FAETP, MAEP, and TETP), mask A has greatest environmental impact with its TETP impact being considerably higher than mask C; over 7 times greater. The transport, packaging, and manufacture stages provide similar impact regardless of the mask due to the same inputs required for each device; the only exception is for mask B that has slightly lower transport and manufacturing impacts due to its lower weight. The RMEP and end-of-life stages have the greatest influence on overall impact. These two stages combined make up over half of the impact for each category, with some categories such as FAETP, MAEP, and TETP consisting almost entirely of the impact from the RMEP and end-of-life stages. It is important to note that since the only difference between masks A&C is the type of plasticiser used, all variation in environmental impact is due to changing the plasticiser from DEHP to NonPht.

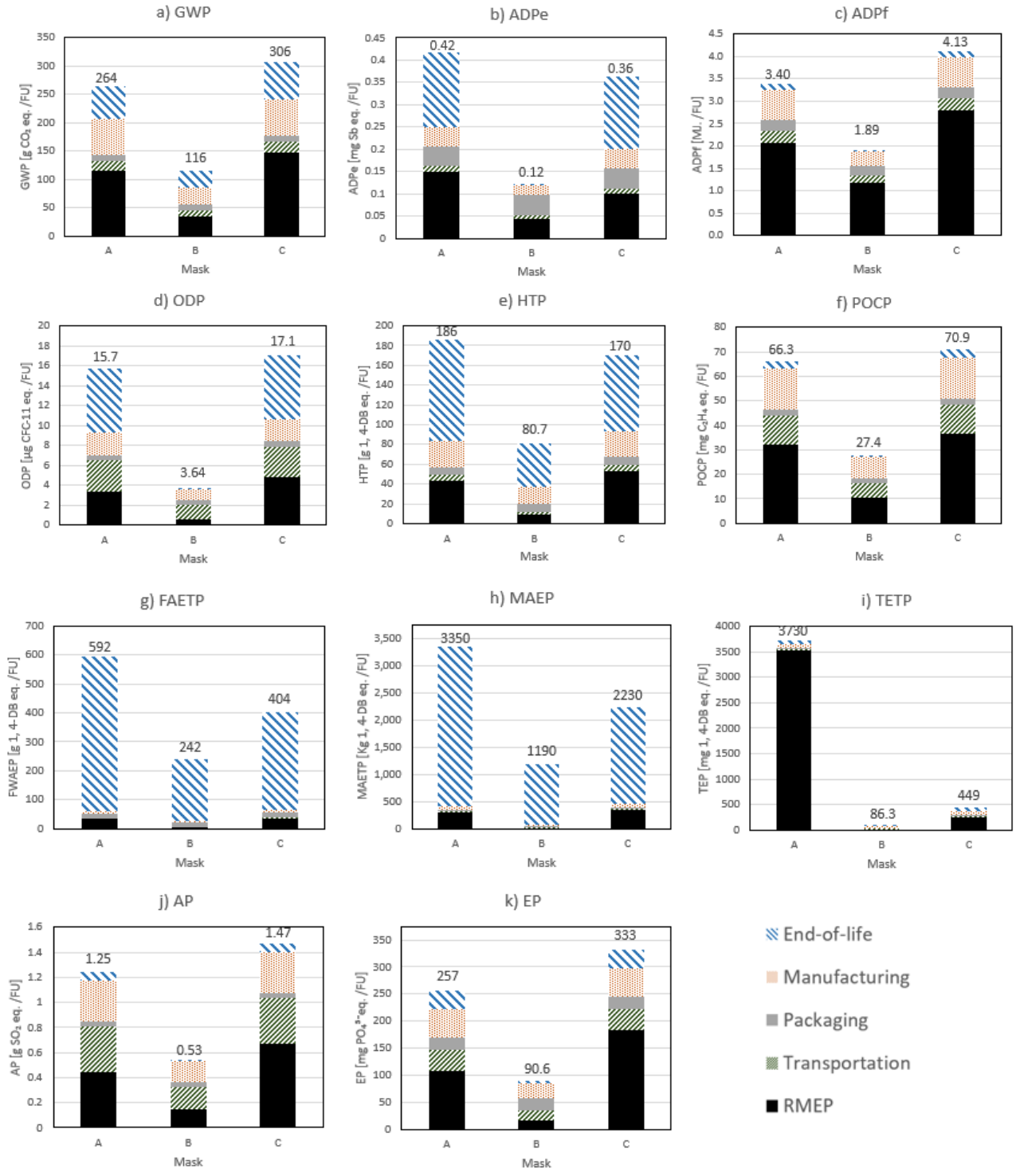


Figure 6: Comparison of environmental impact of three oxygen masks A, B and C. Results expressed per functional unit (FU). Description of masks in Figure 5. ADPe: abiotic depletion potential of elements; ADPf: abiotic depletion potential of fossil resources; AP: acidification potential; EP: eutrophication potential; GWP: global warming potential; HTP: human toxicity potential; MAEP: marine aquatic ecotoxicity potential; FWETP: freshwater aquatic ecotoxicity potential; ODP: ozone depletion potential; POCP: photochemical oxidants creation potential; TETP: terrestrial ecotoxicity potential.

Global Warming Potential (GWP)

Figure 6a shows that for GWP, mask B has the lowest environmental impact of 116 g CO_2 eq/fu, which is 62% and 56% lower than masks A&C, respectively. The RMEP and end-of-life stages of mask B are much lower than that of masks A&C; the environmental impact of the raw materials required for mask B is less than one third of the impact of masks A&C and the end-of-life impact reduced by 46% and 53% from mask A&C to mask B respectively. Some of this can be attributed to the lower material requirements for mask B (47% the weight of masks A&C); e.g., as shown in the 48% reduction in manufacturing and 51% reduction in impact from transport. However, the environmental impact of mask B has decreased greater than would be expected on weight reduction alone because of the material type (see detailed materials analysis in section 4.3.2.). The change in GWP between masks A&C is less sizeable than compared to mask B (C is overall 15.6% higher impact than A). Most of this difference between masks A&C can be found in the RMEP stage, because of the use of NonPht instead of DEHP, respectively. Details of where these variations occur within the materials will be explored in section 4.3.2.

Depletion Potentials (ADPe, ADPf, ODP)

As seen in Figure 6b-d, for ADPe, ADPf, and ODP the variation in impact from masks A&C are relatively small (ADPe: A is +17%, ADPf: C is +20%, ODP: C is +9%). Most of this variation occurs due to changes in the RMEP stage, which for masks A&C, is the result from using NonPht instead of DEHP whilst for mask B is from using TPE instead of plasticised PVC. For ADPe, ADPf, and ODP, mask B has impacts 50-75% lower than masks A&C. Some of this reduction comes from a lower transport and manufacturing impact explained by the lighter weight of mask B; however, the main variations can be seen in the RMEP and end-of-life stages which has an impact lower than would be proportional with just the weight reduction. Figure 6b-d demonstrates that the materials required for mask B, primarily TPE-S, has a lower environmental impact than masks A&C made from plasticised PVC. The impact associated with end-of-life disposal of mask B is small compared to the PVC-based masks (98-99% reduced for ADPe, ADPf, and ODP). This indicates that incinerating mask B is less environmentally impactful in terms of ADPe, ADPf, and ODP than the incineration of the PVC-based masks.

Human health (HTP, POCP)

Figure 6e&f show mask B to have a HTP and POCP impact less than half (52% to 61% lower) of masks A&C. This is mostly due to lower impact from the RMEP and end-of-life stages. For the RMEP stage, mask B has a fifth of the HTP impact compared to masks A&C and less than a third of the POCP impact. Over one third (38% to 52%) of the POCP impact from each mask is due to the RMEP stage. During the RMEP stage, the emissions of sulphur dioxide (SO_2) and carbon monoxide (CO) to air combined provide 60.9% of mask A's total POCP, 59.8% of mask B's, and 75.6% of mask C's. For mask B, the majority of the SO_2 and CO is emitted due to the extraction and pre-processing of the raw materials used for the TPE. For masks A&C, the SO_2 mainly comes from the plasticised PVC whereas over half of the CO emissions are from the extraction the aluminium. For such a small quantity (1.47 g) of the total weight of the mask, the aluminium is particularly impactful during the POCP stage.

The end-of-life is the largest contributing stage to the environmental impact for HTP (mask A: 103 g 1,4-DB eq., mask B: 43.1 g 1,4-DB eq., mask C: 76.6 g 1,4-DB eq.). Most of this impact (58% to 73%) is from emission of Beryllium (Be) to water which for masks A&C, originate solely from the incineration of the plasticised PVC. For mask B, emissions of Be emits 28.0 g 1,4-DB eq.; >99% of which is from the incineration of the TPE. For the end-of-life stage for HTP, mask B is 58% and 44% lower than masks A and C respectively. Some of this reduction is due to mask B's lower weight, however, the decrease in impact from mask C to mask B is less than would be expected on weight alone. Therefore, the incineration of mask C (DEHP-based PVC) is slightly less impactful to HTP based on

weight contribution than mask B (TPE). There is only a slight variation (8% to 10%) between masks A&C for HTP and POCP. For HTP, mask A has a 19% lower RMEP impact than mask C but a 34% higher end-of-life impact.

Aquatic Ecotoxicity potentials (FAETP, MAEP)

For FAETP and MAEP, mask A had the highest impact followed by mask C then mask B. Most of the masks' impact (79% to 94%) is due to the end-of-life stage. For mask A's FWAEP, 489 g 1,4-DB eq. is from Be emissions to water, whereas for mask C only 289 g 1,4-DB eq.; both with >99% from the plasticised PVC. Similar reductions are seen for MAEP (A: 2,880 kg 1,4-DB eq., C: 1,710 kg 1,4-DB eq.). The only variation between mask A and C was the result of switching DEHP plasticiser for NonPht due to no other changes in the life cycle stages. Therefore, showing that the incineration of a product containing the non-phthalate plasticiser has a much higher emission of beryllium than a product containing DEHP.

Mask B has the lowest impact out of the three masks and reduces the environmental impact of FAETP by 59% and MAEP by 65% compared to mask A and FAETP by 40%, MAEP by 47% compared to mask C. Most of the impact is due to the end-of-life stage (89% to 94%). This is again due to the emissions of Be to water for both categories. The incineration of the TPE is responsible for most of the Be emissions for mask B's end-of-life stage for FAETP and MAEP. There is a slight reduction in the RMEP stage which for FAETP primarily consists of emissions of Barium (Ba) to water (1.8 g 1,4-DB eq., 99% coming from the TPE). For MAEP, emissions of Ba to water (6.5 kg 1,4-DB eq) and Hydrogen Fluoride (HF) to air (5.3 kg 1,4-DB eq.) are the main contributing emissions to the RMEP stage, with 99% and 67% of these impacts respectively originating from the extraction and pre-processing of the raw materials used within the TPE.

Ecosystems (TETP, AP, EP)

Mask A has a high TETP, 95% originating from the RMEP stage, particularly from the emission of Cypermethrin (CM) to soil (3320 mg 1,4-DB eq., 94.1%). Almost the entirety (>99.9%) of the CM emissions is due to the extraction and pre-processing of the raw materials for the plasticised PVC. Switching from mask C to mask A results in TETP from the RMEP stage being over thirteen times greater. With CM emissions increasing from 2.58 mg to 3320 mg 1,4-DB eq.

Mask C has an AP 17% higher than mask A and almost three times that of mask B's. For EP, mask C is +30% than mask A and almost four times more impactful than mask B. The environmental impact associated with end-of-life was much lower for mask B than the other masks, but the end-of-life stage had a much lower contribution (1% to 14%) to the overall AP and EP. Mask B was the lowest scoring out of all three masks for TETP, AP, and EP. Reduction from masks A&C to mask B in manufacture and transport impacts were directly correlated to the reduction in the weight of mask B. The reduction in end-of-life and RMEP impacts from masks A&C to mask B was greater than would be expected purely on weight.

4.3.2. Environmental impact of materials

The lower weight of mask B helped reduce its environmental impact by reducing the contribution of all life cycle stages. The lower weight also means that if assuming that 14.5 million MOMs are used each year within UK hospitals (Abbott et al., 2017), switching from PVC-based to TPE masks would reduce materials consumption by 259 tonnes per year (from the original 487 tonnes). Additionally, switching from DEHP-plasticised PVC to TPE-S within MOMs, the greenhouse gas emissions associated with this product would reduce from 4,437 tonnes of CO_2 eq. to 2,700 tonnes of CO_2 eq. per year.

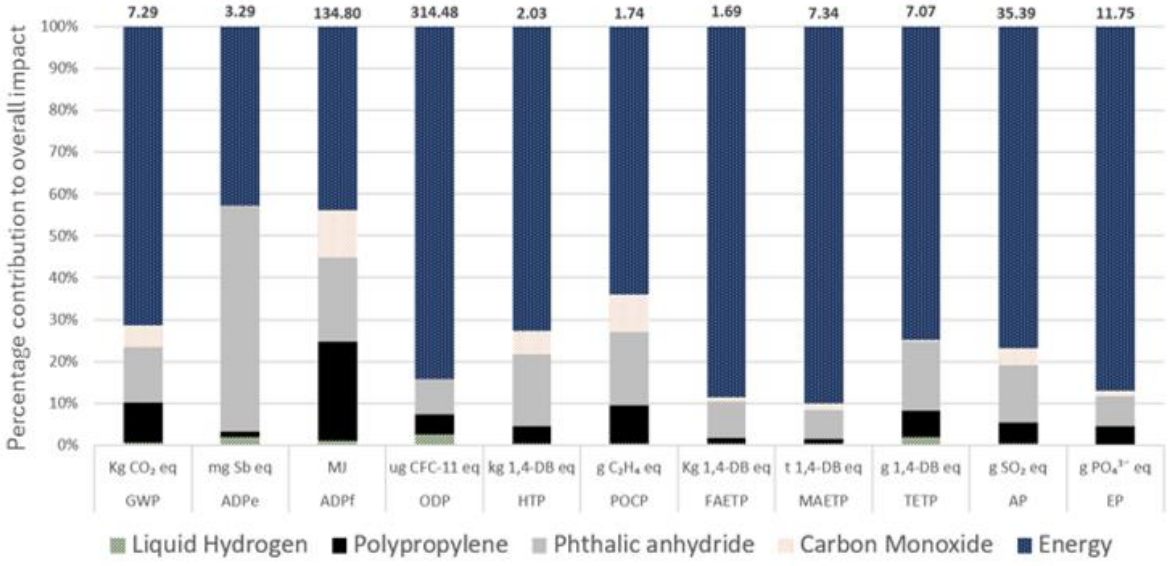
The lighter weight of mask B was partially due to removing excess material (i.e., around nose as seen in Figure 5) as well as utilising the lower density of TPE-S (0.88 g/cc of TPE-S vs 1.20 g/cc for PVC). The analysis in section 4.3.1. demonstrated that the weight difference was not the only aspect reducing the impacts of mask B, but also the materials used. For comprehensive comparison on the materials, Table 7 provides the environmental impact of the main materials used within the three masks (PVC with NonPht, TPE-S, and PVC with DEHP). The plasticiser percentage is modelled the same as is present within the masks, 30-40%, which is known exact for the calculations but kept confidential here. A functional unit of 1 kg of each material was modelled following methodology described in the methodology section. Only the impacts from the raw materials are assessed in this section.

Table 7: Environmental impact of 1 kg of mask materials: Polyvinyl Chloride with DEHP, Polyvinyl Chloride with NonPht, and SEBS-based Thermoplastic Elastomer. Results are displayed for each impact category using absolute values together with a traffic light system - red indicates the highest impact of the three materials, green the lowest impact, and yellow the middle impact.

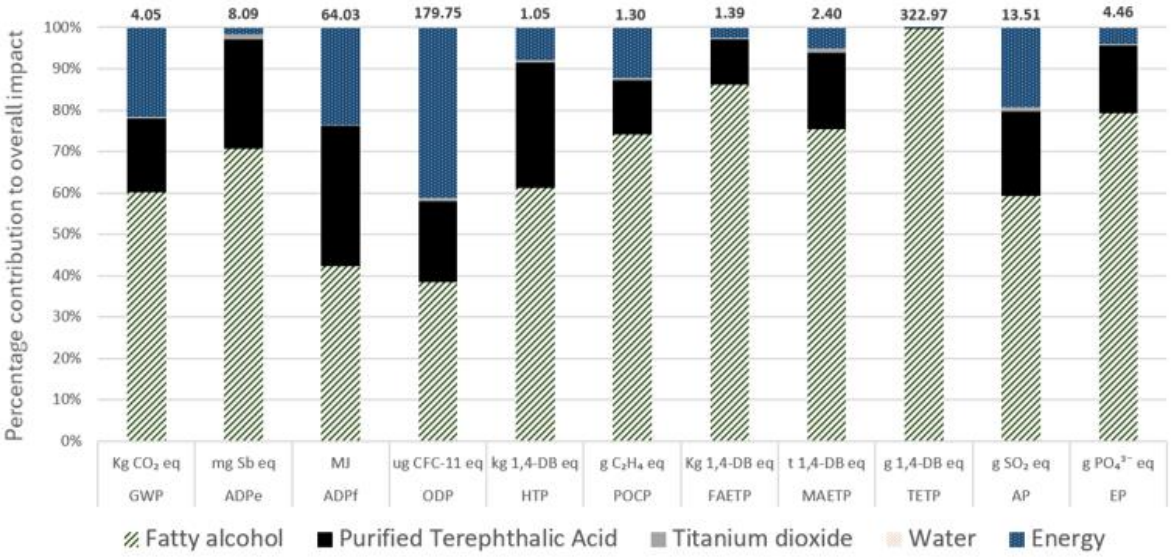
		Material (results per one kg of material)		
Impact category	**Units**	**PVC + NonPht**	**TPE-S**	**PVC + DEHP**
ADPe	*mg Sb eq*	3.15	0.23	1.37
ADPf	*MJ*	53.8	78.5	80
GWP	*kg CO_2 eq*	2.75	2.31	3.95
ODP	*ug CFC-11 eq*	75.6	6.12	125
HTP	*kg 1,4-DB eq*	0.574	0.862	0.935
FAETP	*kg 1,4-DB eq*	0.665	0.291	0.773
MAEP	*kg 1,4-DB eq*	1690	1580	3520
TETP	*g 1,4-DB eq*	124	0.754	6.71
POCP	*g C_2H_4 eq*	0.69	0.863	0.852
AP	*g SO_2 eq*	8.49	11.8	16.6
EP	*g PO_4^{3-} eq*	2.23	0.913	4.92

Table 7 shows that TPE-S has the lowest environmental impact of all the materials for seven of the 11 impact categories with particularly low ADPe, ODP, FAETP, and TETP. For these categories, using TPE-S instead of plasticised PVC reduce the impacts by >50%. TPE-S has the highest impact for POCP but is only +1.3% than PVC plasticised with DEHP. DEHP-plasticised PVC has the highest environmental impact across eight of the 11 categories. The variation in environmental impact by switching from NonPht to DEHP is quite considerable especially for MAEP, AP, and EP. For these three categories, the impact of DEHP-plasticised PVC is around double that of NonPht-plasticised PVC. NonPht-plasticised PVC has the highest impact for ADPe and TETP. For ADPe, environmental impact increases by 129.9% from DEHP-plasticised PVC with 37% of the impact coming from emissions of Gold, 14.5% from Cadmium, and 9.8% from Lead. For each of these emissions, 95% originate from the non-phthalate plasticiser; more specifically, 69% to 71% from the fatty alcohol within the NonPht.

The TETP impact for NonPht-plasticised PVC is significantly greater than both DEHP-plasticised PVC and TPE-S (over 18 and 164 times greater respectively). Most of this impact (118 g 1,4-DB eq., 95.2%) originates from the emission of CM to soil, 97% from NonPht, of which >99.9% is due to the fatty alcohol. The emission of CM has a much lower contribution (<1.2%) to the TETP of DEHP-plasticised PVC and TPE-S indicating that this emission is the main cause of the high TETP. To elaborate on the results presented in Table 7, an LCA of the plasticisers (DEHP and NonPht), excluding PVC, is conducted using a FU of 1 kg of plasticiser; the results are displayed in Figure 7.



a) One kg DEHP plasticiser



b) One kg NonPht plasticiser

Figure 7: Environmental impact of plasticisers – DEHP (a) and NonPht (b) with functional unit of 1 kg of material. Details of impacts per stage can be found in Table A2 in the appendices.

Figure 7 shows the environmental impacts of the plasticisers. Energy required to manufacture DEHP has the greatest contribution to environmental impact across all impact categories except ADPe (where phthalic anhydride is more prevalent) and ADPf (where phthalic anhydride, polypropylene, and carbon monoxide collectively contribute a greater percentage) as seen in Figure 7a. Therefore, focusing on reduction of the environmental impact of the energy used to manufacture DEHP would have the greatest benefit to reduction of overall environmental impact. For NonPht, the fatty alcohol provides over half of the environmental impact for all impact categories except ADPf and ODP (where it consists of 38% to 42%), as displayed in Figure 7b.

Figure 7b shows the fatty alcohol used during manufacturing of NonPht to be the main reason for its high TETP. 1-Octanol is the fatty alcohol used during the esterification step of NonPht manufacture. Potential options for decreasing the environmental impact of the alcohol used during NonPht

manufacture may include increasing efficiency during esterification or using sustainable alternatives such as bio-based fatty alcohols (Xia et al., 2015; Akhtar et al., 2015).

4.3.3. Sensitivity analysis: Energy use of plasticiser production

This section explores the impact that changes in the plasticisers' inventory would have in the impacts of MOMS. Data used for the plasticisers was modelled from literature and by expert's inquires; hence, it is important to test it. In particular, the energy use in the manufacturing of plasticisers may vary due to different machinery, operation scheduling, among others. The sensitivity analysis considers a variation of +/-20% on the energy use in both plasticisers. Table 8 shows the effect on the environmental impact of these materials. As 10.38 g of plasticiser is added per mask, to determine the change per mask, the values shown in Table 8 would need to be divided by around 100 to find the variation on a scale of one mask.

Table 8: Sensitivity analysis on plasticisers DEHP and NonPht with functional unit of 1 kg. Variation of +/- 20% of energy use during production of the plasticisers; results are compared with baseline.

		1 kg DEHP			1 kg NonPht		
Impact category	**Unit**	**Base**	**-20% Energy**	**+20% Energy**	**Base**	**-20% Energy**	**+20% Energy**
GWP	*kg CO_2 eq*	7.29	6.25	8.33	4.05	3.88	4.23
ADPe	*mg Sb eq*	3.29	3.01	3.57	8.09	8.06	8.11
ADPf	*MJ*	134.80	122.96	146.63	64.03	61.03	67.03
ODP	*ug CFC-11 eq*	314.48	261.57	367.40	179.75	164.97	194.53
HTP	*kg 1,4-DB eq*	2.03	1.74	2.33	1.05	1.04	1.07
POCP	*g C_2H_4 eq*	1.74	1.52	1.96	1.30	1.27	1.33
FAETP	*kg 1,4-DB eq*	1.69	1.39	1.98	1.39	1.39	1.40
MAEP	*mg (t) 1,4-DB eq*	7.34	6.02	8.66	2.40	2.38	2.43
TETP	*g 1,4-DB eq*	7.07	6.01	8.13	322.97	322.94	323.01
AP	*g SO_2 eq*	35.39	29.95	40.84	13.51	12.99	14.04
EP	*g PO_4^{3-} eq*	11.75	9.71	13.79	4.46	4.43	4.50

Table 8 shows energy use during material production does have a slight impact (on average +/-14% for DEHP, +/-3% for NonPht) on overall environmental impact of the plasticisers. For DEHP, the change in impact from the baseline varies by between 8.5% to 18%. The greatest variation is observed for ODP where impact increases and decreases by 52.9 ug CFC-11 eq. as energy use changes. The change in environmental impact is less prevalent for NonPht as energy has a lesser overall contribution to its environmental impact (as shown in Figure 7b). The impacts for NonPht varies from 8.2% (i.e., ODP) to no change (i.e., TETP). Overall, sensitivity in energy use during plasticiser production will have variable effect on the environmental impact depending on the impact category. However, changes in the electricity mix could have a larger effect, as this study uses data from 2012.

4.3.4. Scenario analysis: Location

Even though the manufacturing and transport stages are not environmental impact hotspots within the lifecycles of the medical oxygen masks, there are a number of reasons changing manufacturing location is important to be explored. Currently, RMEP and Disposal are the most contributing life cycle stages. During the previous sections the materials used (i.e. the RMEP stage) have already been explored for mitigating opportunities by assessing an alternative material suggestion; thermoplastic elastomer. There are no other materials that have been suggested within literature as appropriate

replacements for PVC within medical oxygen masks for this scenario analysis to explore. The disposal stage is currently modelled as incineration for all three masks studied. According to the HTM 07-01 (HTM, 2022) this is currently the only option for contaminated single-use medical products. It is unlikely that changes to legislation in order to allow alternative disposal routes will be released in the near future. Therefore, changing the disposal scenario for this scenario analysis was deemed a sub-optimal use of this study due to the unlikeliness that practical applications of the results will arise.

Changing the manufacturing location was therefore chosen to be explored as deciding where to buy products from is a key decision consumers can control during purchasing. Furthermore, no previous studies have explored the influence of the manufacturing location on the environmental impact of medical devices and so whether this will cause a significant change is unknown. The results of this scenario analysis are expected to be greatly beneficial for the purchasers of medical devices when deciding what level of consideration manufacturing location should be given especially when aiming to minimise environmental impact.

To evaluate the role of manufacturing site location on the masks' environmental impact, two scenarios are considered: the UK and the USA. These places were chosen as they have large MOMs manufacturing plants. By changing manufacturing location, the following life cycle stages have been altered accordingly: national electricity mix during manufacturing of devices and packaging, and changes in transportation stage (distance of raw materials acquisition, delivery of devices to manufacturer, and from manufacturers to the hospital). All other stages are identical to those described in the life cycle inventory section. For acquisition of raw materials, some of the materials are sourced within the country of manufacture in order to minimise required transportation. However, the plasticised PVC, TPE-S, and LDPE requires a specific composition by particular suppliers and so their location of origin remains unchanged. Table 9 summarises these changes.

Table 9: Transport distance for scenario analysis

Transport stage	Material	Distance	Manufacturing site	
			UK	USA
Raw materials to manufacturer ***Lorry*** *(7.5-16 mton Euro 6 lorry)* ***Boat*** *(Freight, sea, transoceanic ship)*	Plasticised PVC	By Boat (km)	-	20000
		By Lorry (km)	400	-
	TPE-S	By Boat (km)	-	22000
		By Lorry (km)	2000	-
	Polypropylene	By Boat (km)	-	-
		By Lorry (km)	7	100
	LDPE	By Boat (km)	-	22000
		By Lorry (km)	30	-
	Aluminium	By Boat (km)	-	-
		By Lorry (km)	12	12
	Elastic band	By boat (km)	-	-
		By Lorry (km)	140	140
From manufacturer to hospital ***Lorry*** *(7.5-16 mton Euro 6 lorry)* ***Boat*** *(Freight, sea, transoceanic ship)*	Weight of mask + packaging (g)		24.64	42.47
	Distance by Boat (km)		-	18520
	Distance by Lorry (km)		45	250

Figure 8 exhibits the results for the scenario analysis, showing a sample of four indicators – GWP, ODP, HTP and AP. For the other seven indicators, refer to table A3 in the appendices.

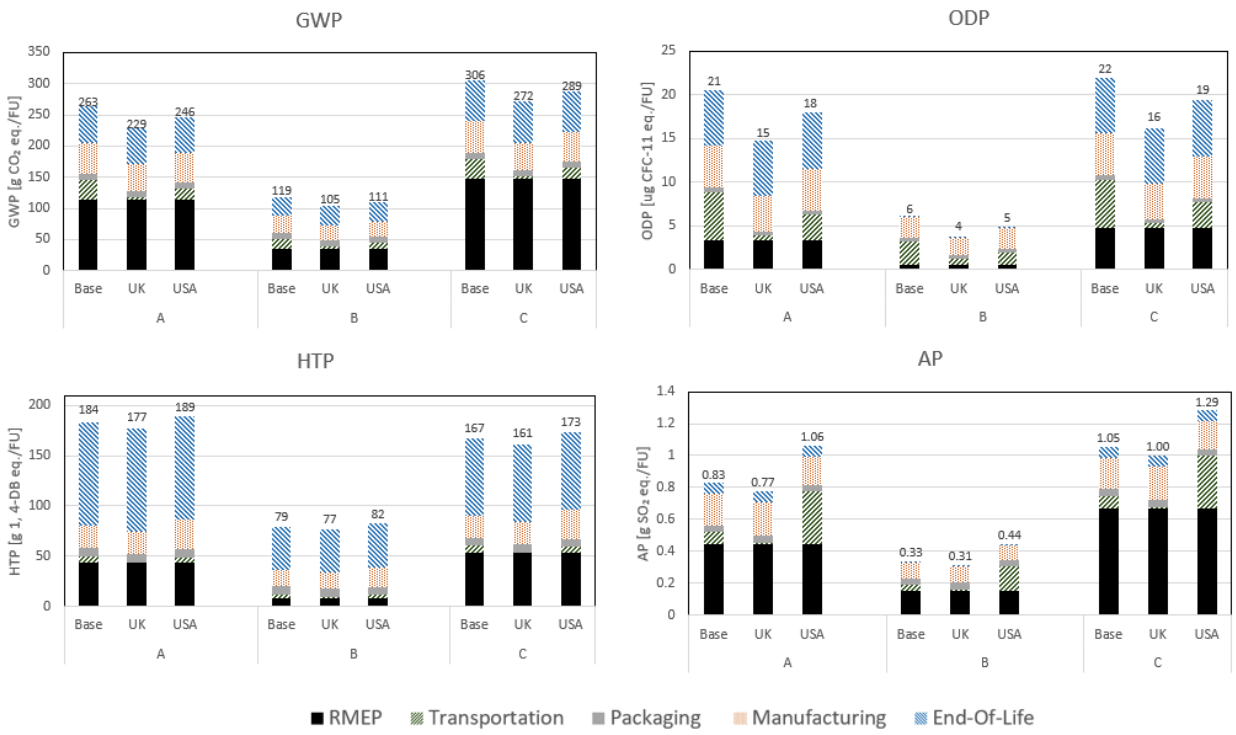


Figure 8: Scenario analysis - Comparison of environmental impact of three oxygen masks A, B and C at three different manufacturing locations: Asian country (baseline), UK, and USA. Results expressed per functional unit. Description of masks in Figure 5. GWP: global warming potential; ODP: ozone depletion potential; HTP: human toxicity potential; AP: acidification potential. For other impacts, see Table A3 in the SI.

As seen in Figure 8, the location of manufacturing site does have an effect on the environmental impact of MOMs, with variations between 1% and 23% across all 11 impact categories. The greatest increase (+23%) can be seen in the AP category when manufacturing the masks in the USA instead of the Asian country (baseline). Manufacturing in the USA has the greatest AP mainly due to the large increase in environmental impact from the transportation stage.

For all categories, the least environmentally impactful location for all masks is in the UK. GWP from transportation reduces significantly (over 74% reduced for all masks) when manufactured in the UK instead of Asia (baseline), as well as slight reductions (10% to 12%) in impact from manufacturing. As the hospital is based in the UK, this reduced transportation distance has resulted in a lower GWP. The reduction in the manufacturing stage can be attributed to the UK's electricity mix having the lowest carbon intensity per kWh out of the three countries studied; Baseline: 315 g CO_2 eq./kWh, UK: 169 g CO_2 eq./kWh, USA: 181 g CO_2 eq./kWh (Wernet, 2016)). This demonstrates that choosing to manufacture in a location with minimal transportation distance from the user will have great effect on lowering environmental impact. Similarly, choosing a location with lower emissions associated with their electricity generation will help reduce the impact further.

4.4. Data Validation

The lack of research exploring the environmental impact of MOMs makes it harder to ensure the findings are supported by other scientific studies. In order to validate the final outcomes of this study, the findings have been compared with studies of similar medical devices, with products which contain similar materials, and manufactured using similar processes. Studies which used similar methodologies as this paper as well as providing evaluation of medical devices were also chosen to aid comparison. For most papers, a full range of environmental impact categories were not provided

but a common impact category shown for each paper was GWP given in g CO_2 eq. per FU of their study. In order to allow comparison of the results of this study, the GWP (g CO_2 eq.) for each product will be divided by the product's weight in order to calculate a GWP per g CO_2 eq./g of product.

Figure 9 shows the GWP for each of the products (in g CO_2 eq./g of product). Details of the analysis, including sources and further description is provided in table A4 in the appendices.

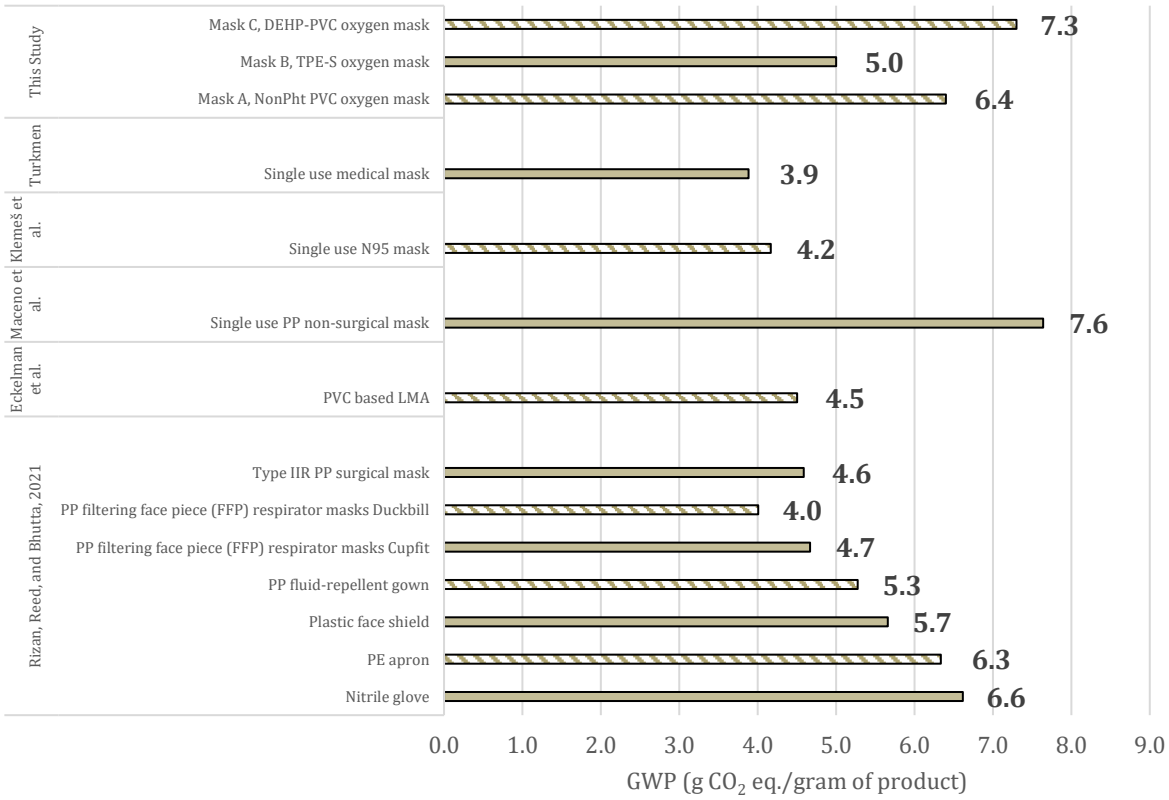


Figure 9: Validation of the study - Comparison of GWP (g CO_2 eq./g of product) of various medical devices found in literature. Functional unit of per gram of product.

Review of the literature found that the results provided correlate with the results of the three masks within this paper. Per gram of product, the three masks from this study emitted 5.0 g CO_2 eq./g to 7.3 g CO_2 eq./g with the two PVC masks (masks A&C) having higher g CO_2 eq./g (A: 6.4 g CO_2 eq./g, C: 7.3 g CO_2 eq./g) than mask B (5.0 g CO_2 eq./g). For some of the devices found in the literature, the impacts are slightly higher or lower than this study, but all fall within the range of 3.9 g CO_2 eq./g to 7.6 g CO_2 eq./g. This variation can be explained by the types of materials found within the devices. For studies where similar materials are used (e.g., PVC-based laryngeal mask airway (LMA) by (M. Eckelman et al., 2012)) the impact is slightly lower than masks A&C. Upon investigation, it was found that no plasticiser was modelled within Eckelman et al.'s study. This is understandable as prior to this research, little LCI data was available for plasticisers. As shown in Table 7, one kg of plasticiser has a GWP of 7.29 kg CO_2 eq./kg (DEHP) and 4.05 kg CO_2 eq./kg (NonPht). This is higher than the GWP of 1 kg of unplasticized PVC (1.98 kg CO_2 eq./kg) (Wernet, 2016) thus showing that adding plasticisers would increase the impact of PVC per kg, and also helps explain why the PVC LMA containing unplasticized PVC has a lower GWP (g CO_2 eq./g) than masks A&C containing plasticised PVC.

For many of the studies, the entire life cycle was included; except (Maceno et al., 2022) where transport is excluded. The papers explored found the same key life cycle stage contributors as this study; the materials (RMEP) and end-of-life stages were shown to be the most impactful phases, with processing and transportation to have least impact. Furthermore, (Atılgan-Türkmen, 2022) showed end-of-life to be the main contributor to FAETP, MAEP, and HTP which concurs with this paper's findings.

4.5. Conclusion

This paper analysed the environmental impact of three low-flow medical oxygen masks (MOMs). Mask B (TPE-S based) is shown to have the lowest environmental impact across all impact categories. The life cycle stages with the biggest contribution were shown to be RMEP and end-of-life. The lighter weight and material composition of mask B were found to reduce the environmental impact of the RMEP, manufacturing, transport, and end-of-life stages across all impact categories. 1 kg of TPE-S material was found to have the lowest environmental impact for seven of 11 impact categories. It is therefore encouraged to replace plasticised PVC within medical devices with TPE-S for optimal environmental impact savings.

Assuming that over 487 tonnes of material is used for oxygen masks within UK hospitals each year, switching from DEHP-plasticised PVC to TPE-S would reduce the impacts of the use of MOMS by 2,700 tonnes of CO_2 eq. per year (from 4,437 tonnes of CO_2 eq.) per year. If plasticised PVC must still be used, 1 kg of PVC plasticised with DEHP material was found to have the highest impact for eight out of 11 of the impact categories so replacing DEHP with NonPht should be pursued instead. Energy used during the manufacturing of DEHP, and the fatty alcohol used during the manufacture of NonPht were the greatest contributors to environmental impact across all impact categories. The scenario analysis demonstrated that environmental impacts can be reduced by manufacturing at a site closer to the location of the hospital and with a low emissions electricity mix.

The findings of this study suggest that future research should focus on lowering environmental impact of MOMs by primarily addressing the material and end-of-life stages. Further research could also examine how to reduce the environmental impact from the constituents of the DEHP and non-phthalate plasticisers.

CHAPTER 5

5: MECHANICAL AND ENVIRONMENTAL EVALUATION OF GROUND CALCIUM CARBONATE ($CACO_3$) FILLED POLYPROPYLENE COMPOSITES AS A SUSTAINABLE ALTERNATIVE TO VIRGIN POLYPROPYLENE.

This chapter addresses objective 2

A publishable article version of this chapter was submitted to the journal 'Results in Materials' on 12th January 2024. Reviewer comments were received on 5th February 2024 with resubmission occurring on 25th February 2024. The revised article was accepted 9th March 2024 and available online 28th March 2024.
The Doi of this published article is: https://doi.org/10.1016/j.rinma.2024.100562

The article is titled: Mechanical and environmental evaluation of ground calcium carbonate ($CaCO_3$) filled polypropylene composites as a sustainable alternative to virgin polypropylene

The URL to access this publication is:
https://www.sciencedirect.com/science/article/pii/S2590048X24000360

Statement of contribution:
As multiple authors are listed to have contributed to this chapter, a statement is provided to demonstrate the roles each author had during its construction and a respective overall percentage to the work as a whole.

In order to facilitate fair assignment of author contribution percentages to each of the respective authors, the following division of work contribution has been allocated:

- 20% will be allocated to chapter conceptualisation and planning.
- 20% will be allocated to the running of any required software or alternative methods to obtain the results.
- 20% will be allocated to the interpretation of the results and any further analysis required.
- 25% will be allocated to the writing and editing of the chapter.
- The final 15% of the work is allocated to supervision. This percentage will be split amongst the supervisors according to their respective involvement.

Christina Webb (Percentage contribution: 80%)
Fulfilled roles: Chapter conceptualisation, Methodology, Data curation, Acquisition of materials, Formal analysis, Operation of all testing equipment, Software, Project administration, Validation, Writing- Original draft preparation, review and editing.

Kun Qi (Percentage contribution: 10%)
Fulfilled roles: Supervision, Preparation of composite samples via injection moulding, Writing (review and editing of final draft).

Lorna Anguilano (Percentage contribution: 5%)
Fulfilled roles: Supervision, Writing (Review & editing of final draft).

Ximena Schmidt Rivera: (Percentage contribution: 5%)
Fulfilled roles: Supervision, Writing (Review and editing of all drafts).

Unlike the other chapters within this thesis, this chapter addresses the issue of sustainable medical devices in a slightly different way and so in order to aid the reader, a description of its relevance to the over-arching aim of this research and how it can be best applied in order to design sustainable medical devices is provided here. Within this chapter, no specific medical devices are being assessed and no particular mitigations within the life cycle stages are examined. Instead, this chapter specifically focuses on the examination of a proposed sustainable alternative to virgin polypropylene; calcium carbonate filled polypropylene.

The current literature has consistently shown that the materials required within medical devices is the most impactful life cycle stage. It is therefore imperative that sustainable solutions are found for the materials currently being used. Polypropylene is one of the most popular materials used within plastic medical devices and so this chapter explores a sustainable alternative. The composites formed when combining calcium carbonate with polypropylene can be used in place of virgin polypropylene in medical devices currently being manufactured. Further studies such as biocompatibility testing will be required before this can be expected to become a manufacturing norm, however, this chapter helps bring the possibility of sustainable alternative medical materials one step closer.

The changes to mechanical properties when incorporating varying percentages of calcium carbonate into polypropylene is shown throughout this chapter. If these changes are acceptable to the tolerances demanded by the manufacturer, then these composites could potentially be incorporated into any medical device that currently uses polypropylene. The environmental impact savings can then be calculated per device using the life cycle assessment environmental impact data calculated. It is then by incorporating these composites into manufacturing designs that the environmental impact of medical devices can be reduced which ultimately helps achieve this thesis' aim of creating sustainable medical devices.

Mechanical and environmental evaluation of ground calcium carbonate ($CaCO_3$) filled polypropylene composites as a sustainable alternative to virgin polypropylene.

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Abstract
Polypropylene (PP) has raised numerous environmental concerns particularly due to the depletion of fossil-fuels and its contribution to climate change. In order to reduce the reliance of virgin PP on petrochemicals and to lower environmental impacts, sustainable composites can be made by

combining with biobased fillers. One widely used filler is calcium carbonate ($CaCO_3$) which, as of yet, has not been studied for its full environmental impact. The mechanical properties of PP containing $CaCO_3$ has also not been explored in depth at higher filler percentages neither the range of filler ratio in large intervals. This study explores the aesthetic, tensile, flexural, and impact properties of injection moulded $CaCO_3$ filled PP with filler content ranging from 0% to 40% at 5% increments. A full environmental analysis is also provided using life cycle assessments. The results show that as filler percentage increased, yield strength decreased (0% $CaCO_3$: 17.68 MPa, 40% $CaCO_3$: 12.73 MPa), but young's modulus, flexural modulus, and impact strength increased (respectively 69%, 51%, and 35% greater than pure PP). Flexural strength increased initially at 5% $CaCO_3$ but then declined as more filler was added. A yellowish hue is observed within all blends which grows stronger with more filler.
The environmental analysis showed that the addition of $CaCO_3$ reduced the environmental impact for all 11 impact categories compared to virgin PP. For every 5% of $CaCO_3$ added, the material's GWP decreases by 100 g CO_2 eq. per functional unit (1000 cm^3) of material. Abiotic depletion of fossil fuels had the biggest decline of 32% when 40% $CaCO_3$ was added. In conclusion, the addition of $CaCO_3$ filler significantly reduces the environmental impact of virgin PP, however, manufacturers will need to decide what allowances are acceptable in terms of mechanical properties. Furthermore, it would be beneficial to explore other factors that affect the properties of $CaCO_3$ filled PP such as particle size, particle distribution, and binding additives.

Keywords: Composite, Calcium carbonate, Flexural properties, Modulus, Environmentally friendly.

5.1. Introduction

In 2020, 380 million tonnes of plastic were produced globally (Nielsen et al., 2020), a number which is growing every year and expected to reach over 1.1 billion tons by 2050 (Muthukumar & Kasiraman, 2023). Polypropylene (PP) is one of the most commonly produced plastics and accounts for 16% of total global plastic production (Alsabri et al., 2022). PP has come under scrutiny for contributing to a variety of environmental issues with depletion of fossil fuels and impact to climate change of particular concern (Moretti et al., 2020). In order to improve the sustainability of PP, a possible approach is to combine virgin polypropylene with materials deemed more sustainable, such as: rice husk (Yam & Mak, 2014; Mohamed et al., 2018), Lignin (Alassod et al., 2020; Abdelwahab et al., 2015), Starch (Kaseem et al., 2012), Chitosan (Alassod et al., 2023), Talc (Tadele et al., 2020), Polylactic Acid (Bai & Dou, 2016), Cellulose (Reale Batista et al., 2020), Jute (Rani Bepari et al., 2019), Kenaf fibre (Mohamed et al., 2018), and Calcium carbonate (Peng et al., 2021).

Out of the mineral-based fillers, ground calcium carbonate ($CaCO_3$) is the most popular (Thio et al., 2002) due to its numerous benefits such as being widely available (Ortiz et al., 2019), cheap to produce (Poudyal et al., 2021), non-toxic (Ortiz et al., 2019), and naturally occurring (Mattila & Zevenhoven, 2014). $CaCO_3$ can be used as a nutrient supplement and FDA approved for use within food and medical applications (Park et al., 2017). $CaCO_3$ is produced from the mining and subsequent grinding of naturally occurring forms of calcium carbonate such as limestone, marble, or chalk (El-Sherbiny et al., 2015). It can regularly be found within polymers such linear low-density polyethylene (Radebe et al., 2023; Barczewski et al., 2017), low-density polyethylene (Sampath et al., 2019; Leow et al., 2023), high-density polyethylene (Abdellah Ali et al., 2023; Sepetcioglu & Aydemir, 2022), polyvinyl chloride (Malak, 2021; Schlickmann et al., 2019; Malak et al., 2022), polystyrene (Gorna et al., 2008; Godard et al., 1993), polylactic acid (Liang et al., 2013) (V. Kumar et al., 2014), and polypropylene (Leong, Ishak, et al., 2004; Wang & Wang, 1999; Jancar et al., 1993; Chan et al., 2002).

$CaCO_3$ has been shown to improve certain mechanical and thermal properties of the resulting polymer composite such as increased thermal resistance (Schlickmann et al., 2019), impact resistance (Eirasa & Pessan, 2009), and elastic resistance (Thenepalli et al., 2015). $CaCO_3$ filled PP in particular has been researched for its effect on yield strength (K. Yang et al., 2006b), young's modulus (Lam et al., 2009), volume strain (Lazzeri et al., 2004), tensile strength (Demjén et al., 1998; (Mitsuishi et al., 1985), impact toughness (Thio et al., 2002), flexural properties (Zebarjad et al., 2004), and rheological behaviour (Karamipour et al., 2011; Han, 1974). It has been found that as filler percentage of $CaCO_3$ within the formulation increases, the potential for issues during processing as well as reduced flexural toughness and strength of the resulting composites could occur (Leong, Abu Bakar, et al., 2004). Despite this, the research currently available do not test high percentages of $CaCO_3$ filler whilst increasing at regular increments. Some papers explore up to 40% $CaCO_3$ but at only 10% increments (Zuiderduin et al., 2003; Supaphol et al., 2004; K. Yang et al., 2006a; K. Yang et al., 2007), whereas others increase by 2-10% increments but only up to 30% (Hanim et al., 2008; Eirasa & Pessan, 2009; Chafidz et al., 2014; Essabir et al., 2017). This limits how accurately manufacturers can extrapolate an ideal percentage of filler to use for their own production requirements.

Studies about samples' appearance once prepared via injection moulding are also lacking. Material manufacturers looking to incorporate $CaCO_3$ into their polypropylene are unable to use scientific literature to decipher how surface appearance of the polypropylene will change as $CaCO_3$ filler is added. Therefore, comparison between colour and aesthetic features of composites containing various concentrations of filler are unable to be made.

In addition to testing mechanical properties, no studies explore the full environmental impact of $CaCO_3$ filled polypropylene composites. This is despite research claiming $CaCO_3$ to be more sustainable based solely on its lack of need for fossil fuels and low embodied energy and carbon footprint (H. Yang et al., 2018). As of 2016, one kg of $CaCO_3$ has a global warming potential (GWP) of 39.6 g CO_2 eq. (Wassenaar, 2016) which includes the mining of the limestone and preparation into processable form, compared to one kilogram of PP which is much greater at 1.95 kg CO_2 eq. (Alsabri et al., 2021). No other environmental impact categories outside of GWP have been investigated in regard to ground $CaCO_3$. PP, however, has been shown to have a wide range of negative effects on the environment including impact on marine life (Andrady, 2011), eutrophication (Yuan et al., 2021), and resource depletion (Tähkämö et al., 2022) to name a few. The production of the raw virgin material of PP constitutes a vast proportion of its overall impact across its lifecycle (Mannheim & Simenfalvi, 2020). Whether replacing a proportion of the virgin PP with $CaCO_3$ will solve this range of environmental problems is yet to be determined.

To fully understand all environmental impacts, a more in-depth and comprehensive analysis will need to be conducted. Life cycle assessment (LCA) methodology is a well-known and standardised framework to assess the environmental impact of products or services by compiling the input and emissions data throughout the lifecycle to calculate overall environmental impact (Kousemaker et al., 2021). As of currently, no environmental assessment study has been conducted on $CaCO_3$ filled polypropylene; a gap this study intends to fill.

5.2. Materials and Method

The following sections first describe the goal of this project (section 5.2.1.) and then explain the samples used (section 5.2.2.). The methodologies used for determining mechanical and aesthetic properties are explain in section 5.2.3., followed by the description of the LCA methodology in section 5.2.4.

5.2.1. Goal

The goal of this study is to explore changes in key mechanical, aesthetic, and environmental properties as varying percentages of $CaCO_3$ filler are added to virgin PP to form PP - $CaCO_3$ composites. The environmental impacts across a comprehensive range of impact categories are provided via the use of the life cycle assessment (LCA) methodology.

5.2.2. Materials

Two commercially available materials were used for this study; Polypropylene (PP) and Ground calcium carbonate ($CaCO_3$). The PP is a polypropylene impact copolymer acquired from INEOS. This material has a melt mass flow index (190 ◦C/21.6 kg) of 20.0 g/10 min, tensile yield stress of 21.0 MPa, and Flexural modulus (23 ◦C) of 850 MPa. A ground calcium carbonate ($CaCO_3$) mineral masterbatch was acquired from Granic with the product number Granic535. This masterbatch has a calcium carbonate content of 83%, with the remaining 17% consisting of a multifunctional copolymer. This material has a melt flow index (190◦C/5 kg) of 1.6 g/10 min and a mean particle size (D_{50}) of 2.5 µm.

Injection moulding processing

Both the $CaCO_3$ and polypropylene were purchased in the form of pellets which were introduced into an injection moulding machine via a hopper allowing for distribution of the $CaCO_3$ within the polypropylene. Measured weight percentages of $CaCO_3$ and polypropylene were added to the hopper to create the various composites of varying filler percentages. $CaCO_3$ masterbatch was added to the polypropylene in percentages of 0% to 40% at 5% increments (therefore equalling 4.15% to 33.2% of pure $CaCO_3$ at 4.15% increments). This results in nine specimens of varying filler percentages being created. An ISO 527 type 1 dumbbell test bar mould with thickness 4mm and 170mm in length was used following standard BS EN ISO 527-2:2012.

5.2.3 Experimental methodology

This study applies three methods (tensile tests accompanied with the Young's modulus formula, 3-point bend tests, and Charpy impact tests) to assess the mechanical properties of the composites. These methods are described below. Aesthetic properties are assessed using visual observation.

Tensile testing

Tensile tests were carried out according to standard ISO 527-1:2019 (ISO, 2019a) using an Instron 5967 tensile test system at a cross-head speed of 10 mm/min. The average value of three samples for each type of composite was taken. The samples were tested at room temperature (20°C). All data was recorded by the Instron test system with no need for an extensometer.

The yield stress was calculated by identifying the greatest tensile stress within the tensile stress-strain curve data and the young's modulus was calculated using the equation:

$$Young's\ modulus\ (E) = \frac{\text{Stress}\ (\sigma)}{Strain\ (\varepsilon)}$$

Flexural (3-point bend) testing

Flexural properties were measured via a 3-point bend test according to standard ISO 178:2019 (ISO, 2019b) using an Instron 5967 test system at a cross-head speed of 10 mm/min. The average value of three samples for each type of composite was taken. The tests were conducted at room

temperature (20°C). The flexural strength and flexural modulus were calculated using the following equations:

Flexural strength: $$\sigma_f = \frac{3F_{max}\mathrm{L}}{2WT^2}$$

Flexural modulus: $$E_f = \frac{L^3 m}{4WT^3}$$

- L (span) = 70 mm
- T (thickness) = 4 mm
- W (width) = 10 mm
- F = force applied
- m = gradient of the initial straight-line section of the load deflection curve

Impact testing

The Charpy impact testing of the composites was conducted on an Instron CEAST impact tester according to standard ISO 179-1:2023 (ISO, 2023). a pendulum of 2 J impact energy was used to measure the specimens over a cross sectional area of 70 mm x 10 mm x 4 mm. For each composite, three specimens were tested. The following equation was used to calculate Charpy impact strength:

Charpy impact strength = $$\frac{\text{Impact energy}}{\text{Specimen thickness} * \text{Specimen width}}$$

- Thickness = 4 mm
- Width = 10 mm

5.2.4. Life Cycle Assessment (LCA) Methodology

For this study, the environmental impact assessments are performed applying the Life Cycle Assessment methodology according to the ISO standards 14040 and 14044:2006 (ISO, 2006a; 2006b), and conducted using the SimaPro software (v8.3.1) (PRé, 2008). The functional unit was set at 1000 cm^3 (which in this case is equivalent to one kg) of composite material with varying percentages of $CaCO_3$ filler (0% to 40% at 5% increments). The scope of this assessment is cradle to gate including the following life cycle stages: raw material extraction, transport to pellet processing, pellet production, and subsequent injection moulding to represent required manufacturing into usable parts.

Background information for product flows were sourced from the Ecoinvent 3.2 database (Wernet et al., 2016) with global market averages used. For the life cycle inventory of the raw materials, unprocessed limestone and granulate polypropylene were the processes selected to model calcium carbonate and polypropylene; these are detailed in table A5 of the appendices.

'Limestone, unprocessed {GLO} market for Alloc Def U' and 'Polypropylene, granulate {GLO} market for Alloc Def U' were selected from the Ecoinvent 3.2 database as the input processes. Data that has been averaged from global production was used.

The transport and pellet production impacts are embedded within the raw material extraction process as provided by the Ecoinvent database. The modelling for transportation (i.e., transport

vehicles and transport distance) as provided by the Ecoinvent database can be found in table A6 of the appendices.

For the injection moulding process, a unit of one kg of the process titled 'Injection moulding {GLO} market for Alloc Def U' was chosen from the Ecoinvent 3.2 database. This is again data that has been averaged from global production. The electricity grid used was also from average global data and the process selected from the Ecoinvent 3.2 database was 'Electricity medium voltage {RoW} market for Alloc Def U'.

The Life Cycle Impact assessment results were calculated using the CML-IA Baseline version 3.03 EU25 methodology including all 11 environmental impact categories.

5.3. Experimental results and discussion

The results from each test are provided and discussed below in separated sections. The aesthetic properties are discussed in section 5.3.1, tensile properties in section 5.3.2., flexural properties in section 5.3.3., impact properties in section 5.3.4., and environmental properties in section 5.3.5. An overall discussion of these properties combined are then discussed in section 5.4. followed by suggestions for future research in section 5.5.

5.3.1. Aesthetic properties

Figure 10 displays images taken of the tensile test pieces created via injection moulding for each formulation. The 0% specimen is shown to have an opaque white colour and even just 5% of filler added creates a noticeable difference in surface colour. 5% filler shows to be a very light cream which becomes only a slightly darker cream at 10% and 15%. A yellowish hue can be seen to become more prevalent as the percentage of $CaCO_3$ filler increases. At 20% filler and above, the yellowish tint appears to no longer grow much stronger but instead maintains a similar dark cream colour. The colour change across all specimens is uniform in that the colour is equally distributed for each piece. There are no noticeable areas of irregular concentration of colour gradients within individual samples. This indicates that there is minimal clumping of $CaCO_3$ particles on a macro scale allowing for the colour to spread evenly.

When the specimens were moulded, no alterations to the injection moulding equipment were required compared to the requirements when moulding pure polypropylene (0% $CaCO_3$). No mixing of the polypropylene pellets and ground calcium carbonate was conducted prior to being placed in the machine but via observation of colour, generalised distribution of materials appears to have occurred. In addition to colour, no observable changes to the macro scale topography were noted. The surface of the composites where $CaCO_3$ particles were added did not appear to have any noticeable roughness or uneven texture compared to the sample of pure polypropylene (0% $CaCO_3$).

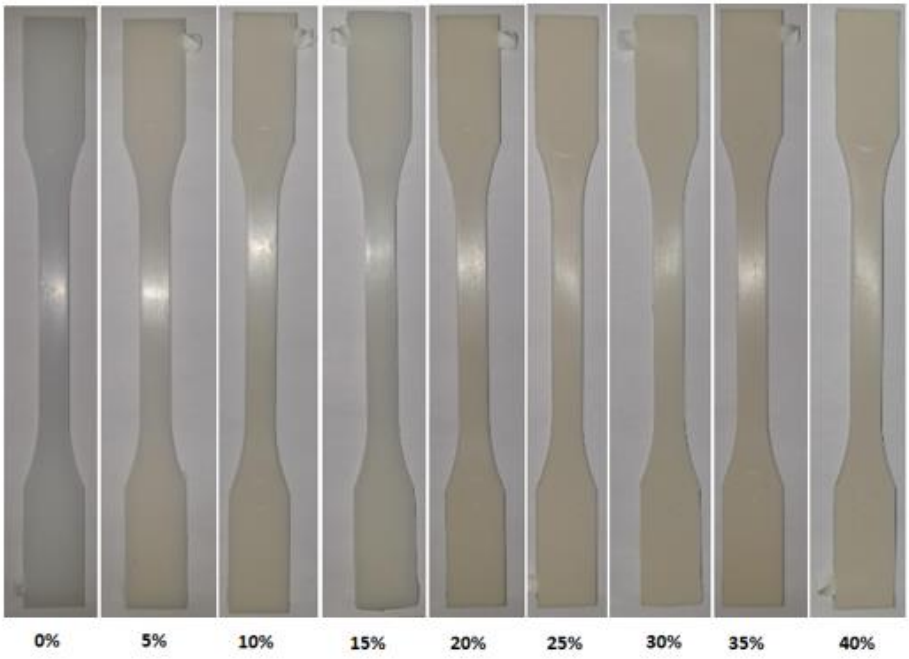

Figure 10: Visual appearance of $CaCO_3$ - polypropylene composites with 5% increments of $CaCO_3$ filler (From left to right, $CaCO_3$ content ranges from 0% to 40%, increasing at 5% increments)

5.3.2. Tensile testing

Figure 11 shows the tensile stress-strain curves for the PP - $CaCO_3$ (0% to 40%) composites. Accompanied alongside the stress-strain curves are the yield strength values and young's modulus of the specimens provided in Table 10.

The stress-strain curves show how all specimens demonstrate tensile behaviour typical of plastic ductile yielding followed by eventual fracture. The specimen containing 0% $CaCO_3$ is shown to have the largest elongation at break, fracturing at a strain of 4.79 mm/mm. The 40% $CaCO_3$ filled PP sample has the lowest elongation at break by a large margin and seen to fracture at 2.5 mm/mm strain, much less than the other specimens and around half of the elongation of pure PP. The other samples are shown to break at values between these two formulations. 30% $CaCO_3$ filled PP has an elongation at break closest to that of pure polypropylene (0% $CaCO_3$) breaking at a strain of 4.40 mm/mm; 0.39 mm/mm less than that of pure PP. It appears that as $CaCO_3$ filler content increases from 5% to 30%, the elongation before breaking increases but then any filler percentage higher, the elongation experiences rapid decrease. At percentages above 30%, breakage is shown to occur at 3.43 mm/mm and 2.5 mm/mm for 35% and 40% respectively. This is a fast decline from the break of 4.40 mm/mm when using 30% $CaCO_3$.

It can be seen in both Figure 11 and Table 10 that as percentage of $CaCO_3$ present increases, the yield strength reduces. This trend is not perfectly linear but does show a steady overall decrease. Pure PP (0% $CaCO_3$) has the greatest yield strength of 17.68 MPa but is only slightly greater than that of 5% and 10% (17.26 MPa and 17.60 MPa respectively). At 15% $CaCO_3$ filler and above, the yield strength demonstrates a larger decrease. For 15% and 20%, yield strength lowers to 15.86 MPa and 15.17 MPa respectively, a 10% and 14% reduction from pure PP (0% $CaCO_3$). Interestingly, at 25% and 30%, the yield strength increases slightly to 16.14 MPa and 16.02 MPa. This is still over 1.5 MPa lower than pure PP but higher than the composites containing lower percentages of filler (15% and 20% $CaCO_3$).

(K. Yang et al., 2006) and (Zuiderduin et al., 2003) studied yield strength up to 30% $CaCO_3$ at 10% increasing filler percentage increments. They both found that yield strength decreases consistently with no percentages where the value increased as higher filler content was added. This study used an average of three samples when calculating tensile properties, all samples of which demonstrated the increased yield strength for 25% and 30% $CaCO_3$ filler. This indicates that another factor is at play which differs between this study and the previous two resulting in the increased yield strength of these specimens. Perhaps at these percentages, changes have occurred between the interaction between the $CaCO_3$ particles and the polypropylene but with current understanding, this will need further investigation.

Just as was seen with elongation at break, when $CaCO_3$ filler percentage is at 25% or 30%, yield strength is closer to pure PP (0% $CaCO_3$) than specimens containing lower percentages of $CaCO_3$ filler (15% and 20%). Also as was seen with elongation at break, yield strength decreases significantly and is the lowest (12.73 MPa) for the sample containing 40% $CaCO_3$. This sudden drop in both elongation at break and yield strength indicates that at this filler percentage and above, the material will have noticeably different tensile properties to pure PP and may not be a suitable material alternative.

Table 10 shows that as $CaCO_3$ filler percentage increases, the young's modulus increases. The pure PP (0% $CaCO_3$) sample has the lowest young's modulus of 733 MPa, whereas 40% $CaCO_3$ filled polypropylene has the highest at 1240 MPa; a 69% increase. Between each increment of +5% $CaCO_3$, the young's modulus can be seen to increase consistently with each addition. As young's modulus measures the stiffness of a material, these results show that as percentage of $CaCO_3$ filler increases, the stiffness of the material also increases.

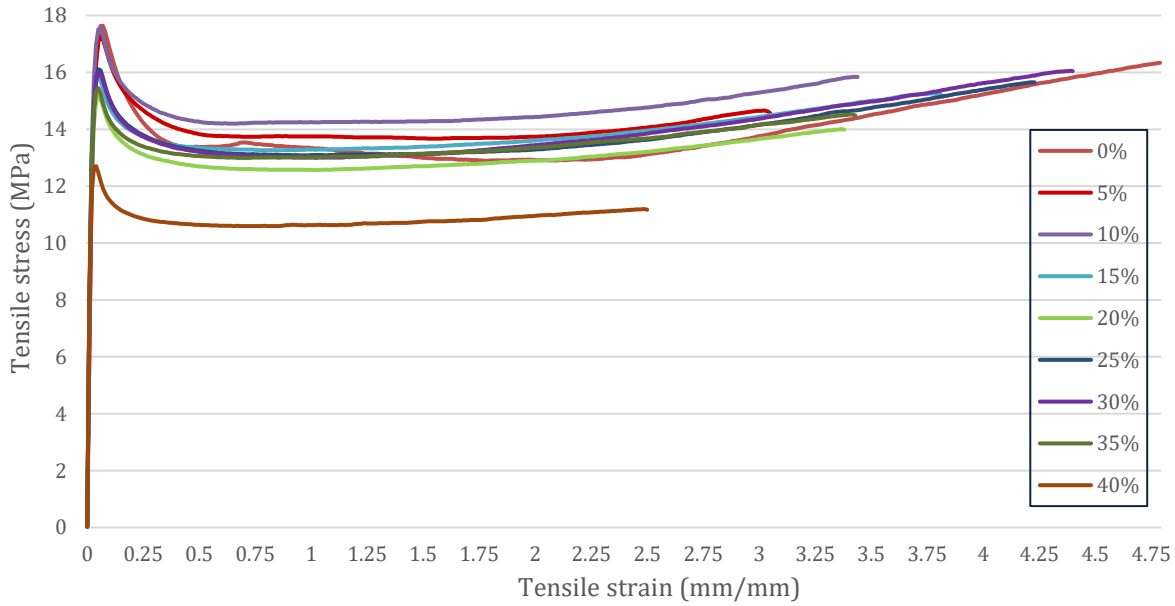

Figure 11 Tensile stress-strain curves of polypropylene composites filled with calcium carbonate ($CaCO_3$) ranging from 0% to 40% at 5% increments.

Table 10: Yield strength and Young's modulus of polypropylene composites filled with calcium carbonate ($CaCO_3$) ranging from 0% to 40% at 5% increments.

Percentage $CaCO_3$ filler	Yield strength (MPa)	Young's modulus (MPa)	Youngs modulus standard deviation
0%	17.68	733	72.3
5%	17.26	818	23.4
10%	17.60	925	47.5
15%	15.86	942	55.5
20%	15.17	961	80.8
25%	16.14	1009	29.2
30%	16.02	1168	78.9
35%	15.46	1205	75.2
40%	12.73	1240	28.9

5.3.3. Flexural (3-point bend) testing

Figure 12 displays the extension-load curves resulting from 3-point bend flexural tests of the PP composites filled with various percentages of calcium carbonate ($CaCO_3$). Accompanied alongside the extension-load curves are the flexural strengths of the specimens and maximum loads (F_{max}) experienced; provided in Table 11.

As can be seen in Figure 12, the 3-point bend tests were continued until 25 mm extension at which point none of the specimens had fractured. The pure polypropylene (0% $CaCO_3$) sample had a flexural strength and maximum force that was at the midpoint of all the samples. Once 5% of $CaCO_3$ was added, the flexural properties increased dramatically. The specimen with the greatest flexural strength (30.71 N/mm^2) and maximum load (46.80 N) was the 5% $CaCO_3$ filled PP. The composites containing 5%, 10%, and 15% $CaCO_3$ filler had very good performance in terms of flexural strength with values higher than that of pure PP. This shows that incorporating small amounts of $CaCO_3$ can positively affect the material's ability to resist deformation. As higher percentages of $CaCO_3$ were added, the flexural strength and F_{max} decreased. The lowest flexural strength can be seen for the 30% $CaCO_3$ filled PP samples with a flexural strength of 20.16 N/mm^2 and maximum load of 30.73 N. Both of these values are 34% lower than the 5% $CaCO_3$ sample and 18% lower than the pure PP (0% $CaCO_3$). A similar study which explored the flexural strength of $CaCO_3$ filled PP up to 25% filler supports these findings as it also found that initial addition of small amounts of $CaCO_3$ increased strength which then gradually decreased as more filler was incorporated (Jing et al., 2018).

As flexural strength refers to a material's ability to resist deformation, these results indicate that adding small percentages of $CaCO_3$ will make PP less likely to deform. It is only until 20% or above of $CaCO_3$ is added before the flexural strength and maximum force of the composite becomes lower than that of pure PP. As filler percentages reach higher levels (30% and above), the flexural strength and F_{max} appears to stay consistent or even increases as is the case of 35% $CaCO_3$ compared to 30% $CaCO_3$. This is represented quite well in Figure 12, where the 30%, 35%, and 40% $CaCO_3$ filled PP samples have extension-load curve that stay consistently close throughout the 3-point bend test. This may indicate that at $CaCO_3$ filler percentages of 30% and above, flexural strength and maximum load no longer continues to reduce. Further tests could be conducted at $CaCO_3$ filler percentages of greater than 40% in future experiments to see if the F_{max} and flexural strength stays constant or changes at much higher filler percentage ranges.

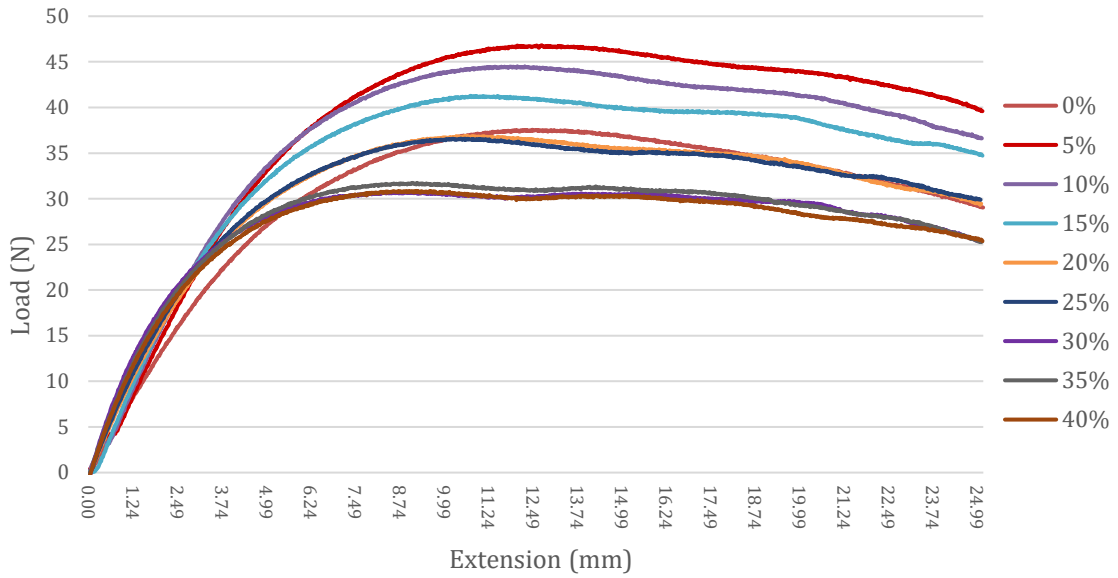

Figure 12: Flexural extension-load curves resulting from 3-point bend tests of polypropylene composites filled with calcium carbonate ($CaCO_3$) ranging from 0% to 40% at 5% increments.

Table 11: Flexural strength and maximum load (F_{max}) of polypropylene composites filled with calcium carbonate ($CaCO_3$) ranging from 0% to 40% at 5% increments.

Percentage $CaCO_3$ filler (%)	F_{max} (N)	Flexural strength (N/mm^2)	Flexural strength standard deviation
0	37.55	24.64	0.40
5	46.80	30.71	0.67
10	44.51	29.21	1.01
15	41.28	27.09	1.09
20	36.87	24.20	1.55
25	36.58	24.01	0.97
30	30.73	20.16	0.31
35	31.73	20.82	1.23
40	30.87	20.26	0.67

Flexural modulus has also been calculated for each $CaCO_3$ – PP sample and this data is shown in Table 12.

Table 12 shows that the pure PP (0% $CaCO_3$) sample has the lowest flexural modulus (856 N/mm^2) out of all of the samples. As $CaCO_3$ filler percentage is increasingly added to the composites, the flexural modulus also increases. The 40% $CaCO_3$ filled polypropylene specimen has the highest flexural modulus of 1289 N/mm^2; 51% higher than pure PP. Flexural modulus measures a materials stiffness during bending meaning these results show that pure polypropylene (0% $CaCO_3$), with the lowest modulus, has the greatest flexibility of all the samples. As more $CaCO_3$ filler is added to the polypropylene, the resulting composite can be seen to increase in flexural modulus and therefore increase in material stiffness with the 40% $CaCO_3$ sample therefore having the greatest stiffness. It can be seen clearly that as greater percentages of $CaCO_3$ filler are added to polypropylene, the resulting material composites become stiffer and at over 15% filler, has lower deformation resistance than pure PP.

Table 12: Flexural modulus of polypropylene composites filled with calcium carbonate ($CaCO_3$) ranging from 0% to 40% at 5% increments.

Percentage $CaCO_3$ filler (%)	Flexural modulus (N/mm^2)	Flexural modulus standard deviation
0	856	8.09
5	955	1.59
10	1056	4.06
15	1081	12.81
20	1099	10.52
25	1127	5.36
30	1217	1.39
35	1264	4.50
40	1289	3.00

5.3.4. Impact testing

Table 13 shows the average Charpy impact data taken from three samples of each of the $CaCO_3$ filled PP composites from filler percentages of 0% to 40% at 5% increments.

Table 13 Average Charpy impact data of three specimens for polypropylene composites filled with calcium carbonate ($CaCO_3$) ranging from 0% to 40% at 5% increments. Standard deviation from each set of three specimens is also provided.

Percentage of $CaCO_3$ filler (%)	Average initial Charpy impact strength (J)	Standard Deviation	Average calculated Charpy impact strength (J/mm^2)
0	1.10	0.09	0.028
5	1.25	0.26	0.031
10	1.07	0.20	0.027
15	1.37	0.15	0.034
20	1.23	0.08	0.031
25	1.09	0.10	0.027
30	1.35	0.06	0.034
35	1.31	0.17	0.033
40	1.49	0.08	0.037

Table 13 shows that Charpy impact strength increases slightly as percentage of $CaCO_3$ filler increases with the sample containing 40% $CaCO_3$ filler having the highest Charpy impact strength of 0.03725 J/mm^2; 35% greater than pure PP (0% $CaCO_3$). This increasing trend, however, is not linear and fluctuations in the impact strength can be observed at different filler percentages. In particular, the 10% and 25% $CaCO_3$ filled specimens which have lower impact strength than pure polypropylene (0% $CaCO_3$). This data suggests that the inclusion of $CaCO_3$ has an inconsistent effect on impact strength. As impact strength is known to be affected by a variety of filler properties (e.g., particle size, particle distribution, matrix – filler binding additives etc.), future research could further help to identify which factors could be key in order to ensure consistent modifications to impact strength.

5.3.5. Environmental Assessment - Results

Figure 13 displays the environmental impacts for the $CaCO_3$ filled PP composites (as filler percentages range from 0% to 40%, increasing at 5% increments) per FU of 1000 cm^3 of composite material. All eleven environmental impact categories as provided by the CML-IA Baseline version 3.03 EU25 methodology are included. Red lines are provided to indicate the impact provided from the injection moulding process. The remaining impact above the line includes the raw material

extraction, transport to pellet production, and pellet processing. These impacts are combined as within the Ecoinvent database, they are embedded together into one process.

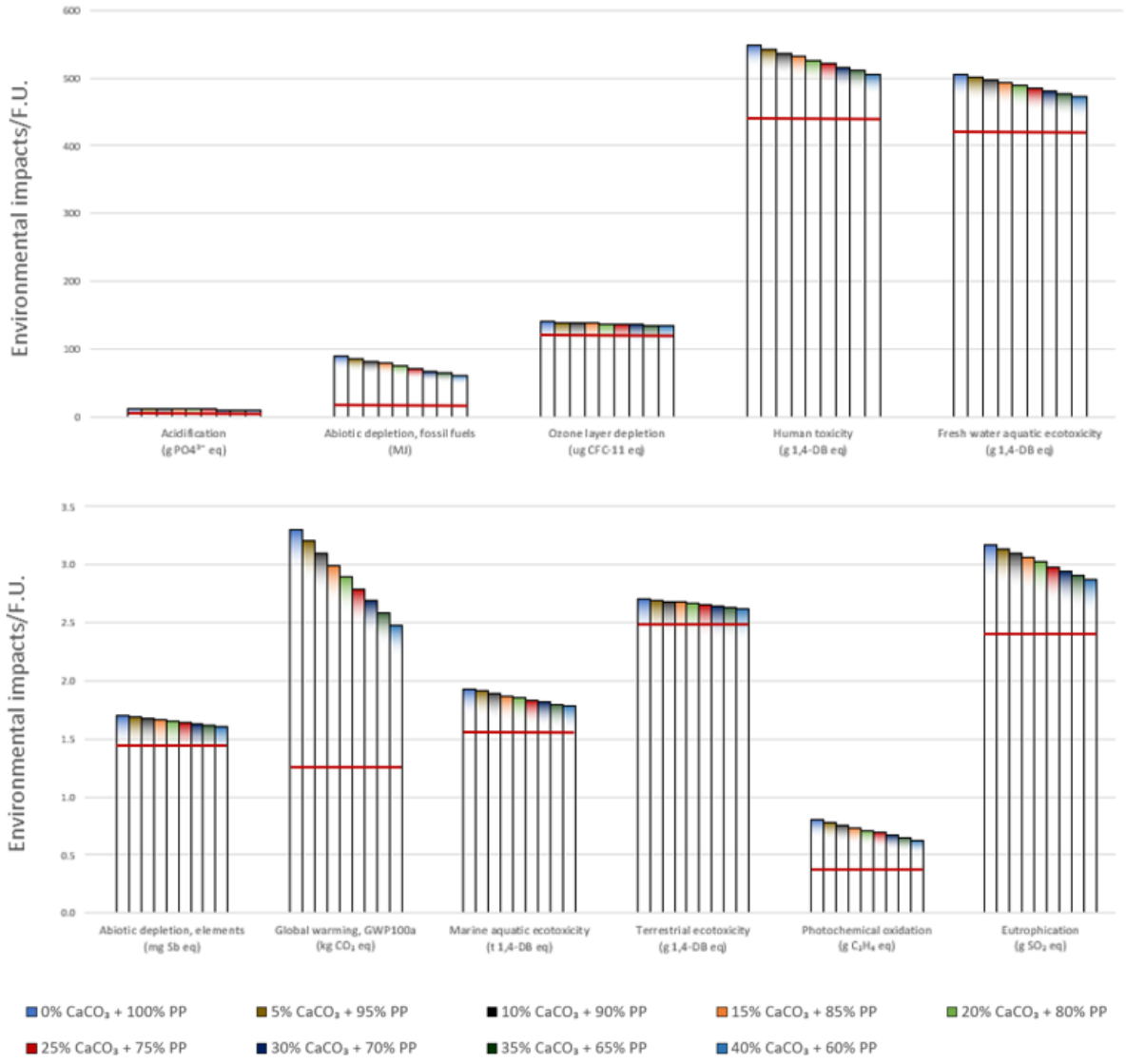

Figure 13: Graphical representation of environmental impact data for polypropylene composites filled with calcium carbonate ($CaCO_3$) ranging from 0% to 40% at 5% increments. All eleven environmental impact categories as provided by the CML-IA Baseline version 3.03 EU25 methodology are included. Results shown per functional unit of 1000 cm^3 of $CaCO_3$ filled polypropylene. Red lines are included to indicate the impact provided from the injection moulding process.

As can be seen in Figure 13, the environmental impact for all eleven categories decreases as $CaCO_3$ filler percentage increases. For each category, the reduction in impact is linearly proportional to quantity of added filler. For example, for every 5% of $CaCO_3$ added, GWP decreases by 100 g CO_2 eq. per FU of composite material. This is consistent whether you are comparing 0% filler to 5% filler or 35% to 40%; the reduction per increment is the same.

The overall environmental impact for all categories can be seen to decrease by 3% to 32% once 40% of $CaCO_3$ has been added. The category with the least reduction of impact (3%) is TETP that decreases from 2.7 g 1,4-DB eq. emissions from the pure PP (0% $CaCO_3$) sample to 2.6g 1,4-DB eq. from the 40% $CaCO_3$ filled PP. The overall reduction is small because the environmental impact from the injection moulding manufacturing stage consists the majority (92%) of the total impact. In fact,

the injection moulding has quite a significant contribution for all categories of between 20% to 92%, as can be seen indicated by the red lines.

The greatest reduction is shown for ADPf which reduces from 89.5 MJ for the pure PP sample to 60.9 MJ for 40% $CaCO_3$ filled PP; 32% lower. It is understandable that ADPf would have such a great reduction as PP is derived from fossil fuels whereas $CaCO_3$ is naturally sourced and does not require fossil fuels within the raw materials. The raw material extraction and pellet processing also has a larger overall contribution to this category of 80% resulting in greater overall reductions as $CaCO_3$ is added. There are no environmental impact categories that are made worst by using $CaCO_3$ so no compromises to certain impact categories would be needed to achieve an overall more sustainable material. Even just small additions of $CaCO_3$ filler within virgin PP would have a positive environmental impact. Manufacturers can therefore use this data to choose what percentage of filler is acceptable in terms of mechanical tolerances and calculate the resulting environmental savings that will be made. Figure 13 showed injection moulding to contribute a large proportion of the total environmental impact. It is, however, important to note that studies have shown that using $CaCO_3$ within PP can improve thermal conductivity of the resulting composite. This enables PP to heat up faster resulting in lower energy requirements during processing (Ebadi-Dehaghani et al., 2013). Manufacturers could potentially measure the change in energy requirements when including $CaCO_3$ into their PP. They could also test whether the operation temperature or run time of the injection moulding machine could be reduced whilst still providing materials of satisfactory quality. These energy savings could lead to further reduced environmental impact and future studies may wish to utilise life cycle assessments to examine the reductions in energy requirements and its resulting change in environmental impact as various percentages of $CaCO_3$ filler are used.

5.4. Overall discussion

To help aid the comparison of the various properties that have been explored within this study, Figure 14 provides a heat map indicating which blends demonstrate desirable or undesirable properties ranging from best (dark green) to worst (red).

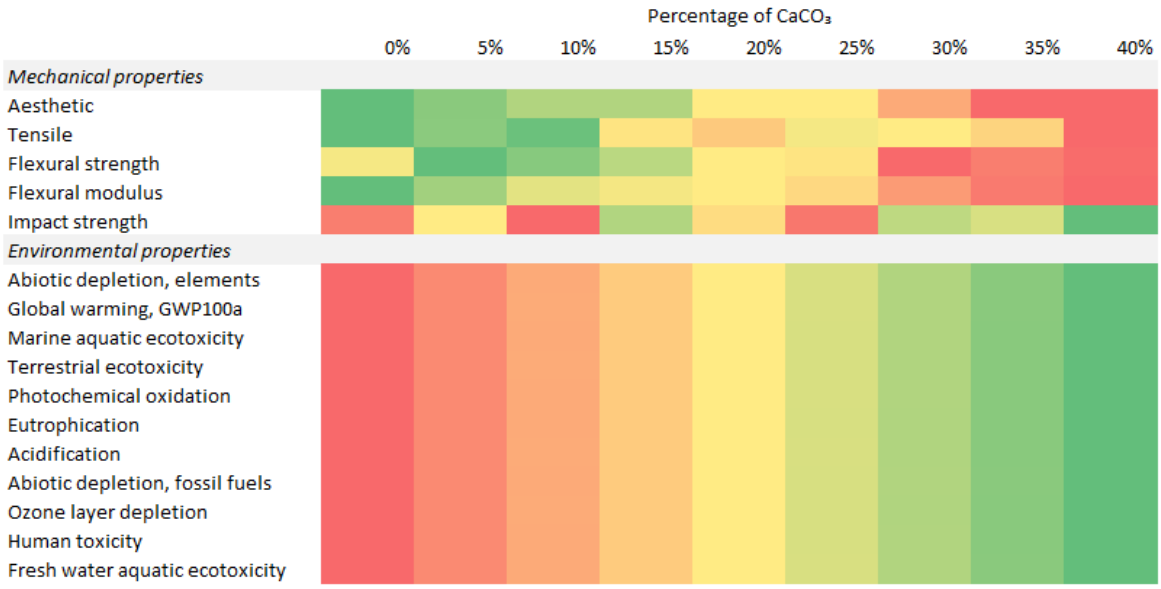

Figure 14 Heat map showing the performance of various properties displayed by polypropylene composites filled with calcium carbonate ranging from 0% to 40% at 5% increments. The colours indicate the following: Dark green – best, Light green – good, Yellow – midway, Orange – bad, Red – worst.

Overall, it has been shown that adding $CaCO_3$ to PP will have variable effect on the mechanical and environmental properties depending on the percentage of filler added. Environmental impacts are consistently shown to improve as more $CaCO_3$ is added but the same cannot be said for the mechanical properties. In terms of processability and aesthetic properties, no changes to the injection moulding equipment were required resulting in easy manufacturing but a yellowish hue can be seen in the resulting moulded pieces. Even with just 5% $CaCO_3$ added, the colour change is noticeable and gets stronger as more $CaCO_3$ filler is added. If a pure white colour is required by the manufacturer, even the smallest amount of $CaCO_3$ will deem this unachievable.

Figure 14 shows the tensile and flexural properties transition from greens and yellows to oranges and reds as more $CaCO_3$ is added. This is due to the yield strength and flexural strength decreasing as well as the Young's modulus and flexural modulus rising when percentage of $CaCO_3$ filler increases. Manufacturers would need to determine how low of the yield and flexural strengths and how high of the Young's and flexural moduli would be acceptable for their product in order to decide on the percentage of $CaCO_3$ filler that can be added for their composite. As environmental impact decreases linearly, the more filler that can be added, the lower the overall impact will be. If a flexural strength closely resembling or surpassing pure PP is desired, then PP containing 20% $CaCO_3$ or less could be used.

Despite the slight overall increase in impact strength as more $CaCO_3$ filler is added, the unpredictable nature of the values as percentage varies makes choosing the best formulation a challenge. This is demonstrated well in Figure 14 as the colours are shown to not follow any particular pattern and behave sporadically. More research will be needed to explore the effect that different factors, such as particle size, particle distribution, and binding additives etc., may have on the impact strength to determine the cause of this inconsistency.

5.5. Suggestions for future research

Previous studies have shown that the mechanical properties of composites containing $CaCO_3$ can be dependent on factors pertaining to the shape, size, and dispersion of the $CaCO_3$ particles. Impact strength, in particular, relies on equal dispersion of similarly sized particles within the polymer matrix (Zhu et al., 2014) due to filler particles acting as stress concentrators within the polymer matrix leading to increase fracturing at areas of agglomeration (Elfakhri et al., 2022). Section 5.3.4. of this study showed that impact strength at varying $CaCO_3$ filler percentages can be unpredictable. Electron microscopes could be used to study the particle size distribution within the composite materials and assess how any changes may affect the mechanical properties. This has been done for studies where $CaCO_3$ has been added to polyethylene (Suwanprateeb, 2000) and when analysing the tensile properties in PP (Budiyantoro et al., 2018).

Changes to the preparation method of the $CaCO_3$ - PP composites could also be explored such as whether premixing prior to injection moulding has any effect on material properties. One study found that a higher back pressure and increased rotation speed of the injection moulding screw can result in superior distribution of filler particles within PP (Budiyantoro et al., 2018). Variations in injection moulding machine settings could therefore be further tested.

One known property of $CaCO_3$ is its high hydrophilicity which contributes to the agglomeration and uneven dispersion of $CaCO_3$ particles (Zhu et al., 2014). Calcium carbonate can be treated with compounds of low molecular weight in order to modify how the particles interact within composites (Deshmukh et al., 2010). For example, stearic acid decreases the polarity of $CaCO_3$ reducing agglomeration (Cao et al., 2016; Shi et al., 2010). Future research could explore how additives, such

as stearic acid, affect the mechanical properties of $CaCO_3$ - PP composites at higher filler percentages.

5.6. Conclusion

In conclusion, as percentage of $CaCO_3$ filler increases from 0% to 40% within polypropylene, the aesthetic and mechanical properties are affected. In terms of aesthetics, the specimens demonstrate a yellow hue in colour which grows stronger as filler percentage increases. No difficulties were encountered when processing the $CaCO_3$ when using settings usually required to mould pure polypropylene. Elongation at break decreases as filler content increases as well as yield strength which decreases from 17.68 MPa to 12.73 MPa from 0% to 40% $CaCO_3$. The Young's modulus rose consistently as filler percentage increased indicating the materials became stiffer as more $CaCO_3$ was added. Flexural strength initially increased from 24.64 N/mm^2 (pure polypropylene) to 30.71 N/mm^2 as at 5% $CaCO_3$ but then declined as filler increased. The flexural modulus consistently increased as more filler was added; pure polypropylene having the lowest flexural modulus (856 N/mm^2) and 40% $CaCO_3$ filled polypropylene the highest (1289 N/mm^2).

Impact strength increased slightly from pure polypropylene (0.0275 J/mm^2) to 40% $CaCO_3$ (0.03725 J/mm^2), however, this change was inconsistent and unpredictable. Future research is encouraged to explore the affect that dispersion, size, and shape of the $CaCO_3$ particles have on the mechanical properties. The environmental analysis showed that for every category, environmental impact decreases proportionally as $CaCO_3$ filler content increases. For every 5% of $CaCO_3$ added, global warming potential decreased by 100 g CO_2 eq. per 1000cm^3 of composite material. Abiotic depletion of fossil fuels experienced the greatest reduction of 32% when 40% $CaCO_3$ was added.

Overall, this study showed that if the changes in mechanical properties are acceptable to the manufacturers' requirements, that significant environmental savings could be made by partially replacing virgin polypropylene with calcium carbonate ($CaCO_3$). Future research is advised on the effect that particle size distribution, premixing, and binding additives have on the mechanical properties of $CaCO_3$ – PP composites in order to help control some of the properties whilst allowing for the environmental savings associated with using calcium carbonate.

CHAPTER 6

6: ENVIRONMENTAL EVALUATION OF PASSIVE HUMIDIFICATION BREATHING SYSTEMS AND ASSESSMENT OF MITIGATIONS OPPORTUNITIES

This chapter addresses objectives 1, 2, and 3

Due to issues of confidentiality, this chapter has not been submitted for publishing but has been allowed to be included as part of this uploaded thesis.

Statement of contribution:
As multiple authors are listed to have contributed to this chapter, a statement is provided to demonstrate the roles each author had during its construction and a respective overall percentage to the work as a whole.

In order to facilitate fair assignment of author contribution percentages to each of the respective authors, the following division of work contribution has been allocated:

- 20% will be allocated to chapter conceptualisation and planning.
- 20% will be allocated to the running of any required software or alternative methods to obtain the results.
- 20% will be allocated to the interpretation of the results and any further analysis required.
- 25% will be allocated to the writing and editing of the chapter.
- The final 15% of the work is allocated to supervision. This percentage will be split amongst the supervisors according to their respective involvement.

Christina Webb (Percentage contribution: 80%)
Fulfilled roles: Chapter conceptualization, Methodology, Data curation, Formal analysis, Software, Project administration, Validation, Writing- Original draft preparation, Review and editing.

Lorna Anguilano (Percentage contribution: 5%)
Fulfilled roles: Supervision, final read of the finished chapter before submission.

Ximena Schmidt Rivera: (Percentage contribution: 15%)
Fulfilled roles: Supervision, Writing (Review and Editing of all drafts)

Environmental evaluation of passive humidification breathing systems and assessment of mitigations opportunities

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Abstract

The increased reliance on single-use devices (SUDs) is a significant contributor to the medical industry's environmental impact. Over 25% of plastic SUDs are made from polyvinyl chloride (PVC) which has generated concerns due to toxic emissions produced during incineration as well as the use of potentially carcinogenic plasticisers. Sustainable alternatives to PVC-based SUDs are available on the market but lack full environmental assessments. This study uses life cycle assessments (LCAs) to explore the environmental impacts of two passive humidification breathing system (BS1 and BS2) including cradle-to-grave lifecycles with 11 impact categories provided via the CML-IA baseline v3.03 methodology. BS1 is comprised primarily of plasticised PVC whereas BS2 is advertised as a sustainable alternative to BS1 as thermoplastic elastomer (TPE) and polypropylene (PP) are used instead of PVC. BS2 is found to have the lowest environmental impact across all 11 impact categories with ADPe, ODP, and TEP being significantly reduced. GWP is lowered by 19% when comparing BS2 to BS1. For six categories, the most impactful stage for BS1 is raw material and pre-processing (RMEP) with >95% bring from the plasticised PVC. For the toxicity potentials (HTP, FWAEP, and MAEP), the disposal stage contributes 70%-97% of the impact for both breathing systems. Sustainable mitigations of the materials used within BS2 were explored with PLA and Calcium carbonate ($CaCO_3$) filled PP composites tested as replacements to virgin PP. PLA raised the impact for nine of the 11 impact categories; whereas $CaCO_3$ lowered for six. GWP was lowered slightly when using PLA instead of virgin PP but was the lowest (12% reduction) when using $CaCO_3$. PLA increased the RMEP stage for nine categories but $CaCO_3$ reduced RMEP for all categories. Both increased the disposal stage for HTP, MAEP, and FWAEP. A scenario analysis explored the potential to disinfect and recycle the breathing systems after use instead of incineration. Manually cleaning had lower environmental impact for all categories compared to mechanical cleaning (via use of a washer-disinfector) due to the reduced use of electricity. Cleaning and subsequent recycling was found to lower environmental impact for five (mechanical) to six (manual) categories compared to incineration.

6.1. Introduction

The impact human activity has on the environment has been of increasing concern with the recently termed 'climate crisis' now classed as one of humanity's greatest threat to life by the United Nations (UN Press, 2021). The medical industry in particular plays a large role in the global environmental decline contributing around 5% of global emissions (Tennison et al., 2021). The United Kingdom's National Health Service (NHS) identified that the increase reliance on single-use devices (SUDs) is having significant contributions to the medical industry's environmental impact (Macneill et al., 2020; NHS, 2020). A large quantity of the environmental impacts from these devices can be attributed to the use and manufacturing of materials as well as end-of-life disposal (Sherman et al., 2020). There is a noticeable lack of environmental assessments done on single-use medical devices,

with passive humidification breathing systems having no studies conducted. With no research available, it is impossible to identify what the current environmental impacts are, where the hotspots lie, and how these impacts can be mitigated. Another factor to consider is that breathing systems can be made of various type of polymeric materials, some of which are advertised as environmentally sustainable with no peer reviewed environmental assessments provided to support these claims.

One material that is prevalent within SUDs is Polyvinyl Chloride (PVC), found in just over a quarter of all single-use plastic medical devices (Researchnester, 2023). This polymer has caused global concern due to the generation of dioxins, vinyl chloride, and heavy metals (Akovali, 2012) and the use of potentially carcinogenic additives such as phthalate-based plasticisers (Caldwell, 2012). Phthalates were first used in medical devices in 1955 (Sampson & De Korte, 2011) but have been increasingly restricted globally due to concerns around leaching from the polymer fibres (Wei et al., 2019) and the risk of infertility and birth defects (Niermann et al., 2015). In order to address the issues surrounding the use of PVC, alternative sustainable materials have been proposed. An example of this is thermoplastic elastomer (TPE) which is advertised as an environmentally friendly material alternative due to not requiring the use of increasingly regulated phthalate-based plasticisers whilst retaining mechanical properties akin to PVC (Payne & Rader, 2020). An application where a PVC-based single-use medical device has been re-designed using TPE is with passive humidification breathing systems. So far, the environmental implications of this change has not been quantified. In fact, as of yet, very few respiratory devices have been researched for their environmental impact demonstrating a need for more baseline data in order to identify where problem areas occur and how optimal changes can be made. More studies are also needed comparing medical devices (in this case breathing systems) made of PVC and TPE in order to quantify the difference in environmental impact when changing material.

To assess the environmental impact of products, the International Organization for Standardization (ISO) recommends life cycle assessments (LCAs) as the best methodology (Kumar et al., 2020). LCAs analyse the environmental impact of materials and energy inputted and the emissions and waste given off when producing a product to give overall environmental impact across a variety of categories (Finnveden et al., 2009). The lifecycle of a product consists of scope-defined life cycle stages (e.g., raw materials, manufacture, transportation, use, and end-of-life) allowing LCA results to be separated by each life cycle stage in order to identify the most impactful areas for improvement. The utilisation of the LCA methodology for assessing the environmental impacts is well established, however, it is still growing within the medical industry and case studies are fairly limited (Svensson, 2017). Full life cycle assessments of passive humidification breathing systems are not available within literature which means the environmental impacts of these systems have not been broken down by lifecycle stage to identify where the largest environmental impacts lie.

Currently, environmental assessment studies using LCA methodology can be found on respiratory medical devices such as anaesthetic equipment (McGain et al., 2017), laryngeal masks (Eckelman et al., 2012), laryngoscopes (Sherman et al., 2018), and non-medical face masks (Lisa Allison et al., 2020; Schmutz et al., 2020); but none on breathing systems. This lack of data is surprising especially considering that the global market for respiratory and airway devices is currently valued at £39.5 billion (Allied, 2022). Within the UK, over 14.5 million surgeries are carried out each year (Abbott et al., 2017) with each one potentially requiring the use of a breathing system. This demonstrates the sheer volume of breathing systems being used and indicates the potential for environmental savings if sustainable changes were established. In addition to a lack of baseline data, very few studies investigate mitigations that can be implemented which address the main environmental impacts and

explore changes to the devices to create sustainable alternatives. So far, only two studies on sustainable versions of medical devices are available; a sustainably designed dialyser (Hanson & Hitchcock, 2009) and a sustainable syringe called 'Syreen' (Moultrie et al., 2015). The study improving the sustainability of the dialyser focused on optimising material strength-to-weight ratio using 3D computer aided design software but did not change the material itself. The sustainable syringe was deemed sustainable as the syringe cannisters were designed to arrive to the consumer prefilled therefore not requiring additional packaging to transport the medicine alongside the syringe. As with the dialyser, these researchers' approach minimised the amount of material used by varying design choices but does not explore environmentally sustainable material alternatives. For both these studies, life cycle assessments were not conducted prior or after design optimisation and therefore the researchers were not able to specify the optimal environmental impact reductions or quantify the reduction in impact. This shows that there is a gap in research for using LCAs to demonstrate that sustainable mitigations can be identified prior to commencement of design changes and that the overall change in environmental impact can also be quantified.

Within this study sustainable materials will be explored as alternatives to the polypropylene (PP) used withing the breathing systems. Current literature on sustainable material replacements to PP within medical devices is at its early stages. Of the research available, two materials have grown in popularity as a replacement for PP; polylactic acid and composites containing mineral-based fillers (e.g., calcium carbonate) (Leong et al., 2005; Saleh et al., 2023).

Polylactic acid (PLA) is a very promising biopolymer derived through the fermentation of renewable resources (e.g., corn and wheat) (Jamshidian et al., 2010). PLA is advertised as a sustainable alternative to petrochemical-based polymers such as PP (Vink et al., 2003; Mehmood et al., 2023) due to its compostable and biodegradable properties (Dubey et al., 2017) as well as its absorption of CO_2 from the atmosphere during the growing phase of its renewable agricultural sources (Morão and de Bie, 2019). Its mechanical properties are similar to, and sometimes even surpass those, of typical synthetic polymers such as PP (Madival et al., 2009; Taib et al., 2023). Some medical devices are already being made using PLA such as bioabsorbable bone plates (Lovald et al., 2009), non-medical face masks (Soo et al., 2022), ventilators (DeStefano et al., 2020), and respirators (Papavasiliou & Chatzimichail, 2021).

Mineral-based filled PP composites are another potential sustainable substitute for virgin PP. A popular mineral used is calcium carbonate ($CaCO_3$) that has been shown to be able to be mixed with PP in order to reduce the virgin fossil-fuel derived polymer and instead replace with a naturally occurring, low environmentally impacting mineral (Lam et al., 2009; Chang et al., 2021). $CaCO_3$ is known to be compatible with polymers without considerably affecting its processability, mechanical properties, or recyclability if low percentages of filler is added (Lam et al., 2009; Chaiyut et al., 2012). A previous study showed that up to 40% of the PP can be replaced with $CaCO_3$ and still be processable using injection moulding machinery (Webb at al., 2024). Fillers are not yet common within the medical device manufacturing industry but has been showing promise in non-healthcare sectors (Myllytie et al., 2016; Mohanty et al., 2018).

6.2. Methodology

For this study, the environmental impact assessments are performed using a Life Cycle Assessment methodology according to the ISO standards 14040:2006 and 14044:2006 ((ISO, 2006a; ISO, 2006b), and conducted using SimaPro software v8.3.1 (PRé, 2008). The following sections describe each of the four steps of the LCA methodology.

6.2.1. Goal and Scope

The goal of this study is to assess and evaluate the environmental impact of passive humidification breathing systems throughout their complete life cycle. Additionally, comparisons will be made between two breathing systems to identify which is more sustainable and where further sustainable mitigations are possible.

The devices studied

This study assesses two passive humidification breathing systems (BS1 and BS2). BS1 is made of majority Polyvinyl chloride (PVC), whereas BS2 is advertised as an environmentally friendly version of BS1 due to the replacement of PVC with Thermoplastic elastomer (TPE) and Polypropylene (PP). Both products are available on the global market as of 2023. These breathing systems are designed to be single-use and are disposed of via incineration. The breathing system design consists of two tubes attached with connectors at each end (total of four connectors), and a red safety cap (see Figure 15). Each breathing system performs the same function and either could be substituted in for use without any required adjustments by the healthcare worker. The PVC within BS1 is plasticised using a non-phthalate-based plasticiser that cannot be disclosed due to confidentiality. This plasticiser shall be referred to as NonPht. BS1 and BS2 are shown in Figure 15.

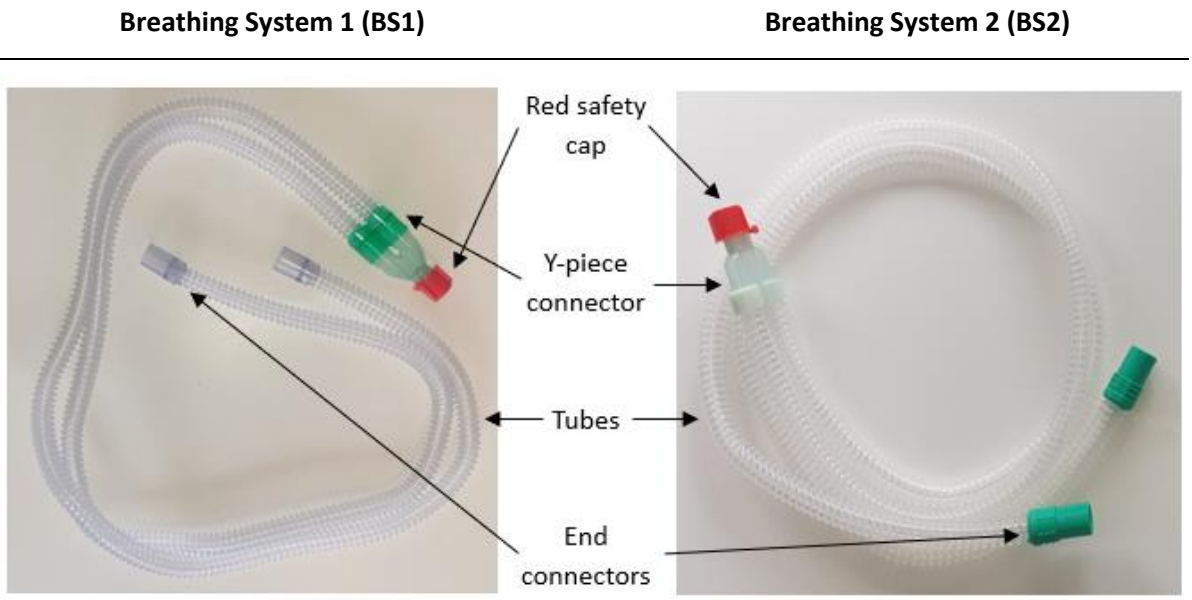

Figure 15: Images of the two breathing systems (BS1, BS2) investigated in this study; for details of materials composition see Table 14. Labels of the system's components are provided on the image.

The functional unit is defined as 'one single-use passive humidification breathing system for adult use in the UK', which is equivalent to 348 g in the case of BS1, and 288 g for BS2.

The scope of the study is from cradle-to-grave which includes raw material extraction and pre-processing, transport within stages (i.e., to the manufacturer, to the hospital, and to final disposal), manufacturing (including material moulding, component assembly, and initial sterilisation prior to dispatchment), packaging, and final disposal. The environmental impact originating from the use

stage has been excluded as this can be attributed to the respiratory machinery generating the gas flow which is outside the scope of this study. The full system boundary is provided in Figure 16.

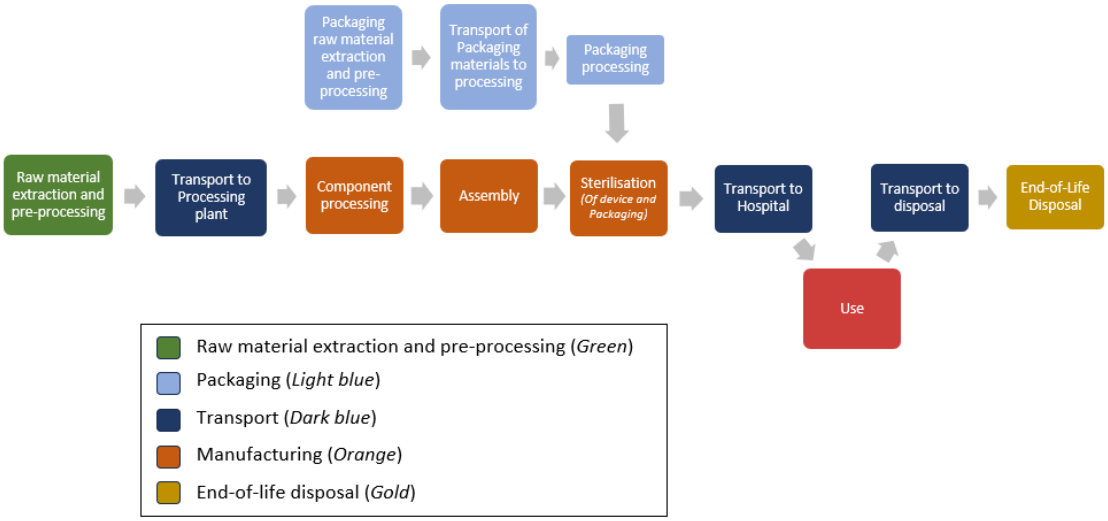

Figure 16: Diagram showing the full Cradle-to-Grave System boundary for the breathing systems studied (use stage is in red as it is excluded). The coloured boxes define the individual life cycle stages which are included; Raw material extraction and pre-processing (green), packaging (light blue), transport (dark blue), manufacturing (orange), and end-of-life disposal (gold).

6.2.2. Life Cycle Inventory data

The following sections provide data for each life cycle stage: raw material extraction and pre-processing, manufacturing, packaging, transport, and disposal.

Raw material extraction and pre-processing stage (RMEP)

The RMEP stage involves the extraction of raw materials and pre-processing (converting extracted raw material into a form which is mouldable by manufacturing equipment). Ecoinvent 3.2 database (Wernet et al., 2016) has been used for the background data. The materials requirements were obtained via material datasheets from the manufacturer. Table 14 summarises the material composition of each breathing system.

Table 14: Life cycle inventory of the raw material and pre-processing stage (RMEP) of the two breathing systems; data is presented per functional unit (one single-use breathing system).

Component	Material	Breathing system	
		BS1[a] Mass (g)	**BS2**[a] Mass (g)
Tubing	PVC[b]	261.3	-
	NonPht	63.4	-
	TPE[c]	-	119.8
	Polypropylene	-	100.0
	LLDPE[d]	-	29.4
	Colourant (LDPE[d])	-	0.3
Connectors	Polypropylene	18.9	34.3
	Colourant (LDPE[d])	0.3	0.3
Dust Cap	HDPE[d]	4.3	4.3
	Colourant (LDPE[d])	0.04	0.04
	Total Weight	**348.24g**	**288.44g**

[a] Description of Breathing systems in Figure 15
[b] PVC: Polyvinyl Chloride,
[c] TPE: Thermoplastic Elastomer
[d] LLDPE: Linear Low-Density Polyethylene, LDPE: Low-Density Polyethylene, HDPE: High-Density Polyethylene

In the case of NonPht, background information was modelled from patents, literature, and consultations with industry. In particular, NonPht was modelled from the patent CN104072365A Google Patents (2013) alongside confirmation with a NonPht manufacturer (modelled off production data from Turkey). This data is shown in Table 15 and displayed per one kg of plasticiser production.

Table 15: Raw materials and energy used for the production of 1 kg of NonPht (CN104072365A - Google Patents, 2013). Background information for product flows sourced from Ecoinvent 3.2 database (Wernet et al., 2016).

1 kg NonPht

Quantity	Product flows	Database source
0.425 kg	Purified Terephthalic acid, at plant/RER U	Ecoinvent3.2
0.668 kg	Fatty alcohol, Market for/RER U	Ecoinvent3.2
0.002 kg	Titanium Dioxide, Market for/RER U	Ecoinvent3.2
0.07 kg	Water, Market for/RER U	Ecoinvent3.2
25.80 MJ	Energy, Market for/RER U	Ecoinvent3.2

Manufacturing stage (Processing, Assembly, and Sterilisation)

The processing facility is based in an European country. The environmental impact data for the machines are sourced from the Ecoinvent 3.2 database (Wernet et al., 2016) and is specified to operate using electricity from the country's national grid. The environmental impact of the electricity used during processing is embedded within the processes themselves from the Ecoinvent database and calculated via the SimaPro software. Ecoinvent 3.2 uses data valid for the year 2012. Processing stages were provided in the form of product data sheets by the manufacturer and via consultations with the machine operators. Assembly has no additional environmental impact as all components

within the breathing systems are attached together either during the manufacturing process or by a human operator.

These breathing systems are available to be purchased as sterile by the hospitals, therefore after manufacturing and assembly, the breathing systems are packaged and undergo Ethylene Oxide (EtO) sterilisation. Each of the breathing systems studied were sterilised onsite by the manufacturer. The sterilisation input and emission data were received by the manufacturer via technical data sheets. Each packaged breathing system is placed into an EtO steriliser which operates at <63°C and sterilises by passing a gaseous mix of EtO and nitrogen into the steriliser. Due to the similarities of size, each breathing system uses the same inputs for sterilisation thus the environmental impact of sterilisation is identical for each breathing system. Table 16 summarises the inventory of the processing stage.

Table 16: Input data for processing and sterilisation per functional unit

Processing		**Breathing system** [a]	
Inputs[b]	**Units**	**BS1**[a]	**BS2**[a]
Injection moulding	g	53.3	39.3
Extrusion moulding	g	294.94	249.14
Sterilisation			
Inputs[b]			
Ethylene Oxide	g	5.84	
Natural gas	m^3	0.021	
Tap Water	g	93.28	
Nitrogen	g	20.84	
Electricity	kWh	0.268	
Direct Emissions			
EtO emission to atmosphere	mg	2	

[a] Description of breathing system in Figure 15

[b] Per functional unit of one breathing system

Packaging

Prior to sterilisation, the breathing systems are packaged. The packaging required for each breathing system is 19 g of LDPE film and is identical for both breathing systems studied. The LDPE is pre-processed into pellets but then requires an extra extrusion processing stage to convert the pellets into a plastic film. This LDPE film is manufactured onsite at the manufacturing plant. The raw materials are transported via a 7.5-16 mton Euro6 lorry from the material extraction site to the processing centre a total of 200 km.

Transportation stage

This stage includes the transport of the raw materials to the device manufacturer, the transport from the manufacturing facilities to hospital, and the transport from hospital to the final disposal. The location of raw material extraction plant for each material was received through product data sheets from the manufacturer and the distance travelled from material extraction site to manufacturer was calculated using Google maps. For this study, a London-based hospital was used. The type of vehicles used to transport the breathing systems to the hospital were acquired from consultation with the manufacturer and hospital and the distance travelled was calculated using Google Maps. After use, the breathing systems are disposed of separate from their original

packaging and taken to a nearby incineration site. The disposal site is 10km away from the hospital and information on the type of vehicle used was acquired from consultation with the hospital waste management team. This data is shown in Table 17.

Table 17: Inventory data use for the transportation stage. Data is presented per functional unit.

Transport stage	Transport data		Breathing system [a]	
		Units	BS1[a]	BS2[a]
Transport of raw materials to device manufacturer **Vehicle:** 7.5-16 mton Euro 6 lorry	Plasticised PVC	g	324.7	-
		km	1700	-
	TPE	g	-	119.8
		km	-	100
	Polypropylene	g	18.9	134.3
		km	100	100
	LDPE	g	0.34	0.64
		km	200	200
	LLDPE	g	-	29.4
		km	-	10
	HDPE	g	4.3	4.3
		km	20	20
Transport from manufacturer to hospital **Vehicle:** 7.5-16 mton Euro 6 lorry	Transport weight (incl. packaging)	g	367.2	307.4
	Distance	km	2200	2200
Transport from hospital to final disposal **Vehicle:** Municipal waste 21mton lorry	Transport weight (incl. packaging)	g	367.2	307.4
	Distance	km	10	10

[a] Description of Breathing systems in Figure 15

6.2.3. End of life Disposal

All of the breathing systems studied are single-use devices and after contact with the patient are placed directly into a waste stream for disposal. The end-of-life scenario modelled for this study is 100% incineration with energy recovery (Great Britain based) which is NHS best practice for contaminated medical devices. It is against best practice (NHS waste disposal regulation HTM 01-07) for contaminated single-use medical devices to be recycled prior to sterilisation or reused and so neither of these scenarios are modelled within this section. For the packaging, the LDPE film is landfilled as is typical within an UK hospital setting.

6.2.4. Impact Assessment

The Life Cycle Impact assessment results were calculated using the CML-IA Baseline version 3.03 EU25 methodology. A recent study (Rejane Rigon et al., 2019) found CML to be the most widely used LCA methodology which is why it was chosen. The 11 impact categories are as follows: abiotic depletion potential of elements (ADPe), abiotic depletion potential of fossil resources (ADPf), acidification potential (AP), eutrophication potential (EP), global warming potential (GWP), human toxicity potential (HTP), marine aquatic ecotoxicity potential (MAEP), freshwater aquatic ecotoxicity

potential (FWAEP), ozone depletion potential (ODP), photochemical oxidants creation potential (POCP) and terrestrial ecotoxicity potential (TEP).

6.2.5. Methodologies for scenario analyses

6.2.5.1. Potential changes in best practices - Disinfection and subsequent recycling of breathing systems'

BS2 is most largely made of PP which consists of 134.3g (47%) of BS2's total weight (see Table 14). For this scenario analysis, LCAs are conducted as were described throughout the methodology section (section 6.2.). For this scenario, the polypropylene found within BS2 is replaced with either Polylactic acid (PLA) or Calcium Carbonate ($CaCO_3$) filled Polypropylene composite. These new modelled breathing systems will be referred to as BS3 (PLA) or BS4 ($CaCO_3$+PP).

As shown in Table 18, apart from the change from PP to PLA or $CaCO_3$+PP, BS3 and BS4 have the same material weight requirements as BS2. Background information for material flows for PLA and $CaCO_3$ were sourced from the Ecoinvent 3.2 database (Wernet et al., 2016). Polylactide, Granulate and Limestone, unprocessed were the selected material from the database; both using global average production data. The environmental assessment are run using the same data as before (no changes to: processing inputs, sterilisation, packaging, and disposal). The distance required to transport the raw materials to the manufacturer in the European country will change as shown in Table 19.

Table 18: Life cycle inventory of the raw material and pre-processing stage (RMEP) of the three breathing systems; data is presented per functional unit.

Component	Material	Breathing systems		
		BS2[a] Mass (g)	**BS3** Mass (g)	**BS4** Mass (g)
Tubing	TPE[b]	119.8	119.8	119.8
	Polypropylene	100.0	-	60.0
	Polylactic Acid	-	100.0	-
	$CaCO_3$[c]	-	-	40.0
	LLDPE[d]	29.4	29.4	29.4
	Colourant (LDPE[d])	0.3	0.3	0.3
Connectors	Polypropylene	34.3	-	20.58
	Polylactic Acid		34.3	-
	$CaCO_3$[c]		-	13.72
	Colourant (LDPE[d])	0.3	0.3	0.3
Dust Cap	HDPE[d]	4.3	4.3	4.3
	Colourant (LDPE[d])	0.04	0.04	0.04
	Total Weight	**288.44**	**288.44**	**288.44**

[a] Description of Breathing system in Figure 15
[b] TPE: Thermoplastic Elastomer
[c] $CaCO_3$: Calcium Carbonate
[d] LLDPE: Linear Low-Density Polyethylene, LDPE: Low-Density Polyethylene, HDPE: High-Density Polyethylene

Table 19: Inventory data use for the transportation stage. Data is presented per functional unit.

Transport stage		Unit	Breathing system BS2[a]	BS3	BS4
Transport of raw materials to device manufacturer **Vehicle:** 7.5-16 mton Euro 6 lorry	TPE	g	119.8	119.8	119.8
		km	100	100	100
	Polypropylene	g	134.3	-	80.6
		km	100	-	100
	Polylactic Acid	g	-	134.3	-
		km	-	200	-
	$CaCO_3$	g	-	-	53.7
		km	-	-	50
	LDPE	g	0.64	0.64	0.64
		km	200	200	200
	LLDPE	g	29.4	29.4	29.4
		km	10	10	10
	HDPE	g	4.3	4.3	4.3
		km	20	20	20
Transport from manufacturer to hospital **Vehicle:** 7.5-16 mton Euro 6 lorry	Transport weight (incl. packaging)	g	307.4	307.44	307.4
	Distance	km	2200	2200	2200
Transport from hospital to final disposal **Vehicle:** Municipal waste 21mton lorry	Transport weight (incl. packaging)	g	307.4	307.44	307.4
	Distance	km	10	10	10

[a] Description of Breathing systems in Figure 15

6.2.5.2. Potential changes in best practices - Disinfection and subsequent recycling of breathing systems

In this scenario analysis, LCAs are run using the same life cycle inventory as provided throughout the methodology section (section 6.2.) and the additional inventory data (Tables 18 and 19) provided in the methodology for section 6.2.5.1. The only change to the breathing systems' life cycles is that the disposal stage (incineration) is excluded and instead the environmental impact of cleaning and subsequent recycling is included. To model the disposal stage of recycling, the materials must undergo sorting, cleaning, melting, and reforming into pellets that can be used by the next manufacturer (Lange, 2021). The data to model the sorting and cleaning process was taken from a study by Franklin Associates (Associates, 2018). The melting and reforming stage uses data from Ecoinvent 3.2 using the processing method 'injection moulding' from global average data (Wernet et al., 2016). The RMEP stage is then consequently changed to accommodate the environmental savings resulting from recycling materials via the avoided burden approach. This is where, by recycling materials, the burden that would have occurred by using virgin material has now been avoided and the savings made are included by removing the raw material required in the RMEP stage (Liu et al., 2022).

These scenarios are currently completely hypothetical as no research has yet been conducted on the practicalities of physically separating the breathing systems for recycling. It will therefore have to be an assumption for this study that the breathing systems are able to be disassembled without difficulty in order to separate the materials present within the breathing systems. It is also assumed

that there would be no issues caused by including $CaCO_3$ into the recycling waste stream alongside PP.

Two cleaning scenarios will be modelled for BS2 and BS4. The first is a manual cleaning scenario where the breathing systems are washed by being submerged in a container of medical device disinfectant (hydrogen peroxide) diluted to a 7.5% concentration which is typically used to clean medical devices within medical facilities (Rutala & Weber, 2008). The Center for Disease Control and Prevention (CDC) advises that hydrogen peroxide should only be reused up to 105 times in order to not risk the disinfectant losing its potency (CDC, 2017). Therefore for this study, it will be assumed that the hydrogen peroxide is used to the maximum of its capacity (105 times) and that each cleaning cycle will be attributed $\frac{1}{105}$ of the total impact. In order to immerse the breathing system, 10 litres of solution is required which was calculated by filling a plastic container to a level at which the system is able to be fully submerged. After a few minutes submerged in the solution, the breathing system is taken out of the container and placed into a new container of fresh water; again 10 litres. This water cannot be reused due to risk of cross contamination so therefore 10 litres of water is required for each breathing system (CDC, 2008). After a few more minutes, the breathing system can be left to drain and air-dry.

Alternatively to manual cleaning, mechanically cleaning the breathing systems requires use of a washer-disinfector. The washer-disinfector modelled for this scenario is a 11 KWh machine, with a 50-minute cycle and uses 36 litres of water per cycle. The washer-disinfector can hold 20 systems per cycle. All information was obtained via machinery technical data sheets and confirmation by NHS sterile services technicians. Both disinfection methods can be conducted in-house and so transportation between the hospital and the cleaning facilities is not required.

6.3. Results and discussion

This section discusses and compares the results of the environmental assessments of both breathing systems in section 6.3.1. followed by two mitigation strategies. One strategy focuses on mitigating the impacts from the materials stage (section 6.3.2.1) whilst another tests the opportunities of changing waste management practices (section 6.3.2.2).

6.3.1. Environmental Assessment

Figure 17 displays the environmental impact for the two breathing systems studied with all 11 impact categories provided. The results of the environmental sustainability assessments are discussed below followed by proposed sustainable mitigations.

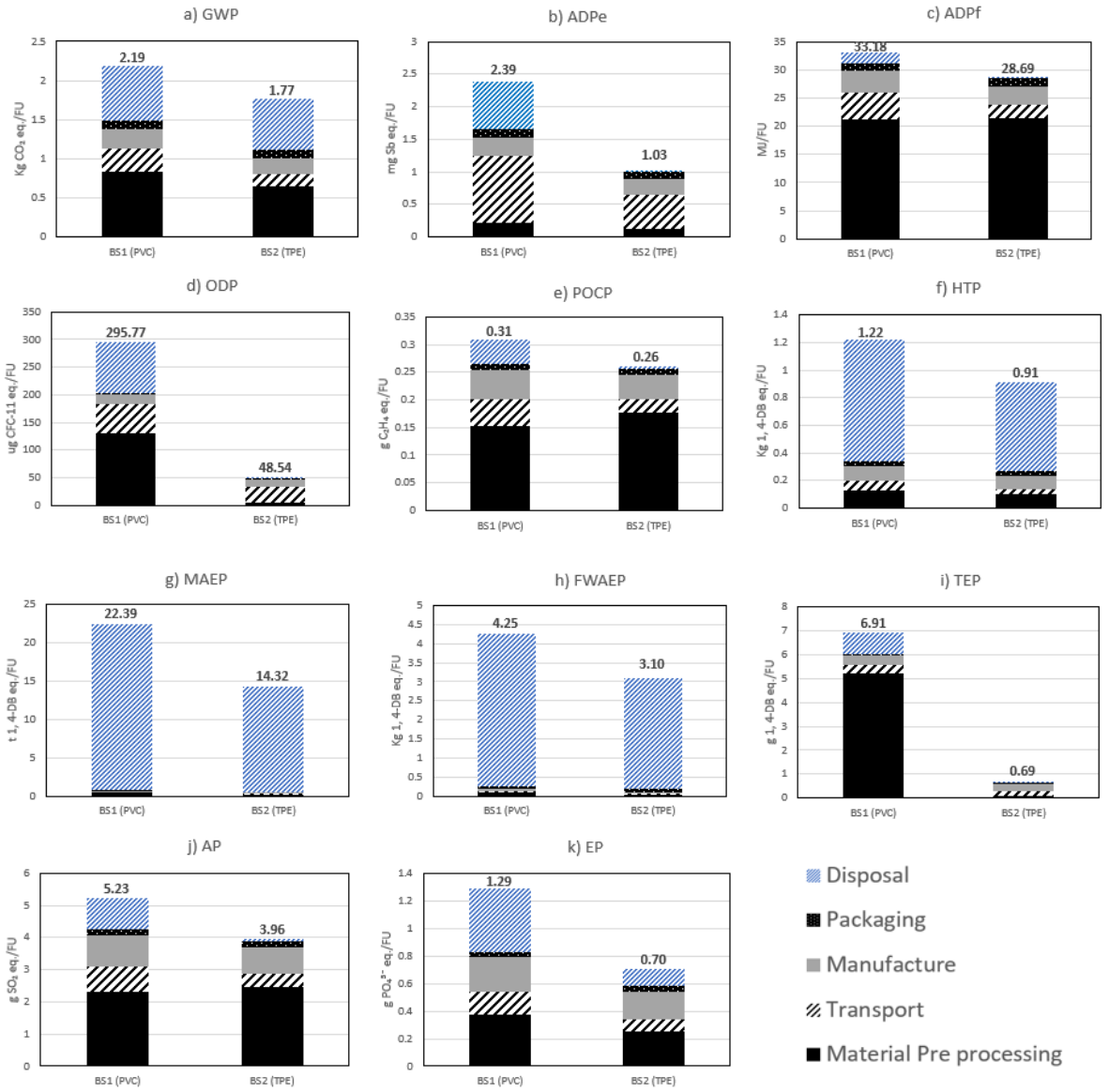

Figure 17: Comparison of environmental impact of two breathing systems (BS1: PVC; BS2: TPE and PP). Results expressed per functional unit (one single-use breathing system). ADPe: abiotic depletion potential of elements; ADPf: abiotic depletion potential of fossil resources; AP: acidification potential; EP: eutrophication potential; GWP: global warming potential; HTP: human toxicity potential; MAEP: marine aquatic ecotoxicity potential; FWAEP: freshwater aquatic ecotoxicity potential; ODP: ozone depletion potential; POCP: photochemical oxidants creation potential; TEP: terrestrial ecotoxicity potential.

Figure 17 shows BS2 to have the lowest environmental impact for all the 11 impact categories. BS2 has particularly low ODP and TEP compared to BS1 (under one sixth) as well as significant reductions (less than a third lower) for ADPe, MAEP, and EP. For GWP, a reduction of 19% can be seen from BS1 to BS2; a saving of 0.42 kg CO_2 eq. per breathing system. For six categories, the most impactful life cycle stage for BS1 is the RMEP stage whereas for BS2, the RMEP stage is greatest for four. In three of the categories (HTP, FWAEP, and MAEP), the disposal stage contributes the majority of the impact (70%-97%) for both BS1 and BS2. Packaging consistently contributes the lowest impact in each category (up to 11%).

Each of the impact categories will now be explored in depth over the following sections.

Global Warming Potential (GWP)

As seen in Figure 17a, BS1 has the greatest GWP of 2.19 kg CO_2 eq., followed by BS2 with 1.77 kg CO_2 eq. These reductions (19%) in GWP from BS1 to BS2 is particularly significant when considering the vast utilisation of breathing systems. Assuming 14.5million breathing systems are used each year within the UK, moving toward BS2 devices would equal saving of 6090 tonnes of CO_2 eq. emissions per year.

For this category, the RMEP stage is the largest contributor to BS1's impact, providing 0.8 kg CO_2 eq. (38%) of total impact followed by the disposal stage (0.71 kg CO_2 eq.), whereas for BS2, the disposal and RMEP stages shared an almost equal contribution (0.66 kg CO_2 eq. vs 0.65 kg CO_2 eq. respectively, both 37%). CO_2 emissions to air contributed to the majority (90%) of BS1's RMEP stage impacts with 95% from the life cycle of the plasticised PVC. Emissions of CO_2 to air are also the most contributing for BS2's RMEP impact (43%) due to the life cycle of PP. The other stages within both breathing systems have much lower contribution; less than 14% of total impact. The transport and manufacturing stages are slightly higher for BS1 compared to BS2; 0.30 kg CO_2 eq. vs 0.20 kg CO_2 eq. and 0.24 kg CO_2 eq. vs 0.20 kg CO_2 eq. respectively. Some of these reductions will be due to the lower weight of BS2 (288 g) that is being transported and requiring manufacturing compared to BS1 (348 g). In addition to this, shown in Table 6, the plasticised PVC within BS1 is required to be transported a great distance (1700 km) to the manufacturer adding to this impact.

Abiotic Depletion Potentials (ADPe, ADPf)

Figure 17b&c show BS1 to have greater ADPe (2.39 mg Sb eq.) and ADPf (33.18 MJ) than BS2 (1.03 mg Sb eq. and 28.69 MJ). For ADPe, BS1 has 2.3 times greater impact than BS2. For ADPf, RMEP is the most contributing stage, providing 64% and 75% of BS1's and BS2's impact respectively. For BS1, the majority (92%) of the RMEP emissions originate from the plasticised PVC; more specifically, 50% from the use of natural gas. Whereas for BS2, PP contributes the most (45%) to the RMEP impact with a impact of 9.6 MJ; 66% of which comes from the use of crude oil. This shows that the most efficient way of reducing the ADPf of BS1 would be to lower the natural gas used within the plasticised PVC and for BS2 to reduce the crude oil used within the PP. As PP is a fossil fuel-based polymer, it could be possible to reduce this impact by using alternative materials that are not fossil-fuel derived.

In the disposal stage, emissions are shown to reduce by 96% from BS1's 0.74 mg Sb eq. to BS2's 0.03 mg Sb eq. Similarly, the ADPf disposal stage for BS1 has an impact of 1.9 MJ but only 0.05 MJ for BS2. For BS1, the greatest emission is gold (Au) which contributes 30% of its ADPe disposal stage impact. This emission of Au is greatly reduced to 0.002 mg Sb eq. in BS2. This shows that replacing plasticised PVC with TPE and PP drastically reduces the emission of Au resulting in a much lower impact from the disposal stage for depletion potential categories. For ADPe, the most contributing stage overall is the transport stage for both BS1 and BS2. Transport is shown here to have a much larger effect on overall impact than it does for any other impact category. For BS1, transport is 43% of the ADPe, and for BS2, 51%. To reduce this, focus should be placed on minimising the distance materials are required to be transported and using the most energy efficient vehicles.

Manufacturing and packaging have a much smaller contribution to BS1's and BS2's ADPe and ADPf, only contributing 5% to 23% of the total impacts. For ADPe, emissions of raw cadmium (Cd) is the biggest contributing impact for both manufacturing and packaging for both breathing systems. For

ADPf, the use of natural gas during manufacturing and the use of crude oil during the packaging stage are the main causes of these impacts.

Atmospheric impacts (ODP, POCP)

For both ODP and POCP (Figure 17d&e), BS1 has the greatest impact of the two breathing systems. The ODP of BS1 is much greater (295.77 ug CFC-11 eq.) than BS2's (48.54 ug CFC-11 eq.); a 6.1 times increase. For POCP, the variation is less pronounced, with BS1 being 19% higher than BS2. In both categories and breathing systems, the RMEP stage is the greatest, except for BS2's ODP where the RMEP stage is reduced so dramatically that it only contributes 9%. The RMEP stage for BS1's ODP contributes 44% of the total impact, almost entirely due to the plasticised PVC; of which 79% is from the emission of bromo-methane (CH_3Br) to air. For BS2, the RMEP stage contributes 4.4 ug CFC-11 eq., a vast reduction in ODP compared to BS1. A particularly drastic decrease can be observed with the emission of CH_3Br with only 0.001 ug CFC-11 eq. now being emitted. The removal of plasticised PVC within BS2 has shown clear advantage when reducing ODP. The RMEP stage is also the biggest contributor to BS1's and BS2's POCP (50% and 68%, respectively). Similar patterns can be seen for POCP with plasticised PVC accounting for 92% of BS1's impact. 59% of BS1's POCP from the RMEP stage originates from the TPE used with emissions of Sulphur Dioxide (SO_2) to air having the greatest contribution (38%).

For both categories, the impact from disposal is greatly reduced from BS1 to BS2 to less than a tenth of the impact. To reduce emissions of the disposal stage, switching to materials which are less environmentally impactful when incinerated, such as is found in BS2, can reduce the ODP and POCP without requiring change to disposal regulations. Additionally, the impact from transport for both categories is shown to decrease by 48% from BS1 to BS2. This will be partially due to the lower weight of BS2 but also the great transport distance required for PVC acquisition. Reducing transportation distance and weight of materials transported will help lower these impacts even further.

Human and Aquatic toxicity potentials (HTP, MAEP, FWAEP)

For HTP, MAEP, and FWAEP (Figure 17f,g,&h), BS1 has the highest impact compared to BS2 (HTP: 1.22 kg 1,4-DB eq. vs 0.91 kg 1,4-DB eq., MAEP: 22.39 t 1, 4-DB eq. vs 14.32 t 1, 4-DB eq., FWAEP: 4.25 kg 1, 4-DB eq. vs 3.10 kg 1, 4-DB eq. The disposal stage is the most contributing life cycle stage for both breathing systems across all three categories, providing 70% to 97% of total impact. For HTP, FWAEP, and MAEP, the disposal impact of BS2 is shown to be 27% to 36% lower than BS1. For both breathing systems, across all impact categories, emissions of beryllium (Be) to water provides the majority of the disposal impact. For HTP, these emissions provide 62% of BS1's impact from disposal and 53% of BS2's. For MAEP, the same emission is responsible for 98% of BS1's disposal impact and 95% of BS2's. Finally, for FWAEP, 90% of BS1's and 77% of BS2's. Reducing the release of Be to water will have considerable effects on the reduction of HTP, MAEP, and FWAEP for both breathing systems.

For MAEP and FWAEP, the other stages collectively only contribute 3% to 6% of the total impact, for HTP, 28% to 30%. This further emphasises that the most important stage to focus on reducing in order to improve impact on human and aquatic toxicity is the disposal stage. Ideally, more sustainable methods of disposal should be explored.

Ecosystems (TEP, AP, EP)

For TEP, AP, and EP (Figure 17I,j,&k), BS1 has the highest impact compared to BS2 (TEP: 6.91 g 1,4-DB eq. vs 0.69 g 1,4-DB eq., AP: 5.23 g SO_2 eq. vs 3.96 g SO_2 eq., EP: 1.29 g PO_4^{3-} eq. vs 0.70 g PO_4^{3-} eq.). BS2's TEP is particularly small; 10% the impact of BS1. There is little variation between the transport, manufacturing, and packaging stages between BS1's and BS2's TEP, but BS2's RMEP and disposal stages can be seen to reduce almost entirely. The RMEP stage provides a large proportion (75%) of BS1's TEP with the plasticised PVC consisting of almost all (99.8%) of this impact. Emissions of cypermethrin (Cm) to soil are responsible for 3.3 g 1,4-DB eq. (64%) of the impact. For BS2, the emission of Cm has greatly reduced to only 0.0005 g 1,4-DB eq. This reduction in emissions by replacing the plasticised PVC in BS1 to TPE and PP in BS2 is very significant and is a very effective way of reducing TEP. The TEP impact from disposal is also noticeably smaller within BS2, with a change in emissions from 0.93 g 1,4-DB eq. to 0.05 g 1,4-DB eq. The main emission when incinerating BS1 is of mercury (Hg) to air providing 0.68 g 1,4-DB eq. (73%). This is also the biggest emission for BS2's disposal stage but the quantity of emissions have reduced greatly to 0.04 g 1,4-DB eq. The incineration of BS2 instead of BS1 has shown to decrease the TEP by 95% and the emissions of Hg to air by 94%.

For AP and EP the variation in impacts between the life cycle stages are also quite small, apart from the disposal stage. BS2's disposal stage is 93% and 74% lower than BS1's for AP and EP respectively. For BS1 the main emission contributing to AP during the disposal stage is of SO_2 to air emitting 0.68 g SO_2 eq. (72%) and for EP, the emissions of phosphate (PO_4^{3-}) to water providing 0.29 g PO_4^{3-} eq. (63%). Both of these emissions are seen to reduce significantly within BS2; emission of SO_2 decrease by 98% and emission of PO_4^{3-} by 97%.

6.3.2. Scenario analysis

6.3.2.1. Mitigations opportunities - Material alternatives

Figure 17 showed that BS2 is the least environmentally damaging device across all impact categories. Assuming both breathing systems are equally favourable in terms of performance and usability, this result effectively makes using BS1 redundant. Therefore, when exploring potential sustainable mitigations options to further reduce environmental impact, focus will be solely placed on altering BS2. Figure 17 showed that for BS2, the RMEP stage was highest for four of the 11 impact categories. The PP was also shown in section 6.3.1. to have the highest contribution to the RMEP stage for GWP and ADP impacts. This section aims to test whether using environmentally sustainable materials as a replacement to polypropylene lowers the environmental impact of BS2, replacing PP content with either PLA (BS3) or a 40% $CaCO_3$ – 60% PP composite (BS4). BS2 is available on the global market as of 2023 whereas BS3 and BS4 are hypothetical devices not currently available.

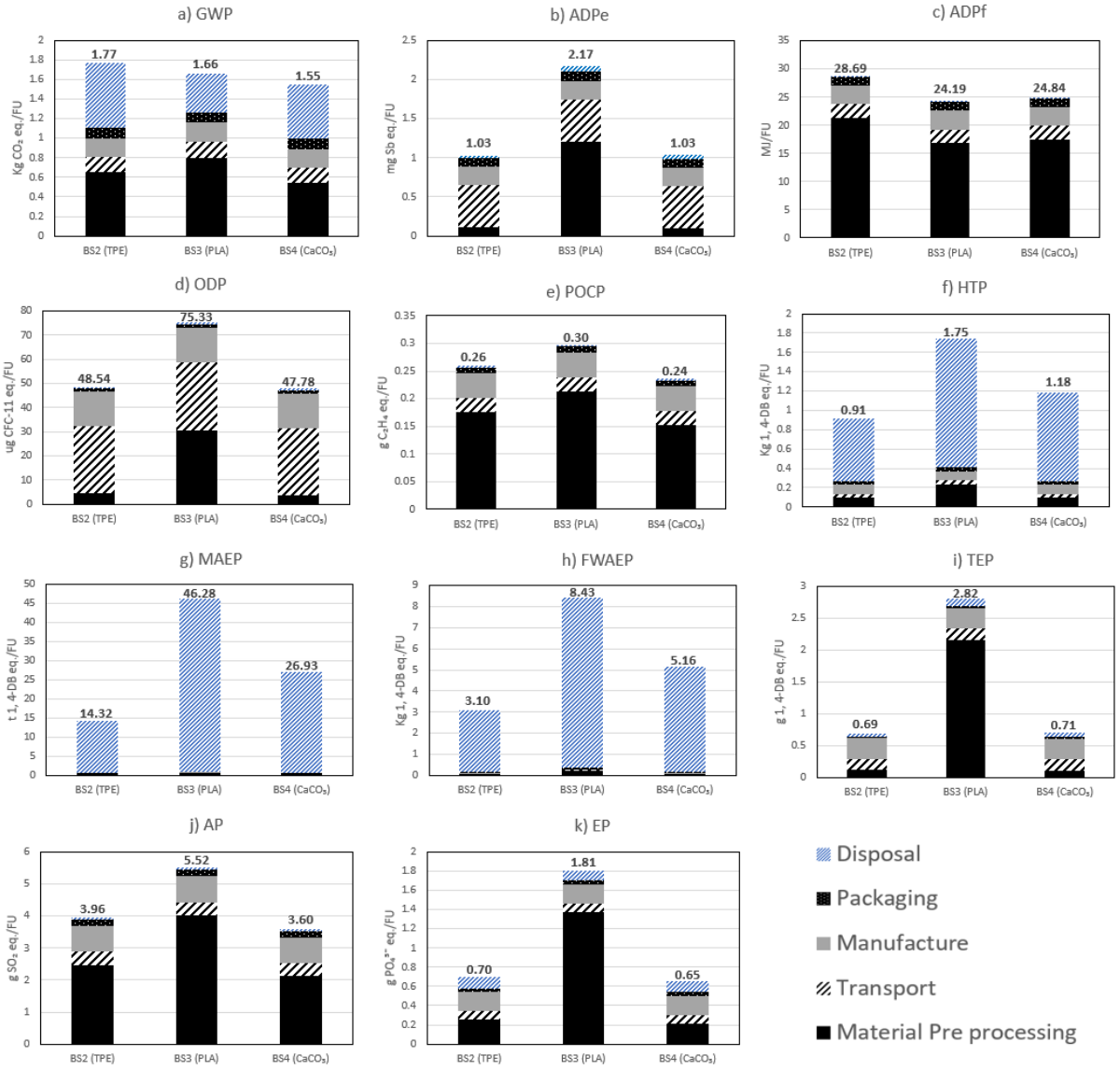

Figure 18: Comparison of environmental impact of three breathing systems (BS2: TPE; BS3: PLA; BS4: $CaCO_3$). Results expressed per functional unit (one single-use breathing system). ADPe: abiotic depletion potential of elements; ADPf: abiotic depletion potential of fossil resources; AP: acidification potential; EP: eutrophication potential; GWP: global warming potential; HTP: human toxicity potential; MAEP: marine aquatic ecotoxicity potential; FWAEP: freshwater aquatic ecotoxicity potential; ODP: ozone depletion potential; POCP: photochemical oxidants creation potential; TEP: terrestrial ecotoxicity potential.

As can be seen in Figure 18, the use of the alternative materials has increased the environmental impact of the breathing system for some of the impact categories. The majority of impact categories increase when using PLA instead of PP whereas four categories increase when using $CaCO_3$ filled PP composite. These changes will now be discussed in more detail, first comparing BS3 (PLA) vs BS2 (PP) and then comparing BS4 ($CaCO_3$) vs BS2 (PP).

BS3 (PLA) vs BS2 (PP)

The use of PLA in place of PP (BS3) is shown to provide a higher impact for nine impact categories with especially high aquatic and terrestrial ecotoxicity impacts (MAEP, FWAEP, and TEP). A slight reduction in GWP can be observed within BS3 compared to BS2. The use of PLA in place of PP has lowered the overall GWP of the breathing system by 0.11 kg CO_2 eq. with most of this reduction due to a lower impact from the disposal stage. The RMEP impact actually increases slightly when using PLA. In fact, for all categories except ADPf, the impact from the RMEP stage increases when using PLA instead of PP. BS3's ADPe, ODP, TEP, and EP in particular experiences a drastic increase (over five times higher) in their RMEP stage. This shows that the environmental impact when growing and producing the raw materials required to manufacture PLA is greater than the production of PP's constituents, despite PLA being bio-based and PP being fossil fuel based. Figure 18 shows that using PLA in place of PP also increases environmental impact from the disposal stage for eight impact categories. For HTP, MAEP, and FWAEP the impact from disposal increases by over double. Section 6.3.1. found that emissions of beryllium to water provides the majority of BS2's impact from disposal (HTP: 0.341 kg 1,4-DB eq., MAEP: 13.1 t 1,4-DB eq., FWAEP: 2.23 kg 1,4-DB eq.). For BS3, this is still the case, but the quantity of Be emitted is much higher (HTP: 1.17 kg 1,4-DB eq., MAEP: 45.0 t 1,4-DB eq., FWAEP: 7.63 kg 1,4-DB eq.).

The only impact categories which decrease by using PLA are GWP and ADPf. The disposal stage of BS2's GWP is shown to emit 0.66 kg CO_2 eq. whereas BS3 emits 0.39 kg CO_2 eq. This reduction in impact from the disposal stage results in the overall GWP from BS3 being than 0.11 kg CO_2 eq. less than BS2 despite the RMEP stage being higher. For ADPf, the lower impact is mainly due to the RMEP stage where BS3's impact (16.81 MJ) is 4.58 MJ lower than BS2's (21.39 MJ); a 21% reduction. As PLA is not derived from fossil fuels, it is understandable why the ADPf would be lower. This lower GWP and ADPf is interesting when viewed in the context of how PLA is currently marketed to consumers. PLA producing companies (e.g., Biopak (Biopak, 2023), NatureWorks (Vink et al., 2004) and Total Corbion (TotalCorbion, 2019)) which promote the use of PLA in the place of petrochemical-based polymers tend to do so by promoting its lower impact on global warming and reduced use of fossil fuels (Bala et al., 2022; Vink et al., 2003; Piemonte, 2011).

Figure 18 shows that for many of the environmental impact categories, it is hard to justify PLA as the environmentally sustainable option as it is currently sold. Despite this, mitigation opportunities should be pursued in order to facilitate the use of PLA due to its biobased origins particularly as fossil-fuel based plastics are depleting. Figure 18 shows that the raw material and pre-processing stage increases for each of the environmental impact categories which is the cause of the PLA breathing system being less environmentally sustainable than the PP breathing system for six of the 11 impact categories. Some studies have explored how to reduce PLA's impact during the growing and processing stage. One promising option is to use food waste instead of growing new crops to be used to synthesise PLA (Swetha et al., 2023). Food waste contains high amounts of carbohydrates which can be used for generation of lactic acid; the monomer that can undergo polymerisation into polylactic acid. This reduces the environmental impact of the land, water, and fertiliser required to grow new crops. Other studies have explored reducing the environmental impact of the processing steps by improving the efficiency of the plant processing steps through the use of bagasse boilers with higher efficiencies, using renewably sourced energy to power the machinery, and reducing use of chemicals during processing (Morão and De Bie, 2019; Rezvani Ghomi et al., 2021).

Two of the biggest advantages of using PLA in place of petrochemical-derived polymers is its biodegradable and compostable properties. Currently, used medical devices are controlled by

regulations which push for incineration but if these rules were ever explored to be changed to allow for composting or biodegradable materials, PLA could become a lot more favourable and the reduction in environmental impact by not requiring incineration could make PLA more advantageous compared to PP.

BS4 ($CaCO_3$) vs BS2 (PP)

BS4 ($CaCO_3$) is shown in Figure 18 to have lower environmental impact than BS2 (PP) for six of the 11 impact categories, higher for four, and stay the same for one (ADPe). The GWP is shown to decrease by 0.22 kg CO_2 eq. when using the $CaCO_3$ filled PP composite in place of virgin PP due to a combination of reduced impacts from the RMEP and disposal stages. The main increases can be observed in the disposal stages; particularly for the human and aquatic ecotoxicity potentials. Shown in section 6.3.1., the majority of BS2's disposal impact is due to the emissions of Be to water. BS4's main emission for these categories is also Be but in larger quantities than BS2 (HTP: 0.67 kg 1,4-DB eq., MAEP: 25.9 t 1,4-DB eq., FWAEP: 4.39 kg 1,4-DB eq.), as was also the case for BS3. Without this increase in impact from disposal, the impact of BS4 across all categories would be lower than BS2. With the incineration of the $CaCO_3$ filled PP being more environmentally impactful than the incineration of the PP, focus should be placed on alternative methods of disposal. As mentioned in section 6.3.2.1., $CaCO_3$ can be mixed with polymers without significantly affecting recyclability (Lam et al., 2009; Chaiyut et al., 2012). Therefore, if the breathing systems were able to be recycled instead of incinerated, the $CaCO_3$ would not affect its ability to do so.

Across all impact categories, the environmental impact from the RMEP stage is decreased within BS4 compared to BS2 with decrease in impact varying from 6% to 17%. The greatest reduction can be seen for ADPf where the RMEP impact lowers from 21.39 MJ (BS2) to 17.54 MJ (BS4); a 18% reduction. Section 6.3.1. showed the use of crude oil was the main cause of BS2's ADPf from the RMEP stage; with an impact of 14.2 MJ. Crude oil is also the highest cause of BS4's RMEP ADPf but produced a lower impact (11.6 MJ) than BS2. This is understandable as $CaCO_3$ is a naturally occurring mineral substance and would therefore require less crude oil to produce compared to a fossil-fuel derived polymer. For this LCA, the manufacturing stage has remained unchanged from the steps described in Table 15 and therefore the manufacturing stage has the same resulting impact as previously. This is due to the fact that the $CaCO_3$ mixed in with the PP undergoes the same injection and extrusion moulding processes as virgin PP and therefore no manufacturing changes are required. However, studies have shown that mixing $CaCO_3$ with PP improves thermal conductivity of the resulting composite (Ebadi-Dehaghani et al., 2013; Patti et al., 2019) allowing for lower energy requirements from the manufacturing machinery (Jones, 1988). Future research may allow for the manufacturing stage to be optimised resulting in further reductions in environmental impacts when using $CaCO_3$.

6.3.2.2. Potential changes in best practices - Disinfection and subsequent recycling of breathing systems

Unlike other single-use devices that are in physical contact with a patient, breathing systems do not physically touch the patient. A filter can be placed at the Y-piece (see Figure 15) to stop the patient from contaminating the breathing system (Halbeis et al., 2008). Despite incineration of single-use devices being encouraged by legal regulations, some facilities have tried utilising the non-contact nature of breathing systems to pursue alternative disposal options. Some studies have explored reusing breathing systems (Carter, 2006; Kranabetter et al., 2006) which could theoretically reduce up to 10% of medical regulated waste (Carter, 2006). However, a number of issues have been brought up such as: the potential contamination if used on a new patient, the requirement of

increased safety checks, the potential need for reprocessing equipment such as autoclaves which some plastics cannot mechanically withstand, and manufacturers of the single-use systems discouraging reuse. Reusing would also make the healthcare professional liable for any infection or potential lawsuit as there are no legal regulations supporting this decision.

Recycling of disinfected breathing systems, however, may be a potential option as this would be perceived differently in regard to legal regulations. A medical device that has no chance of causing infection would be classified as non-hazardous and therefore be able to be placed in the domestic or recycling waste stream (NHS, 2023). Some places are piloting the idea that the breathing systems could be disinfected and then recycled as it would no longer be classed as infectious waste (Goldberg et al., 1996; HTM, 2022). Typical disinfection routes are either via manual cleaning using a chemical disinfectant or by mechanical cleaning using an automated washer-disinfector (Rutala & Weber, 2019). This scenario analysis explores the change in environmental impact if instead of breathing systems being incinerated, they are disinfected prior to recycling. Both manual and mechanical cleaning routes will be explored.

Only BS2 and BS4 will be tested for this scenario. This is due to the fact that for BS1 (PVC) and BS3 (PLA), plasticised PVC and PLA are not able to be recycled with the rest of the recyclable medical waste. Plasticised PVC and PLA require segregation from other recyclable plastics before they can be recycled and there are currently no waste streams available within hospitals to separate these materials into and so would require extra research on a collection scheme to explore (Niaounakis, 2019). $CaCO_3$, however, can be recycled alongside PP and any other recyclable plastics without requiring any extra segregation or collection system (Brunner, 2021).

Results and discussion

Figure 19 displays the environmental impact for BS2 and BS4 provided with three disposal scenarios; incinerated, cleaned mechanically (by washer-disinfector), and cleaned manually (by hand-washing).

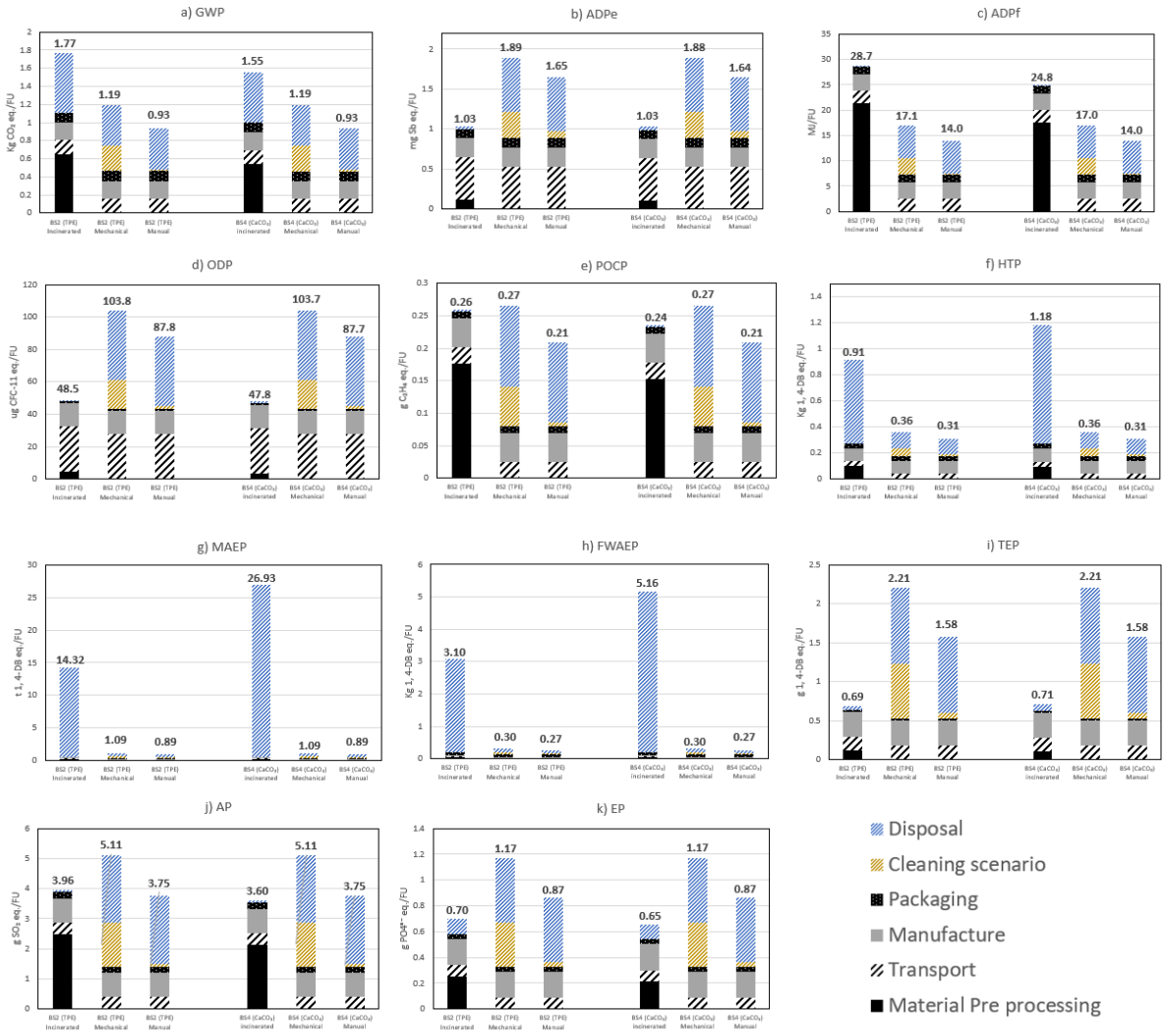

Figure 19: Comparison of environmental impact of two breathing systems (BS2: TPE; BS4: $CaCO_3$) with three disposal scenarios; incinerated, cleaned mechanically (by washer-disinfector), and cleaned manually (by hand-washing). Results expressed per functional unit of one breathing system. ADPe: abiotic depletion potential of elements; ADPf: abiotic depletion potential of fossil resources; AP: acidification potential; EP: eutrophication potential; GWP: global warming potential; HTP: human toxicity potential; MAEP: marine aquatic ecotoxicity potential; FWAEP: freshwater aquatic ecotoxicity potential; ODP: ozone depletion potential; POCP: photochemical oxidants creation potential; TEP: terrestrial ecotoxicity potential.

As can be seen in Figure 19, compared to incineration, cleaning the breathing systems via the manual cleaning scenario (using 7.5% hydrogen peroxide solution) decreases the overall environmental impact for six of the 11 impact categories and increases for five. For the mechanical cleaning scenario, the environmental impacts decrease from the incineration scenario for five of 11 impact categories and increases for six.

GWP is decreased quite significantly when cleaning and recycling the breathing systems instead of incinerating. For BS2 (TPE), GWP decreases by 33% and 47% when mechanically and manually cleaned respectively; for BS4 ($CaCO_3$), GWP decreases by 23% and 40%. A lot of this reduction can be seen to be attributed to the reduction in the RMEP stage due to the avoided burden savings by not using virgin material.

For three of the categories (ADPe, ODP, and TEP), both cleaning scenarios have environmental impacts much greater than incineration which can be seen to be due to the minimal impact that comes from the disposal stage for incineration but a considerable contribution from the cleaning and disposal (i.e., recycling) stages for the cleaning scenarios. For these categories, the cleaning and disposal (recycling) stages for both cleaning scenarios consist 51% to 76% of the total impact. The disposal stage for the incineration scenario, however, only contributes up to 11%. For the mechanical cleaning, the cleaning stage (using the washer-disinfector) contributes a larger percentages of the impact from the cleaning and disposal stages. However, for manual cleaning, the cleaning stage has a much lower overall contribution resulting in this being the more sustainable option of the two cleaning scenarios. It is also important to note that cleaning medical devices instead of incinerating would also require additional labour and logistical organising due to the need to collect, transport, and clean the devices in order to be recycled.

In fact, the manual cleaning scenario has a lower environmental impact than mechanical cleaning for all of the impact categories provided. Despite the mechanical cleaning cycle requiring only 1.8 litres of water per breathing system, 8.2 litres less than the total water usage via the manual cleaning scenario, its overall impact is greater. As the disposal stages for both cleaning scenarios are identical, the only varying factor then is the cleaning scenario itself. For the mechanical cleaning scenario, the majority of impact originates almost entirely (>98%) from the electricity used. Therefore, if this can be reduced by using more sustainably sourced electricity or reducing energy usage, mechanical cleaning may be able to better compete with manual cleaning.

The main decrease in impact when disposing via one of the cleaning scenarios instead of incineration can be observed for HTP, MAEP, and FWAEP. This is due to the large contribution the disposal stage (incineration) has on these categories. The recycling scenarios have less than a third of the impact than incineration for these categories with MAEP and FWAEP being less than one tenth. The largest decrease can be observed for BS4's MAEP where manually cleaning has less than 4% of the impact compared to incineration (26.93 t 1,4-DB eq. versus 0.89 t 1,4-DB eq.). Section 6.4.1 showed replacing 40% of the PP with $CaCO_3$ lowers impact from all categories compared to the original BS2 except for HTP, MAEP, FWAEP, and TEP. This cleaning scenario analysis has demonstrated that cleaning and recycling BS4 instead of incinerating will lower the impact for three of these categories (HTP, MAEP, and FWAEP) to less than the original BS2. This however will also result in slight increases for some (i.e. ADPe, ODP, TEP, AP, and EP) of the remaining impact categories so whether this is acceptable will depend on personal sustainability goals. Furthermore, comparing the cleaning scenarios between BS2 and BS4, BS4 is less impactful or has equal impact to BS2 for all impact categories. Therefore, if cleaning and recycling is to be chosen as the end-of-life disposal route, it is environmentally advantageous to incorporate $CaCO_3$ into the breathing system instead of using 100% virgin PP.

It is important to consider that the cleaning scenarios have additional benefits compared to incineration. After the breathing systems are disinfected, they can potentially be recycled. Recycling materials reduces utilisation of resources allowing for the material to stay within product lifecycles for longer helping to contribute to a more circular based economy. The volume of waste that is diverted from the incineration plants should also be considered. Assuming 14.5 million breathing systems are used within the UK each year, this would mean 4182 tonnes of material could potentially be recycled. The NHS currently pays £910 per tonne of infectious waste but £150 per tonne of domestic waste (data received from private consultation). Placing 4182 tonnes of waste in domestic instead of infectious could save the NHS £3.2 million each year. This is not even taking into account if the materials were to be sold after recycling.

6.4. Conclusion

This paper analysed the environmental impact of two breathing systems (BS1 and BS2), two hypothetical breathing systems using alternative sustainable materials (BS3 and BS4), and three

disposal scenarios (incineration, manual cleaning, and mechanical cleaning). BS1 was a single-use breathing system made from majority plasticised polyvinyl chloride (PVC), whereas BS2 was a single-use breathing system made of thermoplastic elastomer and polypropylene (PP). BS2 had the lowest environmental impact for all of the 11 impact categories with ADPe, ODP, and TEP being significantly reduced with considerable reductions of 19% observed for GWP. It was found that big reductions in impact originating from the RMEP and disposal stages helped contribute to the lower overall impact with plasticised PVC being the cause of most of these impacts. For the human and aquatic toxicity potentials (HTP, MAEP, FWAEP), the disposal stage consists of the majority (70% to 97%) of the emissions for BS1 and BS2 with reductions of 27% to 36% observed from BS2 to BS1. Medical device manufacturers are encouraged to switch from using plasticised PVC within their single-use medical devices and start using TPE. The result of this study also provides information for the general public to bring their concerns to their local governmental representatives and the organisations which provide their healthcare (who are also responsible for choosing which medical devices to purchase) to request that medical devices are made from environmentally sustainable material alternatives such as TPE.

Two alternative materials (BS3: PLA and BS4: $CaCO_3$ filler) were explored as potential replacements of virgin PP within the TPE and PP based breathing system (BS2). It was found that apart from global warming potential and abiotic depletion of fossil fuels, the use of PLA raises the environmental impact for nine categories. The breathing system containing 40% $CaCO_3$ – 60% PP composite was shown to decrease environmental impact of BS2 for six of the 11 impact categories. For HTP, MAEP, and FWAEP, the inclusion of PLA or $CaCO_3$ filler increased the environmental impact of the disposal (incineration) stage compared to BS2. This scenario analysis demonstrated the usefulness of using LCAs to assess the changes varying material alternatives will have on a product before it has been manufactured. This is particularly important for one of the key stakeholders that this paper targets; the medical device manufacturers. The design engineers within these manufacturing companies are implored to use LCAs within their design stages in order to explore potentially environmentally sustainable materials alternatives without requiring physically constructing the device and utilising minimal resources.

A scenario analysis was used to explore cleaning and recycling the breathing systems as an alternative to incineration. Two cleaning scenarios were modelled; manual cleaning (by hand using hydrogen peroxide disinfectant) and mechanical cleaning (using a washer-disinfector). Manually washing the breathing systems decreased environmental impact compared to incineration for six impact categories whereas mechanically cleaning decreased for five categories. An additional drawback to note is that the cleaning scenarios would also require extra labour in terms of collecting, transporting, and disinfecting the medical devices. A large proportion of the mechanical cleaning scenario's impact originated from the washer-disinfector's electricity usage. Using more sustainably sourced electricity or reducing energy usage would help reduce impact.

An interesting discovery during this scenario analysis is that the steps required to recycle the disinfected material was more environmentally impactful than incinerating the same material for seven of the 11 environmental impact categories. Stakeholders such as hospital waste disposal teams and disposal facilities (particularly recycling centres) should find these results particularly important when aiming to reduce the impact of the recycling stage especially since big financial savings can be made by recycling. Assuming 14.5 million breathing systems are used each year within the UK, 4182 tonnes of material could be diverted from the incinerators saving the NHS £3.2 million each year in waste disposal costs.

CHAPTER 7

7: ENVIRONMENTAL EVALUATION AND LIFE CYCLE COSTING OF REUSABLE VERSUS SINGLE-USE ANAESTHETIC FACE MASKS: A UK CASE STUDY

This chapter addresses objectives 1 and 3

A publishable article version of this chapter was submitted to the journal 'Environmental Management' on 9th February 2024. A response to the submission is pending.

Statement of contribution:
As multiple authors are listed to have contributed to this chapter, a statement is provided to demonstrate the roles each author had during its construction and a respective overall percentage to the work as a whole.

In order to facilitate fair assignment of author contribution percentages to each of the respective authors, the following division of work contribution has been allocated:

- 20% will be allocated to chapter conceptualisation and planning.
- 20% will be allocated to the running of any required software or alternative methods to obtain the results.
- 20% will be allocated to the interpretation of the results and any further analysis required.
- 25% will be allocated to the writing and editing of the chapter.
- The final 15% of the work is allocated to supervision. This percentage will be split amongst the supervisors according to their respective involvement.

Christina Webb (Percentage contribution: 80%)
Fulfilled roles: Chapter conceptualization, Methodology, Data curation, Formal analysis, Software, Project administration, Validation, Writing- Original draft preparation, Review and editing.

Lorna Anguilano (Percentage contribution: 2.5%)
Fulfilled roles: Supervision, final read of the finished chapter before submission.

Gera Troisi (Percentage contribution: 2.5%)
Fulfilled roles: Funding acquisition, final read of the finished chapter before submission.

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Environmental evaluation and life cycle costing of reusable versus single-use anaesthetic face masks: a UK case study

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Abstract

In the United Kingdom, healthcare products and services contribute 62% of National Health Service Greenhouse gas emissions. One proposal to reduce this impact is by replacing single-use devices (SUDs) with reusable devices. This study employs life cycle assessment (LCA) and life cycle costing (LCC) methodologies to assess the environmental and economic sustainability of a reusable anaesthetic mask made primarily of Polychloroprene and Polyisoprene (mask A); and two single-use masks; a polyvinyl chloride (PVC)-based mask (mask B), and a thermoplastic elastomer and polypropylene (TPE+PP) based mask (mask C). The reusable mask is shown to be more environmentally sustainable than the PVC single-use mask for nine of the 11 impact categories (via CML-IA impact methodology) and for cost but less environmentally sustainable than the TPE+PP mask for only three (HTP, MAETP, and FAETP). The reusable mask shows massive reductions in environmental impact from the materials and end-of-life stages compared to the single-use masks but the impacts from the reprocessing stage provide over 70% of overall emissions for most of the impact categories. For eight environmental impact categories, including global warming potential and human toxicity potential, mask B (PVC) is the most impactful with raw materials and end-of-life stages having the greatest contribution whereas mask C (TPE+PP) has the lowest environmental impact. The LCC showed mask B to have the greatest life cycle cost (£5.89) compared to C (£4.99) and A (£4.44). Masks B&C's life cycle cost is primarily due to the raw material and end-of-life stages, whereas mask A's is 89% from reprocessing. Sensitivity and scenario analyses tested key factors of mask A's reprocessing stage (number of reprocessing cycles and machinery energy consumption). The number of reprocessing cycles was found to influence the sustainability of the reusable mask compared to the single-use options, mainly when the number of reuses was less than 14. The energy consumption of the reprocessing machinery has more noticeable changes (up to 12%) on the overall impact. In conclusion, to make reusable masks a favourable option compared to single-use, reducing energy requirements and packaging during reprocessing are key to ensure environmental and economic sustainability.

Keywords: Energy consumption, Health economics, Life Cycle Assessment, Reprocessing, Thermoplastic Elastomer

7.1. Introduction

The medical industry's environmental impact has come under great scrutiny over the last few years with studies estimating that 1% to 5% of all global impacts are attributed to healthcare facilities and services (Lenzen et al., 2020). Within the United Kingdom, 62% of total National Health Service (NHS) emissions originate from the NHS supply chain which provides its medical products and services (Tennison et al., 2021). Medical devices has received growing attention due to worrisome levels of natural resource depletion (Chen et al., 2021) and growing volumes of waste associated with single-use devices (SUDs) (Benson et al., 2021)). Despite these concerns, SUDs are still popular due to their

inexpensive and easy-to-dispose-of nature and low risk for cross-contamination (De Sousa, 2020). SUDs are sometimes encouraged to minimise risk of healthcare-associated infections (HAIs) despite a lack of research showing increased infection rates when using reusable devices (Macneill et al., 2020).

To counter growing utilisation of SUDs, reusable devices are proposed as a potential alternative. Reusable anaesthetic masks are available for purchase on the global market and are currently being used within some UK NHS hospitals however little is known about their environmental or economic impact compared to single-use anaesthetic masks. Devices designed for reuse are reprocessed between uses instead of being disposed of and are typically produced using sturdier materials (e.g., silicone and polychloroprene), as opposed to plastic, in order to withstand the reprocessing temperatures and chemicals (Lerouge & Simmons, 2012). Reprocessing between uses allows for one reusable device to be used for multiple patients within its lifespan without the requirement for new materials or manufacturing. It does, however, require material and energy inputs to reprocess the devices, therefore questioning whether there is an overall beneficial or detrimental impact.

Life cycle assessment (LCA) methodology has become increasingly popular over the last few decades as a way of assessing environmental impact including the whole life cycle of a product (Kousemaker et al., 2021). A small number of studies have utilised LCAs to assess the environmental impact of reusable versus single-use medical devices but with contradictory results. Some found reusable devices to reduce waste volume (Kandasamy et al., 2022) and to be more environmentally favourable (McGain et al., 2010a; Sherman, Raibley and Eckelman, 2018; Kümmerer, Dettenkofer and Scherrer, 1996; Adler et al., 2005; Eckelman et al., 2012; Overcash, 2012) due to reductions in raw material requirements and waste generation. Whereas other studies conclude that SUDs are more sustainable because of the high energy and cleaning requirements of reprocessing (Leiden et al., 2020; Davis et al., 2018; McGain et al., 2017) and the use of single-use packaging and trays during the reprocessing stage (Kumar, 2021). Many studies found that the individual factors such as material type used in the devices, energy source mix, and weight of devices within specific case studies can sway whether reusable or single-use is more environmentally impactful (Dettenkofer et al., 1999; Ison and Miller, 2011; Unger and Landis, 2014; Unger and Landis, 2016; McGain et al., 2017). These results demonstrate the need for further studies to identify areas for improvement and to allow healthcare organisations to individualise their sustainability plans (Sherman et al., 2020). There is a gap in the literature of studies examining the environmental impact of single-use and reusable anaesthetic masks. More research is required to examine whether reusable anaesthetic masks reduce or increase overall environmental impact compared to single-use anaesthetic masks. Further studies are also required identifying the 'hotspots' across the lifecycles of anaesthetic masks (single-use and reusable) to find where the greatest environmental impacts lie and explore possible mitigation opportunities.

Life cycle costing (LCC) is a popular methodology used alongside LCAs to decipher the economic impact during the life cycle of a product accounting for each life cycle stage (Hunkeler et al., 2008). Few studies researching reusable medical devices have accompanied their investigations with LCCs. Of the studies which have, three found reusable devices to be cheaper (McGain et al., 2017; Unger and Landis, 2016; McGain et al., 2010), whereas one found disposable devices reduced costs (Voigt et al., 2021). Due to the limited quantity of research exploring this topic, neither reusable nor single-use devices can be concluded as being more economically beneficial. There is a need for more studies investigating the cost of reusable versus SUDs in order to come to a more substantially backed consensus.

Despite a growing demand for respiratory devices and a recent global shortage of surgical masks during the COVID-19 pandemic (Paxton et al., 2020; Burki, 2020; Howard et al., 2021), no studies have researched the impact of reusable versus single-use anaesthetic masks. The number of surgeries requiring anaesthetics in the United Kingdom per year is estimated to be around 3 million (Sury et al., 2014). This number increases dramatically to 32 million when also considering the United States (Matsusaki & Sakai, 2011). Each of these surgeries require the use of an anaesthetic mask demonstrating the large quantity of masks required and the importance of conducting studies exploring this area. Previous research also tends to not include packaging and transport into their calculations not allowing for fully comprehensive investigations. This study aims to fill these gaps by investigating the environmental and economic sustainability of three anaesthetic masks (one being a reusable anaesthetic mask) including their full life cycles and identify the hotspots and opportunities for mitigation.

7.2. Methodology

For this study, life cycle assessment (LCA) and life cycle costing (LCC) methodologies are used to assess the environmental impact and economical cost of reusable and single-use anaesthetic masks. The LCA methodology is conducted according to the ISO standards 14040 and 14044:2006 (ISO, 2006a; 2006b), using SimaPro software version 8.3.1 (SimaPro manual PRe-Consultants, 2008) to aid calculation of impacts. The LCC methodology is run according to the code of practice provided by (Swarr et al., 2011).

7.2.1. Goal and Scope

This study's goal is to calculate and compare the environmental and economic sustainability of reusable and single-use anaesthetic masks across their entire life cycles. The scope of the study is from cradle-to-grave including the raw material extraction and pre-processing, transport between the stages, manufacturing including material moulding, component assembly, packaging, reprocessing of the reusable mask, and final disposal. The environmental impact and cost associated with the use stage of the anaesthetic masks is attributed to the anaesthetic machinery generating the gas flow for the patient, hence is outside the scope of this study and excluded. All three masks are modelled to be used and disposed of within the United Kingdom. Two masks are manufactured and transported from an Asian country and one mask is manufactured and transported from a European country.

Functional unit and system boundaries

The functional unit (FU) is defined as 'the administration of anaesthesia to 50 individual patients via the use of a sterile anaesthetic mask', therefore, the FU for the reusable mask will be one reusable mask and the equivalent FU for the single-use masks is 50 masks. During this study, the efficacy of each device is deemed equal, and each use fulfils the function of providing anaesthesia for one patient over the course of a medical procedure in the UK. A London-based hospital is used for this case study. Figure 20 demonstrates the life cycle stages included within the LCAs of the single-use and reusable masks.

Figure 20 Diagram showing the full Cradle-to-Grave System boundary for the anaesthetic masks studied (use stage is in red as it does not include any material or energy input). Life cycle stages: raw material extraction and pre-processing (RMEP - pink), manufacturing (light green), packaging (blue), transport (dark green), reprocessing (yellow), end-of-life (purple).

The devices studied

Three anaesthetic masks will be explored; as shown in Figure 21. Mask A is a reusable anaesthetic mask primarily consisting of polyisoprene and polychloroprene with the capability to be reprocessed up to 50 times before final disposal. Masks B&C are single-use anaesthetic masks intended to be disposed of after one use. Mask B is made from plasticised Polyvinyl Chloride (PVC). Mask C is advertised as a sustainable alternative to Mask B due to its lighter weight and utilisation of Styrene-Ethylene-Butylene-Styrene (SEBS) based Thermoplastic elastomer (TPE) and Polypropylene (PP) instead of PVC.

Mask A	**Mask B**	**Mask C**
		
Reusable anaesthetic mask	PVC single-use anaesthetic mask	TPE and PP single-use anaesthetic mask

Figure 21: Images and descriptions of the three masks investigated within this study. The images for these masks were taken from the manufacturer's website.

7.2.2. Life Cycle Inventory data

The following sections provide a description and the inventory of each life cycle stage, as seen in Figure 20.

Raw material extraction and pre-processing stage (RMEP)

The RMEP stage involves the extraction of raw materials and pre-processing, converting extracted raw material into a form which is mouldable by manufacturing equipment. The bill of materials was obtained via material datasheets from the manufacturers; Ecoinvent 3.2 database (Wernet, 2016) has been used for the background data. SEBS and the plasticiser (the specific name is not provided for confidentiality) were the only materials not available on the Ecoinvent 3.2 database. SEBS was modelled from private consultation and deemed confidential information (data retrieved from SEBS produced in Germany). The LCI data for the plasticiser was sourced from (ECPI, 2015) and is modelled from average EU-27 production.

Table 20 summarises the material composition of each mask. A full inventory source for these materials can be found in the appendices in table A7.

Table 20: Life cycle inventory of the raw material and pre-processing stage (RMEP) of the three anaesthetic masks; data are presented per functional unit of one mask.

Component	Material	Mask[a]		
		A Mass (g)	**B** Mass (g)	**C** Mass (g)
Mask Shell	Plasticised PVC[b]	-	24.2	-
	Polychloroprene	47.76	-	-
	Polyisoprene	98	-	-
	Polypropylene	-	-	8.40
	LDPE[c]	-	-	0.13
Cushion	TPE-S[d]	-	-	8.7
	PVC[b]	-	9.51	-
Mask Bung	Polysulfone	0.88	-	-
Mask Collar	Polychloroprene	20.3	-	-
Hook ring	HDPE[c]	-	1.84	-
	Polypropylene	-	-	1.48
	Total Weight (g)	**166.94**	**35.55**	**18.71**

[a] Description of masks in Figure 21
[b] PVC: Polyvinyl Chloride
[c] LDPE: Low-Density Polyethylene, HDPE: High-Density Polyethylene
[d] TPE-S: SEBS-based Thermoplastic Elastomer, SEBS: Styrene-Ethylene-Butadiene-Styrene

Manufacturing stage (processing and assembly)

The manufacturing and assembly processes are present within the manufacturing plants and owned by the manufacturer. Masks A and B are manufactured in an Asian country and Mask C is manufactured in a European country. The specific countries are known and used for the study but is excluded here for confidentiality. The environmental impact data for operation of the manufacturing machines are sourced from the Ecoinvent 3.2 database (Wernet, 2016) and is specified to operate using electricity extracted from the specific Asian and European countries' national grid (data valid for the year 2015 is used). Information about the manufacturing stage was provided as product data sheets by the manufacturer and via consultations with the machine operators.

Assembly has no additional environmental impact as the masks are designed to allow the components to be moulded together during manufacturing and the hook rings attached by a human operator. After manufacture and assembly, the masks are packaged.

Table 21: Input processes for the manufacturing stage of each mask type per functional unit

Manufacturing		Mask		
Inputs	**Units**	**A**	**B**	**C**
Injection moulding	g	166.94	26.04	10.01
Blow moulding	g	-	9.51	8.70

Packaging

Table 22 provides the weight and processing steps for each packaging material which were received via material data sheets provided by the manufacturer. The paper and cardboard are virgin materials and purchased ready to be used by the manufacturer. The low-density polyethylene (LDPE) is also

virgin material but requires an extra processing stage (film extrusion) to be converted into a plastic film. The distance of transporting raw materials for the packaging to the processing centre was taken from average distances of nearby material procurement suppliers. The environmental impact of disposal of the packaging is included within this stage and described in the 'end-of-life disposal' section.

Table 22: Materials, weight, and extra processing required for the packaging used per FU of one mask.

Material	Mask A (g)	Mask B (g)	Mask C (g)	Extra processing required after pre-processing	Transport to processing centre (km) *(Vehicle: 7.5-16 mton Euro 6 lorry)*
Paper	37	-	-	None	100
Low density Polyethylene	6	2	4	Extrusion plastic film	200
Corrugated Board box	48	6	11	None	100
Total (g)	*91*	*8*	*15*		

Transport stage

This stage includes the transport of the raw materials to the device manufacturer, from the manufacturing facilities to hospital, to the reprocessing facility and back to the hospital for the reusable, and to the final disposal of the single use and the end of the life of the reusable. The location of the raw material extraction plant for each material was received through product data sheets from the manufacturer and the distance travelled was calculated using Google maps. For this study, a London-based hospital was used. The type of vehicles used to transport the masks to the hospital were acquired from consultation with the manufacturer and hospital team. After use, the masks are disposed of separate from their original packaging and taken to a nearby incineration site. The disposal site is 10 km away from the hospital and the type of vehicle used was acquired from consultation with the hospital waste management team. Data is shown in Table 23.

Table 23: Transport weight and distance travelled as well as type of vehicle used; results shown per functional unit.

Transport stage			Mask		
	Transport data	**Units**	**A**	**B**	**C**
Raw materials to device manufacturer ***Vehicle:*** *7.5-16 mton Euro 6 lorry*	Plasticised PVC	km	-	1700	-
	TPE-S	km	-	-	100
	Polypropylene	km	-	-	100
	LDPE	km	-	-	2050
	HDPE	km	-	20	-
	Polychloroprene	km	200	-	-
	Polyisoprene	km	100	-	-
	Polysulfone	km	100	-	-
Manufacturer to distributor ***Vehicle:*** *Transoceanic Ship, 7.5-16 mton Euro 6 lorry*	Transport weight (incl. packaging)	g	257.94	43.55	33.71
	Distance by Boat	km	13100	13100	-
	Distance by Lorry	km	88.5	88.5	2100
Distributor to UK based hospital ***Vehicle:*** *7.5-16 mton Euro 6 lorry*	Transport weight (incl. packaging)	g	257.94	43.55	33.71
	Distance	km	45	45	45
Hospital to UK based final disposal ***Vehicle:*** *Municipal waste 21mton lorry*	Transport weight	g	166.94	35.55	18.71
	Distance	km	10	10	10

7.2.3. Reprocessing of reusable mask

After each use, mask A is reprocessed at a sterile services facility. This reprocessing stage includes the environmental impact of any packaging or wrap used during a cycle of reprocessing, the transport to and from the hospital and sterile services (10.46 km), and the input and emissions during washing and sterilisation. Mask A can be reprocessed 50 times before final disposal per the manufacturer's recommended safety guidelines.

Reprocessing machinery: Washing and Sterilisation

Reprocessing of a reusable device requires initial washing via a washer-disinfector to remove larger contaminants followed by sterilisation. The washer-disinfector is a 11 KWh machine, with a 50-minute cycle and uses 36 litres of water per cycles; it can hold 60 masks per cycle. The mask is then sterilised in a steriliser that uses 7.4 KWh for a 60-minute cycle; it can hold 180 masks per cycle. All information was obtained via machinery technical data sheets and confirmation by the sterile services technicians.

Packaging

When the device has finished being used, it is placed into a protective pouch to confine any contaminants prior to being transported to the sterile services. For this study, mask A is placed in a moisture retention pouch made of viscose-based film and weighing 11 g. This pouch containing mask A is transported to the sterilisation facilities where the mask is taken out of the pouch and the pouch is disposed of via incineration. The mask is then washed and wrapped in PP based sterilisation wrap; two sheets of 62.7 g/m^2 density wrap and one sheet of 40.7 g/m^2 density wrap weighing a combined total of 22.91 g. This wrap is recycled after use and converted into commercial products. The mask wrapped in sterilisation wrap is then placed in the sterilisation machine.

Transport

The transport stage of reprocessing includes the transport from the hospital to the sterile services prior to reprocessing, then transport back to the hospital afterwards. For both of these trips a 7.5-16 mton Euro 6 lorry is used as confirmed by the hospital waste management team. The distance from the hospital to the sterile services is 10.46 km found using google maps.

7.2.4. End-of-life Disposal

After mask A has been sterilised and reused 50 times, it is disposed of. The end-of-life scenario modelled for this study is 100% incineration with energy recovery (UK-based) which is NHS best practice for contaminated medical devices. Masks B&C are single-use devices and after use are placed directly into a waste stream for incineration. It is against best practice (NHS waste disposal regulation HTM 01-07) for used medical devices to be recycled and so is not modelled within this assessment. For the packaging, the paper and cardboard are recycled at a rate of 69% within the UK and the rest is landfilled (Wrap, 2020). The LDPE film is landfilled as is typical within a UK hospital setting.

7.2.5. Life cycle impact assessment

The life cycle impact assessment results were calculated using the CML-IA Baseline version 3.03 EU25 methodology (Gabathuler, 2006). A recent study (Rejane Rigon et al., 2019) found CML to be the most widely used impact methodology which is why it was chosen. All 11 environmental impact categories that are calculated will be presented in the results to ensure a comprehensive comparison.

7.2.6. Life cycle costing

Life cycle costing (LCC) is an economic analysis tool carried out using the same life cycle stages as the LCA; as detailed by Swarr et al. (Swarr et al., 2011). These stages are as follows: raw materials and pre-processing (RMEP), manufacturing, transport, packaging, and end-of-life. The use phase is excluded due to being outside the scope of this study as was the case with the LCA. The cost of reprocessing is included for the LCC of the reusable mask (mask A).

For this study, the methodology provided for an environmental LCC is used. An environmental LCC is intended to be conducted alongside an LCA as they contain similar methodological steps (Falcone et al., 2016). When used alongside an LCA framework, LCCs are able to link the environmental impact per lifecycle stage with their corresponding economic impact (Falcone et al., 2016). LCAs follow the ISO standards 14040/44:2006 (ISO, 2006a; ISO, 2006b) and LCCs follow the standard ISO 15686:2017 (ISO, 2017). When running an LCA alongside an LCC congruently, it is beneficial to apply the same system boundaries and functional unit in order to aid consistency and comparison (Swarr et al., 2011). This also applies when choosing which life cycle stages to include.

The LCC has been modelled according the following equation which was constructed with using the LCC ISO standard 15686 (ISO, 2017) and the steps detailed by Swarr et al. (Swarr et al., 2011) as well as with reference to the LCA ISO standards 14040/44:2006 (ISO, 2006a; ISO, 2006b),

$$LCC = CC_{RMEP} + C_M + C_T + C_P + (C_R)^* + C_{EoL}$$

**Only applicable to the reusable mask (mask A)*

LCC = Total life cycle cost

C_{RMEP} = Cost of the raw materials and their pre-processing

C_M = Cost of manufacturing

C_T = Cost of transportation

C_P = Cost of packaging

C_R = Cost of reprocessing

C_{EoL} = Cost of End-of-Life disposal

For each stage, the cost associated with the required materials or energy (e.g., cost of raw materials, electricity, and petrol) are calculated. This data only includes the costs that are directly incurred with no value added by the companies. An LCC is not intended to assess the financial cost of services or of the purchasing and selling between businesses but instead is a strategic scientific method of accounting for financial flow throughout the life cycle stages to identify true cost (Hunkeler et al., 2008).

Average market value for each raw material cost (C_{RMEP}) was calculated using regionally appropriated data. For manufacturing data (C_M), average KWh usage was used to calculate the electricity required to process the material. It was found that injection moulding machinery uses on average 1.47 KWh to process one kg of plastics (Elduque et al., 2018) and extrusion blow moulding 2.49 KWh per kg (Kent, 2009). Masks A and B were manufactured in an Asian country where the average cost for electricity per KWh for businesses was used and found to be £0.084 per KWh (GPP, 2023). Mask C was manufactured in a European country with electricity costs of £0.22 per KWh (GPP, 2023).

Two types of transport were used during the life cycles of the three masks: 7.5-16 mton lorry and transoceanic ship. To calculate the cost of petrol (C_T) for the 7.5-16mton lorry, an average miles per gallon (mpg) was found by comparing mpg of popular lorry models. The average was found to be 17 mpg which by further calculations determines that 13.8 litres of fuel is required per 100 km travelled. The majority of lorries are powered by diesel engines (Lloyd & Cackette, 2001). Currently, average diesel costs in the European country are £1.44 per litre and £1.70 in the United Kingdom (Tolls.eu, 2023). The weight of the transported goods will also be taken into consideration during calculations. The average payload weight allowance on a 7.5-16mton lorry is calculated at 5000 kg when using average payload data from current vehicle models (Hunts, 2020). For the cost of transporting via transoceanic ship, a modern container vessel has a fuel consumption of 217 tons of bunker fuel per day which values at £461 per ton (MTS, 2018). It has a maximum container capacity of 7,750 twenty-foot equivalents (TEUs) (MTS, 2018) with each container having a weight-bearing capacity of 28200 kg (Menon, 2022). Using an average cargo ship speed of 20 knots (37 km/h) (MOL, 2022) traveling 13100 km (7073 nautical miles) takes just under 15 days. This data is used to calculate the cost of transporting masks A and B from the manufacturing site in the Asian country to the UK.

Packaging cost (C_P) was determined using the above methods for raw material, transport, and manufacturing costs. Disposal of packaging once the device is removed within the hospital is also included. The packaging is disposed of as non-infectious waste within the hospital costing £0.67 per kg as received from the hospital's waste management team. The reprocessing cost (C_R) was calculated using cost per KWh of UK electricity, cost per litre of water within the UK, and average UK petrol cost. The used masks are disposed of (C_{EoL}) as infectious waste which costs £0.91 per kg as also received from the hospital team. This life cycle costing data is shown in Table 24.

Table 24: Life cycle costing data of three anaesthetic masks A, B, and C. Descriptions of masks in Figure 21. Units expressed per mask.

			Mask		
Stage	**Material**		**A**	**B**	**C**
Raw Materials *Cost per mask*	Plasticised PVC *(includes mask shell and cushion)*	Weight (g)	-	33.71	-
		Cost (pence)	-	6.44	-
	TPE-S	Weight (g)	-	-	8.7
		Cost (pence)	-	-	3.62
	Polypropylene *(includes mask shell and hook ring)*	Weight (g)	-	-	9.88
		Cost (pence)	-	-	1.80
	LDPE	Weight (g)	-	-	0.13
		Cost (pence)	-	-	0.03
	HDPE	Weight (g)	-	1.84	-
		Cost (pence)	-	0.40	-
	Polychloroprene *(includes mask shell and mask collar)*	Weight (g)	68.06	-	-
		Cost (pence)	13	-	-
	Polyisoprene	Weight (g)	98	-	-
		Cost (pence)	23	-	-
	Polysulfone	Weight (g)	0.88	-	-
		Cost (pence)	1.3	-	-
Manufacturing (injection moulding)	Processing weight (g)		166.94	26.04	10.01
	Electricity used (KWh)		0.245	0.03828	0.015

Electricity cost	Cost (pence)	2.1	0.321	0.324
Manufacturing (Blow moulding) *Electricity cost*	Processing weight (g)	-	9.51	8.7
	Electricity used (KWh)	-	0.024	0.022
	Cost (pence)	-	0.202	0.476
Transport *Petrol cost*	Raw materials (pence)	0.09	0.228	0.008
	To hospital (pence)	0.3	0.051	0.288
	To disposal (pence)	0.007	0.001	0.007
Packaging	Material Cost (pence) *(incl. transport to manufacturer)*	2.1	0.308	0.604
	Manufacturing cost (pence)	0.06	0.056	0.112
	Packaging disposal cost (pence)	6.1	0.536	1.006
Reprocessing cost ***Per one cycle***	Transport (pence)	0.015	-	-
	Reprocessing (pence)	5.24	-	-
	Packaging (pence)	2.662	-	-
Disposal cost	Disposed weight (g)	166.94	35.55	18.71
	Cost (pence)	0.152	3.236	1.702

7.3. Results and discussion

Figure 22 displays the environmental impact for the three anaesthetic masks studied with all 11 impact categories provided together with the life cycle costing. The environmental impact categories are as follows: abiotic depletion potential of elements (ADPe), abiotic depletion potential of fossil resources (ADPf), acidification potential (AP), eutrophication potential (EP), global warming potential (GWP), human toxicity potential (HTP), marine aquatic ecotoxicity potential (MAETP), freshwater aquatic ecotoxicity potential (FAETP), ozone depletion potential (ODP), photochemical oxidants creation potential (POCP) and terrestrial ecotoxicity potential (TETP). The results are first discussed for the environmental assessment, followed by a discussion of the economic assessment. Key contributing factors to the impact are explored via a sensitivity analysis and scenario analysis.

7.3.1. Environmental sustainability assessment

Figure 22 shows that mask C has the lowest environmental impact for eight of 11 environmental impact categories and mask A the lowest for the remaining three (HTP, FAETP, and MAETP). Mask B has the greatest impact for eight impact categories with particularly high toxicity potentials (HTP, FAETP, and MAETP). For 10 categories, over 70% of mask A's impact originates from the reprocessing stage. For most categories, the RMEP or end-of-life stages combined contribute between 65%-94% of mask B's overall impact. None of mask C's life cycle stages stand out as particularly impactful, except for HTP, FAETP, and MAETP, where end-of-life contributes 51%, 84%, and 91% of total impact respectively. The impacts for each category are analysed in greater detail below.

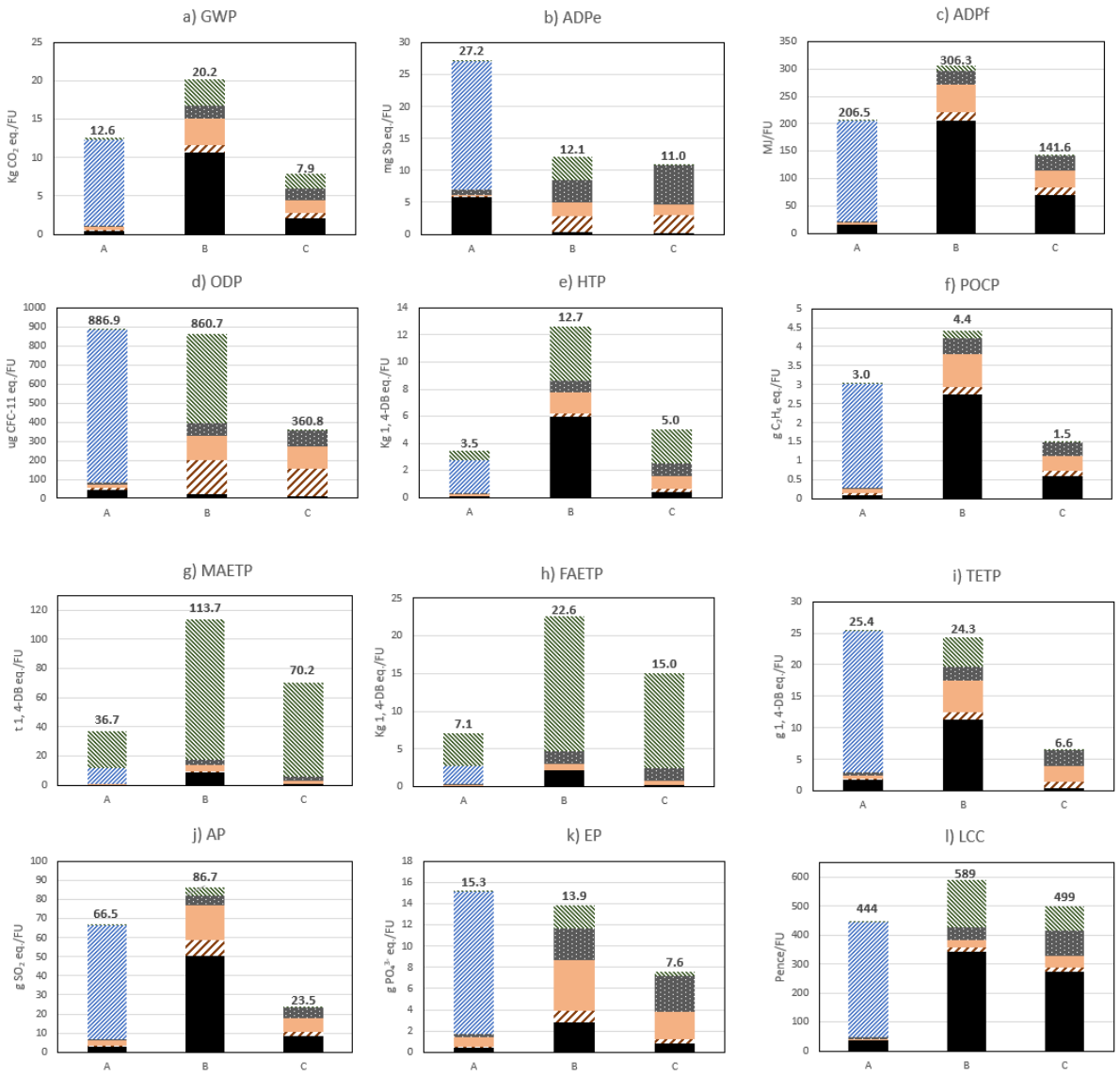


Figure 22: Comparison of environmental impact and life cycle costing of three anaesthetic masks A, B, and C. Results expressed per functional unit (FU) (the administration of anaesthesia to 50 individual patients via the use of a sterile anaesthetic mask). Description of masks in Figure 21. ADPe: abiotic depletion potential of elements; ADPf: abiotic depletion potential of fossil resources; AP: acidification potential; EP: eutrophication potential; GWP: global warming potential; HTP: human toxicity potential; MAETP: marine aquatic ecotoxicity potential; FAETP: freshwater aquatic ecotoxicity potential; ODP: ozone depletion potential; POCP: photochemical oxidants creation potential; TETP: terrestrial ecotoxicity potential.

Global Warming Potential (GWP)

As shown in Figure 22a, mask B has the greatest GWP (20.2 kg CO_2 eq.), followed by mask A (12.6 kg CO_2 eq.), then mask C (7.9 kg CO_2 eq.). Mask A's GWP from the end-of-life stage is much lower (0.27 kg CO_2 eq., 2%) than masks B&C (3.44 kg CO_2 eq. and 1.87 kg CO_2 eq.). This is due to the lower quantity of material incinerated as only one mask A is incinerated per FU. However, 11.2 kg CO_2 eq (89%) of mask A's GWP is from its reprocessing stage; 5.9 kg CO_2 eq (53%) from the use of machinery, 5.3 kg CO_2 eq (47%) from reprocessing packaging, and 0.04 kg CO_2 eq (0.3%) from transport. 79% of the GWP from the reprocessing machinery is due to the washer-disinfector's electricity requirements. More sustainable sources of electricity (e.g., renewable energy) could be

considered which produce less CO_2 emissions than fossil-fuel derived (Ben Jebli et al., 2020). Alternatively, reducing energy consumption during the reprocessing stage perhaps by using more energy efficient machinery will also help lower the environmental impact (as will be tested in the sensitivity analysis). 56% (3.0 kg CO_2 eq) of the GWP contribution from the reprocessing packaging comes from the sterilisation wrap and 44% (2.3 kg CO_2 eq) from the humidification pouches. 2.4 kg CO_2 eq of this impact is due to the PP used within the sterilisation wraps. To reduce these emissions, more sustainably-sourced PP, e.g., recycled PP, or non-fossil fuel derived materials could be used (Freeland et al., 2022; Markl et al., 2018). These changes could help reduce mask A's impact enough to compete with the TPE+PP based single-use mask (mask C).

10.6 kg CO_2 eq. of mask B's GWP comes from the RMEP stage whereas only 2.0 kg CO_2 eq. is from mask C's. Some of this change is attributed to mask C's lower weight, however, this reduction of 81% exhibits that mask C's materials (TPE+PP) have a lower GWP than PVC on a weight-to-weight basis. The emissions of Carbon dioxide (CO_2) to air contributed 93% of mask B's GWP from the RMEP stage with 74% of these emissions originating from the raw material requirements of the plasticiser. To reduce GWP from the raw materials used within the plasticiser, manufacturers could change the raw materials used during production or use an alternative plasticiser. All other stages within masks B&C's life cycles contribute 8%-24% to the overall GWP. End-of-life is the highest contributing stage, consisting of 3.4 kg CO_2 eq (17%) and 1.9 kg CO_2 eq (24%) of masks B&C's overall GWP respectively.

Depletion Potentials (ADPe, ADPf, ODP)

Figure 22b shows mask A to have the greatest ADPe (27.2 mg Sb eq), over two times greater than mask B (12.1 mg Sb eq) and 2.5 times higher than mask C (11.0mg Sb eq). For ADPf (Figure 22c), mask B is the most impactful having an impact 48% higher than mask A and over twice mask C's. For ODP, mask A is the highest but only 26.2 ug CFC-11 eq. (3%) greater than mask B. For these three categories, 74% to 91% of mask A's impact originates from the reprocessing stage. The reprocessing packaging provided over half (52% to 64%) of the impact with the remaining impact from the reprocessing machinery's electricity requirements. The reprocessing packaging has greater ADPe, ADPf, and ODP impact than the packaging required during the whole lifecycle of the single-use masks. This is partly due to the greater quantity of packaging required during one cycle of reprocessing (33.91 g of packaging each cycle compared to 8 g and 15 g of packaging for masks B&C). To reduce the impact of mask A, the electricity and packaging used during reprocessing should take priority.

The other stages have a much smaller contribution to mask A's ADPe, ADPf, and ODP collectively only contributing 7.05 mg Sb eq (26%), 22.7 MJ (11%), and 82.7 ug CFC-11 eq. (9%) to the total impact. This is mostly due to the manufacturing, packaging, and transport life cycle stages being required for only one reusable mask whereas they are required 50 times per FU for masks B&C. Most of mask B's ADPe comes from end-of-life (30%), packaging (28%), and transport (21%) with manufacturing (18%) adding the rest. Mask C is similar to mask B in the respect that packaging (57%), transport (25%), and manufacturing (15%) are also its biggest ADPe contributors. However, its end-of-life stage is much less impactful (0.125 mg Sb eq compared to mask B's 3.64 mg Sb eq.). For ODP, the end-of-life stage is responsible for 463 ug CFC-11 eq (43%) of mask B's impact but 3.1 ug CFC-11 eq (1%) of mask C's, thus demonstrating that incinerating PVC has greater ADPe, ADPf, and ODP than incinerating TPE and PP. For all three categories, the impact from transport is reduced by 49% from mask B to mask C. This is consistent with the lower weight required to be transported for mask C and demonstrates the importance of lightweighting in reducing environmental impact.

Human health (HTP, POCP)

Mask A has the lowest HTP (3.5 kg 1, 4-DB eq) comprised mainly of the reprocessing (70%) stage. The reprocessing stage is also the majority (90%) of mask A's POCP. For HTP, 1.3 kg 1,4-DB eq. originates from operation of the reprocessing machinery; 1.0 kg 1,4-DB eq (78%) from the washer-disinfector's electricity consumption. For POCP, 1.4 g C_2H_4 eq (52%) comes from the reprocessing packaging. Therefore, as mentioned previously, reducing energy demands and packaging required during reprocessing will lower these impacts.

For both HTP and POCP (Figure 22e&f), mask B has the greatest impact. Mask B's HTP (12.7 kg 1,4-DB eq.) is much greater than mask A (3.5 kg 1,4-DB eq.) and mask C (5.0 kg 1,4-DB eq.) with the majority of its impact originating from the RMEP (47%) and end-of-life (32%) stages. Manufacturing, packaging, and transport have smaller contributions (3% to 20%) for both masks B&C. The emissions primarily responsible for mask B's HTP from the RMEP stage is Barium (Ba) released to water (82% of total impact) almost entirely (>99%) due to the raw materials used within the plasticiser. The RMEP consist of only 8.5% of mask C's HTP emitting 0.43 kg 1, 4-DB eq compared to mask B's RMEP emissions of 6.0 kg 1, 4-DB eq. A significantly lower (-78%) POCP from the RMEP stage can be seen from mask B to mask C. This reduction is greater than can be explained by reduced material weight alone so therefore must also be due to the material type. Sulphur Dioxide (SO_2) and Carbon Monoxide (CO) emissions to air, primarily from the raw materials used to produce the plasticiser, is particularly high during the RMEP stage for mask B and contributes 54% and 23% to the total POCP respectively. However, the difference in impacts between masks B&C is too big for the reduction of these emissions to be enough to make mask B overall less impactful.

Aquatic Ecotoxicity potentials (MAETP, FAETP)

For MAETP and FAETP (Figure 22g&h), mask B has the highest impact (MAETP: 113.7 t 1,4-DB eq., FAETP: 22.6 kg 1,4-DB eq.) followed by mask C (MAETP: 70.2 t 1,4-DB eq., FAETP: 15.0 kg 1,4-DB eq.), then mask A (MAETP: 36.7 t 1,4-DB eq., FAETP: 7.1 kg 1,4-DB eq.). End-of-life is the most contributing stage for all masks (62% to 91%). For MAETP and FAETP, mask B's end-of-life emits 96.5 t 1,4-DB eq. and 17.9 kg 1,4-DB eq. respectively; 51% and 42% greater than mask C. Beryllium (Be) to water is the most contributing emission consisting of >84% of mask C's MAETP and FAETP. >99% of the MAETP impact and 88% of the FAETP is due to the incineration of the TPE within mask C. To lower this impact, focus should therefore be placed on reducing the quantity of TPE being incinerated perhaps by lightweighting or replacing with less impactful materials.

Despite the end-of-life impact for mask A being the lowest of the three masks, based on weight of incinerated material alone (166.94 g vs 1800 g and 900 g per FU), mask A's MAETP and FAETP would be assumed to be lower. Over 98% of mask A's MAETP and FAETP comes from incineration of the Polyisoprene, specifically >97% from the emissions of Be to water. To reduce impacts, the Be emissions produced when incinerating Polyisoprene would need to be reduced or an alternative material used. Despite the environmental impact being higher during the incineration of mask A on a weight basis, a lower quantity of material overall is being incinerated. For every 50 masks disposed, mask B requires incineration of 1800 g of material, mask C requires 940 g, and mask A only 170 g. If the goal is to decrease volume of generated waste or reduce material resource depletion, mask A has a clear advantage.

For both categories, mask C has a low contribution (1%) from the RMEP stage. Compared to mask B where the RMEP stage contributes 8% to 9%. 7.4 t 1,4-DB eq. (82%) of mask B's MAETP and 1.8 kg 1,4-DB eq. (85%) of FAETP from the RMEP stage originates from the raw materials required to produce the plasticiser with Ba released to water being the main (71% to 84%) emission produced. Ba released to water is also the largest contributing emission for mask C's MAETP and FAETP but is

produced in a lower quantity (MAETP: 0.4 t 1,4-DB eq, FAETP: 0.1 kg 1,4-DB eq.; both 94% less than mask B). To reduce MAETP and FAETP from the RMEP stage, the impact from the plasticiser (specifically the release of Ba) should become a focus and the materials used within mask C (TPE+PP) should be encouraged over the use of plasticised PVC.

Ecosystems (TETP, AP, EP)

For TETP and EP (Figure 22i&k), mask A has the highest impact (TETP: 25.4 g 1,4-DB eq., EP: 15.3 g PO_4^{3-} eq.), whereas for AP (Figure 22j), mask B is the greatest (86.7 g SO_2 eq.). The variation in total impact between masks A&B for TETP and EP is relatively small; mask A is 5% and 10% higher than mask B respectively. Across all three categories, 88% to 90% of mask A's impact is from the reprocessing stage with the washer-disinfector's energy consumption consisting 51% to 65% of that. Due to mask A's impact being only slightly greater than mask B's, even slight reduction in emissions during reprocessing may cause mask A to become more environmentally favourable than mask B.

For all three categories, mask C has the lowest impacts, >53% lower than the other masks, with particularly small TETP and AP partially due to reduced RMEP emissions. In order for mask A to compete with mask C, its reprocessing stage would need to be reduced by over two thirds. Mask C's RMEP stage emits 0.4 g 1,4-DB eq. (TETP), 8.5 g SO_2 eq (AP), and 0.8 g PO_4^{3-} eq. (AP) which are much lower than mask B's RMEP stage (11.2 g 1,4-DB eq., 50.2 g SO_2 eq., and 2.9 g PO_4^{3-} eq.). 79% of mask B's TETP from the RMEP stage is from emissions of mercury (Hg) to air, 75% of which is due to electricity used during raw material processing required during production of the plasticiser. For AP, 74% is from SO_2 to air which again is primarily (85%) from the plasticiser. The plasticiser is also the main contributor (56%) of EP of which 78% comes from nitrogen oxide (NO) emissions to the air.

For transport and manufacturing, reductions in impacts from mask B to mask C are found to be correlated to the reduced weight of mask C. For EP, The manufacturing stage contributes 4.8 g PO_4^{3-} eq. (34%) of masks B's impact and 2.6 g PO_4^{3-} eq. (35%) of mask C's. 4.5 g PO_4^{3-} eq. (94%) of masks B's EP from the manufacturing stage is due to the injection moulding and blow moulding processes; injection moulding accounting for the majority (3.1 g PO_4^{3-} eq). For both moulding processes, phosphate (PO_4^{3-}) to water makes up 81% of the emissions originating from the use of electricity. This is the same for mask C, where 2.0 g PO_4^{3-} eq. comes from the moulding processing again mainly from PO_4^{3-} to water (81%). For EP, packaging also has a considerable contribution to masks B&C's impacts; 3.0 g PO_4^{3-} eq. (22%) and 3.3 g PO_4^{3-} eq. (44%) respectively. 67% of mask B's impact from packaging and 45% of mask C's originates from the impact of disposal, therefore showing that more sustainable disposal methods of the packaging would make noticeable changes to the overall EP.

7.3.2. Life cycle costing

Mask B has the highest cost (£5.89) per FU, followed by mask C (£4.99) then mask A (£4.44). The majority (89%) of mask A's cost originates from the reprocessing stage (£3.96), whereas the RMEP stage is the largest contributing stage for masks B&C (£3.42 and £2.73 respectively). 52% (£2.06) of mask A's reprocessing cost is due to the cost of electricity required to run the washer-disinfector. A further 26% (£1.05) is from the cost for the PP within the sterilisation wrap. Substantial reductions can be observed for all other life cycle stages for mask A compared to both masks B&C: RMEP (B: -304p C: -235p), manufacturing (B: -24p C: -38p), transport (B: -13p C: -15p), packaging (B: -37p C: -78p), and end-of-life (B: -£1.61 C: -£0.85). This reduced cost can mainly be attributed to mask A requiring only one mask to be manufactured, processed, transported, and disposed. The cost to transport mask C via lorry from the European country to the UK is 14.4p whereas transporting masks A and B and their packaging from the Asian country to the UK via transoceanic ship costs only 0.3p for fuel; a 98% reduction.

Per 50 masks, mask C costs 90p less than mask B, a 15% decrease. The greatest contributing stage to mask B's impact is from RMEP (58%) followed by end-of-life (27%). The least expensive is transport contributing only 14p (2%). The cost to transport mask B's raw materials to the manufacturer is 11.4p whereas mask C's is 0.42p, a reduction of 96%. Mask C has lower associated costs for all life cycle stages compared to mask B except packaging (+41p). A big reduction can be seen in RMEP where cost is £3.42 for mask B but £2.73 for mask C. RMEP is also the most contributing stage for mask C's overall cost (55%), followed by packaging (17%) and end-of-life (17%).

7.3.3. Sensitivity analysis: Energy consumption of reprocessing

The reprocessing stage has significant contribution to mask A's overall environmental impact, accounting for between 28% and 91%; with 10 categories above 70%. The electricity required to operate the reprocessing machinery (washer-disinfector and steriliser) consists of 35% to 65% of the total reprocessing impact across all impact categories. To test the effect that machinery energy consumption has on the environmental impact of mask A, a sensitivity analysis is run where energy consumption is changed by +/- 20%. Figure 23 shows the results.

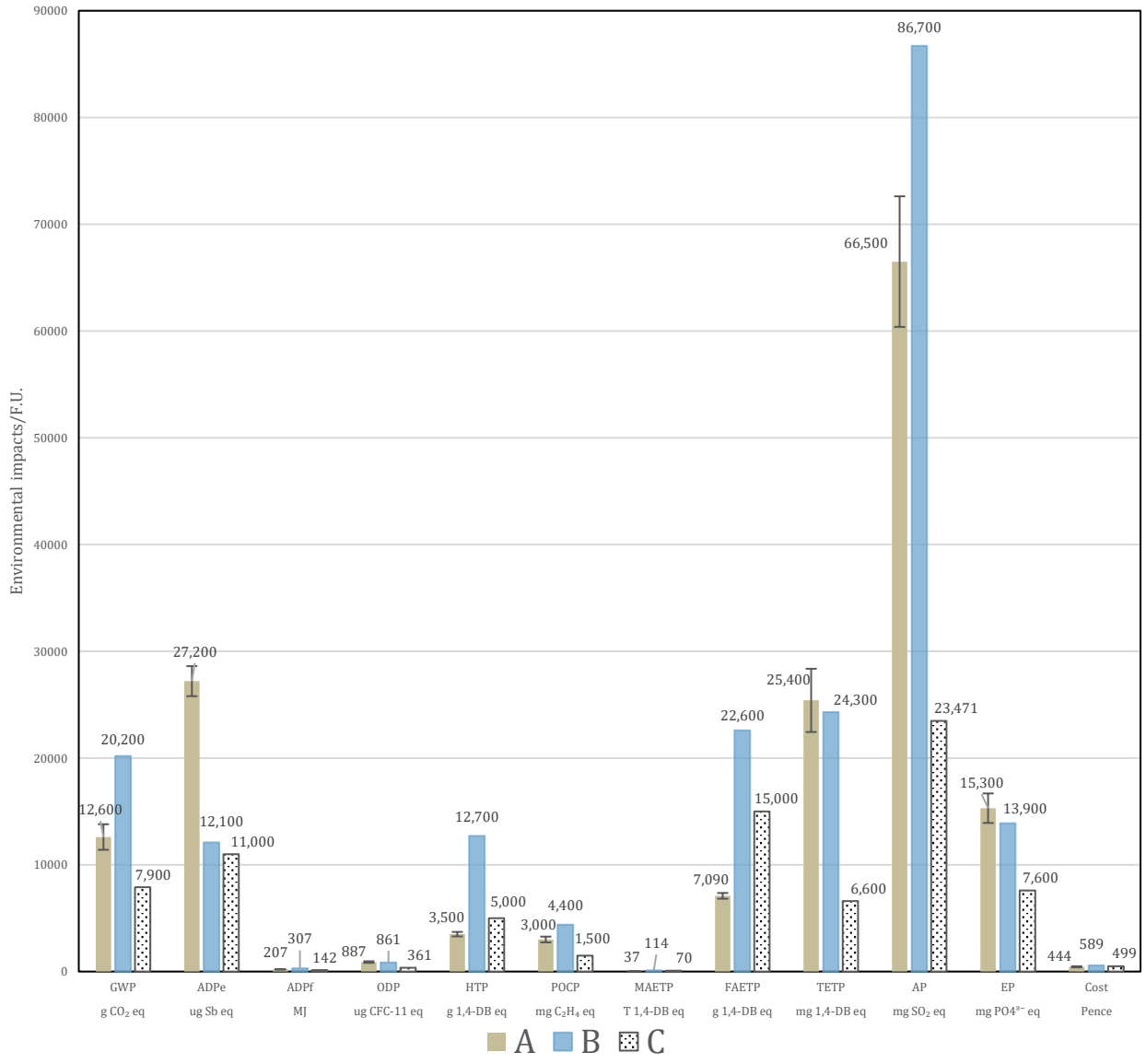


Figure 23: Sensitivity analysis on machinery energy consumption during mask A's reprocessing stage. Results expressed per FU with error bars displaying impact when machinery energy consumption is increased by 20% (upper cap) and decreased by 20% (lower cap). The baseline results and masks

B&C's impacts are provided for comparison. Description of masks in Figure 21. All eleven impact categories and LCC are included; see description in methodology section.

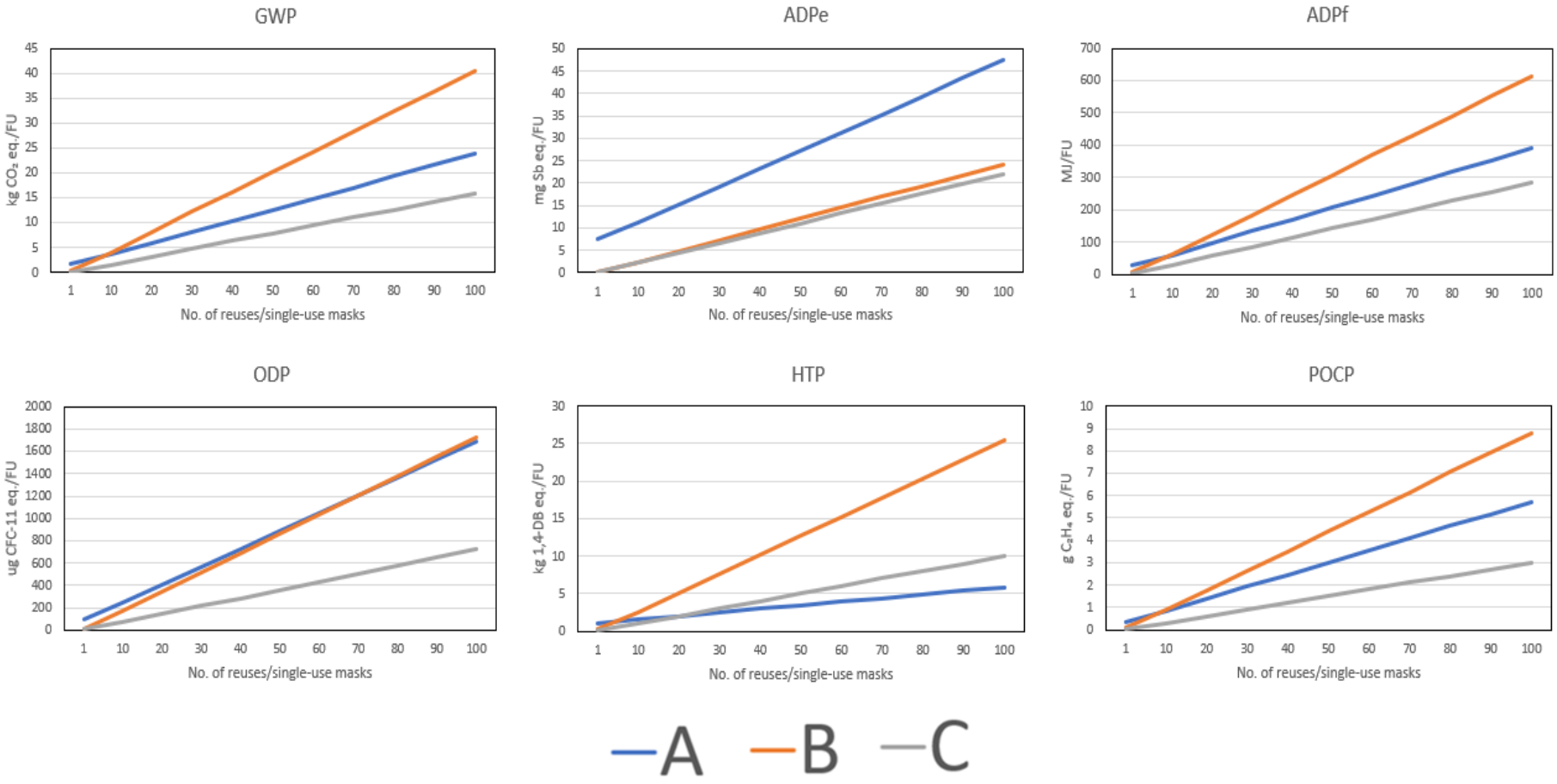
As shown in Figure 23, changing the energy consumption of the reprocessing machinery has an observable influence on the overall environmental impact of mask A; ranging from +/-5% to +/-12%. By reducing the energy usage by 20%, mask A would only be highest for ADPe; mask B would then be the most environmentally impactful mask for 10 of 11 impact categories. When increasing energy usage by 20%, the order of the masks from least to most environmental impactful does not change across all categories. For eight of the 11 environmental impact categories, mask C is less impactful than mask A by at least 31%. Even with energy consumption reduced by 20%, for none of these categories does the impact of mask A reduce enough to compete with the TPE+PP based single-use mask. If further reductions to energy consumption could be made then this would increasingly improve the impact of mask A. Across all impact categories, the largest percentage change occurs for cost where mask A's overall price changes by +/-12% (+/-53.4p). The category in which mask A and mask C are also the closest is for cost. Energy usage increased by 20% would mean that mask A is now only 4p less than mask C. Regardless of increasing energy percentage, mask B is still the most expensive by a considerable margin.

For only two of the environmental categories (GWP and ADPf) could the energy consumption be reduced enough to become less impactful than mask C. GWP would require an 80% reduction and ADPf a 93% before mask A's overall impact is the lowest. The other categories would require reductions in other areas of mask A's life cycle (particularly the packaging used during reprocessing) before being able to compete with mask C.

For some impact categories i.e., ADPe, ADPf, and MAETP, the effect of reducing energy consumption is small varying the overall impact by 3% to 7%. However, for other categories, such as TETP and cost, the variation has a more considerable effect on overall impact (12%). For GWP, reducing the machinery energy by 20%, reduces its overall impact by 1.18 kg CO_2 eq. (9%). In the case of TETP, mask A's current impact is 25.4 g 1,4-DB eq. which is only 1.1 g 1,4-DB eq. greater than mask B's. Reducing the energy usage lowers mask A's impact by 2.9 g 1,4-DB eq. making mask B now the least favourable mask. This also occurs for EP, where mask A is reduced from 15.3 g PO_4^{3-} to 13.8 g PO_4^{3-} (-10%) which is lower than mask B's (13.9 g PO_4^{3-} eq.). Quite observable change can be seen for ODP where mask A increases from 887.1 ug CFC-11 eq. to 962.6 ug CFC-11 eq.; now 101.7 ug CFC-11 eq. greater than mask B.

7.3.4. Scenario: Number of reprocessing cycles

A scenario analysis is provided to test the significance of number of reprocessing cycles on mask A's overall environmental impact. For this analysis, the number of reprocessing cycles is decreased and increased from one to 100 cycles. This is then compared with the equivalent quantity of single-use masks (one and 100 masks). The results are shown in Figure 24.


GWP
kg CO_2 eq./FU
No. of reuses/single-use masks
ADPe
mg Sb eq./FU
No. of reuses/single-use masks
ADPf
MJ/FU
No. of reuses/single-use masks
ODP
ug CFC-11 eq./FU
No. of reuses/single-use masks
HTP
kg 1,4-DB eq./FU
No. of reuses/single-use masks
POCP
g C_2H_4 eq./FU
No. of reuses/single-use masks
A
B
C

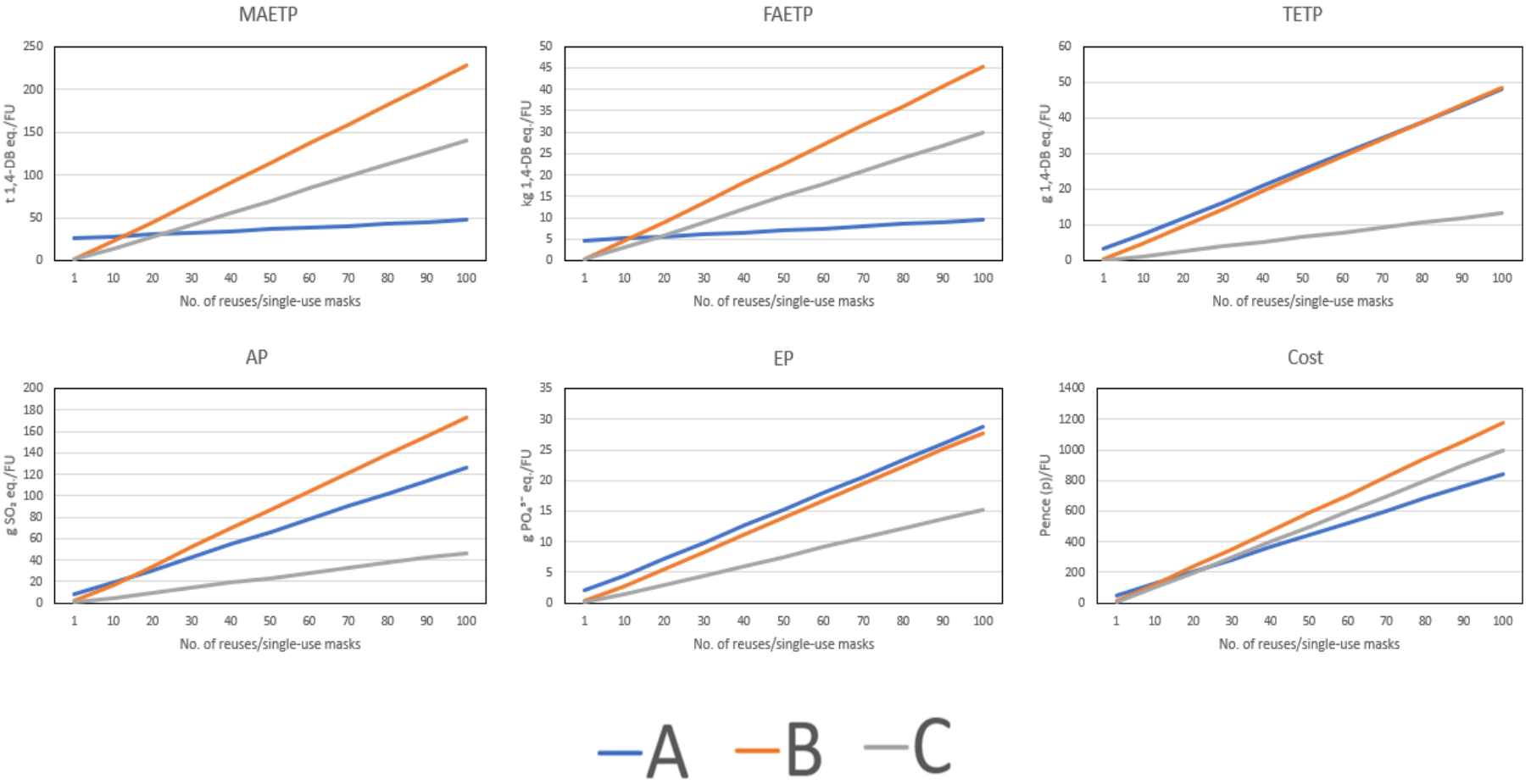


Figure 24: Comparison of environmental impact of three anaesthetic masks. Description of masks in Figure 21. The reusable mask (mask A) is represented in blue, the PVC single-use (mask B) in orange, and the TPE+PP single-use mask (mask C) in grey. Results expressed as the number of reprocessing cycles is decreased and increased from one to 100 reprocessing cycles. This is then compared with the equivalent quantity of single-use masks (one to 100 single-use masks). All eleven impact categories and LCC are included; see description in the methodology section.

Changing the number of reprocessing cycles for mask A and comparing to equivalent quantities of single-use masks has variable effects on the impact categories. For nine of the categories, mask A's reprocessing stage has more of an impact per cycle than of the entirety of the TPE+PP single-use mask (mask C) and therefore for these categories, no matter how many times mask A can be reused, it will not become less environmentally impactful than mask C. HTP, MAETP, and FAETP are the categories where the reprocessing stage is less per cycle than mask C. For HTP, more than 19 reuses would be required before mask A is more environmentally friendly than mask C, more than 21 reuses is required for MAETP, and more than 18 for FAETP. This shows that no matter how many times mask A is reused, unless sustainable changes are made to the reprocessing stage itself, it will not be more environmentally favourable than the TPE+PP single-use mask (mask C) for the majority of the impact categories.

For 10 of the environmental impact categories and the LCC, mask B has a higher impact per mask than the impact from mask A's reprocessing stage. That means for each of these categories, there will be a breakeven point where mask A is more environmentally favourable to mask B. Table 25 shows how many times the reusable mask (mask A) would need to be reused before it becomes environmentally favourable to the PVC single-use mask (mask B) for each category. For only ADPe could the number of reprocessing cycles never be able to make mask A more favourable than mask B as the impact from the reprocessing cycle is greater than the entirety of mask B's life cycle.

Table 25: Number of reuses needed before the reusable mask (mask A) becomes more environmentally favourable than the PVC single-use mask (mask B). Description of masks in Figure 21. All eleven impact categories and LCC are included; see description in the methodology section.

Impact category	GWP	ADPe	ADPf	ODP	HTP	POCP	MAETP	FAETP	TETP	AP	EP	Cost
No. of reuses	8	-	9	75	6	10	13	12	74	14	598	17

As can be seen in Table 25, for seven of the categories, if mask A were to be used 14 or more times, it would be favourable to mask B. For some categories (GWP, ADPf, HTP, and POCP), mask A would only need to be reused a minimum of 10 times to be more environmentally friendly than mask B. Currently the reusable mask has a recommended 50 reuses by the manufacturer. If it were possible to increase this to 74, the TETP for mask A would then become lower than the equivalent required PVC single-use masks. The categories ADPe and EP are then the only categories where it is unrealistic for mask A to have a lower environmental impact than mask B. For ADPe, mask A will always be higher no matter the number of reuses and for EP a very high amount (598) of reuses would be required.

7.4. Conclusion

This study analysed and compared the environmental impact of three anaesthetic masks including a reusable mask; mask A (reusable up to 50 reprocessing cycles), mask B (plasticised PVC-based single-use mask), and mask C (TPE+PP-based single-use mask). It was found that the reusable mask (mask A) performs better than the PVC based single-use mask (mask B) but is outperformed in environmental impact by the TPE+PP single-use mask (mask C). Key stakeholders such as medical device manufacturers and hospital procurement teams should prioritise using TPE within their single-use medical devices over plasticised PVC for not just environmental sustainability reasons but also to reduce overall life cycle costs.

For nine of 11 impact categories and the LCC, mask A's impact originated predominantly (>70%) from the reprocessing stage specifically from the reprocessing machinery's electricity usage and reprocessing packaging. To reduce the environmental impact and cost of mask A, sustainability efforts should therefore be directed on these areas. This could be through increasing energy

efficiency of the machinery, using more sustainably sourced electricity, or reducing quantity of packaging. All other life cycle stages for mask A were lower than those of masks B&C. Therefore, reducing the impact from the reprocessing stage could make reusable masks an attractive sustainable option. Hospitals and reprocessing facilities should explore mitigations effects of reducing the reprocessing stage (i.e., electricity and packaging used during reprocessing) in order to expand the feasibility of using reusable medical devices. With reprocessing being such a large proportion of the reusable anaesthetic mask's environmental impact, it is clear that focus should be placed on this stage. Environmental impact reductions within this stage are also currently available and obtainable; for example, more environmentally sustainable materials can be used for reprocessing packaging and more sustainably sourced electricity can be obtained for use within the reprocessing machinery. If governmental organisations wished to pursue the reduction of single-use medical devices (as is becoming a common goal within legislation such as the Health technical memorandum 07-01 and UK Clinical Waste Strategy (HTM, 2022; NHS, 2023)), they are within their power to require hospitals and reprocessing facilities to explore these sustainable mitigations.

Mask B had the highest environmental impact for seven of 11 impact categories and the LCC. Most of mask B's impact came from the RMEP and end-of-life stages. The environmental impact from RMEP was shown to reduce significantly from mask B to mask A across all impact categories due to the lower quantity and type of materials used. Therefore, If hospitals are unable to switch to reusable masks, they can make significant environmental impact savings by using TPE+PP single-use masks instead of PVC ones. The life cycle costing found mask B to be the most expensive (£5.89); £0.90 more than mask C (£4.99) and £1.45 more than mask A (£4.44). The majority of mask A's cost (89%) was from the reprocessing stage with half of this due to the cost of electricity to operate the washer-disinfector. A sensitivity analysis showed that reducing energy usage by 20% lowers the impact of mask A enough to make it not the most environmentally impactful option for 11 impact categories. A scenario analysis analysed the effect of number of reprocessing cycles on environmental impact and showed that no matter the number of reuses possible per reusable mask, it would never be more environmentally favourable to the TPE+PP single-use mask (mask C) except for HTP, MAETP, and FAETP. It was found that as the number of reuses of mask A decreased lower than 14, mask B became increasingly more environmentally favourable for seven of the impact categories. Therefore as long as mask A is reused above 14 times, it will remain the more sustainable choice in comparison to mask B.

Overall, mask C has the lowest environmental impact across most impact categories but if sustainable changes were made during the reprocessing stage of mask A, in particular to the electricity and packaging used (which contributes around a half of the environmental impact of the reprocessing stage), then it could become a sustainable alternative to single-use masks. The use of anaesthetic face masks will always be required within healthcare but this study has shown that sustainable alternatives are available as of today, it is now up to policy makers and manufacturers for whether it is employed.

CHAPTER 8

8: IMPROVING SUSTAINABILITY WITHIN THE UNITED KINGDOM'S NATIONAL HEALTH SERVICE – A QUALITATIVE PILOT STUDY ABOUT WASTE SEGREGATION

This chapter addresses objective 4

A publishable article version of this chapter was submitted to the journal 'Sustainability' on 6th February 2024. Resubmission occurred on 27th March 2024 with the revised article being accepted 2nd April 2024 and available online 5th April 2024.

The Doi of this published article is: 10.3390/su16073027

The article is titled: A Pilot Study into the Use of Qualitative Methods to Improve the Awareness of Barriers to Sustainable Medical Waste Segregation within the United Kingdom's National Health Service

The URL to access this publication is: https://www.mdpi.com/2071-1050/16/7/3027

Statement of contribution:
As multiple authors are listed to have contributed to this chapter, a statement is provided to demonstrate the roles each author had during its construction and a respective overall percentage to the work as a whole.

In order to facilitate fair assignment of author contribution percentages to each of the respective authors, the following division of work contribution has been allocated:

- 20% will be allocated to chapter conceptualisation and planning.
- 20% will be allocated to the running of any required software or alternative methods to obtain the results.
- 20% will be allocated to the interpretation of the results and any further analysis required.
- 25% will be allocated to the writing and editing of the chapter.
- The final 15% of the work is allocated to supervision. This percentage will be split amongst the supervisors according to their respective involvement.

Christina Webb (Percentage contribution: 80%)
Fulfilled roles: Chapter conceptualisation, Methodology, Data curation, Formal analysis, Software, Project administration, Validation, Writing- Original draft preparation, Review and editing.

Lorna Anguilano (Percentage contribution: 2.5%)
Fulfilled roles: Supervision, final read of the finished chapter before submission.

Ximena Schmidt Rivera: (Percentage contribution: 17.5%)
Fulfilled roles: Chapter conceptualisation, Supervision, Writing (Reviewing and Editing of all drafts)

Improving sustainability within the United Kingdom's National Health Service – a qualitative pilot study about waste segregation

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Abstract
Even though around 85% of medical waste is non-hazardous, the majority is disposed of via incineration or alternative treatment required for only hazardous material. Within the United Kingdom (UK), all waste placed in a waste bin designated for hazardous waste is classified as hazardous whether it was originally or not. Within this pilot study, a focus group and semi-structured interviews were conducted with NHS healthcare workers in order to explore how medical waste is identified as hazardous and why incorrect segregation may occur. The low availability of different bins as well as lack of space and the healthcare workers' busy schedules were identified as main reasons. Bins were sparsely placed and staff lacked time to find the appropriate one leading to incorrect segregation of non-hazardous waste. Lack of information around whether a material was recyclable or not led to less recycled waste. When discussed ways to engage this issue, the majority of medical staff favoured quick forms of information provision, such as posters, whereas one head-nurse proclaimed longer, hands-on style sessions as more effective. The findings of this study provide evidence that governmental strategies focused on sustainable medical waste management should direct their attention to the placement and availability of bins, whilst including "on the ground" personnel in their decision making. It is hoped that the methodology used within this study can be emulated by other healthcare facilities to collectively grow a greater understanding of the sustainability issues faced by the UK healthcare system.

Keywords: Sustainable healthcare, waste management, incinerated waste, medical waste, focus-group

8.1. Introduction

Despite studies showing the negative environmental impact of incineration, most European countries still promote incineration as the primary method of clinical waste disposal (Kumar, 2021). It has been shown that around 85% of waste generated in hospitals globally is non-hazardous and ideally could be treated the same as non-clinical waste (WHO, 2017). Studies across Europe show that over 70% of the contaminated waste stream actually contains waste which was uncontaminated prior to being discarded (Kadamus, 2008; Hutchins & White, 2009; Cesaro & Belgiorno, 2017; Rasheed & Walraven, 2023). This presents a clear opportunity for reducing the environmental impact of clinical waste being incinerated by reducing what is wrongly identified as hazardous (Moultrie et al., 2015). The issue lies where non-hazardous waste is incorrectly placed in waste streams designed for hazardous waste (Harding et al., 2021) resulting in it being classified as hazardous, and subsequently incinerated or disposed via alternative treatment as dictated, in this case, by United Kingdom (UK) regulatory guidelines (DoH, 2013). Over half of the non-hazardous medical waste being incinerated globally is made of recyclable materials such as paper and plastic (Rasheed & Walraven, 2023).

An important step of medical waste management is the sorting of waste before disposal. The European Waste Catalogue (EWC) (which covers all types of waste generated but also includes a guide for medical waste) provides definitions for different types of waste and assigns each a colour

for disposal. Medical waste placed into a specific-coloured bag within European hospitals will be sealed with ties or clips and never reopened at any point to be further sorted (DoH, 2013). It is therefore key that waste is segregated to the appropriate container before it is sealed in order to ensure it will be disposed of in a suitable manner (No Harm Europe, 2020).

Within the UK, yellow and orange-coloured bins are used for hazardous waste; yellow for infectious and contaminated, orange for just infectious. This waste is described as hazardous due to its risk of causing harm due to infection or contamination. Infectious waste is defined as waste that can transmit infection whereas as contaminated waste is waste containing a pharmaceutically-active agent (HTM, 2022). The yellow waste stream must be disposed of via incineration which is the most environmentally impactful and most expensive end-of-life method (Rizan et al., 2021; Windfeld & Brooks, 2015). The orange waste stream may also be incinerated but could instead be rendered safe by alternative treatment (i.e., heated to disinfect the waste) as a less environmentally impactful alternative to incineration (HTM, 2022).

Black and yellow (tiger) striped bins are for non-hazardous and non-infectious waste. Black bins for domestic, and clear bins for recycling. The tiger-striped, domestic, and recycling waste streams contain waste that cannot cause harm or infection and therefore can be landfilled or recycled. These are environmentally favourable options to the hazardous (yellow and orange) waste streams (Rizan, Bhutta, et al., 2021). Some specialised waste disposal streams are also available such as purple for cytotoxic or variously coloured hard boxes for sharp materials. Figure 25 demonstrates the different coloured bins currently available within UK NHS hospitals as well as their description and end-of-life treatment as defined by the regulatory Health Technical Memorandum 07-01 (HTM, 2022).

Colour of waste stream					
	Yellow	Orange	Tiger-striped	Black	Clear
Description	Contaminated and infectious waste	Infectious waste	Offensive and hygiene waste	Domestic	Recycling
Disposal method	Incinerated	Alternative treatment or incinerated	Landfill	Landfill	Recycled

Figure 25: Colour codes for waste segregation within the United Kingdom's National health service retrieved from the UK Health Technical Memorandum 07-01 *(HTM, 2022).*

In previous studies, when waste segregation interventions and educational trainings were introduced on the correct placing of non-hazardous waste within European and American hospitals, the volume of the hazardous waste stream reduced from a half (Mosquera et al., 2014; Johnson et al., 2013) up to three quarters (Wyssusek et al., 2016; Furukawa et al., 2016). Lee et al. (2002) found correct identification of infected devices to be the greatest obstacle to establishing recycling within hospitals (Lee et al., 2002). A study from six operating suites in Australia discovered similar findings where 60% of the general waste was actually recyclable (McGain et al., 2009). Less than 10% of the waste generated by the UK National Health Service (NHS) is currently recycled and the main barriers to recycling include a lack of staff training on what is recyclable, logistical accessibility to recycling bins, and clear guidelines to identify when waste is infectious (Hutchins & White, 2009).

(Anåker et al., 2015) and (Shivalli & Sanklapur, 2014) found nurses are aware of the need for sustainability and want to contribute but face many challenges. A key issue was the lack of clear instructions, training, and feedback (Vogt & Nunes, 2014; Sürme & Maraş, 2022) with 86% of nurses

within one study expressing the need for refresher training (Anåker et al., 2015). Some studies found healthcare workers to have poor knowledge around the correct disposal of waste (Oroei et al., 2014; Mugabi et al., 2019), but less is understood on the most effective way to provide and help nurses retain this knowledge. It was found that easy access to the correct waste stream bin required was crucial for effective waste segregation (Sahiledengle, 2019; Cowie et al., 2020).

A study exploring why waste is incorrectly identified as hazardous within UK NHS hospitals has yet to be conducted. Understanding the reasons behind poor segregation is crucial in order to identify steps to address it. The most current UK medical waste regulation (the NHS clinical waste strategy released in March 2023) aims to reduce incinerated waste to 20% by increasing the quantity of waste that is diverted to alternative treatment and landfill (NHS, 2023). Their approach to accomplish this is concentrated around providing waste segregation training and hiring more waste managers. It is understandable that the regulatory providers decided on this approach if it is assumed that the issue is with healthcare workers not knowing what is hazardous or not. However, with no studies investigating whether this is the cause of poor segregation, they could be potentially focusing on the wrong issue. This study aims to provide evidence to support the NHS's efforts to improve clinical waste strategy by providing qualitative results of the reasons for inaccurate medical waste segregation by staff, as well as to identify the best way to communicate knowledge and guidelines in the matter. This pilot will also provide findings to challenge the NHS's intended course of action together with a framework for researchers and practitioners to scale up this study.

8.2. Methodology

For this study, a focus group and semi-structured interviews were conducted with healthcare workers within the United Kingdom during June and July 2023. The focus group and interviews took place virtually via Microsoft teams. The goal of the study was 'to explore how healthcare workers within the UK National Health Services (NHS) identify when medical waste is hazardous, how waste is segregated, and the preferred methods of communication of training and segregation related information'.

The criteria for participation selection were that the participants currently worked within a United Kingdom based NHS medical facility and that they handled and segregated hazardous and non-hazardous waste as part of their daily job duties. All participants were over the age of 18.

Participants were identified as potential candidates to partake within the study as well as initially contacted through communication leads within various NHS trusts across England. A total of six healthcare workers participated within the study: three as individual interviews and three within the focus group. Participants of varying job responsibilities were encouraged to contribute in order to provide a wide breadth of ideas and perspectives to the questions asked. Of the healthcare workers who contributed, one is a medical doctor, three are nurses, and two were previously nurses who then switched their primary job responsibilities to become head providers of nurse training.

It was decided to do interviews and a focus group to allow a mixture of in-depth responses from participants as well facilitate discussions which could be checked for validity by a variety of sources (Gill et al., 2008). This mixed approach then provided not only a variety of responses but also allowed elaboration on specific aspects if required whilst staying within a reasonable timeframe (Rabiee, 2004).

8.2.1. Focus group

The focus group took place over 90 minutes in July 2023. The focus groups began with an introductory warm-up exercise, to be followed by four questions. Each question was allocated

roughly 15 minutes to allow for discuss. At the end, 15 minutes were allocated for closing statements. A brief PowerPoint was used during the focus group for visual aid. The PowerPoint used allowed for each question to be visually displayed in writing on screen to provide reminders and convenience for the participants. Some images were also shown where appropriate (the PowerPoint slides used for each question are provided in section A8 within the appendices). The warm-up exercise consisted of a description of what each coloured waste stream is used for followed by three images of a blue face mask, plastic packaging, and a used bandage. The participants were then asked which coloured waste stream they would place these items into followed by a reveal of the correct response. This allowed for ice-breaker style introduction to the topic as well as engagement from the participants prior to questioning. The images used during the ice-breaker are provided in section A9 of the appendices.

8.2.2. Semi-structured Interviews

The interviews were conducted individually with three of the participants. The same questions asked during the focus group were also asked during the interviews but no time limits were placed. Each interview did not last longer than one hour by request of the participants and were conducted over Microsoft teams. No visual aid such as PowerPoints were used and instead were just one-to-one conversations. A warm-up exercise was not conducted but the topic of discussion was briefly explained to the participants at the start of the interviews. The participants were also given time at the end of the interview to expand on any previous points discussed or to provide their own insight to the topic of sustainable healthcare.

8.2.3. Questionnaire

Four open-ended questions were provided to each participants for the interviews and focus group. These specific questions were chosen because they address the key aspects of waste segregation whilst also being open-ended and allowing fruitful discussion. Question 1 (Q1) opens the conversation by identifying the initial thought process the healthcare workers have without prompting or encouraging any specific response. Q2 and Q3 then go on to further explore barriers to this segregation process specifically focusing on incorrect segregation of non-hazardous waste and recyclable waste which are key problems as shown within current literature. Finally, Q4 directly addresses which method of communication is most preferred, giving the participants some examples as a guide. During the interviews/focus group, participants were permitted to branch into other related topics if they so desired. The questions provided to the participants are as follows:

Q1	What questions do you consider when deciding whether a device is hazardous or not and therefore which coloured waste bin it will enter?
Q2	Are there situations where you are unsure whether waste is hazardous or not and so erred on the side of caution and placed it in the hazardous waste stream?
Q3	What barriers do you face when identifying if something is recyclable?
Q4	What method is best to communicate information and training on correct waste segregation (e.g., types of plastics that are recyclable, situations which makes a device hazardous etc.) which requires minimal distraction to your primary job role?

8.2.4. Ethical considerations

Written consent (via consent forms) was received from all participants prior to commencement of the study. The participants were provided written details about the nature of the study as well as any information about what the study would entail and how the results would be used. Participation was completely voluntary and the participants were allowed to withdraw from the study at any point with no need for explanation. Participants provided informed consent for the publication of this paper. Ethical approval was received prior to any contact with the participants from the Brunel University London research ethics committee. The aim of the study, how it was to be conducted, prepared participant information sheets, and risk assessment of any potential issues regarding the questions to be asked and how they were to be asked were all submitted to the committee for thorough review. Changes required were made prior to any recruitment of participants and were ensured to be designed to minimise any potential harm or issues that could arise due to this study. The assigned ethical approval reference number as set by the committee is 41309 and the ethics approval was given June 2023.

Information about the participants such as their names, job description, and location of employment were collected but only made available to the principal researcher. After the analysis was conducted, all participant data was anonymised so that no identifiable information is provided. Participants have been labelled with general titles in order to aid analysis within this paper without alluding to any specific descriptions of the participant. These titles are as follows: Doctor, Nurse 1, Nurse 2, Nurse 3, Head nurse, and Training lead. The appropriate title will be provided alongside any associated quotes provided within the results and discussion section.

8.2.5. Analysis

To analyse the responses, the focus group and interviews were recorded and transcribed Microsoft teams, which were then manually checked by the primary researcher to ensure accuracy. These transcriptions were transferred to the qualitative analysis software NVivo (Dhakal, 2022) where they were coded and a thematic analysis conducted. The full steps of a thematic analysis (as outlined within (Braun & Clarke, 2006)) are as follows:

1. Familiarisation with the data (i.e. transcription, comprehension of the data, general noting of initial identifiable themes)
2. Identify common themes whilst systematically reading through the data
3. Collate all data associated with each theme and identify repetition
4. Review themes
5. Define the features of the themes and the research outcome they suggest
6. Analyse the themes including use of relevant quotes to produce meaningful findings

From the data, eight themes were identified. Figure 26 helps demonstrate how these themes have been generated using examples of quotes from the transcript.

Question	Example quote	Theme identified
Q1 - Identifying when something is hazardous	"In your mind, yeah, you know, but it's not even a checklist. It's automatic because you've done it so many times"	High competence with hazardous waste segregation
	"I normally go off, whether it's had contact with, any bodily fluids or anything like that"	Contamination with bodily fluids
Q2 - Incorrect segregation of waste	"The tiger bags are the ones where I work that usually aren't available"	Poor availability of bins
	"I think being a busy clinician it is about what's available to you"	Lack of time
	"Our clinics bases are usually not fit for purpose a lot of the time in terms of space"	Lack of space
Q3 – Barriers to recycling waste	"I find plastic items the most difficult to decide on as some can be recycled and some can't and it's not always easy to work out"	Lack of information
Q4 - Preferred training and information provision	"A poster on the wall saying what things can go in, what bins and what can be recycled would be really, really helpful"	Bin labels and posters
	"Hands-on is real life and any training real life is better than just giving them something to read"	Longer training sessions

Figure 26: Themes identified within the transcripts generated from the interviews and the focus group.

8.3. Results and Discussion

The results will be discussed following question order (Q1-4), identifying recurring themes within the answers provided by participants. They are followed by suggestions for change.

8.3.1. Question 1: Identifying when something is hazardous

Two key themes were identified when the first question (Q1) was answered. The first theme was that the medical staff are confident in their ability to identify when waste is hazardous and have enough knowledge around each patient in order to make informed decisions. The second theme was that even though the healthcare workers knew how to determine when medical waste is hazardous, waste which came in contact with bodily fluids was automatically placed in one of the hazardous waste streams (yellow or orange) despite the fact that this is not necessary if the waste is not infectious or contaminated with pharmaceutically-active agents (HTM, 2022).

Theme: High competence with hazardous waste segregation

The responses received from all of the participants indicated that ample training was provided on identifying when waste is hazardous and that healthcare workers are attentive when segregating hazardous from non-hazardous waste. Interestingly, this finding contradicts two previous studies (Oroei et al., 2014; Mugabi et al., 2019) which identified a lack of knowledge when discerning what waste is infectious or not. It is important to note that these studies were not conducted within the UK and that their participants also expressed disinterest with the importance of waste segregation.

Correct segregation of hazardous medical waste is highly regulated within the United Kingdom which may explain why participants of this study stated that they receive extensive training and are confident identifying when waste is infectious.

When Q1 was asked, each participant provided a thorough breakdown of all the considerations they have when deciding if waste is hazardous. These considerations included: the previous diagnosis of the patient, the contact the waste had had with the patient, the level of potential cross contamination with other surfaces and staff, and if it had come in contact with bodily fluids (HTM, 2022). Multiple participants described their thought process as automatic. The head nurse mentioned the importance of experience when it comes to waste segregation.

"It's not even a checklist, it's automatic because you've done it so many times", "Experience plays a huge part in what we do"- Head Nurse

Even for situations where the healthcare worker was unsure deciphering between different types of non-hazardous waste, it was clearly stated that hazardous waste would never enter the non-hazardous waste stream. For situations where the worker was not certain, then it would most likely end up in a hazardous waste bin (yellow or orange coloured). This was done to reduce the likelihood that hazardous waste would enter the non-hazardous waste stream due to the severity for harm to the general public.

"I do not think that there's ever been a time where I thought that something might be infectious and put it in a black bin or I would definitely always go for orange or yellow if I was not sure." – Training Lead

This shows the significance of ensuring hazardous waste is correctly disposed of when considering the potential consequences improper segregation could have on the public's health. Minimising any doubt when deciding which waste is hazardous would help alleviate uncertainly and direct some of that waste from the hazardous waste stream into offensive, general, or recycling bins (refer to Figure 25 for descriptions). If all waste that is unknown to be hazardous is placed into hazardous waste bins, then reducing uncertainty would help divert some of that waste. One way to lessen doubt would be to provide workers with any extra information required to make an informed decision. The head nurse described the stages at which patient details would be provided to staff:

"We have two main handovers. Start of shift and finish of shift, but in between we have what we call a catch up. So when we are handed over, we do get given history and if someone has got something infectious, we will be told so. If it was something that we know is infectious then we definitely would be putting it in the in the coloured bag." – Head Nurse

As no change-over of patients would occur without a thorough debrief, this must then indicate that healthcare workers are informed when a patient is non-infectious as well as infectious. Waste produced by a non-infectious person has a much lower likelihood of needing to be placed in the yellow or orange waste streams. There must therefore be a disconnect between staff knowing a patient is non-infectious but still being unsure if the waste produced is hazardous. This may suggest that healthcare workers lack confidence in placing waste into non-hazardous waste streams even when they know a patient is non-infectious. Training could help emphasise that non-hazardous waste should be segregated correctly just as much as hazardous waste is. For example, a study found that within developed nations, education for healthcare workers is one of the key aspects required to ensure non-hazardous waste is not incorrectly identified as hazardous (Windfeld & Brooks, 2015). So far, importance has clearly been placed on ensuring hazardous waste is never incorrectly segregated; however, with the issue of sustainability becoming an increasingly greater global crisis, an equal

amount of importance should also be placed on confidently identifying when waste is non-hazardous and segregating that correctly as well.

Theme: Contaminated with bodily fluids

All participants mentioned that when medical waste had been contaminated with bodily fluids, it would be higher risk and placed in waste bins for hazardous waste (yellow or orange).

I normally go off whether it has had contact with any bodily fluids or anything like that. They always go in the infectious bags." - Nurse 2

"I ask myself could this be contaminated with blood or body fluid and is it offensive? If yes it goes in the orange clinical waste bin." – Nurse 1

"Within my ward, there's always going to be bodily fluids involved and with the bins available, I have no choice; they've always got to go in the orange." - Nurse 3

This shows that it is common practice for medical waste contaminated with bodily fluids to be placed in the infectious waste streams. This raises the issue of why all medical waste contaminated with bodily fluids is placed in the infectious waste streams even if the patient themselves was not infectious. Current UK governmental guidelines (HTM, 2022) specify that medical waste that is not infectious but could be deemed offensive (such as dressings contaminated with non-infectious fluids) should be placed in the tiger-striped bags. Only the yellow-coloured waste stream is required to be incinerated (orange can be incinerated but it is not always necessary; shown in Figure 25). Therefore, directing waste from the yellow or orange bins into the tiger bins by correctly recognising when bodily fluids are non-infectious would reduce the volume of waste that is incinerated. If healthcare professionals are automatically placing medical waste contaminated with bodily fluids into the hazardous waste streams without first checking if the patient is infectious, then they are unnecessarily increasing the quantity of waste being incinerated.

This instinctual nature that healthcare workers appear to have when segregating waste contaminated with bodily fluids indicates that behavioural change may be necessary when dealing with non-infectious bodily fluids. A good example of the unnecessary incineration of non-infectious waste was provided by the head nurse. The head nurse described an issue they faced during training where the incontinence pads that they had used, that had not been in contact with any patients, were required to be placed in the infectious waste stream due to preconceptions from cleaning staff that any appearance of bodily fluids meant it had to be infectious.

"For our training for when we take blood, we use red dye. The red dye goes on the inco pad which is not infectious; it's not even bodily fluids. I asked our waste management guy, what bag should we put this in, because we were putting it in an infectious waste. He said it shouldn't go in infectious, it should go in your normal black bag. However, in the same meeting, there was a supervisor of our housekeepers that said, 'if any of my housekeepers saw an inco pad with red on it in a non-bodily fluid or infectious bag waste, they will not take that bag'." – Head Nurse

This provides a clear opportunity for staff to be encouraged to consider whether the bodily fluid they are disposing of requires treatment as if it is infectious and also identifies issues around communication between staff and the cleaning teams. A similar disconnect appears to also occur when disposing of PPE used by the healthcare worker versus PPE used on patients.

"Waste generated by others is more likely to go into orange for safety, waste generated by myself I will usually make an extra effort to get it into a tiger bin if I think it is safe to do so. PPE used on patients is more likely to go in orange." – Doctor

"I would be more cautious with PPE etc. produced by others and would lean towards contamination, the orange bag." - Nurse 1

If the patient is non-infectious, then the waste they generate is also non-infectious and can be placed in the tiger, domestic, or recycling bins. However, when there is a lack of certainty or confidence around determining what waste is generated by a non-infectious person, it will increase the quantity of waste which is needlessly incinerated. Perhaps training focused on identifying when waste is non-infectious would help foster a culture where waste contaminated with bodily waste is not primarily treated as infectious and grow confidence in staff when placing non-infectious waste in tiger bins.

8.3.2. Question 2: Incorrect segregation of waste

When answering Q2, three main obstacles were brought up: poor availability of bins, lack of time available to the healthcare workers, and lack of space within the medical facilities.

Theme: Poor availability of bins

The poor availability of bins within healthcare facilities was by far the most brought up issue by the participants. Previous studies also identified access to bins as crucial to correct waste segregation (Sahiledengle, 2019; Cowie et al., 2020). Each participant mentioned how most coloured bins were not present within their workspace with mainly only two bins (orange and black) available.

"I only have a choice of two bins. Orange for clinical waste and black for all other waste. A recycling bag has been placed in the kitchen, but only because an individual person instigated it; it is not the norm. What would be better is having the different coloured bins more available in each area." – Nurse 1

"Most clinical waste bins are orange in most places so more often than not if I have any suspicion of it being infectious, it will go in orange, partly for convenience." – Doctor

"The tiger bags are the ones where I work that usually are not available. We have recyclable, we have a black bin and we have the orange bin." - Nurse 3

"Things that have come into contact with specimens like samples and stuff, not all of that necessarily needs to go in orange bags. We don't even have a black bin in the labs, so everything goes in the clinical waste, which I don't think it really needs to." - Nurse 2

If the appropriate bins are not available, regardless of whether the staff knows the waste is non-infectious, it may still end up in the infectious waste stream. In these cases, the first approach to limit quantity of waste that is incinerated would be to allow the healthcare workers access to the bins they are missing; specifically, tiger-striped bins for non-infectious clinical waste and recycling bins for non-infectious non-clinical waste. No amount of waste segregation training would help if the lower environmentally impactful and non-incineration route waste streams are not provided. The participants emphasised that they and their colleagues can only work with what they are given and having the right bin available was very important.

"If all you have available is an orange or black bin, your hand is forced. If you feel like it should not be going into domestic you have got nowhere else to put it other than in that high incineration location.

I think there are a lot of people that know some waste does not need to be in an orange, but what else have I got… nothing. So that's kind of it, that's choice made." – Training Lead

Lacking the equipment required to adequately fulfil their job role responsibilities is a significant obstacle and one which was expressed by every participant. This signposts that this issue may be widespread across large parts of the UK's healthcare system. Repeating this study to various other facilities would help indicate the size of this problem and the urgency in which it should be addressed.

Theme: Lack of time

A second issue that was discussed is the lack of time that the participants had to make decisions about waste placement. Having clearly labelled bins close to where they are working was highlighted as key when segregating waste in order to minimise time thinking about where the appropriate bins are located as well as the time it would take to walk to it.

"As a busy clinician it is about what is available to you and the right bin being in the right location. If you have got to traipse halfway across the ward to go and throw something away, you are going to go for the one that is nearest to you.", "If the only bin available in front of you is a tiger bin, but you have not actually touched anything that is needed to go in and it could have gone in a domestic, you are going to use the one that is there because you are probably already five minutes late for your next patient." – Training Lead

"Sometimes you are so busy and the closest bin to you is a bin that is not suitable, but you are so busy that you cannot even walk ten steps and I do not condone it, but I understand." – Head Nurse

Dealing with highly time-constrained and fast-paced environments such as within medical facilities, it is essential that any chance to reduce wasted time and mental energy during decision making is taken advantage of. Ideally, the layout of the facilities should be optimised to identify which bins are required and where in order to allow access to the appropriate waste stream in the most convenient way possible.

Theme: Lack of space

Connected to the previous issue of lack of time, a primary reason that the right bin is not available close to the healthcare worker was found that there is simply not enough space to fit the number of potentially required bins.

"Ideally, we should have a tiger-striped bag as well, the black and yellow, for offensive waste. We do not have one and I feel that is mainly down to not having enough room for lots of bags." - Nurse 1

"I think the biggest thing with us is always space. We work in a hospital where when they move our patients and us to different wards, the space is never ever considered in terms of working space both in clinics and nursing offices. We end up having to adjust to space that is usually not working area friendly. So in terms of having the right bins available, that is why half the time they never are.", "Our clinics bases are usually not fit for purpose a lot of the time in terms of space. The ward I work on, the clinic is small, so the bins that you can fit in that space are limited, which is why we have not got all the choices." - Nurse 3

"Right bin and right places I think are really, really key. I think that it comes down to that that space issue." – Training lead

Not having the space to fit the bins required could cause big issues when it comes to not only the types of bins available to the staff but also the extra time required to find where the required bin is. This is a particularly difficult issue for established medical facilities as expanding the space in which the staff are required to work might require extensive expansion projects or relocation which may not be feasible.

Identifying the type of bins that are required most for each section of a facility would help in providing the most appropriate bins in the limited space available. Less used bins could be removed from an area to make space for a more appropriate bin. Assessing the needs of each area of the medical facility and the kind of waste they are producing (particularly if it is likely to be hazardous or not) could help the waste management team determine the requirements of each section/ward. For example, a study in America tracked how quickly certain bins inside of a hospital required emptying in order to decide which bins were required more in each area. They found this reduced cost and increased efficiency of waste management (Rosales et al., 2015). Another study by Ishaq et al. find that placing sensors within medical waste bins to notify the waste management team how quickly various bins become full helps with optimising placement of bins where they are most needed (Ishaq et al., 2023).

Furthermore, no studies have yet been conducted on how the bin type and size influences waste management within hospitals by affecting where the bins can fit within the hospitals. Non-clinical studies have shown that varying the shape of bins can optimise space and workload (Neumann & Medbo, 2010). This could be a potential solution to be employed within the UK NHS facilities.

8.3.3. Question 3: Barriers to recycling waste

Before waste can be considered for the recycling waste stream, it must first be classified as non-infectious which a previous study found to be the biggest hindrance to a successful recycling initiative (Lee et al., 2002). Once this classification has been made, and assuming a recycling bin is present for the healthcare worker to use (again another key issue (Hutchins & White, 2009)), further problems are still present to segregate recyclable waste. The participants stated that easily recognisable recyclable items (similar to those recycled at home) are the easiest to be placed in the recycling bins; e.g., clear plastics cups or food containers. For other recyclable items, lack of information was a big issue.

"If patients are drinking out of general stuff, then they get recycled, anything domestic we are pretty good at sorting through." - Nurse 3

"The only thing I can think of for recycling would be if I was clearing a patient table, in which case it would probably be foodstuffs or plastic bottles or things like that." – Training lead

Theme: lack of information

The participants mentioned some issues they faced when trying to recycle non-infectious waste, all of which revolve around the lack of information provided about the type of material the waste is made of. This appears to be a common theme within current literature as lack of labelling and not knowing what materials the products are made of makes it difficult to recycle (Richardson et al., 2014; Leissner & Ryan-Fogarty, 2019).

"I find plastic items the most difficult to decide on as some can be recycled and some cannot and it is not always easy to work out." - Nurse 1

"Labelling is confusing with recycling, especially soft plastic as opposed to hard plastic." - Nurse 3

"Lack of labelling on medical packaging to indicate recyclability. Being unsure if something is made of composites or not. As well as thin films and thin wrappings of varying thicknesses; I know very thin films are usually not recyclable but I do not know about the thicker ones." - Doctor

"When things are made of multiple different components so that you've got a harder plastic bottom and then a softer plastic top and knowing which bit of things can be recycled is sometimes challenging.", "If you have got to stand there for even ten or fifteen seconds and try and muddle through whether you think something is recyclable or not when you are already really busy, that might be a challenge too far." – Training lead

Having clear labels on the different materials of the products and packaging will help the healthcare workers identify what can and cannot be recycled. Even simple symbols such as a 'R' on recyclable materials could go a long way in providing valuable information to healthcare workers. Currently in the UK, On-Pack Recycling Labels, the Mobius loop, and Resin identification codes are the most recognisable symbols to indicate that something is recyclable or what recyclable material it is made of (UK, 2019). A similar approach could be applied to medical packaging as is now commonplace on commercial products.

In addition to labelling, increasing the number of products and packaging that are recyclable would help decrease the volume of waste entering the general waste stream. An issue discussed was on the problems caused when trying to recycle waste made of multiple materials; i.e., composite materials. One issue is when identifying whether each component is recyclable or whether they need to be separated prior to disposable. The training lead had worked previously on this issue within their hospital and offered the following advice:

"My team are finding that it is really, really difficult when different products are made out of such different materials and it would be a lot more useful if actually what was coming in, the base material, was something that meant that everything could be recycled together. So rather than having to think oh actually this glove is made of a nitrile base and this mask has got a polypropylene base, therefore they need to go in two separate bins which we do not have the space for." – Training lead

This again puts the onus on the manufacturers to design their products and packaging to be recyclable as well as simplified in the type of materials being used. More enforced unified standards on the type of materials being used for medical products and their packaging would help healthcare workers immensely when sustainably disposing of medical waste.

Separate from labelling and increasing the recyclability of waste, the participants also suggested that further training on identifying the types of recyclable materials could help during segregation. Specifically, there appeared to be some confusion around the different terms that are used for certain types of sustainable materials.

"I think specific training would be really good cause we've all got heaps of mandatory training anyway, so it would be really useful to have. We are told what colour bins are used for what, but they do not go into specifics about what can be recycled and what cannot, which would be really helpful." - Nurse 2

"I've come across a lot of people who do not necessarily fully understand the difference between if something's recyclable or compostable and the fact that the bins on the in the hospital site are recycling bins and you cannot put things that are compostable into a recycling bin", "I think there is a lot of confusion about the terms which make it a little bit difficult for people and then it sort of comes

back to that sort of cognitive effort of trying to work out whether something can be recycled or not." – Training lead

Clarifying to staff the differences between recyclable and compostable as well as explain the different types of materials which are recyclable could help aid their decision to recycle even when labels are not present on the material. Having the information provided to the staff would be most ideal as there is then no room for error, but if manufacturers do not provide this, the workers having their own specialised training could help fill these gaps in information.

8.3.4. Question 4: Preferred training and information provision

When asked how the participants would prefer to receive extra training or information regarding the segregation of waste in the future, a clear favourite was discovered. The majority of participants expressed their interest in having quick to digest forms of information such as clear labels or posters on or above the bins they are working with. Only one participant recommended longer-style trainings.

Theme: Bin labels and posters

Most of the participants favoured shorter forms of information provision over the longer training sessions or courses. The reasons for this included the limited time healthcare workers have to undertake longer sessions as well as the already overwhelming number of courses they are required to take. Posters or labels that can be read quickly were mentioned to be the most effective in communicating the information needed.

"In my clinical role I have very little time for non-clinical education - so I would say brief targeted interventions such as posters, face to face verbal advice from a knowledgeable colleague or screensavers are likely best." - Doctor

"I think labelling is probably the most effective, more than the training online because unfortunately I've just finished a run of fourteen mandatory courses in the past two weeks. So I can tell you I don't want to look at another course." - Nurse 3

Even more specifically, having posters or labels on or above bins that indicated the types of waste that should be entering that waste stream was agreed by everyone to be beneficial. Some suggestions for these labels/posters include pictures of what types of waste should go where, reminders about what types of waste are recyclable, and a pouch for the label/poster to be kept in to allow for the information to be changed if necessary and for the pouch to be wipeable in the case of contamination.

"So just a poster on the wall saying what things can go in, what bins and what can be recycled would be really, really helpful, especially of things that I use regularly. So just a poster on the wall to remind people would be really helpful. Maybe even just above the bins so that you can see would be really, really helpful." - Nurse 2

"Stickers on the top of each lid indicating with pictures what goes where." - Nurse 1

"Yeah, it is too much information. Whereas the thing sliding on top of the bin there that go inside wipeable and plastic is definitely a great idea. So things like concertinas and those then stuck above the bin and on the bin is perfect actually; and wipeable, so it's all good." - Nurse 3

Two participants mentioned how their medical facilities are already trialling these bin labels and posters which have so far been received well by staff.

"What you will see in our bins now on the lid it says what are what sort of things you can put in. Every bin has been done in such a way that on top it says what can go in these bins. It's not exhaustive, but it helps." – Head nurse

"So at my trust, we've received a grant to print out massive full size bin lid labels which have got on it a little bit more information. There's posters that go with it, they're going to go up behind the bins." – Training lead

Other studies in America, Spain, and Australia, agreed with these findings and when they conducted similar styles of interventions (specifically short presentations and the use of posters) on the correct placing of non-infectious waste, they found these successfully lowered the volume of waste classified as infectious (Johnson et al., 2013; Mosquera et al., 2014; Wyssusek et al., 2016). These types of labels and posters appear to have many benefits with few downsides. It was discussed that having a quick reminder to staff of what waste should go where would be helpful in cases of indecision. Times where healthcare workers are unsure of whether the best place for their medical waste (for example, could it potential be placed in the tiger bin instead of orange, is it recyclable or not etc.) a simple label or poster could be the deciding factor in whether the most sustainable choice is made. An additional benefit is that if these labels/posters are placed in pouches then they would be able to be removed or updated. If the type of coloured bin were to be changed at any point, the label could be replaced as well allowing for each switch over of available waste streams.

Theme: Longer training sessions

One participant partially disagreed with the other healthcare workers in that they did not think quick to read forms of information provision was the most effective. The head nurse, whose current primary role was to train future nurses, strongly favoured hands-on simulation style training as opposed to labels or posters.

"Nurses do not have time to read because we are so short of staff and we are so busy. Now, I'm not condoning that they do not read, however, there is a reason why simulation is preferred by every university and it's becoming bigger and bigger because it is close to real life. So hands on and any training real life is better than just giving someone a leaflet to read." – Head Nurse

It is understandable that being provided a more in-depth, hands-on style training could be more effective as these types of trainings require full engagement by the staff. However, also taking into consideration previous comments made by the other participants, these sessions also require a lot more time and energy from the healthcare workers. With the number of mandatory courses already partaken by staff, the decision to add more would require individualised consideration from each medical facility to decide whether this extra time and energy is an acceptable demand on their staff. In some situations, a combination of hands-on training as well as the quicker to read labels and posters may be the best approach.

8.4. Suggestions for change

At the end of the interviews and focus group, the participants were asked if they had any final remarks about the topic of sustainable waste disposal or whether they had any suggestions for changes that they would recommend. The following were mentioned:

Using co-creative approaches

One key aspect that was mentioned was how any future changes are only best if made to fit the unique requirements of the facility they are intended for. The participants stated any changes would

need to be addressed with the staff before implementation to ensure they are suitable and pragmatic. Specific wards may have unique methods of operating that new procedures should take into consideration in order to not cause any disruption or unease among staff.

"If you try and go in as a manager and try and impose and say oh you do not need this, you just need one of those, it is different in every single place. So I think co-creation of location of bins and what is actually needed in terms of the different types is really important. Working with the people who work on that ward, they know how they behave and they know what they need where." – Training lead

"We have slightly different issues sometimes with what we can put out on the ward is limited by what behaviours are going on the ward at the time. Which means when you are again limited as to what we can use where. So it is the nature of the wards that often dictate." - Nurse 3

This demonstrates the importance of co-creation approaches and communication throughout every level when attempting to implement sustainable changes. For example, a systematic review of literature addressing interventions within healthcare facilities found that changes that were collaborative and encouraged involvement from the staff had the most effective outcomes (Chauhan et al., 2017). The methods employed during use of this pilot study could be an effective way of giving healthcare workers a voice when it comes to improving sustainability within the healthcare system.

The Role of Manufacturers

Another suggestion provided was focusing on changes the manufacturers could make to allow their products and packaging to be more easily segregated.

"If everything was made out of something that meant that things could be lumped together to be recycled together, that would kind of help to solve with the space issue." – Training lead

"If plastic goes into the incinerator, then one of the byproducts of that is the chlorine that comes from burning the plastic. If things were made of a biodegradable material or a recyclable material, even if they did not make it into the recycling stream, the waste that is left at the end of the incineration process would be less harmful. If there is something we can put back onto the manufacturers to make it so that what we are getting is less wasteful or can be reused and if we can get those materials back out and get it into a circular economy, great. But if they do have to be incinerated, how can we do that in a way that is less harmful." - Training lead

When healthcare facilities receive medical products, they no longer have any say over what material the product is made of. Pressure should be placed on the manufacturers to make their products and packaging from more sustainable materials. This may be by making them from non-composite materials or materials that together can be recycled, so that the staff are able to place the entire waste into the recyclable waste stream (Guerritore et al., 2022). For products that are likely to come in contact with infectious substances, regardless of if it is made of recyclable material, the waste will end up in the infectious waste stream (HTM, 2022). For these materials, manufacturers should explore whether different materials could be used which when incinerated produces less environmentally impactful fumes; for example biopolymers that have been shown to have a low pollutant potential from incineration (Endres & Siebert-Raths, 2011). Putting the emphasis on how manufacturers can change their practices would reduce pressure placed on medical staff that are already experiencing high demands for their time and energy.

8.5. Recommendations for Policy Change

The NHS clinical waste strategy 2023 (NHS, 2023) is currently the UK's most recent initiative to reduce the amount of incinerated clinical waste within NHS trusts. An additional desired aim is to

reduce carbon emissions generated by the NHS in order to aid the delivery of the NHS' net zero goals by 2040. The strategy's primary objectives include: increasing recording of waste data, increase training for staff, employing waste managers, and setting targets for percentage of waste which is disposed of as infectious. Despite these objectives, no specifics are mentioned within the strategy guidance document of why waste is being incorrectly segregated and does not detail the type of training the healthcare workers are intended to receive.

Using the findings from this study can help guide the clinical waste strategy on how best to focus their efforts. This study found that:

1. Trainings provided to healthcare workers should focus on identifying when medical waste is non-hazardous and emphasising that waste coming from a non-infectious person does not have to be placed in the hazardous waste bins.
2. Staff should also be encouraged to consider whether waste that is contaminated with bodily fluids has come from a non-infectious person and therefore be more confident when placing it in the tiger-striped bins.
3. Appropriate forms of information should be provided to staff with a clear favouritism shown towards easy-to-read forms such as labels and posters. If governmental guidance encouraged the use of bin labels and posters, healthcare workers may find it easier to classify waste without requiring more intensive forms of training such as mandatory courses. Finding solutions to the low availability of bins should take high priority in order to provide healthcare staff with the resources they need in order to correctly segregate waste.
4. Waste management teams within medical facilities should assess whether the bins currently available to staff are being used to their full potential or whether it would be more favourable to have an alternative bin in their place.
5. Waste managers should personalise their placement of bins to the specific medical facility they are working at and in particular consider the staff voices to understand issues such as amount of space available to the staff, type of bins available, etc.
6. Managers could optimise the utilisation of the space available perhaps by moving bins, using more creative solutions, or improve designs tailored to the reality of the trust.

Currently the clinical waste strategy does not put any onus on the role of the manufacturers when considering how waste can be sustainably disposed of. Ideally, legislation should encourage manufacturers to use recyclable materials as well as clearly label which materials they are using that are currently recyclable. Composite materials should aim to be minimised or be able to be recycled together as one attached unit.

8.6. Recommendations for future research

As this research was designed as a pilot, the discoveries made during the conduct of the study is just as important to future developments as the results themselves. It was found that running a focus group as well as individual interviews provided a wide range of detailed answers to the questions provided. One particular difficulty faced was the lack of time the healthcare workers had available to participate in the study. These time constraints also limited the number of participants who were able to contribute. By allowing the option of participants to be interviewed, it was found that this allowed flexibility for those who had tight schedules. The 1-2-1 style approach meant interviews could be kept as long or short as was required by the participant and was a highly valued tool.

The focus group was also favoured due to the insightful interactions sparked between participants. There was a sense of comradery developed during the session and every participant expressed their enjoyment from taking part and their willingness to cooperate in future studies. As challenges were

faced whilst recruiting willing participants, this was helpful feedback to receive. For future researchers planning to conduct their own study, using this mixed methods approach to their study may help them not only recruit members but also retain interest after completion.

With the emphasis placed on improving sustainability within healthcare now widely felt throughout the UK, this study has shown that it is possible for barriers to be identified and solutions found. Each NHS trust is required to have a sustainability plan (i.e., 'green plan') on how they will address environmental issues within their specific facility. This pilot study could be a potential starting point for trusts that are unsure of where to address their efforts. Despite the significance of the findings found during this study, the scale of which it was conducted has been limited. However, if the methods used where to be emulated within multiple facilities, a growing consensus of the problems faced could be generated. Each trust could identify what problems they face as told by the workers themselves in order to provide individualised solutions as well as identify sustainability barriers on a regional scale.

8.7. Conclusion

In conclusion, it has been shown that a variety of obstacles are present which impede UK healthcare workers' ability to correctly segregate clinical waste within NHS trusts. Medical staff are shown to be competent when it comes to identifying hazardous waste, but more work can be done to correctly segregate non-hazardous waste into more sustainable waste disposal streams. Currently, all clinical waste that comes into contact with bodily fluid is automatically classified as infectious where this does not necessarily need to be the case. Specific interventions should be introduced to encourage staff to consider whether a piece of medical waste is non-infectious and subsequently place it in tiger-striped, domestic, or recycling bins.

The availability of the required coloured bins was found to be a big hindrance to successful waste segregation. In most cases, it was found that only orange and domestic bins were available to the staff. Assessing whether different bins could be provided would be key in facilitating the diversion of non-infectious waste from hazardous waste streams, thus reducing incineration. Having the right bin available would also help with the lack of time that healthcare workers have available to dispose of waste. Space within the medical facilities may present an issue to having the appropriate bins present. It was found that lack of information about what materials are recyclable discouraged waste to be placed in the recycling bags. Manufacturers should be pressured to label their products and packaging with indications of which materials are recyclable.

The majority of participants expressed that quicker to read forms of information provision, such as posters, were preferred. Specifically labels stuck onto the lids of bins or posters placed above the bins were popular suggestions. These labels and posters can be used to help remind staff what types of waste should go in which bin as well as aid in what types of materials are recyclable. Overall, this study has provided guidance on how waste can be more sustainably segregated with UK NHS trusts. The results of this research should prove invaluable and help guide future legislation and practical interventions in an informed direction as well as provide a framework for future researchers to conduct their own similar studies.

CHAPTER 9

9: CONCLUSION

This chapter summarises the main findings presented within chapters 4, 5, 6, 7, and 8 of this thesis. The overall summary and how this research has addressed the objectives are provided first, followed by recommendations for healthcare providers, potential future work, and finally a future perspective closing statement surrounding sustainability within healthcare.

Throughout this dissertation, multiple medical devices have been explored for their environmental impact and a variety of methodologies have been employed to address the complex issues which hinder sustainability within the medical industry.

Objective 1 defined the need to calculate initial environmental impacts of medical devices throughout their life cycles and identify areas for improvement. Objective 2 detailed that alternative materials should be investigated. Objective 3 focused on exploration of alternative end-of-life treatment of medical devices and objective 4 explored barriers to the utilisation of these alternative methods of disposal.

In order to address these objectives, the summary will be split by highlighting the main findings from each chapter.

9.1. Chapter 4

Chapter 4 addressed objectives 1 and 2 by providing an environmental evaluation of three oxygen masks consisting of different materials; phthalate plasticised polyvinyl chloride (PVC), non-phthalate plasticised PVC, and thermoplastic elastomer (TPE).

- Phthalate-based plasticisers were shown to have a higher environmental impact than non-phthalate-based plasticisers. The plasticiser used contributed a significant portion of plasticised PVC's high environmental impact.

- Environmental impacts were significantly reduced for every impact category when using TPE instead of PVC.

- Raw materials and preprocessing (RMEP) and end-of-life (EoL) were the most contributing stages to environmental impact throughout the entire life cycle of all oxygen masks. Big reductions were observed within the RMEP and EoL stages when switching from PVC to TPE.

- Freshwater aquatic ecotoxicity potential and marine aquatic ecotoxicity potential consisted predominantly of impact originating from the end-of-life stage for all oxygen masks.

- The transportation and packaging stages had the smallest overall contribution to the environmental impact of each oxygen mask. Choosing a manufacturing location that is close to the place of use lowers the environmental impact further.

9.2. Chapter 5

Chapter 5 addressed objective 2 by investigating the mechanical and environmental properties of calcium carbonate ($CaCO_3$) filled polypropylene composites.

- Adding $CaCO_3$ to polypropylene lowers the environmental impact for all impact categories within the resulting composite.

- For every 5% of $CaCO_3$ added, the composite's GWP decreases by 100g CO_2 eq. per functional unit (1000cm^3) of material. Abiotic depletion of fossil fuels had the biggest decline of 32% when 40% $CaCO_3$ filler was added.

- Some properties (tensile strength, tensile modulus, and flexural modulus) declined as increasing percentages of $CaCO_3$ were added.

- Flexural strength increased up to 20% of $CaCO_3$ filler added.

- If the change in mechanical properties are within the range acceptable to the medical device manufacturer, then $CaCO_3$ filled polypropylene composites offers a lower environmentally impactful option to virgin polypropylene.

9.3. Chapter 6

Chapter 6 addressed objectives 1, 2, and 3 by providing an environmental evaluation of two breathing systems consisting of different materials; non-phthalate plasticised PVC and thermoplastic elastomer (TPE). Chapter 6 also examined the environmental impact when swapping polypropylene within the TPE-based breathing system with $CaCO_3$ filled polypropylene composite or polylactic acid (PLA). An alternative end-of-life method to incineration was explored where the breathing systems were cleaned (manually or via a washer-disinfector) and subsequently recycled.

- Environmental impacts were reduced for every impact category when using the TPE-based breathing system instead of the PVC-based breathing system. ADPe, ODP, and TEP were significantly reduced with considerable reductions of 19% observed for GWP.

- The raw materials and preprocessing (RMEP) and end-of-life (EoL) stages contributed the greatest environmental impact throughout the entire life cycle of the breathing systems.

- Using $CaCO_3$ filler decreased the overall impact of the breathing system for six impact categories whereas PLA was found to increase it for nine of the eleven environmental impact categories.

- The environmental assessment found that cleaning and then recycling reduced the overall impact of the breathing system for six categories of the 11 categories (when manually cleaned) and five categories (when mechanically cleaned).

- A large proportion of the mechanical cleaning scenario's impact originated from the washer-disinfector's electricity usage. Manually cleaning had lower environmental impact for all categories compared to mechanical cleaning (via use of a washer-disinfector) due to the reduced use of electricity.

9.4. Chapter 7

Chapter 7 addressed objectives 1 and 3 by providing environmental and economic evaluation of three anaesthetic masks; one reusable made of polyisoprene and polychloroprene, one single-use made of phthalate-based plasticised PVC, and another single-use made of TPE. The environmental and economic impacts generated over the full life cycle of the reusable anaesthetic mask was compared to an equal functional unit of single-use anaesthetic masks.

- Environmental impacts were significantly reduced for every environmental impact category and cost when using the TPE-based single-use anaesthetic mask instead of the plasticised PVC-based single-use anaesthetic mask.

- The reusable mask was less impactful than the plasticised PVC mask for nine of the 11 impact categories whereas it was less impactful than the TPE mask for only three categories (HTP, MAETP, and FAETP).

- The reprocessing stage consisted the majority of the reusable mask's impact for almost all categories; specifically from the electricity used by the washer-disinfector and the sterile packaging used during reprocessing.

- Reducing the energy consumption of the washer-disinfector by just 20% has significant savings on the overall environmental impact of reusable masks and would become more sustainable than the PVC masks for ten of the 11 impact categories.

- Reusable anaesthetic masks were the least expensive compared to both of the single-use anaesthetic masks. 89% of the cost originated from the reprocessing stage. Lowering use of electricity and packaging would reduce the cost of reusable masks even further.

- The cost for both single-use masks was primarily due to the raw material and end-of-life stages.

- The number of reprocessing cycles was shown to have a formidable effect on the overall sustainability of reprocessable masks. The reusable masks were required to be reused at least 21 times in order to stay less environmentally impactful than the plasticised PVC single-use masks for the majority of the impact categories.

9.5. Chapter 8

Chapter 8 addressed objective 4 by investigating potential barriers to improving the management and utilisation of sustainable alternative methods of disposal of medical devices within a UK hospital setting. Qualitative methods (a focus group and interviews) were used to explore why a large quantity of medical waste is currently being needlessly incinerated and the potential for medical waste to be redirected from waste streams designed for incineration and instead to be landfilled or recycled.

- It was found that numerous issues occur within a UK medical setting that results in overuse of the waste streams for incineration. The lack of available bins for offensive and recyclable waste was a great hindrance when allowing medical staff to place non-hazardous waste into their appropriate waste stream.

- Reorganisation of bin placements to be specific for the requirements of each ward would help provide the correct waste stream where it is needed and also reduce time travelled to find the correct bin.

- A trend of medical staff automatically placing waste contaminated with bodily fluids, whether it is hazardous or not, into waste streams for incineration was identified. Specific training should be provided to staff to emphasise that not all bodily waste is required to be incinerated.

- Lack of information around whether a material was recyclable or not led to less recycled waste.

- Providing labels or posters to place on or above bins that remind workers of what types of waste should or should not be placed within each waste stream would be favourable to the medical staff. This would also allow easy changing of the coloured bin waste streams if required by replacing the label/poster with a new one.

Overall recommendations for healthcare providers

This research has evaluated environmental and economic sustainability within respiratory and airway medical devices and provided evidence to support practical changes which can be implemented across the life cycle of medical devices.

- Upon the completion of environmental evaluations of various medical devices, it has been found that the material and end-of-life stages are consistently the most impactful for single-use devices and therefore these stages should become the focus when implementing future changes.

- The use of life cycle assessments has demonstrated the importance of using life cycle thinking when assessing appropriate sustainable solutions to the design of medical devices. By taking a holistic approach when deciding on the most beneficial changes, various aspects of the product's life can be taken into consideration and the optimal solution can be uncovered using scientifically supported methodologies.

- Medical device manufacturers should be encouraged to use less environmentally impactful materials such as TPE to replace PVC and $CaCO_3$ filled polypropylene composites to replace polypropylene. Phasing out the use of phthalate-based plasticisers within PVC by switching to non-phthalate-based plasticisers would also help reduce environmental impact.

- End-of-life options as alternatives to incineration are available such as reusing or cleaning and subsequent recycling. The environmental impacts of these options would need to be further mitigated before they become environmentally favourable to single-use devices.

- Providers of medical device cleaning services should aim to lower the environmental impact of the electricity and sterile packaging used during reprocessing in order to allow reusable devices to become a viable sustainable option.

- The issue of non-contaminated devices being incorrectly identified as hazardous and incinerated would need to be addressed in order to not hinder any efforts particularly when making devices recyclable. Manufacturers should be encouraged to identify what materials within their products are recyclable and increase the quantity of recyclable content during design considerations.

- Governmental/NHS policies should encourage non-hazardous medical waste to be correctly placed in the waste streams designed for alternative treatment, landfill, or recycling. This may require hospitals to ensure the correct waste streams are available and that adequate information is provided to staff, particularly in terms of what materials are recyclable and situations when devices contaminated with bodily fluids are not required to be incinerated.

Future Work

There are a few areas for future work that is suggested to further advance the field of sustainable medical devices. These include:

- It is advised that life cycle assessment should be included at early stage of the medical device design and manufacturing and make these studies available, as currently there is a limited number that have been assessed and as more data is gathered, further trends can be identified and required areas for mitigation can be made increasingly universal.

- Future studies may wish to explore the replacement of PVC within currently used medical devices with TPE to demonstrate that this replacement is practical and to help encourage manufacturers to emulate this design choice. A cost analysis of changing materials would also assist manufacturers in making informed decisions for their future production of medical devices.

- The biocompatibility of $CaCO_3$ filled polypropylene composites would need to be tested at various filler percentages to ensure safety if used within medical devices. Despite calcium carbonate being non-toxic, official studies would be required before medical manufacturers can use it within their devices.

- Research is encouraged in the area of reducing electricity and packaging used during reprocessing of reusable devices to test whether these impacts can be brought low enough to compete with single-use devices. As shown within chapter 7, even just a 20% reduction would have a big effect on the environmental impact of reusable medical devices.

- Multiple studies and interventions could be conducted within hospitals with the aim of increasing effective waste segregation and test opportunities for recycling and reusing certain devices. For example, piloting the use of bin labels in order to provide segregation education to staff and optimise placement of different waste streams; implementing training on segregating non-hazardous waste and measuring the change in waste quantities produced; and running focus groups and interviews with a range of different medical facilities and staff to confirm the findings from this dissertation are universal or suggest other issues found.

Concluding remarks

Upon starting this dissertation, the issue of sustainability within healthcare appeared daunting and the looming nature of the climate crisis (particularly in the light of the recent global pandemic) becoming an ever-growing issue. However, throughout this research journey, the influx of support and sheer enthusiasm observed by individuals and organisations alike within this sector has sparked a hopeful envision of the future. Despite the problems as they are currently presented within academic realms and the public media, this researcher remains optimistic about the field of sustainable healthcare. A vast increase in interest in this topic indicates a humanistic nature to fix what is broken and displays an unrelenting drive to find pragmatic solutions; one which is unlikely to diminish anytime soon.

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Appendix

Chapter 4

***Table A1**: Inventory source for materials used within manufacturing of masks*

Material		Source
	PVC	Polyvinyl Chloride suspension polymerised (GLO) Market for Alloc Def U*
	DEHP	(Yang, 2002)
	NonPht	(*CN104072365A - Preparation method of dioctyl terephthalate - Google Patents*, 2013)
TPE-S	SEBS	GaBi Data on Demand process data set: Styrene ethene butene styrene copolymer (SEBS, TPE-S)
	Polypropylene	Polypropylene Granulate (GLO), Market for Alloc Def U
	White mineral oil	White mineral oil, at plant/RNA
	Polypropylene	Polypropylene Granulate (GLO), Market for Alloc Def U
	LDPE colourant	Polyethylene Low Density Granulate (GLO), Market for Alloc Def U
	Aluminium	Aluminium, wrought alloy (GLO) market for Alloc Def U*
	Textile	Textile woven cotton GLO Market for Alloc Def U
	Synthetic Rubber	Synthetic rubber GLO Market for Alloc Def U

**Taken from the Ecoinvent3.2 LCI database*

***Table A2:** Material impacts for 1 kg plasticiser*

		1 kg DEHP					1 kg NonPht				
Impact category	Unit	Liquid H_2	PP	Phthalic anhydride	CO	Energy	Fatty alcohol	Purified Terephthalic Acid	TiO_2	Water	Energy
ADPe	*mg Sb eq*	0.06	0.04	1.78	0.00	1.40	5.71	2.14	0.11	1.1e-4	0.12
ADPf	*MJ*	1.51	31.72	27.35	15.05	59.17	27.01	21.87	0.13	3e-4	15.02
GWP	*kg CO_2 eq*	0.04	0.70	0.97	0.38	5.20	2.43	0.73	0.01	3e-5	0.88
ODP	*ug CFC-11 eq*	7.82	15.26	26.83	0.00	264.57	69.08	35.33	1.43	2.8e-3	73.90
HTP	*kg 1,4-DB eq*	0.01	0.09	0.35	0.11	1.48	0.65	0.32	0.006	1e-5	0.08
FAETP	*g 1,4-DB eq*	0.01	0.02	0.14	0.02	1.49	1.20	0.15	0.008	4e-5	0.03
MAETP	*kg 1,4-DB eq*	22.06	90.53	505.19	106.87	6615.6	1811.72	440.45	27.30	0.046	122.03
TETP	*g 1,4-DB eq*	0.14	0.44	1.17	0.03	5.29	321.71	1.06	0.02	3e-4	0.17
POCP	*g C_2H_4 eq*	0.01	0.16	0.31	0.15	1.11	0.96	0.17	0.008	1e-5	0.16
AP	*g SO_2 eq*	0.12	1.79	4.80	1.45	27.23	8.00	2.77	0.13	1e-4	2.61
EP	*g PO_4^{3-} eq*	0.03	0.51	0.84	0.15	10.21	3.54	0.72	0.023	6e-5	0.18

***Table A3:** Scenario analysis, results for Masks A, B, and C from new manufacturing site locations: Baseline, UK, and USA. Functional unit per one mask.*

		A			B			C		
		Base	**UK**	**USA**	**Base**	**UK**	**USA**	**Base**	**UK**	**USA**
ADPe (mg Sb eq)	RMEP	0.15	0.15	0.15	0.045	0.045	0.045	0.1	0.1	0.1
	Transport	0.012	0.010	0.013	0.007	0.013	0.008	0.012	0.010	0.013
	Manufacture	0.043	0.069	0.050	0.024	0.036	0.027	0.043	0.069	0.050

	Packaging	0.045	0.046	0.046		0.045	0.046	0.046		0.045	0.046	0.046
	End-of-life	0.166	0.166	0.166		0.002	0.002	0.002		0.164	0.164	0.164
ADPf (MJ)	RMEP	2.06	2.06	2.06		1.19	1.19	1.19		2.79	2.79	2.79
	Transport	0.28	0.05	0.26		0.14	0.06	0.13		0.28	0.05	0.26
	Manufacture	0.99	0.87	0.89		0.62	0.57	0.58		0.99	0.87	0.89
	Packaging	0.23	0.23	0.23		0.23	0.23	0.23		0.23	0.23	0.23
	End-of-life	0.14	0.14	0.14		0.00	0.00	0.00		0.14	0.14	0.14
GWP Units (g CO_2 eq)	RMEP	114.28	114.28	114.28		35.45	35.45	35.45		148.0	148.0	148.0
	Transport	19.13	3.31	18.01		9.39	3.87	8.74		19.13	3.31	18.01
	Packaging	10.84	10.04	10.11		10.84	10.04	10.11		10.84	10.04	10.11
	Manufacture	68.58	44.43	46.47		35.57	24.13	25.13		68.54	44.43	46.47
	End-of-life	57.40	57.40	57.40		31.18	31.18	31.18		66.13	66.13	66.13
ODP (µg CFC-11 eq)	RMEP	3.34	3.34	3.34		0.50	0.50	0.50		4.74	4.74	4.74
	Transport	3.15	0.59	2.98		1.55	0.70	1.45		3.15	0.59	2.98
	Packaging	0.41	0.46	0.49		0.41	0.46	0.49		0.41	0.46	0.49
	Manufacture	2.48	4.00	4.73		1.25	1.97	2.32		2.48	4.00	4.73
	End-of-life	6.43	6.43	6.43		0.05	0.05	0.05		6.43	6.43	6.43
HTP (g 1, 4-DB eq)	RMEP	43.20	43.20	43.20		8.79	8.79	8.79		53.30	53.30	53.30
	Transport	6.16	0.74	5.73		2.99	0.89	2.74		6.16	0.74	5.73
	Packaging	7.97	7.86	8.09		7.97	7.86	8.09		7.97	7.86	8.09
	Manufacture	25.77	22.20	29.45		17.96	16.27	19.70		25.80	22.20	29.45
	End-of-life	103.0	103.0	103.0		43.05	43.05	43.05		76.59	76.59	76.59
FAETP (g 1, 4-DB eq)	RMEP	34.30	34.30	34.30		3.69	3.69	3.69		37.30	37.30	37.30
	Transport	1.90	0.38	1.81		0.94	0.47	0.89		1.90	0.38	1.81
	Packaging	16.20	16.22	16.59		16.20	16.22	16.59		16.20	16.22	16.59
	Manufacture	10.07	10.73	21.92		5.50	5.81	11.11		10.06	10.73	21.92
	End-of-life	530.0	530.0	530.0		215.2	215.2	215.2		338.0	338.0	338.0
MAETP (kg 1, 4-DB eq)	RMEP	309.0	309.0	309.0		17.50	17.50	17.50		360.0	360.0	360.0
	Transport	7.30	1.01	6.83		3.57	1.26	3.30		7.30	1.01	6.83
	Packaging	26.48	25.61	26.30		26.48	25.61	26.30		26.48	25.61	26.30

	Manufacture	76.38	49.97	71.02		37.61	25.12	35.08		76.39	49.97	71.02
	End-of-life	2930	2930	2930		1106.5	1106.5	1106.5		1758.5	1758.5	1758.5
TETP (mg 1, 4-DB eq)	RMEP	3530	3530	3530		12.26	12.26	12.26		253	253	253
	Transport	27.33	3.519	25.48		13.30	4.358	12.279		27.38	3.519	25.48
	Packaging	15.06	14.99	14.96		15.06	14.99	14.96		15.06	14.99	14.96
	Manufacture	87.24	84.89	84.29		42.46	41.39	41.09		87.23	84.89	84.29
	End-of-life	69.8	69.8	69.8		3.58	3.58	3.58		66.9	66.9	66.9
POCP (mg C_2H_4 eq)	RMEP	32	32	32		10.5	10.5	10.5		36.6	36.6	36.6
	Transport	11.938	0.532	10.88		5.707	0.614	5.098		11.938	0.532	10.88
	Packaging	2.471	2.332	2.296		2.471	2.332	2.296		2.471	2.332	2.296
	Manufacture	16.95	12.7	11.63		8.735	6.73	6.22		16.966	12.7	11.63
	End-of-life	3.08	3.08	3.08		0.154	0.154	0.154		3.1	3.1	3.1
AP (g SO_2 eq)	RMEP	0.444	0.444	0.444		0.152	0.152	0.152		0.671	0.671	0.671
	Transport	0.363	0.009	0.329		0.173	0.010	0.153		0.363	0.009	0.329
	Packaging	0.046	0.042	0.041		0.046	0.042	0.041		0.046	0.042	0.041
	Manufacture	0.328	0.208	0.178		0.163	0.106	0.092		0.328	0.208	0.178
	End-of-life	0.069	0.069	0.069		0.0041	0.004	0.0041		0.069	0.069	0.069
EP (mg PO_4^{3-} eq)	RMEP	108	108	108		16.65	16.65	16.65		184	184	184
	Transport	38.38	1.991	35.02		18.40	2.195	16.45		38.38	1.991	35.02
	Packaging	23.77	23.61	25.98		23.77	23.61	25.98		23.77	23.61	25.98
	Manufacture	51.226	46.3	118.21		25.33	23.01	57.01		51.22	46.3	118.21
	End-of-life	35.2	35.2	35.2		6.512	6.512	6.512		35.6	35.6	35.6

***Table A4**: Sources for data validation*

Study	Source	Relevance
Environmental impact of personal protective equipment distributed for use by health and social care services in England in the first six months of the COVID-19 pandemic.	(Rizan, Reed, et al., 2021)	LCAs of nitrile gloves, LDPE aprons, plastic face shields, PP fluid-repellent gowns, PP (FFP) respirator masks, Type II PP surgical masks and Type IIR PP fluid-resistant surgical masks.
Comparative Life Cycle Assessment of Disposable and Reusable Laryngeal Mask Airways	(M. Eckelman et al., 2012)	LCA of a PVC based Laryngeal Mask Airway medical device
Life cycle assessment of single-use surgical and embedded filtration layer (EFL) reusable face mask	(A. W. L. Lee et al., 2021)	LCA of single-use surgical masks

Life cycle assessment and circularity evaluation of the non-medical masks in the Covid-19 pandemic: a Brazilian case	(Maceno et al., 2022)	LCA of single-use non-medical masks
The energy and environmental footprints of COVID-19 fighting measures - PPE, disinfection, supply chains	(Klemeš et al., 2020)	LCA of single-use N95 mask
Life cycle environmental impacts of disposable medical masks	(Atılgan-Türkmen, 2022)	LCA of single-use medical masks

Supplementary information References

Atılgan-Türkmen, B. (2022) 'Life cycle environmental impacts of disposable medical masks', *Environmental Science and Pollution Research*, 29(17), pp. 25496–25506. Available at: https://doi.org/10.1007/S11356-021-17430-5/FIGURES/3.

Eckelman, M. *et al.* (2012) 'Comparative life cycle assessment of disposable and reusable laryngeal mask airways', *Anesthesia and analgesia*, 114(5), pp. 1067–1072. Available at: https://doi.org/10.1213/ANE.0B013E31824F6959.

Klemeš, J.J., Fan, Y. van and Jiang, P. (2020) 'The energy and environmental footprints of COVID-19 fighting measures – PPE, disinfection, supply chains', *Energy (Oxford, England)*, 211, p. 118701. Available at: https://doi.org/10.1016/J.ENERGY.2020.118701.

Lee, A.W.L. *et al.* (2021) 'Life cycle assessment of single-use surgical and embedded filtration layer (EFL) reusable face mask', *Resources, Conservation and Recycling*, 170, p. 105580. Available at: https://doi.org/10.1016/J.RESCONREC.2021.105580.

Maceno, M.M.C. *et al.* (2022) 'Life cycle assessment and circularity evaluation of the non-medical masks in the Covid-19 pandemic: a Brazilian case', *Environment, Development and Sustainability*, pp. 1–28. Available at: https://doi.org/10.1007/S10668-022-02388-2/TABLES/6.

Rizan, C., Reed, M. and Bhutta, M.F. (2021) 'Environmental impact of personal protective equipment distributed for use by health and social care services in England in the first six months of the COVID-19 pandemic', *https://doi.org/10.1177/01410768211001583*, 114(5), pp. 250–263. Available at: https://doi.org/10.1177/01410768211001583.

***Table A5**: Inventory source data for materials used within manufacturing of calcium carbonate – polypropylene composites*

Material	Source
Unprocessed limestone	Limestone, unprocessed {GLO} market for Alloc Def U*
Polypropylene	Polypropylene, granulate {GLO} market for Alloc Def U*

**Taken from the Ecoinvent3.2 LCI database*

***Table A6:** Inventory source data for transport and injection moulding process.*

Input	Input value	Source
Transport vehicle	0.2887 tkm	Transport, freight train {GLO} market for Alloc Def U*
	0.4504 tkm	Transport, freight lorry unspecified {GLO} market for Alloc Def U*
	0.5248 tkm	Transport, freight sea transoceanic ship {GLO} market for Alloc Def U*
Injection moulding	1 kg	Injection moulding {GLO} market for Alloc Def U*

**Taken from the Ecoinvent3.2 LCI database*

***Table A7**: Inventory source for materials used within manufacturing of masks*

Material		Source
	Plasticised PVC	Polyvinyl Chloride suspension polymerised (GLO) Market for Alloc Def U
		PlasticsEurope, (2015) 'Eco-profiles and Environmental Product Declarations of the European Plastics Manufacturers'
TPE-S	SEBS	GaBi Data on Demand process data set: Styrene ethene butene styrene copolymer (SEBS, TPE-S)
	Polypropylene	Polypropylene Granulate (GLO), Market for Alloc Def U
	White mineral oil	White mineral oil, at plant/RNA
	Polypropylene	Polypropylene Granulate (GLO), Market for Alloc Def U
	HDPE	Polyethylene High Density Granulate (GLO), Market for Alloc Def U
	LDPE	Polyethylene Low Density Granulate (GLO), Market for Alloc Def U
	Polychloroprene	Synthetic rubber (GLO) market for Alloc Def U
	Polyisoprene	Latex (GLO) Market for Alloc Def U

All taken from the Ecoinvent3.2 LCI database

Figure A8: *PowerPoint slides used for the four questions asked during the focus group.*

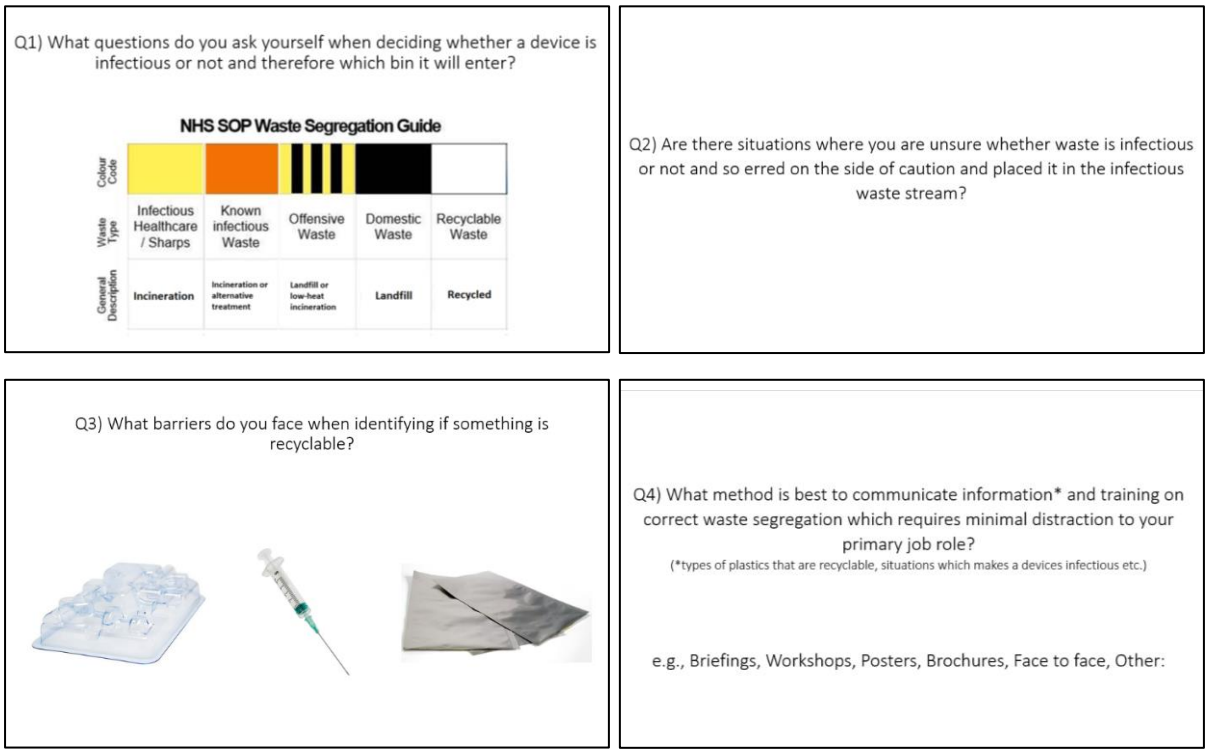

Figure A9: *Image used during the ice-breaker questions asked during the focus group.*