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Life cycle environmental evaluation of medical oxygen masks in the UK

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ABSTRACT

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. 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'. The results account for all 11 impact categories as provided by the CML-IA baseline v3.03 methodology. 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. 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 scores highest, whereas mask A is highest for the other five categories (with large impacts in human toxicity and ecotoxicities). Two scenario analyses show the importance of supply chain logistics (i.e., the location of the manufacturing site and location of end user) 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 4437 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 2755 tonnes of CO_2 eq. per year.

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. The demand for disposable oxygen masks heavily increased during the COVID-19 pandemic due to the prevalence of respiratory infections (Pathak et al., 2023). 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. For additional context, this is out of a total 156,000 tonnes of clinical waste that is produced by the UK NHS each year (Rizan et al., 2021). 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.

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 (DHSC, 2013). This is done to reduce risk of contamination (Unger and Landis, 2016) and costs associated with

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cleaning and reprocessing. If a medical device is deemed to have been in contact with hazardous or infectious substances then, by UK law, it is required to be incinerated (DHSC, 2013). Studies have shown that 85% of medical waste is actually non-hazardous and could be treated the same as non-clinical waste (WHO, 2014). Research has found that the key factor contributing to the high rate of incineration of used medical devices within the UK is incorrect waste segregation by the healthcare staff resulting in non-hazardous and non-infectious devices to be classified as hazardous or infectious and subsequently incinerated (Webb et al., 2024). The potential alternative end-of-life scenarios for MOMs includes alternative treatment (heating of waste to disinfect it), landfill, or recycling (NHS, 2023). However, none of these options are feasible until the issue of incorrect waste segregation is addressed.

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, 2000; Unger and Landis, 2016; 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., 2020). 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, 2014), due to its ease to manufacture, low-cost, strong mechanical properties, inertness, and non-toxicity (Chiellini et al., 2013). PVC alone without additives is comprised of carbon, hydrogen, and chlorine which are not particularly environmentally damaging substances on their own (Tötsch et al., 1992). However, 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. When chlorine is reacted with ethylene to produce dichloroethane, it is then cracked to produce vinyl chloride which is a known carcinogen (Ackerman Rachel Massey et al., 2003). Incinerated PVC creates hazardous flue gas residues and releases toxic dioxins (Buekens and Cen, 2011; Bidoki and Wittlinger, 2010) and chlorinated by-products (Aracil et al., 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 and 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 (Chemanalyst, 2023) 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 (Cheng et al., 2019). None of the constituents of TPE-S have been highlighted as posing any major threat to the environment. The only issue that has been raised is the required use of fossil-fuels during production which contributes to the global depletion of petrochemical resources and associated carbon dioxide emissions (Jeon et al., 2024). Medical devices containing TPE-S as an alternative to PVC are already available on the market.

There is a lack of studies which investigate the environmental sustainability of materials used within medical devices. 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 et al., 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 et al., 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.

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).

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. 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 Fig. 1.

2.1.1. 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 Fig. 2. The non-phthalate-based plasticiser used within mask A is known and used for the calculations during this study but due to confidentiality reasons, the specific commercial name cannot be provided and so shall be referred to as NonPht. Despite not being able to give the exact name of the plasticiser, the input

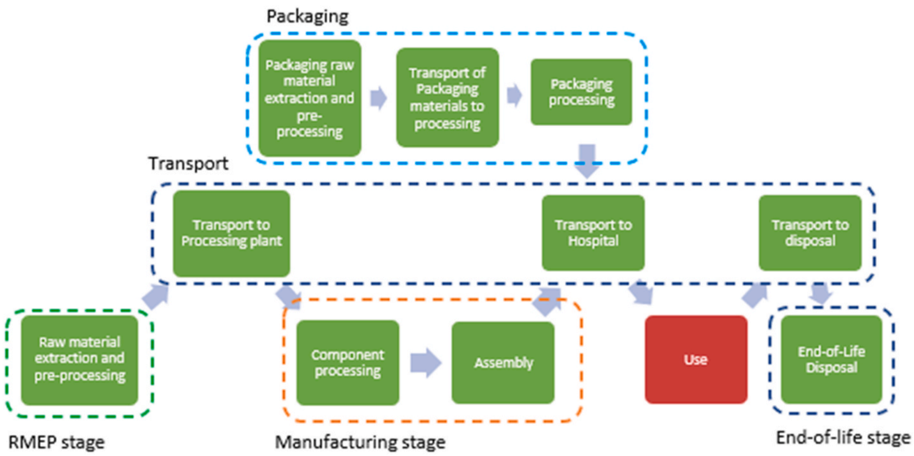


Fig. 1. Diagram showing the full life cycle of the MOMs studied (use stage is in red as it does not include any material or energy input). The coloured dotted lines define the individual life cycle stage, which are raw materials (green), packaging (light blue), transport (dark blue), manufacturing (orange), and end-of-life (pink) life cycle stages. (For interpretation of the references to colour in this figure legend, the reader is referred to the Web version of this article.)

Mask A	Mask B	Mask C
		
Made of PVC using NonPht	Made of TPE-S and PP with a simplified design	Made of PVC using DEHP (hypothetical mask)

Fig. 2. 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.

data used to model the plasticiser is provided by the Google Patent CN104072365A - (2013). Future researchers can model it themselves from this data if required.

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%–50% oxygen concentration at flows of 5–8 L per minute. These masks are designed to be single-use and are disposed of via incineration. They are all produced in a country within South Asia (the exact country is not disclosed for confidentiality reasons but has been used during this study's calculations). 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 Fig. 2). 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 35–38% (the exact percentage is known and used for the calculations but not provided here for confidentiality). This range of percentages provided allows for the exact percentage to remain unknown whilst minimalising the change to results if this study were to be recreated by other researchers. 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.

European regulations on phthalate use during the 2010's dictated that the use of non-phthalate-based plasticisers were to replace the previously used DEHP plasticiser. As a theoretical comparison, mask C has been included within this study despite it not being 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. This is an important mask to include within this study because despite the use of DEHP being banned within the EU, a recent study found that over 62% of currently available plastic medical devices still had DEHP present (Vanhorebeek et al., 2022). If manufacturers can justify that the use of DEHP has benefits to the patient which outweighs the risks, then the Medical Device Regulations will allow their continued use (GOV.UK, 2023). This has resulted in the phasing out of phthalate-based plasticisers to be slow and DEHP is still widely present within purchasable medical devices (Vanhorebeek et al., 2022). Including mask C within this study has the aim of demonstrating to the reader the environment impact which results from the continued use of this plasticiser. Except from change in plasticiser, all other material requirements are the same for these masks A and C. Fig. 2 summarises the masks selected for this study.

2.2. 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.

2.2.1. 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 (Steubing et al., 2016) has been used for the background data. The materials requirements were obtained via material datasheets from a manufacturer. Table 1 sumarises the material

Table 1
Life cycle inventory of the raw material and pre-processing stage (RMEP) of the three MOMs; data are presented per functional unit.

Component	Material	Ecoinvent process used	Mask[a]		
			A	B	C
			Mass (g)	Mass (g)	Mass (g)
Mask Shell	Plasticised PVC[b]	Polyvinylchloride, suspension polymerised {GLO} Alloc Def U	28.05	–	28.05
	TPE-S[c]	Polypropylene, granulate, {GLO} Alloc Def U White mineral oil, at plant/RNA	–	7.53	–
	Polypropylene	Polypropylene, granulate, {GLO} Alloc Def U	–	7.09	
	Colourant (LDPE[d])	Polyethylene, low density, granulate, {GLO} Alloc Def U	–	0.08	
Mask Connector	Polypropylene	Polypropylene, granulate, {GLO} Alloc Def U	2.98	–	2.98
	Colourant (LDPE[d])	Polyethylene, low density, granulate, {GLO} Alloc Def U	0.03	–	0.03
Nose Clip	Aluminium	Aluminium alloy, metal matrix composite {GLO} Alloc Def U	1.47	–	1.47
Elastic Band	PET[e] Polyester	Polyethylene terephthalate, granulate, bottle grade, {GLO} Alloc Def U	0.73	0.73	0.73
	Elastane	Synthetic rubber {GLO} Alloc Def U	0.36	0.36	0.36
	Total Weight		**33.62g**	**15.79g**	**33.62g**

[a] Description of masks in Fig. 2.
[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.

composition of each mask.

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). To allow reproducibility of this study, it can be disclosed that the environmental impact data of SEBS is a very close resemblance to that of 'Synthetic rubber {GLO} Alloc Def U' which is a process that can be found within the Ecoinvent v3.2 database. This has also been confirmed to be a suitable substituent by the Simapro technical team. For this study, however, the exact data for SEBS will be used. The LCI data for DEHP was taken from (Li, 2013) where the average of European data was used as production location. This data is shown in Table 2 and displayed per 1 kg of plasticiser production. Background information for product flows sourced from Ecoinvent 3.2 database (Steubing et al., 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). >The manufacturing stages required to transform the raw materials into the shape required for each of the masks are shown in Table 3.

2.2.2. Manufacturing stage (processing and assembly)

The processing machinery are all present within the same manufacturing plant within South Asia and owned by the manufacturer. The environmental impact data for the machines are sourced from the Ecoinvent 3.2 database (Steubing et al., 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. 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 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. Some medical devices require heat or chemical sterilisation before dispatchment (e.g., ethylene oxide, steam sterilisation, or dry heat), however, these medical oxygen masks are classed as non-sterile class I medical devices due to their low risk to patient health and non-invasive nature (UK, 2016). Therefore, there are no additional sterilisation steps during or after manufacturing to take into consideration.

Table 2
Inventory data to produce 1 kg *of DEHP* (Li, 2013).

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

Table 3
Input data for the manufacturing stage. Data is presented per functional unit.

Processing	Ecoinvent process used	Mask [a]		
Inputs		A	B	C
Injection moulding (g)	Injection moulding {GLO} Alloc Def U	31.06	14.7	31.06
Sheet Rolling (g)	Sheet rolling, aluminium {GLO} Alloc Def U	1.47	–	1.47
Elastic band sewing (g)	–	1.09	1.09	1.09

[a] Description of mask in Fig. 2.

2.2.3. Packaging stage

The packaging required for each mask is identical. Table 4 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. As the oxygen masks are non-sterile medical devices, the packaging is only required to fulfil the role of protective packaging and therefore no additional steps such as modified air or terminal sterilisation is required (ISO, 2020).

2.2.4. 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 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

Table 4
Inventory data of packaging stage per functional unit. The packaging is the same for all three type of masks.

Component	Material	Ecoinvent process used	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	Kraft paper, unbleached {GLO} Alloc Def U	0.85	None	100	10
Polybag	Low density Polyethylene	Polyethylene, low density, granulate, {GLO} Alloc Def U	2.29	Extrusion plastic film	200	10
Carton	Corrugated Board box	Corrugated board box {GLO} Alloc Def U	5.71	None	100	10
Total weight (g)			8.85			

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 10 km 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 5.

2.2.5. *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. The Ecoinvent process selected to model incineration was 'municipal solid waste (waste scenario) {GB} treatment of municipal solid waste, incineration Alloc Def U'. It is against best practice (NHS waste disposal regulation HTM 01–07) for used single-use medical devices to be reused or recycled and so neither of these scenarios are modelled within this assessment.

2.3. *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.

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). To aid evaluation throughout this section, it is important to note that none of the impact categories are inherently more significant in terms of environmental damage than one another (Mikosch et al., 2022). Some categories may be subjectively more relevant based on the goals of the individual or organisation conducting the evaluation but for this study no superiority judgements have been made on the specific impact categories. Instead, the overall concluding environmental superiority of the masks are based on the number of categories in which they are more or less impactful than the other masks.

The environmental impact results of the three oxygen masks are discussed in section 3.1. where comparisons between the masks as well as between life cycle stages will be examined. Two scenario analyses of changing manufacturing and end user location are discussed in section 3.2, validation of the results is shown in section 3.3., and an overall comparison of the costs and benefits for each mask is provided in section 3.4. An in-depth analysis of the materials used within the masks is provided in section 3.5. followed by a sensitivity analysis of the plasticiser data in section 3.6. Future research suggestions are provided in section 3.2 and limitations of the study in section 3.8.

3.1. *Environmental impacts of oxygen masks*

Fig. 3 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) scores highest. For the remaining five categories (particularly the toxicity potentials HTP, FAETP, MAEP, and TETP), mask A has greatest environmental impact with its TEP 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

Table 5
Inventory data use for the transportation stage. Data are presented per functional unit.

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

[a] Description of mask in Fig. 2.

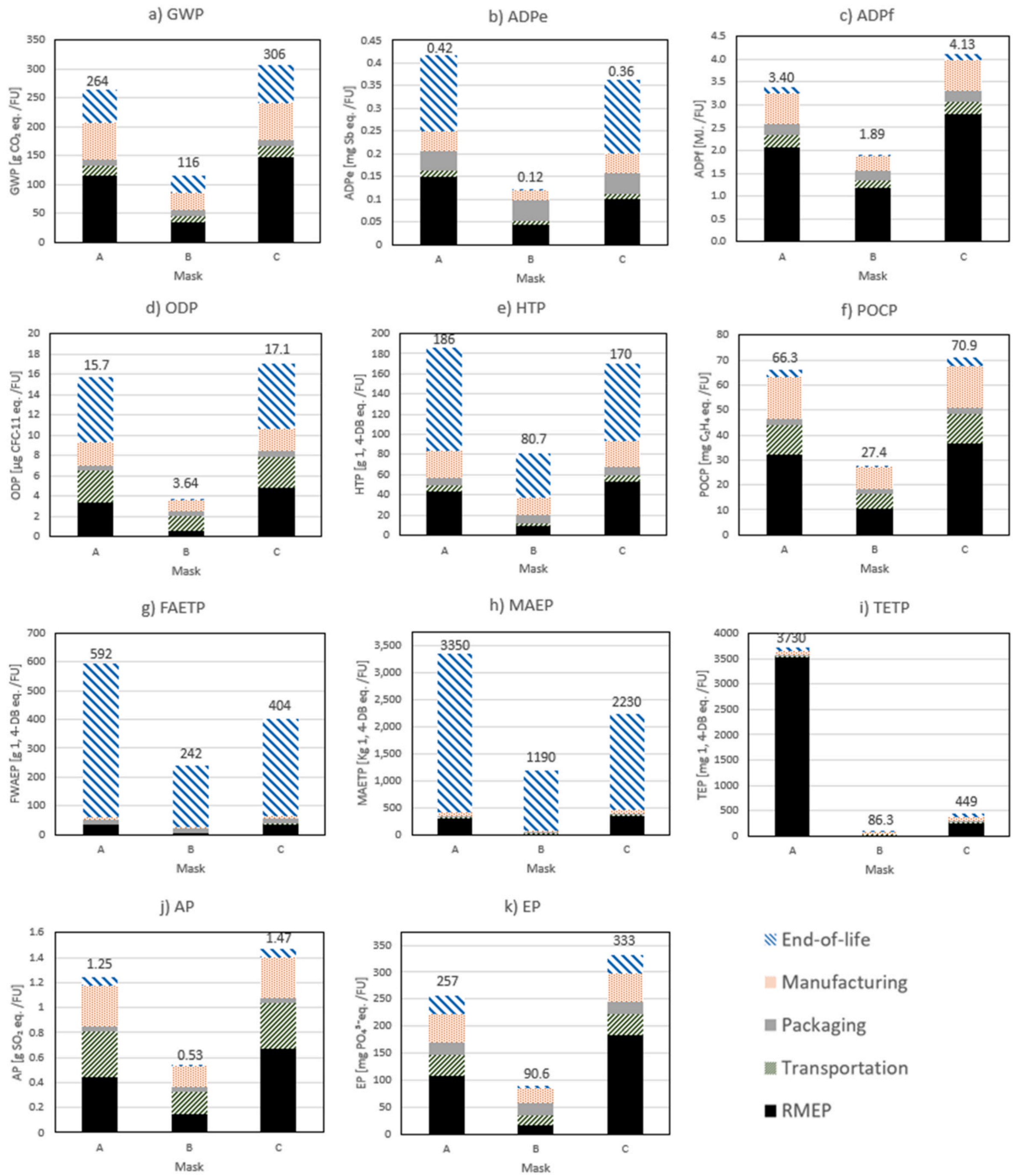


Fig. 3. Comparison of environmental impact of three oxygen masks A, B and C. Results expressed per functional unit (FU). Description of masks in Fig. 2. ADPe: abiotic depletion potential of elements; ADPf: abiotic depletion potential of fossil resources; AP: acidification potential; EP: eutrophication 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.

inputs required for each device; the only exception is for mask B that has slightly lower transport and manufacturing scores 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.

3.1.1. Global warming potential (GWP)

Fig. 3a shows that for GWP, mask B has the lowest environmental impact of 116g 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 score 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 transport score. 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 3.5). 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 3.5

3.1.2. Depletion potentials (ADPe, ADPf, ODP)

As seen in Fig. 3b–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 a score lower than would be proportional with just the weight reduction. Fig. 3b–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 score 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.

3.1.3. Human health (HTP, POCP)

Fig. 3e&f shows mask B to have a HTP and POCP impact less than half (52%–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%–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 score, 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 (1.47g) 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 score 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%–73%) is from emission of Beryllium to water which for masks A&C, originate solely from the incineration of the plasticised PVC. For mask B, Beryllium 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%–10%) between masks A&C for HTP and POCP. For HTP, mask A has a 19% lower RMEP score than mask C but a 34% higher end-of-life score.

3.1.4. Aquatic ecotoxicity potentials (FAETP, MAEP)

For FAETP and MAEP, mask A scored highest followed by mask C then mask B. Most of the masks' impact (79%–94%) is due to the end-of-life stage. For mask A's FWAEP, 489g 1,4-DB eq. is from Beryllium emissions to water, whereas for mask C only 289g 1,4-DB eq.; both with >99% from the plasticised PVC. Similar reductions are seen for MAEP (A: 2880 kg 1,4-DB eq., C: 1710 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%–94%). This is again due to the emissions of Beryllium to water for both categories. The incineration of the TPE is responsible for most of the Beryllium 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 to water (1.8g 1,4-DB eq., 99% coming from the TPE). For MAEP, Barium to water (6.5 kg 1,4-DB eq) and Hydrogen Fluoride to air (5.3 kg 1,4-DB eq.) are the main contributing emissions to the RMEP stage, with 99% and 67% of these scores respectively originating from the extraction and pre-processing of the raw materials used within the TPE.

3.1.5. Ecosystems (TETP, AP, EP)

Mask A has a high TETP, 95% originating from the RMEP stage, particularly from the emission of Cypermethrin to soil (3320 mg 1,4-DB eq., 94.1%). Almost the entirety (>99.9%) of the Cypermethrin 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 Cypermethrin 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%–14%) to the overall AP and EP scores. 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 scores were directly correlated to the reduction in the weight of mask B. The reduction in end-of-life and RMEP scores from masks A&C to mask B was greater than would be expected purely on weight.

3.2. Scenario analysis: location of manufacture

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 the 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 section 2.2. 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 6 summarises these changes.

Fig. 4 exhibits the results for the scenario analysis, showing a sample of four indicators – GWP: global warming potential, ODP: ozone depletion potential, HTP: human toxicity potential, and AP: acidification potential For the other seven indicators, refer to Table A1 in the SI.

As seen in Fig. 4, 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.

Table 6
Transport distances for scenario analysis: change of manufacturing location.

Transport stage	Material	Distance	Manufacturing site	
			UK	USA
Raw materials to manufacturer	Plasticised PVC	By Boat (km)	–	20000
***Lorry** (7.5-16 mton Euro 6 lorry)*		By Lorry (km)	400	–
***Boat** (Freight, sea, transoceanic ship)*	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	Weight of mask + packaging (g)		24.64	42.47
***Lorry** (7.5-16 mton Euro 6 lorry)*	Distance by Boat (km)		–	18520
***Boat** (Freight, sea, transoceanic ship)*	Distance by Lorry (km)		45	250

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%–12%) in manufacturing score. 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: 315g CO_2 eq./kWh, UK: 169g CO_2 eq./kWh, USA: 181g CO_2 eq./kWh (Steubing et al., 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.

3.2.1. *Scenario analysis: end user location*

Within this section, a scenario analysis is provided to test the change in environmental impact when the location of the end user is altered. The three countries with the highest import rates of surgical masks and respirators over the last three years will be tested which are: the United States (USA), Germany, and France (WTO, 2022; Eurostat, 2020; WITS, 2022). Two changes to the life cycle stages will be required for this scenario analysis: the distance travelled from manufacturer to end user (the updated data is provided in Table 7) and the Ecoinvent processes used for end-of-life incineration (changed to the country of final use). For this scenario analysis, the end user will be based on the largest hospital system within the countries studied. For the USA, this is HCA Healthcare in Tennessee, for Germany this is Charité – Universitätsmedizin Berlin, and for France this is Pitié-Salpêtrière Hospital within Paris.

The Ecoinvent processes selected to model incineration is 'municipal solid waste (waste scenario) {RoW} treatment of municipal solid waste, incineration Alloc Def U' for the USA, 'municipal solid waste (waste scenario) {DE} treatment of municipal solid waste, incineration Alloc Def U' for Germany, and 'municipal solid waste (waste scenario) {FR} treatment of municipal solid waste, incineration Alloc Def U' for France.

Fig. 5 provides the results for the scenario analysis, showing a sample of four indicators – GWP: global warming potential, ODP: ozone

Table 7
Transport distances for scenario analysis: change of end-user location.

Transport stage	Distance	UK (baseline)	End user location		
			USA	Germany	France
From manufacturer to hospital	Distance by Boat (km)	22000	21000	14000	9700
***Lorry** (7.5-16 mton Euro 6 lorry)* ***Boat** (Freight, sea, transoceanic ship)*	Distance by Lorry (km)	190	1300	300	700

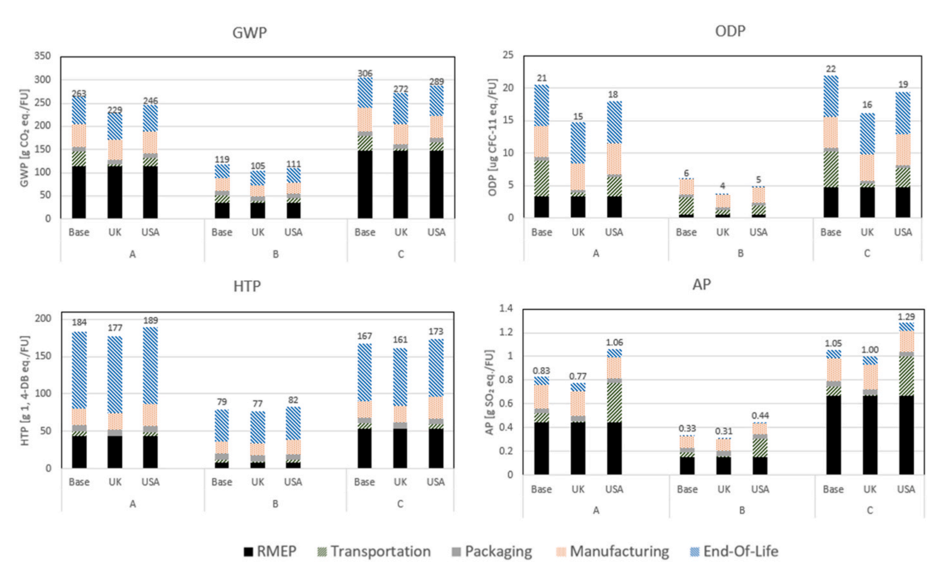


Fig. 4. Scenario analysis - Comparison of environmental impact of three oxygen masks A, B and C at three different manufacturing locations: Asian country (baseline), UK, and USA. Results expressed per functional unit. Description of masks in Fig. 2. GWP: global warming potential; ODP: ozone depletion potential; HTP: human toxicity potential; AP: acidification potential. For other impacts, see Table A1 in the SI.

depletion potential, HTP: human toxicity potential, and AP: acidification potential.

As can be seen from Fig. 5, changing the location of where the masks are distributed does affect the overall environmental impact. The largest variation can be seen within the acidification impact category for all three masks. Switching from distributing the masks to the UK (baseline) to the USA has been shown to increase the acidification potential for masks A, B, and C by 36%, 45%, and 29% respectively. What is important to note is that there is almost no change in environmental impact from the end-of-life stage regardless of which country the masks are incinerated in. The majority of the change in impact is due to the transportation distances. This would explain why switching to distributing to the USA has such a large increase in environmental impact. The transoceanic distance between the manufacturer (in South Asia) and the USA is the greatest compared to the UK, Germany, and France. In addition to this, a larger distance to transport the masks via road from the port to the hospitals within the USA is required due to the larger land mass from coast to the inland of America.

Interestingly, transporting to Germany and France instead of the UK (baseline) decreases GWP, ODP, and HTP but raises AP. Table 7 showed that transporting to Germany and France requires a shorter distance by boat but a greater distance by lorry than transporting to the UK. This must then indicate that by reducing transoceanic transport, the GWP, ODP, and HTP can be reduced but if larger travel via road is required then the acidification potential will rise as a result. Overall, this scenario analysis has shown that the key factor that should be considered when exporting medical devices is the transport distance and mode of transport used depending on which environmental impact categories are required to be minimalised.

3.3. 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.

The reader should be aware that there are limitations to comparing these products as they have different functional units and are made of varying materials. It is therefore essential that direct comparisons are not made between the exact scores of these devices as they will vary in weight and material composition. This section is only intended to serve as a guiding reference to the environmental impact scores of similar devices in order to ensure no obvious outliers are present within this study compared to the current literature.

Fig. 6 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 A2 in the SI.

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 scores are slightly higher or lower than this study, but all fall within the range of 3.4 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 example, the LCA of the steel dental bar (3.4 g CO_2 eq./g) shows the CO_2 to be lower than the masks even with weight considered. However, upon analysing this LCA, the study actually comprises only 9% of the steel itself and 91% of the packaging used for the steel bar which is made of plastic and paper. The plastic and paper is what has given the study a lower average GWP per g/product compared to the masks within this paper. For studies where similar materials are used (e.g., PVC-based laryngeal mask airway (LMA) by (Eckelman et al., 2012)) the score 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 will be shown in Fig. 8, 1 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) (Steubing et al., 2016) thus showing that adding plasticisers would increase the score 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

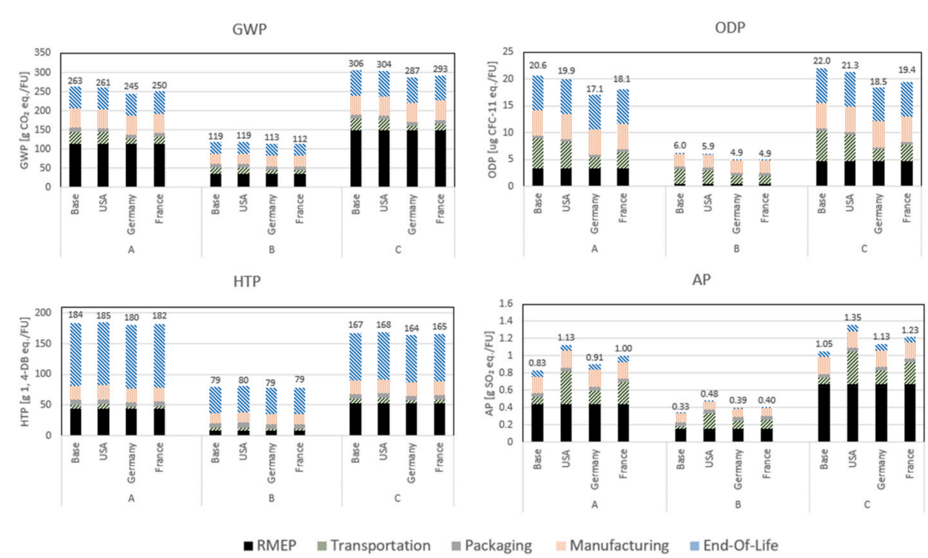


Fig. 5. Scenario analysis - Comparison of environmental impact of three oxygen masks A (NonPht-plasticised PVC), B (TPE), and C (DEHP-plasticised PVC) exported to four different end user locations: UK (baseline), USA, Germany, and France. Results expressed per functional unit. Description of masks in Fig. 2. GWP: global warming potential; ODP: ozone depletion potential; HTP: human toxicity potential; AP: acidification potential.

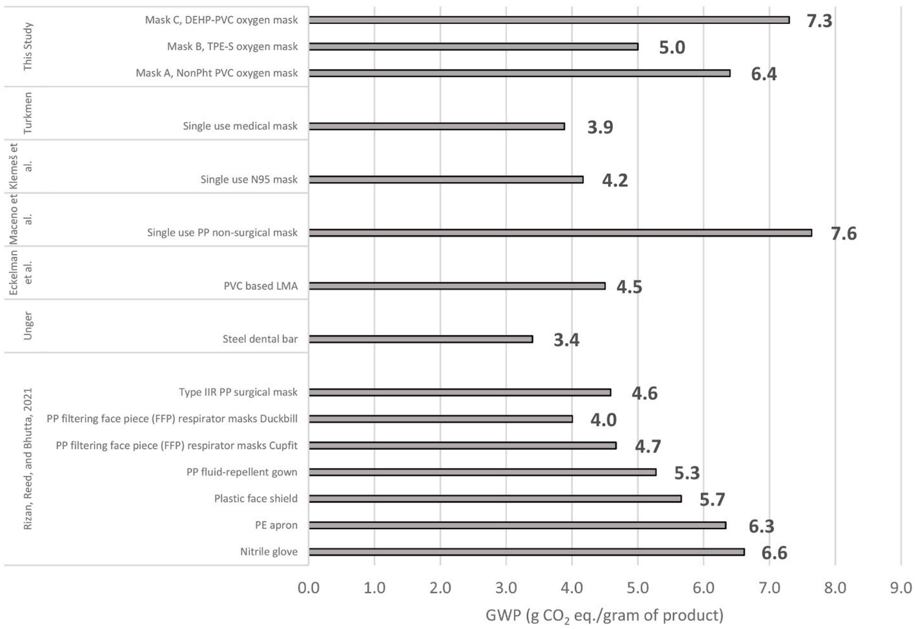


Fig. 6. Validation of the study - Comparison of GWP (g CO_2 eq./g of product) of various medical devices found in literature. Functional unit of per g of product.

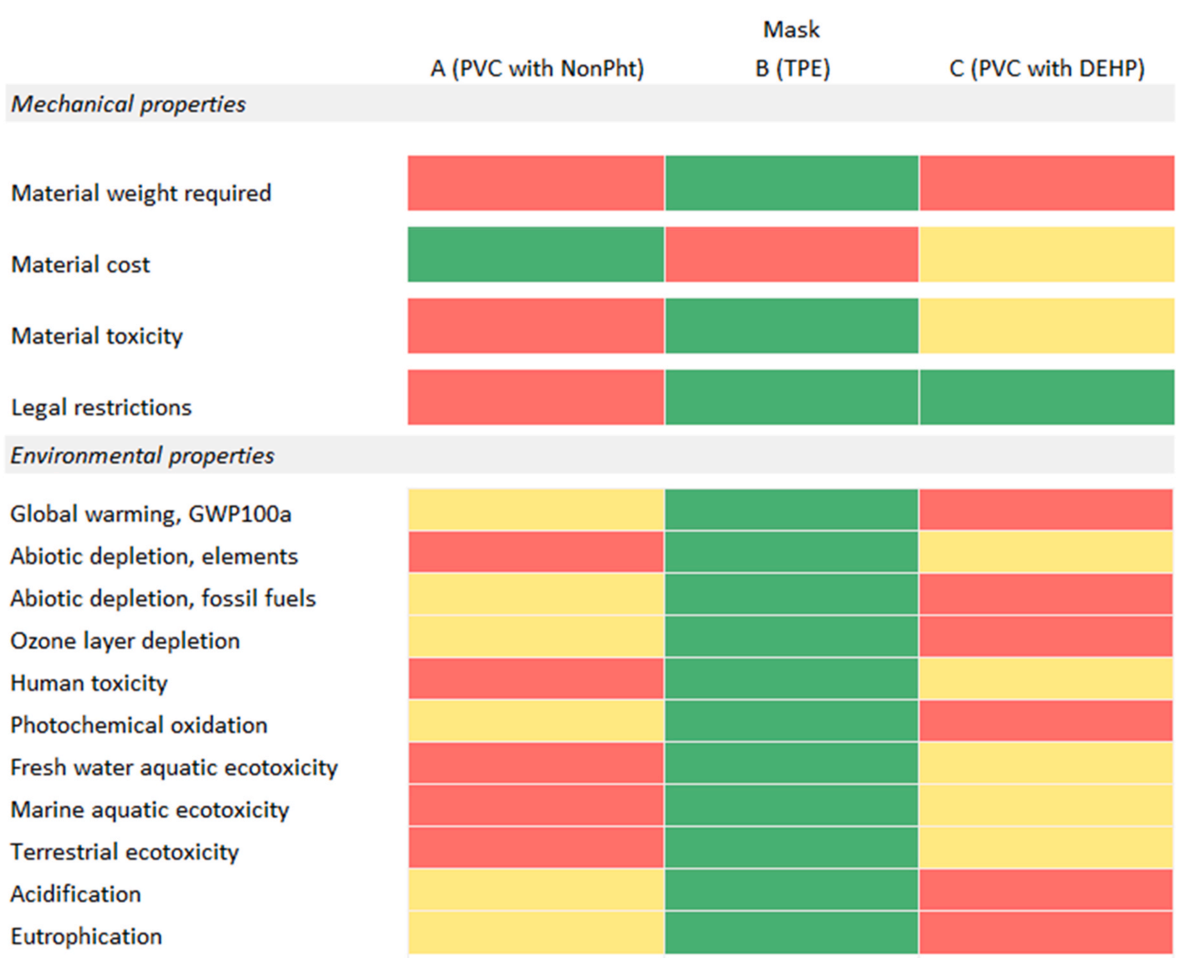
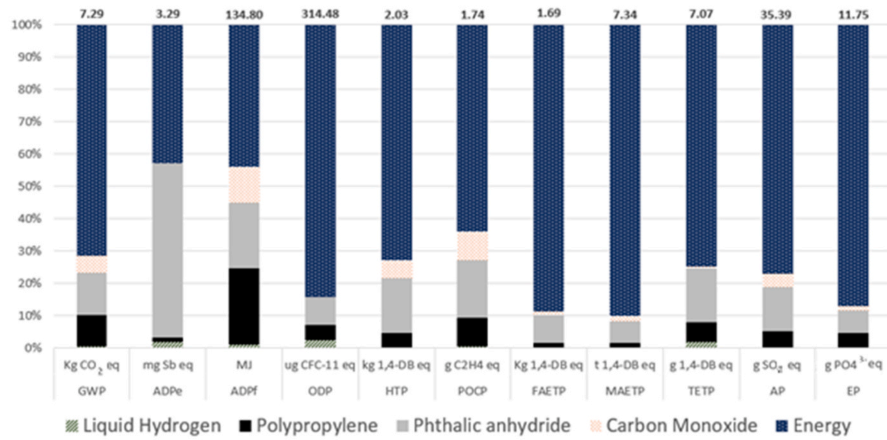
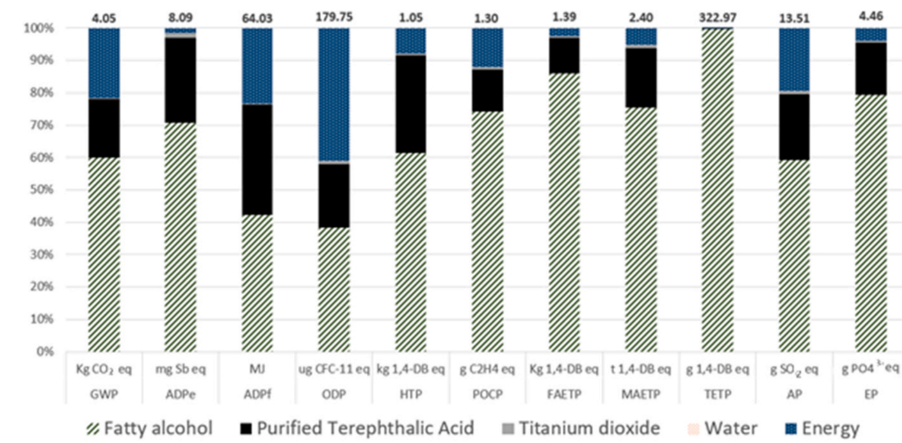


Fig. 7. Heat map showing the performance of various properties displayed by the three medical oxygen masks: A (made using polyvinyl chloride plasticised with a non-phthalate-based plasticiser), B (made using Thermoplastic elastomer), C (made using polyvinyl chloride plasticised with a phthalate-based plasticiser. The colours indicate the following: Green – best, Yellow – midway, Red – worst. (For interpretation of the references to colour in this figure legend, the reader is referred to the Web version of this article.)



a) 1Kg DEHP plasticiser



b) 1Kg NonPht plasticiser

Fig. 8. Environmental impact of plasticisers – DEHP (a) and NonPht (b) with functional unit of 1 kg of material. Details of impacts scores per stage can be found in Table A3 in the supplementary information (SI).

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.

3.4. Overall comparison of the three oxygen masks

To aid overall comparison of the various benefits and disadvantages between each oxygen mask, a visual representation of the results is provided in Fig. 7 by the use of a heat map.

As can be seen from Fig. 7, mask B (made from TPE) is the most beneficial for all categories except cost. For manufacturers to decide whether they would like to switch from using PVC within their medical devices to TPE, the main deciding factor will be whether the economic cost is justified when considering all the material toxicity, material weight, lower legal restrictions, and environmental benefits from doing so.

The lower weight of mask B also helped reduce its environmental impact by reducing the contribution to all life cycle stages. The lighter weight of mask B was partially due to removing excess material (i.e., around nose as seen in Fig. 2) as well as utilising the lower density of TPE-S (0.88g/cc of TPE-S vs 1.20g/cc for PVC). 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 4437 tonnes of CO_2 eq. to 1682 tonnes of CO_2 eq. per year; a saving of 2755 tonnes CO_2 eq.

It is also important to note the economic differences between PVC and TPE. For a long time, PVC has been favoured for its advantageous cost. The constituents of PVC (carbon, hydrogen, and chlorine) are cheap to acquire as well as PVC production being well established for many decades (Ackerman Rachel Massey et al., 2003). In 2018, 44 million tonnes of PVC was produced globally (Statista, 2020) compared to a 2022 estimation of 5 million tonnes for TPE (Chemanalyst, 2023). This large production volume of PVC provides additional economic benefits by providing the 'economies of scale' effect as well as ensuring there are large established production factories already in operation (Ackerman Rachel Massey et al., 2003). From 2022, rough estimates of the cost of TPE was £2 per kg (Xometry, 2020) compared to PVC costing £0.9 per kg (Statista, 2022). It can be hoped that as production of TPE increases, then the prices will subsequently reduce as has been the case with PVC. Furthermore, lower weights of TPE compared to PVC are required to fulfil the same function for the medical devices studied within this paper, which would help reduce the cost for material required per mask.

3.5. Environmental impact of the materials

Prior to this study, the three materials used within the masks were not available on any life cycle inventory database. Therefore, this section explores the environmental impact of 1 kg of each of these materials in order to expand on current life cycle inventory data and allow their use in further LCA studies.

For a comprehensive comparison on the materials, Table 8 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, 35–38%, which is known exact for the calculations but kept confidential here. 1 kg of each material was modelled following methodology described in section 2. Only the impacts from the raw materials are assessed in this section.

Table 8 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%–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 (118g 1,4-DB eq., 95.2%) originates from the emission of Cypermethrin to soil, 97% from NonPht, of which >99.9% is due to the fatty alcohol. The emission of Cypermethrin 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 8, an LCA of the plasticisers (DEHP and NonPht), excluding PVC, is conducted using a FU of 1 kg of plasticiser, and the results are displayed in Fig. 8. The constituents of the plasticisers are provided in Table 2.

Fig. 8 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 Fig. 8a. 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%–42%), as displayed in Fig. 8b.

Fig. 8b shows the fatty alcohol used during manufacturing of NonPht to be the main reason for its high TETP score. 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).

3.6. Sensitivity analysis: energy use of plasticiser production

This section explores how changing the plasticisers' energy requirements effects the overall environmental impact of the plasticisers. Data used for the plasticisers was modelled from literature and by expert's inquires (see details in section 2.2.1); 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. 20% was chosen because a reduction of this amount was deemed a reasonable and achievable change for manufacturers to achieve. Additionally, in 2012, the European Union (EU) released the energy efficiency directive which set the target for all EU countries to reduce their energy consumption by 20% by 2020 (EU, 2012). This further supports the decision to test changes by 20% as companies should already be familiar with this goal. Table 9 shows the effect on the environmental impact of these materials. As 10.38g of plasticiser is added per mask, to determine the change per mask, the values shown in Table 9 could be divided by around 100 to find the variation on a scale of one mask.

Table 9 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% and 18%. The greatest variation is observed for ODP where impact score increases and

Table 8

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 score of the three materials, green the lowest score, and yellow the middle score.

		Material (results per 1kg)		
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 9
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

decreases by 52.9ug 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 Fig. 8b). The impact scores 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.

3.7. Future research

There is further work that can be done to optimise the three oxygen masks within this study that does not necessitate changing material. Further research is encouraged to investigate the following.

- Future researchers may wish to explore the potential of optimising the weight of the masks. Using lightweighting simulation software can help identify if there are areas on the masks that use an unnecessary amount of material in order to fulfil its desired function and provide the required mechanical properties. For example, it may be possible to lower material thickness in areas by introducing rib design or optimising mask shape (Culley, 2001).
- Reducing the quantity or material type used for packaging would help reduce the environmental impact of the life cycle of the masks without requiring changes to the masks themselves. The packaging currently consists of paper, low density polyethylene, and cardboard. Using recycled content within these materials or encouraging the recycling of the packaging once discarded would help lower environmental impact (Peretz et al., 2021).
- Energy efficiency optimisation is encouraged during the manufacturing stage; particularly for the injection moulding machinery which consists the majority of the manufacturing processing used for these masks. Ways of achieving this could be through accelerated cooling, a change in materials used within the machine, or using electricity derived from renewable resources (Rashid et al., 2020; Strielkowski et al., 2021).
- Switching from the use of PVC to TPE within medical devices will come with its own societal and economic costs associated with a change in required machinery, a change in suppliers, and requirements for staff to be trained on manufacturing the new material. Future studies may wish to explore the potential economic costs of implementing these changes as well as perform a logistical analysis of how these changes can be made taking into consideration the impact on the workers and stakeholders involved.

3.8. Limitations

This section addresses the limitations identified in this research in order to provide transparency and inform user of how use this information. The limitations are as followed.

- There are a limited number of studies that calculate the environmental impact of medical masks to enable fair and accurate comparison and validation of the results of this study. This has been attempted using all available literature within section 3.3., but it would be desirable to further compare the results in the future as additional studies are produced.
- The life cycle assessments conducted within this study have been based on data from version 3.2. of the life cycle inventory database 'Ecoinvent'. The most recent version as of June 2024 is version 3.10. It would therefore be desirable for future studies to use the latest LCI data, if available, as this may result in slight changes to the overall absolute results.
- This life cycle assessment was conducted for three specific masks; the results could be used to inform stakeholders and policies, sector analysis, validate results and other studies in relation to the environmental impacts associated with MOMS. However, for manufacturers and end users of these kind of products, it would be desirable to conduct a life cycle assessment of their specific products to determine their impacts, the stage contribution and identify opportunities to improve the product's environmental performance.
- The results of this study have suggested that mask B (the TPE + PP based mask) has major environmental benefits in comparison to the PVC based masks. Before these conclusions are to be used for policymaking or marketing purposes, it is advised that an independent review is run by a review panel to ensure the results are up to current standards.
- Finally, various scenario analyses have been tested throughout this study to ensure validation of the results and testing of the various variables that could affect the masks' environmental impacts. However, it would be beneficial to have additional sensitivity analyses run in future studies, such as an uncertainty analysis, as these were not technically possible to conduct here due to limited access to additional LCA software licences.

4. 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 with reductions of at least 40% compared to the PVC-based masks across all impact categories. The global warming potential, abiotic depletion of elements, and terrestrial ecotoxicity potential were especially high for mask A (NonPht-plasticised PVC-based mask) which originated from the RMEP and end-of-life stages. In fact, the life cycle stages with the biggest contribution were shown to be RMEP and end-of-life for all of the masks studied. The majority of the environmental impact from the RMEP stage for masks A and C originated from the plasticised PVC; more specifically, from the plasticiser used. The end-of-life scenario (i.e., incineration) has been shown to comprise the vast majority of the impact (79%–94%) for the aquatic ecotoxicity potentials with >99% of this impact due to the incineration of the plasticised PVC for the PVC-based masks.

The lighter weight and material composition of mask B were found to reduce the environmental score of the RMEP, manufacturing, transport, and EoL 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 with a particularly low abiotic depletion of elements and ozone depletion potential; both over 83% lower than 1 kg of plasticised PVC. Only for photochemical oxidants creation potential was 1 kg of TPE more impactful than both of the plasticised PVCs and only by 1.3% compared to PVC plasticised with DEHP. Therefore, medical device manufacturers are encouraged to replace plasticised PVC with TPE-S for optimal environmental impact savings.

Switching from DEHP-plasticised PVC to TPE-S-based medical oxygen masks would reduce the impacts of the use of MOMS by 2755 tonnes of CO_2 eq. per year (from 4437 tonnes of CO_2 eq.). If plasticised PVC must still be used, 1 kg of PVC plasticised with DEHP material was found to have the highest impact score 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 for the production of the plasticisers. Therefore, in order to reduce the environmental impact of these plasticisers, focus should be placed on these areas. However, the sensitivity analysis showed that reducing the energy consumption during the production of DEHP by 20% would still not make it sustainably favourable to NonPht.

The scenario analysis demonstrated that environmental impacts can be reduced by manufacturing at a site closer to the location of the end-user and within a country that has a low emissions electricity mix. For this study a London-based hospital was used to represent the end-user and it was shown that manufacturing within the UK reduces total global warming potential across the entire mask lifecycle by over 11% when compared to the current manufacturing location of South Asia.

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 implement practical reductions to the environmental impact from the constituents of the DEHP and non-phthalate plasticisers using the areas of focus suggested within this study.

CRediT authorship contribution statement

Christina Webb: Writing – review & editing, Writing – original draft, Visualization, Validation, Software, Project administration, Methodology, Investigation, Formal analysis, Data curation, Conceptualization. **Lorna Anguilano:** Supervision. **Gera Troisi:** Funding acquisition. **Ximena Schmidt Rivera:** Writing – review & editing, Supervision.

Declaration of competing interest

The authors declare the following financial interests/personal relationships which may be considered as potential competing interests:

Christina Webb reports financial support was provided by UK medical device manufacturer. This research was undertaken whilst receiving a studentship by a UK medical device manufacturer. The authors declare no conflicts of interest. The funders had no role in the design of the study; in the collection, analyses, or interpretation of data; in the writing of the manuscript; or in the decision to publish the results. If there are other authors, they declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

Data availability

All data used in this article has been described in the inventory section and in additional SI

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Appendix A. Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.jclepro.2024.142903.

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