Journal of Cleaner Production 108 (2015) 363–376

Contents lists available at ScienceDirect

Journal of Cleaner Production

journal homepage: www.elsevier.com/locate/jclepro

Exploratory study of the state of environmentally conscious design in the medical device industry

James Moultrie [a, *], Laura Sutcliffe [a], Anja Maier [b]

[a] University of Cambridge, Department of Engineering, United Kingdom
[b] Denmark Technical University, Management Engineering, Denmark

ARTICLE INFO

Article history:
Received 6 March 2013
Received in revised form
12 August 2014
Accepted 4 June 2015
Available online 8 July 2015

Keywords:
Design for environment (DfE)
Medical devices
Ecodesign
Design for sustainability (DfS)

ABSTRACT

This exploratory study seeks to explore the current state of design for the environment (DfE) in the development of medical devices; an historically risk averse industry that lags behind others in terms of addressing environmental considerations. A cross-sectional survey of 34 medical device designers, primarily in the UK and USA, was conducted in order to fulfil this objective. Findings indicate that there is significant motivation to enhance DfE practice, but that there are multiple barriers to this. Major barriers identified are a perception of the high cost of DfE, the industry's current reliance on a single-use business model for many current products and a lack of education about DfE topics on all sides. Designers felt that the most significant opportunities to implement DfE are in situations where they are able to exert direct control, mainly in the early stages of the design process. Issues noted include raw material choice and packaging decisions. The nature of single use business models is also critical, pointing towards the needs for a systemic rather than product focus. For this to be achieved, financial rewards must be evident to firms and the changing regulatory landscape might also make a more significant impact.

1. Introduction

As part of the wider effort to create a more sustainable mode of existing, businesses are under increasing pressure to produce environmentally benign goods and services. Research activity in this area has been growing and as a result, more environmentally conscious products are being developed and consumed (e.g. Albino et al., 2009). The importance of eco-design in industry is not disputed and efforts are increasing to provide support or guidance to firms (e.g. Pigosso et al., 2013). However, there is little evidence of work specifically targeted at the medical device sector. This study is thus explicitly concerned with better understanding environmentally conscious design in the medical device sector, where the investment required in developing new products is very large and the environmental impact of devices is highly significant. For example, it is reported by Kadamus (2008) that 6600 tons (short tons, 1 short ton = 2000 lb or approximately 907 kg) of medical waste are generated every day by healthcare facilities in the US, much of which comprises medical devices. A large portion of this waste is considered hazardous, since it has been in contact with the bodily fluids of patients. Approximately 12% of this waste is non-hazardous plastic. Other environmental issues include the use of rare or harmful materials. For example, healthcare is the fourth largest contributor of mercury to the environment and a significant contributor of dioxins, another serious environmental pollutant (Zimmer and McKinley, 2008). Yet, it is reported that the healthcare sector in general has lagged behind other industries in the area of implementing environmentally conscious practices and literature on the subject is scarce (Karlsson and Ohman, 2005).

There are growing legislative pressures on the medical device industry to eliminate or reduce the impact of waste and especially of hazardous or toxic substances. Throughout the EU, all electrical devices are subject to the Waste Electrical and Electronic Equipment Directive (EU Directive, 2012/19/EC),[1] and this piece of legislation is closely tied with another ruling, the Restriction of Hazardous Substances Directive (EU Directive, 2012/19/EC),[2] which restricts the use of some materials deemed dangerous in the manufacture of electrical items. Medical devices can be exempt from this legislation if they are expected to be ineffective as a result. Medical devices are covered by The EU's 2009 Ecodesign Directive

* Corresponding author.
E-mail address: jm329@eng.cam.ac.uk (J. Moultrie).

[1] http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32012L0019.
[2] http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32002L0095.

http://dx.doi.org/10.1016/j.jclepro.2015.06.014

(EU Directive, 2009/125/EC)[3] which outlines requirements for energy-related products and includes the explicit consideration during the design phase.

Recognising that there is a significant problem where the designers of medical devices play an important role. But, there is little evidence regarding the knowledge and awareness of environmental concerns amongst these designers. Through this work we aim to take first steps in exploring the state of environmentally conscious design in the medical device industry, which is so far little discussed in the literature.

1.1. Definitions and terminology

Definitions of medical devices vary among different geographical areas, but in general they include articles manufactured specifically for diagnostics, monitoring, treatment, or modification of the human body, that are not solely pharmaceutical goods.

In the United States, medical devices are controlled and regulated by the FDA (Food and Drug Administration). In Europe, regulation is slightly more complicated, because the definition of a medical device is provided by the EU, but individual countries take on the task of approving devices for use inside their own borders (e.g. the MHRA (Medicines and Healthcare products Regulatory Agency) in the United Kingdom). USA and European definitions for medical devices are given below, since these are the two largest markets for medical devices (Epsicom, 2011a,b).

- In Europe, a medical device is defined as “Any instrument, apparatus, appliance, software, material or other article, whether used alone or in combination, together with any accessories, including the software intended by its manufacturer to be used specifically for diagnostic and/or therapeutic purposes and necessary for its proper application, intended by the manufacturer to be used for human beings for the purpose of: diagnosis, prevention, monitoring, treatment or alleviation of disease; diagnosis, monitoring, treatment, alleviation of or compensation for an injury or handicap; investigation, replacement or modification of the anatomy or of a physiological process; control of conception and which does not achieve its principal intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its function by such means.” (European Union, 2007).
- In the US, the FDA defines medical devices as “An instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including a component part, or accessory which is: recognized in the official National Formulary, or the United States Pharmacopoeia, or any supplement to them; intended for use in the diagnosis of disease or other conditions or in the cure, mitigation, treatment or prevention of disease in man or other animals; or intended to affect the structure or any function of the body of man or other animals, and which does not achieve any of its primary intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of any of its primary intended purposes” (FDA, 2011a).

Europe and the US are the leaders in the medical device world and these two definitions amount to much the same thing. Other countries use broadly similar definitions (for example Australia's, which can be found in their Therapeutic Goods Act, 1989), and means that there is little if any ambiguity in understanding what is meant by a medical device for research purposes. The definition is, however, necessarily broad, and covers a wide range of complexity; from simple tongue depressors, through syringes, blood pressure monitors, surgery tools up to large X-ray or MRI (magnetic resonance imaging) machines with many components.

In setting out the breadth of devices encompassed in these definitions, Hede et al. distinguish between class I devices (e.g.: tongue depressor) which are subjected to the least regulatory controls and Class III devices (e.g.: cardiac pacemaker) which must adhere to the most stringent regulatory controls, as they present a higher degree of risk to human health in cases of malfunction or erroneous use (Hede et al., 2013), see Table 1.

Table 1
Examples of medical devices (Hong, 2010).

Class	Description	Example
Class 1	Medical devices with minimal potential harm	Stethoscope (mechanical), thermometer (capillary, mercury), Centrifuge (tabletop)
Class 2	Medical devices with low potential harm	Stethoscope (electronic), Thermometer (electronic), Electroencephalograph, CT system, Electrocardiographic analyser
Class 3	Medical devices with moderate potential harm	Bone absortiometric ultrasound system, Condon, Haemiodialysis system, Prosthesis vascular (peripheral)
Class 4	Medical devices with high potential harm	Prosthesis vascular (central), Breast prosthesis (internal, gel-filled), Orthopaedic fixation plate (biodegradable)

Designing with the environment in mind also comes with a wide range of terminology; Design for Environment (DfE), ecodesign, green design, environmentally conscious design and more (Braungart et al., 2007). Alongside this plethora of terminology is a correspondingly wide range of definitions (Fletcher and Goggin, 2001). Despite the multitude of definitions available for these terms, they are all geared towards generating better environmental outcomes through design. In this work, the terms “DfE” and “environmentally conscious design” have been used to encompass these ideas, although the other terms, where they are used are intended to be interchangeable with these.

1.2. Development of environmentally conscious medical devices

Developing medical devices is complex, financially risky, requires large upfront investment and involves long lead times to market (Medina et al., 2013; Pietzsch and Pate-Cornell, 2008; Johnson and Moultrie, 2012). Most devices that enter clinical trials will fail before they reach the market and those that do end up on sale will have been through a lengthy and difficult testing process to ensure that the high standards required for use in humans are met. Rigorous (and necessary) focus on safety and efficacy has meant that efforts to minimise environmental impact are often deprioritised or postponed (Medina et al., 2013). In this respect, it is widely believed that the healthcare industry lags behind other

[3] http://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1407837072522&uri=CELEX:32009L0125.

industries in terms of DfE implementation (Karlsson and Ohman, 2005).

Despite lagging behind other industries in DfE activity, the medical device industry faces sustainability concerns common to the design process in many commercial areas; those around energy use, waste, consumption of scarce materials, consequences of waste and so on. These issues are relevant across all stages of the product life cycle from the extraction of raw materials, through manufacture, distribution, use and end of life. On top of this, the medical device industry faces some issues specific to healthcare and these are tightly tied with the process of new product design. Some of these major concerns are described below:

- *Waste*: The healthcare sector generates multiple and complex waste streams (Zimmer and McKinley, 2008). Several small scale studies or estimation exercises (e.g. Kadamus, 2008; Hutchins and White, 2009) have been undertaken, showing that vast amounts of waste are produced by medical facilities and that typically, much waste that ends up in sharps or biological waste bins is uncontaminated and could be disposed of through other means or recycled. Not only is there a clear opportunity for improvement on a purely environmental basis, but waste that is disposed of as hazardous and as a result is expensive to process (e.g. NHS Sustainable Development Unit, 2010; Zimmer and McKinley, 2008).
- *Toxic substances*: As well as concerns around waste, the industry faces growing pressure to eliminate toxic or hazardous substances, particularly mercury, from its products (EU, 2007). Other substances such as polyvinyl chloride (PVC) have also come under increasing scrutiny. PVC in particular has been the focus of attention since the phthalates used to soften the plastic can leach into substances with high lipid content and exposure to high doses of these phthalates can lead to reproductive problems as well as toxic effects in the heart, lungs and kidneys (Tickner et al., 2001). There is some debate about the level of risk actually posed to human health, but in the face of controversy about these chemicals, it is likely that the medical device industry will be expected to respond to these concerns and design products accordingly. As substances like these become subject to stronger controls from regulatory bodies, it is likely that regulation in other areas will also tighten. Medical devices were previously exempted from the EU Waste Electrical and Electronic Equipment Directive, which governs the end of life requirements for electrical goods in the EU. However, since 2012 medical devices are no longer exempt unless they will become bio-hazardous during the course of their use (Directive 2012/19/EU), and the healthcare industry in the EU will have to change to accommodate this. This, alongside increasing producer responsibility obligations in general, will put pressure on the medical device manufacturing industry (Marshal et al., 2009).
- *Single use business model*: Closely tied with issues surrounding waste disposal is the industry's favoured single-use device business model. During the 1980s and 1990s business models for single-use devices began to emerge. Many products are marked by the manufacturer for use only once and so they are discarded when they have been opened, irrespective of whether they have been used with a patient. This practice generates huge quantities of waste and single-use medical devices have been under close scrutiny in this respect for several years (Stripple et al., 2008). In many cases disposal is appropriate (e.g. where a device that cannot be sterilised comes into contact with bodily fluid), but in other cases safe reuse is possible, even though the product is marked as single-use. In the US, organisations that take care of the safe reprocessing of single-use devices have started to emerge (e.g. Stryker Sustainability Solutions), although the use of reprocessed devices is far from common place, and is otherwise virtually unheard of in the western world.

The topics discussed here do not by any means represent all the issues facing designers in the medical device industry seeking to implement DfE, but these major areas are the starting point for discussion. However, this discussion is currently very much in its infancy within the industry, despite the presence of organisations advocating greener practice in the healthcare industry in general.[4] As a result, it is difficult to uncover much evidence of environmentally conscious product design in the medical device industry. There are a few isolated published or documented examples of deliberate DfE work in the industry such as Hanson and Hitchcock (2009), and the environmentally friendly syringe "Syreen" designed by Engineering Consultancy, Cambridge Consultants Limited (www.cambridgeconsultants.com) but by and large, the medical device design industry is only just getting started in this area. Individual companies may promote their own environmental credentials, albeit often as part of an overall commercial strategy.[5] Furthermore, the isolated nature of individual case examples demonstrates the lack of knowledge about environmentally conscious design practice in the medical device industry as a whole. This lack of case-studies is significant, as designers by their nature take inspiration from prior design work.

The characteristics of environmental impacts vary by industry sector, as do the opportunities for improvement (Vezzoli and Sciama, 2006; Pearson, 2008). Thus, in order to make improvements in the medical device sector, it is necessary to focus on design issues of specific relevance to this sector alone. In conjunction with industry-specific design concerns, it is also necessary to understand the motivating factors to practise DfE in the first place. Previous work by (e.g.) Borchardt et al. (2010) demonstrates that factors influencing the use of DfE may be internal or external to the company in which the design takes place. Internal factors would typically be company such as management initiatives; external pressures would be issues such as client or user demands, regulatory requirements and national (or international) level governmental pressure. With this approach in mind, this study aimed to assess the current state of DfE practice in the medical device industry. It is believed that this 'baseline' of understanding is a critical foundation on which to build further understanding of how, ultimately, more environmentally benign medical devices might be created.

2. Method

To address the gap articulated above, this exploratory study specifically aimed to:

1. Explore designers' attitudes to DfE in medical devices
2. Understand which areas of DfE designers felt were most relevant to their work
3. Establish what, if any, DfE in medical devices they had undertaken
4. Discover whether medical device designers use any tools to help them in pursuit of DfE objectives
5. Gather opinion about DfE in medical devices from practitioners in the field more generally

[4] Examples include Health Care Without Harm (http://www.noharm.org), The Climate and Health Council (http://www.climateandhealth.org) and The Centre for Sustainable Healthcare (http://sustainablehealthcare.org.uk).

[5] e.g. Novo Nordisk: Our Triple Bottom Line. Retrieved 10 18, 2012, from http://www.novonordisk-us.com/documents/article_page/document/Triple_Bottom_Line.asp.

To achieve this, a cross-sectional survey of medical device designers was conducted to gather information on current DfE practices and understand trends and perceptions in the medical device industry. This approach was chosen in preference to interviews with individual designers, as it was felt that whilst this might yield detailed data, it would by its very nature provide only a very narrow view into practices in this field. In addition, selecting specific candidates for interview who are representative of their peer group would have been problematic. Indeed, the danger of an interview based approach would have been the selection of candidates for interview who by their expressed interest in the subject might be adopting more advanced practices than some of their colleagues. Also, it is sometimes difficult to compare data from semi-structured interviews, which by their nature enables the interviewer to follow new leads and explore new territory as a conversation progresses. Instead, the intention of this study was to collect comparable evidence from as many medical device designers as possible, in order to address the gap perceived in knowledge which characterises a wider set of practices across this sector. In fulfilling these objectives, the survey collected data from within the industry, examining both internal practices at the companies in which the designers were working and external factors that may influence the designers. The target audience for this survey was practising or ex medical device designers.

The survey was designed and distributed using online survey tools from Qualtrics (www.qualtrics.com) and was presented in a neutral colour scheme. Questions were arranged into short sections, with the intention that questions progressed from general to specific. In addition, questions that were viewed as most valuable to the study were placed towards the beginning of the questionnaire, to increase the likelihood of gaining useful responses. Sections were as follows:

- *Introduction*: An introductory message summarising the context for the survey which offered background information and assured of participant confidentiality.
- *Screening question*: As an online survey, it is possible that it might be completed by respondents not in the target group. In order to ensure that only people in the target group responded to the survey, a screening question was included; “Are you, or have you been, involved in the design of medical devices?” Those who failed the screening question were excluded from the rest of the survey.
- *About you*: Participants were asked some basic details about their job and the organisation for which they worked.
- *Designing for environmental sustainability*: This section asked about the drivers of DfE practice and how important participants perceived it to be. In addition, participants were asked to identify the major barriers to DfE implementation and whether or not participants had used any tools to assist in the implementation of DfE principles.
- *Sustainability concerns*: Designers were asked how important a variety of specific DfE issues were in their work and whether or not they had addressed those issues in the design of previous medical devices.
- *Further comments*: Participants were invited to leave any further thoughts on the topic of DfE in medical devices.
- *Demographic information*: Finally, respondents were asked for information about their location, age and gender, as well as the size of the firm in which they worked.

The survey was initially piloted using a group of ten subject-naive people, in order to check that questions were unambiguous and that the instructions were correctly interpreted by participants. The release version of the survey was then finalised, incorporating necessary modifications from the pilot phase. The survey was distributed by giving potential participants a link to the survey's online location. The full survey is reproduced in the Appendix to this paper.

Online distribution was considered the most desirable option on the grounds of cost, speed of response collection and ease of secondary participant recruitment (recruitment of people who were not sent the link first hand by the researchers). Participants were recruited by email, or in person, beginning with industry professionals known to the authors and their immediate contacts. Potential participants contacted in this way were invited to pass on the web link for the survey to others. Participants were also recruited through the alumni network at the University of Cambridge and via posts in online forums for medical device engineers. It was believed that ensuring participant anonymity was necessary in order to gain responses. However, a downside of this approach is that it almost impossible to identify the specific mechanism by which a particular respondent became aware of the study and thus, we have no data on the success of each of the various participant recruitment strategies.

The survey was ‘live’ online for a period of two months after which it survey was closed and results were drawn together for analysis. Two months was believed to be a sufficient period of time to ensure that the survey was both circulated widely and that potential respondents were given sufficient time to respond. During this period, frequent reminders were sent using the mechanisms described above.

3. Sample

42 people responded to an invitation to take the survey, eight of whom were eliminated by the preliminary screening question (Appendix, Q1.1). Respondents who had completed the screening question successfully but left no further information or left responses consisting only of nonsense character strings, were eliminated at the outset and are not included in the 42 responses referred to above. This left 34 complete responses to the survey from people who were in the target group – medical device designers.

Respondents included 29 men and 5 women. 88% of respondents were in the United Kingdom and 12% were in the United States. The majority of respondents (64%) were aged between 25 and 34 years, although there were exceptions in both directions. Participants worked for organisations that varied in size from a single person to more than 1000 employees, the modal class being organisations with between 11 and 50 employees, to which 44% of respondents belonged. 67% of respondents had worked in an industry unconnected to medical devices at some point in their career; 33% had worked solely in the medical device arena. Respondents had self-identified as having experience in the design of medical devices. Of the 34 respondents, 12 were from technology based firms with a background in the medical sector, 10 were from specific medical technology firms, 10 were from design service firms with a specialism in medical devices and the remaining 2 were in the healthcare sector. The majority of respondents were designers or design engineers (7), some at a more senior level (7). Six respondents described themselves as consultants/senior consultants. The remaining respondents included 4 researchers, 3 Directors/CEOs, 2 in commercial management, 2 in project management and 3 ‘others’.

No attempt was made to specify or constrain respondents in terms of the specific nature of the medical devices which they design. Issues around environmental design are relevant to the development of all devices, whether they are complicated electromechanical machines or simple solutions.

As an exploratory study, we acknowledge that this sample is comparatively small, it is also necessary to note that this is a very specialist field. The majority of respondents are also comparatively young and this may well reflect the approach taken to data collection. Overall, we believe that this sample is characteristic of the sector and that the responses are representative. However, we also recognise that care must be taken in generalising the results to be reflective of the whole population.

4. Results and analysis

Due to the nature of the data collection method, the sample represents English-speaking designers who had either been touched directly by one of the recruitment methods detailed in the previous section, or had had the survey link passed to them. It is inevitable that some designers will have felt more inclined to fill in a survey about environmentally conscious design than others and some of these might well have had at least a passing interest in sustainability. This does not necessarily mean that all participants had a special affinity with the subject matter, but it is impossible to tell to what extent this influenced the data, and there is no control for this in the analysis process. In detailing these results, a mixture of straightforward graphical representations, statistical techniques and quotes from participants have been used, where appropriate, in line with the spectrum of questions posed.

4.1. Attitudes to DfE

16 respondents indicated that they thought the impetus to design for the environment was increasing; a further 16 believed that it was "remaining about the same", and the remaining 2 thought that it was decreasing. This is shown in Fig. 1. We might conclude from this that there is substantial belief that the need to consider the environment is increasing, but also that there is still a belief among designers that it is *not* increasing.

Participants were asked to score a list of five potential drivers for action in DfE, derived from literature as described in the introduction. In addition to these factors, a further driver was added to account for the case that the designer felt personally motivated to design for the environment, in addition to other factors. Scoring was on a scale from 0 to 100 with 0 indicating that the issue was not a driver for DfE, 100 indicating a very strong driver. Participants were also offered the option to specify another driver and to rate this in the same way. Respondents placed the given drivers in the following order (strongest to weakest).

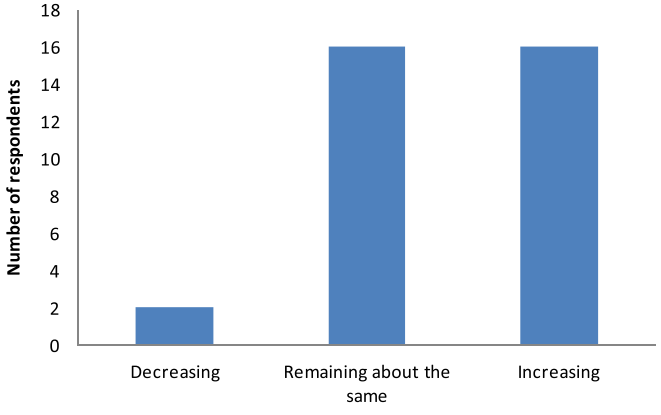

Fig. 1. Survey participants' opinions on the impetus to design for the environment ($n = 34$).

- Other (explained further below)
- Regulatory mandate
- Client demand
- Pressure from government organisations
- Individual choices of designers
- Internal company pressure

The importance values assigned to these drivers are shown in Fig. 2.

It is interesting to note that the dominant drivers for DfE are 'external' to the firm. Indeed, the designer's intrinsic motivation is actually viewed as more influential than pressure within the firm. It might be speculated that this lack of company motivation is driven by financial gains due to a predominantly singly-use business model. It also highlights that without external pressure, change is unlikely to come from within, unless the firm perceives clear competitive advantage.

The 'other' category accounts for a broad spread of ideas and interests which respondents felt was not encapsulated in the five notions presented. Interestingly, where respondents had chosen to add their own driver, they always assigned this the highest score; presumably because they felt that an important issue had been missed. Issues raised in this way included:

- Cost reduction (3 respondents)
- Problems with raw materials (1 respondent)
- Improvements in technology which make DfE less commercially risky (1 respondent).

It should be noted that although the 'other' category overall is dominant, we cannot say that these items individually are more (or less) important than the five predetermined items.

Participants were then asked to identify how DfE manifested itself in the work that they actually did, by choosing from a list of statements that covered a range of scenarios (e.g. "it is not important but we will comply with the law where we have to"). Respondents were asked to select the description that they felt best fit their attitude towards DfE. These scenarios and the number of respondents choosing each option can be seen in Fig. 3. This illustration shows that the most common scenario is that designers choose to incorporate DfE practice into their work voluntarily, but that other things are more important. Overall, these responses indicate that DfE is a low priority for designers, with consideration only given when either they are required to by either clients or legislation. This confirms the views expressed in Fig. 2.

4.2. Specific design issues

Participants were presented with a list of DfE considerations generated from literature, broken down into product life cycle phases to aid clarity. They were then asked to assign a score from 1 to 5 to indicate how important each issue was in their design work (1 represented issues that were unimportant and 5 represented issues that were very important). Respondents were also asked separately to what extent they had tacked the same set of issues during the course of their work. Data from responses to these questions were used to rank the design issues for both perceived importance and the extent to which the designers in the sample had tackled them. A summary is given in Table 2 and a plot detailing the two sets of ranks is given in Fig. 4.

The two sets of ranks were analysed using Spearman's correlation coefficient to ascertain their level of covariance, in other words to determine to what extent a high rank in one list was associated

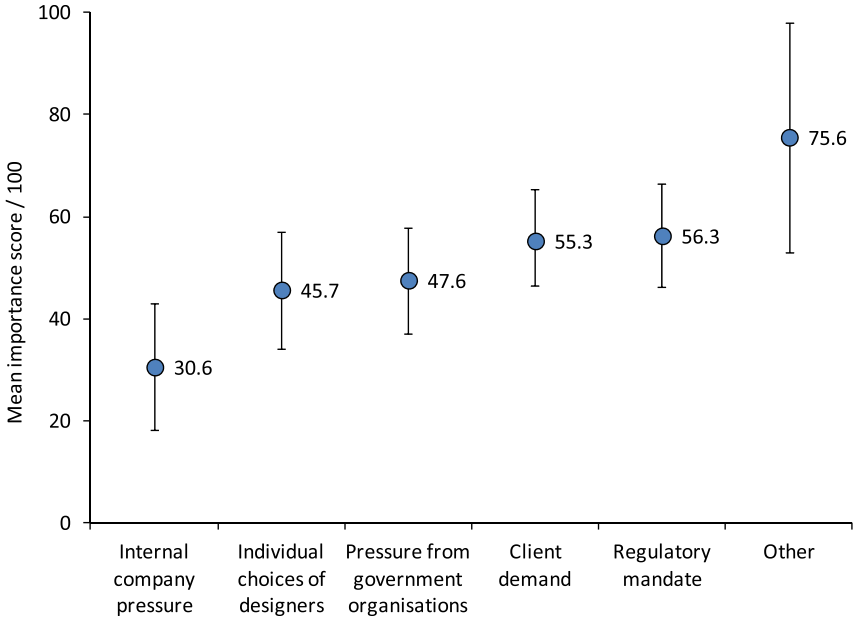

Fig. 2. Drivers for DfE in medical devices (error bars represent 95% confidence intervals for each mean) ($n = 34$).

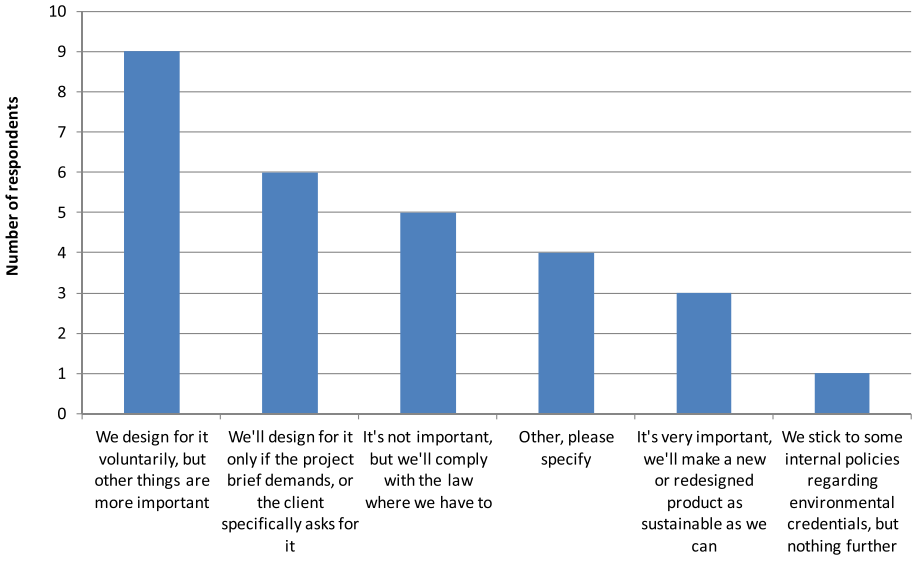

Fig. 3. How DfE manifests itself in the work of medical device designers ($n = 34$).

with a high rank in the other list.[6] Spearman's rank correlation coefficient for this data set was computed as $r_s = 0.818$ ($t = 7.79$, $p < 0.001$), indicating that there was a strong correlation between the two sets of ranks, in other words, if designers considered a DfE issue to be important, then they were also more likely to have tackled it.

There are several places where there is a notable disparity between the ranks in the two lists for a particular design issue. These can be seen as the outliers in Fig. 4 (these are circled). The points below and right of the main cluster represent over-implemented issues (that is to say that they scored disproportionately highly for having been addressed compared with their score for importance) and points above and left of the main cluster represent issues that are under implemented (that is to say that they are considered important but comparatively little action has been taken to address them). Overall, there were fewer issues which were viewed as 'under-implemented' compared with those that are 'over-implemented. This suggests that designers might believe that enough is being done to tackle key issues overall.

Under implemented issues include:

- *Harmful substances in bill of raw materials*: ranks 1st in importance, but 4th in level of implementation, suggesting room for improvement.

[6] Spearman's rank was used since it could not be assumed that the underlying data was normally distributed. An alternative analysis could have been conducted by determining the Pearson product–moment correlation coefficient for the unranked data, but this test is more sensitive to outliers and requires that the data be normally distributed.

Table 2
DfE issues ranked by importance and the degree to which they had been tackled (ranging from 1 unimportant to 5 very important).

Rank by mean importance score assigned by designers	Rank by whether or not designers had tackled the issue	Mean importance score assigned by designers	Number of designers who had tackled the issue	Life cycle phase	Design issue
1	4	4.2	19	Raw material sourcing	Harmful substances in bill of raw materials
2	16	3.9	10	Raw material sourcing	Use of mercury
3	1	3.5	22	Use	Lifetime/upgradeability
4	4	3.4	19	Use	Single use components
5	4	3.3	19	Distribution	Space efficiency of packaging
6	4	3.1	19	Distribution	Amount of packaging
7	9	3.1	16	Manufacturing	Processes used in assembly
8	9	2.9	16	Raw material sourcing	Use of scarce materials (e.g. precious metals)
9	14	2.8	11	End of life	Designed for reuse
10	2	2.8	20	End of life	Designed for disassembly
11	2	2.8	20	Use	Energy consumed during use (including sterilisation requirements)
12	11	2.8	13	Manufacturing	Solid waste produced
13	11	2.7	13	Distribution	Materials used in packaging, including recyclability
14	8	2.7	17	Manufacturing	Use of PVC
15	18	2.7	9	Distribution	Method of transport
15	14	2.7	11	Use	Solid waste produced
17	16	2.6	10	Manufacturing	Processes used in raw material conversion
18	22	2.5	8	Manufacturing	Waste water produced
19	18	2.5	9	End of life	Designed for recyclability
20	13	2.5	12	Raw material sourcing	Recycled, reused, or remanufactured content
20	18	2.5	9	Distribution	PVC content of packaging
22	23	2.4	7	Use	CO_2 emissions during use
22	26	2.4	5	End of life	Proportion which must be land-filled or incinerated
24	23	2.4	7	Distribution	Distance from production site to buyer
25	9	2.4	16	Use	Waste water produced
26	23	2.3	7	Manufacturing	Energy sources used in assembly
27	26	2.3	5	Raw material sourcing	Diversity of raw materials
28	29	2.2	2	End of life	Designed for remanufacture
29	18	2.0	9	Manufacturing	Energy sources used in conversion processes
30	28	1.9	4	Raw material sourcing	Energy sources used in extraction
31	30	1.8	1	Raw material sourcing	Processes of extraction

- *Use of mercury*: this is the largest disparity for under-implementation, which ranks second for importance but only sixteenth for actually having been addressed.

Over-implemented issues include:

- *Designed for disassembly*: Ranked second highest for implementation and 10th for importance.
- *Energy consumed during use*: Ranked equal second for implementation and 11th for importance.
- *Use of PVC*: Ranked 14th for importance and 8th for level of implementation.
- *Waste water produced*: ranked only 25th for importance but 10th for level of implementation.

Other potentially over-implemented issues included addressing the energy sources used in the conversion of raw materials and the use of recycled/reused or remanufactured components in production. It is also necessary to note that items which are fully implemented become standard practice and as a result, their relative importance would be expected to fall in comparison to new issues.

Responses were also analysed in order to ascertain whether individual life cycle phases were considered significantly more or less important than the others, or had been tackled in preference to the others. The raw scores from the questions about importance were grouped according to life cycle phase and then subjected to one-way ANOVA testing. No significant difference in the mean importance values assigned to issues was detected at the life cycle phase level ($F(4, 728) = 1.62$, $p = 0.168$). Yes/no data for whether individual design issues had been tackled was transformed into numerical values, and then grouped by life cycle phase in the same way as the importance scores, above. One-way ANOVA was then conducted in order to see whether some life cycle phases had been tackled in preference to others. This analysis showed that one or more significant differences existed between the means of the five groups ($F(4, 726) = 5.05$, $p < 0.001$). Post-hoc analysis using the Tukey–Kramer test revealed that both the distribution and end of life phases had been tackled significantly more than the extraction of raw materials ($p < 0.01$). All other interactions were insignificant, meaning that in general DfE effort had been spread fairly evenly among the life cycle phases outside of the two interactions mentioned previously.

4.3. Barriers to implementing DfE in the medical device industry

Participants were asked what they perceived to be the major barriers to the implementation of environmentally conscious design in medical devices. Responses were collected using a free form text field. This led to answers of varying length and complexity. Since the data collected was qualitative, the information was coded by first providing a broad or high-level classification to each comment in order to provide an initial grouping of ideas. Where more than one idea was represented in a statement, then this was allocated to two groups. These groups were then reviewed again until no new or alternative groupings or themes emerged. These themes represent the key barriers perceived by the designers in the sample and are outlined below. The order in which they are listed is not significant.

- *Cost*: this was by far the most commonly cited barrier (17 out of 34 respondents mentioned it in some form), although few specified where these costs originated or with what they were associated. Those that did also associated increased cost with

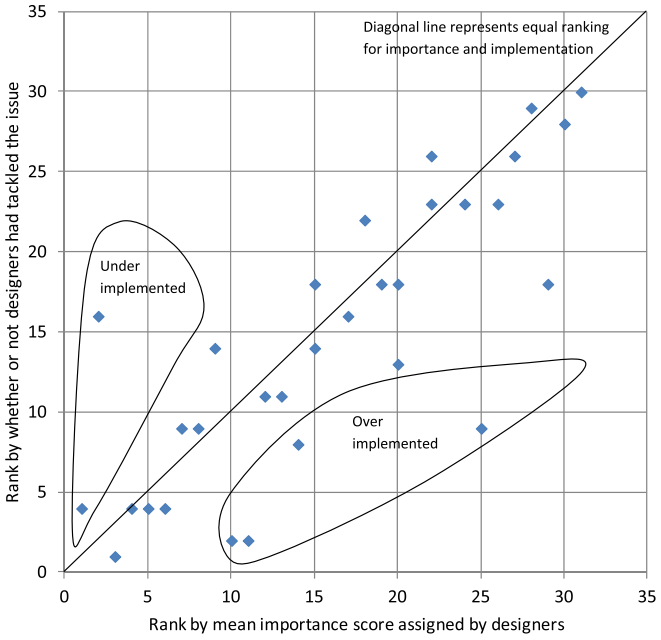

Fig. 4. Design issue ranks: importance assigned by designers against the degree to which they had been tackled.

extra time spent in the design process, the cost of environmentally friendly materials, and the initial investment required to move towards designing sustainably. One respondent said that clients resisted extra costs associated with designing for the environment. Another said: "The industry is very cost conscious. Unless environmental considerations are enforced through regulation they may not be considered unless the sustainable options clearly positively affect revenue. In the medtech industry, where reimbursements are fixed and in the current climate may not be increased for the next year, the device/consumable would need to be cheap as well as green." This indicates that DfE must support cost reduction rather than contradict it if it is to cease to be a barrier. Other responses indicate that this can indeed be the case: "*Quite a lot of these issues are just good design and save cost anyway.*"

- *Other design factors take priority*: Some participants highlighted the number of other things that they were asked to consider in the design process as a reason for not actively practising design for environment techniques; "*We have so many other constraints to fit, it [DfE] often gets pushed aside.*" Typically respondents listed these other, to them more important considerations or objectives, as safety, efficacy and reliability.
- *Client perceptions and demands*: Some respondents referred to a lack of client demand, or particular attitudes to the way in which designing for the environment should be implemented: "There seems to be an inherent fear of recycling anything biological regardless of how it has been processed. It seems like clients are more willing to have environmentally conscious design upfront that minimises materials, shipping etc. than have to deal with processing later."
- *Regulatory issues*: One participant perceived regulatory activity (in the UK) to be discouraging activity in DfE by encouraging growth in the use of single-use devices. Two participants expressed concerns over gaining regulatory approval to use newly developed materials in medical devices. It was also noted that once a device has been given regulatory approval, it is difficult to implement design changes retrospectively.
- *Business model*: Several respondents indicated that the current business model in medical device manufacture (single-use items or components rather than durable or reusable equipment) was a hindrance to implementing environmentally conscious design: "For medical devices, there is an ever increasing trend towards increasing the amount of disposable parts, driven by ease of use, sterility, and preference (by business investors and users) for pay-per-use business models rather than investment in durable equipment"
- *Risk*: In an historically risk averse industry, it is no surprise that designers perceive the DfE arena as risky.

4.4. Urgent DfE issues to tackle in the medical device industry

Participants were asked what they thought the most urgent issues to tackle in the area of DfE for medical devices. Responses were collected using a free form text field and all responses were coded using the same procedure described above. The resulting concerns fell into four categories, which are detailed and discussed below. Where appropriate, illustrative quotes are given from the responses collected.

- *Product-specific design issues*: Many comments mentioned product specific design issues. These ranged from the effective use of materials, through the overuse of batteries to end of life handling. Recycling and packaging were mentioned more than other topics, and, in particular, packaging seemed to be an area that was perceived as readily tackled: "I don't think there is any excuse for not using environmentally low-impacting materials and processes in medical device packaging." A small number of designers alluded to the need for greater understanding of how third parties interact with medical devices, indicating that more information or research may be needed in this area before design improvements can be implemented.
- *Education of designers and clients*: This issue also appeared in responses to the question about barriers to DfE implementation, indicating that it is both important and problematic. "Educating the manufacturers [clients] that intelligent design in a sustainable manner can save money." Other responses indicated that "*freely available and consistent guidance*" was necessary. This supports the suggestion that designer education may be both inconsistent and important.
- *Business model*: The concern most widely discussed was the issue of the proliferation of single use devices, and the business models that rely on the continued supply of single-use goods. (The most common barrier to DfE implementation cited was the cost involved – as described above). It was acknowledged by many respondents that single-use medical devices can have deleterious consequences for the environment: "This topic is a tricky balance. When medical parts were all stainless steel, reused and sterilised, there were issues with cross infection, and costs of sterilisation. Single-use disposables are a safer product, that in many ways can consume less energy, but will result in landfill." Several of the designers in the sample felt that this issue should be the priority for DfE in medical device design, saying that the top concern should be "*finding out how to make single-use disposable devices that are environmentally friendly.*" At the moment, it appears that there is greater incentive to stick to a single-use model; "Sometimes products are deliberately designed to be single-use to match the business model or to make it easier for the user, even if functionally they could be reused." In addition, designers drew attention to the fact that, although they may be able to design for DfE, the overall impact of such work is dependent upon the cooperation of the whole system, both locally and globally: "Whilst the blister packaging used to package products is PETG and can be recycled, it is

frequently not. The same is true for the cardboard packaging used to contain them. If the design is to be environmentally friendly then the hospitals need to have systems in place to deal with the designs/materials (…) Whilst legislation can force manufacturers to be more environmentally friendly the end user needs to have systems in place to perform this process."

- *Industry paradigm*: Designers in the sample acknowledged the industry setting as a function of their ability to change and shape business models: "Sustainable design is still relatively new in the product development industry, and is certainly not common practice everywhere. It will take time for engineers and designers to adjust their approach to produce more sustainable designs, and it will take even longer for this to happen in conservative sectors such as medical, military and other high-reliability applications." And, "In countries or places where these methods are not available it is easier for medical companies to supply single-use devices that are less environmentally friendly but clinically effective."

Finally, it was acknowledged that a culture of cautious behaviour is present in the medical device industry and one designer even singled this out as the most urgent issue to tackle.

4.5. Role of government and regulation

Comments from designers suggested that governments could apply financial pressure (either directly or indirectly) in order to make the industry move towards more sustainable designs: "*Make it expensive to not be environmentally conscious and the market will move very quickly.*"

This could be done either by applying pressure directly to manufacturers, or by applying pressure to end users (say, hospitals) by, for example, making waste very expensive to dispose of, making low-waste devices much more attractive to buyers. There is also sentiment that suggests such moves will have to be imposed, rather than encouraged: "I am not expecting medical device manufacturers to go green unless the regulators force [it] upon them."

This opinion contrasts with that of others in the sample who placed different factors, such as the need for designer education or revision of business models as the most important problem to tackle. Overall, this implies that there is a wide range of attitudes towards environmentally conscious design within the industry, and thus potentially a wide range of levels of implementation.

5. Discussion and conclusions

Results show that there is motivation to design for the environment in the medical design field, although this is not consistent. A large portion of the practitioners in the sample recognised that there is a growing need to act upon environmental sustainability issues in the design of medical devices, although a similarly large proportion thought that this need was remaining static. The more detailed questioning revealed that the prevalent attitude among the sample was to implement DfE voluntarily, but to place other considerations first. Only a small minority said that they 'do the minimum' to remain compliant with law, and there was some indication that clients are increasingly requesting environmentally conscious design. Taken together, these findings point towards more DfE activity in the industry in future.

5.1. Drivers for DfE in the medical device sector

Results indicate that designers feel that the major drivers for DfE in the medical device industry are business imperatives; the law and the wishes of the client. This is unsurprising, as failure to respond to either of these would result in serious problems at organisational level. It is, notable, however that both the individual choices of designers and pressure from governmental organisations were considered to be more important than company initiatives, indicating that in general, the perceptions and motivations of individuals to produce environmentally conscious designs are ahead of co-ordinated policy and efforts from their companies as a unit. This suggests that implementation of DfE principles could be patchy, and will depend on the views of the particular designer, rather than being guided at the company level.

Van Hemel and Cramer (2002), in their cross-industry survey, also find that client demand and regulatory issues are the top two drivers for DfE activity, although they specifically identify lack of client demand as a more important reason to delay DfE implementation than a lack of regulations. The medical designers in this survey suggested that regulatory mandate was a stronger driver than client demand. This is likely to be a consequence of both the heavily regulated nature of the medical device industry and the lack of user choice in the UK (where most of the survey respondents were located, and where centralised healthcare in the form of the NHS, means that decisions about which medical devices to use are often taken away from patients and sometimes from clinicians). It is not known whether more importance would have been given to client demand as a driver if more respondents had been from countries without centralised healthcare.

It is not clear why internal company pressure is perceived as the weakest of the drivers. Potential explanations include poorly implemented or weak policy, policy that is overwhelmed by other priorities or simply that policies do not exist at all. PR and press attention were identified by respondents as an additional driver, and it would be interesting to uncover how strong this influence is in future work. This contrast between the desire for positive PR but at the same time a lack of company pressure for DfE might suggest that firms are seeking to persuade customers of their eco-credentials but are not matching this with concerted action. The notion that design constraints in non-DfE areas, such as safety, can stimulate DfE activities as well as inhibiting it showing that DfE activity can both complement and constrain wider design objectives. In addition, the perceived riskiness of DfE as a strategy varies among designers. Some see the risks reducing as environmentally conscious technologies become more widely implemented and trusted. It is evident that in order for DfE initiatives to be adopted, they must first and foremost deliver commercial or competitive advantages to the firm. If these financial rewards were more evident, then action might become more of an internal driver.

5.2. Current DfE activity in the medical device sector

Statistical analysis of survey responses showed that if designers considered a specific DfE issue to be important, they were also more likely to have tackled it. This finding is both logical and at the same time slightly surprising. It is logical because issues that are perceived to be important are naturally tackled first. It is slightly surprising since most of the literature points to an industry where little DfE activity is taking place. It seems that some of the top priorities are already receiving attention from designers, and this in turn suggests that structures and systems for the incorporation of DfE concerns may already exist in some companies. With the exception of the inclusion of mercury in devices, the top few issues for importance also scored well for having been tackled, similar to Van Hemel and Cramer's (2002) study of eco-design in SMEs.

The issues that scored highly for importance are *all* issues that designers can control directly and comparatively easily during the early stages of the design process. Concerns that appeared at the bottom of the importance list, also tended to have low scores for

having been tackled. These were mainly issues over which designers had little control, and which could not be reliably "designed in" to a device. As an example, the inclusion of harmful substances in the bill of raw materials was considered more important and had been tackled by more designers than the processes involved in the extraction of those materials.

The confirmation that distribution and end of life issues had been tackled significantly more than the extraction of raw materials further supports the assertion that designers have tackled the issues over which they have the most control in preference to others since it is far easier to design "for" the distribution process (via good packaging design) and for the product's end of life, than it is to control the way raw materials are processed through the design of the product. However, although designers may have a lack of direct control, they do have a significant influence through the materials that they select.

Packaging in particular has relatively few barriers in terms of DfE implementation, since designing with the environment in mind generally means using less material, which supports cost reduction, and is less important clinically, although sterility requirements remain.

5.3. Difficulties in implementing DfE

The most prominent difficulty that emerged as a roadblock to implementing DfE was that of perceived cost. Often those commissioning the work (a client, or another department within a company) had a pre-existing belief that DfE would mean additional net expense. This perception must be dispelled either though education or demonstration if more work is to take place in the area. Cost optimisation is a core business tenet, so DfE must support work in this area if it is to achieve wider acceptance.

There were some suggestions that clients currently seem more willing to accept DfE work at the front end of the product life cycle than to face the more complex issues associated with the product's end of life. The evidence for this, though, was anecdotal and warrants deeper investigation, given that it contradicts the findings above, which suggest that end-of-life was one of the better-addressed life cycle phases.

The reprocessing of single-use devices is currently discouraged in the UK (the single-use business model is discussed in more detail below), and there was also some sentiment that newer materials may cause regulatory difficulties if they are used in devices. In these ways regulation is currently seen as a hindrance, but designers could easily see ways in which regulation could be used to force DfE rather than discourage it (e.g. by making it financially punitive to have devices with certain characteristics through either taxes or fines). The potential impact of regulators in future is discussed below.

The risk-averse nature of the medical device industry and the perceived riskiness of DfE were identified as a major hurdle. Research suggests that some risk aversion is justified since being the first to market with explicitly green products does not guarantee success (Marcus and Fremeth, 2009). Yet, it is highly likely that while designers see, and respond to, the cautious nature of the industry, in some cases they can also exploit areas in which the perceived risk is starting to reduce, as DfE methods and practice become more common place.

5.4. Issues in urgent need of tackling

The diversity of the issues that were perceived as urgent was telling in itself; action is needed from government, from industry, from companies and from individuals. At national level, the indication from some designers that regulatory intervention would be necessary to induce change indicates that on at least some level there is a lack of forward motion in DfE implementation in the medical device industry. There is some indication that regulation is increasing (most medical devices fall under EU WEEE legislation from 2012 onwards, as mentioned in Section 1.2) and as such it is likely that there will indeed be regulatory push in some areas in the future.

The discussion surrounding single-use medical devices is evolving rapidly, and is likely to produce interesting conflicts between medical device manufacturers, whose income depends on selling a steady stream of single-use goods, and hospitals and other healthcare facilities that wish to cut costs as safely as possible while maintaining patient confidence in the treatment they receive. Business incentives for manufacturers are currently largely to remain with a single-use model. It is here that significant effort is needed as these problems are associated with a complex product service system, in which the manufacturer is but one player (Lindahl et al., 2013). The whole system must be addressed and not just the 'device' in isolation. Thus, whilst individual firms may be able to secure financial returns for ecodesign (Plouffe et al., 2011), in medical device development, the challenge is to focus on optimization of the whole system and not just the needs of an individual player. Thus, a move towards product service systems offers the potential to better address many environmental concerns, but to do so demands cooperation from stakeholders which are currently often in competitive or transactional role (Mont, 2002).

At the company level, there is a clear need to tackle the patchy nature of designers' education around DfE topics. Many designers admitted that they were looking for guidance, or said that their clients (or other departments in the company) needed to better understand the issues at hand before there would be a noticeable change in the outputs of design work.

At the level of the individual designer, some issues were highlighted as "easy wins", such as packaging, where it is fairly straightforward to take into account clinical requirements while drastically reducing the amount of material used, as discussed above. It is highly likely that issues such as this will be tackled first, particularly where these design modification can support cost reduction strategies. Other urgent issues such as recycling are likely to be more difficult, and therefore slower, to implement, since they require system change as well as design change to ensure that designs that enable recycling actually result in the reprocessing of the waste.

At all levels it was acknowledged that it will take time to see changes within this highly conservative industry.

5.5. Methodological limitations

Data collection was conducted solely online and only in English, which restricted participation to English speakers with online access. It is, however, unlikely that anyone actively engaged in the commercial field of medical device design routinely operates without internet access. The online and anonymous format of the survey also meant that there was no interaction between the researchers and respondents. This prohibited any discussion of long or complex responses. An attempt was made to counter the effects of this by providing large text boxes for responses for open-ended questions, nevertheless, this limitation remains.

Distribution of the survey's location via email and through the internet came with an associated lack of control: once the web link to the survey had been sent out for the first time, the data gatherers did not know with certainty whether those who had filled it in were in the target group, despite the presence of a yes/no screening question.

Since the size and other characteristics of the underlying global population of medical device designers are unknown, it is difficult to make assertions about how representative the sample was of this population. As discussed previously, it is likely that most, but not all of the designers who filled in the survey had at least a passing interest (if not necessarily knowledge) in sustainability. This, added to the snowball style of recruitment described in Section 2, means that the responses seen may collectively lean slightly towards the perception that DfE is more important than if the entire population had been surveyed.

5.6. Conclusions and future work

This study aimed to take an important step towards exploring the state of environmentally conscious design in the medical device industry, to address a gap in the current knowledge of such practice. The survey gathered information from 34 medical device designers, encompassing their motivation to design for the environment, their experience with doing so and their major concerns with respect to the environmental impact of their products.

Analysis of the data revealed that DfE in the medical device industry is a complex mixture of standard environmental concerns in a sector that lags far behind others in terms of implementation, and considerations that are highly specific to this tightly regulated, safety focused world. Although there is evidence that the medical device industry lags behind others in terms of DfE implementation, there is also evidence that DfE work is taking place, although it is patchy in application. There is a need to educate both designers and customers/users in the need for more environmentally sustainable medical solutions, and in the appropriate techniques to develop products to cater for this need.

As DfE comes to the fore in healthcare, the viability of the single-use device business model will come under more scrutiny and innovative new ways of addressing this problem will need to be found. In particular this may point towards a move in the direction of product–service systems, and McAloone (2011) indicates that more and more businesses (from across industries) are beginning to consider this model as a serious business proposition. However, design solutions to meet the demands of the whole system cannot by their very nature be optimal for any individual parts of the healthcare system. Defining these key trade-offs is a critical design challenge, requiring input and negotiation from all members of this complex system. Similarly, issues that were found through this research to be important, but were not found to have been adequately addressed thus far will need to be addressed in the near future, in particular the elimination of harmful substances such as mercury from devices themselves. With this in mind, DfE efforts going forward in the medical device industry should:

- Optimise DfE at a system level, rather than at a single device level.
- Support designer education on the relevant topics.
- Acknowledge the specific needs of the medical device industry around safety, efficacy and reliability.
- Be specific to the medical device industry and its particular DfE needs.

The outputs of this study should therefore be used as a foundation for further exploration of the best ways to enable more DfE activity in the industry.

As an exploratory study, this survey has indicated some valuable opportunities for further study. This study has not set out to narrow the domain of 'medical devices'. However, it is likely that the design issues faced when developing simple reusable devices differ from those encountered when designing complicated machinery. Thus, a future study might explore these different contexts independently. The sample for this study is small, and a wider scale study might also elicit some original insights.

Acknowledgements

This research was supported using funding from the Engineering and Physical Sciences Research Council (EPSRC) in the United Kingdom, grant number EP/E001769/1.

Appendix. Survey structure and data types

Section	Question	Question or text	Form of data output
Opening text		This survey aims to explore how designers are interacting with environmental sustainability concerns in the medical device world. It is aimed at those who are, or have been, involved with the design of medical devices. The survey should take around 12 min to complete. We recognise that sustainability is a multi-faceted concept, embracing social and economic components as well as environmental concerns. This research is focused specifically on improvements that could be made to products' environmental credentials. We recognise that sustainability will always fight for attention with other design issues, and that medical safety and efficacy are always the top priorities. We are interested in how designers are engaging with this emerging area of interest. All data provided will be treated as strictly confidential. No data or comments that could positively identify an individual, or the organisation they work for, will be included in any material that is released as a result of this research. The raw data will be seen only by those conducting the survey at the University of Cambridge.	
1. About you	1.1	Are you, or have you been, involved in the design of medical devices?	Yes/No (if no, then survey ends)
	1.2	What is your job title?	Free form text

(continued on next page)

(*continued*)

Section	Question	Question or text	Form of data output
	1.3	What is the name of the organisation you work for? If you are freelance, please put 'Freelance'. If you do not currently work in the medical device design field, please put the last company you worked for in the area.	Free form text
	1.4	What are your organisation's main products or services?	Free form text
2. Designing for environmental sustainability	2.1	In your experience, is the impetus to consider environmental sustainability in the design of medical devices: - Increasing - Remaining about the same - Decreasing	Choice of one from three
	2.2	Please drag the sliders [immediately below the question] to indicate how significant you believe the following drivers to be in providing impetus for environmentally conscious design in medical devices. - Internal company pressure - Individual choice of designers - Pressure from government organisations - Client demand - Regulatory mandate - Other	Score from 0 to 100 for each driver. "Other" option accompanied by free form text field
	2.3	During the design process for products that you work with, how important is the explicit consideration of environmental sustainability? Please choose the statement that most closely corresponds with how you work, or make an entry into the "Other" box if none of these descriptions accurately reflect your situation. - We design for it voluntarily but other things are more important - We will design for it only if the project brief demands or the client specifically asks for it - It is not important but we will comply with the law where we have to - It is very important, we will make a new or redesigned product as sustainable as we can - We stick to some internal policies regarding environmental credentials, but nothing further - Other	Choice: one statement out of six. "Other" option accompanied by free form text field
	2.4	What do you perceive to be the major barriers to implementing environmentally conscious design in medical devices?	Free form text
3. Sustainability concerns: Our work takes a life cycle approach to thinking about sustainability in medical devices. In the following questions (one part for each life cycle phase), please indicate what level of concern each one holds for your work.	3.1	Raw material sourcing - Harmful substances in the bill of raw materials - Use of mercury - Use of scarce materials (e.g. precious metals) - Recycled, reused or remanufactured content - Diversity of raw materials - Energy sources used in extraction of raw materials - Processes of extraction	Each item scored on a 1–5 scale, where 1 = issue is not a concern, 5 = issue is a major concern
	3.2	Manufacturing - Processes used in assembly - Solid waste produced - Use of PVC - Processes used in raw material conversion - Waste water produced - Energy sources used in assembly - Energy sources used in conversion processes	Each item scored on a 1–5 scale, where 1 = issue is not a concern, 5 = issue is a major concern
	3.3	Distribution - Space efficiency of packaging - Amount of packaging - Materials used in packaging including recyclability - Method of transport - PVC content of packaging - Distance from production site to buyer	Each item scored on a 1–5 scale, where 1 = issue is not a concern, 5 = issue is a major concern
	3.4	Use - Lifetime. upgradeability - Single use components - Energy consumed during use (including sterilisation requirements) - Solid waste produced - Cos emissions during use - Waste water produced	Each item scored on a 1–5 scale, where 1 = issue is not a concern, 5 = issue is a major concern

(*continued*)

Section	Question	Question or text	Form of data output
	3.5	End of life - Designed for reuse - Designed for disassembly - Designed for recyclability - Proportion which must be land-filled or incinerated - Designed for remanufacture	Each item scored on a 1–5 scale, where 1 = issue is not a concern, 5 = issue is a major concern
	3.6	Are there any issues that are a cause for concern that do not appear on these lists?	Free form text
4. Sustainability issues that you have addressed: Have you addressed, or are you currently addressing, any of the concerns mentioned in the previous section during your medical device design work?	4.1	Raw material sourcing - Harmful substances in the bill of raw materials - Use of mercury - Use of scarce materials (e.g. precious metals) - Recycled, reused or remanufactured content - Diversity of raw materials - Energy sources used in extraction of raw materials - Processes of extraction	Yes/No response for each item
	4.2	Manufacturing - Processes used in assembly - Solid waste produced - Use of PVC - Processes used in raw material conversion - Waste water produced - Energy sources used in assembly - Energy sources used in conversion processes	Yes/No response for each item
	4.3	Distribution - Space efficiency of packaging - Amount of packaging - Materials used in packaging including recyclability - Method of transport - PVC content of packaging - Distance from production site to buyer	Yes/No response for each item
	4.4	Use - Lifetime. upgradeability - Single use components - Energy consumed during use (including sterilisation requirements) - Solid waste produced - Cos emissions during use - Waste water produced	Yes/No response for each item
	4.5	End of life - Designed for reuse - Designed for disassembly - Designed for recyclability - Proportion which must be land-filled or incinerated - Designed for remanufacture	Yes/No response for each item
	4.6	Are there any issues that you have tackled that do not appear on these lists?	Free form text
	4.7	Disregarding other design pressures, what do you consider to be the most urgent issue to tackle in the area of environmentally conscious design in medical devices?	Free form text
5. Further comments: This short section is for any further thoughts you may have about environmentally sustainable design in the medical device space.	5.1	If you have any experience with or insight into issues surrounding environmental sustainability in medical device design, please use this box to leave any comments.	Free form text
	5.2	If you would be willing to talk with us more about this area of research, please leave your contact details in the box below.	Free form text
6. Demographic information: Finally, please tell us a little more about you, so that we can start to understand whether particular trends are associated with location, company size, and so on. This data is confidential and you will remain anonymous. This is the last set of questions.	6.1	Have you ever worked in another industry?	Yes/No
	6.2	If you have worked in another industry, what is/was it?	Free form text
	6.3	Where are you located?	Choice: one out of eight location categories
	6.4	How many people work at the company you work for? Please refer to the organisation you named at the beginning of the survey.	Choice: one out of six size groups
	6.5	Which age range do you fall into?	Choice: one out of seven age groups
	6.6	Are you: [male/female]?	Are you: [male/female]
Closing message		Thank you for taking the time to complete the survey, we appreciate your input. Please feel free to pass on the link to the survey to contacts who may be interested: [link to survey]. If you are interested in receiving the results of the survey once the data has been analysed, please email us at: [email address].	

References

Albino, V., Balice, A., Dangelico, R.M., 2009. Environmental strategies and green product development: An overview on sustainability-driven companies. Bus. Strategy Environ. 18 (2), 83–96.

Borchardt, M., Wendt, M.H., Pereira, G.M., Sellito, M.A., 2010. Redesign of a component based on ecodesign practices: environmental impact and cost reduction achievements. J. Clean. Prod. 19, 49–57.

Braungart, M., McDonough, W., Bollinger, A., 2007. Cradle-to-cradle design: creating healthy emissions – a strategy for eco-effective product and system design. J. Clean. Prod. 15, 1337–1348.

Espicom, 2011a. The Outlook for Medical Devices in Western Europe.

Espicom, 2011b. The Medical Devices Market, USA.

European Union, 2007. Directive 2007/51/EC of the European Parliament and of the Council Amending Council Directive 76/769/EEC Relating to Restrictions on the Marketing of Certain Measuring Devices Containing Mercury.

European Union, 2012. Directive 2012/19/EU of the European Parliament and of the Council on Waste Electrical and Electronic Equipment (WEEE) (Recast).

Fletcher, K.T., Goggin, P.A., 2001. The dominant stances on ecodesign: a critique. Des. Issues 17, 15–25.

Hanson, J.J., Hitchcock, R.W., 2009. Towards sustainable design for single-use medical devices. In: 31st Annual International Conference of the IEEE, EMBS, Minneapolis, Minnesota, USA, September 2–6, 2009.

Hede, S., Nunes, M.J.L., Ferreira, P.F.V., Rocha, L.A., 2013. Incorporating sustainability in decision-making for medical device development. Technol. Soc. 35 (4), 276–293.

Hong, S.H., 2010. Medical device clinical trial. J. Kor. Med. Assoc. 53 (9), 769–773.

Hutchins, D., White, S., 2009. Coming round to recycling. BMJ 338, 746–748.

Johnson, J., Moultrie, J., 2012. Technology confidence in early stage development of medical devices. Int. J. Innov. Sci. 4 (2), 57–70.

Kadamus, C., 2008. Sustainable Design for Medical Devices. Medical Design. www.medicaldesign.com (accessed 25.01.13).

Karlsson, M., Ohman, D., 2005. Material consumption in the healthcare sector: strategies to reduce its impact on climate change – the case of Region Scania in South Sweden. J. Clean. Prod. 13, 1071–1081.

Lindahl, M., Sundin, E., Sakao, T., 2014. Environmental and economic benefits of integrated product/service offerings quantified with real business cases. J. Clean. Prod. 64, 288–296.

Marcus, A.A., Fremeth, A.R., 2009. Green management matters regardless. Acad. Manag. Perspect. 23, 17–26.

Marshal, J., Hinton, M., Wrobel, L., Triosi, G., 2009. Designing Sustainable Medical Devices. Medical Device and Diagnostic Industry. http://www.mddionline.com/article/designingsustainable-medical-devices (accessed 21.01.13).

McAloone, T.C., 2011. Boundary conditions for a new type of design task: understanding product/service systems. In: The Future of Design Methodology. Springer, London, pp. 113–124.

Medina, L.A., Okudan Kremer, G.E., Wysk, R.A., 2013. Supporting medical device development: a standard product design process model. J. Eng. Des. 24, 83–119.

Mont, O.K., 2002. Clarifying the concept of product–service system. J. Clean. Prod. 10, 237–245.

NHS Sustainable Development Unit, 2010. Procuring for Carbon Reduction (P4CR). In: http://www.sdu.nhs.uk/corporate-requirements/interventions/procurement.aspx (accessed 21.01.13).

Pearson, J., 2008. No silver bullets: on the humility of designers. Des. Manag. Rev. 19, 14–21.

Pietzsch, J.B., Pate-Cornell, M.E., 2008. Early technology assessment of new medical devices. Int. J. Technol. Assess. Health Care 24, 36–44.

Pigosso, D.C.A., Rozenfeld, H., McAloone, T.C., 2013. Ecodesign maturity model: a management framework to support ecodesign implementation into manufacturing companies. J. Clean. Prod. 59, 160–173.

Plouffe, S., Lanoie, P., Berneman, C., Vernier, M.-F., 2011. Economic benefits tied to ecodesign. J. Clean. Prod. 19 (6–7), 573–579.

Stripple, H., Westman, R., Holm, D., 2008. Development and environmental improvements of plastics for hydrophilic catheters in medical care: an environmental evaluation. J. Clean. Prod. 16, 1764–1776.

Tickner, J.A., Schettler, T., Guidotti, T., Mccally, M., Rossi, M., 2001. Health risks posed by use of di-2-ethylhexyl phthalate (DEHP) in PVC medical devices: a critical review. Am. J. Ind. Med. 39, 100–111.

Van Hemel, C., Cramer, J., 2002. Barriers and stimuli for ecodesign in SMEs. J. Clean. Prod. 20, 439–453.

Vezzoli, C., Sciama, D., 2006. Life cycle design: from general methods to product type specific guidelines and checklists: a method adopted to develop a set of guidelines/checklist handbook for the eco-efficient design of NECTA vending machines. J. Clean. Prod. 14, 1319–1325.

Zimmer, C., McKinley, D., 2008. New approaches to pollution prevention in the healthcare industry. J. Clean. Prod. 16, 734–742.