Assessing the Environmental Trade-Offs of Medical Device Technology

Device complexity can be a double-edged sword for sustainability. On the one hand, designers need to find effective ways to encourage patient adherence and reduce the number of wasted devices and treatments. On the other, they need to balance this against the environmental impact of introducing more complex parts to the device in order to achieve this. So how do you determine the environmental trade-offs of device complexity in your medical device development?

Adherence & digital technology

Before you can make an informed decision on the environmental trade-offs of added device complexity, it's important to understand the adherence issue and how this also contributes to the sustainability challenge. Treatment through 'at home' or 'on-the-go' drug delivery is fast becoming normal practice for many conditions. Despite this, several years ago the World Health Organization (WHO) estimated that only 50% of patients successfully take their medication as prescribed.[1] The WHO also suggested that poor adherence is not only detrimental to patient health, it also has a direct impact on the environment due to overuse of both medicines and devices.[2]

In order to tackle this, device developers have been confronting the issue of non-adherence from the 'bottom up'. Following a user-centred approach, designers are striving to ensure patients have the right tools, instruction, and support to help improve device usability and reduce the burden of taking medication. As part of this, many developers are looking to new technologies to help.

Advances such as on-board electronic sensing, monitoring and connectivity have indeed paved the way for improvements in patient adherence. Digital connectivity within inhaler devices, for example, can provide users with feedback on correct usage and help them monitor and log other valuable data. While real world data on the benefit of digital technologies is limited, the goal of the medical device industry is for patients to become more likely to adhere to treatment regimens and better equipped to manage their own health conditions. This could then in turn reduce the need for further environmentally costly healthcare interventions.

The environmental trade-off of increased complexity

While these new device technologies could help improve the issue of patient adherence, there is inevitably an environmental cost. In order to achieve improved usability, devices have become increasingly complex, using more intricate components and manufacturing methods. Not only is substantial energy needed to achieve this during production, the amount of environmental waste also increases when these complex products reach their end of life.

To date, the regulatory position has been that the health benefits for the patient should outweigh the environmental impact of the device. This way of thinking is however quickly becoming outdated, with an increasing drive in the industry to ensure that complex device technology is only used where it really adds value.

Compared to other sectors, such as consumer goods, the healthcare industry has been relatively slow to adopt the principles of environmental sustainability. While there has been a general lack of published data on the topic, particularly in the drug delivery space, it is up to medical device developers to incorporate environmental assessment tools into their developments, to help support more sustainable decision-making.

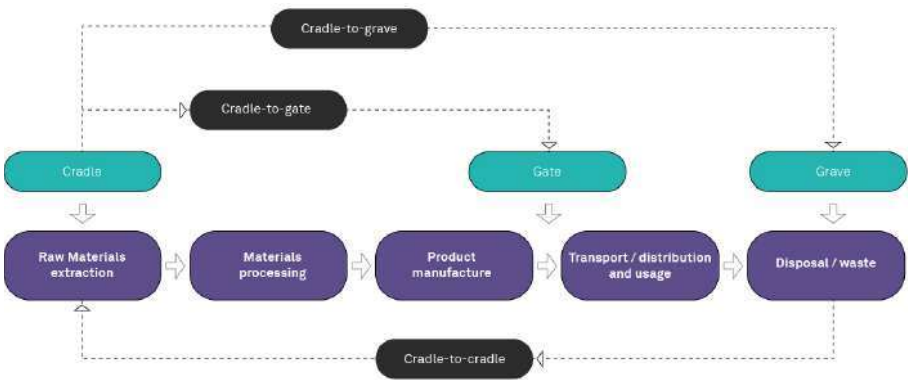
Using Life Cycle Assessment

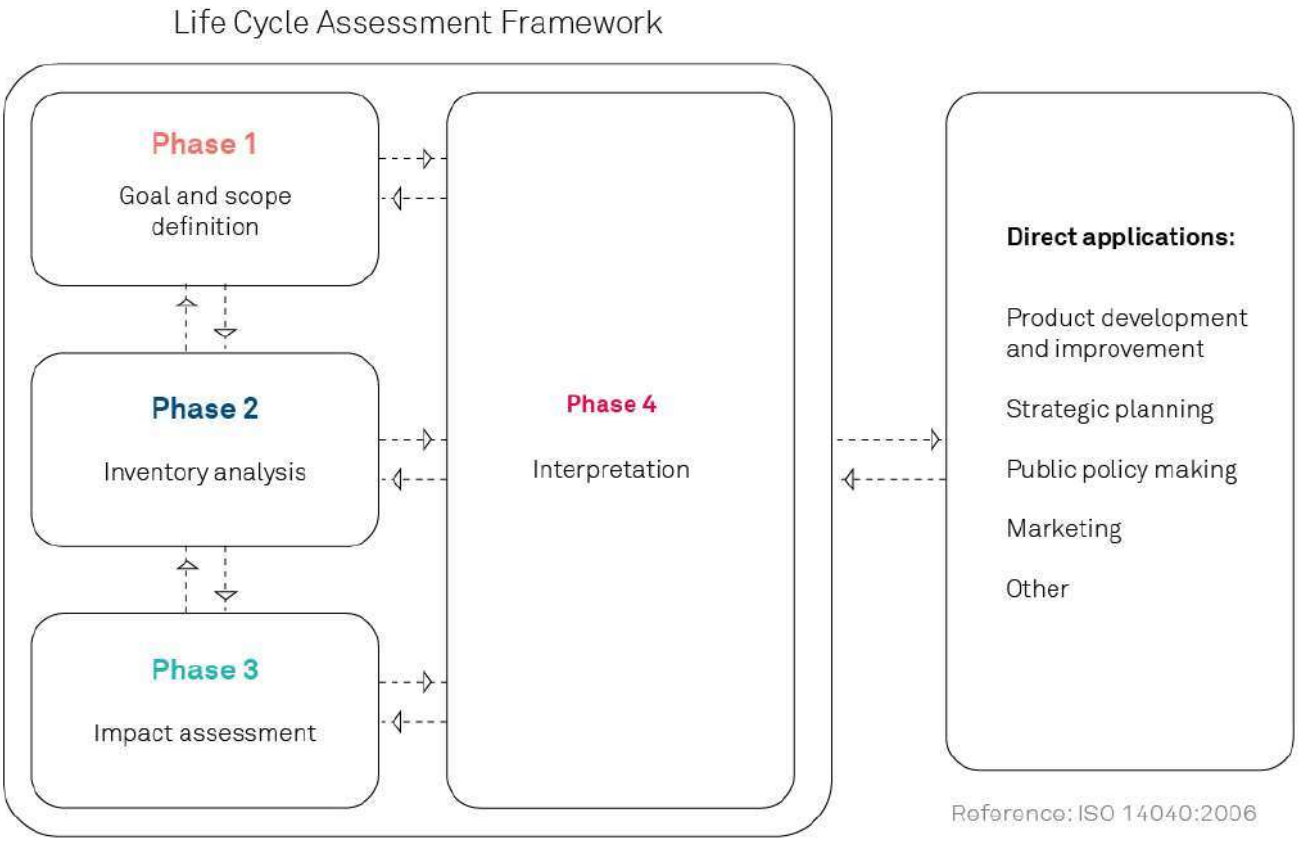
There are a number of tools for measuring carbon footprint within a device development. One of these is the Life Cycle Assessment (LCA) methodology. An LCA-based approach offers a valuable means for carrying out a systematic evaluation of carbon footprint for device technologies that contain many different materials and use various manufacturing methods. By following an LCA methodology, medical device developers and manufacturers can gain an effective framework for the systematic evaluation of the environmental impact of mass-produced medical devices. It is a relatively simple process that can be effectively implemented into a development process, to help drive environmentally sustainable decision making and strategies.

An LCA can be deployed from the beginning of a new device development (or selection) process to ensure that data driven decisions can be taken at key milestones or phase exit points. With the correct tools and templates, the assessment can be relatively simple to carry out and produce results that are easy to understand. The ISO 14040 series of standards provide a methodology for carrying out an LCA in a phased approach, covering four main phases:[3]

1. the goal and scope definition
2. inventory analysis
3. impact assessment
4. the interpretation phase.

The process should be iterative, with the results of one phase forming the inputs for the next. There are then a few variations of LCAs which can be used, depending on the data that is available and practicality.





A cradle-to-grave, or 'full', LCA follows five general stages:

1. raw materials extraction
2. materials manufacture
3. product manufacture
4. transport and usage
5. disposal/waste.

When a full LCA is not feasible, there are also some variations. A 'cradle-to-gate' LCA assesses the product up to the stage it leaves the factory, while a 'cradle-to-cradle' LCA replaces the disposal and waste stage with a recycling process, whereby raw materials would be reused for another product.

Conducting an LCA requires a vast amount of valid input information to provide an estimate of carbon footprint, (this being the measure of carbon dioxide and other gases which accumulate in the atmosphere and in turn increase the earth's average temperature). Here the term carbon footprint acts as a proxy for the larger impact factor referred to as Global Warming Potential (GWP).

The results for an LCA are typically given in grams of CO_2 equivalent (g CO_2-eq), using the IPCC 2007, 100-year GWP.[4] This value is determined by the sum of each greenhouse gas (GHG) emission, which is then converted to grams of CO_2-eq based on their GWP.

When conducting an LCA, product specific characteristics, such as the mass of each component, are considered as 'foreground data'. This is then calculated alongside 'background data', or Life Cycle Inventory (LCI) data, such as data on manufacturing processes and material properties.

Drawing insights from LCA

To illustrate the value of conducting LCAs as part of a development process, Team Consulting recently carried out a cradle-to-gate LCA on three hypothetical pressurised metred dose inhalers (pMDIs) of varying complexity. The analysis focused on the mechanical and electronic components of the devices in order to assess the carbon footprint of each part.

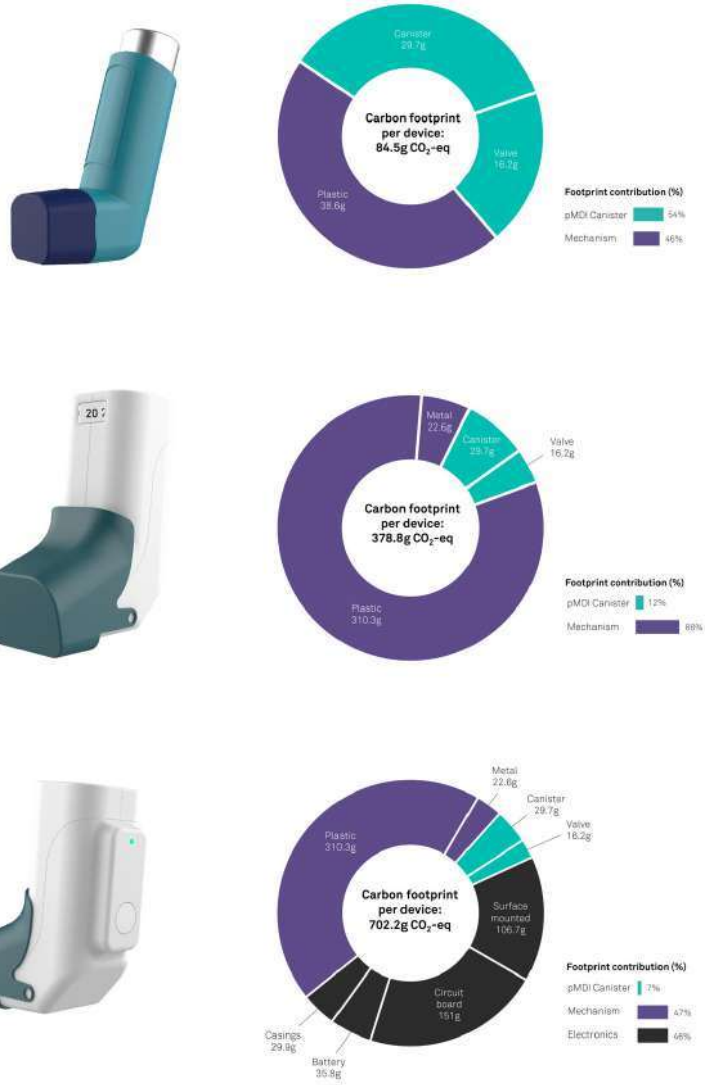
Simple pMDI device: the first device was a simple pMDI inhaler, where the primary container, encompassing a pressed aluminium canister body and canister metering valve assembly, formed the bulk of the product. The device had a simple construction, made up of two injection moulded polymer parts.

Complex pMDI device with integrated breath actuation mechanism (BAM): for the second device, we analysed a complex pMDI inhaler with BAM and a dose counter. In addition to the primary container, this device had 17 basic components and contained a mixture of injection moulded polymer and pressed metal parts, as well as a formed spring.

Advanced pMDI device with BAM and digital connectivity: the third pMDI device was based on the same device architecture as the second device, but with an added digital connectivity module. This sensing module was made up of a series of key electronic components, as well as a microcontroller unit (MCU) mounted on a printed circuit board (PCB), along with a replaceable battery.

While the study focused only on the device technology, excluding drug formulation, active pharmaceutical ingredients, primary packaging, transportation and usage, the assessment provides an interesting insight into the carbon impact of adding device complexity. The findings show a significant increase in the carbon footprint of the device as the number of components and physical mass of the device technology increases.

For the simple pMDI device, without any connectivity or electronics, the canister body appeared to have the greatest single contribution of CO_2-eq (35%, 30g CO_2-eq). When electronics and a digital connectivity module were added in the third device, these relatively small features almost doubled the CO_2-eq compared to all the other mechanism components combined (323g CO_2-eq for the



electronics components compared to 332g CO_2-eq for the mechanical parts). We often focus on larger materials and plastics when considering CO_2 emissions, however smaller components such as electronics clearly also have a major impact on the overall carbon footprint of a device.

Circuit boards also appeared to have the most significant carbon output relative to their size. Even without electronic components, a bare printed circuit board contributed to over 21% (151g CO_2-eq) of the carbon footprint for the entire device, despite being relatively small. Of course, it is indeed their small size and ready availability that can give the false impression that electronics and sensing technologies come with a lower environmental impact compared to other larger mechanical and plastic components. In fact, the opposite is often true. Intense mining processes are needed to source raw materials, while a vast amount of water and electricity is needed to manufacture the electronic components and PCBs. Clearly, electronics in devices come with a high carbon cost.

Moving towards more sustainable decision making

Pharmaceutical companies are increasingly considering environmental concerns as an important part of device development, with many placing sustainable development at the core of their values and strategy. Product developers therefore have a responsibility (and the influence) to ensure that the CO_2-eq 'spend' for their future device technologies are monitored and minimised throughout the development stages.

Early engagement with tools such as LCA in the development process can provide design teams with valuable data for highlighting carbon footprint hotspots. This can allow them to focus design efforts to mitigate issues in these areas before they are translated into the final product or supply chain. As with other critical development processes such as risk management, future development records could also benefit from including a 'sustainability management file', documenting the history of assessment and mitigation of areas that effect the sustainable credentials of the final product.

While carbon footprint is an important factor in sustainable decision-making, it is not the only factor that needs to be considered. Improving the usability of a device is an important factor that should also be considered, owing to the potential to improve adherence and reduce the need for secondary healthcare interventions. Hopefully, sustainability in future medical device developments will be given the same importance and detailed consideration as other commercial factors such as time and costs. However, it will also be important for the environmental credentials for new device technologies to always be carefully balanced against potential usability and adherence gains.

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