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Technical Validation of an Environmental Model of Aurora EV-ICD: Recommendations to Guide Environmental Criteria in Health Technology Assessment

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Disclosure

This project was funded by Medtronic Ltd.

Contents

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	Contents
1	Background and introduction
2	Methods to source environmental data
3	Methods – basic model validation
4	YHEC recommendations – approach to reporting environmental impact

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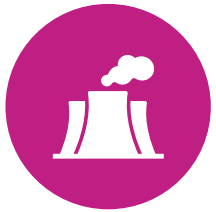
Background



NHS England contributes 25,0000 tonnes of carbon dioxide equivalent (CO_2^e) of carbon dioxide equivalent (CO_2^e) emissions per annum; equivalent to 40% of public sector's emissions [1]. The goal is to reach net zero emissions by 2045 for all services and products, including from procured health technologies [2].

While net zero CO_2^e emissions is the current focus of international target setting, a broader focus on other environmental impacts is critical to support healthcare sustainability [3].

One of the approaches that health technology assessment (HTA) agencies can use to take environmental information into account is called an "information conduit" (IC); this involves an HTA agency republishing environmental data that is in the public domain or has been submitted to a HTA agency (e.g. by a manufacturer) without further assessment [4].

Medtronic and YHEC partnered to produce an IC determining environmental outcomes for patients who have the Aurora single chamber extravascular implantable cardioverter defibrillator (Aurora EV-ICD) for tachyarrhythmia management implanted compared with an alternative implantable defibrillator [5].

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Methods to source environmental data

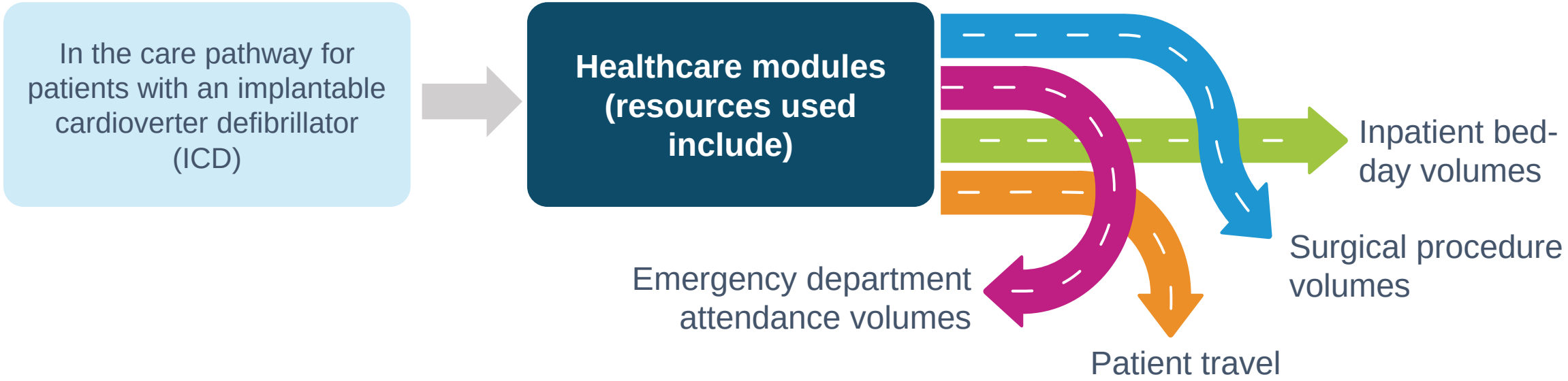
- Three units of analysis (defined as the performance characteristics and services delivered by the product being studied) were identified in the health economics data. The units of analysis require healthcare intervention across the patient care pathway and, therefore contribute to environmental impact [6, 7, 8, 9]:

Device-related infection

Avoidable shocks

Syncope episodes

Methods to source environmental data



- These healthcare modules are known areas of environmental hotspots [10].
- The environmental model estimates a broad range of environmental outcomes generated by the specified healthcare utilisation modules including CO_2^e emissions, water consumption (m_3) and waste volumes (kg) over a 10-year time horizon.

Methods – basic model validation

The key aims of this process were to validate an environmental model created by Medtronic and provide recommendations to support appropriate framing and reporting of the environmental data

This model validation did not include validation of the overall disease pathway structure of the model, validation of treatment effectiveness inputs, nor the lifecycle assessment of the physical product

A multi-step process was completed to internally validate the environmental model including the use of GHG protocols, ISO 14000 standards, and the Publicly Available Specification (PAS) guidance [6, 11, 12].

YHEC applied a checklist that was specifically designed for health technology environmental sustainability models.

The checklist applies a range of credibility and face validity tests such as reviewing hospital episode statistics (HES) codes and CO_2^e emissions attributed to the appropriate use of a unit of analysis. For example, CO_2^e emissions from a surgical procedure module.

YHEC ensured that all sources were generalisable to the NHS and that current sources were used (i.e. recently published data) [6, 13]. YHEC cross-validated all model inputs against the original sources to ensure that all data had been typed correctly and could be reconciled against the reference sources.

Methods – basic model validation

- Interpretation of the model based on the GHG Protocol, ISO BSI 14000 Standards and PAS 2050 guidance [6, 11, 12], included checking the following:

Terminology, labelling and referencing

Assumptions

Model justification

Sensitivity (scenario) analysis

Data collection techniques

Uncertainty modelling

Data calculation techniques

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Methods – basic model validation

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Figure 1. A checklist specifically designed for health technology environmental sustainability model validation

Table 1.1: Interpretation of model

	Check	Yes/No	Action required?
Terminology, labelling and referencing			
1	Does the analysis follow either greenhouse gas (GHG) or life cycle assessment (LCA) protocols, standards, or sector specific guidance in its reporting?	Yes. The analysis follows the 2015 Sustainable Healthcare Coalition (SHC), Care Pathways Guidance.	Yes. Please outline these guidance documents have been consulted in your report to the NHS. See Section 3 recommendations.
2	Is correct terminology used throughout the report?	No. For example, the "module" calculates the performance of a representative patient staying in hospital as an inpatient against the sustainability metrics and a "unit of analysis" is defined as the performance characteristics and services (including the module(s)) delivered by the product being studied.	Yes. Please see Section 3 recommendations.
3	Have appropriate units been used throughout the analysis?	Yes.	No.
4	Are results labelled correctly (including stating the time period that the results reflect, e.g., annual CO2e emissions)?	Yes.	No.
5	Does the analysis provide global warming potential (GWP) values? If so, has the source for these been provided?	No. The values used in this analysis are based on data reported in the SHC guidance. The SHC guidance does not reference global warming potential values (GWP).	No.
6	Has all data been appropriately referenced?	Yes.	No.
Model justification			
8	What are the key drivers of the model and why?	This environmental model compares the difference in specified modules identified along the patient care pathway in relation to carbon emissions, water consumption and waste volumes generated. The modules selected for analysis are known environmental hotspots in healthcare utilisation and therefore this model highlights important environmental outcome data aligned with NHS targets.	Yes. Please see Section 3 recommendations.
9	Is the model representative of real world	Yes. This model utilises published data applicable to the UK NHS setting.	No
10	Is the goal of the analysis clearly defined?	No. The goal of this report is to analysis identify effective mitigation strategies to reduce health technology associated GHG emissions, water use and waste generation.	Yes. Please see Section 3 recommendations
11	Does the analysis include a full or partial environmental life cycle assessment?	No. The focus is on the use stage of the life cycle of the ICDs.	No. This is not applicable in this case.
12	Is the scope of the analysis clearly defined? e.g., cradle to gate, cradle to grave, or a focus on a specific stage of the life cycle? For each included process/ product, does the analysis denote the relevant scope (1-3)?	No. This analysis focuses on the use stage of the product life cycle of ICDs being compared to generate environmental savings. For each included process/product it would be useful for this submission to include a table in the supplementary materials to denote the relevant scope (1-3).	Yes. Please see Section 3 recommendations

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- A prioritisation list based on the GHG Protocol, ISO BSI 14000 Standards and PAS 2050 guidance determined by resource availability, the time frame for the submission and to support internal resource planning [6, 11, 12]:

1. Outline the goal of the analysis.
2. Outline the base case (line) scenario.
3. Define the scope including the functional unit of analysis (including the reference flow).
4. Setting the boundary of the analysis (including the time horizon, included, and excluded activities).
5. Define the data sources used in the analysis.
6. Outline units of analysis.
7. State the site of analysis.
8. Define all assumptions for the methods included.
9. Report sensitivity (scenario) analysis.
10. Report uncertainty analysis.
11. Provide a process map.
12. Outline methods to include life cycle costing (LCC) within care pathway.
13. Defines adherence to the five data quality indicators.
14. Report quantitative results using tables and graphs, were appropriate.
15. Report qualitative findings.
16. Outline any literature search methods.
17. Define adherence to the five data quality indicators.
18. Supplementary materials.

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YHEC recommendations – approach to reporting environmental impact

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Table 2. Reports the model level of adherence to the five data quality indicators the GHG Protocol standards [6]

Product Life Cycle Accounting and Reporting Standard Five Data Quality Indicators	Level of adherence
Technological representativeness (the degree to which the data reflect the actual technology(ies) used in the process).	Comparable ICDs.
Geographical representativeness (the degree to which the data reflects actual geographic location of the processes within the inventory boundary (e.g. country or site)).	The same UK NHS site has been used throughout the analysis.
Temporal representativeness (the degree to which the data reflect the actual time (e.g. year) or age of the process).	The age of the data is reasonable. The data used represents a proportionate time of the year to reflect seasonal variation of data.
Completeness (the degree to which the data are statistically representative of the process sites).	This is acceptable.
Reliability (the degree to which the sources, data collection methods, and verification procedures used to obtain the data are dependable).	This is acceptable.

Abbreviations: ICD - implantable cardioverter defibrillator.

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YHEC recommendations – approach to reporting environmental impact

Table 3. An example of how the environmental outcomes might be summarised within the report. Calculations are based on the Sustainable Healthcare Coalition (SHC) Care Pathways data [10]

UK NHS patients implanted with Aurora EV-ICD instead of S-ICD over a 10-year time horizon				
	Module			
Environmental outcome (environmental savings)	Reduced device related infection requiring surgical revision, inpatient bed days and patient travel	Reduced shock episodes requiring inpatient bed stays	Reduced syncope episodes requiring A4&E visits	Total environmental savings over 10 years
Greenhouse gas (GHG) emissions ($kgCO_2^e$) avoided	9,423	23,900	966	34,289
Fresh water use (m_3) avoided	15,086	36,692	1,463	53,241
Waste avoided (kg)	795	1,980	20	2,795

Abbreviations: ICD - implantable cardioverter defibrillator.

Conclusion

- Evaluating and reporting a broad range of environmental outcomes to the NHS is encouraged by NHS decision makers.
- Overall, YHEC considers that the model structure is appropriate and suitable. The model is logical and simple, whilst still adequately representing the decision problem and enabling comparison between health technologies.
- YHEC does not foresee any issues if the model structure, assumptions, inputs, and outcomes are clearly defined in a report. YHEC recommends a specific structure to report this environmental analysis, based on the ISO BSI standards.
- This analysis focuses on the environmental hotspots within the use stage of the ICD life cycle: a product life cycle assessment is recommended that focuses on reporting known environmental hotspots.
- This novel framework can be applied to assess and produce a wider range of environmental outcomes (data) that facilitates broader understanding of unintended consequences of healthcare decision making.

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Thank you

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