Response to Letter to the Editor Concerning the Article "The Clinical and Economic Impact of Extended Battery Longevity of a Substernal Extravascular Implantable Cardioverter Defibrillator"

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Abstract

Abtract not needed for a response to a Letter to the Editor

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"The Clinical and Economic Impact of Extended Battery Longevity of a Substernal Extravascular Implantable Cardioverter Defibrillator"

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We have read the comments made by Mealing and colleagues and appreciate the opportunity to further clarify certain aspects of our work. Thank you for your interest in our manuscript. The model employed a 3-month cycle time, selected because of the life-long time horizon. No patient in the model was "immune" to complications as the full cohort of patients having a replacement faced the probability of complication at the transition between the 'generator replacement' and 'replacement complication' states. This was intended to

represent an average timing of peri-procedural complications which could occur either during the procedure or for 6-12 months afterward. The complications have proper impact on the overall mortality and cost calculations, and any error related to timing would be limited to a one-cycle difference in the discounted results which is minimal.

The perspectives for each country were chosen to represent the stakeholder most likely to impact the decision of ICD type given an indication for therapy. In the US, a fractionated payer system pays for a generic procedure and does not differentiate between models, so the choice is made at the hospital. The rest of the countries have more unified payers with some even employing model-specific reimbursement payment amounts.

Device longevity was not fixed in the model, there was a time-varying probability of device replacement. It was based on clinical observation from patients in the Pivotal study (NCT04060680) combined with engineering model projections as displayed in Figure 2. We did acknowledge uncertainty about this in the limitations ("Modeled longevity... could be impacted by changes in technology") and incorporated a robust sensitivity analysis varying the expected longevity by two standard deviations based on current data. We acknowledge that the substernal defibrillator is new technology, but there is robust post-market clinical study activity that will enhance the evidence base (NCT06048731). We accounted for concerns about uncertainty in cost parameters a similar way and found in the sensitivity analysis that cost had an even smaller impact on model outcomes.

The substernal ICD carries a strong mechanism for comparative energy efficiency. With a projected 60% improvement in device longevity, one would expect the avoided replacement surgeries and cost savings predicted by this model.