NICE National Institute for Health and Care Excellence

Medical Technologies Evaluation Programme

MT 294 ENDURALIFE-powered CRT-D devices for heart failure

Expert Adviser Questionnaire Responses

Name of Expert Advisers	Job Title	Professional Organisation/ Specialist Society	Nominated by	Ratified
Dr Roy Gardner	Consultant Cardiologist	British Society for Heart Failure	Specialist Society	-
Dr Ernest Lau	Consultant Cardiologist	British Cardiovascular Society	Sponsor	Expected
Dr David Jay Wright	Lead Clinician for Heart Failure	British Cardiovascular Society	Sponsor	Yes
Dr Chris Plummer	Consultant Cardiologist	British Cardiovascular Society	NICE	Yes
Dr Zaheer Yousef	Consultant Cardiologist	British Cardiovascular Society	NICE	Yes

YOUR PERSONAL EXPERIENCE (IF ANY) WITH THIS TECHNOLOGY

Question 2: Please indicate your experience with this technology?

Expert Advisers	I have had direct involvement with this	I have referred patients for its use	I manage patients on whom it is used in another part of their care pathway	I would like to use this technology but it is not currently available to me
Dr Roy Gardner Consultant Cardiologist	**Yes**	**Yes**	**Yes**	**No**
Dr Ernest Lau Consultant Cardiologist	**Yes**	**Yes**	**No**	**No**
Dr David Jay Wright Lead Clinician for Heart Failure	**Yes**	**Yes**	**Yes**	**No**
Dr Chris Plummer Consultant Cardiologist	**Yes**	**Yes**	**Yes**	**No**
Dr Zaheer Yousef Consultant Cardiologist	**No**	**No**	**No**	**Yes**

Any Comments?	
Dr Roy Gardner Consultant Cardiologist	**Blank**
Dr Ernest Lau Consultant Cardiologist	**i personally implant CRTDs from all manufacturers and have direct experience in the performance of different device models over a protracted period of time (up to 10 years) in real life clinical use.**
Dr David Jay Wright Lead Clinician for Heart Failure	**Blank**
Dr Chris Plummer Consultant Cardiologist	**This battery technology is used in the devices from one of our standard device manufacturers**
Dr Zaheer Yousef Consultant Cardiologist	**Blank**

Question 3: Have you been involved in any kind of research on this technology? If Yes, please describe?

Expert Advisers	Yes/No	Comment
Dr Roy Gardner **Consultant Cardiologist**	**No**	**Blank**
Dr Ernest Lau **Consultant Cardiologist**	**Yes**	**I have researched both the theoretical (in terms of electrochemistry) and practical (in terms of clinical audit data from my own and other centres) plausibility of signficiant differences in the battery technologies and CRTD longevity by different manufacturers,**
Dr David Jay Wright **Lead Clinician for Heart Failure**	**Yes**	**I have conducted an audit within my hospital looking at the length of time from ICD implant to routine battery change. We utilise techniologuy from 2 manufacturersso effectively this represents a direct comparison.**
Dr Chris Plummer **Consultant Cardiologist**	**Yes**	**I was the local PI on the SIMPLE trial of defibrillation testing. Although this did not involve research on the battery technology, it was sponsored by Boston Scientific..**
Dr Zaheer Yousef **Consultant Cardiologist**	**No**	**Blank**

THIS PRODUCT (TECHNOLOGY) AND ITS USE

Question 4: How would you best describe this technology?

Expert Advisers	It is a minor variation on existing technologies with little potential for different outcomes and impact	It is a significant modification of an existing technology with real potential for different outcomes and impact	It is thoroughly novel - different in concept and/ or design to any existing
Dr Roy Gardner **Consultant Cardiologist**	No	**Yes**	No
Dr Ernest Lau **Consultant Cardiologist**	No	**Yes**	No
Dr David Jay Wright **Lead Clinician for Heart Failure**	No	**Yes**	No
Dr Chris Plummer **Consultant Cardiologist**	No	**Yes**	No
Dr Zaheer Yousef **Consultant Cardiologist**	Blank	**Yes**	Blank

Any Comments?	
Dr Roy Gardner **Consultant Cardiologist**	Blank
Dr Ernest Lau **Consultant Cardiologist**	**The chemistry and total capacity of a battery are only two fo the factors affecting its performance in practical use. The internal architecture and quality control in manufacturing are also very important. For example, (non-rechargeable) household batteries of the same chemistry and total capacity from different manufacturers last for different durations in use.**
Dr David Jay Wright **Lead Clinician for Heart Failure**	**Any increase in longevity of ICD device function will reduce the potential for complications to patients and reduce health care costs.**
Dr Chris Plummer **Consultant Cardiologist**	**A potentially improtant advance in an exisisting technology.**

Dr Zaheer Yousef **Consultant Cardiologist**	**It's analagous to mobile phone technology. The phone itself (cardiac device) is not changing, but the battery is. With a mobile phone, longer battery life means less frequent charging. With the cardiac device, less frequent invasive generator/box changes would be needed. Each box change carries a risk and hardware cost.**

Question 5: What is the most appropriate use (e.g. clinical indication) for the technology?

Expert Advisers	Comment
Dr Roy Gardner **Consultant Cardiologist**	**It is the new battery technology behind Boston Scientific's CRT-D and ICDs, and has the potential to extend into other implantable devices in the future**
Dr Ernest Lau **Consultant Cardiologist**	**1. Protect patients with damaged hearts (by coronary artery disease or other heart muscle disease prcoesses) from sudden cardiac death due to ventricular tachyarrhythmias** **2. Improve heart failure (better quality of life; increase exercise tolerance, reduce hospital admissions) attributable to or aggravated by conduction system disease.**
Dr David Jay Wright **Lead Clinician for Heart Failure**	**This technology will be used for any patient who requires an ICD or CRTD device. Current national implantation figures demonstrate an ICD implant rate of 100/M population and a similar CRTD implantation rate per M population.**
Dr Chris Plummer **Consultant Cardiologist**	**Patients with heart failure and a clinical indication for CRT-D according to NICE guidance TA314. Many patients with an indication for CRT-D could potentially benefit from a significant increase in battery longevity.**
Dr Zaheer Yousef **Consultant Cardiologist**	**Patients meeting NICE recommendations for CRT-D (TA314) would potentially be eligible for this technology; i.e. typically patients with severe heart failure (EF <35%) and variable degrees of functional limitation (NYHA) and ECG abnormalities (QRS duration in the context of LBBB) as tabulated in TA314.**

COMPARATORS (including both products in current routine use and also "competing products")

Question 6: Given what you stated is the appropriate indication (clinical scenario) for its use, what are the most appropriate "comparators" for this technology which are in routine current use in the NHS?

Expert Advisers	Comment
Dr Roy Gardner **Consultant Cardiologist**	**Battery technology from other device manufacturers (e.g. St Jude Medical, Medtronic, Biotronik and Sorin). The battery capacity is said to be double that of Medtronic's**
Dr Ernest Lau **Consultant Cardiologist**	**ICD battery chemsitry used to be exclusively lithium/silver vanadium oxide (Li/SVO), but that has been supplanted by either the Li/SVO and lithium carbon monofluoride (Li/CFx) hybrid (Li/SVO-CFx) or lithium maganese dioxide (Li/MnO2) in the latest device models. All ICDs and CRTDs curretntly in use (in service in patients) in the NHS use one of the 3 chemistries. All new ICD and CRTD implants use either Li/SVO-CFx or Li/MnO2 batteries. The ENDURALIFE battery may be distinct from other ICD batteries not only because of the Li/MnO2 chemistry, but also because of its internal archiecture and quality control in maunfacturing.**
Dr David Jay Wright **Lead Clinician for Heart Failure**	**The comparators for this product will be the longevity from implant to routine box change of devices from other manufacturers eg Medtronic, St Jude and Biotronik. I do not have National figures for the market share of each manufacturer.**
Dr Chris Plummer **Consultant Cardiologist**	**Other CRT-D devices currently available for use in the UK**
Dr Zaheer Yousef **Consultant Cardiologist**	**Existing CRT-D devices, but without the proposed extended battery technology**

Question 7: "Competing products": Are you aware of any other products which have been introduced with the same purpose as this one?

Expert Advisers	Comment
Dr Roy Gardner **Consultant Cardiologist**	**No**
Dr Ernest Lau **Consultant Cardiologist**	**ICD batteries are made either by the device manufacturers themselves (Medtronic, Boston Scientific) or third party vendors (Greatbatch, Litronik). Medtronic, St Jude Medical and Livonova all use Li/SVO-CFx hyrid batteries for their new ICD models. The ENDURALIFE Li/MnO2 battery is exclusive to and also exclusively used by Boston Scientific for all its new ICD models. Biotronik uses mostly Li/SVO-CFx batteries but also a small portion of Li/MnO2 batteries in its new ICD models. Apart from changing the battery chemistry, most manufacturers have also increased the total capacity to a level comparable (or even exceeding) the ENDURALIFE battery (around 1.9 Ampere-hours) used by Boston Scientific in its CRTDs.**
Dr David Jay Wright **Lead Clinician for Heart Failure**	**See answer to question 6**
Dr Chris Plummer **Consultant Cardiologist**	**All manufacturers are now focussing on battery longevity as this has a significant impace on cost-effectiveness.**
Dr Zaheer Yousef **Consultant Cardiologist**	**No, but existing CRT-D devices have bespoke functionalities which can be activated to limit battery use; e.g. user-defined pacing vectors which can drain less battery. The absolute benefits of these functionalities are minimal (months) in comparison to the additional years gained with the new technology.**

POSSIBLE BENEFITS FOR PATIENTS

Question 8: ***What are the likely additional benefits for patients of using this technology, compared with current practice/ comparators?***

Expert Advisers	Comment
Dr Roy Gardner **Consultant Cardiologist**	**Fewer/or even no generator (battery) changes, meaning less surgical procedures, and therefore less risk of infection, etc in the long term. Despite the better battery, the volume is less than other manufacturer's products**
Dr Ernest Lau **Consultant Cardiologist**	**Increased CRTD longevity will:** **1. Reduce the frequency of device replacement for patients, which means** **1a. Fewer invasive procedures for the patients (reduce morbidities)** **1b. Remove the need of device replacement completely for certain age groups (e.g. over 85 years old)** **2. Reduce device-related complications (notably infection) - higher risk with device replacement than new implantation** **2a. Reduce the morbidities and potential mortality for patients (sepsis and lead extraction)** **2b Reduce the possibility of prolonged hospital stay**
Dr David Jay Wright **Lead Clinician for Heart Failure**	**Longer time from implant to routine box change - fewer procedures** **Reduced risk of infection and resultant device extraction**
Dr Chris Plummer **Consultant Cardiologist**	**Reduced number of generator replacement thereby reducing the risks associated with these procedures. This could also significantly reduce overall costs if the Enduralife device price were similar to other devices.**
Dr Zaheer Yousef **Consultant Cardiologist**	**Longer battery life means less frequent invasive battery change procedures would be required. Each battery change procedure carries a clinical risk; typically infection, damage to existing leads, bleeding (combined risk ~1-2%). There are also potential cost savings through reduced hardware costs (less frequent device changes).**

Question 8.1: Is each additional benefit likely to be realised in practice? What are the likely obstacles?

Expert Advisers	Comment
Dr Roy Gardner **Consultant Cardiologist**	**Yes;no foreseeable obstacles**
Dr Ernest Lau **Consultant Cardiologist**	**Yes to each.** **The obstacles lie mainly with the healthcare providers**
Dr David Jay Wright **Lead Clinician for Heart Failure**	**All benefits are likely to be realised in clinical practice if the longevity of these devices is proven to be superior to that of devices from other manufacturers. There is limitted data on longevity of devices in the UK. All the manufacturers are constantly changing the technology to provide improved longevity. Thus comparisons are only relevant in the absence of a technology change. All comparisons will take a minimum of five years for adequate data collection.**
Dr Chris Plummer **Consultant Cardiologist**	**There is no advantage in simply delaying a generator replacement - the advantages come if fewer generator replacements are needed in a patient's lifetime. This is highly dependent on the relative life-expectancies of the patients and the devices.**
Dr Zaheer Yousef **Consultant Cardiologist**	**Yes, however the new technology must demonstrate that the ICD function of the device will not be compromised. Battery technology is complex and has been the misfortune of earlier CRT-D (and ICD) technologies.**

Question 8.2: How might these benefits be measured? What specific outcome measures would enable assessment of whether additional benefits for patients are being realised?

Expert Advisers	Comment
Dr Roy Gardner **Consultant Cardiologist**	**Length of time between box changes**
Dr Ernest Lau **Consultant Cardiologist**	**1. Device survival curve in clinical use (e.g. median time to device replacement due to battery depletion)** **2. Interaction between device longevity and patient survival** **3. Number of device replacements for battery depletion per annum** **4. Number of device-related complications (infection and lead failure) per annum** **5. Number of device system explantation and lead extraction per annum** **6. Number of days of in hospital stay due to device-related complications per annum**
Dr David Jay Wright **Lead Clinician for Heart Failure**	**the best comparison would be of time from implant to routine box change for all ICds and CRTDs. Complication rates and mortality figures might also be obtained using NICOR and HES data review.**
Dr Chris Plummer **Consultant Cardiologist**	**Manfacutrers are able to project battery life using accelerated testing but this is only an approximation to clinical practice**
Dr Zaheer Yousef **Consultant Cardiologist**	**Number of box changes, time from initial implant to box change, life-time device cost to patient.**

Question 8.3: How good is this evidence for each of these additional benefits?

Expert Advisers	Comment
Dr Roy Gardner **Consultant Cardiologist**	**Pretty convincing**
Dr Ernest Lau **Consultant Cardiologist**	**The clinical evidence for ENDURA-powered CRTDs lasting longer than other contemporary CRTDs (largely powerd by Li/SVO batteries) is strong (multi-center independent registries). How ENDURA-powered CRTDs compare to the newer generation of CRTDs powered by large capacity Li/SVO-CFx batteries is unknown.** **Longevity claims by different manufacturers for their own models are very difficult to compare because of different assumptions used in their projections.** **Strong observational data from North America in terms of device-related complications, and higher rates for such post device replacement compared to** **new implantation**
Dr David Jay Wright **Lead Clinician for Heart Failure**	**The evidence for potential benefit requires a long period of observation of device longevity and complication rates. No one data set will adequately fullfill this. Thus data will need to be collected from several sources.**
Dr Chris Plummer **Consultant Cardiologist**	**The technology is promissing but robust data are required to substantiate the claims of doubled device longevity - it is not enough to show a doubled battery capacity. Evidence of battery longevity in other manufacturers' current devices is also required to evaluate the relative advantages.**
Dr Zaheer Yousef **Consultant Cardiologist**	**If the benefits as claimed can be substantiated, the benefits to the NHS would be very significant.**

Question 8.4: Please add any further comment on the claimed benefits of the technology to patients, as you see applicable

Expert Advisers	Comment
Dr Roy Gardner **Consultant Cardiologist**	**Low profile device meaning cosmetically more appealing**
Dr Ernest Lau **Consultant Cardiologist**	**Patients generally defer to their physicians in their device choice**
Dr David Jay Wright **Lead Clinician for Heart Failure**	**The fewer box changes required and complications encountered the better the quality of life and productivity of the patient cohort.**
Dr Chris Plummer **Consultant Cardiologist**	**This is an important focus in this field.**
Dr Zaheer Yousef **Consultant Cardiologist**	**An additional advantage is that the extended battery life does not compromise the size of the device.**

POSSIBLE BENEFITS FOR THE HEALTHCARE SYSTEM

Question 9: What are the likely additional benefits for the healthcare system of using this technology, compared with current practice/ comparators?

Expert Advisers	Comment
Dr Roy Gardner **Consultant Cardiologist**	**If a generator change can be avoided this would save the NHS a vast amount of money - each generator costs between £5,000-10,000**
Dr Ernest Lau **Consultant Cardiologist**	**Increased CDTD longevity will:** **1. Reduce the frequency and cost of device replacement** **2. Reduce device-related complications** **3. Reduce the cost of treating device-related complications (3 months in hospital stay; up to £100 k per patient).** **4. Resources currently used for device replacement can be used to treat more new patients needing CRTDs earlier (shorter waiting time)**
Dr David Jay Wright **Lead Clinician for Heart Failure**	**Reduced cost from box changes and potential complications thereafter**
Dr Chris Plummer **Consultant Cardiologist**	**Reduced cost and improved cost effectiveness.**
Dr Zaheer Yousef **Consultant Cardiologist**	**Less frequent elective admissions for box changes, fewer generator replacement-related complications (device infection involves very significant risks to the patients and complex device extraction procedures). Also, potential cost savings are possible.**

Question 9.1: Is each additional benefit likely to be realised in practice? What are the likely obstacles?

Expert Advisers	Comment
Dr Roy Gardner **Consultant Cardiologist**	**Yes - we have ensured that the Enduralife products come with a cast-iron warranty, so e.g. if an ICD battery lasts less than 10 years, we get another generator free-of-charge.**
Dr Ernest Lau **Consultant Cardiologist**	**Yes to each benefit** **The obstacles are:** **1. No standardised ways for manufacturers to project the longevities of their device models in clinical use** **2. No easy ways for physicians and procurement to verify manufacturers' claims for the longevities projected for their device models to make informed and rational device choice on behalf of patients and the NHS** **3. No esotablished and accepted methods of factoring device longevity into evaluating the price of a CRTD device (upfront cost versus cost spread over the device's working lifespan)** **4. Physicians' preference in device choice for other characteristics (e.g. pacing vectors, handling of accompanying leads, MRI conditionality)**
Dr David Jay Wright **Lead Clinician for Heart Failure**	**Yes. Difficult to prove as per the answer to 8.1**
Dr Chris Plummer **Consultant Cardiologist**	**If the battery claims are correct, these benefits are likely to be realised**
Dr Zaheer Yousef **Consultant Cardiologist**	**Realisable benefits within 7-8yrs; the typical life span of existing CRT-D batteries.**

Question 9.2: How might these benefits be measured? What specific outcome measures would enable assessment of whether additional benefits for the healthcare system are being realised?

Expert Advisers	Comment
Dr Roy Gardner **Consultant Cardiologist**	**Number of generator changes required per patient, and time-line between each procedure. These devices have a "fuel guage" too which assesses battery longevity**
Dr Ernest Lau **Consultant Cardiologist**	**1. Overall cost savings from CRTD replacement** **2. Cost savings from treating device-related complications** **3. Reduction in waiting time for new device implantation**
Dr David Jay Wright **Lead Clinician for Heart Failure**	**The cost of any box change or complication can be calculated from the national Teriff and the actual cost of the device units from each manufacturer. This data would need to be collected from NHS England.**
Dr Chris Plummer **Consultant Cardiologist**	**It is possible to measure device longevity using a variety of sources including the NICOR database**
Dr Zaheer Yousef **Consultant Cardiologist**	**see above**

Question 9.3: How good is this evidence for each of these additional benefits?

Expert Advisers	Comment
Dr Roy Gardner **Consultant Cardiologist**	**Reasonably good**
Dr Ernest Lau **Consultant Cardiologist**	**Clinical evidence has mostly been as in the answer to question 8.3. The true financial impact depends on the costs of the different procedures, consumables and each day of hospital stay.**
Dr David Jay Wright **Lead Clinician for Heart Failure**	**Difficult to prove unless accurate data is available comparing the box change and complication rates from each manufacturer over a similar period of time. The cost per device will also need to be made available and to my knowledge each Hospital negotiates a different unit cost.**
Dr Chris Plummer **Consultant Cardiologist**	**The implications for cost-effectiveness could be tested in the models used in NICE TA314.**
Dr Zaheer Yousef **Consultant Cardiologist**	**Very good**

Question 9.4: Please add any further comment on the claimed benefits of the technology to the healthcare system, as you see applicable

Expert Advisers	Comment
Dr Roy Gardner **Consultant Cardiologist**	**Although these generators appear to have the best batteries on the market, we have also found them to be the cheapest by some considerable margin**
Dr Ernest Lau **Consultant Cardiologist**	**Blank**
Dr David Jay Wright **Lead Clinician for Heart Failure**	**Blank**
Dr Chris Plummer **Consultant Cardiologist**	**A reduced number of generator replacementswould also increase capacity for other procedures.**
Dr Zaheer Yousef **Consultant Cardiologist**	**This technology could have far reaching beneits to the NHS; many implantable devices (not just cardiac) could potentially benefit from longer battery life.**

FACILITIES, TRAINING AND FUNCTIONING

Question 10: Are there any particular facilities or infrastructure which needs to be in place for the safe and effective use of this technology?

Expert Advisers	Comment
Dr Roy Gardner **Consultant Cardiologist**	**No**
Dr Ernest Lau **Consultant Cardiologist**	**No (all facilities or infra-structure already in place in all implanting centres)**
Dr David Jay Wright **Lead Clinician for Heart Failure**	**No, already in place**
Dr Chris Plummer **Consultant Cardiologist**	**No**
Dr Zaheer Yousef **Consultant Cardiologist**	**No**

Question 11: Is special training required to use this technology safely and effectively?

Expert Advisers	Comment
Dr Roy Gardner **Consultant Cardiologist**	**No**
Dr Ernest Lau **Consultant Cardiologist**	**No (all staff experienced in device procedures alreay have the necessary training)**
Dr David Jay Wright **Lead Clinician for Heart Failure**	**No**
Dr Chris Plummer **Consultant Cardiologist**	**No**
Dr Zaheer Yousef **Consultant Cardiologist**	**No**

Question 12: Please comment on any issues relating to the functioning, reliability and maintenance of this technology which may be important to consider if it is introduced

Expert Advisers	Comment
Dr Roy Gardner **Consultant Cardiologist**	**We have been using Boston products for some time and they appear reliable**
Dr Ernest Lau **Consultant Cardiologist**	**The ENDURALIFE battery has a good performance record in real life clinical use. There are no particualr issues related to its functioning, reliability and maintenance.**
Dr David Jay Wright **Lead Clinician for Heart Failure**	**None evident**
Dr Chris Plummer **Consultant Cardiologist**	**It is important to realise that the battery is not the only CRT-D component which could fail. All other components would need to function longer that the new battery.**
Dr Zaheer Yousef **Consultant Cardiologist**	**Device battery technology is complex and this new technology would require extensive quality assurance (see 8.1)**

COSTS

Question 13: Please provide any comments on the likely cost consequences of introducing this technology. In particular, please comment on the implications of this technology replacing the comparator/s you have described above

Expert Advisers	Comment
Dr Roy Gardner **Consultant Cardiologist**	**Despite the better battery and low volume design, Boston are actually our cheapest provider and yet still offer 10 year warranties on their ICDs**
Dr Ernest Lau **Consultant Cardiologist**	**May be £2000 more expensive per device than comparators (difficult to tell, as the cost per unit depends on the "deal" struck between procurement and the manufacturer)**
Dr David Jay Wright **Lead Clinician for Heart Failure**	**See answers to question 9**
Dr Chris Plummer **Consultant Cardiologist**	**As above, if this technology is as described, costs could be reduced.**
Dr Zaheer Yousef **Consultant Cardiologist**	**In the long-term, there are likeley to be cost savings through less need for generator changes. These savings however would need to be seen in the context of the new upfront costs of the new technology.**

GENERAL ADVICE BASED ON YOUR SPECIALIST KNOWLEDGE

Question 14: Is there controversy about any aspect of this technology or about the care pathway?

Expert Advisers	Comment
Dr Roy Gardner **Consultant Cardiologist**	**Not to my knowledge**
Dr Ernest Lau **Consultant Cardiologist**	**Other manufacturers may challenge the longevity data of Boston Scientfic ENDURALIFE-powered CRTDs**
Dr David Jay Wright **Lead Clinician for Heart Failure**	**The comparison with the performance of devices from other manufacturers will need to be on a like for like basis. to demonstrate a new advantage in longevity will take many years so we must rely on data currently available. the data necessary for an accurate comparison will need to come from several sources.**
Dr Chris Plummer **Consultant Cardiologist**	**No**
Dr Zaheer Yousef **Consultant Cardiologist**	**No**

Question 15: If NICE were to develop guidance on this technology, how useful would this be to you and your colleagues?

Expert Advisers	Comment
Dr Roy Gardner **Consultant Cardiologist**	**I think useful to my colleagues**
Dr Ernest Lau **Consultant Cardiologist**	**Would be useful in terms of providing a standardised and rational framework for basing device choice.**
Dr David Jay Wright **Lead Clinician for Heart Failure**	**Very useful in deciding what device should be implanted into patients. At present the decision making is almost arbitrary.**
Dr Chris Plummer **Consultant Cardiologist**	**Yes**
Dr Zaheer Yousef **Consultant Cardiologist**	**The existing TA314 provides sufficient guidance for the indications of these devices. A separate guidance is not required.**

Question 16: ***Do any subgroups of patients need special consideration in relation to the technology (for example, because they have higher levels of ill health, poorer outcomes, problems accessing or using treatments or procedures)? Please explain why***

Expert Advisers	Comment
Dr Roy Gardner **Consultant Cardiologist**	**All patients receiving an ICD or CRT-D could potentially benefit from this technology**
Dr Ernest Lau **Consultant Cardiologist**	**The very old patients (> 85 years) - may need only one device during the remaining lifespan with no need for replacement ever** **The very young patient (e.g. < 30 years) - reduce the number of device replacements required during their lifespans**
Dr David Jay Wright **Lead Clinician for Heart Failure**	**Yes, Young patients requiring an ICD or CRTD as they are more likely to require recurrent box changes and will thus be at increased risk of complications such as infection. A reduction in the number of box changes required by then would be a significant benefit.**
Dr Chris Plummer **Consultant Cardiologist**	**No, an improved battery life would benefit all patients who survive long enough to benefit.**
Dr Zaheer Yousef **Consultant Cardiologist**	**The young and very elderly are most likley to benefit. In the very elderly, it would be advantageous to implant a device with long battery life so that no future box changes would be needed. Conversly, in the young, it is useful to have a device with a long battery life so that the number of box change procedures throughout the patients's life can be limited.**

CONFLICTS OF INTEREST

Question 18.1: Do you or a member of your family have a personal financial interest? The main examples are as follows:

Expert Advisers	Consultancies or directorships	Clinicians receiving payment for a procedure	Fee-paid work	Shareholdings	Financial interest in a company's product	Expenses and hospitality	Funds	Personal non-pecuniary interest
Dr Roy Gardner Consultant Cardiologist	**Yes**	No	**Yes**	No	No	No	No	**Yes**
Dr Ernest Lau Consultant Cardiologist	**Yes**	No	**Yes**	No	No	No	No	No
Dr David Jay Wright Lead Clinician for Heart Failure	**Yes**	No	No	No	No	No	No	No
Dr Chris Plummer Consultant Cardiologist	No	No	**Yes**	No	No	**Yes**	No	No
Dr Zaheer Yousef Consultant Cardiologist	**Yes**	No	**Yes**	No	No	No	No	No

If you have answered YES to any of the above statements please describe the nature of the conflict(s) below.

Dr Roy Gardner Consultant Cardiologist	**I am the Treasurer of the British Society for Heart Failure. Boston Scientific is one of the Society's Friends. I have worked as a Consultant to Boston Scientific as part of a international research study to predict cardiac decompensation (MULTISENSE). I have also been an investigator for several device studies (St Jude, Boston Scientific, Medtronic, and Biocontrol)**
Dr Ernest Lau Consultant Cardiologist	**I currently consult for St Jude Medical. I may consult for Boston Scientific in the future. I have published an abstract based on an internal audit on CRTD longevity in my hospital.**

Expert Advisers	Consultancies or directorships	Clinicians receiving payment for a procedure	Fee-paid work	Shareholdings	Financial interest in a company's product	Expenses and hospitality	Funds	Personal non-pecuniary interest
Dr David Jay Wright **Lead Clinician for Heart Failure**	**I have been paid for educatiuonal lectures and product advisory boards by several device manufacturers including Boston Scientific, medtronic, St Jude and Biotronik**							
Dr Chris Plummer **Consultant Cardiologist**	**I have been paid to attend advisory boards, spoken at educational meetings, received sponsorship to attend international scientific meetings and participated in clinical trials for Boston Scientific, Medtronic and St Jude Medical.**							
Dr Zaheer Yousef **Consultant Cardiologist**	**I hold a consultancy contract with St Jude Medical (CRT-D device manufacturer) for advisory board work relating to heart failure and device therapy. I also hold shares in Spire Health Care (<0.1% of total shares in Spire Group)**							

Question 18.2: Do you have a non-personal interest? The main examples are as follows:

Expert Advisers	Grant for the running of a unit	Grant or fellowship for a post or member of staff	Commissioning of research	Contracts with or grants from NICE
Dr Roy Gardner Consultant Cardiologist	No	**Yes**	No	No
Dr Ernest Lau Consultant Cardiologist	No	No	No	No
Dr David Jay Wright Lead Clinician for Heart Failure	No	**Yes**	No	No
Dr Chris Plummer Consultant Cardiologist	No	**Yes**	**Yes**	No
Dr Zaheer Yousef Consultant Cardiologist	No	**Yes**	No	No

If you have answered YES to any of the above statements please describe the nature of the conflict(s) below.

Dr Roy Gardner Consultant Cardiologist	**St Jude Medical sponsor a research fellow and Boston Scientific sponor a research physiologist in my department.**
Dr Ernest Lau Consultant Cardiologist	Blank
Dr David Jay Wright Lead Clinician for Heart Failure	**Liverpool Heart and Chest Hospital has a clinical fellow sponsored by Medtronic and a research fellow sponsored by Boston Scientific**
Dr Chris Plummer Consultant Cardiologist	**My department has received grants for clinical fellows and have undertaken research projects sponsored by Boston Scientific, Medtronic and St Jude Medical.**
Dr Zaheer Yousef Consultant Cardiologist	**I hold an unconditional education grant with St Jude Medical which funds the salary of a research fellow working with me in the NHS**

Question 18.3: Do you or your organisation or department have any links with, or funding from the tobacco industry?

Expert Advisers	Yes or No?	*If you have answered YES to any of the above statements please describe the nature of the conflict(s) below.*
Dr Roy Gardner **Consultant Cardiologist**	No	Blank
Dr Ernest Lau **Consultant Cardiologist**	No	Blank
Dr David Jay Wright **Lead Clinician for Heart Failure**	No	Blank
Dr Chris Plummer **Consultant Cardiologist**	No	Blank
Dr Zaheer Yousef **Consultant Cardiologist**	No	Blank