Proposal for the development of Guidelines for the De-activation of Implantable Cardiac Defibrillators in End of Life Care

Heart failure is increasing in prevalence and incidence and modern treatments aim to slow it's progression (Gibbs et al 1998). As incidence and prevalence increase, the introduction of modern, interventional therapies increases. More patients are treated with implantable cardiac devices - implantable cardiac defibrillators (ICD), cardiac resynchronisation therapy (CRT) devices, and CRT devices with attached defibrillators (CRT-D). While CRT devices can significantly improve symptoms and prognosis, heart failure remains a progressive disease and a leading cause of death in the United Kingdom (BHF, 2007).

Many potential dilemmas and ethical issues arise when considering implantation and deactivation of ICDs in patients with chronic heart failure. Use of advance care planning can improve patient knowledge and choice in this area, and ultimately improve end of life care.

Many patients with HF are unaware of the life-threatening nature of their condition and as a result are denied the opportunity to discuss plans for end of life care (Millerick 2008). When a patient's condition deteriorates and is unresponsive to conventional therapy, there is a crucial need to reassess priorities and provide supportive, palliative care. An advanced care plan (ACP) is essential to enable quality palliative care. ACPs should incorporate a comprehensive assessment including clarity of prognosis and treatment status and discussion of wishes regarding ICD deactivation towards the end of life (see Appendix 1) .

There is evidence that clinicians rarely discuss ICD deactivation with patients, even with those who are near the end of life. This may be because some clinicians feel deactivating ICDs is withdrawal of support, which makes them feel uncomfortable (Goldstein et al. 2004). Some clinicians might feel ethically challenged and have reservations regarding treatment withdrawal. The uncertainty of prognosis in HF may be another reason why ICD deactivation is not commonly discussed. The patient

with HF has an unpredictable, though mainly declining, disease trajectory (Stewart et al 2001), making decisions regarding treatment options very difficult. Treatment withdrawal does not mean care is withdrawn, only that the focus of care has changed. When a patient dies after withdrawal of treatment, it is the underlying illness that ultimately causes the death (Mueller et al, 2003). ICDs can prolong the dying process, which is not always in the best interest of the patient.

The rationale for implantation of ICDs and CRT-Ds is to enhance patient care by improving symptoms and quality of life and preventing sudden death, but the treatment of HF necessitates the need to be realistic, aware of patients' potential problems, and plan ahead. When providing information regarding device support, the future implications should also be discussed, thus preparing the patient for the potential need for device deactivation at a later date.

Evidence shows that CRT, in addition to optimal medication, can improve exercise tolerance, quality of life and NYHA class (Abraham et al. 2002, Bristow et al. 2004). Bristow et al.'s (2004) study compared 3 groups of patients with heart failure – those on optimal medication therapy only, those with CRT and optimal medication, and those with CRT-D and optimal medication. The authors' found that CRT reduced the combined risk of death or hospitalisation from any cause. However, the addition of an ICD did not have any significant effect on these combined outcomes. Lam et al. (2008) found there was no significant incremental survival value of CRT-D compared with CRT. More recent evidence has found that the addition of a defibrillator improves the rate of sudden deaths, but makes no significant difference to overall long-term survival rate (Stabile et al. 2009). Thus it is not always appropriate to add ICD therapy to CRT and this should always be a consideration when undertaking assessment for device therapy. SIGN 95 (2007) recommend CRT is considered for patients with HF due to left ventricular systolic dysfunction (LVSD), who are symptomatically New York Heart Association (NYHA) classification III or IV, with a prolonged QRS duration. CRT-D is recommended as a consideration for patients with NYHA class III-IV symptoms and prolonged QRS duration, who also meet criteria for ICD implantation (SIGN 95, 2007), this being, the presence of moderate to severe LVSD at least one month following myocardial infarction and, the occurrence of non-sustained ventricular tachycardia, severe LVSD, or prolonged QRS duration (SIGN 94, 2007). Significantly, these groups of patients, who are symptomatic despite optimal medication, are also the groups in

which palliative care needs should also be considered even if they are referred for device therapy. Within SIGN 94, 95 guidelines there is scope to distinguish between the need for CRT only and CRT-D. Thus, how appropriate CRT –D is, as opposed to CRT without a defibrillator device, in these patient groups should be always be questioned. However, anecdotal evidence suggests that very few patients are given the choice between CRT and CRT-D implantation. This highlights the need for provision of clear and concise information regarding interventional procedures. The latest patient information leaflet from Chest, Heart and Stroke, Scotland (2010), Living with an ICD, provides information regarding ICD deactivation at end of life and advises that specialised, palliative care will be available at this time. On review of the literature regarding comparisons of CRT and CRT-D devices (Stabile et al., 2009, Lam et al., 2008, Bristow et al., 2004) as well as the mortality and morbidity comparisons, the financial implications of CRT versus CRT-D were considered. However, none of the literature considered the implications of added ICD therapy in relation to end of life and palliative care. The authors were clearly looking at the benefits of device therapy in terms of prolonged survival, but despite HF being a chronic disease, they did not consider the implications of ICD activity in end of life care.

Evidence (Berger, 2005, Nambisan and Chao, 2004, Mueller et al, 2003)) indicates a need to develop guidelines and protocols regarding ICD deactivation in end of life care to enable fulfilment of patient' wishes. Clinicians may feel more comfortable withdrawing treatment if their input is protocol or guideline driven. Nambisan and Chao (2004), discuss a case where a patient with metastatic lung disease with an ICD, was prevented from dying peacefully as no plans had been made to deactivate the device, despite a DNAR order being drawn up. The patient developed fast atrial fibrillation which triggered her ICD and, several shocks were administered while she was fully conscious. In this case the patient was hospitalised and arrangements were eventually made, though not without great difficulty, to have the ICD deactivated. However, had this occurred in the patient's home the situation would have been very different. This demonstrates the need for early discussion regarding ICD deactivation. Many terminally ill patients, regardless of their primary diagnosis, will develop multiple organ failure towards the end of life. This can trigger electrolyte disturbances, which in turn can cause arrhythmias and activation of an ICD. The provision of quality palliative care should ensure the dying process is as peaceful as possible. Patient's wishes regarding cardiopulmonary resuscitation (CPR)

should be documented in an ACP. If the patient does not wish CPR in the event of a cardiac arrest, a Do Not Attempt Cardiopulmonary Resuscitation (DNACPR) form should be completed and kept in an easily accessible place. If DNACPR is requested the deactivation of ICDs should also be discussed at this time and, arrangements for deactivation made as soon as possible to prevent distressing situations at the end of life.

Patients require clear and concise information regarding the implications of device therapy at the end of life. This enables informed choices to be made regarding treatment and assists the development of ACPs to ensure all health care providers are aware of plans for end of life care. Jaarsma et al (2009) recommend discussing ICD deactivation early in the end-stage of HF, although, ideally, these discussions should occur prior to device implantation, or at the earliest opportunity, to avoid unnecessary distress near the end of life. There is a clear need for guideline development to ensure clinicians are comfortable in facilitating ICD deactivation, and to enable prompt deactivation once decisions are made.

Appendix 1

Comprehensive Assessment checklist

Clarity of treatment status:

Patient's medication optimised	Yes/No	Date
NYHA Class III/IV	Yes/No	Date
Unstable for > 3 months	Yes/No	Date
Further investigation/intervention indicated	Yes/No	Date

Poor prognosis:

Palliative care and comfort measures only	Yes/No	Date

Advanced Planning:

Patient treatment status clarified/documented	Yes/No	Date
Is CPR likely to be effective?	Yes/No	Date
DNAR status clarified	Yes/No	Date
Device in situ	Yes/No	
Type of device:		
CRT	Yes/No	
CRT-D	Yes/No	
ICD	Yes/No	
Device de-activation	Yes/No	Date
Device de-activated planned	Yes/No	Date
Reason for device not being de-activated		

Priorities of Care:

Preferred place of care - Home / hospice / hospital /other -

Symptom management	Yes/No	Date
Medication review	Yes/No	Date

Social care review:

Care package	Yes/No	Date
Carer	Yes/No	Date

General Practitioner review:

Medication review	Yes/No	Date
DS 1500	Yes/No	Date
Gold Standards Framework Register	Yes/No	Date
Electronic palliative care summary	Yes/No	Date
Emergency care summary for A&E/ OOH	Yes/No	..Date
Liverpool care pathway (as appropriate last 72 hours)	Yes/No	Date
Verification of expected death form (if at home in last 72 hours)	Yes/No	Date

References

Abraham, W.T., Fisher, W.G., Smith, A.L., Delurgio, D.B., Leon, A.R., Loh, E., Kocovic, D.Z., Packer, M., Clavell, A.L., Hayes, D.L., Ellestad, M. Messenger, J., (2002) "Cardiac resynchronization in chronic heart failure", *New England Journal of Medicine,* Vol. 346, no.24, pp 1845-1853.

Berger, J.T. (2005) "The ethics of Deactivating Implanted Cardioverter Defibrillators", *Annals of Internal Medicine,* Vol. 142, pp 631-634

Bristow, M.R., Saxon, L.A., Boehmer, J., Krueger,S., Kass, D.A., De Marco, T., Carson, P., Di Carlo, L., DeMets, D., White, B.G., De Vries, D.W., Feldman, A.M., for the Comparison of Medical Therapy, Pacing and Defibrillation in Heart Failure (COMPANION) Investigators (2004) "Cardiac-Resynchronization Therapy with or without an Implantable Defibrillator in Advanced Chronic Heart Failure", *The New England Journal of Medicine,* Vol. 350, no. 21, pp 2140-2150

British Heart Foundation (2007) "Implantable cardioverter defibrillators in patients who are reaching the end of life", BHF, London.

Chest, Heart & Stroke, Scotland (2010), "Living With an ICD", CHSS, Edinburgh.

Goldstein, N.E., Lampert, R., Bradley, E. Lynn, J. Krumholz, M., (2004) "Management of Implantable Cardioverter Defibrillators in End-of Life Care", *Annals of Internal Medicine,* Vol. 141, pp 835-838.

Jaarsma, T., Beattie, J.M., Ryder, M., Rutten,F.H., McDonagh, T., Mohacsi, P., Murray, S.A., Grodzicki, T., Bergh, I., Metra, M., Ekman, I., Angermann, C., Leventhal, M., Pitsis, A., Anker, S.D., Gavazzi, A., Ponikowski, P., Dickstein, K., Delacretaz, E., Blue, L., Strasser, F., McMurray, J. (2009) "Palliative care in heart failure: a position statement from the palliative care workshop of the Heart Failure Association of the European Society of Cardiology", *European Journal of Heart Failure,* Vol. 11, pp 433-443

Lam, S.K.H., Tse, H., Lau, C. (2008) "CRT Begets CRT-D: Is One Better Than the Other?", *Journal of Electrophysiology,* Vol. 19, no.12, pp 1266-1269.

Millerick, Y., (2008) "Integrating palliative care recommendations into clinical practice for chronic heart failure", *British Journal of Cardiac Nursing,* Vol. 3, no.12, pp 579-585.

Mueller, P.S., Hook, C.C., Hayes, D.L. (2003) "Ethical Analysis of Withdrawal of Pacemaker or Implantable Cardioverter-Defibrillator Support at the End of Life", *Mayo Clinic Proceedings,* Vol. 78, pp 959-963

Nambisen, V., Chao, D., (2004) "Dying and defibrillation: a shocking experience", *Palliative Medicine,* Vol. 18, pp 482-483

Scottish Intercollegiate Guidelines Network (2007) "Management of chronic heart failure: A national clinical guideline", Guideline 95, SIGN, Edinburgh.

Scottish Intercollegiate guidelines Network (2007) "Cardiac arrhythmias in coronary heart disease: A national clinical guideline", Guideline 94, SIGN, Edinburgh.

Stabile, G., Solimene, F., Bertaglia, E., La Rocca, V., Accogli, M., Scaccia, A., Marrazzo, N., Zoppo, F., Turco, P., Iuliano, A., Shopova, G., Ciardiello, C., De Simone, A. (2009) "Long-Term Outcomes of CRT-PM Versus CRT-D Recipients", *Pacing and Clinical Electrophysiology,* Vol.32 , pp 141-145

Stewart, S., MacIntyre, K., Hole, D., Capewell, S., McMurray, J. (2001) "More 'malignant 'than cancer? Five - year survival following a first admission for heart failure", *European Journal Heart Failure,* Vol. 3, pp 315-322