Results Between 2015–2021, 1681 cases were discussed. Table 1 demonstrates VC baseline characteristics. Overall, most cases were New Diagnostic Case (39%), followed by Re-discussion (33%) and New Case Consultation (27%). Re-discussion cases have increased since VC first started. Mean age was 76.2 (SD 11.3) years old, with almost equal males and females (51% and 49%). In total, 333 GPs used the service. The majority of cases being discussed were from outside of Dublin (75%). VC patients were complex, with a mean of 7.1 (SD 3.4) comorbidities, and on a mean of 9.3 (SD 4.0) medications. VC patients had a mean clinical frailty score of 3.8 (SD 1.7) which is significantly (P = 0.006) higher compared to the HFU (2.8 [SD 1.4]). In total, there were 955 (57%) medication adjustments advised, 343 (20%) echocardiograms and 145 (9%) natriuretic peptides (NP) requested as an outcome from the VC. Overall, there were 217 (13%) onward referrals of any sort. This included hospital outpatient (n = 98, 6%), HFU (n = 52, 3%) and HF specialist nurse (n = 16, 1%). Figure 1 demonstrates ‘What the GP would have done if there was no VC service’. Without the VC service, there would have been 93% of onward referrals to the hospital. This would have included outpatient clinics (n = 641, 50%), HFU (n = 441, 34%), and acute (n = 92, 7%) or emergency services (n = 18, 1%). Figure 2 demonstrates the incremental use of GP requested NP and echocardiography as a potential marker of improved HF diagnostic knowledge transfer to the community.

Conclusions HFVC is now established, in particular for more frail patients. There has been an increase in re-discussion cases, which demonstrates that VC can be used as a tool for continued care, in addition to a service that reduces onward hospital referrals. We have witnessed evolving practice change in community reflecting improved understanding of community HF care. This platform should be looked at in general cardiology and other chronic disease management settings.

Methods A systematic literature review was conducted using Ovid, MEDLINE, Embase, and the Cochrane Central Register of Controlled Trials (CENTRAL) of studies of prospective design evaluating pre specified high-risk medical devices in the field of cardiovascular medicine between January 2000 and August 2021. We included selected high-risk devices that received CE Mark approval from the year 2000 onwards. The date of CE-Mark approval was defined through press releases available online, information provided by regulatory sources such as notified bodies, and personal communications with the corresponding manufacturers. We focused on any study of prospective design (non-randomised or randomised clinical trials of any design) in humans. We excluded retrospective studies, case reports, reviews, systematic reviews, meta-analyses, and expert opinion documents. We performed title and abstract screening, full-text review, risk of bias evaluation and data collection independently and in duplicate.

Results The following classes of high-risk medical devices in the cardiovascular field were evaluated: left atrial appendage occlusion (LAOO), transcatheter aortic valve implantation (TAVI); transcatheter mitral valve repair/replacement (TMVR); leadless pacemakers; subcutaneous implantable cardioverter-defibrillators (S-ICD), bioresorbable scaffolds for percutaneous coronary intervention; and surgical heart valve replacement for native aortic and mitral valve pathologies. For the latter group, a total of 17 surgical aortic valves and 4 surgical mitral valves were included. An interim report of the systematic review of the CORE-MD consortium with a focus on surgical heart valve replacement will be available for presentation at ICS 2022. To date, the literature search has identified 3696 and 4901 potentially eligible papers in the surgical mitral valves category and surgical aortic valves categories, respectively.

Conclusion The goal of the CORE-MD consortium is to develop awareness of and expertise within the clinical community in Europe in relation to the regulation of high-risk medical devices. Data from the systematic review of high-risk cardiovascular devices will enable comparison of strength of evidence within and across classes of devices in cardiovascular medicine and facilitate comparison against high-risk devices in other medical specialties including orthopaedics and diabetes.

Moderated poster session 2

24 SYSTEMATIC REVIEW OF STRENGTH OF EVIDENCE SUPPORTING THE APPROVAL AND CLINICAL USE OF HIGH-RISK MEDICAL DEVICES IN CARDIOVASCULAR MEDICINE: AN UPDATE FROM THE CORE-MD CONSORTIUM

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Introduction Implementation of the new Medical Device Regulation (MDR) 2017/745 by the European Union (EU) challenges the medical community to engage with regulators, notified bodies and industry to develop transparent, rigorous and proportionate methods to evaluate the clinical safety and efficacy of medical devices and monitor their performance. Against this background, as part of the EU Horizon 2020 funded project – CORE-MD – we performed a systematic review of clinical evidence available for selected class III implantable devices used in cardiovascular medicine.

25 A SNAPSHOT OF CARDIOVASCULAR HEALTH IN BONE MARROW TRANSPLANT RECIPIENTS IN IRELAND

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Introduction Bone Marrow Transplantation has been completed in Ireland in a single site, St James’s Hospital, since 1984. The European Society for Blood and Marrow Transplantation (EBMT), Transplantation Complication Working Party (TCWP) published recommendations in 2016 on screening and preventative practices on cardiovascular disease in post-Bone Marrow Transplant (BMT) patients, as there is evidence of both earlier onset and overall increased risk of cardiovascular disease in this patient cohort. There is a paucity of evidence identifying the prevalent risk factors amongst the Irish cohort of BMT recipients, and the affect these risks have on their cardiovascular outcomes.
Aim The aim of this study is to identify the current modifiable cardiovascular risk profile of patients attending the post-BMT Long-Term Outcomes clinic, over a 3-month period, and their subsequent cardiovascular outcomes.

Methods Retrospective data collection from patient medical records was completed. Inclusion criteria of allogeneic transplant prior to 2020, and over the age of 18 at time of BMT. Data was analysed using IBM SPSS.

Results 141 patients (median age at transplant of 44 years) met inclusion criteria, with a mean follow-up post-BMT of 8.21 years (range 1.30–35.95 follow-up years). 60% of the cohort were overweight. There was a 10% pre-BMT prevalence of diagnosed hypertension and a 28% post-BMT prevalence of diagnosed hypertension. Of those with an active diagnosis of hypertension, 62% were uncontrolled on review in clinic. 25% of patients not formally diagnosed with hypertension were found to be hypertensive on review in clinic. Untreated or uncontrolled hypertension was statistically more likely in those >6 years post-BMT (47.5% vs 28.8%; p=0.029) (figure 1). There was a 7% pre-BMT prevalence of diagnosed dyslipidaemia and a 25% post-BMT prevalence of diagnosed dyslipidaemia. Of those with an active diagnosis of dyslipidaemia, 30% were uncontrolled on review in clinic. 16% of the patient cohort are at high risk of developing dyslipidaemia. There was a 10% prevalence of diabetes mellitus and a 15% prevalence of iron overload. There was a 5% incidence of non-fatal major adverse cardiovascular/cerebrovascular events (MACE) since transplant.

Conclusion Modifiable cardiovascular risk factors are prevalent amongst the post-BMT cohort. These patients are at higher risk of poor cardiovascular outcomes due to their post-BMT status and thus require close monitoring of these modifiable risk factors. This could be included as a routine aspect of their post-BMT clinic reviews. There is scope for further research in this area, including formalising a screening process to ensure prompt diagnosis of modifiable cardiovascular risk factors. Identification of management structures, such as joint haematology-cardiology clinics, could ensure earlier patient intervention, avoiding additional pressure on general cardiology outpatient services.

AMPUTATORY CARIOLOGY UNIT – AN INNOVATIVE, SAFE, HIGH QUALITY SERVICE, REDUCING HOSPITAL ADMISSIONS

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Abstract 25 Figure 1 Prevalence and control of hypertension by years after transplantation

Introduction The COVID-19 pandemic emphasised the need for re-design of Acute and Emergency Medicine service provision. Ambulatory Emergency Care (AEC) refers to investigation, care and treatment of patients for whom admission to hospital would have been the default if the service did not exist. In 2021, Southern Health and Social Care Trust introduced an innovative Ambulatory Cardiology Unit (ACU) to address an unmet need, reducing pressure on inpatient beds and Emergency Department. National guidelines have identified patients suitable for ambulatory care.

Methods A pre-intervention audit was undertaken to identify patients who could be managed in an ambulatory setting avoiding hospital admission. After introducing ACU a post-intervention audit was conducted evaluating: 1) Patient safety 2) Impact on flow 3) Return on investment. Critically, an anonymous patient survey was simultaneously conducted to determine patient satisfaction with the new service.

Results A 3 month pre-intervention audit identified 115 patients who would be suitable for ambulatory care. The mean length of stay of these patients was 2.96 days. Post-intervention audit: In the first 3 months of ACU, 137 patients were referred to the unit from Emergency Department. 18% of these patients had been referred to Cardiology services in the previous 12 months and were awaiting outpatient assessment. Following triage, 90% of referrals were accepted. The remaining 10% did not meet clearly defined inclusion criteria. Figure 2 shows accepted referrals to ACU. Patient safety: There was less than 2% re-attendance with no adverse patient outcomes identified at 30 days. Flow: Mean time from triage to review was 4 days (inclusive of bank holidays and weekends). Following appropriate same day investigations, 66% of patients were suitable for discharge with a diagnosis and management plan. Return on investment: Over 3 month period...