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eprints@whiterose.ac.uk https://eprints.whiterose.ac.uk/ New cross-specialty guidelines for the prevention and management of implantable cardiac electronic device infection.

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Infections related to implantable cardiac electronic devices (ICEDs) including permanent pacemakers (PPM), implantable cardiac defibrillators (ICD) and cardiac resynchronisation therapy devices (CRT) are increasing in incidence in the USA.^{1,2} Approximately 40,000 ICEDs were implanted in the UK in 2010 and the number of ICD and CRT implantations is increasing by 12-15% year on year.³ Whilst robust data on infection rates within the NHS are not available, anecdotal evidence suggests that this is increasingly common. ICED infections present complex clinical scenarios not simply because a medical device is involved but also because these devices have both intravascular and extravascular components and infection may involve the generator, device leads and native cardiac structures alone or in combination. ICED infections can be life threatening and all cause mortality approaches 35%. Diagnosis is often difficult and the possibility of ICED infection frequently overlooked, resulting in treatment delay. Hospitalisation is usually required for prolonged intravenous antimicrobial therapy (with associated risk of toxicity) and consideration of technically challenging reintervention. The parallels with infective endocarditis (IE) affecting native cardiac structures and implanted prosthetic valves are obvious.

Concerned by a widespread lack of awareness of the scale of the problem and the lack of a standardised approach to the prevention and treatment of ICED infection, the British Society

for Antimicrobial Chemotherapy (BSAC) established a Working Party in collaboration with the key UK national societies to develop guidelines that would: 1) improve the quality of care provided to patients with ICEDs; 2) provide an educational resource for all relevant healthcare professionals; 3) encourage a multidisciplinary approach to the management of ICED infection; 4) promote a standardised approach to the diagnosis, management, surveillance and prevention of ICED infection through pragmatic evidence-rated recommendations; 5) advise on future research and audit projects. The new guidelines⁴ are complex, reflecting the magnitude of the problem, the need for specialist input and a reluctance to provide a "one size fits all" approach. They also promote a whole-health service approach by attempting to locate all key issues related to the diagnosis, treatment and prevention of ICED infection in one document.

Prevention is better than cure. The environment in which an ICED is implanted is therefore crucial to prevent infection since most infections probably originate at the time of device insertion. In 2014, it is astonishing that operating theatre standards, including rigorous requirements for ventilation, have not been universally adopted in cardiac catheter laboratory or radiology suites where ICED implantation procedures are performed. Single dose antimicrobial prophylaxis using glycopeptides as the primary agent of choice is recommended immediately prior to device insertion, even though high-level evidence to support this recommendation is lacking.⁴

Non-specialists are discouraged from treating inflamed generator pockets or insertion wounds with empirical antimicrobial therapy since this hampers diagnosis and delays appropriate management.⁴ Early blood cultures, before the initiation of antimicrobial therapy are vital, although approximately 15% of ICED infections are currently culture-negative,⁴ and all cases of suspected ICED infection should be discussed with experts at the implanting centre. The guidelines call for a low threshold of diagnostic suspicion in patients with an ICED and a protracted non-specific illness, recurrent "chest infections", or unexplained staphylococcal bacteraemia - it is not widely appreciated that 30%–45% of patients with a staphylococcal bacteraemia and an ICED in situ have ICED infection.

ICED infection is associated with biofilm formation and eradication of infection is very unlikely without device removal (even though 3–15% of patients decline re-intervention or are unsuitable for ICED removal).⁴ Antimicrobial treatment strategies are potentially complex and should therefore be discussed by the multidisciplinary team with consideration of (i) plans to remove the infected ICED, (ii) alternative device salvage strategies, (iii) the presence of ICED-IE, and (iv) the presence and extent of extra-cardiac foci of infection. The guidelines

propose strategies for maximizing the potential success of each approach.

Inevitably, rigorous guidelines that aim to raise treatment standards carry major service implications. The recommendation that infected ICED removal should only be undertaken in recognised centres with appropriate operator and procedural expertise and accompanying immediately available surgical facilities will not be popular in the UK, especially in smaller ICED implanting centres whose activity is threatened by minimum procedural volumes specified within new commissioning standards. Implementation of the guideline recommendations will also be hampered by lack of suitably trained staff and appropriate resources in competition with other priorities in cardiac rhythm management currently challenged by long waiting lists. Resulting delay in infected ICED removal will inevitably result in unduly prolonged antimicrobial therapy and inpatient care. As the number of implanted ICEDs continues to rise, careful future planning and estimation of the service requirements for device surveillance and treatment of infection will be vital to allow efficient use of scarce NHS resources.

Finally, literature reviews undertaken within the guideline development process highlighted the lack of accurate contemporary epidemiological information concerning infection rates, patient outcomes, causative pathogens and their antimicrobial susceptibility. Moreover, the lack of high quality evidence to support the recommended strategies for prevention and treatment of ICED infection was abundantly clear. High quality audit and research are needed to improve patient experience, efficiency of service delivery and clinical outcomes – these guidelines provide an opportunity for the UK to lead the way.

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