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NHS Foundation Trust

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4 July 2019

Margaret Jones
HM Assistant Coroner for Stoke on Trent and North Staffordshire
Coroner's Chambers
547 Hartshill Road
Stoke-on-Trent
ST4 6HF

Sent by way of email: coroners@stoke.gov.uk

Dear Mrs Jones,

**Inquest touching the death of Mr Geoffrey Duke**
**Response to Regulation 28 Report to prevent future deaths**

I write in response to the Regulation 28 Report made by you following the Inquest into the death of Mr Duke, which concluded on 14 May 2019.

University Hospitals Birmingham NHS Foundation Trust (the Trust) has carefully considered the concerns raised within your report to prevent future deaths. Before I address the specific concern you raise, I would like to provide some detail as to the number of pacemakers placed within our Trust and the outcome of an audit that has been undertaken which includes the incidence of pacemaker related infection.

**1. Review of pacemaker complications for both new implants and upgrades**

The incidence of pacemaker related endocarditis is low in comparison to other systemic infections. Most recent data suggests an incidence of approximately 4.5 cases per 1,000 pacemaker implants, giving an incident of 0.45%. The infection rate following a pacemaker change has an incidence of 1% within the first year.

There were 1474 new implants/upgrades/ device changes undertaken by our Trust during the last financial year. Infection is a recognised complication of these procedures. Most recent audits of new implants undertaken in the Trust show an infection rate of 0% at 3 months on our QEHB site in 2018 and 0.65% at our Heartlands, Good Hope and Solihull sites in 2015. There is ongoing audit however based on the evidence we have, we have not noticed any increase in reporting of infection post procedure. International published data (see reference below)

suggests infection rates of 0.5-0.8% for new implants and 1-4% for device revisions (generator changes, upgrades or lead replacements).

**2. Treatment provided to Mr Duke**

Mr Duke had a dual chamber pacemaker fitted in 2007 for complete heart block. Most devices require a battery change at around 5 to 7 years depending on use. Mr Duke underwent a box change on 15 June 2016 which also included a change of the atrial lead as the impedance had dropped significantly. There were no complications noted following the change in June 2016.

Mr Duke attended our ambulatory care clinic on 6 February 2017 where he was assessed by a Consultant Physician. His presentation was in keeping with a diagnosis of community acquired pneumonia for which he received antibiotics. Blood cultures were taken which were negative at this time, which would have been against the diagnosis of a pacemaker related endocarditis.
Mr Duke was asked to return on 8 February when he was noted to be improving. We did not see Mr Duke again.

**3. Cardiology referral for unwell patients who have undergone pacemaker procedure**

We have an embedded referral process to our cardiology team on each of our sites for patients who present with suspected acute cardiac problems. This consists of a daily Consultant Cardiologist ward round at the Queen Elizabeth Hospital and a Consultant of the week available for consultation at Heartlands, Good Hope and Solihull Hospitals.

Our data shows that there are on average 15 – 20 referrals per day to the cardiology team on each of our sites (60 - 80 referrals per day across our Trust) of patients with suspected acute cardiac problems. We are satisfied that our cardiology referral process works effectively across all our sites which can be evidence by the number of referrals to the cardiology team per day.

We do know that device related endocarditis is a rare and often covert infection. There is no national algorithm available to assist in the diagnosis of pacemaker related endocarditis and no evidence base to design a specific algorithm. It is recognised nationally that awareness of device related endocarditis amongst physicians is an issue and that in the absence of clear signs of pacemaker pocket infection, a diagnosis of pacemaker related endocarditis is often delayed as referenced in the '*Guidelines for the diagnosis, prevention and management of implantable cardiac electronic device infection. Report of a joint Working Party project on behalf of the British Society for Antimicrobial Chemotherapy (BSAC, host organization), British Heart Rhythm Society (BHRS), British Cardiovascular Society (BCS), British Heart Valve Society (BHVS) and British Society for Echocardiography (BSE) J Antimicrob Chemother 2014)*'.

## 4. Action Plan

Having reviewed our referral process to our cardiology teams, we are satisfied that we have in place an effective referral process however as a result of your report we have undertaken a review of our endocarditis guidelines to ensure they are robust and we are assured that our guidelines are comprehensive and include specific reference to device related infection and endocarditis and therefore do not require any amendment.

Our review of the literature suggests that one of the key issues in the delay in diagnosing device related endocarditis is a lack of awareness amongst both patients and acute physicians.

To raise awareness of pacemaker related endocarditis amongst our acute physicians, we are undertaking a programme of education which will be provided via our grand round to alert our staff to the possibility of pacemaker endocarditis. This will be undertaken in the next academic term (September - December 2019).

We will also be sending out a 'Lesson of the Month' which is an email which goes out to all staff with the aim to raise awareness of the signs and symptoms of pacemaker related endocarditis. This will be circulated within the next 4 weeks.

We have also reviewed the patient information leaflets which are provided to all patients following pacemaker insertion. The leaflets already contain information on symptoms which might represent possible infection and provide details of who the patient should contact if they are concerned. Whilst we are satisfied that the information leaflets contain sufficient information for patients, we will be updating them to include additional instructions where patients have symptoms of possible infection, in particular the leaflet will indicate that if the patient has a fever and temperature above 38 degrees Celsius, then they should a) seek medical attention and b) inform their treating clinician that they have a pacemaker and that device related endocarditis should be considered. Our aim is to update the leaflets by the beginning of November 2019.

I would like to assure you that the concerns raised within the Regulation 28 Report have been taken extremely seriously which I hope is demonstrated by the steps we have taken in reviewing our processes and guidelines and which we will be taken to raise awareness of device related infection.

Yours sincerely,

**Professor Simon Ball**
**Medical Director**