NHS
West Norfolk
Clinical Commissioning Group

King's Court
Chapel Street
KING'S LYNN
Norfolk
PE30 1EL

Tel: 01553 666900
www.westnorfolkccg.nhs.uk

25 May 2018

FREEDOM OF INFORMATION – DECISION NOTICE

Dear Requester

FOI Reference Number: 17145

I refer to your email of 11 May requesting information in respect of innovation technology tariff devices.

I can confirm on behalf of NHS West Norfolk CCG and in accordance with S.1 (1) of the Freedom of Information Act 2000 (FOIA) that we do not hold the information that you have requested. A response to each element of your request is detailed below:

Response
The information sought is not held by the CCG however may be held by the Academic Health Science Network which should be able to assist you further and can be contacted via the Chief Executive, Piers Ricketts, at piers.ricketts@eahsn.org

Request
I am writing to you regarding the usage of the AliveCor Kardia ECG device which has been made available to your organisation from your local AHSN under the Innovation and Technology Tariff from NHSE.

In January of this year I wrote to the National Data Guardian and outlined my concerns regarding this device and its ability to send ECG data back to the US manufacturers. I received the response, attached, from Dame Fiona Caldicott expressing her concerns.

Whilst advice from your local AHSN may tell you to operate these devices in "Guest" mode, I have concerns that as the device sends a copy of clinical ECG data to the US, for the manufacturers commercial gain, that the second principle of the Data Protection Act 1998 which states that: Personal data shall be obtained only for one or more specified and lawful purposes, and shall not be further processed in any manner incompatible with that purpose or those purposes." is thus breached as the patient never consents that their data may help the R&D efforts of a US organisation.

During the NICE Scoping Workshop for Lead-I electrocardiogram (ECG) devices for detecting atrial fibrillation on Monday 22 January 2018, representatives from the US manufacturer admitted to the workshop that their device was not GDPR compliant. Might I make the suggestion that you ensure that you are operating the device in accordance with both the Data Protection Act and forthcoming GDPR regulations by obtaining written patient consent from every patient that they are happy for their data to be used by a third party US company for commercial gain.

I have a suspicion that by the end of the year more NHS patients will have delivered their ECG data unwittingly to the US company than the UK had Facebook users whose profiles were data mined by Cambridge Analytica.

Therefore under the Freedom of Information Act 2000 I request the following information from your authority. Please provide me with:

1- The number of AliveCor Kardia devices that your organisation has received under the Innovation technology Tariff.
2- The estimated usage of these devices, how many readings per device per month to date.
3- The number of cases of true positive Atrial Fibrillation that devices have found.
4- The Guidance information that you have received with regards their usage from your AHSN.

Please provide me with a printed response. If it is not possible to provide the information requested due to the information exceeding the cost of compliance limits identified in Section 12, please provide advice and assistance, under the Section 16 obligations of the Act, as to how I can refine my request. If you have any queries please don't hesitate to contact me via email and I will be happy to clarify what I am asking for, my details are outlined below.

Above all please ensure that you are compliant with both DPA and GDPR when operating this device.

I hope that this answers your queries with the information we currently hold, but if I can be of any further assistance please do not hesitate to contact me.

If you are dissatisfied with the handling of your request, you have the right to ask for an internal review. Internal review requests should be submitted within two months of the date of receipt of the response to your original letter and should be addressed to

Arden & GEM CSU
FOI Team, Room 18
Scarsdale
Newbold Road
Chesterfield
S41 7PF
Email agcus.foi.norfolkwaveneyccgs@nhs.net

If you are not content with the outcome of your complaint, you may apply directly to the Information Commissioner for a decision. Generally, the ICO cannot make a decision unless you have exhausted the complaints procedure provided the CCG.

The Information Commissioner can be contacted at: Information Commissioners Office, Wycliffe House, Water Lane, Wilmslow, Cheshire SK9 5AF, telephone 0303 123 1113, email casework@ico.org.uk

Yours faithfully

Philip Humphreys
FOI Manager
Arden & GEM CSU

On behalf of
NHS West Norfolk CCG