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Request for Information Reference: 05.19.30

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Email only

17 June 2019

Freedom of Information Act 2000 – Request for Information

Thank you for your request for information received on 20 May 2019 in relation to the County Durham and Darlington NHS Foundation Trust (Trust). We are dealing with your request under the provisions of the Freedom of Information Act 2000.

You requested information regarding surgical mesh. Specifically you requested information as follows:

Re- paragraph 11, please would you confirm whether the Clinical Advisory Group has:

- a) Provided a definition if the procedures and scope of the high vigilance restriction, and if it has, please provide copies of the relevant documents:***
- b) Advised on appropriate confirmation processes to ensure the appropriateness of any mesh procedures intended, and if it has, please provide copies of the relevant process documents:***
- c) Recommended a process for provider trust Medical Directors to sign off a surgeon's competence for mesh procedures and any alternative operations, and, if so, please provide copies of any recommended processes; and***
- d) Advised on best options to ensure patient information and consenting processes are in place in a trust, and, if so, please provide a copy of such advice.***

Re paragraph 6, please would you confirm the following:

a) Surgeons should only undertake operations for SUI if they are appropriately trained, and only if they undertake operations regularly

i. What level of specialist training and/or accreditation NHS England regard as sufficient for a surgeon to be regarded as 'appropriately trained'

ii. Has the level of specialist training and/or accreditation specified in answer to (i) been communicated to trusts, and, if so, when did this take place and could we please have a copy of the communication(s)

b) Surgeons report every procedure to a national database

i. Whether a national database for the reporting of procedures using surgical mesh/tape inserted vaginally to treat stress urinary incontinence and urogynaecological prolapse has been established, and, if so, when was it established?

ii. If the answer to (i) is yes, when was the existence of that database communicated to trusts, with what accompanying guidance for its use and could we have a copy of all related documents?

c) A register of operations is maintained to ensure every procedure is notified and the women identified who has undergone surgery

i. Has a national register of procedures been established, and, if so, when was this done?

ii. What guidance has been issued to trusts concerning the use of such register and could we have a copy

iii. Alternatively, is it expected that trusts will establish their own registers, and, if it is, what evidence that this has been done?

d) Reporting of complications via MHRA is linked to the register

i. What procedure has been established to ensure that the reporting of complications via MHRA is linked to such a register?

ii. When was the procedure at (i) established, and how and when was its existence communicated to trusts and could we have a copy of those communications?

iii.

e)

Identification and accreditation of specialist centres for SUI mesh procedures, for removal procedures and other aspects of care for those adversely affected by surgical mesh.

- i. What criteria and procedure have been established for the accreditation of specialist centres for SUI mesh and related procedures, who were they established by and could we have a copy of all relevant documentation***
- ii. What organisation is to administer any such criteria and procedures?***

We have advised the client (anonymous under the Act) that on our reading of the HV restriction letter completion of the work specified at paragraph 15 is a prerequisite for the cessation of the high vigilance restriction. Please would you also therefore inform us, so far as it is different from the answers already provided to the questions above, what stage has been reached in the following processes, when are they expected to be completed and can we see all documentation associated with them#

A. completion, through Specialised Commissioning, of the consultation of the new service specification for complex SUI and prolapse procedures, mesh removal and the procurement of a small number of designated specialist removal services that will support urogynaecological/ female urology networks; and

B. pursuing the commissioning of a national clinical audit / registry for urogynaecological procedures for SUI and prolapse

County Durham and Darlington NHS Foundation Trust replies:

The questions as written appear to be directed to NHS England as the commissioner of services. We would advise, in accordance with Section 16 of the Act (duty to provide advice and assistance), that you contact NHS England for the requested information via the following email address: england.contactus@nhs.net

The Trust can advise as follows:

Following the 2018 NHSE/I advice to acute trusts, the urogynaecology department at the Trust ceased ALL surgery for stress urinary incontinence and is awaiting the final outcome and guidance from both NICE, NHSE/I and the Cumberlege Review before restarting any continence surgery based on the full recommendations made for all surgical procedures. The urogynaecology department at the Trust does not and has not used mesh for the treatment of pelvic organ prolapse.

In line with the Information Commissioner's directive on the disclosure of information under the Freedom of Information Act 2000 your request will form part of our disclosure log. Therefore, a version of our response which will protect your anonymity will be posted on the County Durham and Darlington NHS Foundation Trust website.

If you have any queries or wish to discuss the information supplied, please do not hesitate to contact me on the above telephone number or at the above address.

If you are unhappy with the way your request for information has been handled, you can request a review by writing to:

The Chief Executive
County Durham & Darlington NHS Foundation Trust
Darlington Memorial Hospital
Hollyhurst Road
Darlington
DL3 6HX

If, you remain dissatisfied with the handling of your request or complaint, you have a right to appeal to the Information Commissioner at:

The Information Commissioner's Office
Wycliffe House
Water Lane
Wilmslow
Cheshire
SK9 5AF

Telephone: 0303 123 1113
Website: www.ico.gov.uk.

There is no charge for making an appeal.

Yours sincerely

Joanna Tyrrell
Freedom of Information Officer