Freedom of Information request 014825
20/6/19

Use of surgical mesh following publication of the NICE guidelines,
Freedom of Information request reference INC 014825

Please find the Trust's responses to your questions answered in turn below.

Question 1
Would you please confirm whether the CAG has:

a) Provided a definition of the procedures and scope of the high vigilance restriction, and, if it has, please provide copies of the relevant documents.

Response:
The Trust has not received a definition of the procedures and scope of the high vigilance restriction from CAG.

Question 2
Would you please confirm whether the CAG has:

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.

Response:
The Trust has not received advice on appropriate confirmation processes to ensure the appropriateness of any mesh procedures intended from CAG.

Question 3
Would you please confirm whether the CAG has:

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.

Response:
The Trust has not received a recommended process for provider trust Medical Directors to sign off a surgeon's competence for mesh procedures and any alternative operations from CAG.

Question 4
Would you please confirm whether the CAG has:

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.

Response:
The Trust has not received advice on best options to ensure patient information and consenting processes are in place in a trust from CAG.

Question 5

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

Response:
Yes, Surgeons should only undertake operations for SUI if they are appropriately trained, and only if they undertake operations regularly.

Question 6

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

Response:
NHS England would hold this information.
From a Trust point of view the surgeon's competence in the procedure must be signed off in advance by the Trust's Medical Director as part of the high vigilance procedure. The surgeon would need to be accredited to Consultant level and Urogynaecology trained and have actively maintained their skills.

Question 7

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)?

Response:
The level of specialist training and/or accreditation specified in answer to (i) has not been communicated to the Trust.

Question 8

b) Surgeons report every procedure to a national database

Response:
Procedures reported to the BSUG specialty database.

Question 9

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 it was established.

Response:
Yes, a national database for reporting of procedures using surgical mesh/tape inserted vaginally to treat stress urinary incontinence and urogynaecological prolapse has been established. The BSUG national database was established in 2018.

Question 10

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?

Response:
Please see the NICE guidance under the following link 2nd April 2019:
https://www.nice.org.uk/guidance/ng123/resources/urinary-incontinence-and-pelvic-organ-prolapse-in-women-management-pdf-66141657205189
see page 8 item 1.2.2
However, you will be aware of this as your news release refers to it:
https://www.thompsons.law/news/news-releases/medical-negligence-news/nhs-england-and-nhs-trusts-to-face-legal-challenge-if-they-ignore-high-vigilance-restriction

Please see NHS Improvement and NHS England notification:
https://improvement.nhs.uk/documents/5122/MESH_letter_-_Extension_of_pause_on_the_use_of_vaginal_mesh_29_March_2019.pdf

Question 11

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

Response:
As well as the national database, the Trust holds its own Theatre Register book and all admissions into the Trust are recorded on the Trust's patient administration system and clinically coded.

Question 12

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

Response:
Please see response to Question 9

Question 13

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

Response:
Please see response to question 10

Question 14

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

Response:
Please see response to question 11

Question 15

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

Response:
We have not reported any procedures that developed complications previously (prior to 2018) to MHRA, however since the guidance in April, local SOP is to be altered to reflect this

NICE Guidelines state page 36, item 1.10.6
The responsible consultant must ensure that details of any confirmed mesh related complications are: recorded in a national registry (see the section on collecting data on surgery and surgical complications in this guideline) and reported to the Medicines and Healthcare products Regulatory Agency (MHRA).
[2019]

Responsible consultant is aware of this and currently in the process of streamlining reporting complications to the national database and reporting to MHRA.

Question 16

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

Response:
This will be included in the SOP which is currently being reviewed

Question 17

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 communciations?

Response:
Please see response to question 10

Question 18

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

i) What criteria and procedures have been established for the accreditation of specialist centres for SUI mesh and related procedure, who were they established by and could we have a copy of all relevant documentation?

Response:
The Trust does not identify and accredit specialist centres for SUI mesh procedure for removal procedures and other aspects of care for those adversely affected by surgical mesh'

The NICE Guidelines as at page 66 states:
'The committee were unable to make generalised recommendations on assessing possible mesh related complications because of the wide variety of procedures and implanted materials used, and the many different complications that might result from these. They therefore agreed that women with suspected mesh-related complications should be referred to a specialist centre unless they have an uncomplicated, small mesh exposure that can be treated with topical oestrogen'.
The NHS Improvement and NHS England notice states:

'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.'

ii) What organisation is to administer any such criteria and procedures?

The Trust does not administer any such criteria and procedures.

Question 20
We have advised Sling the Mesh 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 services that will support urogynaecological/female urology networks.

Response:
Processes are still in development to satisfy all the requirements for undertaking specialised urogynae procedures. At the moment we are not undertaking any mesh procedures for SUI

Question 21

B) Pursuing the commissioning of a national clinical audit/registry for urogynaecological procedure for SUI and prolapse.

Response:
Currently Under development, expected to be completed January 2020

Question 22

C) When would you expect all of the conditions within the HV restriction letter to be met?

Response:
January 2020