

7 June 2018

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██████████
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By email

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Dear ██████████

Request under the Freedom of Information Act 2000 (the “FOI Act”)

I refer to your email of May 1st 2018 in which you requested information under the FOI Act from NHS Improvement. Since 1 April 2016, the Patient Safety functions under section 13R of the NHS Act 2006 have been exercised by the NHS Trust Development Authority, as part of the integrated organisation known as NHS Improvement.

Your request

You made the following request:

“Please can I request the following information:

- 1. Please can you provide how many incidents have been reported to the National Reporting and Learning System (NRLS) on any type of vaginal mesh implant in each of the following years: 2016, 2017, 2018 (in financial or calendar years).*
- 2. How many adverse incidents have been reported on any type of vaginal mesh implant in each of the following years: 2016, 2017, 2018 (in financial or calendar years).*
- 3. Please can you provide any further information with regards to these reports available on the NRLS (in Q1) or adverse incidents (in Q2).*
- 4. Please can you provide how many incidents have been reported to the National Reporting and Learning System (NRLS) on any type of hernia mesh implant in each of the following years: 2016, 2017, 2018 (in financial or calendar years).*
- 5. How many adverse incidents have been reported on any type of hernia mesh implant in each of the following years: 2016, 2017, 2018 (in financial or calendar years).*
- 6. Please can you provide any further information with regards to these reports available on the NRLS (in Q4) or adverse incidents (in Q5).*

Please also send a response to Anna, copied in here.”

NHS Improvement asked you to clarify questions 2 and 5, to which, in your email dated May 8th 2018, you confirmed that these were to include StEIS data. It was also advised that neither the National Reporting and Learning System (NRLS), which collects patient safety incidents (defined as any ‘unintended incident which could have or did lead to harm for one or more patients receiving NHS care’), nor the Strategic Executive Information System (StEIS), which collects ‘serious incidents’, necessarily hold information relating to incidents considered ‘adverse’. In relation to this particular request, the MHRA’s Yellow Card Data would be the primary source for such information. We routinely share all incidents reported to the NRLS as being related to medical devices or medication with the MHRA, who can be contacted via the link provided below:

<https://yellowcard.mhra.gov.uk/contact-us/>

Decision

NHS Improvement holds the information that you have requested and has decided to release all of the information that it holds

The information we hold is from the NRLS and StEIS.

By way of background, some information about the NRLS may be helpful. The primary purpose of the NRLS is to enable learning from patient safety incidents occurring in the NHS. The NRLS was established in late 2003 as a largely voluntary scheme for reporting patient safety incidents, and therefore it does not provide the definitive number of patient safety incidents occurring in the NHS.

All NHS organisations in England and Wales have been able to report to the system since 2005. In April 2010, it became mandatory for NHS organisations to report all patient safety incidents which result in severe harm or death. All patient safety incident reports submitted to the NRLS categorised as resulting in severe harm or death are individually reviewed by clinicians to make sure that we learn as much as we can from these incidents, and, if appropriate, take action at a national level. Whilst the vast majority of reports to the NRLS are made by healthcare staff, we also have a portal where patients and public can anonymously report incidents that they believe could be used for national learning.

The NRLS is a dynamic reporting system, and the number of incidents reported as occurring at any point in time may increase as more incidents are reported. Experience in other industries has shown that as an organisation’s reporting culture matures, staff become more likely to report incidents. Therefore, an increase in incident reporting should not be taken as an indication of worsening of patient safety, but rather as an increasing level of awareness of safety issues amongst healthcare professionals and a more open and transparent culture across the organisation.

StEIS is a database used for the notification of appropriate parties that Serious Incidents have occurred and to manage progress of investigations, as set out in the Serious Incident

Framework 2015, please note it does not hold the full investigation report for Serious Incidents. The revised Serious Incident Framework published in March 2015 builds on previous guidance that introduced a systematic process for responding to serious incidents in NHS-funded care. It replaces, the National Patient Safety Agency (NPSA) National Framework for Reporting and Learning from Serious Incidents Requiring Investigation (2010) and NHS England's Serious Incident Framework (March 2013). The framework takes account of the changes within the NHS landscape and acknowledges the increasing importance of taking a whole-system approach, where cooperation, partnership working, thorough investigation and analytical thinking is applied to ensure organisations identify and learn what went wrong, how it went wrong and what can be done to minimise the risk of the incident happening again.

Serious Incidents (SIs)

As set out in the Serious Incident Framework 2015, serious incidents are events in health care where the potential for learning is so great, or the consequences to patients, families and carers, staff or organisations are so significant, that they warrant using additional resources to mount a comprehensive response, and in particular, an investigation.

The purpose of Serious Incidents investigation is to identify the factors that contributed towards the incident occurring and the fundamental issues (or root causes) that underpinned these, so that changes can be made to reduce the risk of recurrence.

Serious Incidents are reported by providers to their commissioners using StEIS in order to facilitate the management of the response to a Serious Incident, including the investigation.

Determining whether something is a Serious Incident or not can be difficult. Fundamentally this is a local decision that should be made using reference to the existing Serious Incident Framework. This says that outcome alone is not always enough to delineate what counts as a serious incident. The NHS strives to achieve the very best outcomes but this may not always be achievable. Upsetting outcomes are not always the result of acts or omissions in care”.

The StEIS database was designed to allow commissioner oversight of individual Serious Incident investigations. It was not designed to support trend analysis.

A search of the main NRLS database was carried out on 29 May 2018 of all incidents reported as occurring between 1 January 2016 to 16 May 2018, where the free text description of the incident contained the requested, specific key search terms of vagina/vaginal plus mesh and hernia plus mesh, including misspellings. A search of reports to the NRLS made via the patient and public reporting portal between 21 April 2016 and 1 April 2018 containing the term 'mesh' was also conducted. Note that due to a technical issue we were not able to search for more recent reports made via this portal. A search of the StEIS was also carried out of all incidents reported between 1 April 2016 and 31 March 2018, where the free text contained the specific key search term 'mesh'. The agreed key search phrases will pick up many appropriate incidents, however, we cannot guarantee that there are not additional relevant incidents that an alternative keyword search strategy might not have found.

Please also note that incidents reported to StEIS may also be reported to the NRLS.

Our clinical teams reviewed all incidents which contained these keywords and excluded those where the reference to mesh was very clearly background to the incident, rather than an incident that, even possibly, described harm or potential harm related to mesh. Examples of the kinds of incident reports we excluded are reports describing stock shortages of mesh, or where a medication error occurred in the immediate period after surgery involving mesh. For the sake of completeness we have included all remaining incidents in our reply, including incidents where any direct connection between the mesh and the reported incident is unclear, such as a post-operative wound infection.

Question 1

Table 1: The number of reported NRLS incidents returned by a combination of the search terms 'vagina' and 'mesh' (excluding reports where the terms were clearly background mentions), by calendar year and degree of harm.

YEAR	Reported degree of harm (severity)					Total
	No Harm	Low	Moderate	Severe	Death	
2016	0	1	0	0	0	1
2017	1	2	1	0	0	4
2018	2	3	1	0	0	6
Total	3	6	2	0	0	11

Via the patient and public reporting route, we received a total of 12 reports related to vaginal mesh during the stated period. We have included these for completeness although the date the incident occurred was not provided in any of these reports. Eleven of these reports were submitted on 28 September 2017 and one was submitted in November 2017. Eleven were described as causing severe harm and one was described as causing moderate harm. Further details of these can be found in Annex 1 of the attached file.

Question 2

A search of the StEIS returned no reports of serious incidents relating to vaginal mesh implants between the financial years of 2016-2018

Question 3

Further details regarding the NRLS reports, relating to vaginal mesh, can be found in annex 2.

Question 4

Table 3: The number of reported NRLS incidents returned by a combination of the search terms 'hernia' and 'mesh' (excluding reports where the terms were clearly background mentions), by calendar year and degree of harm.

YEAR	Reported degree of harm (severity)					Total
	No Harm	Low	Moderate	Severe	Death	
2016	1	1	2	0	0	4
2017	7	2	4	0	0	13
2018	1	1	0	0	0	2
Total	9	4	6	0	0	19

Via the patient and public reporting route, zero reports relating to hernia mesh were found.

Question 5

A search of the StEIS returned 9 reports of serious incidents describing hernia mesh implants, (excluding reports where the terms were clearly background mentions), between the financial years of 2016-2018.

Question 6

Further details regarding both the StEIS and NRLS reports, relating to hernia mesh, can be found in annexes 3 and 4 of the attached file, respectively.

Review rights

If you consider that your request for information has not been properly handled or if you are otherwise dissatisfied with the outcome of your request, you can try to resolve this informally with the person who dealt with your request. If you remain dissatisfied, you may seek an internal review within NHS Improvement of the issue or the decision. A senior member of NHS Improvement's staff, who has not previously been involved with your request, will undertake that review.

If you are dissatisfied with the outcome of any internal review, you may complain to the Information Commissioner for a decision on whether your request for information has been dealt with in accordance with the FOI Act.

A request for an internal review should be submitted in writing to FOI Request Reviews, NHS Improvement, Wellington House, 133-155 Waterloo Road, London SE1 8UG or by email to nhsi.foi@nhs.net.

Publication

Please note that this letter [and the attached information] will shortly be published on our website. This is because information disclosed in accordance with the FOI Act is disclosed to the public at large. We will, of course, remove your personal information (e.g. your name and contact details) from the version of the letter published on our website to protect your personal information from general disclosure.

Yours sincerely,

NHS Improvement