NHS Improvement
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10 September 2018

[redacted]

By email
[redacted]

Dear [redacted],

Request under the Freedom of Information Act 2000 (the "FOI Act")

We refer to your email of **4 July 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 send me all the records relating to reports of adverse events involving medical devices made through the NRLS over the last 10 years, excluding personal details relating to patients and/or reporter.*

I would like the above information to be provided to me in an electronic format as a spreadsheet."

On 24 July 2018, NHS Improvement advised that this search, performed as initially specified, would return approximately 500,000 results, far in excess of what we would be able to provide. In the interests of providing advice and assistance, NHS Improvement offered to supply a comparable dataset, achievable within the time constraints of the FOI Act. In your reply, you requested a phone conversation to discuss suitable options, which was accepted and took place on 13 August 2018.

Subsequently, also on 13 August 2018, you confirmed that the request had been refined to include the following variables, only:

- Incident category (IN05)
- Apparent contributing factors (IN06)
- Specialty (PD05)

- Degree of harm (PD09)
- Type of device (DE01)
- Device name (DE03)
- Patient age range (PD01_B)
- Date of incident (IN01)

Whilst this did not reduce the number of results returned, the omission of variables containing lengthy free text significantly reduced the burden on the authority. Please note that the age range bands have been broadened to reduce the risk of deductive disclosure.

Decision

NHS Improvement holds the information that you have requested. Please refer to the attached file.

A search of the NRLS was carried out on 23 August 2018 of all incidents reported as occurring between 1 January 2008 and 31 December 2018, uploaded to the NRLS by 22 August 2018.

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

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