

19 June 2018

Wellington House  
133-155 Waterloo Road  
London SE1 8UG

T: 020 3747 0000  
E: [nhsi.enquiries@nhs.net](mailto:nhsi.enquiries@nhs.net)  
W: [improvement.nhs.uk](http://improvement.nhs.uk)

By email

Dear [REDACTED],

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

We refer to your email of 21 May 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:

*“I would like to request the details of every death and severe injury reported in the NRLS figures from 2008 to 2017 where the incident type is classed as involving a medical device or equipment. The breakdown of these figures, which can be found in the public domain, is pasted below.*

*Please include all details of the incident in the free text report, any action taken as a result of the incident, the location of the incident and age group (by five year age band) of the patient*

<b>Date</b>	<b>Incident type</b>	<b>Number of Death / Severe</b>	<b>Source</b>
Jul 2016 - Jun 2017	Medical device / equipment	41	<a href="https://improvement.nhs.uk/documents/2546/NaPSIR_Jul-Sep_2017_-_England_V1.0.xlsx">https://improvement.nhs.uk/documents/2546/NaPSIR_Jul-Sep_2017_-_England_V1.0.xlsx</a>
Jul 2015 - Jun 2016	Medical device / equipment	57	<a href="https://improvement.nhs.uk/documents/831/QDS_Jul-Sep_2016_-_England_V1.6_final_ed.xlsx">https://improvement.nhs.uk/documents/831/QDS_Jul-Sep_2016_-_England_V1.6_final_ed.xlsx</a>
Jul 2014 - Jun 2015	Medical device / equipment	83	<a href="http://webarchive.nationalarchives.gov.uk/20171030133052/http://www.nrls.npsa.nhs.uk/EasySiteWeb/getresource">http://webarchive.nationalarchives.gov.uk/20171030133052/http://www.nrls.npsa.nhs.uk/EasySiteWeb/getresource</a>

			<a href="#">axd?AssetID=135592&amp;type=full&amp;serviceType=Attachment</a>
Jul 2013 - Jun 2014	Medical device / equipment	66	<a href="http://webarchive.nationalarchives.gov.uk/20171030133054/http://www.nrls.npsa.nhs.uk/EasySiteWeb/getresource.axd?AssetID=135404&amp;type=full&amp;serviceType=Attachment">http://webarchive.nationalarchives.gov.uk/20171030133054/http://www.nrls.npsa.nhs.uk/EasySiteWeb/getresource.axd?AssetID=135404&amp;type=full&amp;serviceType=Attachment</a>
Jul 2012 - Jun 2013	Medical device / equipment	66	<a href="http://webarchive.nationalarchives.gov.uk/20171030133119/http://www.nrls.npsa.nhs.uk/EasySiteWeb/getresource.axd?AssetID=135250&amp;type=full&amp;serviceType=Attachment">http://webarchive.nationalarchives.gov.uk/20171030133119/http://www.nrls.npsa.nhs.uk/EasySiteWeb/getresource.axd?AssetID=135250&amp;type=full&amp;serviceType=Attachment</a>
Jul 2011 - Jun 2012	Medical device / equipment	112	<a href="http://webarchive.nationalarchives.gov.uk/20171030133113/http://www.nrls.npsa.nhs.uk/EasySiteWeb/getresource.axd?AssetID=135200&amp;type=full&amp;serviceType=Attachment">http://webarchive.nationalarchives.gov.uk/20171030133113/http://www.nrls.npsa.nhs.uk/EasySiteWeb/getresource.axd?AssetID=135200&amp;type=full&amp;serviceType=Attachment</a>
Jul 2010 - Jun 2011	Medical device / equipment	111	<a href="http://webarchive.nationalarchives.gov.uk/20171030133312/http://www.nrls.npsa.nhs.uk/EasySiteWeb/getresource.axd?AssetID=133437&amp;type=full&amp;serviceType=Attachment">http://webarchive.nationalarchives.gov.uk/20171030133312/http://www.nrls.npsa.nhs.uk/EasySiteWeb/getresource.axd?AssetID=133437&amp;type=full&amp;serviceType=Attachment</a>
Jul 2009 - Jun 2010	Medical device / equipment	113	<a href="http://webarchive.nationalarchives.gov.uk/20171030133118/http://www.nrls.npsa.nhs.uk/EasySiteWeb/getresource.axd?AssetID=94741&amp;type=full&amp;serviceType=Attachment">http://webarchive.nationalarchives.gov.uk/20171030133118/http://www.nrls.npsa.nhs.uk/EasySiteWeb/getresource.axd?AssetID=94741&amp;type=full&amp;serviceType=Attachment</a>
Jul 2008 - Jun 2009	Medical device / equipment	196	<a href="http://webarchive.nationalarchives.gov.uk/20171030133122/http://www.nrls.npsa.nhs.uk/EasySiteWeb/getresource.axd?AssetID=65322&amp;type=full&amp;serviceType=Attachment">http://webarchive.nationalarchives.gov.uk/20171030133122/http://www.nrls.npsa.nhs.uk/EasySiteWeb/getresource.axd?AssetID=65322&amp;type=full&amp;serviceType=Attachment</a>

”.

## **Decision**

Whilst NHS Improvement holds the information that you have requested we have not been able to progress the full request because to do so would exceed the cost limit under section 12 of the FOI Act.

### **Section 12 – Exemption where cost of compliance exceeds appropriate limit**

Under section 12(1) of the FOI Act, NHS Improvement is not required to comply with any request that potentially exceeds the relevant cost limit. The relevant cost limit is £450, which is set out in The Freedom of Information and Data Protection (Appropriate Limit and Fees) Regulations 2004. This equates to a period of approximately eighteen hours in which to locate, retrieve and extract the information that you have requested.

## Advice and assistance provided under section 16 of the FOI Act

We are mindful of our duty under section 16 of the Act to provide reasonable advice and assistance to you, and specifically to advise how you might narrow your request so that it complies with the time limit.

For the more recent period in question (July 2012 – June 2017) we were able to locate the raw data that was used to create the published aggregate data which you referenced in your initial email. This meant we could extract the incident level data for the specified incidents, using some straightforward linking of data tables and queries of the data

However, to retrieve the data for the older time period (July 2008 – June 2012) would take us over the limit. In this instance, providing incident level data would require us to extensively check and modify code and re-create each of the raw datasets before we could extract the relevant incidents and this would not be doable within the given timeframe.

The only approach that allowed us to provide you with suitable information within the cost limit involved using only data that was readily available. The attached Annex sets out the details of the relevant information that we hold and have been able to provide within the time constraints set out in section 12.

## About the NRLS

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](mailto: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**