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21 December 2016

[redacted]
By email
[redacted]

Dear [redacted]

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

I refer to your emails of 25 October and 23 November in which you requested information under the FOI Act from NHS Improvement. Since 1 April 2016, Monitor and the NHS Trust Development Authority ("the TDA") are operating as an integrated organisation known as NHS Improvement. For the purposes of this decision, NHS Improvement refers to the TDA, which since 1 April has been responsible for exercising certain patient safety functions previously exercised by NHS England.

Your request

You made the following request:

"3. Please take this as [redacted] *a freedom of information request for all information held by you about Indapamide".*

Following a request for clarification to your original request you further added, by email on 23 November 2016, that

"Re concern 1 [redacted] *and/or Indapamide, Please search from 1st January 2015 until the 23rd November 2016 and include emails sent and received and file notes and any other data sent/received/held and/or processed. In particular, but not limited to the emails of* [redacted] *and Patient safety and* [redacted]*. Please obtain and keep and include in your searches NHS email file logs relating to the above emails.*

We particularly require copies of all emails being the full email trail with the subject matter complainant [redacted] *and PHSO Acknowledgement* [redacted] *for example an email from* [redacted] *dated 22 June 2015 12:28 and 16th September 2015 10.02 and the emails from* [redacted] *sending my concerns/complaints to whoever is responsible for patient safety in the NHS".*

Decision

NHS Improvement holds some of the information that you have requested. NHS Improvement has decided to release some of the information as explained below.

[redacted]

Some of the information we hold on Indapamide is from the National Reporting and Learning System (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.

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.

A recent search of the NRLS was carried out of all incidents reported as occurring between the dates 1st January 2015 to 23 November 2016 if these had been uploaded to the NRLS by 28 November 2016 and where the freetext contained the term 'Indapamide' including misspellings. Whilst we have chosen key word searches in good faith as most likely to identify requested incidents we cannot guarantee that there are not additional relevant incidents that an alternative keyword search strategy might have found.

I can inform you that as a result of this search, 280 patient safety incident reports were identified that contained the term 'Indapamide'. Please see Table 1 below which shows a breakdown of the incidents by level of harm and category as reported by the original reporter. You should note that these are only records where the drug name has been mentioned in an incident report, and does not necessarily mean the incident involved error or adverse effects from Indapamide.

Table 1: Number of patient safety incidents which included the term 'Indapamide' by reported category and level of harm as reported by the original reporter

Reported incident category	No Harm	Low	Moderate	Severe	Total
Access, admission, transfer, discharge (including missing patient)	4	1			5
Clinical assessment (including diagnosis, scans, tests, assessments)		1	1		2
Consent, communication, confidentiality	1				1
Documentation (including electronic & paper records, identification and drug charts)	6				6
Implementation of care and ongoing monitoring / review				1	1
Infrastructure (including staffing, facilities, environment)	1				1
Medication	213	24	7		244
Patient accident	4	1	1	1	7
Self-harming behaviour	1	2			3
Treatment, procedure	9				9
Other	1				1
Total	**240**	**29**	**9**	**2**	**280**

We also have access to the Strategic Executive Information System (StEIS). 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.

A search of STEIS was also carried out of all incidents reported as occurring before 23 November 2016 if these had been reported to STEIS by 29 November 2016 and where the free text contained the term Indapamide or the misspelling 'Indepamide'. As a result of this key word search a total of 9 incidents were identified as containing the terms above. Please see Table 2 below which provides a breakdown of the incidents by category as reported by the original reporter. You should note that these are only records where the drug name has been mentioned in a Serious Incident report, and does not necessarily mean the Serious Incident involved error or adverse effects from Indapamide.

Table 2: Number of Serious Incidents reported to STEIS that referenced 'Indapamide' by reported category

Reported SI category	Number
Slips/Trips/Falls	2
Slips/trips/falls meeting SI criteria	2
Medication incident meeting SI criteria	2
Delayed diagnosis	1
Drug Incident (general)	2
Total	**9**

Please note that to provide you with a full summary of the information contained in each of the 289 incidents records identified via the NRLS and StEIS searches summarised above would exceed the time and cost limits as specified within the FOI Act, we are therefore applying section 12 of the Act on this occasion.

As well as a search of the NRLS and STEIS we also conducted a search for the term 'Indapamide' within the electronic records held by individuals within NHS Improvement, namely, [redacted] and the Complaints Team, and the Medications Team within Patient Safety. We were unable to conduct a search of [redacted] files as they are NHS England employees and not employees of NHS Improvement.

As a result of the search we have identified a number of emails. We are however not disclosing those emails pursuant to the FOI Act. The information in those emails is either:

> (1) Information relating to Indapamide which you have sent to us. As such this is information which is reasonably accessible to you and exempt under section 21(1) of the FOI Act.
>
> (2) Information which constitutes your personal data and therefore exempt under section 40(2) of the FOI Act. [redacted]

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 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,

Patient Safety Team, NHS Improvement