

1 July 2016

Sent by email only to ndgoffice@nhs.net

Dame Fiona Caldicott
National Data Guardian
3rd floor
1 Trevelyan Square
Board Lane
Leeds LS1 6AE

Dear Dame Fiona,

Request for information

Thank you for your letter.

I hope you find the information provided useful. We have worked with our partners at DeepMind to provide the responses.

For ease we have followed your numbering and added the newly requested information under a separate heading.

1. We agree with the overall characterisation of the project in this paragraph. We can confirm that the current focus of Streams is to improve the management of acute kidney injury (AKI) through more efficient presentation of data; in this case being a combination of the national AKI alert and the information a clinician requires to put the result into context and act on that alert. At the same time we would note that, acknowledging the patient benefit that may result from a project to develop AI tools, our research goals extend to more general patient deterioration as well as acute kidney injury.

2. We agree with the summary of current state. Streams is not currently in use at Royal Free Hospital (RFH) and is not presently in deployment on the market generally. Specifically, we would like to clarify that only small scale testing of the pre-production prototype version of Streams has taken place to date, with a focus on refining the design and functionality of the application. This included testing of core functionality (e.g. wireless connectivity), real-world usability, and validation of the data presented in the application by reference to existing clinical systems (e.g. for demographics, patient location, responsible consultant, clinical history). This testing was carried out at the Royal Free Hospital with technical support from DeepMind on 14th-16th December 2015, 6th-12th February 2016 and 9th-11th May 2016. We can provide more precise information on those tests if helpful.

3. We agree with your summary on this point. Streams presently uses the nationally mandated algorithm which has been developed by NHS England to ensure a timely and consistent approach to the management of AKI across the NHS. The algorithm can be found here. The algorithm was

introduced in a patient safety alert by NHS England in 2014 (the alert itself can be found here, and the accompanying press release here).

4. We would be happy to assist in providing more information on this point or clarification as required. We can confirm that, as previously stated, the prototype of Streams used at RFH utilized the demographic data, test results and coded procedure/diagnosis data provided by the hospital. This also includes outpatient and GP blood test results (as these must be used when calculating the baseline), however alerts are currently generated for inpatients and emergency department patients at RFH only.

As we discussed, this information can be incredibly helpful for clinicians and may have an appreciable effect on the prioritisation and effectiveness of care. The NHS England NPSA algorithm mandates the use of 1 year of retrospective creatinine data. However in making an assessment of patients with AKI clinicians utilise a variety of data beyond just this 1 year of creatinine. They often look back at older blood tests (e.g. to see that the patient has had 4 previous AKIs in the preceding 3 years), other test results (e.g. to see signs of: hyperkalemia, primary renal disease, and kidney stones), or medical history (e.g. previous renal transplant); all of which would affect the management of a patient with AKI. These historic data are made available in the app for clinicians delivering care to patients, they are not used for any app improvement, machine learning or algorithm development purposes. Use for such purposes would only be conducted in the future on anonymised data with appropriate research governance and ethical approval in place.

5. We would wish to help clarify some of the details applicable to your panel's understanding of this point. DeepMind was acquired by Google in 2014. Whilst Google does not operate a fully provisioned data centre in the UK, DeepMind does independently contract for server space in a separate secure data centre facility in London, which is used by Streams. For group contractual reasons, the agreement for DeepMind's use of that space is entered into between Google (UK) Limited and [REDACTED] (the relevant data center provider). DeepMind's Information Governance Toolkit, covering amongst other things, the use of this facility, achieved 100% level 3 compliance in 2015 and was recently audited by HSCIC.

6. Your understanding of this point is correct. Our assessment is that the use of Streams by clinicians in the fulfilment of their duties at the RFH is direct care. As we have discussed, a significant part of the value and utility of Streams lies in the ability of clinicians to access timely information in a useful format throughout the performance of their duties, and to make more fully informed judgments as to patient care and prioritization as a result. This is a function which is uniquely and specifically tied to the provision of direct care to any relevant number of patients being attended to by a clinician at any one point in time. Whilst the population of those patients may - and will by necessity - vary over time, the intended benefit of the application remains constant, and focussed on direct patient care. This is, in our view, very different from systems or tools that use a wide range of patient data for the purposes of research, analysis or identification of trends across a population and which are not designed or intended to be used by clinicians at or near the point of delivery of care.

7. We can confirm that your understanding of our position on this issue is correct. DeepMind is a data processor for the Royal Free London and its use of the information in question was and is at all times strictly limited to the terms of our agreement and subject to the ultimate control of the RFH as a data controller. In relation to Streams, data was only used by DeepMind for the provision of the service to RFH, and as noted above, that use was only for the direct care of patients.

8. The Royal Free London and its partners DeepMind are strongly committed to transparency and we are looking into the best way of informing patients about our agreement with DeepMind via the privacy statement on our website. We would welcome any opportunity to contribute to any best practice which you or your panel may recommend.

9. We can confirm that your understanding here is correct, but note that, for completeness, data is decrypted within the backend application so that it can be processed to generate the AKI alert. We would be happy to provide any further technical details on encryption that is required.

10. We can confirm your understanding here is correct. We are presently working with the MHRA to ensure that when Streams is ready to be fully released, it complies with all the applicable EU/UK medical device legislation; namely that it is fully certified, CE-marked and registered with the MHRA.

11. We can confirm that this is correct. As you will be aware, we submitted an application for Research Ethics Committee (REC) approval for the AKI research project with RFH the Health Research Authority in November 2015, a summary of which was publicly available. At present we're awaiting further approvals and no work has started. We can confirm that any research work undertaken with a goal of developing new algorithms will use anonymised or pseudonymised data.

Further questions

A] We can clarify that the Information Sharing Agreement is a controller-processor arrangement. As you know, the document itself was drafted jointly by the Royal Free London and DeepMind to clearly state the trust's responsibilities as data controller and to contain all of the requisite obligations on DeepMind as the data processor. When doing so, DeepMind and the trust made specific reference to the requirements of the Data Protection Act and to relevant guidance from the ICO. Whilst the Data Protection Act does not specify the precise format the agreement must take, we ensured that the relevant set of obligations were contained (including, for example, that the contract is made or evidenced in writing, that it requires DeepMind as data processor to act only on instructions from the data controller, and that it requires DeepMind as data processor to comply with obligations equivalent to those imposed on the data controller by the seventh principle). We – the Royal Free London NHS Foundation Trust – have also been in communication with the Information Commissioners officer regarding this matter.

B] As data controller, the RFL believes the transfer of the data in question is both necessary and proportionate to the purposes.

We believe it would have been impossible to provide the Streams application with the features and functionality we intended it to have (and the benefits which clinicians want) without creating a data environment that was unique to Streams; attempting to further process the data from existing NHS IT systems would not have been possible, or resulted in the same benefits to clinicians.

The scope of the data transferred is required given that failure to share a full historical dataset effectively would, once Streams is fully deployed, carry the risk of avoidable harm if a patient presented to hospital and relevant information could not be effectively presented to a clinician using Streams. Secondly, as stated previously, whilst some data inevitably always sits at rest (as is the case in any similar system dealing with patient data) only identifiable information that is directly relevant to the care of a specified patient being attended to by a given clinician in the course of their duties, at any given point in time, is presented in Streams.

Finally, we would like to reaffirm our understanding of the potential benefits to patients and the degree of significance that the transfer may have in that regard: namely, that AKI is a serious condition. Alongside sepsis, it has been identified as the NHS as one of the two specific priorities for the NHS in 2015/6 for improving patient outcomes. There are often delays in the diagnosis of AKI and this is because it is difficult to ascertain the precise conditions signifying the onset of AKI. The Royal Free London believes that it is important to work together with organisations such as

DeepMind and others in the medical profession to strive towards better outcomes in this area, and the proportionality of any data transfer should be viewed in light of all of the above.

C] We would like to clarify your understanding of current state with Streams before providing some more information on the framework in which tests have been conducted.

As previously stated, Streams is not currently in use at RFH and is not presently in deployment, or on the market generally. Specifically, we would like to clarify that only small scale testing of the pre-production prototype version of Streams has taken place to date, with a focus on refining the design and functionality of the application. This included testing of core functionality (e.g. wireless connectivity), real-world usability, and validation of the data presented in the application by reference to existing clinical systems (e.g. for demographics, patient location, responsible consultant, clinical history).

This testing was carried out by RFH with technical support from DeepMind on 14th-16th December 2015, 6th-12th February 2016 and 9th-11th May 2016. We can confirm that this testing was carried out RFH with the support of DeepMind in its capacity as a data processor for RFH, and in accordance with the clinical safety process mandated for the deployment of any new IT system in the hospital that is intended to be relied on for direct patient care.

This clinical safety verification process is still in progress, and while Streams was not, and will not be relied on for patient care until this process has concluded, it is both normal practice and a clinical safety requirement that this testing on live data is carried out prior to the hospital issuing "clinical authority to deploy" any new IT system (in line with ISB0160).

I hope you find the information provided useful. If you require anything further please do not hesitate to contact me.

Yours sincerely



Professor Stephen Powis
Medical director