National Data Guardian

3rd Floor North
1 Trevelyan Square
Boar Lane
Leeds LS1 6AE
Fiona.Caldicott@dh.gsi.gov.uk

Our ref – 534
Letter via email 13th June 2016

For the attention of Professor Stephen Powis,
Medical Director,
Royal Free London NHS Foundation Trust

Dear Stephen

Your attendance at the National Data Guardian's Panel

Thank you for coming to meet me and my advisory panel on Thursday 26th May. We are grateful to you, your colleagues and representatives of Google DeepMind for making the time to come at short notice, and provide us with more information about the work you are doing.

The discussion was illuminating and constructive, enabling us to understand the situation much more clearly than some of the media reporting of your project has allowed.

However, given the short amount of time available and the wide ranging discussion, we would find it useful to check our understanding with you at this point.

I have summarised below the details that I believe we established during the meeting. It would be most helpful if you could let us know if we have understood the issues correctly or provide further clarity where necessary.

Following the conversation and some reflection my panel and I would also like to ask you three further questions which were not directly addressed in our discussions. These follow separately below.

1. The aim of this project is to improve the detection and management of acute kidney failure. In order to do this the project has developed an app which will alert clinicians to inpatients whose blood test results indicate that they may need attention. One of the key benefits of the app is that the alert is presented to the clinician on a hand-held device in a much more timely way than has traditionally been possible. Another is that, alongside the alert, the app will present the clinician with other relevant, contextual clinical information about the patient to whom the alert relates.

2. The app has been deployed to a limited number of clinicians at this stage as a pilot exercise. You are awaiting feedback on this before you roll it out more extensively.

3. The app uses the nationally mandated algorithm; it would be helpful if you could share the mandate and the national specification. There is a longer term ambition to further develop the app that goes beyond this specification to potentially improve the algorithm. [See Point 11 below].

4. Inpatient data extending back over the last five years has been provided to Google DeepMind for use in the app. This includes pathology data, secondary use data, imaging data and PAS data. In the future outpatient and primary care data may also be included. The sole purpose for which Google DeepMind has this data is so that the app can show relevant previous clinical information collected about the patient in question, that can be presented to the clinician alongside the alert. During our conversations, we think that it was stated that none of this earlier data beyond the national mandate specification was being used to improve the app. However we did not have time to fully explore this and would welcome more clarity on the point.

5. Google DeepMind is a subsidiary of Google Limited's London Data Centre, which has the Information Governance Toolkit submission and score, and that is published.

6. The contract between the parties is a data sharing contract for direct care, and states that Google DeepMind may not use any of the data shared for research or other secondary purposes. You have assessed the project that you are undertaking as falling entirely into the category of direct care.

7. As you regard the project as only direct care, you judge that consent for patient data to be used to enable the app can be regarded as having been provided implicitly.

8. There is fair processing information on the Royal Free website, which refers to the fact that information is shared with other organisations, including non-NHS organisations, for the provision of care, but details of specific organisations or projects, such as this project with Google DeepMind, are not given.

9. The hosting arrangements at Google were penetration tested and that data shared is encrypted in flight, at rest and then decrypted on the clinician's handheld device.

10. When the app is ready for widespread rollout, it will be registered as a medical device with the MHRA.

11. In the long term, Google DeepMind would like to create an algorithm that would improve upon the mandated NHS algorithm. If further work were undertaken to develop this, it could be done with anonymised or pseudonymised data and approvals would be sought from the HRA and relevant NHS ethical committee approval.

Further questions:

A] It appears from the copy of the contract that we have seen in the media, that a data controller to data controller contract for direct care was used. Is that the case? If so, please can you let us know why you regarded that as more appropriate than using a data controller – data processor contract.

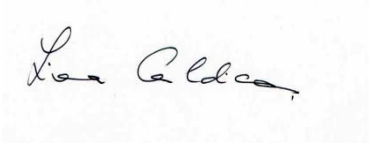
B] You have stated that a data controller – data processor contract was used for the development of the app for direct care. Do you think that the degree of sharing of personal confidential data was proportionate to such a project?

C] Is the app being developed within a clinical safety framework so that hazard logs are kept to ensure that the product works, is safe to deploy and meets any standards required by the MHRA for the development & deployment of medical devices?

My panel and I are keen to be confident that we have a clear understanding of this piece of work and so I do hope that you will be able to help us.

Please do contact my office if you have any queries about the issues we are seeking to confirm and clarify: ndgoffice@nhs.net.

Yours sincerely



Dame Fiona Caldicott, MA FRCP FRCPsych
National Data Guardian

Cc.David Sloman, Chief Executive, Royal Free London NHS Foundation Trust
Cc. Mustafa Suleyman, Co-founder, Google DeepMind