

Letter via email

Our ref - 534  
26th August 2016

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

Dear Professor Powis

**Re: Request for information**

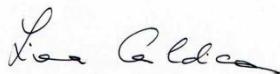
Thank you for your letter dated 1<sup>st</sup> July in response to my correspondence of 13<sup>th</sup> June. I am grateful to you and colleagues for addressing our questions in detail.

Due to the summer break, the next meeting of my advisory panel is on the 19<sup>th</sup> September. We wish to discuss your response further then and I hope to be able to write to you again shortly after that meeting.

In the meantime, you may already be aware that Dr Julian Huppert, an independent reviewer for Google DeepMind Health, has written to me regarding the definition of direct care. I thought it would be helpful for you to see my response to this request. I have attached Dr Huppert's email to me and my response for your information.

Please do contact my office if you have any queries.

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

Enc.

Email from Dr Julie Huppert 06.07.16

**Direct Care definition - correspondence from DeepMind Health Independent Review Panel**

Dear Dame Fiona,

We have recently been asked to serve as (unpaid) Independent Reviewers for Google DeepMind Health, and one of our roles is to look in detail at how DeepMind Health uses patient data, and to confirm that it complies with the highest ethical and regulatory standards.

As you will be aware, there has been some discussion in the media about the Streams product from DeepMind Health, currently under development, and the Information Sharing Agreement they have with the Royal Free. We assume you are aware of the detailed issues from your discussions with DeepMind Health.

One issue that has been raised with us, particularly by MedConfidential, is whether their use counts under the definition of 'direct patient care'. We have sought to form our own independent judgement of this, but conclude that the definition as currently presented is not sufficiently clear, leaving an unhelpful grey area. In this case, data on a substantial number of patients is stored to provide an individual baseline figure for each patient, if they return. We would be very grateful if you could let us know clearly your view on this crucial point. When we discussed this issue as a panel, we did not have the benefit of seeing your report, which came out today, but this does not seem to be resolved therein.

We think it would be helpful if you could consider clearly some guidance on this area, and exactly where you consider the division to fall between direct and indirect patient care. We think that would be of great assistance not only to us and to DeepMind Health, but to all the many other organisations that currently operate in this field.

We would also suggest that you consider whether it is appropriate to have two necessarily broad categories of direct patient care and indirect patient care, or whether there is a third category that covers situations like this one. If so, we would suggest that it should have significantly stronger requirements, such as requiring logs of data access and patient notification.

We look forward to hearing from you.

Yours sincerely,

Julian

On behalf of the Panel of Independent Reviewers for Google Deepmind Health  
<https://deepmind.com/health/independent-reviewers>

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Dr Julian Huppert

Website: <http://www.julianhuppert.org.uk>  
Twitter: <https://twitter.com/julianhuppert>  
Facebook: <https://www.facebook.com/julian.huppert>

Our ref-534  
29<sup>th</sup> July 2016

Letter via email

For the attention of Dr Julian Huppert,  
Independent Reviewer for Google DeepMind Health

Dear Dr Huppert

**Definition of Direct Patient Care**

Thank you for your recent correspondence asking me to consider the development of guidance regarding the definition of 'direct care'.

When undertaking my previous reviews, which were published in 1997 and 2013, the review team gave a great deal of thought to the definition of 'direct care'. When undertaking my recent review of data security, consent and opt-outs, which was published on the 6<sup>th</sup> July 2016, the review team did not hear evidence that led us to believe that we needed to revisit or clarify this definition.

The definition provided in the second of my reviews (The Information Governance Review<sup>1</sup>) is the definition that I understand most health and care organisations reference when making information sharing decisions. The definition provided in the glossary to this report is:

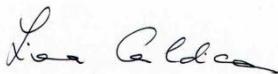
*"A clinical, social or public health activity concerned with the prevention, investigation and treatment of illness and the alleviation of suffering of an identified individual. It includes supporting individuals' ability to function and improve their participation in life and society. It includes the assurance of safe and high quality care and treatment through local audit (identified patient safety), the management of untoward or adverse incidents."*

Chapter 3 of this report also discusses in more detail further considerations around and limitations on the use of data for direct care.

Both the Royal Free and Google DeepMind have been very helpful in providing information in response to the questions that my advisory panel and I have asked of them regarding the development of the Streams product. We have not yet had the opportunity to complete our review of this information in its entirety, and therefore I cannot yet conclude if advice from me, in my role as the National Data Guardian, would be helpful in the development and use of such products.

Once we have completed our review of the information provided, I would be very happy to have a discussion with you, and your fellow Independent Reviewers, regarding any advice that might be helpful on this subject.

Yours sincerely



Dame Fiona Caldicott, MA FRCP FRCPsych  
National Data Guardian

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<sup>1</sup> <https://www.gov.uk/government/publications/the-information-governance-review>