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Our ref: 651
21 August 2018

Letter via email

Dear Elizabeth,

Thank you for asking me, as per your letter of 9th August 2018, to give my views on the approach taken to confidentiality in Linklaters' audit of the Royal Free's use of Streams[1]. I was pleased to discuss this matter with you and offer my advice during the investigation your office undertook and concluded last year. I do welcome the opportunity to revisit the issue following the publication of the third-party audit, which was a result of the undertaking that the trust signed with you, following that investigation.

As you note in your letter to me of 9th August, the Health Research Authority is organising a workshop in September to discuss this matter. I agree that this is very helpful. A representative from my advisory panel and my office will be taking part.

In the meantime, I have taken time to consider the Linklaters' audit and to discuss this issue with members of my advisory panel. I have a number of concerns with the position on confidentiality taken in Linklater's audit report.

At the heart of this is my fundamental disagreement with a central claim in the audit. Namely, that the touchstone of whether there is a breach of confidence is to be judged from the point of view of the clinician, rather than the patient. I am firmly of the view that it is right to place the patient's perspective, not the professional viewpoint, at the centre of judgements about where confidential data may or may not be used. I take this view for number of reasons.

The common law duty of confidence and a 'clinician conscience' test

Before turning to the arguments in the Linklaters' audit about the duty of confidence, it is important to be clear that as National Data Guardian I am not empowered to make rulings on the common law, which is a role of the courts. However, in considering this matter my panel and I have borne case law in mind, alongside relevant professional guidance and our understanding of patient and public expectations on the use of health and care data.

[1] https://s3-eu-west-1.amazonaws.com/files.royalfree.nhs.uk/Auditing/Streams_Audit.pdf

The audit seeks to argue that the duty of confidence can be set aside where the reasonable health professional's conscience would not be troubled by the disclosure. As mentioned above, we find this problematic.

Looking at this from the point of view of case law, we noted that this argument depends largely on the *Source Informatics* [R v Department of Health ex parte Source Informatics 2000] case. We were surprised to see such a heavy reliance on a case which firstly looked at the use of anonymised, rather than confidential, information and, secondly, was decided before the Human Rights Act 1998 came into force[2]. More recent case law casts doubt on the continued appropriateness of this test and moves us firmly towards the position that the 'reasonable expectations' of the patient should be the test as to whether a duty of confidence arises[3].

I believe that placing the patient's expectations at the centre of matters of confidentiality is right, not solely for the reason that it is more legally contemporaneous than the approach in the audit. It is also in line with professional guidance[4] and with the direction of travel of data protection law, with its greater emphasis on the rights of the data subject and its acknowledgement of the imbalance of power that there may be between data subjects and controllers. This is clearly much more compatible with the welcome move we have seen in recent years from a paternalistic to a collaborative approach to delivering healthcare[5]. It resonates with the emphasis I have long sought to place on the principle that there should be 'no surprises' for the patient about who has had access to their confidential information. My panel and I are concerned about the implications for public confidence inherent in a test of clinicians' conscience, which would take us in the opposite direction.

Implied consent and direct care

The Linklaters' audit includes a discussion of implied consent for direct care of the individual, this being the common law legal basis on which the Royal Free said that information had been processed for testing at the time of the original ICO investigation.

We agree that there is little case law addressing the question of the limits of implied consent. However, within the health sector's custom and practice, one of the conditions underpinning the use of implied consent for sharing confidential information is that the information being shared is for the delivery of direct care or local clinical audit. This is reflected in policy and guidance[6].

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[2] In particular as this was warned against by Lord Woolf CJ in *A* v *B Plc and Another* [2002] "authorities which relate to the action for breach of confidence prior to the coming into force of the 1998 Act … are largely of historic interest only". [9]

[3] For instance, in *Campbell* v *MGN*, Lord Hope opined, "Where the person is suffering from a condition that is in need of treatment one has to try, in order to assess whether the disclosure would be objectionable, to put oneself into the shoes of a reasonable person who is in need of that treatment. Otherwise the exercise is divorced from its context." [98]

[4] Such as the *NHS Confidentiality Code of Practice 2003*, which in point 9 states "A duty of confidence arises when one person discloses information to another (e.g. patient to clinician) in circumstances where it is reasonable to expect that the information will be held in confidence." Or the General Medical Council's 2017 guidance *Confidentiality: good practice in handling patient information*, which emphasises in a number of places that clinicians should consider how their patients would expect information to be used.

[5] *Montgomery v Lanarkshire Health Board* (Scotland) [2015] UKSC 11.

[6] Such as the *Information Governance Review* (2013), the General Medical Council's 2017 guidance *Confidentiality: good practice in handling patient information*

The audit rightly states that my panel and I have been examining the concept of implied consent and noted that it is "coming under strain"[7]. This is not because we have concerns about the proper use of implied consent. Our concerns are about its misuse. We made this clear in a report on part of this work (the Sheffield seminar referenced in the last footnote) when we said: "*For many years the NHS has depended on implied consent to allow information about patients to flow among the teams of doctors, nurses, therapists and the ancillary staff working under their direction to provide individual care. This approach appears to have been accepted by patients and it has not been challenged in the courts. There is no desire to remove this underpinning of the arrangements for managing the confidentiality of the hundreds of thousands of patients who use NHS services every day, doing so in a way that permits relevant information to be available to the teams providing care. However, the National Data Guardian has become aware that the boundaries of implied consent described in the IGR [Information Governance Review] are coming under strain…*"

As part of this work we have considered the important role that the reasonable expectations of the patient might play in ensuring valid use of implied consent, given the emphasis that the courts have placed on the concept of 'reasonable expectations' since the incorporation of the Human Rights Act into UK law. The audit discusses that my panel and I have also considered whether reasonable expectations itself might be used as a legal basis for sharing, separate from consent, and expresses some support for the utility of this test. I would like to note here that this work on reasonable expectations and these considerations are still ongoing. For reasons set out above, I would also not concur with the conclusion of this section of the audit, namely that a clinicians' conscience test would be preferable.

The audit puts forward the position that the Royal Free's use of confidential patient information for testing of Streams can be considered to be an aspect of direct care[8]. My view remains as it did when I wrote to the trust in February 2017: that the use of 1.6 million identifiable patient records for safety testing cannot be described as direct care, even if the eventual intention was to use Streams for direct patient care. As I said then *"Given that Streams was going through testing and therefore could not be relied upon for patient care, any role the application might have played in supporting the provision of direct care would have been limited and secondary to the purpose of the data transfer."* I believe that the clinical testing stage should be considered separately from the operation of a system.

I also believe that proportionality questions remain where it is proposed that such a large amount of data, both in terms of the number of individuals and the breadth of the information about them, is used for the testing and operation of a system which will benefit disproportionately few patients. I make this point not to question the undoubted

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[7] *Sharing patient data: exploring consensus on reasonable expectations*, July 2017 https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/663089/Exploring_consensus_on_reasonable_expectations_-_July_2017_seminar_FINAL.pdf

[8] See section 31.4: *Secondly, we consider this use is "providing…care" to patients. The testing and operation is carried out for the sole purpose of eventually using Streams to provide care to those patients.) and* section 32.5: *Provide Choice to Patients*: Information in Streams is used for the purposes of that patient's care. Patients are given the right to object to their data being included in Streams…. We think the operation and testing of Streams is compatible with this requirement.

value and benefit of the system, but to suggest that this use of data might be analogous to risk stratification for case finding.

Other aspects of the audit

The audit seeks to describe the relationship between the Royal Free and DeepMind as one of "confidential agent". We are not sure that introducing another concept into this field is necessary or helpful.

The audit also states that a breach of confidence would only arise if there were detriment caused. We believe it would be unhelpful to the protection of public confidence in a confidential health care service if it was necessary to demonstrate any detriment beyond interference with an individual's reasonable expectation of privacy[9].

Supporting innovation

As you and I have discussed, the use of new technology holds great potential to improve patient care and the use of data to develop, test and operate such technology is essential.

I note the evidence in the audit that Streams makes a positive difference to patient care, helping clinicians more quickly and easily identity patients who need attention. This is to be welcomed.

The evidence of engagement with the public undertaken by the NDG and many others is that patients and the public want to see data used to make improvements in care. They also want to know about how data is used and that there are clear rules in place that are consistently applied. I believe that the approach to confidentiality laid out in the Linklaters' audit is inconsistent with the common understanding of the duty of confidentiality, inconducive to building public trust and would not want to see this approach take hold elsewhere in the system.

In my letter to the Royal Free of February 2017, I recognised that further guidance would be useful to organisations that are undertaking work to develop and test new technologies, where that work might require the use of identifiable patient data at some stages. I was pleased to see the publication of a *Clinical Safety Guidance Governance and regulatory requirements for decision supporting and making software in the NHS and Adult Social Care*[10] in January this year, which contains some useful advice and signposting.

You and I have discussed and agreed that further guidance would be helpful to organisations such as the Royal Free which wish to be involved in the development and use of innovative technology that can help patients. In relation to the common law of confidence, I would recommend that this guidance should underline the importance of considering issues such as proportionality, transparency and patient expectations, acknowledging that the more unexpected or controversial a specific use of data, the more

[9] This position is supported by contemporary common law: doubt about the need for further detriment can be found as far back as 1969 in *Coco v A N Clark Limited* (1969) 86 RPC. It is also acknowledged not to be necessary to show further detriment more recently in *Ash v McKennitt* [2006] EWCA Civ 1714, *AG v Guardian Newspapers* (No 2) [1990] 1 AC 109 and *R v Department of Health ex parte Source Informatics Ltd* [2001] QB 423 which the audit report references in other parts.

[10] https://digital.nhs.uk/services/solution-assurance/the-clinical-safety-team/clinical-safety-documentation

effort must be made to ensure that this falls within the reasonable expectations of patients. I will be speaking to my sponsor in the Department of Health about how this might be achieved.

With kind regards

Dame Fiona Caldicott, MA FRCP FRCPsych
National Data Guardian

CC Victoria Cetinkaya Information Commissioner's Office