Freedom of Information Act 2000 (FOIA)

Decision notice

Date: 01 August 2013

Public Authority: Queen Mary, University of London
Address: 327 Mile End Road
London Borough of Tower Hamlets
E1 4NS

Decision (including any steps ordered)

1. The complainant has requested information relating to a clinical trial carried out by Queen Mary University of London (QMUL).

2. The Commissioner's decision is that QMUL has correctly applied section 40(2) to the withheld information.

3. The Commissioner does not require the public authority to take any steps as a result of this decision notice.

Request and response

4. On 4 December 2012, the complainant wrote to QMUL and requested information in the following terms:

   Please may I request the following under the Freedom of Information Act.

   1) The raw data of the PACE trial (White et al., 2011). This is all the final data before analysis by the authors of the PACE trial.

5. QMUL responded on 4 January 2013. It stated that the information was exempt from disclosure by virtue of section 40(2) and section 41 of the FOIA. It further stated that it believed it was also exempt under section 43 of the FOIA.

6. Following an internal review QMUL wrote to the complainant on 1 February 2013. It stated that the information was exempt under sections 40(2), (41)(1) and 38 of the FOIA.

7. During the course of the Commissioner's investigation QMUL confirmed that it was relying solely on sections 40(2) and 41(1) to withhold the requested information.

Scope of the case

8. The complainant contacted the Commissioner on 7 February 2013 to complain about the way her request for information had been handled.

9. The Commissioner considers the scope of this case to be to determine if QMUL has correctly applied the exemptions it has cited.

Background

10. The PACE Trial was one of the first large scale, randomised trials to evaluate the effectiveness of various treatment options for Chronic Fatigue Syndrome/Myalgic Encephalomyelitis (CFS/ME). Thus the trial required the collection of vast amounts of medical baseline and treatment results over the period 2005-2010 from the 640 patients who participated in the Trial.

Reasons for decision

Section 40(2) – third party personal data

11. Section 40(2) provides an exemption for information which is the personal information of an individual other than the applicant, and where one of the conditions listed in sections 40(3) or 40(4) is satisfied.

12. In this case the relevant condition is contained in section 40(3)(a)(i). This applies where the disclosure of information to any member of the public would contravene any of the principles of the Data Protection Act (DPA) 1998. This is an absolute exemption, and is therefore not subject to a public interest test.

13. QMUL has sought to rely on this exemption to withhold the requested information in its entirety.

14. In order to establish whether this exemption has been correctly applied the Commissioner has first considered whether the withheld information is the personal data of third parties, namely those taking part in the PACE Trial.

15. Personal data is defined in the DPA as information about a living individual who can be identified from that information, or from that information and other information in the possession of, or likely to come into the possession of, the data controller.

16. QMUL has explained that the information in scope of the request is stored in multiple databases including (further details in Annex 1):

    (a) The full recordings of all treatment sessions and psychiatric interviews

    (b) Actigraphy recordings

    (c) Schedule database

    (d) Numerical and text trial main database

17. QMUL has explained that the raw trial data consists to a large degree of the medical and mental health baseline and ongoing assessment of treatment results as observed and/or self-reported over five years by each of the 640 patients who participated in the trial and/or their clinicians.

18. QMUL stated that these data clearly relate to each one of the patients involved and are highly personal text commentary and audio recordings and medical notes documenting the ongoing medical status of each of these patients to their respective clinicians. As such, QMUL considers this to be sensitive personal data as defined in the DPA[1].

19. The Commissioner has viewed a sample of this withheld information and has established as well as the sensitive data as set out above it also contains information relating to patients' domestic circumstances and employment as well as names of hospitals and individual doctors.

20. In considering whether all the raw data requested is personal data the Commissioner has noted the detailed description given by QMUL in Annex 1 of this notice as to the content of these databases. He has also taken into account his Code of Practise on Anonymisation: managing

[1] http://www.legislation.gov.uk/ukpga/1998/29/section/2

data protection risk[2]. This refers to the motivated intruder risk of re-identification and the issues for an organisation to consider when making a decision on whether datasets such as in this case will lead to the identifiability of individuals On page 25 of this Code of Practise it is acknowledged that when considering large datasets or collections of information such as in this case it will be difficult to conduct an assessment of the likelihood of individuals having and using the prior knowledge necessary to facilitate re-identification. As such it will often be acceptable to make a more general assessment of the risk of prior knowledge leading to identification, for at least some of the individuals recorded in the information and then make a global decision about the information.

21. Given the above and the arguments provided by QMUL regarding the possibility of identification even in pseudonymised formats if this could indeed be done, which are referred to later in this notice he is satisfied that the general assessment and global approach taken by QMUL in concluding all the requested information is personal data is the correct approach to take here.

22. The Commissioner is therefore satisfied that all the information is the personal data of third parties and that some of it is sensitive personal data.

Would the disclosure be fair?

23. The Commissioner has gone on to consider whether the disclosure of this information would be in breach of the first principle of the DPA.

24. The first principle requires, amongst other things, that personal data is processed fairly and lawfully. The Commissioner has first considered whether the disclosure of the withheld information would be fair.

25. In considering whether disclosure of this information would be fair the Commissioner has taken the following factors into account:

    - whether disclosure would cause unnecessary or unjustified damage or distress to the individuals concerned;

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2 http://www.ico.org.uk/for_organisations/guidance_index/~/media/documents/library/Data_Protection/Practical_application/anonymisation_code.ashx

- the individuals' reasonable expectations of what would happen to their information; and

- are the legitimate interests of the public sufficient to justify any negative impact to the rights and freedoms of the individuals concerned.

26. QMUL argued that, medical data is by its very nature 'sensitive', and it considered that this information would prove to be a source of considerable embarrassment, distress or humiliation if disclosed publicly.

27. Furthermore, QMUL argued that this medical data relates to a mentally and physically debilitating condition of unknown cause, suffered by a small minority of the population and which presently has limited interventions. CFS/ME is often long term with serious financial, professional and personal consequences.

28. QMUL explained that these patients did not give explicit consent to process this data further for public disclosure. In addition they were also expressly advised of the specific and limited purposes for its further processing beyond it being held and used by the local PACE trial clinicians and provided with specific assurances of data confidentiality as the basis for their voluntary participation in the clinical trial. The Trial Protocol End Note at page 104[3] says:

"Will you keep my details confidential?

Yes. All your details and all recordings will be kept strictly confidential and held in a locked filing cabinet or on a secure computer. People on our research team will only see your records if they need to for the research. Your GP and any other doctors you are consulting will be told you are joining our study. And occasionally, other researchers will need to see your notes so they can audit the quality of our work. An audit might be run by one of the universities helping with our study or hospital regulatory authorities, or by one of the organisations funding our study"

[3] http://www.pacetrial.org/docs/trialinfo.pdf

The Patient Consent Form

"13. I understand that information collected about me for the trial, including my personal details, a copy of this consent form and all of the questionnaires I complete for the trial, will be held securely by the local trial staff and at the PACE trial coordinating centre at Queen Mary, University of London. I give permission for this to happen."

29. QMUL therefore argued that the participants would have no reasonable expectation that their medical information would be disclosed beyond the specified purposes, never mind to a member of the public and the world at large.

30. Given the above, the Commissioner is satisfied that it is unlikely any of the trial participants would have had any reasonable expectation that the withheld information would be disclosed under the FOIA.

Consequences of disclosure

31. QMUL considered that there is no reason to doubt that most people of normal sensibilities would wish to keep such discussions and notes of their symptoms, feelings and physical abilities under these circumstances private and would realistically be greatly distressed to have them disclosed.

32. QMUL also argued that once published to the world at large, if someone were to use it to identify individuals who are suffering from CFS/ME and participated in the trial, it could result in damage and/or distress to them. In an area of contentious research and treatment, patients or QMUL should not have to prove that patients have been or will be vilified or ridiculed in the public CFS/ME fora for participating in a research trial in order to keep their medical treatment data which results from that participation, confidential.

33. Furthermore, QMUL considered that even if all the data was not deemed to be sensitive personal data, it could also prove a source of great embarrassment or humiliation if publicly disclosed. As CFS/ME has no known cause with varying physical symptoms, including fatigue or exhaustion, that are by necessity often self-reported has led to unjustified labels such as 'malingerer' being applied to its sufferers. The possibility that an entire database of CFS/ME patients' benefits/work status could be disclosed and lead to individuals being identified publicly as recipients/shirkers would likely cause great personal distress.

34. In relation to the legitimate interests in disclosure of this information the complainant stated that the public is entitled to and has an interest in having full access to the raw anonymised data. This statement was made at the internal review stage, and was not the initial request. It

therefore appears that the complainant believes that the information requested i.e. the 'raw data' is in an anonymised form.

35. QMUL has argued that although this is a relatively large study, sufferers of CFS/ME comprise only 1% of the general population. Given the vast fields of data relating to each individual patient, it is highly likely that these individuals could be readily identified from the totality of the data should it be disclosed to the public, even in pseudonymised formats, and even if such pseudonymisation could be done - which it considers is doubtful given the format of a vast amount of the data such as audio files recording the patients' own voices and that of their clinicians. Moreover, as the CFS/ME patient community is very close, active and motivated in numerous cases to challenge the outcomes of studies in which the results do not comport with their beliefs as to the causes and treatment of CFS/ME, the possibility that individuals would be sought to be identified in this regard once the data were made public cannot be considered speculative or remote.

36. The Commissioner refers back to his earlier analysis in paragraphs 15-22 of this Notice in which he accepted that the information held comprises personal data. Taking into account the arguments from QMUL on pseudonymisation he therefore agrees that even in pseudonymised form there is a real prospect of individuals being identified from the information.

37. QMUL stated that given the level of public transparency and now independently replicated results, it would appear that there is no legitimate interest which would justify the vast disclosure of sensitive personal data.

38. The Commissioner accepts that there is a general public interest in terms of transparency and accountability of public sector organisations and specifically about the outcomes of medical research trials. However, the Commissioner does not consider that any legitimate interest extends to disclosure of the personal data of the participants of that trial.

39. The Commissioner is unable to conclude that disclosure of the withheld information is necessary to meet a legitimate public interest.

40. Based on the above, the Commissioner is satisfied that the withheld information is personal data and that disclosure would breach the first data protection principle as it would be unfair to the individuals concerned.

41. As the Commissioner has determined that it would be unfair to disclose the requested information, it has not been necessary to go on to consider whether disclosure is lawful or whether one of the conditions in Schedule 2 or 3 of the DPA is met.

42. The Commissioner therefore upholds QMUL's application of the exemption provided at section 40(2) of the FOIA. Consequently, he has not gone on to consider the application of section 41.

Annex 1

i. The full recordings of all treatment sessions and psychiatric interviews

All therapy sessions, all sessions with the doctor, and the standardised psychiatric interview held by the research assistant at baseline, were audio-recorded, with patients' informed consent. This is kept in 640 encrypted CDs, one for each patient, which include an average of 13 sessions of therapy, 3 sessions with the doctor, and one psychiatric interview, amounting to an average of some 15 hours of records. The data are in the form of audio-recordings that could be listened to with normal media software on a computer. These data comprise patients' accounts of personal information of relevance to their illness, and the progress of their treatment and therapy. It is (sensitive) personal data that cannot be released without contravening the Data Protection Act 1998.

ii. Actigraphy recordings

All patients at baseline wore an actigraph on their ankle, which recorded their physical movements for seven days and nights. These data are binary in form and are kept in 640 very large datasets on CDs. One would need the appropriate software to read these data.

iii. Schedule database

All patients' record of their visits to clinics, who saw them and when. This is available in MS Excel form.

iv. Numerical and text trial main database

Each variable measured in the PACE trial has its own individual database, in STATA format, although they could be converted, with time, into an MS Excel sheet. Each of these individual databases consist of many individual sub-variables, such as date the data was recorded, which follow-up interview collected at, then the content of each variable, such as whether collected, the data itself, which may be up to 60 individual columns, depending on the particular variable, and any derived data. All such variable databases also contain text data which records any comment the patient said or wrote on the questionnaire used. All such variable databases also contain 15 sub-variables, regarding the patient's identification number, date randomised in treatment modality, centre where randomised, and baseline data such as treatment group, whether depressed at baseline, and whether they met alternative definitions for the illness. These data are necessary for a proper (baseline adjusted) analysis of any PACE variable, and contain significant identifying data. Each variable database consists of some 2560 rows of data (640 x 4 follow up visits) and between 30 and 130

columns of data, depending on the content of a particular variable. Altogether there are some 40 such individual variable databases.

Right of appeal

43. Either party has the right to appeal against this decision notice to the First-tier Tribunal (Information Rights). Information about the appeals process may be obtained from:

    First-tier Tribunal (Information Rights)
    GRC & GRP Tribunals,
    PO Box 9300,
    LEICESTER,
    LE1 8DJ

    Tel: 0300 1234504
    Fax: 0116 249 4253
    Email: informationtribunal@hmcts.gsi.gov.uk
    Website: www.justice.gov.uk/guidance/courts-and-tribunals/tribunals/information-rights/index.htm

44. If you wish to appeal against a decision notice, you can obtain information on how to appeal along with the relevant forms from the Information Tribunal website.

45. Any Notice of Appeal should be served on the Tribunal within 28 (calendar) days of the date on which this decision notice is sent.

Signed .....

Pamela Clements
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