

Freedom of Information Act 2000 (FOIA)

Decision notice

Date: 9 January 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 copies of all meetings of the PACE Trial Steering Committee, Trial Management Group and Data Monitoring Ethics Committee.
2. The Commissioner's decision is that Queen Mary, University of London (QMUL) has correctly applied section 36(2)(b) of the FOIA.
3. The Commissioner does not require the public authority to take any steps.

Request and response

4. On 15 April 2012, the complainant wrote to QMUL and requested information in the following terms:

I would like you to supply me with copies of minutes from all meetings of the PACE Trial Steering Committee, Trial Management Group, Data Monitoring and Ethics committee.

5. QMUL responded on 14 May 2012. It stated that it did not hold the minutes of the Data Monitoring and Ethics Committee (DMEC) meetings. With regard to the minutes of the other groups, QMUL advised that it did hold this information but that it was exempt under section 36(2)(b)(i) and 36(2)(b)(ii) of the FOIA.
6. Following an internal review QMUL wrote to the complainant on 11 July 2012. It stated that it upheld its original position and in addition it considered that section 36(2)(c) also applied.

Scope of the case

7. The complainant contacted the Commissioner to complain about the way his request for information had been handled. The complainant provided detailed arguments to the Commissioner as to why he felt the minutes of the Trial Steering Committee (TSC) and Trial Management Group (TMG) should be disclosed and provided a number of links to other articles relating to the PACE Trial and treatment of CFS/ME. The Commissioner received the complaint on 26 July 2012.
8. The Commissioner considers the scope of this case to be to determine if QMUL has correctly applied section 36 of the FOIA.

Background

9. The PACE trial was a clinical trial carried out by QMUL commencing in 2002. This PACE (Pacing, graded Activity and Cognitive behaviour therapy: a randomised Evaluation) trial was a large scale trial to test and compare the effectiveness of four of the main treatments available for people suffering from chronic fatigue syndrome (CFS), also known as myalgic encephalomyelitis (ME).
10. Results from the PACE trial have been published in The Lancet and the QMUL website (<http://www.pacetrials.org/>) provides further information and details of the trial.
11. The Commissioner notes that the PACE trial is controversial and there are some organisations and individuals opposed to the treatment methods used.

Reasons for decision

12. Section 36(2) of the FOIA states that:

"Information to which this section applies is exempt information if, in the reasonable opinion of a qualified person, disclosure of the information -

(b) would, or would likely to inhibit -

- (i) the free and frank provision of advice, or*
- (ii) the free and frank exchange of views for the purposes of deliberation, or*

(c) would otherwise prejudice, or would be likely otherwise to prejudice, the effective conduct of public affairs.

13. The exemptions listed in section 36(2) are qualified exemptions so are subject to the public interest test. However, before considering the public interest the Commissioner must first consider whether the exemptions are engaged.
14. For any of the exemptions listed in section 36(2) to apply the qualified person for the public authority must give their reasonable opinion that the exemption is engaged. The qualified person for QMUL is the Principal, Professor Simon Gaskell. QMUL has provided the Commissioner with evidence to demonstrate that the opinion has been sought and provided.
15. The Commissioner is satisfied that Professor Gaskell is a qualified person for QMUL and that his opinion was given at the relevant time. He has gone on to consider whether that opinion was reasonable.
16. QMUL advised that the qualified person is a scientist and researcher with many years' experience, fully familiar with the workings of a medical research project and understood the issues presented in this case to form his own opinion.
17. The Commissioner has been provided with a copy of the submission made to the qualified person, which included information supporting a recommendation.
18. The submission argued that releasing the meeting minutes;
 - could have major implications as to how trials are conducted on a national level in future;
 - will alter the way in which trials are run;
 - will alter the way in which minutes are recorded, particularly in controversial areas of medicine such as this.
19. In addition, QMUL stated that a previous FOIA release of information had already damaged the trial, by delaying the analysis.
20. QMUL has provided sufficient evidence to illustrate that the qualified person was provided with documentation explaining that he was required to form a reasonable opinion in relation to the application of section 36(2)(b)(i) and 36(2)(b)(ii) of the FOIA to the information withheld by QMUL.

21. In reaching a view on whether the opinion is reasonable the Commissioner will consider the plain meaning of the word 'reasonable' – i.e. whether the opinion is in accordance with reason, not irrational or absurd.
22. The qualified person has stated that in his opinion the disclosure of the requested information "*would undoubtedly inhibit, and arguably endanger, current and future trials*".
23. The Commissioner considers that, given the candid nature of discussions and the expectation of confidentiality from those concerned, it is reasonable for a qualified person to conclude that disclosure of the minutes would inhibit (i) free and frank provision of advice (ii) free and frank exchange of views. The Commissioner is satisfied that the opinion was reasonably arrived at, and he agrees that the exemption is engaged.
24. Section 36(2)(b) is a qualified exemption and therefore it is subject to the public interest test. The Commissioner must consider whether, in all the circumstances of the case, the public interest in maintaining the exemption outweighs the public interest in disclosing the information. As the Commissioner agrees that the exemption is engaged he has gone on to consider the public interest test.

Public interest arguments in favour of disclosing the requested information

25. QMUL has recognised that there is a public interest in releasing the requested information in that research is publicly funded; it would increase understanding of how the trial was managed and how decisions were made, and its effectiveness.
26. QMUL recognised there is a public interest in the disclosure of research that is publicly funded as here, to permit, among other things, the public to monitor the expenditure of public funds.
27. It also recognised that in the conduct of public affairs the public interest in providing a space to think or engage in debate freely to reach a decision that affects the public usually lessens when the decision has been made or the policy reached.
28. There is an important public interest in the transparency/accountability of public authorities and the ability of the public to monitor activities of public bodies and understand how decisions were taken that affect them.
29. The complainant also provided arguments as to why the public interest favoured disclosure of the requested information.

30. He believed consideration needed to focus on how the meaning of free and frank exchange of views is being interpreted in this instance, and whether an inhibition in the way FOIA defines it, could even have arisen during such meetings, or likely to in the future if similar smaller studies were to be given further public funding.
31. It was the complainant's view that section 36 if used inappropriately can have the opposite outcome of its intended use and access needs to happen in certain circumstances to ensure a free and frank exchange of views is actually taking place.
32. The reason the complainant was of this opinion is that despite the fact that ME is listed under Diseases of the Nervous System by the World Health Organisation at reference G93.3, it is well known that a huge amount of controversy surrounds the illness and two sides within medicine (psychiatric v biomedical) have a long history of opposing one another as to the medical approach believed necessary to manage, treat and cure the condition: psychiatry favours using a far less stringent criteria to identify and research the illness within the population, whilst those from a biomedical opinion on the whole favour a far more stringent criteria to the point that both are likely to be looking at different conditions.
33. The complainant further stated that there is also enough circumstantial evidence to show that there is collusion between government and the Insurance industry (see Annex 1 ^{[1][2]}) in order to limit the financial burden ME has placed on both, and that psychiatry is being favoured over biomedical to enable them to achieve that. The current standoff and related research is clearly of public concern as it is thought to be causing an entrenchment of views within psychiatry, along with unwillingness to give ground and make way for other avenues of research.
34. Whilst this situation continues, the complainant believes, it is unlikely that a fully informed public debate will ever be able to happen that would enable the situation to change and bring about an improvement to the lives of ME sufferers.
35. The complainant therefore felt it was reasonable to assume all involved with PACE who attended the meetings concerned, were of the same mindset. They were obviously aware that funding had been made available and that availability had raised a fair amount of criticism from within the ME community from those favouring a biomedical approach ^{[2][3]} yet that criticism was largely ignored and the trial still went ahead, and with alterations granted that on the surface appear more to enable it to be able to do so, than any real regard for maintaining an acceptable level of a good scientific standard ^[4].

36. The complainant further stated that added to that when a comparison is made, the concerns put forward by those critical of PACE, (not only at its outset, but during and after publication) (see Annex 1 ^[2] ^[3] ^[5] ^[6] ^[7] ^[8]) do seem to have had excellent foresight as the published results are extremely poor.
37. The complainant firmly believes the evidence relating to PACE, when viewed collectively and in context highlight and supports the need for transparency and openness to happen. This would allow the public to fully inform themselves and if necessary be in a good position to safeguard against various influences and internal pressures possibly allowing for collective and individual interests to take precedence at such meetings.

Public interest arguments in favour of maintaining the exemption

38. QMUL stated that faculty members including scientific researchers often share their thoughts and views with one another. This is especially true where the scientific examination of an issue is a collaboration among scientific researchers such as with the examination of treatment outcomes in the PACE clinical trials.
39. It is further true that in this case the requested minutes reflect the opinions/exchanges of the principal investigators and other members of the research team on a range of issues regarding the structure, proper conduct and ongoing evaluation of the trials. The confidentiality of such discussion and debate can be vital to the development of scholarship, knowledge, and scientific truth which is the public mission of QMUL.
40. Faculty members and other researchers and individuals with whom they collaborate in these endeavours must be afforded privacy in their exchanges in order to pursue knowledge and develop lines of argument and scientific findings without fear of reprisal for findings or ideas that are controversial and without the risk of premature disclosure of those ideas.
41. QMUL further argued that it was also reasonable to conclude that disclosure would inhibit the quality and freedom of future exchanges among academic researchers who continue in the field and to recruit important participants outside academe to get involved in the studies.
42. A review of the minutes in question reveals sensitivity among the researchers in light of the highly politicised and polemic nature of elements of the public debate noted above.
43. This occurred in an environment where researchers fully expected the meetings to be closed to the public and the minutes to be confidential.

44. These responses express strong views as to the negative impact on future exchanges and the willingness of some important participants to be involved, for example, patient representatives whose role is to help ensure a public oversight and balance of views and who would not participate if their identities or view/statements as reflected in the minutes were disclosed to the public.
45. Furthermore, QMUL stated that there are other studies planned and beginning. Disclosure of the identity/opinions of the participants in the completed study could likely impact on participation and exchange of views and analysis on other studies. Since ME/CFS is an area where there is a significant need for ongoing research, the public interest in continuing to perform such studies in an atmosphere conducive to academic freedom is great with the potential prejudice to its quality and successful completion real and significant.
46. QMUL explained that the research and its findings have been fully and timely published in a respected peer reviewed journal, The Lancet, with access to the findings fully available to the public.
47. Moreover, these findings have been subject to extraordinary public scrutiny. The Lancet, in response to extensive public commentary, in an unusual procedure, subjected the study to a further peer review process.
48. QMUL also stated that while the requestor here suggests that the minutes would be helpful to provide the public information as to the findings in light of investigator's conflict of interests these interests were disclosed with the published study. It does not consider that the disclosure of the minutes in question would provide further information in this regard to the public.
49. In addition, QMUL stated that in this case, there is an ongoing scientific process, both with new studies, one of which it advised as being just underway and there is another planned longitudinal evaluation of data from the study in question. There is, therefore, a continuing need to protect the free and frank exchange of views in such ongoing studies and there is a public interest in protecting academic freedom and the College's future effective conduct of its public affairs mission to engage the effective conduct and evaluation of scientific knowledge here without fear of public reprisal.
50. QMUL has also provided copy correspondence from a patient representative group.
51. This letter states that it was an active and full member of the TMG and observers of the TSC. It believed that this was important in influencing

trial design and implementation to the benefit of patients and their carers'.

52. It was of the view that releasing the requested information would be prejudicial to the conduct of such committees in current and future studies and trials of treatment of CFS/ME.
53. It further stated that it was essential that patient/member organisations such as theirs are able to participate in such committees and have discussions that are not inhibited in any way. Knowledge that minutes may be released in this way will have a negative effect on its further decisions to participate in future committees.
54. Furthermore, it stated that if it had known that minutes were likely to be published it would not have committed itself to participate in the way it did. It believed that this was even more the case for individual patient representatives.
55. Finally, it stated that it was essential that a range of stakeholders and patient organisations are supported to engage in groups such as these without fear of public recrimination or condemnation. It believed that releasing the requested information would likely damage future studies and trials by inhibiting participation by patient representatives and patient organisations.
56. During the internal review process further consideration was given by QMUL to the public interest.
57. The internal review of the trial minutes, manuals, trial protocol, the Lancet publications, the interview statements and other material indicated that, in contrast to the complainant's suggestion, the PACE trial was not related to a debate about psychiatric understanding versus biomedical.
58. The trial was intended and designed to test treatments currently available within the NHS that were based in reversing maintaining factors in the illness, not causative factors *per se*, which were a mixture of physical (e.g. deconditioning) and psychological (e.g. coping behaviours) factors. The review indicated that the statement of the Trial Senior Statistician concurred and indicated no scientific justification existed for disclosing the minutes.
59. QMUL explained that attempting to evaluate if there was proper balancing of the complainant's public interest rationale of determining suggested collusion, predetermined results, conflicts of interests and lack of scientific rigour as requiring the minutes' disclosure, the internal review of the trial management group indicated that it contained more physicians than psychiatrists.

60. A review of the background literature on CFS/ME indicated that medical authorities, including investigators, do not regard the illness as purely psychological in its nature, but as both physical and psychological.
61. Similar claims of collusion between government, researchers and the insurance industry regarding disability-related benefits or insurance payments with respect to a number of the trial researchers involved in the PACE trial were found to have been previously reviewed in another context but found wanting previously as indicated by the decision in *R (on the application of Fraser and another) v Nat'l Inst for Health and Clinical Excellence and another* [2009] EWHC Admin (452) including the unusual Afterword, by Simon J.
62. As part of this further evaluation, the QMUL staff member reviewed The Lancet 2011 trial outcomes article and The Lancet process. This found that The Lancet not only published the main results of the PACE trial in a 2011 article that was initially peer-reviewed by several referees, but also in response to the referenced criticisms cited by the complainant, had apparently conducted a second evaluation.
63. QMUL explained that The Lancet is known to the academic medical community as a highly respected journal. Research metrics show that it is the second most highly cited medical journal in the world. Not only did this dual peer review take place, in another unusual accompanying editorial The Lancet addressed considerations similar to those raised as contributing to the public interest by the requestor here. The journal stated: "White and colleagues have been accused of having "formed their opinion about the intended outcome" before the trial began. This view is unjustified and unfair. The researchers should be praised for their willingness to test competing ideas and interventions in a randomised trial. The evidence might even suggest that it is the critics of the PACE trial who have formed their opinions first, ignoring the findings of this rigorously conducted work" (The Lancet, 2011).
64. After having reviewed all of the above, the staff member prepared a report for the Principal entitled 'Analysis for Qualified Person's consideration on internal review'. This was provided to the Principal for his further opinion as to whether the exemption should be maintained on 2nd July 2012. On 11th July 2012, the Principal determined that the opinion to maintain the exemption should stand.
65. QMUL stated that independent advice had been sought and given in many areas in connection with the Trial by the TSC. This included, for example, issues of patient safety, trial implementation, and review of the clinical interventions used. These advisers must be free to give their opinions based on their expertise and which must be fully minuted in

order to document and be able to re-examine why decisions were made in the course of a long-term study.

66. QMUL considered that publication of the requested information where this advice is reflected would prejudice the provision of full and frank advice by these advisers in light of possible hostility and public reprisal from a small, but notable part of the CFS/ME activist patient community.

Balance of the public interest arguments

67. In finding that the above exemption is engaged, the Commissioner has already accepted that the disclosure of this information is likely to result in the inhibition set out in the exemption. However, in considering the balance of the public interest, the Commissioner takes into account the severity, frequency, or extent of any inhibition that would or might occur. He has considered the nature and content of the withheld information and the timing of the request.
68. The withheld information consists of minutes of meetings of the TSC and TMG. The Commissioner has examined these and has ascertained that they related to a number of issues, for example, the structure of the clinical trial. The information contains a number of views and opinions which were expressed in those meetings, and details a number of options explored and actions to be taken.
69. The Commissioner understands that these meetings have now ceased as the trial has been completed and the results published.
70. The Commissioner considers that participants of such meetings need time and space for free and frank discussions regarding the best and most appropriate way to conduct clinical trials, provide advice and decide upon options to take.
71. The Commissioner considers that there is a strong public interest in openness, transparency and accountability in the decision making processes of public authorities. He also considers that there is a strong public interest in allowing the public to be better informed about the way clinical trials are conducted.
72. The Commissioner also acknowledges the strength of feeling of the complainant and others concerned with the treatment of CFS/ME.
73. The Commissioner has considered the severity, extent and likely frequency of inhibition to the provision of advice and the free and frank exchange of views for the purposes of deliberation which disclosure of the withheld information would be likely to pose. He is satisfied that QMUL is entitled to protect a safe space for discussion about the

implementation and set up of clinical trials, particularly when further trials are ongoing and planned for the future.

74. Given the nature of the withheld information, the Commissioner considers that significant prejudice would be likely to occur if the withheld information were to be disclosed.
75. The Commissioner further considers the prejudice will be the loss of the experienced researchers to other institutions that can guarantee them privacy and confidentiality, and that this is real. The Commissioner accepts that this is an important factor and affords significant weight to it.
76. QMUL maintains that, if the withheld information were to be disclosed, this would be likely to inhibit the effectiveness of the discussions which could result in poorer decision making, and perhaps inhibit some individuals from participating altogether.
77. The Commissioner recognises that should these minutes be disclosed, this would be likely to erode some of the trust that participants have that information they provide will not be made publicly available. As such the Commissioner considers this to be a relevant argument weighing in favour of maintaining the exemption.
78. Although there is a strong public interest in transparency and accountability in public authorities, the Commissioner considers this has been satisfied to some extent by the publication of the trial results.
79. Therefore the Commissioner's conclusion is that, in all the circumstances of the case, the public interest in maintaining the exemption outweighs the public interest in favour of disclosing the requested information.
80. The Commissioner considers that section 36(2)(b)(i) and 36(2)(b)(ii) can be applied to all the withheld information. He has therefore not gone on to consider the application of section 36(2)(c).

Right of appeal

81. 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

82. 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.

83. 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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Annex 1

1] **Inquiry into the Status of CFS / M.E. and Research into Causes and Treatment: 6.3 How the Department for Work and Pensions Formulates CFS/ME Policy**

http://www.erythos.com/gibsonenquiry/Docs/ME_Inquiry_Report.pdf

[2] **Magical Medicine:How To Make a Disease Disappear**

<http://www.investinme.org/Documents/Library/magical-medicine.pdf>

[3] **A Summary of the Inherent Theoretical, Methodological and Ethical Flaws in the PACE Trial**

http://www.theoneclickgroup.co.uk/documents/ME-CFS_res/

[4] **PACE Trial Protocol: Final Version**

<http://www.meactionuk.org.uk/FULL-Protocol-SEARCHABLE-version.pdf>

[5] **Responses to PACE questions tabled by the Countess of Mar in the House of Lords**

<http://www.meactionuk.org.uk/Responses-to-PACE-questions-CoM.htm>

[6] **The PACE trial in chronic fatigue syndrome**

[http://www.thelancet.com/journals/lancet/article/PIIS0140-6736\(11\)60684-3/fulltext](http://www.thelancet.com/journals/lancet/article/PIIS0140-6736(11)60684-3/fulltext)

[7] **Recent Correspondence With The Lance Regarding PACE**

<http://pacedocuments.blogspot.co.uk/2011/04/recent-correspondence-with-lancet-re.html>

[8] **REPORT: Complaint to the Relevant Executive Editor of The Lancet about the PACE Trial Articles Published by the Lancet**

<http://www.meactionuk.org.uk/COMPLAINT-to-Lancet-re-PACE.htm>