In response to ICO decision notice FS-50558352: 'Timing of changes to PACE Trial recovery criteria'

(Last updated: 10th April 2015)

In response to QMUL's refusal to grant this FOI request after an internal review, I submitted a complaint to the ICO. I sent the correspondence from the whatdotheyknow.com thread and the following supporting document, which is similar to what was posted there, but for completeness I have placed it online for others to view:

https://sites.google.com/site/pacefoir/FOIR2_online-correspondence.pdf

https://sites.google.com/site/pacefoir/FOIR2_supporting-document.pdf

Unfortunately, QMUL managed to persuade the ICO case worker to rule that this request was "vexatious":

https://ico.org.uk/media/action-weve-taken/decision-notices/2015/1043579/fs_50558352.pdf

I did not expect such difficulty getting simple answers about a publicly funded clinical trial. Due to health-related limitations and other commitments, I doubt that I can sustain the time and effort required to pursue this particular case further myself. The public should not have to depend on a First-tier Tribunal just for a chance at getting clarification about trial methodology.

The disappointing ICO decision notice was emailed to me on the 18th March 2015. I have since written the following response for the record, addressing the main assertions and conclusions in the decision notice (which in my opinion were based on misguided assumptions and an imbalanced consideration of the evidence).

https://sites.google.com/site/pacefoir/FOIR2_response-to-ICO-decision-notice.pdf

- Part 1 of 2: ON THIS SPECIFIC FOIA REQUEST -

Ensuring accuracy, and utilizing the FOIA to answer questions about a publicly funded clinical trial, are legitimate activities. Seeking resolution for confusion among the community is a legitimate motivation. There is no convincing reason why clarifying information on trial methodology should be withheld from the public. Without clarification, the ambiguity remains and people are left to draw their own tentative conclusions about what happened, based on the information currently available.

There are conflicting interpretations of what happened regarding the timing and nature of changes to the recovery criteria as previously defined in the PACE trial protocol (published in 2007). [1] It is unclear what exactly happened, and when it occurred. I presented information at the beginning of this request which explained how this confusion has arisen. The FOIA seemed to be the most plausible way of getting clear answers, so I submitted a request. Instead of spending a few minutes providing clarification, QMUL ended up working on an "extremely detailed submission" to speculate about my motives and persuade the ICO to rule that this request was likely to be part of a wider effort to discredit and harass. [2]

The ICO (the Commissioner or case worker) stated that it "has considered all of the evidence put forward by both the complainant and QMUL" yet "will not consider the detail of the PACE trial itself". In my opinion this indicates that the ICO did not adequately consider the reasoning behind the request, the relevant issues highlighted, or the references provided. Their focus was on subjective interpretations of tone, the circumstances of an alleged campaign to discredit the PACE trial results and investigators in any way possible, and claims of feeling harassed or burdened. QMUL's subjective feelings were taken into consideration, along with misplaced assumptions about my own motivations, while relevant facts about the PACE trial which justified this request in the first place were apparently deemed outside the scope of the ICO's judgement for this case.

The ICO decision notice does not include the five paragraph introduction I provided to justify the questions. [3] There are recommendations to keep requests simple, but I wanted QMUL to be informed of the relevant background. QMUL claimed that it was "an attempt to find out information which the complainant believes will discredit the trial and those involved". My intention is not to discredit the trial or those involved, but simply to resolve the ongoing confusion by seeking maximum transparency in relation to a publicly funded clinical trial that has been described by its investigators as 'definitive'. I would have been satisfied with any information or explanation which conclusively resolved the issues presented. It is unclear how releasing information about trial methodology could discredit any study if it was conducted and reported properly. Accurate details about prominent protocol changes are still relevant when fully evaluating the reports of clinical trials.

While QMUL asserted that the questions were leading so any response would only lead to further requests, I purposely constructed the request so that further requests on this issue would not be necessary. The ICO asserted that the questions were "accusatory in tone", "suggesting that the position is different from that set out over several years by QMUL". Yet the position set out by QMUL is unclear and somewhat contradictory, hence the reason for a request. The ICO implies that some of my questions are properly addressed in the FAQ articles on pacetrial.org, but that is incorrect. [4]

QMUL took issue with the phrase "confirm or deny" for some questions, as they "are not valid requests under FOIA" and "worded in such a way as to suggest that the requestor appears to be fishing for information based on suspicion or general scepticism and to elicit a specific reply". However, I worded them to receive clear unambiguous answers, and at the beginning of the list I stated "or clarify, the following". QMUL and the ICO either did not consider the word "clarify" which applied to all questions, or are overemphasizing a technicality which I did not intend. The FOIA covers recorded information and I expected whatever information clarified the questions presented. None of the answers would be strictly limited to a simple Yes or No. A search for "confirm or deny" on whatdotheyknow.com also reveals requests where such wording was not interpreted as accusatory and in many cases information was released regardless of whether it was the correct phrasing.

The FOIA 2000 (UK) [5] is complicated and I was new to the nuances of making a request. Even if some of the wording of the request may not have been optimal, QMUL has shown no willingness whatsoever to engage with me or work out a compromise on the questions asked in order to resolve this issue (which the ICO guidelines suggest as an alternative to resorting to the section 14 exemption i.e. vexatious requests). [6] I do not believe that compliance with this request would have been unjustified, disproportionate, or significantly detrimental, relative to the purpose and value of the request.

My later correspondence to QMUL, after they dismissed (without any explanation) my sincere request for information as vexatious, attempted to further explain the concern and confusion that has arisen. I had hoped that if it was made clear why the issue exists and if they were reminded of their obligations, then they would want to clarify the matter. QMUL took issue with this because it "used challenging language to apparently question the credibility of the trial". I mentioned some common and verifiable concerns which are relevant; a few of these concerns are shared by a systematic review (p42) commissioned for the U.S. Department of Health and Human Services. [7] Other researchers and experts have also criticized the revised recovery criteria. [8] QMUL asserted that "the tone of the correspondence is bullying in nature". My tone and language was frank on the relevant issues reflected in the references provided, but was not aggressive or abusive and should not have caused distress, nor was it intended to do so. This request does not meet any of the general indicators of a vexatious request when all this is taken into account. The ICO guidelines on s.14 [6] state that a public authority cannot take into account anything that happened after 20 working days from the original request, but QMUL did exactly that to argue their case.

QMUL appear to argue that reasonable questions and relevant critical assessments which justify those questions are distressing and harassing (seemingly without any regard for the validity or relevance of those questions and

assessments). It is difficult to see how QMUL can express familiarity with various online comments about the trial, yet also be oblivious to the relevant issues I raised in my correspondence. There is another more recent example of the PACE trial investigators dismissing academic discussion as a campaign of harassment, when the April 2015 edition of Lancet Psychiatry published reasonable letters addressing various issues relating to the trial. The investigators failed to meaningfully respond to the letters but asserted that the letters "might reflect the apparent campaign to bring the robust findings of the trial into question". [9] Contrary to what Chalder et al. asserted in their reply, the points raised in those letters have not been properly addressed elsewhere.

The FOIA is applicant and motivation blind, at least outside s.14. I stated that my motivation was resolving an important issue for the benefit of the patient community, and I asked QMUL to help resolve it. This was overruled by QMUL's inaccurate insight into my true intentions and their assertions of feeling harassed.

QMUL asserted that the trial results have been "independently verified" (no details on which results or what methods); that is irrelevant to this particular request, as my questions were related to how their own major protocol changes came about.

I made a mistake on the number of working days QMUL took to respond to the initial request (21 days not 24 days), but the ICO decision notice does not mention that QMUL then took an unusual 48 working days for the internal review. Public authorities are expected to carry out internal reviews within 20 working days. [10]

1. http://www.publications.parliament.uk/pa/ld201213/ldhansrd/text/130206-gc0001.htm
2. https://ico.org.uk/media/action-weve-taken/decision-notices/2015/1043579/fs_50558352.pdf
3. https://www.whatdotheyknow.com/request/timing_of_changes_to_pace_trial
4. http://www.pacetrial.org/faq
5. http://www.legislation.gov.uk/ukpga/2000/36/contents
6. https://ico.org.uk/media/for-organisations/documents/1198/dealing-with-vexatious-requests.pdf
7. http://www.effectivehealthcare.ahrq.gov/ehc/products/586/2004/chronic-fatigue-report-141209.pdf
8. http://www.apa.org/monitor/2014/10/beyond-tired.aspx
9. http://www.thelancet.com/journals/lanpsy/article/PIIS2215-0366%2815%2900114-5/fulltext
10. http://ico.org.uk/for_the_public/official_information

- Part 2 of 2: ON THE ALLEGATIONS OF A VEXATIOUS CAMPAIGN -

BioMed Central published the PACE trial protocol in 2007, stated that "once approved, the authors/investigators are unlikely to be able to make revisions to their protocol", and strongly advised their readers to contact the authors or evaluate future papers to make sure that the protocol was followed. [1] BioMed Central believes that publishing protocols will help to prevent unacknowledged post-hoc revisions. [2]

Extensive deviations from the trial protocol have since occurred, after the trial was completed. Concerns were raised publicly, over trial results promoted to patients and clinical commissioners as 'definitive'. AllTrials.net calls for the full methods and all results from all trials past and present to be reported. There is an estimated 17 million ME/CFS patients around the world. Under the FOIA (UK), asking a public authority any question can be treated as a formal request, regardless whether the Act is cited. This includes emailing anyone who works for a public authority, such as the principal investigators of clinical trials.

QMUL stated that 35 requests totalling 160 questions have been received since February 2011. [3] This averages to less than one request per month, and some are public knowledge on websites such as whatdotheyknow.com and ico.org.uk. Several more papers have been published since 2011, so the requests may be spread out and cover a wide range of issues. QMUL did not specify what proportion of the 35 requests were assessed to be "vexatious". Compare the above figures with a campaign headed by Ben Goldacre in 2006,

where 106 requests were sent to Durham County Council over two weeks. [4]

Some requests to QMUL were related to obtaining the primary outcomes and recovery rates for the PACE trial, as defined in the published trial protocol in 2007, but never published (there seems to be no intention to do so). The total number of requests submitted may relate largely to a genuine interest in the research, the quality of the published measures, the technical concerns about the changes to the trial protocol, the remaining questions or ambiguities that have arisen, and the failure to release information on established outcomes as outlined in the published trial protocol. I maintain that QMUL should consider the extent of which failings on its side have contributed to such requests being generated.

QMUL stated that there has been a "stream of similarly themed requests". Details about most requests are not public, so it is unsurprising that independent requests have shared similar themes if multiple individuals have similar questions or concerns based on the limited information currently available to the public. QMUL complained about "the persistent and aggregated burden" but acknowledged that "the quantity of requests alone could not be described as overwhelming". QMUL complained that they see no end in sight to the requests, yet they also explained that only one single request relating to the PACE trial has been received since July 2014, which seems to contradict the repeated impression that QMUL are under ongoing attack from requests. QMUL engaged in unsubstantiated speculation that requests may have been co-ordinated to prevent aggregation (requests submitted within 60 working days can be grouped together as one if there is evidence they are part of a campaign), and that requests will resume if its decision is not upheld by the ICO. QMUL persistently refuse to release important information which should end the basis of a significant proportion of requests.

QMUL alleged that there is a campaign to access information which those campaigners believe might discredit the trial. I cannot speak for other requesters and I am not responsible for whatever the public does with information when released, but again, it is unclear how releasing trial information (e.g. protocol-defined outcomes and clarifying details about major deviations from the published trial protocol) could discredit any study if it was conducted and reported properly.

QMUL and the ICO dismiss the need for dissemination of trial information by FOIA, based on the argument that trial results have been and continue to be published. The ICO also believes or assumes that QMUL has reliable processes in place for review and dissemination which ensure that as much information as possible is in the public domain. Those views do not take into account the specific reasons for this request, or that information can be and has been released in a very selective manner. The FOIA was set up to create a public statutory right of access to information held by public authorities, helping to bring balance where currently available information is lacking or where important information is withheld. The ICO has apparently deferred judgement to QMUL, without investigating the evidence that review and dissemination have been inadequate on this issue.

QMUL's other evidence for the campaign against the trial consisted of the following examples given by the ICO: online correspondence critical of the trial to the Lancet and on the BMJ website, part of a single post on a patient forum by someone who wanted to see more information about the trial released through the FOIA, and an unspecified hashtag on Twitter purportedly used to "promote attacks on the trial". Again, no consideration or distinction was given for the validity of the comments made, and it seems that everything was lumped together as evidence for a malicious campaign. I am not responsible for, and do not necessary concur with the details of, commentary other individuals have written by their own accord.

QMUL mentioned correspondence on the BMJ website which is critical of the trial. [5] The BMJ encourages patient engagement, while the terms and conditions do not allow inappropriate content. QMUL and the ICO cast doubt over my motives by attempting to associate me with a campaign for posting on the BMJ. They seem to suggest that posting critical commentary anywhere online is campaigning to discredit and harass, rather than individuals with genuine interest in the subject trying to engage in reasonable debate based on their

understanding of the information available (i.e. post-publication review).

In my later correspondence with QMUL and my submission to the ICO, I pre-empted the conjecture about an anti-psychiatry campaign, as I carried out research and QMUL has previously made such allegations. I do not claim to represent the patient community, but do believe that the concerns of patients are clearer when more attention is paid to the underlying basis of their arguments rather than to sweeping generalisations and prejudiced stereotypes about their beliefs and motives. QMUL (and ICO) apparently dismisses all critical commentary and questioning of the PACE trial as an anti-psychiatry campaign, and uses misunderstandings or conspiracy theories to refuse the release of information which the public has a right to know.

I also pre-empted section 12 (i.e. cost-limitations), as it is discussed in the ICO guidelines on s.14 (i.e. vexatious requests), and because it was an issue with a publicly known request which QMUL initially dismissed as exempt under s.14, but later changed to s.12 after an internal review. I attempted to consider every possible response in order to be thorough.

Withholding important information about the methodology of a publicly funded clinical trial should not be automatically covered by "academic freedom". The public has a right to the requested information, as public authorities are legally obliged to comply with the FOIA, and should not be exempted from it simply because individual employees are uncomfortable answering questions. Academic freedom also does not guarantee that clinical trials are immune from public questioning or critical assessments. Expressing concerns and asking questions are legitimate activities. The FOIA and ICO legislations are not intended to protect the interests and comfort of individual public employees at the expense of the overall public interest.

If Professor White handles requests as implied, and QMUL are aware of comments on the BMJ website (going back to at least 2013), then they must also be aware of multiple factual errors in the recovery paper; yet no corrections have been published despite Cambridge Journals' expectation that authors alert them of errors. [6]

Making sure that trial protocols are followed, and that deviations are properly justified or accurately explained, is also a legitimate public interest and expectation. [7] This is particularly important when there is confusion or debate over what happened and methodological concerns have been raised over the changes that occurred.

The wider research community is welcoming mainstream efforts towards increased transparency and openness to scrutiny. This includes adherence to published protocols, or providing clear explanations and valid justifications for significant deviations. QMUL should not regard such expectations from the PACE trial as unreasonable attempts to discredit it and harass them. Where is the specific evidence that such expectations constitute genuine harassment or malicious intent, and advances an argument stemming from "a black and white view of the mind/body problem"? The public should not be refused important trial information, simply because of generalized assertions about a campaign to discredit and harass researchers, for publishing results which supposedly challenge the ideology of a group of patients and advocates. Trial transparency means giving enough detail to allow full understanding of the rationale, design, and all results. Circumstantial and often misinterpreted evidence of a campaign does not negate the importance of ensuring that claims made by public bodies, in reports of clinical trials or in published academic papers, are accurate, transparent, and informative.

1. http://www.biomedcentral.com/imedia/2095594212130588_comment.pdf
2. http://www.biomedcentral.com/authors/protocols
3. https://ico.org.uk/media/action-weve-taken/decision-notices/2015/1043579/fs_50558352.pdf
4. http://www.badscience.net/2006/11/you-vexatious-troublemakers
5. http://www.bmj.com/search/%22PACE%20trial%22%20CFS
6. http://journals.cambridge.org/action/stream?pageId=6728&level=2
7. http://www.plosclinicaltrials.org/article/info:doi/10.1371/journal.pctr.0020018