

DETERMINATION: Facts

FITNESS TO PRACTISE PANEL HEARING: Commencing 3 January 2012

Dr Iain STEPHENSON (4069256)

Dr Stephenson:

At the outset of proceedings the Panel acceded to an application from Ms Nicholls, on behalf of the GMC, to delete paragraph 5(a) of the allegation. In addition, typographical errors were corrected in paragraphs 2, 4 and 13. You admitted paragraphs 1 to 12 in their entirety, paragraph 14, paragraph 15(a) in relation to paragraphs 4, 5, 6, 7, 8 and 12 and 15(b) in relation to paragraphs 4, 5, 6, 7, 8, 9 and 12. They were announced as admitted and found proved. With the agreement of all parties, paragraphs 6 and 7 were subsequently amended to specify the subject numbers of the patients to which they refer. You confirmed that those paragraphs remained admitted.

The Panel has considered each of the outstanding paragraphs of the allegation separately. In doing so it has considered all of the evidence adduced in this case and has taken account of Ms Nicholls' submissions on behalf of the GMC and your submissions. It has borne in mind that the burden of proof rests on the GMC throughout and that the standard is the civil standard of proof, namely the balance of probabilities.

The Panel has heard evidence from Mrs Phayre Elverstone (nee Parkinson), Professor Karl Nicholson, Professor of Infectious Diseases at Leicester University, Mrs Helen Mather, Dr Adrian Palfreeman and Dr Paul McNally. You have also given oral evidence. The Panel has had regard to all of the documentation submitted by Ms Nicholls and by you. That includes the relevant study documentation, witness statements from several of your colleagues, including Dr Tristan Clark and Senior Research Nurse/Trial Manager Ms Sally Batham, and some email correspondence between you and colleagues.

The Panel has accepted the advice of the Legal Assessor, who advised the Panel that the more serious the allegation the less likely it is that the event occurred and, hence, the stronger should be the evidence before the Panel concludes that the allegation is established on the balance of probability. Cogent evidence is generally required to satisfy a Panel that a doctor has been fraudulent or behaved in some other reprehensible manner. With regard to dishonesty, he has referred the Panel to the two-stage test as set out in the decision of the Court of Appeal in the case of R v Ghosh [1982] QB 1053. In determining

whether your actions were dishonest, it must first of all decide whether, according to the ordinary standards of reasonable and honest people, what was done was dishonest. If it was not dishonest by those standards, that is the end of the matter. If it was dishonest by those standards, then the Panel must consider whether you must have realised that what you were doing was dishonest by those standards.

The Panel has made the following findings on the facts.

Paragraphs 1 to 12 -

1. During 2010 you held the post of Honorary Consultant Physician at The University Hospital of Leicester NHS Trust;
2. You were the Principle Investigator in the study; 'Evaluation of heterosubtypic immune responses in older people before and after seasonal and pandemic influenza vaccination, an Open Label Study (UHL10548).' ('UHL 10548');
3. You were the co-investigator in the study, A phase II, randomised, partially observe-blind, single-centre study to evaluate safety and immunogenicity of MF59-adjuvanted or non adjuvanted H5N1 booster influenza vaccines in adults primed with MF59-adjuvanted influenza A/Vietnam/1194 (H5N1) vaccine (UHL 10492). ('The Prime Boost Study');
4. On the vaccine log for Study UHL 10548 you forged the signature of Dr Tristan Clarke. Those forgeries appear against the following dates
 - a. 21 October 2009,
 - b. 22 October 2009,
 - c. 23 October 2009,
 - d. 31 March 2010,
 - e. 8 April 2010,
 - f. 5 May 2010;
5. In the study file for UHL 10548 you forged the signature on the Curriculum Vitae of
 - [a. Deleted]**
 - b. Professor Karl Nicholson,
 - c. Dr Tristan Clarke;
6. On the vaccine log for study UHL 10548 you recorded that volunteers (subject numbers 54, 55 and 56) had been administered with the vaccine designated for UHL 10548 when they had not;
7. On 12 May 2010 you asked Nurse Phayre Parkinson to countersign the vaccine log to confirm that two volunteers (subject numbers 55 and 56) had been administered the UHL 10548 vaccine, when it had not been administered;
8. You destroyed the UHL 10548 Vaccine Log Sheet in relation to subjects 52 to 56;

9. You replaced the destroyed Vaccine Log Sheet with two new Vaccine Log Sheets of your own creation;

10. You consented volunteers to participate simultaneously in UHL 10548 and the Prime Boost Study;

11. You took part in UHL 10548 as a volunteer;

12. To disguise your involvement in UHL 10548 you changed the spelling of your name in trial records;

- have been admitted and found proved in their entirety.

Paragraph 13 -

On the 4 June 2010 you asked Dr Tristan Clarke to backdate his signature on documents where you had forged his signature;

- has not been found proved.

You have agreed in evidence that you had a conversation with Dr Clark on 4 June 2010. You described it as a very difficult conversation because you were telling him about the investigation into your conduct of the research study and that you had, on a number of occasions, forged his signature on the vaccine log. You deny, however, that you asked Dr Clark to backdate his signature and you have given evidence that this would not have been possible because, by the time of your conversation, the research file had been removed to the University's research and development department. Dr Clark, whose evidence was presented in the form of his written witness statement dated 27 September 2011, recalls the conversation with you on 4 June 2010 and he says that, at the time, he presumed that you wanted him to check the vaccine boxes and then countersign the fake signatures. However, he goes on to say that he supposes you may have been asking him to claim that the signatures were his and that, in any case, he is not sure exactly what you were asking him because he cut you off before you could clarify it. In these circumstances, the Panel is not satisfied on a balance of probabilities that you asked Dr Clark to backdate his signatures on the vaccine log as alleged.

Paragraph 14 -

Your actions in relation to paragraph 10 and 11 were inappropriate;

- has been admitted and found proved

Paragraph 15 -

Your actions in relation to paragraphs 4, 5, 6, 7, 8, 9, 12 and 13 were

a. dishonest,

- has been admitted and found proved in relation to paragraphs 4, 5, 6, 7, 8 and 12

- has been found proved in relation to paragraph 9.

- falls in relation to paragraph 13, which has not been found proved.

b. inappropriate.

- **has been admitted and found proved in relation to paragraphs 4, 5, 6, 7, 8, 9 and 12**
- **falls in relation to paragraph 13, which has not been found proved.**

Paragraph 15(a) in relation to paragraph 9

In considering whether you were dishonest when you replaced the Vaccine Log Sheets as alleged in paragraph 9, the Panel has noted the background to and context of your actions at this point in time. On 5 and 12 May 2010, you were engaged at the hospital clinic with the recruitment of subjects to the Prime Boost Study. Subjects 54, 55 and 56 were recruited to the Prime Boost Study and they were each given the vaccine for that study. You then took the opportunity to recruit them, at the same time, into your Open Label Study.

You have conceded in evidence, consistent with your admissions in relation to paragraph 10, that this dual-recruitment was not best practice and the Panel considers that you went to some lengths to disguise it. In the original Vaccine Log Sheet, you recorded vaccine administration dates for all three subjects. You located the tear-off labels from the Open Label Study vaccines and placed them on the log sheet. You then asked Nurse Parkinson to countersign the log evidencing the administration of vaccine to subjects 55 and 56, and forged Dr Clark's signature as a countersign for subject 54 for the same purpose. On the face of this document, therefore, subjects 54 to 56 appeared to have been given vaccine allocated to your Open Label Study. In fact, they had not. They had been given vaccine allocated to the Prime Boost Study and you destroyed the Open Label Study vaccine.

Nurse Parkinson has given evidence that, when you asked her to countersign for subjects 55 and 56 on 12 May 2010, she thought they were subjects from the Prime Boost Study, in which she had been involved. Nonetheless, she subsequently worried that her countersigning was not contemporaneous. She also realised, after talking to a nurse colleague, that the tear-off vaccine labels she had seen were a different colour and therefore not for the Prime Boost Study. She told you that she wanted to withdraw her countersigning. You scribbled out her first signature and, she states at her direction, put a line through the second one, which is the appropriate method for making any correction.

Nurse Parkinson reported her concerns to Ms Batham and you attended a meeting with Ms Batham and Professor Nicholson. You have given evidence that, at that meeting, you admitted the dual-recruitment of the three subjects and asking Nurse Parkinson to countersign. Professor Nicholson and Ms Batham recall only one dual-recruitment subject being discussed. You accepted that Nurse Parkinson had appeared to be very upset and you confirmed that you immediately crossed out her signatures when she asked you to do so.

You have told the Panel in evidence that, over the weekend following your conversation with Professor Nicholson, you reflected on the situation and decided to remove the original log sheet and replace it with two new sheets. You went on to tell the Panel that you did this so as to ensure that the records on the Study file correctly

documented the situation regarding the dual-recruitment of subject numbers 54 to 56. You said that there was no intention on your part to cover anything up, but you wished as part of the exercise to remove from the record the appearance of Nurse Parkinson's signatures.

In relation to subject numbers 54 to 56, it is right to observe that the replacement sheet which you created does appear to record accurately, in contrast with what appeared on the original log sheet, the dual-recruitment of these subjects and the fact that they had not received vaccine allocated to your Open Label Study. Further, an apparently true, reference to these subjects is contained in a file note which you wrote on 17 May 2010 and placed on the Study file. It is also right to observe that Nurse Parkinson's signatures no longer appear on this replacement sheet.

The Panel, however, rejects the explanation you have given in evidence as being the whole truth for what you did for the following reasons.

As a senior and experienced clinician and researcher, you knew, as you have accepted before the Panel, that you should not destroy clinical or research records. If you wished to amend an existing record, you should, as you well knew, have put a line through that original record so that it remained available for all to see and then added any corrections you wished to make with an appropriate explanation. The Panel does not think that the destruction of the original log sheet can be seen in isolation from the creation of the new sheets and it has concluded that you went about "setting the record straight", as you would have the Panel accept, in a wholly inappropriate and clandestine manner. Were it not for the fact that, unknown to you, someone had made a copy of the original log sheet, the information on it would have been lost forever once you destroyed the original and the Panel has no doubt that you believed this to be the case.

The Panel has also attached considerable significance to the fact that, in addition to the inaccurate information concerning subject numbers 54 to 56, which was addressed in your revision of the log sheet relating to these people, the original log sheet also contained against subject numbers 52 and 54 signatures purporting to be those of a research colleague, Dr Tristan Clark, which you have admitted forging.

It might be said that the disappearance of Dr Clark's signature from the replacement sheet dealing with subject numbers 54 to 56 was a consequential outcome of creating an accurate record relating to these people, bearing in mind that they had not in fact received any vaccine.

The same cannot be said of the disappearance of Dr Clark's signature from the replacement sheet you created for subject numbers 52 and 53. These two people had not been dual-recruited; they had been appropriately recruited into your Open Label Study; and they had each received two doses of vaccine. All this information was correctly recorded on the original log sheet. The only falsity on the original log sheet relating to these two subjects was the forged signature of Dr Clark against subject number 52.

When you decided to destroy the original sheet and create replacement sheets, there was no need to have done so, or to have made any alterations, in respect of the recruitment and vaccination of subject numbers 52 and 53. The replacement sheet for these subjects which you created had to be a copy of the original log sheet made by you and from which you deliberately blanked out Dr Clark's signature. On the balance of probabilities, the Panel infers from the fact that you did interfere with the record relating to subject numbers 52 and 53, which had nothing to do with setting the record straight about the dual-recruitment of subject numbers 54 to 56, that you intended by this action to cover up your forgeries of Dr Clark's signature. This action would in the Panel's view be regarded as dishonest according to the ordinary standards of reasonable and honest people and the Panel is also satisfied that you must have realised that what you were doing was dishonest by those standards.

The Panel will now invite further evidence and submissions as to whether, on the basis of the facts found proved, your fitness to practise is impaired.