**THE APPEALS COMMITTEE OF THE HUMAN FERTILISATION AND EMBRYOLOGY AUTHORITY**

**JONATHAN WATT-PRINGLE QC (CHAIR), MS CATHARINE SEDDON AND PROF SAMUEL STEIN**

**IN THE MATTER OF:**

**ST JUDE'S WOMEN'S HOSPITAL (CENTRE 0198)**

**Appellant**

**and**

**THE HUMAN FERTILISATION AND EMBRYOLOGY AUTHORITY**

**Respondent**

Jenni Richards QC (instructed by Hempsons) for the Appellant

Alison Foster QC (instructed by Field Fisher) for the Respondent

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**DECISION**

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Introduction

1. The Appeals Committee heard this appeal over a period of five days, between 21st and 24th July and then on 11th September. Following deliberation, we announced our decision:

(1) The Appellant has discharged the burden of proving on the balance of probabilities that the decision of the Licensing Committee on 10th November 2014 should be overturned.

(2) Unanimously we concluded that (a) it would be disproportionate and inconsistent with previous HFEA decisions to refuse to renew the licence, but that (b) Mr Adeghe's conduct subsequent to the taking of consent from Mrs A on 20th August 2010 warrants the renewal of the licence to be for two years only and the attachment of special conditions thereto.

(3) The Appellant's licence should be renewed for a period of two years commencing on the date on which the written reasons are given.

(4) A written notice of the Appeal Committee's decision, a statement of the reasons for the above findings and details of the additional conditions will be provided in writing by 18th September 2015.

2. In this Decision we set out our reasons for our decision. The following should be noted:

    a. The section headed "The Proper approach in this appeal" has been written by the Chair without any input from the other two members of the Appeals Committee ("AC").

    b. Paragraphs 3 to 45 of the Decision represent the view of the majority of the AC. Ms Seddon agrees with parts of therof, but takes a different view from the majority on the issue of whether Mr Adeghe gave truthful evidence. She also takes a different view on whether or not he was a suitable person to be a Person Responsible ("PR"), although she considers that he is now a suitable person. Her reasons for reaching these conclusions are attached.

Background

3. St Jude's Women's Hospital in Wolverhampton has held a licence for the provision of fertility services since 2002. Mr Jude Harris Adeghe, FRCOG, owns the clinic and has been the medical director of and the PR for the clinic since 2002. There is a satellite clinic in Newcastle-under-Lyme, which is not licensed for IVF,

but is used for preliminary IVF preparations and for treatment and diagnostic procedures unrelated to fertility. The Wolverhampton clinic carries out an average of about 200 cycles per year. There are eight staff members, including nurses, secretarial staff and embryologists.

4. Before 2002 Mr Adeghe had set up an IVF unit in the large general hospital in Wolverhampton in 1997, and was the PR there. Between 1997 and 2014 no concerns have been raised as to his suitability to fulfil the role of PR.

5. The Human Fertilisation and Embryology Act 1990 ("the Act") contains the legislative framework which governs assisted reproduction and embryo research in the United Kingdom. It empowers the HFEA to grant a licence to premises to undertake gamete and embryo storage and transfer; and makes it a criminal offence to provide such services without a licence. Most licences are granted for a period of four years, and clinics are inspected periodically during that period and also before the renewal thereof.

6. St Jude's most recent licence was due to expire on 31st January 2014 and the HFEA carried out inspections in the course of 2013 for the purposes of considering whether or not to renew the licence. Whilst the renewal process was being undertaken, the GMC forwarded to the HFEA a "complaint" which had been made by Ms A, a patient who had undergone treatment at the clinic on 20th

August 2010. At the end of its own investigations the GMC decided not to refer the matter to its fitness to practise panel.

7. As a result of the report from the GMC, Dr Bloor and Ms Gill Walsh of the HFEA inspected St Jude's on 5th February 2014. Following that inspection, the HFEA wrote to St Jude's on 25th February 2014 to warn it that it would not recommend the renewal of the licence. The HFEA's Licence Committee ("the LC") accepted this recommendation at its meeting on 8th May 2014; and, in response thereto, the clinic exercised its right to make oral representations in relation to that proposed decision. Thereafter the LC heard evidence from Mr Adeghe and Dr Bloor, considered a volume of documents and the written and oral submissions from counsel for the HFEA and St Jude's.

8. On 10th November 2014 the LC decided that Mr Adeghe was not a suitable person to act as PR within section 16(2)(cb) of the Act, and accordingly refused to renew the clinic's licence. St Jude's appeals against that decision.

<u>The case of Ms A</u>

9. The LC's decision was based upon its conclusions concerning the taking of consent at the clinic. That issue had been triggered by the case of Ms A, and it is necessary to describe her case and the aftermath in a little detail.

10. Ms A was receiving treatment at the clinic as an NHS patient. She attended St Jude's on 20th August 2010 to undergo egg collection. According to the clinical records she was sedated for the procedure at 09.15 and the procedure was finished at 09.45. Ms A was then given some water, tea and toast and then discharged at 11.20. At some point after the procedure but before her discharge, she signed a consent form in relation to the donation of some of her eggs.

11. The LC described the taking of consent after sedation as "wholly wrong"; and it is agreed by all that a consent should not have been taken from Ms A so soon after sedation. That is because the sedative used, Midazolam, has a hypnotic effect and can affect the memory. Indeed, the relevant guidance notes indicated that patients should not drive a car, operate machinery or sign legal documents for 24 hours after undergoing sedation with this drug.

12. The issue before the LC was whether the unacceptable practice followed in the case of Ms A was a single occurrence or whether it reflected a wider practice at St Jude's. Mr Adeghe gave evidence that this was an isolated aberration by the nurse who took the consent, Mrs Maman; that he became aware of it only some three to four months later; and that he had taken remedial steps to ensure that staff did not repeat the mistake. The LC rejected Mr Adeghe's evidence.[1]

[1] See, in particular, paragraphs 41 – 48 and 62 – 67 of the decision.

The proper approach in this appeal

13. Ms Foster QC and Ms Richards QC did not agree about the weight that the AC should give in this appeal to the decision of the LC.

14. Ms Foster QC submitted that the AC must exercise its own discretion on all matters, since that is what is meant by a "fresh decision" under section 20B(1); and the LC's decision does not bind the AC, since it must bring its own mind to bear on each matter in contention. In her opening submissions Ms Foster suggested that we should not ignore the LC decision, unless we could find an obvious flaw in their reasoning; but she accepted that, though we might not consider the LC's decision flawed, it was possible for us to reach a different conclusion on the basis of the evidence placed before us. Shortly before the adjournment Ms Foster added that the LC's decision as to a witness's credibility must be given some weight; but, because the AC has had its own opportunity to hear the witness and form a view of his/her credibility, our own impression must predominate.

15. Ms Richards QC argued that the LC determination should not be the focus of the AC's consideration, since the AC was required to decide *de novo* whether or not to renew the clinic's licence. She also argued that the burden of proof on the clinic was to show why the renewal of the licence should be granted, not of establishing why the decision of the LC should be overturned, since that would be inconsistent with the requirement of section 20B that the AC should take a

fresh decision: and, to the extent that Regulation 23 provides otherwise, it is inconsistent with section 20B and must be disapplied. In her written Closing Submissions Ms Richards QC submitted that the AC should not consider whether the LC "got it wrong" or whether there were "flaws" in its reasoning or fault in the assessment of the evidence; and that it would be wrong for the AC to accord "some weight" or to confer some evidential status to the LC's decision.

16. I disagree with Ms Richards' construction of Section 20B, for it needlessly creates a conflict between sub-section (1) and Regulation 23. In my view the two provisions are compatible. Section 20B provides in general terms that "Reconsideration shall be by way of a fresh decision"; and Regulation 23 requires in general terms the appellant to establish that the LC's "decision … should be overturned".

17. Plainly, an appeal to the AC is quite different from appeals in the civil courts. In particular, the AC is not restricted to evaluating the LC's decision in the light of the evidence at first instance, but may consider new material[2] and hear oral evidence from witnesses[3] (as we did). Furthermore, Regulation 23 provides that "the appellant shall bear the burden of establishing to the Committee that the decision of the Authority being reconsidered should be overturned."

[2] Regulation 16(2)(i) of the Human Fertilisation and Embryology (Appeals) Regulations 2009 ("the Regulations").
[3] Regulation 25(1) (d) and (e).

18. The effect of these provisions is that the AC has a wider remit than civil appellate courts. In the light of the evidence placed before us, we have to reach our own conclusions on to the issues in the case. We do not have to be persuaded that the LC was wrong in its determination; rather Regulation 23 requires only that the appellant should persuade us that the LC's decision "should be overturned". It is therefore quite possible that the LC reached a decision which was correct on the basis of the evidence before them, but that their decision should be overturned because, for instance, additional evidence has come to light which has led us to reach a different conclusion on the issues in the case.

19. Of course, the AC can examine the LC's process of reasoning – we have done so - and, where it appears sound, adopt it. On matters of evidence, however, the LC's conclusions concerning a witness's credibility are unlikely to be helpful, since we, too, have had the advantage of hearing and observing the witness giving evidence. Inevitably, we must reach our own conclusions about his or her reliability. Similarly, when it comes to discerning the meaning of documents, we must reach our own conclusions as to their meaning and their relevance to the issues in the case.

20. In this case we have one particular advantage over the LC, in that additional objective evidence had been assembled which was relevant to the central issue of whether the case of Ms A was a single serious breach of proper practice or was part of a more common practice at the clinic.

The issues

21. In order to decide whether Mr Adeghe has discharged the onus of demonstrating on the balance of probabilities that the decision of the LC should be overturned, the following issues should be addressed:-

    a. Was there a practice at St Jude's of consents for egg donation being taken whilst patients were under conscious sedation, or was the case of Ms A an isolated case?

    b. Did Mr Adeghe give untruthful evidence?

    c. Is Mr Adeghe a suitable person to be the PR of St Jude's in the light of ---

        i. the unacceptable way in which the consent was taken in the case of Ms A;

        ii. the way in which he dealt with the case once he became aware of it; and/or

        iii. the information that St Jude's provided to NHS patients concerning egg-sharing?

    d. Further, if we decided that the decision of the LC should be overturned, what is the appropriate order to make in this case?

Was there a practice at St Jude's of consents for egg donation being taken whilst patients were under conscious sedation?

22. This issue has been clearly answered by an independent audit of the patient records carried out by Ms Ellie Suthers after the LC's decision in this case. She

examined all the records of patients who underwent vaginal egg collection procedures at St Jude's from 2009 to 2014 inclusive. She concluded that the case of Ms A was "a single, isolated event". Ms Suthers is a former HFEA inspector, and the Respondent accepted that she is a person of integrity and competence. Having carried out its own audit, the HFEA does not challenge Ms Suthers's analysis.

23. We accept Ms Suthers's conclusion and it follows that we conclude that the Appellant has established that the inappropriate manner in which a consent was taken from Ms A was an isolated event. Accordingly, we consider that the LC's contrary conclusion on this point cannot stand.

Did Mr Adeghe give untruthful evidence?

24. Mr Adeghe gave evidence over two days and he was extensively cross-examined by Ms Foster QC. In view of the fact that the LC concluded that he was a dishonest witness, we paid particular attention to his demeanour and to the way in which he gave his evidence; and, where possible, we assessed his evidence against contemporaneous documents. Where appropriate, we also took account of the inherent probabilities. We considered him to be an honest witness.

Mrs Maman's letter dated 14th March 2014

25. In reliance upon the letter written by Mrs Maman dated 14th March 2014 Ms Foster QC accused Mr Adeghe of lying when he said that he had discovered Mrs

Maman's breach three to four months after the consent was taken, and that he had expressed his disapproval to her at that time.

26. In our view it would be inappropriate to conclude that Mr Adeghe is dishonest on the basis of that two-page document. It is addressed "To Whom it May Concern" and was prepared by Mrs Maman for submission to the GMC, which was considering the complaint of Ms A. We have not seen any of the GMC documents or heard any of the details of the complaint. It is clear from the contents of the letter that Mrs Maman wrote it in order to answer criticisms which had apparently been directed at her. She did not provide a witness statement in this case and she did not give evidence before us: consequently, the contents of her GMC submission are untested hearsay. There is nothing expressly stated in the document which can justify concluding that Mr Adeghe was a dishonest witness; and we consider it to be unfair and wrong to reach that conclusion on the basis of an inference drawn from a piece of untested hearsay.

<u>The inspection on 5th February 2014 and Ms Walsh's note</u>

27. Ms Gill Walsh was and remains a senior inspector employed by the HFEA. She is familiar with St Jude's, which she has inspected on a number of occasions down the years. Following receipt of the GMC complaint it was decided that she and Dr Bloor would inspect the clinic on 5th February 2014. By e-mail dated 31st January 2014 Ms Walsh confirmed what she had told Mr Adeghe when he phoned her a couple of days before: the HFEA had received an anonymous

complaint relating to the patient pathway, which required them to inspect "a small number of patient records to review"; this would not take "terribly long", and the visit would also be used to obtain an update on the progress with the practical implementation of the recommendations made following the licence renewal inspection. Ms Walsh added that Dr Bloor, Head of Inspection, would be accompanying her, but her "… attendance is purely a matter of inspector availability and timing and is of no greater significance."

28. In the event, the visit lasted over four and a half hours, and gave rise to an undated note prepared by Ms Walsh, upon which the HFEA places great reliance. It is said that she made notes during the visit and that these were used by her as the basis for the typed note. The original notes were destroyed, as were those made by Dr Bloor. Ms Walsh's typed note runs to just over three pages, but it is only the first page which has particular relevance to the matters with which we are concerned. It records that Ms Walsh and Dr Bloor saw Mr Adeghe, Mrs Maman, Mr Skriskandkumar (the embryologist), Ms Loveridge (a nurse) and Ms Bateman (the counsellor). Under the heading "Mr Adeghe confirmed to GW verbally in the presence of DB and KM that …" various matters are recorded under 10 bullet points. A number of them are contentious.

29. There is no statement from Ms Walsh, and neither we nor the LC heard evidence from her. That is a pity.

30. Ms Richards QC mounted a powerful attack on the reliability of that note, which is summarised in paragraph 49 her closing submissions. We consider that the points she makes have considerable force. In particular:-

    a. Mr Adeghe was never sent a copy of Ms Walsh's note and asked to confirm its accuracy.

    b. The note cannot possibly be a reliable minute or typed up version of whatever notes Ms Walsh may have made during the inspection. Not only does it not reflect the sequence of events during the visit, as Dr Bloor accepted, but it fails to record anything of substance concerning one of the major purposes of the visit, viz to follow up the clinic's progress in meeting the recommendations of the earlier inspection renewal report.

    c. In the light of Ms Suthers's audit, Mr Adeghe's consistent evidence that Ms A's case was an isolated case cannot be dismissed as false; on the contrary. That being so, it follows that there was no reason for him to have told Dr Bloor and Ms Walsh during the inspection on 5th February 2014: "On occasion, but stressed not usual practice, consent to donation is sought on the day of egg collection following the procedure dependant on the number of oocytes retrieved. (ie > 10)".[4] Moreover, as Dr Bloor accepted in cross-examination, the number of eggs referred to was wrong, since the issue of donation could arise when more than six eggs were retrieved.

[4] Second bullet point.

d. It is unlikely that Mr Adeghe would have told Ms Walsh that all egg collections were conducted under intravenous conscious sedation.[5] As he said, there was no reason for him to have told her something of which she was well aware.

e. The note wrongly records that Mr Adeghe would get the patient to sign the consent form,[6] whereas that was done by the nurse specialist. Dr Bloor accepted that Mr Adeghe would not have made that statement.

f. The note also wrongly records that 10mg diazimols are used for sedation.[7]

g. Dr Bloor agreed in cross-examination that the last four bullet points were not things which Mr Adeghe said and that the note gave a misleading impression that he was confirming these matters; rather, it was Ms Walsh writing down her own thoughts and findings.

31. In evidence Dr Bloor sought to confirm some of the bullet points in Ms Walsh's note. However, we feel unable to rely upon her evidence in this regard. Before the LC Dr Bloor's evidence was that it was she who had questioned Mr Adeghe, while Ms Walsh made notes of the interview. Her evidence to us was that Ms Walsh had done both the questioning and the note-taking. It seems to us unwise to place much reliance on a witness's recollection of answers given to questions over 18 months earlier, when she was confused as to whether or not it was she who had conducted the interview.

[5] First bullet point.
[6] Fourth bullet point.
[7] Eighth bullet point.

32. For the above reasons, we do not consider that the hearsay evidence of Ms Walsh's undated note or such confirmation thereof as Dr Bloor sought to provide are able seriously to challenge Mr Adeghe's evidence concerning the visit.

The email exchange on 7th February 2014

33. In support of its case that Mr Adeghe is a dishonest witness the HFEA also relies upon two short e-mails exchanged between Ms Walsh and Mr Adeghe on 7th February. Ms Walsh wrote, inter alia:

> "You will recall in the course of our discussions you informed Debra Bloor and I that, on occasion it is your practice to seek consent to donation of eggs … after conscious intravenous sedation has taken place. … We have concerns that the practice of seeking (verbal and written) consent following the administration of intravenous sedation which may influence a patient's ability to provide informed, valid consent is not suitable practice. We therefore require that you cease this practice with immediate effect until further notice and provide written conformation [sic] of your agreement to this by return."

34. In his response Mr Adeghe did not dispute the assertion concerning the occasional practice alleged. The HFEA rely upon his e-mail principally to support their case that Ms A's was not the only case of post-sedation consent at St Jude's; and also as evidence that Mr Adeghe was seeking to justify the practice. This is said to be an illustration that he had no understanding of the seriousness of the breach of proper practice that had occurred in Ms A's case. We do not consider that Mr Adeghe's reply supports either of these contentions. First, in the light of Ms Suthers's conclusions, it would have been odd for Mr Adeghe tacitly to admit an "occasional practice" which did not exist. Secondly, and unfortunately, it appears that Mr Adeghe dashed off a response within "a few minutes" of receipt and without much reflection – a practice that is all too common with e-mail correspondence. In the context of the HFEA's investigation, referred to in

paragraph 15 of Ms Richards' Closing Submissions, we accept that Mr Adeghe would have concentrated on providing the assurance that such an event would not occur again. Thirdly, his statement that post-sedation consent "is not our standard practice" should not be taken to mean that it was an *occasional* practice. "Practice" has a number of different meanings, one of which connotes a single event. Indeed, Dr Bloor confirmed in cross-examination that the HFEA understood Mr Adeghe to be saying that this was something that had occurred only once.

35. For the above reasons, we do not consider that Mr Adeghe has given dishonest evidence.

Is Mr Adeghe a suitable person to be a PR?

36. We accept that the obtaining of valid consent is a vitally important part of the proper IVF practice and regulation. It follows that any breach, such as occurred in the case of Ms A, is a serious matter and that it must raise questions as to the suitability of the senior person in the clinic where it occurs.

37. We have carefully considered all the circumstances of this case and we do not consider that the breach in Ms A's case warrants the conclusion that Mr Adeghe is not fit to be the PR of St Jude's. First, it was not he who took the consent, but Mrs Maman. She was an experienced nurse, who had worked for St Jude's for some eight years without anything of this sort happening before. Secondly, we

accept that what Mrs Maman did was in breach of the training and practice in the clinic. In addition to Mr Adeghe's evidence, we heard evidence from Ms Loveridge, a fertility nurse at St Jude's. She confirmed that she was trained by Mr Adeghe in the proper practice concerning consents when she began working at the clinic. Unfortunately, even the best training and systems are subject to breaches as a result of human fallibility.

38. Mr Adeghe's evidence was that he took various steps when he became aware of the improper consent taken from Ms A. These included admonishing Mrs Maman, who confirmed that she had not done it before and would never do it again. He also had a team meeting, attended by the other staff in which they were informed of Ms A's case. These steps indicate that he did appreciate that what had occurred was a serious breach of the important requirements concerning proper consent. In that respect, we do not accept the HFEA's case that he showed insufficient insight to be a suitable person to act as PR. However, we consider that his remedial measures were not sufficiently rigorous. We consider that Mrs Maman should have been more severely admonished, with a written warning; that she should have received further training and advice; that the team meeting should have been formally minuted; and that Ms A should have been contacted, informed of the concerns and asked whether she was prepared to confirm the consent that she had signed on 10th August 2010. In evidence, Mr Adeghe conceded that he should have contacted Ms A.

39. Mr Adeghe has repeatedly stated that what occurred in Ms A's case was wrong and that it should never occur again. Despite the fact that we consider that his response at the time should have been more robust, we consider that he does have a proper insight into the importance of consent and that any deficiencies in this regard will have been dispelled by the searing experience of these proceedings.

The information provided to NHS donors

40. The HFEA also relied upon the issue of egg-sharing by NHS patients as a basis for asserting that Mr Adeghe is not a suitable person. The LC dismissed this contention. None of the evidence we have considered prompts us to doubt this part of their decision.

41. We do not wish to lengthen this decision by setting out detailed reasons for our conclusion on this point. It suffices to say that we are in broad agreement with paragraphs 52 to 58 of Ms Richards's Closing Submissions. In particular, nowhere in its publications has the HFEA suggested that egg donation by NHS patients to private patients is improper. That remains the case over a year after the HFEA became aware of Ms A's case. Furthermore, the HFEA Executive characterised the perceived inadequacies in the information provided to NHS patients as a major, rather than a critical, non-compliance.

42. Accordingly, we consider that Mr Adeghe is suitable to be a PR and that St Jude's licence should be renewed.

Proportionality, transparency and consistency

43. Even if we were wrong in our findings of fact, we nevertheless consider that the LC's decision should be overturned for the following reasons. First, the penalty imposed by the LC was inconsistent with and disproportionately harsh when compared with the HFEA's approach in previous cases involving breaches of proper practice concerning consent.[8] A number of those cases appear to have involved significantly more serious breaches of consent requirements than in this case, but none led to the refusal of a licence. Secondly, we accept that Mr Adeghe is committed to addressing the serious issues which arose in the case of Ms A and that there is no ongoing risk to patients. In this regard we are fortified by the view of the Executive Licensing Panel on 12th December 2014:

> "… the PR repeated his intention never to repeat the relevant activities which were at the centre of the Executive and the LC's concern and we do not believe there is evidence of serious measurable risk to patients from this …."

We consider that there is no appreciable risk of repetition of this breach of proper practice. Thirdly, there would be a deleterious impact on the PR, the staff of St Jude's and prospective patients which would be disproportionate, given the absence of risk to patients.

[8] In Bundle C, at Tab 3, the appellant's solicitors have assembled the details of some 13 cases, a number of which concerned consent. The HFEA has not sought to distinguish these cases or drawn our attention to other relevant cases.

Conclusion

44. But for the unfortunate case of Ms A, St Jude's licence would probably have been renewed for a period of four years on 1st February 2014.

45. As is apparent from paragraph 38 above, we consider that Mr Adeghe's response to the case of Ms A was not as robust as it might have been. For that reason we consider that the licence should be renewed for a period of two years, commencing on 18th September 2015, and subject to the following special conditions:

    a. By 4 pm on 11th December 2105 Centre 0198 shall formulate comprehensive written policies on all matters of the obtaining of consent from patients.

    b. By 4 pm on 11th December 2105 the Centre shall review and revise its patient information leaflet concerning egg sharing and egg donation.

    c. As soon as the above two conditions have been met, the documents and all of the Centre's policies and procedures shall be submitted to an independent external expert for review.

    d. By 4 pm on 31st January 2016 and thereafter by 4 pm on 31st of every successive January the Centre shall ensure that all clinical and nursing staff at the Centre have received training, which is consistent with the CPD standards of their respective professions, in the obtaining of consent from patients, the regulatory framework and HFEA guidance. Full records of the content of the training shall be kept on file.

17th September 2015

**DISSENTER'S FINDINGS OF FACT AND REASONS ON KEY ISSUES:**

**Was there a practice at St Jude's of consents for egg donation being taken whilst patients were under conscious sedation, or was the case of Mrs A an isolated case?**

1. I agree with my colleagues on this point.

**Did Mr Adeghe give untruthful evidence?**

2. I find that Mr Adeghe did give untruthful evidence for the following reasons:

    a. In respect of whether, during discussions with HFEA inspectors on Feb 5th 2014, Mr Adeghe referred to an occasional practice of taking consent post-sedation, I did not find Mr Adeghe's evidence credible.

    b. By contrast, I found Dr Bloor to be a credible, measured and convincing witness, whose evidence on this point I prefer.

    c. Notwithstanding some areas of doubt regarding the accuracy of the notes of the Feb 5th meeting (about which I agree with the findings of my colleagues), I nonetheless find it reasonable to give weight to the fact that the email of Feb 7th 2014 from Gill Walsh to Dr Adeghe is wholly consistent with her note of the Feb 5th meeting on this key point. Crucially, in his email reply, also of Feb 7th, Dr Adeghe does not take issue with Gill Walsh's characterization of what he said. Indeed, in my view, he clearly seeks both to explain and to justify what happened in the single case of Mrs A.

    d. In relation to the three courses of action Mr Adeghe said he took once he realized what had happened in Mrs. A's case, I also find

his evidence lacked credibility. He described expressing his dissatisfaction on discovering what Mrs Maman had done some 3 months after the event, his verbal disciplining of her and an all-staff meeting that he held in order to ensure that such practice would never happen again. Yet all three points are wholly inconsistent with his email response to Gill Walsh on Feb 7th 2014, more than 3 years after the event, in which he reveals a stark lack of awareness that what happened in Mrs A's case was a serious breach of HFEA standards and must never be repeated: "*However, if it is that the HFEA is not happy with this approach, which is not our standard practice anyway, we will not be doing so in the future*."

**Is Mr Adeghe a suitable person to be the PR of St Jude's in the light of the unacceptable way in which the consent was taken in the case of Mrs A?**

3. The practical, emotional and psychological implications of egg donation must all be considered carefully by a donor whose capacity at the time of signing consent cannot be questioned. Any instance of consent-taking post-sedation risks undermining the critical importance of the two cornerstones of valid consent: decision-making that is "fully informed" and "freely given". Further, it risks undermining public confidence in the regulation of this area of medicine.

4. In my view, given the fundamental importance of consent, as PR of a small clinic with only 8 staff, Mr Adeghe must take responsibility for the manner in which all consent is taken, including in the case of Mrs A. Further, I do not find it credible that Mrs Maman, if properly trained in consent procedures and appropriately managed by Mr Adeghe, would have acted unilaterally in deciding to take consent post-sedation. It follows that the way in which consent was taken in

Mrs A's case constitutes a very serious error of judgment on the part of Mr Adeghe at the very least because he must have failed properly to train and/or supervise the person to whom he delegated the responsibility for taking consent.

**Is Mr Adeghe a suitable person to be the PR of St Jude's in the light of the way in which he dealt with Mrs A's case once he became aware of it?**

5. For the reasons given above, I do not accept the actions Mr Adeghe said he took once he became aware of the case.

6. Furthermore, in my view Mr Adeghe displayed a serious and long-standing lack of insight as to the gravity of Mrs A's case. I cite the following points:

   a. In his Feb 7 2014 email to Gill Walsh, he still seeks to justify the practice over six months after he had received a copy of the complaint to the GMC regarding Mrs A's case in August 2013 ("*necessitated by desire to help needing* (sic) *patients*".);

   b. In the same email, he seeks to minimize the significance of post-consent sedation (Indeed, even in evidence to the Appeals Committee, he said "*It wasn't that Mrs A didn't want to donate. She'd always been clear that she did want to donate*");

   c. He took no formal disciplinary action against Mrs Maman. Indeed, in evidence to the Appeals Committee, he explained his thinking at the time by saying he "*didn't want to deflate her morale*" and that he had "*a duty of care to staff too and she had employment rights*";

   d. He failed to prioritise any appropriate re-training of Mrs Maman. (Although he told an HFEA Licensing Committee he had arranged at the time for her to go to the Birmingham

Women's Hospital, the director of that centre confirmed that the visit was in fact in 2013 – not 2010 - and that "*no training of any sort was requested or given*");

e. He did not contact Mrs A as soon as possible to explain the breach of protocol he had identified and to confirm her consent to egg donation.

f. At no point did he report the matter to the HFEA.

7. For all these reasons, I find that the HFEA was justified in holding significant doubts about Mr Adeghe's suitability to be a PR.

8. However, I am also of the view that, since February 2014, Mr Adeghe, a medical professional whose character and reputation were previously unblemished, has taken significant steps to address his failings in this regard. He has demonstrated genuine remorse, an insight into the significance of the breach of practice in Mrs A's case and a determination never to allow such practice again; he has also committed to re-training of staff, a review of all his policies, full cooperation with the HFEA in future and peer review of his clinical practice. In my view, therefore, he has succeeded in re-establishing his suitability as a PR.

9. In sum, despite maintaining the gravity of the case for which I hold him responsible and the worrying lack of insight I find he displayed, even at the point of being confronted, over three years after the event, by HFEA inspectors, I am satisfied that, as of today, Mr Adeghe <u>is</u> a suitable person to be a PR of St Jude's.

**Is Mr Adeghe a suitable person to be the PR of St Jude's in the light of the information that St Jude's provided to NHS patients concerning egg-sharing?**

10. I agree with my colleagues on this point.

**Further, if we decided that the decision of the LC should be overturned, what is the appropriate order to make in this case?**

11. Even though I disagree on certain findings of fact for the reasons set out above, I am in full agreement with my colleagues in determining the appropriate order: I take the view that proportionality and consistency with previous HFEA licensing decisions in addition to the reasons given by the Executive Licensing Panel for allowing Mr Adeghe to continue his clinical practice under Special Directions during the appeal process, compel the granting of a renewed licence albeit one limited in length and subject to the conditions as outlined in the judgment of this Appeals Committee.

Catharine Seddon. 17.9.15

**ST JUDE'S v HFEA – LEGAL RULINGS**

**21 July 2015 – Day 1 – Transcript page 15-16 – Re: Status of Dr Bloor**

I am asked to rule on the question of whether Dr Bloor, who is the main and only witness for the respondent in this appeal, should be allowed to remain in the room when Mr Adeghe and the other witness to be called by the appellant, Ms Loveridge, give their evidence. One of the problems in the way of this application by the respondent are the mandatory terms of regulation 27(8), which in clear language says:

> "Except in the case of an expert witness the appellant, or where appropriate the appellant's representative, a witness shall not be allowed to attend the proceedings until after the witness has completed giving evidence and been formally released by the Chair."

Clearly Dr Bloor is neither the appellant or the appellant's representative and the only basis upon which she could be allowed to attend before she has completed her evidence is if she qualifies as an expert witness. She has made two witness statements which are before us, totalling in all some 116 paragraphs and running to about 40 pages. Understandably a great deal of her evidence is of a factual nature though from time to time she does express opinions, which arguably qualify as expert opinions.

I have been taken by Ms Foster to various paragraphs in her two statements, six in the second statement and two in the first, which she says deal with matters of expert opinion evidence rather than pure factual evidence.

I'm not satisfied that all of those paragraphs can be classified in that way, but overall it seems to me that overwhelmingly the evidence in Dr Bloor's two statements is more of a factual nature than substantially of an expert nature. I do not therefore accept that she qualifies under the exception under regulation 27(8) as an expert witness. To the extent that the HFEA is disadvantaged by the fact that she cannot, according to the regulations, be in this room when the appellant's witnesses give their evidence we can, if it's necessary, have short breaks so that particular instructions can be taken from her on points which it is felt by those representing the HFEA require to be dealt with there and then.

So that is my ruling on that question.

**23 July 2015 – Day 3 – Transcript page 139 – Re: Use of Eggs donated by Mrs A**

[at 2.40pm] The proceedings that have taken place since about 2.10 pm this afternoon are in private and you may not publish any of the information which you have heard outside this room.