

# Minutes of Authority meeting held on 19 July 2022

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## Details:

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Area(s) of strategy this paper relates to:	The best care – effective and ethical care for everyone The right information – to ensure that people can access the right information at the right time Shaping the future – to embrace and engage with changes in the law, science and society
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Agenda item	2
Meeting date	14 September 2022
Author	Debbie Okutubo, Governance Manager

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## Output:

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For information or decision?	For decision
Recommendation	Members are asked to confirm the minutes of the Authority meeting held on 19 July 2022 as a true record of the meeting

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Resource implications

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Implementation date

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Communication(s)

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Organisational risk	<input type="checkbox"/> Low	<input checked="" type="checkbox"/> Medium	<input type="checkbox"/> High
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Annexes

## Minutes of the Authority meeting on 19 July 2022 held via teleconference

Members present	Julia Chain Catharine Seddon Jason Kasraie Tim Child Frances Flinter	Gudrun Moore Alex Kafetz Frances Ashcroft Graham James Geeta Nargund
Apologies	Zeynep Gurtin Alison Marsden	Alison McTavish Jonathan Herring
Observers	Steve Pugh (Department of Health and Social Care – DHSC) Amy Parsons DHSC	
Staff in attendance	Peter Thompson Richard Sydee Clare Ettinghausen Rachel Cutting	Debbie Okutubo Shabbir Qureshi Sonia Macleod Ana Hallgarten

### Members

There were 10 members at the meeting – six lay and four professional members.

## 1. Welcome and declarations of interest

- 1.1. The Chair opened the meeting by welcoming Authority members and staff present online. The Chair stated that the meeting was audio recorded in line with previous meetings and for transparency reasons, and that the recording would be made available on our website to allow members of the public hear it.
- 1.2. Declarations of interest were made by:
  - Tim Child (PR at a licensed clinic)
  - Jason Kasraie (PR at a licensed clinic) and
  - Geeta Nargund (Clinician at a licensed clinic).

## 2. Minutes of the last meeting

- 2.1. Members agreed that the minutes of the meeting held on 18 May 2022 were a true record of the meeting and could be signed by the Chair.
- 2.2. The status of all matters arising was noted.

## 3. Chair and Chief Executive's report

- 3.1. The Chair gave an overview of her engagement with key stakeholders and the decision-making committees of the Authority. The Chair commented that the final meeting of the Legislative Reform Advisory Group (LRAG) had occurred and wanted to say her and the board's thanks to all stakeholders who were part of LRAG.

- 3.2.** It was noted that some grassroots organisations had requested that the Chair participate in their discussions on fertility issues, which could mean that more awareness was being raised.
- 3.3.** It was noted that a new Secretary of State for Health had not yet been appointed but that the board will be kept abreast of developments. The DHSC representative, Steve Pugh commented that we had a Junior Minister for Health and Social Care, James Morris should political decision need to be made.
- 3.4.** The Chief Executive provided an update on the key external activities that he has been involved in since the last Authority meeting.
- 3.5.** He highlighted the associated media work seen in the press lately which was a reflection on some of our work in particular donor anonymity.
- 3.6.** Members were advised that there were currently no issues that required ministerial decisions so we were getting on with our jobs without political engagement.
- 3.7.** Members asked if the legislative reforms will still happen considering what was happening politically. The Chief Executive responded that we would continue to do what we are doing but until the government commits to a legislative timetable there are no guarantees.
- 3.8.** Members requested that they be pre-warned if we are going to speak to the press as patients and the press were asking questions about the recent press coverages that they had no answers to.

#### Decision

- 3.9.** Members noted the Chair and Chief Executive's report.

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## 4. Committee Chairs' reports

- 4.1.** The Chair invited Committee Chairs to add any other comments to the presented reports.
- 4.2.** The Licence Committee Chair (Alison Marsden) sent her apologies for the meeting but sent in comments to the Chair. The Committee considered some thought-provoking research licence applications recently. At the May meeting, discussions had resumed on a research licence application involving some complex PGT-A related issues (having previously requested more information from the applicant) – which was granted.
- 4.3.** It was noted that the July meeting minutes was still being finalised where they had two cases with complex issues. They were also delighted to have all new members who had joined the Licence Committee now on board.
- 4.4.** The Statutory Approvals Committee (SAC) deputy Chair (Gudrun Moore) commented that they had met three times since the last Authority meeting and that most items were approved. At the meeting held on 30 June, some decisions were deferred.
- 4.5.** The Audit and Governance Committee (AGC) Chair (Catharine Seddon) gave a synopsis of the last meeting held in June, at which the Authority Chair was also present. She commented that there were two internal audit reports presented, one of them was the effectiveness of the Inspection process which had received substantial audit rating. She also gave assurance to the board that the auditors present at the meeting had said there were no qualifications to our accounts but until the reconciliation had occurred with the actual income rather than the current

estimated figures, they would be unable to sign off the accounts. She invited the Director of Finance and Resources to give an explanation.

- 4.6.** The Director of Finance and Resources stated that further work was being done to get the actual figures from clinics rather than go on estimates and until that happened we would not be laying our accounts in front of Parliament. It was noted that the hope was to conclude this piece of work by the end of July.
- 4.7.** The AGC Chair continued that there would be refresher training on the analysis of financial statements for AGC members and that this would be opened up to Authority members who would like to participate.
- 4.8.** The Scientific and Clinical Advances Advisory Committee (SCAAC) Chair (Tim Child) gave a summary of the last SCAAC meeting. It was noted that amongst the discussions at the meeting there was a discussion on Treatment add-ons expansion of evidence base and that the conclusion was that in the absence of good robust randomized controlled trials (RCTs) or meta-analysis, expanding the evidence base may be necessary and helpful when assigning treatment add-on ratings.
- 4.9.** Following the European Society of Human Reproduction and Embryology (ESHRE) conference the annual SCAAC horizon scanning meeting occurred where they had a good discussion.

#### Decision

- 4.10.** Members noted the Committee Chairs' updates.

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## 5. Performance report

- 5.1.** The Chief Executive commented that some key performance indicators had been redefined. There were three red indicators in May:
  - HR2: Turnover
  - C1: Efficiency of the end-to-end inspection and licencing process
  - C4: Mito application average processing.
- 5.2.** Members were advised that staff turnover has remained high and that it was not relenting.
- 5.3.** C1 - Efficiency of the end-to-end inspection and licensing process: five inspections were over the 70 working day target. One took 154 days due to Inspector commitments, the other four narrowly missed the key performance indicator (KPI); one was due to a person responsible (PR) challenging a non-compliance.
- 5.4.** C4 - Mito average processing time: both of the applications due in the month were above the 90-working day target by four days.
- 5.5.** With PRISM, there were some clinics that were yet to deploy and may not be online until September. Members were assured that we continue to actively engage with clinics to support them in improving submission rate quality to PRISM.
- 5.6.** Members asked about the red indicators and if a review should be done. The Chief Executive responded that all the RAG ratings were set by the Authority and they were internal indicators which were not reported externally whether they are met or not. However, it helped us be

accountability to the Authority and also gave a picture of the constraints that we were working under which opened up the conversation with members.

- 5.7.** Some members commented that we should not change targets as repeated discussion drives progress. It was noted that at the AGC meetings, they continue to look at the matrix around the corporate culture of recruitment and retention.
- 5.8.** Members commented that if people were using the HFEA as a steppingstone to get jobs that were promotions, then it was a positive thing and the Authority should embrace it.
- 5.9.** In terms of financial performance, members commented that the number of fresh cycles was reducing and asked if this was having an overall effect on income received by the Authority. The Director of Finance and Resources responded that cycles that are billable have seen a drop since the pandemic but we were however yet to do the analysis to see if there are trends. This will be looked at, at a future date.
- 5.10.** The Chair commented that herself and the Chief Executive have regular catch ups over staff pay and they also look and think of everything other than pay that would help retain staff. The Chair also said that when we agreed the fee increase the intention was to come back to the board and do a proper review as the five-pound increase was a stopgap.

### Strategy and Corporate Affairs

- 5.11.** The Director of Strategy and Corporate Affairs presented this item. She introduced her new heads including Amanda Evans, the Head of Research and Intelligence; Angharad Thomas, the Head of Communications and Rachel Cooper, the Legal adviser to the policy team.
- 5.12.** She commented that the directorate has been busy and a lot has been done in terms of the storage work. It was noted that stakeholder group meetings and the Legislative Reform Advisory Group (LRAG) meetings continued to happen. The Ethnic Diversity in Fertility Treatment group that Tim Child chairs has also met in that time since the last Authority meeting.
- 5.13.** Members were advised that at the last Ethnic Diversity in Fertility Treatment group meeting, it was agreed that there would be recommendations to clinics to review their websites to make them more inclusive and that an update would be reported at the September Authority meeting.
- 5.14.** It was noted that the next persons responsible (PR) event will be held in October and that feedback received from previous events had always been positive.
- 5.15.** Members commended the ongoing work on ethnic diversity and inclusion on asked how members could support the Authority in reaching patients from ethnic backgrounds and how these patients could access material that will be produced in different languages. Members welcomed the image reviews on clinic websites and suggested that it was important and good that this was happening.
- 5.16.** Staff responded that there would be different materials and videos was one of the pieces of work that was required and that the work would be phased in.

### Compliance and Information

- 5.17.** The Director of Compliance and Information presented to the Authority. Members were advised that the new storage regulations went live on July 1 and that there was a dedicated area on the Clinic portal for help and guidance. It was noted that the next task was to produce short training videos on consent.

- 5.18.** The new consent forms had gone live and feedback received from clinics had been positive. The Director of Compliance and Information was chairing drop-in sessions as part of the guidance on how to complete consent forms.
- 5.19.** There was good progress being made on the backlog on the Opening the Register (OTR) service. Someone left in the team but the position has now been recruited to. A number of cases were closed in June and 84 received in the month but the waiting list continued to reduce.
- 5.20.** Members were advised that there was a nationwide shortage of one of the medicines used but we have been told that from mid-August the situation should improve this however has led to delays. Professional members on the Authority commented that this is a major problem and another drug was also affected.
- 5.21.** For the IT infrastructure, penetration tests are scheduled for September and we are trying to recruit a data analyst.
- 5.22.** For the Inspections team, the business support team has now been recruited to and they are settling in.
- 5.23.** Members commented that for PGT applications, that part of the portal crashed all the time and it was very frustrating for clinic staff and requested that this be looked into.
- 5.24.** Members commended the Director of Compliance and Information and her team on the work done on consent forms and the drop-in sessions. The Director of Compliance and Information requested that the sessions be publicised across the sector.
- 5.25.** The Director of Compliance and Information thanked DHSC colleagues and noted that were now looking into how changes would be implemented.
- 5.26.** The Chair on behalf of the board thanked the Director of Compliance and Information and her team for the hours dedicated to the drop-in sessions.

### Finance and Resources

- 5.27.** The Director of Finance and Resources presented this item. He commented that we had not closed last year's accounts due to issues mentioned above but that we should be able to close it before the end of the month.

### Decision

- 5.28.** Members noted the performance report.

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## **6. Treatment add-ons: updating the rating system and evidence base**

- 6.1.** The Scientific Policy Manager presented this item. Members were reminded that Treatment add-ons had been discussed at three Authority meetings since September 2021.
- 6.2.** Since March 2022 further work had been carried out on the presentation of the ratings system and the potential inclusion of additional outcomes.
- 6.3.** Members were invited to comment. They congratulated the team for a job well done and asked if treatment outcomes went beyond live births.

- 6.4.** They also asked if ‘no effect on treatment’ meant ‘no beneficial effects’ because such add-ons would not do anything.
- 6.5.** Members also asked for examples of safety concerns. The Chair of SCAAC gave examples of some safety concerns.
- 6.6.** Members asked if numbers were published in relation to the studies done.
- 6.7.** In response to some of the questions, the Scientific Policy Manager responded that we planned to develop a decision tree and algorithm and it would be shared with SCAAC. A decision would also be made on whether we want to publish summaries of RCT’s and that the SCAAC minutes were published.
- 6.8.** Members wanted assurances that the information on the website will be user friendly with clearer explanations in plain English. The Scientific Policy Manager responded that once the webpage had been developed it would be tested with users.
- 6.9.** The Chair of SCAAC commented that the first category:
- ‘On balance, the first category evidence from high quality studies shows this add-on is effective at improving treatment outcomes for most fertility patients’
- should be considered. He commented that we need to align with other agencies to make us more robust. Also, that there will be cost implications for consequential changes.
- 6.10.** Members wanted clarity on what was meant when we say ‘most’ fertility patients. Also, if there was evidence for 35+ or 40+ age categories and lastly how the ranking for the webpage could be improved. The Chair of SCAAC responded that the current system says ‘most’. We were therefore continuing with the existing language.
- 6.11.** Members requested that the webpage be made to be shareable on other sites.
- 6.12.** Members had concerns on the red rating due to the language used where it said ‘potential safety concerns’.
- 6.13.** Members commented that the symbols will mean different things in different settings, also that the lack of advice on costs of add-ons should be evaluated. Some members suggested that there should be a parallel between public interest and transparency.
- 6.14.** Members stated that we need to do this properly and asked if there were the resources to do it properly as reliance on SCAAC and a single statistician was a single point of failure.
- 6.15.** The Scientific Policy Manager commented that we were looking to have a social media campaign and that a new standard operating procedure (SOP) was being developed for new publications. During patient interviews, patients were more concerned with harm than safety and they commented on that the most. Lastly that the lack of transparency in costs was not within our regulatory gift.
- 6.16.** The Director of Strategy and Corporate Affairs commented that we have data on how our website is used. In the Code of Practice there is a requirement for all medical establishments to refer to HFEA when they speak about add-ons. The commitment to patients should be that if any new evidence or information comes to light it will be reviewed by SCAAC.



- 6.17.** The Chief Executive commented that very little research was ground-breaking, as the work gets more involved we would need to be more flexible and review the ratings. It also needed to be reiterated that standard treatment remained effective and this needed to be put out there.
- 6.18.** The Chair of SCAAC commented that there are a number of specialists on the committee therefore the frequency of updates will need to be made available as soon as possible. Members agreed that we should publish when the next review will be done.
- 6.19.** The Director of Strategy and Corporate Affairs reminded the board that we had publicly stated that it was under review and that we publish summaries in Clinic focus and we also publish the SCAAC meeting minutes.
- 6.20.** The Chair summarised the discussion and commented that Treatment add-ons will keep being refined and that the capacity to review add-ons will need to be built into the system.

#### Decision

- 6.21.** The Authority approved the option C and the wording attached to each circle/symbol for developing the treatment add-ons ratings system.
- 6.22.** The Authority agreed the proposed changes to the criteria the HFEA use when rating add-ons subject to SCAAC re-looking at consequential changes to the criteria HFEA use when deciding whether to rate an add-on.

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## **7. Modernising Fertility Regulation - update**

- 7.1.** The Public Policy Manager presented this item. Members were reminded that the aim of this work was to deliver an outline proposal on the Modernisation of the HFE Act to the DHSC around the end of the year.
- 7.2.** Members were informed that three LRAG meetings had taken place discussing:
- Consent and data sharing
  - Donor anonymity and information provision and
  - Scientific Developments.
- 7.3.** It was noted that the drafting of the consultation had begun with a communications plan and that the risks outlined at the May Authority meeting continued to apply.
- 7.4.** It was noted that the next steps in the consultation would allow the HFEA to set out why specific changes to the Act may be necessary, and outline proposals for reform.
- 7.5.** Following discussion, the Chair commented that the Director of Strategy and Corporate Affairs will send out a request to all Authority members for any member that could provide assistance.
- 7.6.** On behalf of the board, the Chair expressed gratitude to the LRA group for their assistance and support in shaping the changes requested. It was noted that they had met four times to help gather views and develop ideas.
- 7.7.** In response to a question, it was noted that there was a LRAG member who was a Royal College of Obstetricians & Gynaecologists (RCOG) member on the group. It was reiterated that LRAG members were there in their professional capacity rather than representing any group.



- 7.8.** Authority members were informed that regarding data sharing, LLAG members had agreed that amending the Act to permit easier sharing of fertility patient data in medical settings outside the fertility clinic would aid patient protection and safety. It would also improve care, speed up diagnosis, and provide important centralised records for research or commissioning. The Chair commented that this was all still subject to further discussion.
- 7.9.** Members commented that regarding Artificial Intelligence (AI) it should be clear what areas of AI was going to be pursued and if we wanted to link in with Genomics England. It was suggested that there could be a HFEA/Genomics Chair meeting.
- 7.10.** In response to a comment, it was noted that limit on costs was in the paper as one of the things we were looking to change in the Act.
- 7.11.** Members cautioned that political differences needed to be borne in mind and that we should endeavour to future proof what changes we were putting forward. We should also consider including all fertility patients in the category of vulnerable people.
- 7.12.** Also, to bear in mind that this was a once in a lifetime generational opportunity for change.
- 7.13.** Members further commented that raising items like 14-day rule was subject to political constraints, discussions therefore needed to be held elsewhere.
- 7.14.** The Director of Strategy and Corporate Affairs asked if members felt that we or LLAG had missed anything that they felt need to change in the Act.
- 7.15.** The Chair commented that we need to remember that we are not re-writing the whole Act but recommending changes in areas we felt needed to be updated.

#### Decision

- 7.16.** Members agreed the plan for a targeted consultation to take place later this summer.

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## **8. Any other business**

- 8.1.** The Chair reminded members that the Away day private session was on September 13 and part of what would be discussed was Modernising the Act, she urged members to try and attend.
- 8.2.** On the issue of effectiveness of the board, there was going to be a full board review this year so the Away day was also going to be a good opportunity to discuss and make the board a more effective one. There would also be time in the evening to socialise over dinner.
- 8.3.** A member asked that in light of the rising cost of living and covid rates if fees could be added to the agenda at the away day. The Chair agreed that it would be considered.
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## Chair's signature

I confirm this is a true and accurate record of the meeting.

Signature

A handwritten signature in cursive script that reads "Julia Chain".

Chair: Julia Chain

Date: 14 September 2022