# Authority paper

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| **Strategic delivery** | **Setting standards** | ☐ | **Increasing and informing choice** | ☐ | **Demonstrating efficiency, economy and value** | ☑ |
| **Paper title** | Committee roles and the delegation of functions | | | | | |
| **Agenda item** | **11** | | | | | |
| **Paper number** | [HFEA (21/01/2015) 745] | | | | | |
| **Meeting date** | 21 January 2015 | | | | | |
| **Author** | Sam Hartley, Head of Governance and Licensing | | | | | |
| **For information or decision?** | Decision | | | | | |
| **Recommendations** | 1) Consideration of initial treatment and storage licence applications is delegated to ELP; and<br>2) The Ethics and Standards Committee is abolished, and its functions delegated to either the Authority, an individual member, or the Executive. | | | | | |
| **Resource implications** | If agreed, the recommendations will, overall, save Authority member time and resource in terms of Committee attendance, paper production and reading. | | | | | |
| **Implementation** | 1 April 2015 | | | | | |
| **Communication** | Changes to Standing Orders will be approved at the Authority's March meeting and cascaded to members of the Executive. No external communication necessary. | | | | | |
| **Organisational risk** | Low | | | | | |
| **Annexes** | n/a | | | | | |

HUMAN FERTILISATION & EMBRYOLOGY AUTHORITY

## 1. Introduction

1.1. At the Authority's workshop in October, Authority members considered the role that they wanted to play in the future, in light of the reduced and changing membership, new strategy, and future issues emerging for the Authority. Authority members gave a strong steer on a number of issues, and asked the Executive to conduct some further thought on how such issues could be approached. In general terms, those issues were:

- The overall approach and working practices of Authority members;
- Whether there were further delegations possible from Licence Committee to the Executive Licensing Panel (ELP);
- The approach taken to policy and ethical issues, and the implications for the Ethics and Standards Committee (ESC);
- The approval process for the Pre-Implantation Genetic Diagnosis (PGD) applications.

1.2. This paper outlines the Executive's current thinking on the first three matters identified by the Authority at its workshop in October. It asks for general approval to the recommendations, and will be followed by changes to Standing Orders at the March Authority meeting.

1.3. The Executive has given thought to the consideration of PGD applications. The implications of a move away from the current procedure are considerable and are being worked on by the Executive. These will be reported to the Authority at its meeting in March.

## 2. Overall approach

2.1. There are significant challenges in populating the regular committees that sit with Authority members. The Authority board members must walk the line between providing the overall strategic leadership, scrutiny and challenge to the Executive that a board should do, while also exercising directly a number of the Authority's statutory powers and functions. All in the context of a reduced and changing membership at board level, and accompanying pressures on member time, committee quoracy and the day-to-day effective functioning of the Authority.

2.2. The proposals in this paper are predicated on clearing from Authority members' in-trays such items and functions that could, with robust systems in place, be conducted elsewhere. Or could be carried out in a more efficient, less time consuming, fashion. The proposals aim to reflect the wish of members to spend more time on issues that directly related to the Authority's strategic vision – high-quality care for everyone affected by assisted reproduction. This may mean longer and more diverse public Authority meetings, or the use of longer workshops for wider strategic and policy matters (see section 4). But even with such changes, if agreed, pressures will remain on Authority members' time.

2.3. There are some more prosaic changes that can be made to working practices that will allow more flexibility and in carrying out business, such as more use of video conferencing. For regular licensing and Statutory Approvals committee meetings, it may be preferable to meet with only four members at each meeting on a rolling basis, rather than always inviting all six members to each meeting. Members are invited to express views on such advances, but the Executive acknowledges that members have different views and will continue to keep its approach to committee meetings under review.

## 3. Licensing

### Matters reserved to the Licence Committee

3.1. Under the current Standing Orders, the Licence Committee considers complex or controversial issues including, but not limited to, Grade A incidents in clinics, research licence applications and renewals, and proposals to revoke or take other enforcement action against clinics. In the Executive's view, it is currently entirely right and appropriate for Authority members to exercise such functions. Our consideration of the other issues that Authority members, through the Licence Committee, should consider has been framed by the aim of retaining for the Committee any 'complex or contentious' issues.

3.2. However, in addition to such items, the Committee considers applications for new Treatment and Storage licences. Generally, these applications are non-controversial, with centres having not conducted any licensed activities the focus tends to be on premises, staffing and paperwork. While novel in the sense that they are for new clinics, in fact the issues that the Committee considers are relatively consistent across centres. There are rarely complex or controversial issues for the Committee to turn its mind to.

3.3. In light of this, the Executive considers that delegating the consideration of new Treatment and Storage licences to ELP will save the Authority members reading and consideration time, and allow meeting time to better spent on other more contentious items. The impact on ELP resources can be accommodated; further members are being appointed and trained in order to share the load of work on the Panel.

3.4. The Inspectorate would retain the ability to put initial applications that they viewed as complex or controversial, or providing a different challenge to the Authority, direct to a Licence Committee. This approach is not without risk of allegations of unfair treatment from centres whose application might be put to the Licence Committee rather than ELP; however, it is felt that through the use of the Management Review process consistency would be achieved. This would also mirror the current process for existing clinics that are already licensed and where formal enforcement action is being considered.

3.5. Consideration has been given to whether initial applications for research licences could also be delegated to ELP, therefore saving further time and resource for Authority members. The Executive's view, however, is that such items do fall under the descriptor 'complex or controversial'. No two research projects are the same, and new and different considerations are present in every application. It is the Executive's view, at this stage, that thorough scrutiny on the use and/or creation of embryos (among other activities) in research is more appropriately carried out by those vested directly with the statutory power – i.e. Authority members. We do not therefore propose to delegate the consideration of initial research licence applications to ELP.

### Recommendation

3.6. **The Authority is asked to agree that the consideration of new Treatment and Storage licence applications is delegated to the ELP. If agreed, this change will be reflected in the amendments to Standing Orders to be agreed by the Authority at its March meeting and to come into effect from 1 April 2015.**

## 4. Ethics and Standards Committee

4.1. At the workshop in October, the Authority gave full and thorough consideration to the role that the Ethics and Standards Committee (ESC) plays. Currently, it has been delegated:

- The power to approve and issue the Authority's General Directions, Code of Practice and Compliance and Enforcement and Licensing tools;
- The functions of monitoring and reviewing those publications, providing advice to the Authority on matters of policy, and identifying emerging ethical and scientific issues.

4.2. The Committee is supposed (under the Standing Orders) to meet six times per year. In practice, however, the Committee has met only three times in the last calendar year – at other times, business has not required the committee to meet. In terms of fulfilling its delegated powers, it has considered and approved changes to the Code of Practice on one occasion, and has approved changes to General Directions once.

### A possible future model

4.3. In practice, the majority of substantive items (i.e. not including minutes/matters arising/workplan etc) that were considered by the Committee in the last year were for information only. Many such items were of major policy or sector-wide interest, and at their workshop in October members voiced the general view that such items could, and arguably should, be considered by the full Authority at its public meetings – these were the debates in which members felt that they could add most value. Given that steer, the Executive has considered the agenda items at the past four ESC meetings and suggested alternative audiences for such items, in table 1, below.

Table 1: substantive items considered by ESC at its last four meetings and possible future audience

| **Item** | **Decision/ information** | **Possible new forum/decision maker** |
|---|---|---|
| New developments in Embryo Testing | Information | SCAAC/Authority |
| Interpretation of statutory language 'suffers from' | Decision | Authority |
| Surgical procedures | Information | Individual Authority member |
| Code of Practice updates | Decision | Substantive matters of policy: Authority<br>Typographical or minor language matters: individual member |
| New technologies in Embryo Testing | Information | SCAAC/Authority |

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| Regulators' Code | Information | Executive (e.g. SMT/CMG) |
| General Direction 0005 update | Decision | Individual Authority member |
| Patient complaint-handling | Information | Annual review reported to Authority |
| RBAT outputs annual update | Information | Annual report to Authority |
| Summary of inspection findings | Information | Annual report to Authority |
| Ethical and regulatory horizon scanning | Information | Annual Authority workshop |
| Code of Practice, Consent Forms and Directions update | Information | Authority (if at all) |
| Implications of EU directive | Information | Individual Authority member |

4.4. The Executive has proposed four potential audiences/decision makers. In addition to the full Authority considering matters of policy, horizon scanning or annual updates at its meetings or workshops, it is felt that individual members could play a role in signing-off the exact language of Code of Practice or general Direction paperwork. A lead 'Policy' member, akin to the existing model of lead 'Equalities' member, could take responsibility for such changes, and also in assisting/guiding the Executive on planning and drafting items that are to be considered by the full Authority. If agreed, that member's attendance at and/or membership of other Committees would be adjusted accordingly to ensure their workload remained manageable.

**Recommendation**

4.5. **The Authority is asked to agree that the Ethics and Standards Committee be abolished, with its functions being transferred to the full Authority, an individual Authority member, or the Executive. If agreed, the exact details will be reflected in the amendments to Standing Orders to be agreed by the Authority at its March meeting and to come into effect from 1 April 2015.**