Regulatory reform: Licensing

Introduction

1. The HFEA's regulatory framework is set out in the Human Fertilisation and Embryology Act 1990 (as amended) (the Act). The Act sets out the conditions that govern the procurement, creation, distribution, storage and use of gametes and embryos. With limited exception, such activities can only take place under a licence granted by the HFEA and undertaking these activities without a licence is a criminal offence.
2. The regulatory framework was largely left intact when the Act was last updated in 2008 which means the HFEA is regulating with a set of powers which are over 30 years old. Yet the fertility sector has changed markedly over that time in terms of its size, ownership structure, services offered and much else. Moreover, policy thinking on regulation more generally has developed significantly over that time too. All of this suggests that a review of the regulatory framework governing fertility treatment in the UK is long overdue.
3. This paper sets out several areas of the existing licensing framework that might benefit from reform. The focus is only on the arrangements for clinics providing fertility treatments (the term is used here to cover both treatment and storage). Research licensing will be considered separately.
4. In thinking about the licensing framework set out in the Act, it is helpful to break it down to its key elements:
    - Compliance and enforcement;
    - The length of the licence;
    - The protection of the patient;
    - The licensed entity and the role of the Person Responsible.
5. The remainder of this paper considers each element in turn. Each section begins with a short summary of the current situation, followed by an identification of the issues where the Act is showing its age and concludes with a set of potential options for change. The aim is to provoke debate on the merits of those options.

Compliance and enforcement

The current situation

6. There is currently a tension between the Regulators' Code and the Act. This is most apparent in the idea that good regulation involves an expectation that regulators should act proportionately, which is usually taken to mean the least necessary action to address regulatory risks and non-compliance.
7. Leaving aside the informal steps that can be taken to promote compliance (recommendations, management meetings with the PR etc) the Licensing Committee of the HFEA have limited options for responding to the most serious non-compliances. In such circumstances the committee can suspend with immediate effect, revoke a licence, or vary a licence to impose additional conditions. Yet the Act is drafted in such a way that it can only consider varying or suspending a licence if it has the power to revoke, or if it suspects that there are grounds to revoke.

8. There are no other formal sanctions available and, to date, the HFEA hasn't resorted to the kind of informal sanctions that some other regulators have used, e.g. 'naming and shaming' or publicising when regulatory action is being considered.

Issues

9. **The options available to the HFEA in the event of serious non-compliance are limited** – the requirement that the test for revocation is met before other sanctions are available, makes it hard for Licencing Committees to take proportionate action. What is lacking is a wider range of licensing options which would allow the sanction to better match the seriousness of the non-compliance.
10. **There are no financial penalties available to the HFEA to shape clinic behaviour or to address serious non-compliance** – financial penalties are commonly available as sanctions against providers of other healthcare services and in many other regulated activities, e.g. charities, political parties, financial conduct.

Options for change

11. **The options available to the HFEA in the event of serious non-compliance are limited** – the Act requires a 'ladder of escalation' which would provide a broader suite of sanctions in addition to the current powers. Regardless of the level of sanction, enforcement action would always be subject to formal decision making against appropriate thresholds. While the power to revoke a licence should remain as an appropriate sanction for the most serious non-compliances, references to having to have "grounds to revoke" should be removed from the sections on variation and suspension. Instead, there should be a power to impose conditions, suspend all or part of a service (for a defined period) and to fine (see below), where there have been critical or major non-compliances with the Code of Practice. In effect, this would re-order the sanctions in a logical and more proportionate order and enable an approach more in line with the Regulators' Code.
12. **There are no financial penalties available to the HFEA to shape clinic behaviour or to address serious non-compliance** – a power to fine could be added to the Act though it will require detailed work on what kinds of non-compliances might warrant a fine and the appropriate level of any fine. In thinking about these issues the Health and Care Act (Regulations 2014) is perhaps instructive. This allows the CQC to fine a service provider where it fails to provide safe care or provides treatment that results in avoidable harm to a service user or exposes them to a significant risk of exposure to harm. The CQC also has the power to issue Fixed Penalty Notices and warning notices, with powers which flow from a breach of a warning notice.

The length of the licence

The current situation

13. Treatment and storage licences can be issued under the Act for up to five years but are typically issued for a maximum of four because of the requirement to inspect at least every two years.

Issue

14. **The existing rules are rigid and are arguably out of step with modern risk-based regulation** – the requirement to inspect at least every two years, means there is no scope to exempt clinics from an inspection as a reward for good performance. A more risk-based inspection cycle – and we have recent experience of elements of such a model with the introduction of a number or changes to the current inspection regime during Covid - would vary the frequency of inspection according to risk. Such an approach would also be more closely aligned with the Regulators' Code principle that

regulators should base their regulatory activities on risk. The growth of groups of clinics, some of which have common operating procedures is also relevant here.

Option for change

15. **The existing rules are rigid and are arguably out of step with modern risk-based regulation** – the Authority could be given greater freedom as to how often inspections are to be conducted. Such freedom could either sit within the existing idea of periodic licences (whether five years as now or longer) or, a more radical option would involve the move to granting all, or the best performing, clinics an indefinite licence, subject to periodic inspection and annual fees. The latter approach would take away the artificial 'cliff edge' of a licence renewal and send a signal that once licensed the clinic met the standards required until performance suggested otherwise. If the latter option was pursued an additional statutory power to be able to grant licenses for a specified duration in certain circumstances would allow the length of licence to be used as an improvement tool in itself.

The protection of the patient

The current situation

16. The Act is focused on the special status of the embryo, not the patient. As such it reflects the concerns of the time that Warnock was drafted and pre-dates the move toward more patient-centred health care. In response the HFEA's enforcement documents do refer to actual or potential risks to the safety of patients, gametes or embryos, but there is no statutory reference to the "patient". And there is nothing in the Act that puts the patient or patient centred care as a focus – as is evident from the periodic calls for a "welfare of women" test to match the existing "welfare of the child" – to inform the work of the HFEA.

Issue

17. **A lack of focus on the needs and protections of patients is out of step with modern healthcare** – evident most recently in the Cumberlege Report, 'First Do No Harm' (2020). Regulations for example allow the CQC to focus its inspections around five themes: are services Safe? Effective? Caring? Responsive to people's need? and Well-led? And the GMC has an overarching objective to protect, promote and maintain the health and safety of the public.

Option for change

18. **A lack of focus on the needs and protections of patients is out of step with modern healthcare** – an over-arching objective regarding patient care could be inserted into the Act with a requirement that HFEA decision-making and compliance by its LH/PRs should have reference to it. There is then an open question of the nature of that reference, which could range from a flexible but ill-defined "have regard", to something more concrete and capable of evidencing, e.g. included as one of the statutory responsibilities of the PR.

The licensed entity and the role of the Person Responsible

The current situation

19. Under the Act licences are granted to "Licence Holders" (which may or may not be the same as the "Person Responsible"). The LH can be a corporate entity such as a health trust, a private business or an individual.

20. Every clinic must also have a PR (and they must be an individual). As the name suggests the PR is the person whom the regulatory regime holds accountable for the conduct of all licensed activities in the clinic. The PR is required to have certain academic and professional qualifications, work experience and registrations. The LH and the PR must both be considered 'suitable' and the Authority must be satisfied as to the character of the PR.
21. The Act also sets out the powers and duties of the PR, though these fall short of a formal job description. The HFEA has issued a key behaviours and role description which sets out what is expected of a PR in their role as clinic leaders and has developed the PR Entry Programme to support PRs. There is no formal provision for deputy PRs or for the role to be shared. And the law does not permit a PR to delegate their responsibilities.

Issues

22. **The Act does not define what sort of person or entity can be a "Licence Holder"** – and therefore it is not clear who is "suitable" to be a LH or how this is assessed. The holders currently vary from private business entities to hospital trusts to individuals who are also PRs. There are no requirements for private providers to be financially viable or any formal restrictions on who can be involved in the ownership or governance of a fertility business and, as a consequence there is no scrutiny of the owners/shareholders of a private clinic or its financial viability, unlike in the school or care sectors.
23. **The current 'suitability' test for the PR does not provide an adequate regulatory tool** – experience to date in both the fertility sector, and arguably the wider health and care sector, suggest that 'suitability' is too vague a test to be always effective in deciding whether to approve a PR. Given the vital role the PR plays in clinic leadership this is in some cases a real weakness.
24. **The Act places onerous responsibilities on the PR but provides her/him with no formal powers/influence to facilitate change** – it is widely accepted that it is the PR who sets the culture for most clinics. In the clinician/owner model that used to dominate the private sector that was rarely an issue, as the owner and the PR were one and the same. Increasingly, private sector clinics are part of group structures and/or financed by private equity and some individual PRs may find it hard to facilitate change. Experience suggests that PRs in clinics that are part of a larger NHS Trusts face similar problems.
25. **In some settings the responsibilities of the PR role may be too much for one person or too inflexibly defined to accommodate group structures** – in a modern workforce it may be appropriate to allow for job sharing and/or a deputy PR role.

Options for change

26. **The Act does not define what sort of person or entity can be a "Licence Holder" –** the LH could be made mandatory and distinct from the PR, and the expectation might be set that the LH was the business/NHS Trust who was providing the service. At a level below the Act, the HFEA could set out what matters it needed to be satisfied about in relation to a LH. There are several possible models here, including the requirements that exists for CQC providers or schools and children's services. The HFEA could require limited information about the owners and managers (directors) of a business – for example, for the purposes of assessing suitability, to enforce debts, to consider whether the new LH might have an adverse impact on the quality of services offered.
27. **The current suitability test for the PR does not provide an adequate regulatory tool** – a more structured set of criteria might provide a more rigorous test, particularly where a PR moves from one licensed clinic to another. Elements of the 'duty of candour' test might be a useful starting point here.

28. **The Act places onerous responsibilities on the PR but provides her/him with no formal powers/influence to facilitate change** – there are several existing models which may be relevant: for example, the CQC registration process designates a "Registered Manager" who is legally responsible and accountable for meeting the CQC's fundamental standards for quality and safety; and there is a similar role in pharmacy registration. While the Act could be amended to ensure that PR has the authority to make decisions (and whether there should be any exemptions for NHS providers), it is an open question as to whether that change alone will be sufficient.
29. In some settings the responsibilities of the PR role may be too much for one person or too inflexibly defined to accommodate group structures - provision could be made for more than one PR to be appointed, along the lines allowed by the CQC. If this element of the Act were amended it would also be worth looking at the risks and benefits of allowing PRs to act for more than one clinic in a group structure.

Discussion

30. The Advisory Group are invited to consider the issues identified and potential options for change as set out above. In summary:

Compliance and enforcement

- Issue: The options available to the HFEA in the event of serious non-compliance are limited
  - Option for change: re-order sanctions in more logical and proportionate manner
- Issue: There are no financial penalties available to the HFEA to shape clinic behaviour or to address serious non-compliance
  - Option for change: a power to issue a fine could be added to the Act

The length of the licence

- Issue: The existing rules are rigid and are arguably out of step with modern risk-based regulation
  - Options for change: greater freedom over timing of inspections; EITHER within existing framework of periodic licences OR grant clinics an indefinite licence, subject to periodic inspection and annual fees

The protection of the patient

- Issue: A lack of focus on the needs and protections of patients is out of step with modern healthcare
  - Option for change: an over-arching statutory objective regarding patient care

The licenced entity and the role of the Person Responsible

- Issue: The Act does not define what sort of person or entity can be a "Licence Holder"
  - Option for change: LH could be defined in the Act and supported by guidance on requirements

- Issue: current suitability test for the PR does not provide an adequate regulatory tool
  - Option for change: a more structured set of criteria to provide a more rigorous test, particularly where a PR moves from one licensed clinic to another
- Issue: The Act places onerous responsibilities on the PR but provides her/him with no formal powers/influence to facilitate change
  - Options for change: several existing models e.g. CQC “Registered Manager”; similar role in pharmacy registration; Act could be amended to ensure that PR has the authority to make decisions
- Issue: In some settings the responsibilities of the PR role may be too much for one person or too inflexibly defined to accommodate group structures
  - Option for change: more than one PR to be appointed