The Regulation of groups of clinics

Strategic delivery:	☒ Safe, ethical, effective treatment	☐ Consistent outcomes and support	☐ Improving standards through intelligence
Details:			
Meeting	Authority		
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Author	Nick Jones, Director of Compliance and Information		
Output:			
For information or decision?	For decision		
Recommendation	That we move to regulating groups of clinics (where there is demand) to promote further improvement in clinic performance. The Authority is asked to consider these proposals and endorse the approach set out.		
Resource implications	Within existing resources		
Implementation date	Immediately, in consultation with clinic groups		
Communication(s)			
Organisational risk	☒ Low	☐ Medium	☐ High
Annexes	None		

Human Fertilisation & Embryology Authority

1. Introduction

1.1. Over the last few years the number of licensed treatments that take place in clinics that are part of a 'group' of licensed clinics has increased markedly. These developments raise questions about the appropriate organisation of the regulatory regime, which is based on the model of separate, stand-alone clinics, whether in the NHS or the private sector, led by an identified person responsible (as required by the HFE Act).

1.2. To date, we have met the challenges posed by the growth of group structures by piloting an approach with the more integrated groups. This approach reflects the fact that groups take a variety of forms and are at different levels of maturity. While this approach has worked well, we now are of the view that the fertility market has reached a sufficient stage of development that we should set out a broad policy position on the regulation of group structures, and move to implement this where there is demand.

1.3. The steps we have taken in this direction have already paid dividends for the groups of clinics involved in terms of a reduction in some regulatory activity, involving, for example, the multiple assessment of shared quality management systems at different sites. Such an approach also meets the requirement placed upon us to undertake our regulatory activity proportionately and efficiently (for example, being aware of the 'business impact' of our inspection and monitoring activity). Adopting a more transparent policy position on these issues cements the benefits achieved so far and offers the prospect of more effective regulation still, focussing on better outcomes for patients.

1.4. This paper first outlines the current position of clinic groups within the overall landscape of licensed clinics and activity. It then sets out the steps we have taken to date to regulate some clinics at a group level, before going on to suggest a model which can be rolled out more widely.

2. Background

2.1. There are currently 87 licensed clinics providing comprehensive treatment and storage IVF services. Of those, 31 are located within NHS Trusts and are by their very nature not part of the group structures which are the focus on this paper. Of the 56 clinics in private ownership, some 38 are in a group structure of one form or another. They undertake an increasingly large proportion of treatment cycles undertaken, some 30,000 of nearly 78,000 (38%) of all cycles in the year-ending December 2017.

2.2. While the growth of group structures is relatively new, it is worth reminding ourselves that it has been a feature of the sector from its early years - for example, the Care group began to establish a presence in many cities in England in the mid-1990s (and has recently moved into Ireland).

2.3. The growth of clinic groups is, in large part, a response to the significant increase in activity levels which has led to opportunities for economies of scale

and an influx of private capital. However, the forms taken depend on a variety of factors which are often local and contextual – such as partnerships based on incremental, organic growth; partnerships formed because of relationships of senior clinicians/proprietors; and a more deliberate approach based on acquisitions and takeovers. Those involved see advantages such as sharing of expertise and knowledge; economies of scale (as noted above) and greater consistency, for example in the development of IT systems and websites; and enhanced purchasing power due to scale. Conversely, we are also aware that some are wary of too much integration as failings in one part of the group can have adverse reputational consequences on the others.

2.4. To illustrate further, and to show the scale of activity within such groupings, we have developed an informal typology or categorisation of the various group structures in the current UK fertility market. These are not hard and fast and there is some fluidity between the types.

- **Integrated model -** based on a common operating system with a high degree of central control: IVI Group (currently three clinics in England with plans for more); Create (four clinics and a satellite); Bourn Hall (three clinics and satellites – in the East of England) and Care group – six clinics. Approximately 13,500 cycles are performed annually by clinics in this arrangement.
- **Federated model** - based on an autonomous role for the individual clinics (and lead clinicians), with central services provided with permission and where it makes sense to do so (marketing, website, IT, purchasing): The Fertility Partnership (eight clinics across the UK); London Women's Clinic (four clinics in England and Wales). Approximately 12,000, cycles are performed annually by clinics in this arrangement.
- **Franchise** - consultant led model within the independent hospital operating model, with high local autonomy with marketing and legal services provided at a central level only: BMI (four clinics in England) and Nuffield (three clinics). Approximately [3,000] cycles are performed annually by clinics in this arrangement.
- **Location specific** - first encountered in 'research' clinics with different research projects licensed by the HFEA in the same institution, this model is now seen in treatment clinics located in separate premises but in the same broad vicinity. Typically, this model involves a high degree of shared processes and functions - for example, the three clinics within the ARGC grouping in London. Approximately 1,500 cycles are performed annually by clinics in this arrangement.

2.5. The development of group structures in the fertility market in the UK is for the most part outside of the regulatory regime. The HFE Act gives us no powers to approve commercial arrangements, although a change of ownership may lead to a change in the Person Responsible which requires our approval, or it may lead to questions as to the 'ownership' or the accountability for stored gametes and embryos, which again would trigger our intervention.

2.6. New group structures may also give rise to transitional issues where we do have a role - for example, senior and experienced staff may be affected by the changes and well-established ways of working may be subject to change, both of which have the potential to impact on the quality of services offered to patients. For all these reasons, we have tried to keep abreast of these developments and it should be noted that we are overall supported in this by clinic leaders who usually work hard to keep us informed

3. An outline model for the regulation of clinics in a group structure

3.1. As noted above, recently we have developed a set of operating procedures to better regulate groups of clinics, for example with the Care Group and Bourn Hall clinics. This approach has been developed with the respective corporate centres to reflect the model employed and is seen by both the clinics and us to be working well.

3.2. The HFE Act provides some constraints on what we can do - we must, for example, licence every separate premises even if they are within a group - but within the requirements of the law, our approach to the regulation of groups of clinics can be summarised as one of 'earned autonomy'. Where core activities, operating procedures and policies are shared we aim to reach a single group-wide assessment of those shared elements, simplifying the inspection process by reducing duplication, and allowing a focus on the elements that are particular to the individual clinic undergoing inspection. In return, where we find non-compliances in those shared elements we expect to see a group wide response.

3.3. As noted above, each group will have a distinct approach. At the same time, it is possible to undertake regulatory activity within a consistently applied framework. For example, in taking each component of the HFEA Code of Practice it is evident that some components can be assessed only at the local clinic level and others have a local clinic and group aspect – on a continuum. The table below takes each CoP component (at a high level – some have several sub-levels) and shows that some areas can be assessed at group level (once) and at local clinic level by way of checking or confirmation. Other areas will simply continue to be inspected at a local clinic level.

CoP	Clinic	Group	Notes
1	**Staffing**		Support to PRs provided by centre
2	**Counselling**		Local review in line with group policy
3	**Information and consent**		Information policies and technical infrastructure
4	**Multiple births**		Policy and performance comparisons

5	**Welfare of the Child**		Local review in line with group policy
6	**Embryo testing**		Local review in line with group policy
7	**Donation and surrogacy**		Local review in line with group policy
8	**Use of gametes and embryos**		Adherence to policies and performance comparisons across clinics in the group
9	**Research and training N/A research only**		
10	**Facilities and administration**		The role of the quality management system is crucial
11	**Treating people fairly**		Local review in line with group policy
12	**Record keeping**		Document control arrangements
13	**Mitochondrial donation**		N/a given scale

3.4. This approach means that in practice we:

- Identify a lead inspector for the group, for relationship management purposes;
- Ensure that the clinics' quality management system is operated within the respective clinics (and then to be tested at inspection);
- Ensure there are sufficient resources within the group to support a clinic's quality management efforts, for example in auditing and follow-up, in sharing good practice, and in the collection and reporting of performance information;
- Assess at renewal inspections how the overall arrangements for ensuring quality apply at that clinic – for example those activities that are led from the centre and those that are undertaken locally – and whether they are effective and well-supported;
- Take a lighter touch approach at the next renewal inspection within the group of those areas that were identified as working well elsewhere, but have higher expectations of those areas identified as requiring improvement.
- Expect to see the group using each clinic inspection as an opportunity for learning and improvement across the group.

3.5. We now believe that the number of groups within the fertility market has developed to a state where we can consider rolling out this model more widely. In saying this we need to recognise that not all groups will wish to move to this model, and much will depend on the maturity of the group, the extent of which processes are shared and the willingness to make changes across the group to non-compliances found in individual clinics.

3.6. In moving to this group regulatory model we propose to adopt the following operating principles:

- Intelligence-led: Building on the establishment of the intelligence team to consolidate our understanding of clinics within a grouping. Taking already available information from the risk tool and Choose a fertility clinic outcomes to form new insights about the performance of clinics within and across the group.
- Formed by relationship management: Formalise arrangements such that each identified group has a named Inspector, Senior Inspector, or in some instances Chief Inspector, with formal opportunities for discussion about the operation of the group, and clinics within it. The seniority of the individual is less important than the requirement to understand the relationship and share knowledge within the team.
- Tailoring inspections: Being more aware and have a greater understanding of which activities are undertaken where. This could involve the consolidation and streamlining of pre-inspection processes such as the completion of the self-assessment questionnaire, and the submission of standard information in line with general directions.
- Centring on the patient: That there is clarity as to accountability, so patients are clear who is providing a service. For example, some clinics are centralising - the patient contact function or their arrangements for investigating adverse incidents. Some groups may also direct patients toward particular locations for some licensed activity such as PGD, PGS or even standard IVF and ICSI treatments. We need to understand those flows and our reporting must provide clarity relating to such arrangements such that patients can see we are acting to protect their interests always, regardless of arrangements put in place by clinics.
- Meet our statutory requirements: That we continue to inspect at a two-yearly interval (as required by legislation) and to license the premises to which a licence applies, but that we do so intelligently and considering the way that the clinics organise themselves and where the licensed activities take place.
- Promoting effective leadership: In the coming year, more broadly, we will have an increasing focus on leadership in clinics. In the light of pressures faced by clinics relating to growth and the need to maintain and grow market share, and in their ability to exercise control when the span of influence expands, we will want to explore leaders' capacity and ability to maintain and improve performance.

4. Next steps

4.1. If the Authority is content with these proposals we will work up the detail and write to all the clinics in each group to test their appetite to move to this evolving regulatory model.

4.2. For those clinics that choose to move down this path we will take the opportunity of the forthcoming reallocation of clinic portfolios across the inspectorate to identify new relationship management arrangements. We will also work alongside intelligence and Register colleagues and begin to put in place group baseline reports that will describe arrangements and form the basis for future inspection reporting.

5. Recommendation

5.1. That we move to regulating groups of clinics (where there is demand) to promote further improvement in clinic performance. The Authority is asked to consider these proposals and endorse the approach set out.