

Compliance activities 2014/15: a review

Strategic delivery: Setting standards Increasing and informing choice Demonstrating efficiency economy and value

Details:

Meeting	Authority
Agenda item	10
Paper number	HFEA (16/09/2015) 767
Meeting date	16 September 2015
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Output:

For information or decision?	Decision
Recommendation	<p>The Authority is asked to</p> <ul style="list-style-type: none"> • note and comment on this paper; • review the supporting papers and evidence, • consider and agree final recommendations for the update of the Compliance and Enforcement Policy; • consider and agree the current and future direction of our regulatory activities
Resource implications	In budget
Implementation date	To be determined once in principle decision is made on future direction of regulatory regime
Communication(s)	Publication of review on HFEA website to be communicated through Clinic Focus article. Conclusions of the review to be communicated through usual stakeholder engagement channels.
Organisational risk	<input type="checkbox"/> Low <input checked="" type="checkbox"/> Medium <input type="checkbox"/> High

Annexes

1. Background

- 1.1. Our Strategy for 2014-17 signals an ambition for high quality care for everyone affected by assisted reproduction. Within this framework our regulatory activities are directed to the improvement of the quality and safety of care.
- 1.2. This paper introduces a suite of papers that analyse and comment on the impact of our regulatory activities^{1,2,3}. It also sets out how our working priorities have evolved to maximise the chance of our having an even more positive impact in the light of our findings and experiences..
- 1.3. To ensure that the Compliance and Enforcement Policy – our framework for taking action when there are concerns about quality of care – remains properly aligned to our regulatory activities and ultimately to the licensing process that our regulatory activities serve, we have undertaken a review of the policy and its supporting documents and the recommendations from that review are presented⁴.
- 1.4. The Act (section 8ZA(2)) specifies that in carrying out its functions the Authority must have regard to the principles of best regulatory practice (transparency, accountability, proportionality, consistency) [8ZA (2)]. We also committed in our strategy to ensure the HFEA remains demonstrably good value for the public, the sector and Government. These requirements need not necessarily be in tension and our experience to date is that they are not. Equally it's important that the Authority has an opportunity to scrutinise and challenge our regulatory approach and consider recommendations for improvement so that we have the best chance of balancing all of our obligations.
- 1.5. To date, we have made an annual report of our regulatory activities to a *committee* of the Authority - more lately the (now dissolved) Ethics and Standards Committee, and before that its predecessor Compliance Committee. Following a review of our committee structures and in consideration of the importance of our strategy it has been decided these are matters that are now more properly considered at a full meeting of the Authority with the discussions that this prompts forming the basis of future conversations about our regulatory approach.

2. Establishing effectiveness

- 2.1. Our strategy commits us to measure the extent by which we have improved the quality and safety of care through our regulatory activities.

¹ Summary of Inspection Findings between April 2013 and March 2014 and April 2014 and March 2015

² Analysis of Risk tool outputs 2014/15: patterns, lessons and future actions

³ Clinical Governance Activities: learning and culture

⁴ Review of the Compliance and Enforcement Policy and supporting documents

- 2.2. The cause and effect of regulatory activities is however tricky to measure. For example, our existence and the development and production the Code of Practice which provides a set of rules to guide clinics – may themselves promote compliance and with it, improvement. Further, the prospect of inspection (especially unannounced inspection) may catalyse compliance. On the whole it is our experience that clinics want to provide good quality care and to be seen to be compliant.
- 2.3. Taking these limitations into account we aim to keep our regime under review and to continually evolve our regulatory approach in line with our strategic goals.

3. Assessing our performance

- 3.1. As to criteria for assessing our own performance, a starting point might be the Regulators' Code (2014) that we are bound by. The main points of the code are set out below with a brief self-assessment of our own compliance shown in italics. The Code states that regulators should:
 - 3.2. Carry out their activities in a way that supports those they regulate to comply and grow: Our approach is supportive. Our starting point is that clinics are compliant and inspection is an opportunity of validating that assumption. We try to work with clinics to support plans to innovate and grow although there are inevitably tensions from time to time in balancing regulatory requirements.
 - 3.3. Provide simple and straightforward ways to engage with those they regulate and hear their views: We seek feedback; we engage using a variety of mechanisms – clinic focus, licensed centres' panel, annual conferences, Chair and Chief Executive's visits to clinics.
 - 3.4. Base their regulatory activities on risk; the Act provides a statutory framework which we cannot vary but within this constrain we take into account the history of regulatory compliance; we adapt our themes taking into account evidence of high-frequency non-compliance; we have adopted a risk tool that flags up performance concerns at individual clinics.
 - 3.5. Share information about compliance and risk: In the past few years we have established good links with the MHRA, CQC and GMC in particular ensuring there are no barriers to effective information sharing and we have agreements in place with our fellow regulators in each of the countries of the UK.
 - 3.6. Ensure that their approach to their regulatory activities is transparent: We publish the basis on which we do our work; together with the outcomes of inspection including the report and the minutes of all licensing decisions – including those related to incidents (and we produce an annual report on incidents reported. We believe we can do more here - and the opportunities presented by website changes (further to IfQ) are considerable.

4. Evolution of the regulatory regime

- 4.1. The tone or personality we adopt in our work is influenced by many factors. Given that it is so instrumental in the work we do it is worth being more explicit within this set of papers. Whilst not easy to capture, we have attempted to characterise the tone of our regulatory approach below.
- 4.2. A fairly evenly balanced focus on identifying (and therefore reducing) harms, and promoting improvement.
- 4.3. Being resolute and using tough enforcement powers when necessary combined with being approachable, customer-facing, preventive and problem-solving when possible. We do not see a tension in adopting these different styles as the situation warrants.
- 4.4. We adopt a high-trust model – but a model in which trust is earned through disclosure of problems (incidents and material events); implementation of recommendations for improvements, and; that clinics strive for and are motivated by quality and improvement.
- 4.5. Given that the regulatory landscape in which we operate changes continually we must expect to adapt and change. A raft of new requirements was transposed into the Act in 2007. Notably at this time, it became a mandatory requirement for clinics to have *documented* and *validated* processes and procedures and to establish a quality management system (QMS) to support continuous improvement. In response the HFEA's inspection regime became focused on clinics' documentation.
- 4.6. Further changes to the Act in 2009 significantly updated the consent regime and introduced complex new consent requirements which in turn resulted in a continued focus on clinics' consent procedures and documentation of consent.
- 4.7. In 2012 the HFEA extended its remit to inspect a number of additional clinical activities (safeguarding, infection control, medicines management and the pre-, peri- and post-operative pathway) so that clinics in England that only carry out HFEA licensable activity could be exempted from the requirement to be registered with the CQC.
- 4.8. It was (and remains) straightforward to inspect documentation. It is harder to assess the quality of processes themselves and to evaluate the quality of services provided and experienced by patients.
- 4.9. Learning from our governance and inspection activities suggests that while clinics "tick the boxes" in carrying out audits and in conducting root cause analysis to identify the causes of incidents, complaints and or poor performance, in common with the healthcare sector in general, these activities may not always be effective in identifying opportunities for improvement. In consideration of this, since 2014 we have aimed to phrase recommendations for improvement to encourage clinics to consider *why* a non compliance has

evaded their QMS, *why* an incident has occurred or *why* a patient has experienced poor service. Having identified the root cause we encourage clinics to identify corrective actions *specific to their own circumstances* and then to assess the *effectiveness* of the corrective actions. We are also working one to one with clinics that see recurrence of C grade incidents or whose root cause analysis could be better. This approach aims to support the continued development of a “learning culture” that we hope will be more effective in driving improvement.

- 4.10. Since April 2015 we have also specifically focused on whether clinics have learned from incidents (both their own and those documented in our annual review), complaints and guidance in the course of interim inspections.
- 4.11. We don't anticipate that it will be easy to influence culture in clinics or that the approach will deliver fast results. However we do believe that a change in approach is warranted if we are to continue to raise the bar to encourage continuous improvement in the quality of service provided by clinics.

5. Summary

- 5.1. The tools we have are generally well calibrated and effective in motivating regulatory compliance. To reflect our strategy and practice however, our regulatory tools in the form of the Compliance and Enforcement Policy and associated documentation should be revised to emphasise that regulatory action will be initiated where there is considered likely to be a risk to patients, their embryos or gametes or where there are concerns about quality of service provided to patients.
- 5.2. Our analysis of risk tool alerts suggests that clinics had fewer alerts related to success rates in 2014/15. While it is difficult to establish a cause and effect of our regulatory activities in respect of this improvement the ongoing reduction suggests that centres are taking action to continually improve success rates. It is likely that the HFEA's proactive real time monitoring – most significantly interventions should performance trends continue on a negative trajectory - plays a role in encouraging this.
- 5.3. Although a small number of clinics continue to struggle to meet the 10% multiple birth target we continue to have bespoke conversations with these clinics to motivate and encourage change: ultimately however, if these interventions fail to have an impact then it is recognised that the significant risk posed by multiple births are such that regulatory action may be initiated in line with the Compliance and Enforcement Policy.
- 5.4. Alerts related to errors in the submission of information to the HFEA register about treatments involving donor gametes increased in 2014/15: the HFEA's IfQ programme is expected to have a significant impact on the improving the

quality of data submission although it is likely to be some time before this work has a measurable impact.

- 5.5.** Analysis of incidents suggests that clinics may need more time to embed learning and more support to extract learning from incidents. On this basis we have refreshed our approach to inspection and our governance activities to try to support and encourage clinics in the continued development of a learning culture.
- 5.6.** Analysis of inspection findings supports a conclusion that the sector is largely compliant. The focus of interim inspections was refreshed in April 2015 taking into account the most frequent non compliances and this will ensure that our regulatory activities continue to be risk focussed. Our analysis shows that recommendations for improvement are implemented within prescribed timescales supporting a conclusion that our inspection activities have a tangible impact.
- 5.7.** Feedback from the sector on their experiences of inspection and inspection reports is positive with PRs reporting that inspection visits lead to improvements in service delivery and patient care.

6. Recommendation

- 6.1.** The Authority is asked to
 - note and comment on this paper;
 - review the supporting papers and evidence,
 - consider and agree final recommendations for the update of the Compliance and Enforcement Policy;
 - consider and agree the current and future direction of our regulatory activities.