Compliance activities 2015/16: a review

Strategic delivery:	☒ Setting standards	☐ Increasing and informing choice	☐ Demonstrating efficiency economy and value
Details:			
Meeting	Authority		
Agenda item	9		
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Author	Sharon Fensome-Rimmer Contributory Authors, Erin Barton, Andrew Leonard, Sara Parlett		
Output:			
For information or decision?	For information		
Recommendation	To note the report and the summary of actions in section 4		
Resource implications	In budget		
Implementation date	Through ongoing compliance activities.		
Communication(s)	Through Authority report, and then targeted communications with key findings		
Organisational risk	☐ Low	☒ Medium	☐ High
Annex – Risk tool and inspection findings charts			

1. Background

1.1 This is the second annual report to Authority on 'compliance activities.' It provides an overview of the type and number of non-compliances found on inspection or identified through our risk tool or other reporting mechanisms. It also reviews the actions we have taken in the inspection year April 2015 to end March 2016 to promote compliance by licensed clinics and research centres with the Act. The paper is therefore also an assessment of the effectiveness of the regulatory methods we employ and, most importantly, the extent to which they have had an impact on the sector.

1.2 Our Strategy signals an ambition for high quality care for everyone affected by assisted reproduction and our regulatory activities are directed to the improvement of the quality and safety of care.

1.3 The Act (at section 8ZA (2)) requires that the Authority, when carrying out its functions, must have regard to best regulatory practice (transparency, accountability, proportionality and consistency). At the same time, it must also ensure added value for the public, the sector and the Government.

1.4 The aim here is to provide the Authority with an opportunity to scrutinise our regulatory approach to ensure that not only are our statutory obligations met, but that it contributes to our strategic intent – high quality care.

1.5 The structure of this paper is as follows. Section 2 suggests a frame for considering the regulatory impact we hope to have; section 3 summarises our activities in relation to the tools at our disposal, forming some conclusions from the analysis in the annex to this report. Section 4 sets out how we intend to adapt our work going forward in the light of this review by way of recommendations to the Authority.

2. Assessing our own performance

2.1 It is relatively easy to assess our performance in terms of inputs (inspections carried out etc.); far harder to do so in terms of outcomes (quality of service at a given clinic etc.). This paper covers a lot of ground, covering both inputs and outcomes. In reaching an assessment of impact it may be helpful to have in mind both some externally established criteria for what makes effective regulation, and also the 'tone' that shapes how we go about our task.

2.2 A starting point for an assessment of our regulatory performance is to have in mind the Regulators' Code (2014) that we are bound by, and which the Authority must have regard to when considering the standards we set, and the way we go about testing clinics' performance in meeting those standards.

In brief, the Code requires us to

- Carry out our activities in a way that supports those we regulate to comply and grow

- Provide simple and straightforward ways to engage with those we regulate and hear their views
- Base our activities on risk
- Share information about compliance and risk – to avoid duplication and overlap of regulatory activity carried out by others
- Ensure our approach to regulatory activities is transparent

2.3 The 'tone' we adopt in going about our work can be summarised as follows. The Authority may wish to comment on whether this strikes the right balance as there should be an alignment (as we believe there is) between the Authority (in reviewing our activities at a strategic level, and as members of licencing committees) and the Executive. As such we:

- Try to balance identifying and reducing harms, and promoting improvement;
- Are resolute in applying informal and formal powers when necessary – which isn't very often – combining this with being approachable, customer facing, preventive and problem-solving. We are skilled in moving from one to the other;
- Adopt a high-trust model – but a model in which trust is earned through disclosure of problems; our requirements are implemented and 'insight' is demonstrated. This approach has come under pressure this year in the face of significant 'tests' that some clinics have not been up to meeting – in relation to legal parenthood consent failures;
- Adapt and change to new requirements - this year has seen no significant new requirements being introduced nor changes to inspection methodology, albeit significant challenges as regards long-established requirements (e.g. consent);
- Try to focus on how clinics' activities in undertaking audits and root cause analysis identify opportunities for improvement which are then implemented. Whilst this approach aims to support the continued development of a learning culture it is long and slow work. But one that we must persevere with.

3. The year – in summary

3.1 This section summarises the main aspects of our work, alongside the particular challenges seen this year. The findings are drawn from two principal sources: information on non-compliances from inspections and performance alerts from our risk tool. The annex to this report sets out these findings in detail and the relevant figures and charts are referred to throughout to aid understanding.

3.2 The key headlines from this data is as follows:

- There was 60% more inspection activity than in the previous year and we met our target of completing the licensing of a clinic within 70 days from the date of inspection to the licensing decision being communicated to the clinic.
- A large majority of clinics perceive the inspection to be effective and it promotes improvement. Very few significant or serious concerns are identified at inspection. There is a robust process for escalating concerns.
- Clinics inspected further to a renewal of licence this year did not have a significant difference as regards the number or seriousness of non-compliances compared to the same type of inspection four years' ago but there were differences as to the type of non-compliance.
- The areas where non-compliance is most prevalent are equipment and materials, QMS, consent and surgical procedures. Neither the types of activities a clinic undertake, nor its size influence the numbers of critical, major and other non-compliances reported.
- Analysis of risk tool 'alerts' suggests they catalyse improvement. However, the number and type of adverse incidents reported remains consistent and there needs to be a shift in culture towards learning from incidents.
- The compliance and enforcement policy introduced in October 2015 has been effective in ensuring the consistency of regulatory interventions. However, a significant number of legal parenthood problems have emerged during the year. We have been, and continue to be, active in ensuring families are supported and action taken with clinics. Nevertheless, it underlines some of the limitations of any regulatory regime.

The programme of inspection

3.3 The inspection year was a very full one – around 30% more activity than in the previous year (due to the anniversary of licences, largely but not completely out of our control).

- 104 inspections were carried out.
- There were 35 treatment and or storage renewal inspections,
- And 36 treatment and or storage interim inspections.
- There were 15 research renewal inspections and five research interims.
- There were 13 additional inspections of which four were initial license inspections.

3.4 The inspectorate team is well-established, knowledgeable and hardworking. We measure the efficiency of our inspection activities by means to two principle targets:

- The average number of working days taken for the whole licensing process, from the day of inspection to the decision being communicated to the centre – our target is 70 days and our performance was 60.2 days
- 90% of inspection reports returned to the Person Responsible (PR) following inspection for review within the 20 working days - around half of reports met this target with the majority of the balance missing the target by a few days. These are usually sensible judgment calls and (given the overall target is met) is not a cause for concern or heightened managerial oversight.

Clinic feedback on inspection

3.5 For the most part the inspection process works: the inspectors judgements are recognised as fair and their recommendations help clinics to improve. We know this because around two thirds of PRs in the year responded to our invitation to provide feedback following their inspection using a formal online survey tool. Some 93% of respondents considered that their inspection visit had promoted improvements to the way the clinic carries out its work. And 88% of respondents were satisfied with their inspection report and with the recommendations and timescales for implementation within it.

3.6 Of those that responded, fewer than five clinics made negative comments, relating either to the disruption to the clinic's ability to carry out its work during an unannounced inspection, imprecisely worded recommendations for improvement, or the timescales by which recommendations were to be implemented. Where PRs have expressed dissatisfaction with an aspect of the inspection it is usually, though not always, where multiple and/or serious breaches were observed.

Findings from inspection

3.7 The evidence presented here suggests that assisted reproduction sector is a largely compliant one. That is to say that in 2015/16 we saw very few, under five, serious or significant concerns that resulted in a management review and escalation to Licence Committee for consideration. That is clearly good news, but it is not grounds for complacency. As chart 1 (annex) shows there are still too many inspections which find a significant number of critical and major non-compliances.

3.8 Our inspection activity is greatly informed by the capability presented by our 'licensing' system – Epicentre, which Members will recall was the subject of some investment in 2010-12. Epicentre holds a database of the licensing history and other valuable information relating to every clinic and allows us to prepare a pre-inspection notebook with all key historical data about that clinic. It also enables the team to log all actions identified at inspection and monitor to the point of satisfactory implementation. Chart 2 (annex) shows the different types of severity of non-conformities correlated to centre activity and size. Chart 3 (annex) shows the number of non-compliances (of varying severity) by inspection types, and chart 4 (annex) shows that 445 non-conformities were identified resulting in recommendations for improvement - an average of 5.6 per inspection. In effect these are 5.6 opportunities for improving the quality of care, per inspection. We have a very good system for ensuring these opportunities are carried through. Chart 4 also shows the number of frequently observed non-compliances by clinic size and suggests the most common types of non-compliance relate to equipment and materials, QMS, consent and surgical procedures. This is further correlated in chart 5 (annex).

3.9 Given the depth of information we hold about clinics' performance going back over time, we have been able to compare performance of some clinics since the time of their last renewal inspection. There were 29 clinics that were inspected in 2011/12 and in 2015/16. The average number of non-compliances overall was similar, with marginally more critical and major non compliances observed in 2015/16. For individual clinics there is no clear relationship between the numbers of non-compliances observed between the two periods. An increase was observed in non-compliances related to confidentiality, counselling, import/export, infection control and medicines management. This is as much a function of a change in the inspection focus as a dip in performance. As such, the level of non-compliance at one renewal inspection does not apparently predict the level at the next inspection.

3.10 Non-compliance relating to surgical procedures and consent-type non compliances were amongst the six most prevalent types in 2015/16, as charts 4 & 5 (annex) shows. Along with equipment and materials and the clinic's quality management system. Other trends have also been observed such as procuring, processing and transporting gametes and embryos; and premises and facilities.

3.11 Moreover, looking at the compliance history over time it can also be concluded there is no relationship between the number of non-compliances (either all or combined critical and major) and the number of incidents reported, or risk tool alerts issued and the compliance level on renewal inspection.

3.12 Neither the types of activities a clinic undertake, nor its size influence the numbers of critical, major and other non-compliances reported. – see table 1 (annex). This supports a conclusion that the same inspection regime should be applied to all licensed clinics.

3.13 As the inspectorate team become more experienced it is reasonable to conclude more non-conformities will be observed. At the same time, clinics become more experienced and knowledgeable at conforming, to the point of status quo.

3.14 From charts 1 through to 5 (annex) it is reasonable to conclude that the inspection process is robust and effective.

3.15 The inspectorate team continues to maintain its focus on a clinic's quality management system given the (wider) evidence that an effective QMS improves outcomes. We also see merit in undertaking workshops with clinics to embed practices – in relation to root cause analysis, the effect of 'human factors' on practice, and improvements to auditing techniques.

The risk tool

3.16 Our ability to undertake ongoing monitoring of a clinic's performance between inspection visits has been greatly enhanced by the introduction in 2011 of the risk-based assessment tool (RBAT) that provides information about clinics' performance in near to real-time. RBAT provides us with a number of important performance indicators, notably relating to outcomes in terms of both clinical pregnancy rates and multiple pregnancy rates; the submission of register information relating to treatments using donor gametes; and the timeliness of payments of our monthly invoices.

3.17 Our assessment of clinic performance is based on the analysis of information submitted to us. Where the trend analysis performed by RBAT suggests that there may be a dip in performance, an automated alert is sent to the PR and the clinic is expected to act on this alert and investigate any possible causal factors and take corrective action if appropriate. Inspectors and/or members of the register information and finance teams also carry out targeted follow-up where appropriate.

3.18 The data from alerts in RBAT is set out in Charts 6 and 7 (annex) and can be summarised as follows. Clinics' performance in 2015-16 has worsened compared to the previous year in relation to the submission of critical treatment information – mainly due to the activity being undertaken by our teams elsewhere (relating to IfQ developments) and for these reasons we do not adopt a punitive approach here. The number of alerts relating to invoice payments has significantly decreased suggesting that clinics' performance in meeting our now enhanced performance expectations have been successful. Further, in relation to success rates and multiple birth rates the volume of alerts has remained constant albeit the population of clinics receiving these alerts has changed – suggesting an improvement in performance by some.

3.19 Of the 10 clinics receiving the highest number of alerts last year, five of those clinics remain in the same category – suggesting either difficulties that can take time to improve (e.g. shifting multiple birth rates) or limitations in terms of those clinics' culture of improvement. It is clear that some refocusing of our performance as regards some clinics' multiple birth minimisation plans is necessary to move the overall sector average performance closer to the 10% target.

3.20 By providing the information required for clinics to monitor their own performance in comparison to national norms, we help clinics that may be struggling to improve the quality of care given to patients. The risk tool alerts are having an effect. Success rates have improved since the introduction of the system, but the overall trend in success rates since 1991 is up, reflecting a range of factors, notably improvements in clinical practice. However, what the tool does is enable the Executive to focus its efforts on potential poor performers and help those clinics that may be struggling to improve the quality of care given to patients.

Adverse incidents

3.21 There is a separate and detailed report relating to incidents on the agenda. An estimated 1% of the c70,000 cycles of IVF treatment that are carried out in the UK each year are affected by some sort of adverse incident. The PR for a licensed clinic has a statutory duty to report and analyse the causes of incidents[1]. However, the numbers will vary each year-depending on the number of cycles carried out and incidents reported. For the calendar year 2015 we received reports of 517 incidents out of c.70,000 treatment cycles. We have a duty[2] to investigate and take appropriate control measures in relation to reported incidents[3], and the incidents reported during the year represent an increase of around 4% after adjustments for increases in activity volumes. Receiving reports of adverse incidents, logging and monitoring root cause analyses carried out by clinics and carrying out focused visits or workshops, and addressing trends at inspection is part of the team's work. Our effectiveness in ensuring lessons are learned to prevent the recurrence of avoidable incidents must be considered alongside our other activities.

Policy

3.22 Following last year's report to Authority a revised compliance and enforcement policy was introduced, from 1 October 2016. This has been effective in both focusing our interventions and in maintaining a level of consistency across those interventions at different clinics. The challenge for all regulatory bodies is an environment where regardless of the identity of the 'regulation officer' a regulated body can expect similar treatment based on objective standards. The policy has been particularly effective in establishing the centrality of the 'management review' where a concern is identified with the potential for escalation. In the year a number of management reviews were undertaken by the executive and documented.

3.23 The policy also clarified and made more explicit the relationship between a clinic's performance and a recommendation as regards the length of licence it can expect. The new HFEA website (currently in public beta) will provide greater transparency to this decision as it will appear on the Choose a Fertility Clinic profile page of each clinic. It is important to recognise that whilst the event of an inspection is key and at a point where we hope to see good services and a demonstration of how those standards will be maintained throughout the year by audit and improvement – there is also an opportunity for a clinic to deal with (some) concerns identified following the inspection and prior to the consideration by a licensing committee.

[1] An incident is a serious adverse event or reaction as defined at 27.2 and 27.3 of the Code of Practice.
[2] S.15A of the Act.
[3] Further information on our approach to incident handling can be found at http://www.hfea.gov.uk/6678.html

Legal parenthood

3.24 Our response to failures by clinics to take consent to legal parenthood correctly has formed a significant, and additional, part of our activity throughout the year – and continues to do so. Since 6 April 2009, the partners of women treated with donor sperm or embryos, where the couple is neither married nor in a civil partnership, have had to give their written consent in order to become the legal parent of any child born as a result of treatment. Legal parenthood is important as it gives a lifelong connection between a patient and a child, and affects things like nationality, inheritance, contact and financial responsibility.

3.25 We have been working in support of families affected since the issue first came to light (in 2013). In particular, in September 2015[4], we had in-depth contact with all clinics in relation to seeking their assurance as to understanding better the number and type of anomalies. Around half of all clinics had cases where it was possible that a declaration of parenthood where there was a defect in the arrangements for consent (c.70 cases).

3.26 Some of those cases have since been the subject of a declaration of parenthood in court; and some families (in the light of clear advice) have decided not to take action; and a significant number have still to be determined in court.

3.27 To date, no cases have come to light where treatment took place after September 2015. While it is impossible to predict if any will, the steps we have taken (in our communications, at conferences, and through inspection) have raised sector awareness of the problems created by defective arrangements relating to consent. That such a high volume of cases came to light indicates the limitations of any regulatory or inspection regime – regulators set standards and inspect against those standards; they do not treat patients directly.

[4] Further to the judgment made in September 2015 by Sir James Munby, President of the Family Division of the High Court

4. The Authority is asked to note this report, in summary:

4.1 The tools we have are generally well calibrated and effective in motivating regulatory compliance, overall. We meet the statutory tests and we have a stable team using a range of tools which are now established and work well.

4.2 We must continue to do our job and to do it well – and continue to seek feedback from those we inspect that is largely positive. It is preferable to work with people and organisations than to do things to them – the results will be more effective.

4.3 Our analysis shows that recommendations for improvement are implemented within prescribed timescales supporting a conclusion that our inspection activities have a tangible impact. 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.

4.4 That said, there is evidence of both persistent poor performance and some evidence of a culture that does not value learning or embedding a service robustly founded on quality.

4.5 We now have a substantial body of evidence from inspections, from the risk tool analysis (particularly in relation to multiple birth minimisation effectiveness) and from adverse incidents and legal parenthood failings – to better identify those clinics that may be coasting or struggling to comply. We have seen the limitations in clinics' own systems for identifying errors and learning from them in a robust way.

4.6 This must prompt us to think about what we need to do to have an effect on that culture. To that end, we are:

- Trying to get upstream of the problem - embarking on a series of workshops geared towards individual clinics, as we have seen some evidence (from our recent experience of taking clinics through root cause analysis training, for example) that this leads to fewer reported incidents alongside a better appreciation of what drives quality.
- Making a clearer link between clinic quality and performance - ready to apply proportionate steps, for example recommendations relating to licence lengths that are likely to better demonstrate to patients a clinic's performance in providing high quality care.

- Adjusting to new business models - starting to work alongside clinics working under a ‘group’ structure to better understand the risks at the group and clinic level and looking for trends and disparities. In doing so we will adopt a ‘risk based approach’ looking to see how the group’s overall quality system performs in relation to the evidence we see in each inspection of a clinic within the group. We can also apply this approach to the incident reporting system.
- Examining the data we hold more effectively - carrying out more frequent analysis of incidents, at four month intervals, again exploring trends and more actively addressing the common occurrences to resolve the majority of problems. We will provide workshops to clinics providing some training on root cause analysis techniques. We will take proven methodologies from other industries, disseminating the knowledge within the team and in turn to the sector. Moreover, we will look towards sectors such as aviation and aerospace to explore how human factors can be adapted in the sector.
- Improving clinics’ capacity for self-improvement - issuing a root cause analysis template has been designed that sets out the stages of an investigation in a methodical way. This is available to all clinics that require assistance.

Annex

Inspection Findings.

Chart 1

The number of critical and major non compliances found on inspection, 2014/15 and 2015/16

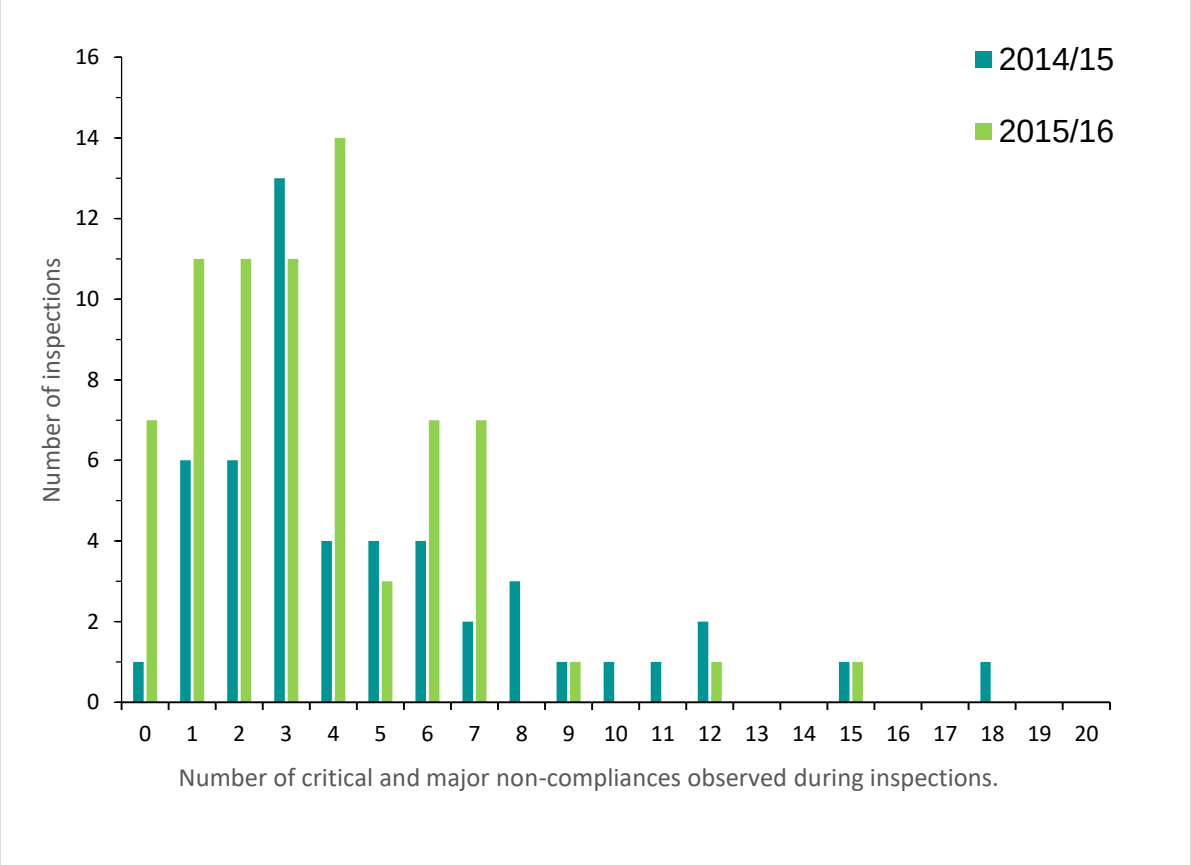


Chart 2

The number per inspection in 2015/16 of non-compliances of differing severity by centre activity/size

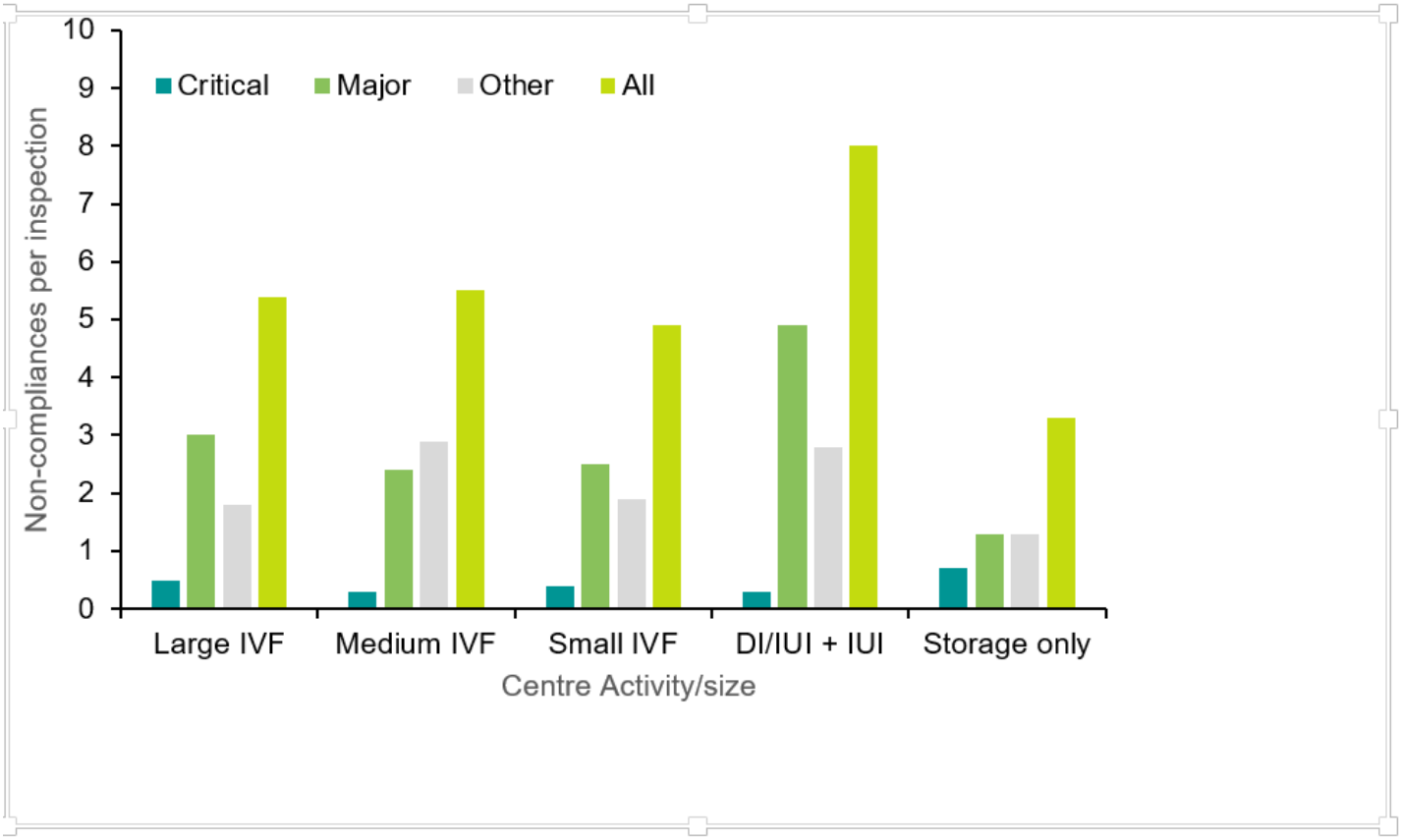


Chart 3

The number per inspection in 2015/16 of non-compliances of differing severity by inspection type.

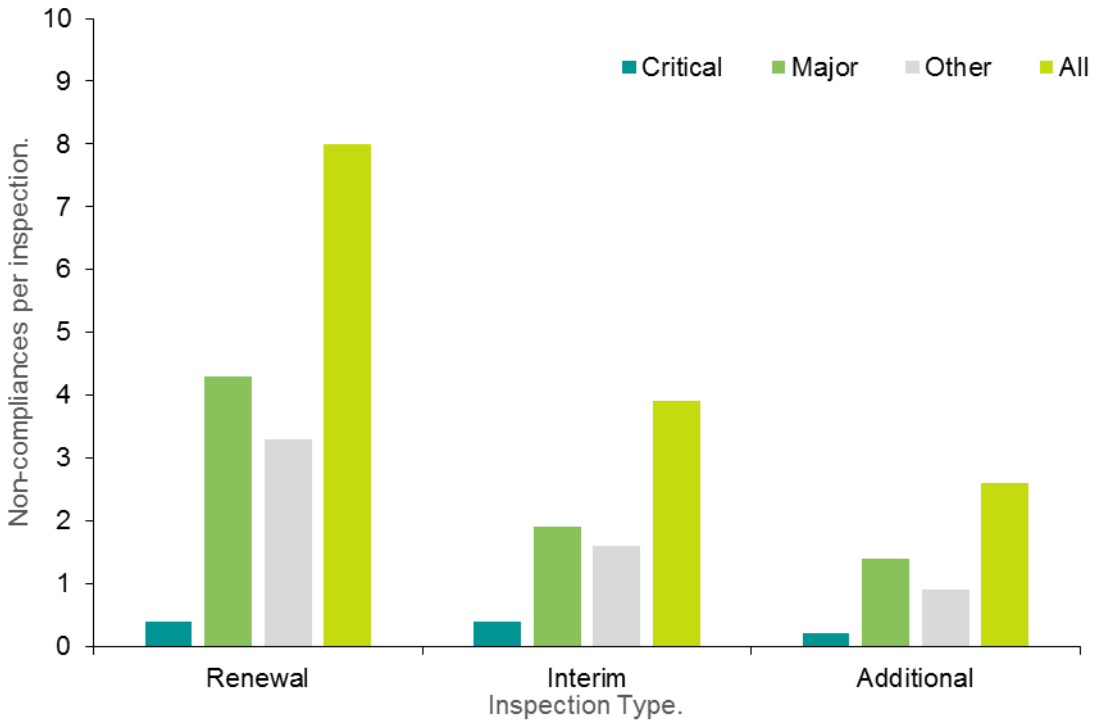


Chart 4

Frequently observed critical and major non-compliance types by clinic size and activity 2015/16

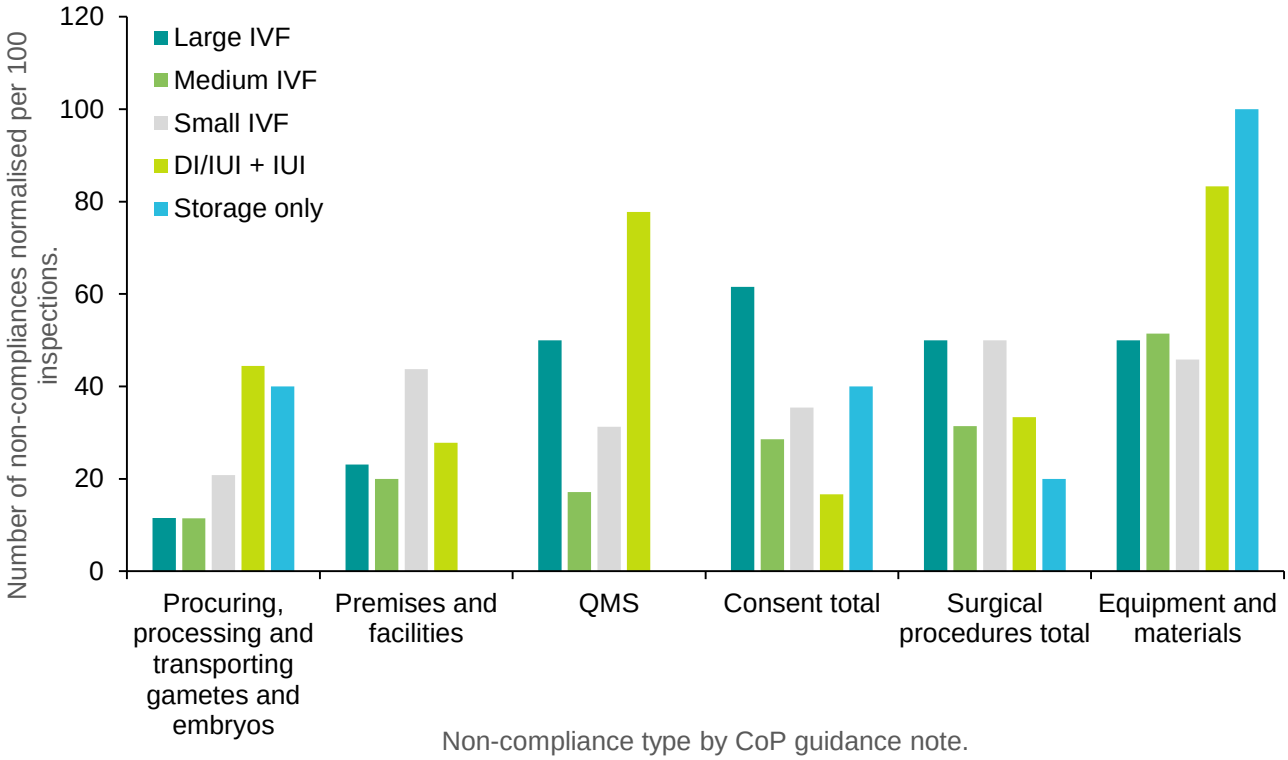


Chart 5

The number of non-compliances by guidance note and severity 2015/16

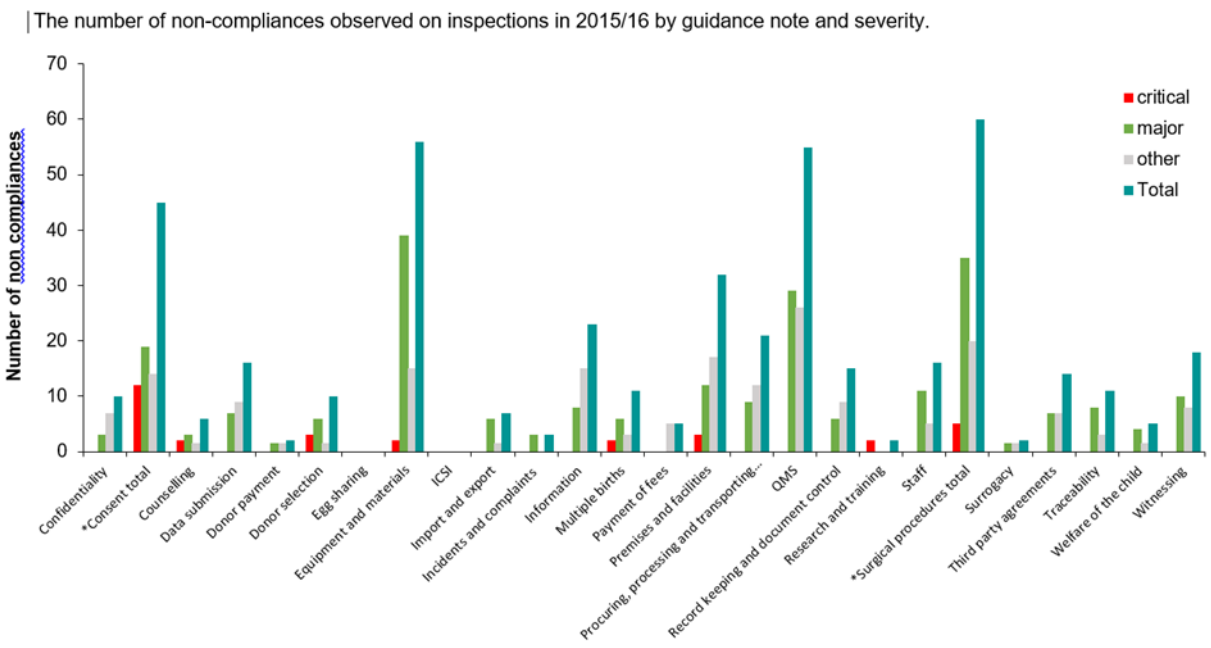


Table 1

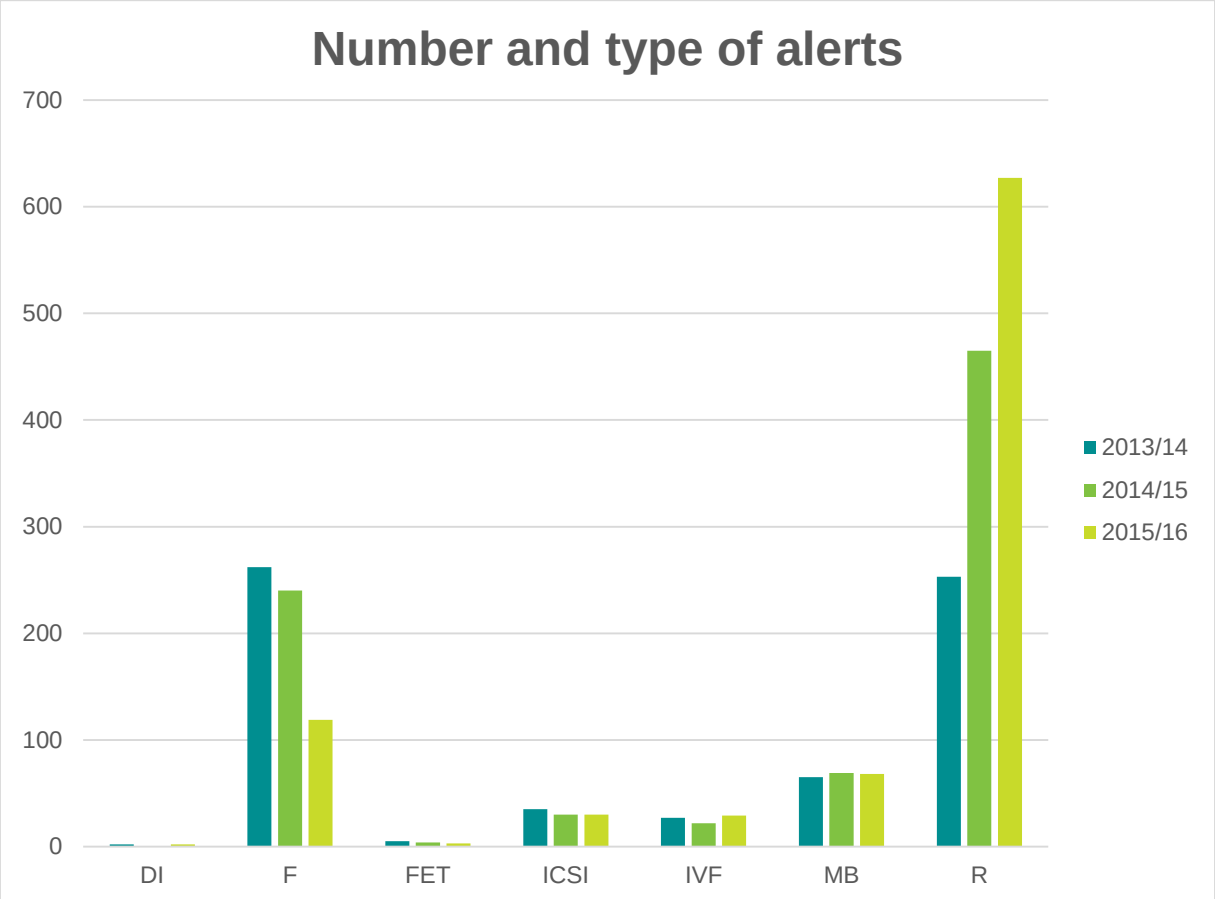
Non-compliances grouped by severity

Non-compliances grouped by severity - critical (C), major (M), other (O) - identified on renewal and interim inspections, and on all inspections to clinics of varying size and activities in 2014/15 and 2015/16. Non-compliance detection rates per inspection are also shown. Notable decreases (Green) in non-compliance detection rates in 2015/16 versus 2014/15 are highlighted.

2014/15									
	Non-compliances found					Number per inspection			
Inspection type	C	M	O	All	Inspections	C	M	O	All
Renewal	15	139	138	292	27	0.6	5.1	5.1	10.8
Interim	9	49	23	81	16	0.6	3.1	1.4	5.1
Additional	8	22	5	35	9	0.9	2.4	0.6	3.9
Clinic size/activity									
Large IVF	6	48	53	107	13	0.5	3.7	4.1	8.2
Medium IVF	6	45	42	93	15	0.4	3.0	2.8	6.2
Small IVF	18	91	55	164	17	1.1	5.4	3.2	9.6
DI/IUI + IUI	2	20	11	33	5	0.4	4.0	2.2	6.6
Storage only	0	6	5	11	2	0.0	3.0	2.5	5.5
Grand Total	32	210	166	408	52	0.6	4.0	3.2	7.8
2015/16									
	Non-compliance found					Number per inspection			
Inspection type	C	M	O	All	Inspections	C	M	O	All
Renewal	15	151	114	280	35	0.4	4.3	3.3	8.0
Interim	14	69	59	142	36	0.4	1.9	1.6	3.9
Additional	2	13	8	23	9*	0.2	1.4	0.9	2.6
Clinic size/activity									
Large IVF	7	39	24	70	13*	0.5	3.0	1.8	5.4
Medium IVF	6	47	57	110	20	0.3	2.4	2.9	5.5
Small IVF	12	79	60	151	31*	0.4	2.5	1.9	4.9
DI/IUI + IUI	4	64	36	104	13	0.3	4.9	2.8	8.0
Storage only	2	4	4	10	3	0.7	1.3	1.3	3.3
Grand Total	31	233	181	445	80*	0.4	2.9	2.3	5.6

*Four additional inspections (to two large and two small clinics) were amalgamated with the inspections which precipitated them (two interim and two renewal).

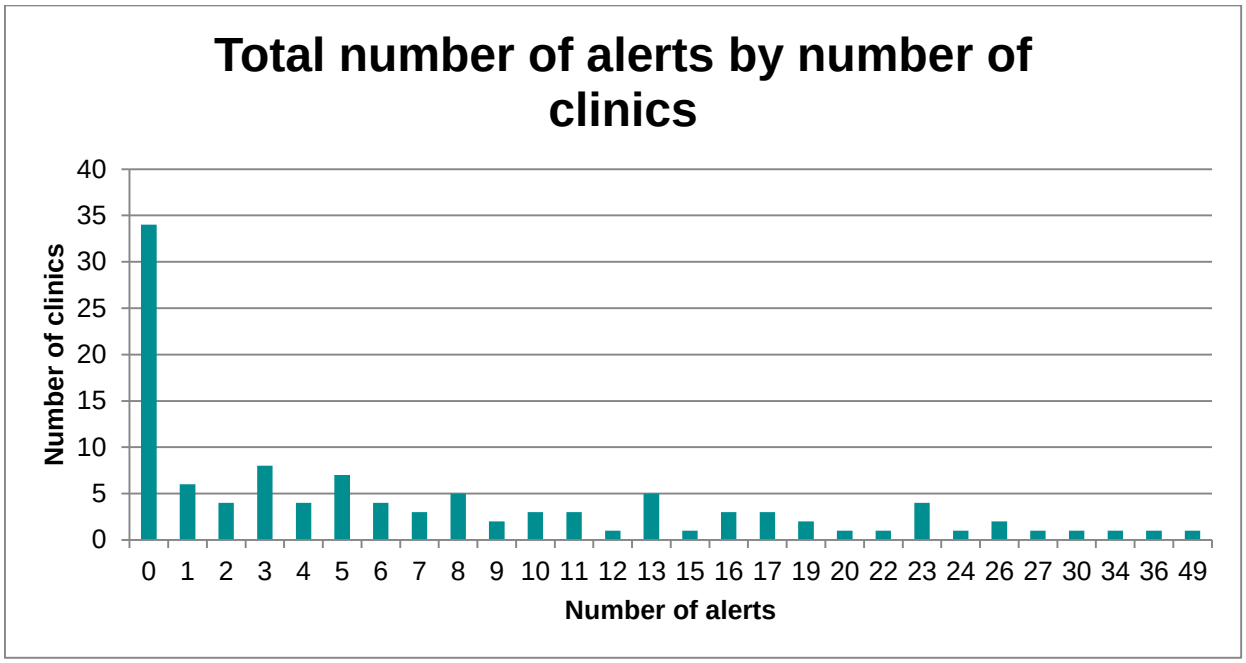
Chart 6
Risk tool: Analysis of alerts between April 2015 and March 2016 and compared with data from 2014/15 and 2013/14.



F, Finance; the sum of all alerts related to delay or non-payment of invoices
R, Register; the sum of all alerts related to errors in reporting of treatments involving donor gametes
MB, Multiple births; the sum of all alerts related to trends in clinical multiple pregnancy rates as measured against the 10% multiple birth rate target
ICSI: the sum of all alerts related to trends in clinical pregnancy rates following ICSI treatments
IVF; the sum of all alerts related to trends in clinical pregnancy rates following IVF treatments
DI; the sum of all alerts related to trends in clinical pregnancy rates following DI treatments
FET; the sum of all alerts related to trends in clinical pregnancy rates following frozen treatment cycles (IVF and ICSI).

This chart shows that the sector as a whole received more alerts relating to late payment of fees and accurate reporting of treatments involving donor gametes than relating to success rates. This is unchanged from the previous two reporting years. The chart does however show a significant decrease in the number of finance alerts sent to clinics as compared to the previous years. The number of alerts related to trends in success rates following IVF, ICSI and FET have not changed significantly.

Chart 7



In 2015/16, 34 of the 112 clinics included in the analysis received no alerts; a further 29 had between 1 and 5 alerts; 17 clinics had between 6 and 10 alerts and 32 clinics had >10 alerts.

The number of clinics receiving >10 alerts in 2015/16 has increased from that in 2014/15 by 5.

It should be noted that clinics that provide basic partner services or storage only do not pay monthly fees, do not provide treatment with donor gametes and make only a single annual data submission to the HFEA recording their success rates (this means that success rates and multiple pregnancy rates are not continuously monitored through the risk tool for these clinics). These clinics represent the majority of those receiving no or very few alerts.