

Compliance activities 2014/15: analysis of risk

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

Details:

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For information or decision?	For information
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Resource implications	In budget
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Organisational risk	<input type="checkbox"/> Low <input checked="" type="checkbox"/> Medium <input type="checkbox"/> High

Annexes Annex 1: charts derived from analysis of risk tool alerts between April 2014 and March 2015 and comparison with data from 2013/14 and 2012/13.

1. Background

- 1.1. The compliance cycle, with inspection at its core, defines the HFEA's regulatory regime. We inspect every two years as required by law and follow up recommendations made during inspections to ensure necessary actions have been implemented. Our ability to undertake 'on-going' monitoring of a clinic's performance between inspection visits has been greatly enhanced by the introduction in April 2011 of the risk based assessment tool (RBAT) that provides information about licensed clinics' performance in near to real time.
- 1.2. Clinics have been able to access their own RBAT outputs through the clinic portal since April 2012 and information from RBAT analysis has routinely been included in inspection reports since then.
- 1.3. The risk tool measures performance in relation to the following indicators:
 - outcomes in terms of both clinical pregnancy rates and clinical multiple pregnancy rates;
 - submission of critical register information relating to treatments using donor gametes;
 - timeliness of payment of monthly HFEA invoices.
- 1.4. Performance is based on the analysis of information submitted to the HFEA. Where the trend analysis performed by RBAT suggests that there may be a dip in performance, an automated alert is sent to the Person Responsible (PR) and clinics are expected to act on these alerts to 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.
- 1.5. This paper provides an update to the review of RBAT outputs completed in 2014 and aims to identify trends; establish performance against the benchmark analysis undertaken in 2014; and identify actions for the future in relation to the focus of our regulatory interventions.

2. Analysis of RBAT outputs April 2014 to March 2015

- 2.1. There is no "normal" range for the number of alerts issued to a clinic. Alerts are generated by trend analysis and do not by themselves indicate poor practice or performance. The aim of alerts is to prompt clinics to review practices **before** performance is negatively affected.
- 2.2. The system uses information submitted to the HFEA's register as the basis of nearly all monitoring. This limits the impact of RBAT in relation to clinics that provide only basic partner treatment services (IUI with partner sperm) as these clinics do not submit information to the HFEA register. While this limitation is acknowledged, it is also recognised that the nature of the services provided by these clinics also limits their risk factors.

- 2.3.** It is also important to note that there is a considerable variation in the number of treatment cycles carried out by clinics. Around 36,000 treatment cycles were carried out by 19 of the 111 clinics included in the analysis. This represents approximately 50% of the treatment activity of the sector in 2014/15. Inevitably, these clinics carry out more complex treatments (involving donor gametes for example) and the volume of their activity means that the significance of any change in performance is identified quickly: this is because a certain volume of activity has to be included in any statistical analysis before it can be identified that a trend represents a true change in performance rather than the result of chance.
- 2.4.** Annex 1 sets out a number of charts derived from analysis of RBAT alerts between April 2014 and March 2015. In summary, it shows that clinics' performance in this period has improved in relation to success rates and timeliness of payment of fees, but has worsened in relation to submission of critical register information.
- 2.5.** Chart 1 shows that more alerts continue to be issued to clinics as a result of delayed payment of fees and invoices and inaccuracies in the reporting of treatments involving the use of donor gametes than in relation to concerns about success rates. However, the chart also shows that the number of finance alerts has decreased from the previous year.
- 2.6.** There are various factors that contribute to clinics delaying payment of invoices. For example some clinics do not have robust processes to deal with absences of staff responsible for processing our invoices. However, in general most clinics pay invoices within the stipulated timeframes. The introduction by the HFEA of an automated debt chasing system in March 2015 has reduced the average days to payment of invoices to 34 days from 47 days before the introduction of this system.
- 2.7.** The number of alerts related to negative trends in success rates following IVF, ICSI and FET decreased in 2014/15. This demonstrates that clinics are taking action to continually improve their success rates. The exception to this is in the number of alerts relating to clinical multiple pregnancy rates and more detailed analysis of this observation is below.
- 2.8.** Chart 2 shows that while the majority of clinics received very few alerts, 27 clinics received more than 10 alerts in 2014/15. This is the same number as in 2013/14; approximately half of these clinics have remained in the list in 2014/15.
- 2.9.** Chart 3 shows the 'top 10' clinics that had the highest number of alerts in 2013/14 and 2014/15. Eight clinics in the top 10 in 2013/14 have remained in the list in 2014/15. All of the clinics in this chart could be considered worthy of scrutiny, but in order to determine where risk lies, the data have been further analysed (see below).
- 2.10.** Chart 4 again shows the 10 clinics that had the highest number of alerts in 2014/15 but divided into two alert categories. This demonstrates that the majority of alerts were either finance or register information related.

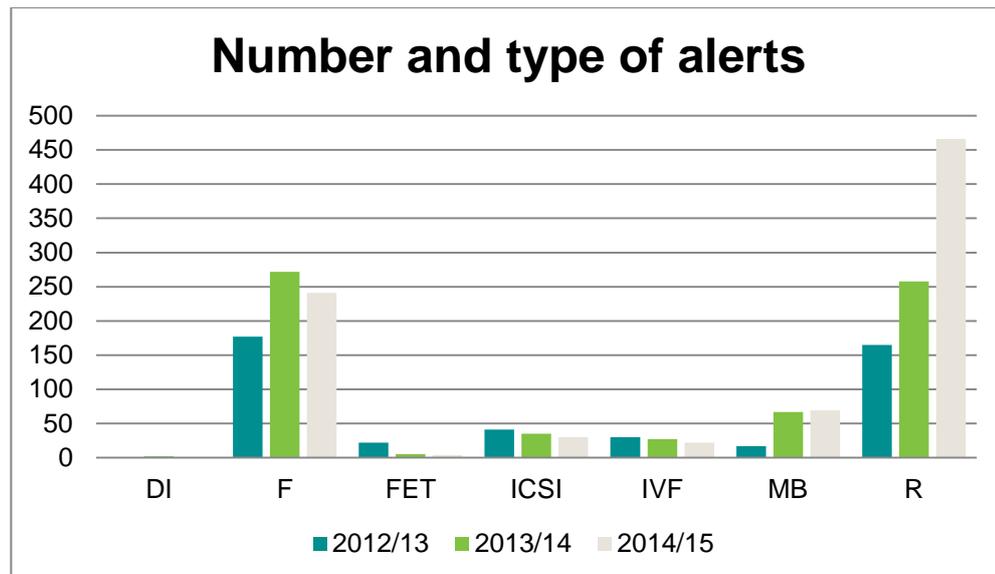
- 2.11.** The number of alerts relating to submission of critical information to the HFEA register has increased significantly since the last reporting year. The HFEA has implemented an extensive programme (Information for Quality, IfQ) to streamline and improve systems for the submission of treatment information to the HFEA register. Information team resources have been diverted to focus on the development of new systems rather than (as previously) focusing efforts on poor performing clinics. It is expected that the new systems will have a significant impact on the quality of register submissions but that these improvements will not start to take effect until the IfQ programme is complete.
- 2.12.** In order to aim our resources at the areas of risk associated with our strategic aims, alerts relating to success rates and multiple pregnancy rates have been further analysed.
- 2.13.** Chart 5 shows the three clinics that had five or more alerts related to success rates in 2014/15. This chart demonstrates a negative trend in performance for one clinic and an improvement for three clinics compared to the previous year.
- 2.14.** Success rates for one of these clinics for the period April 2014 to March 2015 show the clinic's success rates are in line with the national average. This suggests appropriate action was taken by the clinic in response to the alerts.
- 2.15.** For the other two clinics, success rates for the period April 2014 to March 2015 are lower than average at a statistically significant level. Both clinics are being monitored closely by the Executive and the clinics are taking action to review their practices.
- 2.16.** Chart 6 shows the clinics that had four or more alerts related to multiple pregnancies.
- 2.17.** Two of these clinics have responded and appear to have taken effective action such that the clinics' multiple live birth rates are likely to be consistent with the 10% multiple live birth rate target.
- 2.18.** The other two clinics have clinical multiple pregnancy rates that are likely to be significantly higher than the 10% multiple live birth rate target for the April 2014 to March 2015 time period. Both clinics are being monitored closely by the Executive.
- 2.19.** The small increase in the number of alerts related to clinical multiple pregnancy rates in 2014/15 is surprising, as clinics have had since October 2012 to adjust to the 10% multiple live birth rate target. However, data for the sector shows that in 2013/14 19 clinics had a multiple pregnancy rate that was likely to be higher than the 10% multiple live birth rate target, whilst in 2014/15 this had decreased to 15 clinics. This reflects findings documented in our 'Improving outcomes for fertility patients: multiple births 2015' report published recently. This suggests that clinics are taking action to review the effectiveness of their multiple births minimisation strategies: it is likely that the HFEA's proactive real time monitoring through RBAT plays a role in encouraging this behaviour.

3. Conclusions and actions

- 3.1. This review of RBAT outputs should be interpreted cautiously because, as noted above, alerts are not indicators of poor performance per se. They are issued to prompt clinics to take action before there is an impact on performance.
- 3.2. The reduction in alerts related to success rates suggests that clinics are continually improving success rates. There has also been a reduction in the number of finance alerts and it is anticipated that these will continue to fall in the next year due to the new automated debt chasing system.
- 3.3. There was an increase in alerts relating to trends in clinical multiple pregnancy rates. This is disappointing but as documented in the 'Improving outcomes for fertility patients: multiple births 2015' report, fewer clinics had a multiple pregnancy rate that was likely to be higher than the 10% multiple live birth rate in 2014/15 compared to 2013/14. This suggests that clinics are taking effective action in relation to these alerts albeit more slowly than we might have hoped.
- 3.4. The number of alerts related to submission of information relating to donors and/or treatments using donor gametes has increased indicating clinics' performance has declined. Action is being taken by the HFEA through the IfQ programme to streamline systems and processes.
- 3.5. As follow up to this analysis, we will initiate a cross directorate review of the 10 clinics with the highest number of alerts to ensure that everything that can/should be done to support these clinics is being done. Other clinics' responses to alerts will continue to be monitored during the time between inspections and regulatory action taken when it is warranted.
- 3.6. By providing the information required for clinics to monitor their own performance in comparison to national norms, the HFEA targets and helps clinics that may be struggling to improve the quality of care given to patients. Overall, clinics respond positively to requests to act on these alerts.

Annex 1: Charts derived from analysis of RBAT alerts between April 2014 and March 2015 and compared with data from 2013/14 and 2012/13.

Chart 1



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 relevant target

ICSI; the sum of all alerts related to trends in clinical pregnancy rates following ICSI treatments

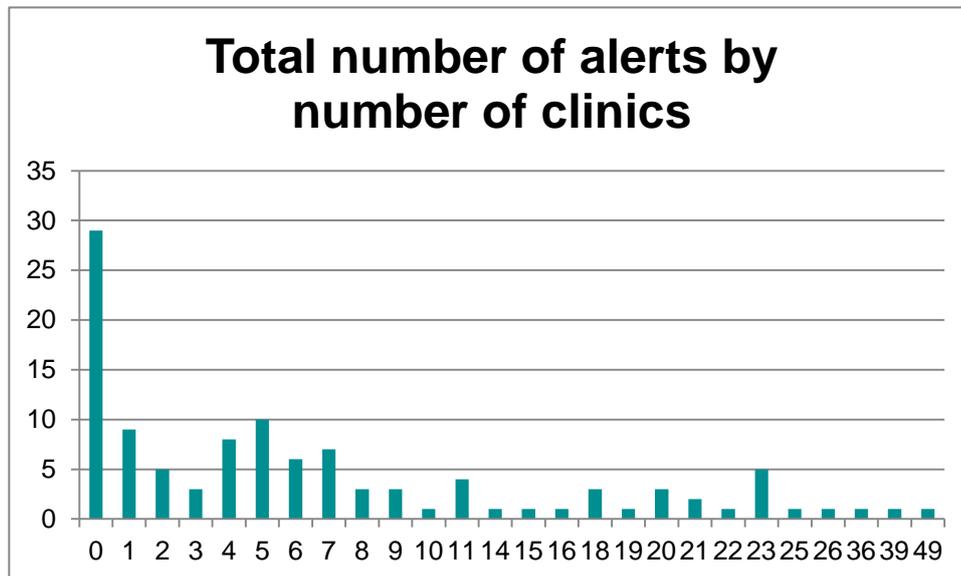
IVF; the sum of all alerts related to trends in clinical pregnancy rates following IVF treatments

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 decrease in the number of finance alerts sent to clinics as compared to the previous reporting year. The number of alerts related to trends in success rates following IVF, ICSI and FET have continued to decrease.

Chart 2

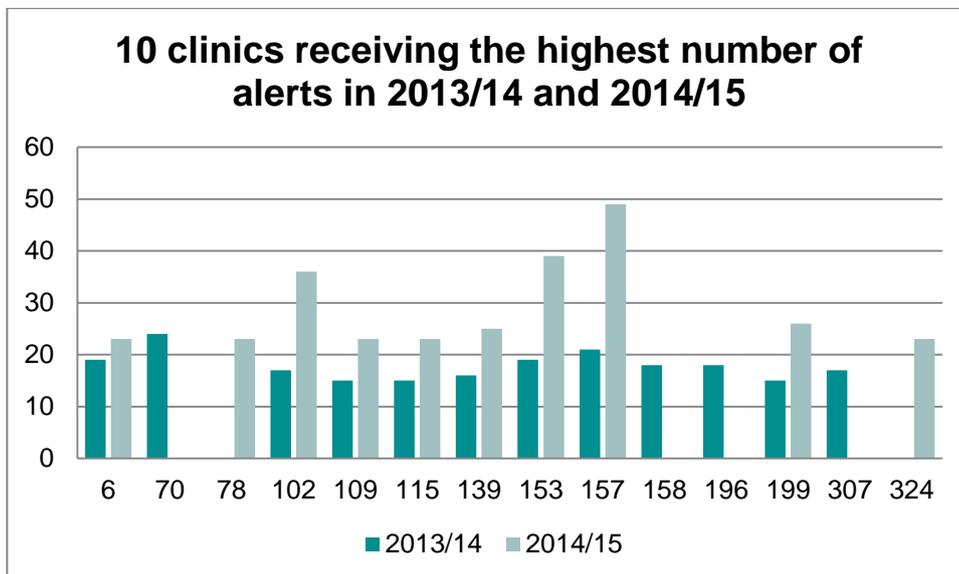


In 2014/15, 29 of the 111 clinics included in the analysis received no alerts; a further 35 had fewer than 5 alerts; 20 clinics had between 6 and 10 alerts and 27 clinics had >10 alerts.

The number of clinics receiving >10 alerts in 2014/15 is the same as that in 2013/14.

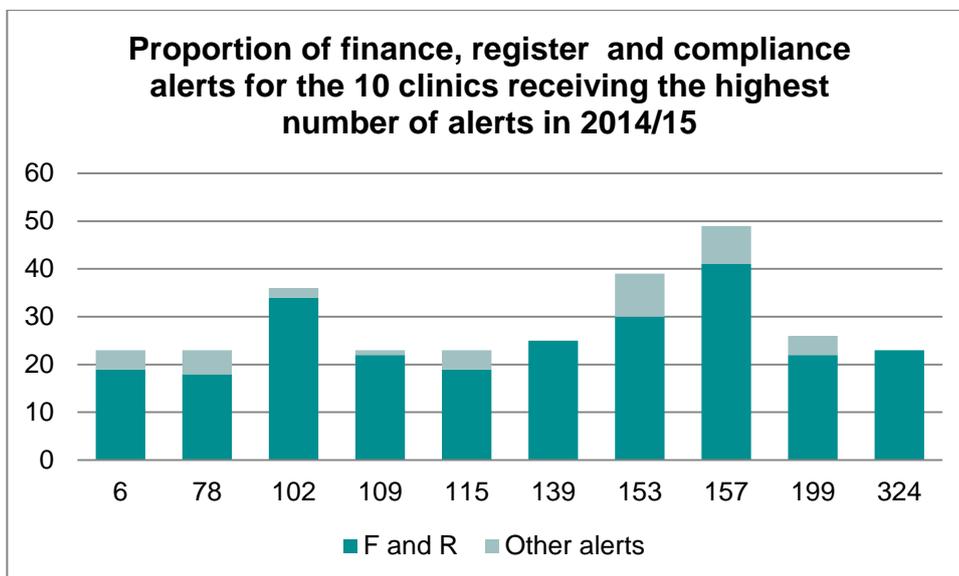
It should be noted that clinics providing basic partner services or storage only do not pay monthly fees, do not provide treatment with donor gametes and make only a single annual data submission to the HFEA recording their success rates (this means that success rates and multiple pregnancy rates are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

Chart 3



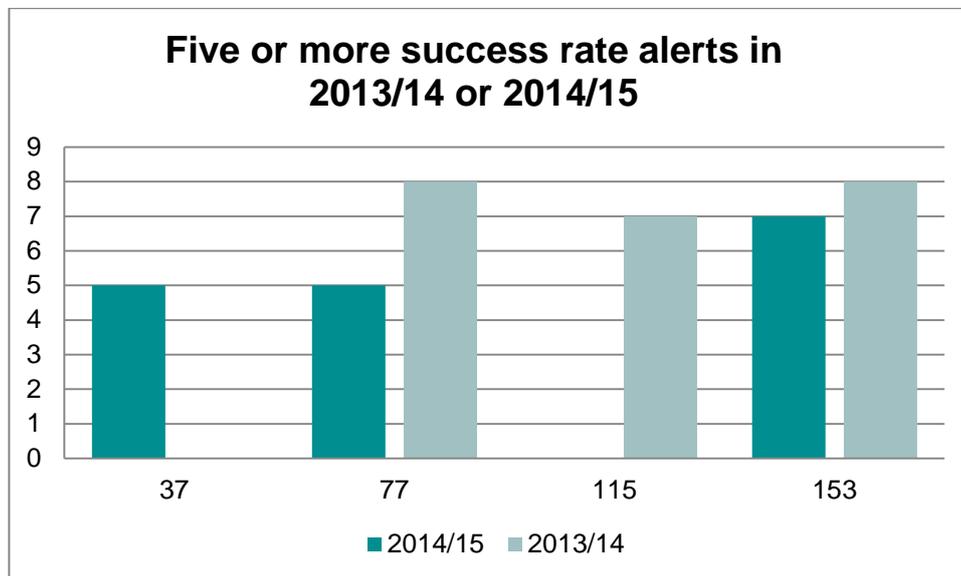
This chart shows the 10 clinics that received the highest number of alerts in either 2013/14 or 2014/15. Eight clinics that were in the 'top 10' in 2013/14 have remained in the list in 2014/15. All of the clinics in this chart could be considered worthy of scrutiny but in order to determine where risk lies, the data have been analysed further below.

Chart 4



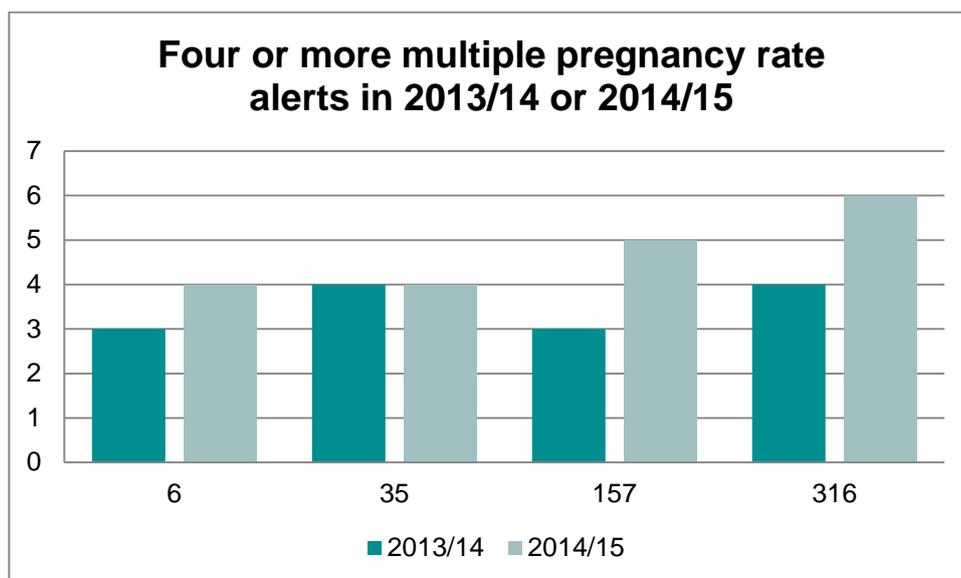
This chart shows the 10 clinics that received the highest number of alerts in 2014/15. A significant proportion of these alerts related either payment of invoices or submission of critical information to the HFEA register.

Chart 5



No clinic received more than 7 alerts related to success rates in 2014/15. This chart shows that three clinics were sent five or more alerts related to success rates in 2014/15; the same number as in 2013/14. It is important to note that all three clinics that received 5 or more alerts last year have all showed an improvement this year. It should be noted that multiple birth rate alerts are not included in this analysis.

Chart 6



Four clinics have received four or more alerts related to multiple pregnancies in 2014/15. Only two clinics received four or more alerts in 2013/14. However, sector wide data shows a decrease in the number of clinics with a multiple pregnancy rate likely to be higher than the 10% target compared to the previous year.