Compliance activities 2014/15: analysis of inspection findings

Strategic delivery:	☒Setting standards	☐ Increasing and informing choice	☐ Demonstrating efficiency economy and value
Details:			
Meeting	Authority		
Agenda item	12		
Paper number	HFEA (16/09/2015) 769		
Meeting date	16 September 2015		
Author	Andrew Leonard, Senior Inspector		
Output:			
For information or decision?	For information		
Recommendation	N/A		
Resource implications	N/A		
Implementation date	N/A		
Communication(s)			
Organisational risk	☐ Low	☒ Medium	☐ High
Annexes	Annex 1: Analysis of data on inspection findings		

1. Background

1.1. This report provides an analysis of non-compliances found in the course of renewal and interim inspections between 1 April 2014 - 31 March 2015 and a comparison with the 2013/14 inspection findings.

1.2. Non-compliances with the Act and requirements of the HFEA Code of Practice (CoP) observed on inspection are classified as critical[1], major[2] or 'other'[3] depending on the associated risks. Post inspection the HFEA's compliance team record the findings of inspections in an electronic system (the post inspection tool) which groups non-compliances according to the HFEA CoP guidance note they are most relevant to.

1.3. This analysis is based on information extracted from this post inspection monitoring system on 30 July 2015.

1.4. We have not included the findings from inspections of research centres in this analysis because these non compliances are very specific and observations are not more generally applicable.

2. Overview of inspection findings

2.1. In 2014/15 there were 59 inspections of treatment and/or storage clinics:

- 28 renewal inspections
- 14 interim inspections and
- 17 inspections of other types (initial/new premises/additional/clinical governance).

2.2. It is important to note the number of inspections carried out and, to some extent, the type of clinic inspected because this impacts on the number of non-compliances. Table A at annex 1 shows a breakdown of the number of inspections by clinic type and size of IVF clinic for 2014/15 and 2013/14. The table shows that fewer inspections were carried out in 2014/15 than in the preceding year. We conducted a larger proportion of inspections at large clinics compared to 2013/14 and smaller proportion at treatment only clinics. Large clinics tend to provide more complex treatments and as a result are subject to compliance with more requirements than treatment only clinics.

[1] An area of practice which poses a significant risk of causing harm to a patient, donor, embryo or to a child who may be born as a result of treatment services, or a significant shortcoming from the statutory requirements

[2] An area of practice which poses an indirect risk to the safety of a patient, donor, embryo or to a child born as a result of treatment services. This area of non-compliance may also indicate a major shortcoming from the statutory requirements and/or indicate a failure by the Person Responsible to carry out their legal duties.

[3] An 'other' area of practice that requires improvement is any area of practice, which cannot be classified as either a critical or major area of non compliance, but which indicates a departure from statutory requirements or good practice.

2.3. Only renewal and interim inspection findings are entered into the monitoring system and so only the findings of these inspections are included in this analysis. This work identified that the findings of four inspections were not recorded in the system and action has been taken to resolve the technical and training issues that led to this omission (Table A at annex 1).

2.4. All inspections in 2014/15 identified non-compliances, although three inspections identified only 'other' non-compliances. When critical and major non-compliances are considered, 32 inspections identified fewer than 10 non compliances while six inspections identified more than 10 non compliances (see Figure 1). Management review meetings were held with respect to four of the clinics where more than 10 non compliances were observed and licences of less than the usual four years were issued in all four cases. With respect to the two clinics having more than 10 non compliances but where licences for four years were issued, the risks associated with the non-compliances were not considered serious enough to warrant a management review. This gives us confidence that we are applying our compliance and enforcement policy appropriately and consistently where there are regulatory concerns.

2.5. Table B at annex 1 shows that when the data are normalised to take into account that fewer inspections were carried out in 2014/15 than in 2013/14, there has been an increase in the number of non-compliances identified per inspection in 2014/15 compared to the previous year with a significant increase in the number of critical non-compliances observed.

2.6. Some of the increase may be attributable to non compliances identified in the course of inspection of clinical areas of practice (safeguarding, infection control, medicines management and the pre-, peri- and post-operative pathway) which have only been inspected since we extended our remit when CQC introduced a policy that clinics in England that only carry out HFEA licensable activity do not need to have CQC registration in addition to their HFEA licence[4].Four of the 22 critical non-compliances identified related to these areas of practice. We have also applied additional scrutiny to inspection of viral screening requirements; the use of suitably approved medical devices; and consent on the basis of observations of non-compliance from previous analyses. Six of 22 critical non-compliances were related to consent.

2.7. It is not considered likely that clinics inspected in 2014/15 are inherently less compliant and our procedures for inspecting are unchanged (and so consistent with other years) and reports continue to be subject to considerable quality assurance to ensure consistency. We do strive continually to develop and adapt our regulatory regime based on our experiences and this is the likely cause of the observed increase in the frequency of non-compliances.

[4] Where we identify non-compliance with these requirements these are referenced against "suitable practices" in the monitoring system (see Figure 4).

3. The relationship between clinic size and type and performance

3.1. It is important for us to consider whether clinics of different size or type have a different pattern of non compliance. This is because right touch regulation requires us to apply our resources where they are most effective.

3.2. Figure 2 shows the variation in the number of non-compliances between clinics of different size or providing treatment of differing complexity[5]. The figure shows that there is an increased frequency of non-compliance observed on inspection of IVF clinics of different size with smaller clinics generally having more non-compliance. It is possible that large clinics (those providing more than 1000 cycles of treatment in a year) may have more resources available to ensure regulatory compliance with medium and small clinics having progressively fewer resources. Clinics offering only relatively basic treatment also have progressively less non-compliance than small IVF clinics but this is likely to arise because these clinics are subject to fewer regulatory requirements. While interesting, these differences are too small to usefully influence how we apply our inspection regime however.

3.3. Figure 3 shows that the five most frequently observed non-compliances are broadly seen on inspection of clinics of all sizes and types. Again, this supports a conclusion that the same inspection regime should be applied to all licensed clinics. It should be noted however that clinics offering more basic treatment services are only subject to compliance with the relevant subset of requirements so the inspection process is inherently adapted to be proportionate on the basis of centre type.

4. Types of non-compliance found on inspection

4.1. Table C and Figure 4 show the most frequently observed types of non-compliances observed in the two years from 2013 to 2015. The areas of practice most frequently observed as requiring improvement were:

- The quality management system (QMS)
- Consent
- Equipment and materials
- Procuring, processing and transporting of gametes and embryos
- Witnessing
- Traceability

[5] The frequency of non-compliances has been normalised to account for the different number of inspections in each category

4.2. Almost identical results were obtained when only critical and major non-compliances, which carry a higher risk to patients and their gametes and embryos, were considered (Table D).

4.3. Clinics have been required to have a QMS since 2007: it is the mechanism by which clinics are expected to achieve continuous improvement. Clinics struggled initially to implement all of the requirements and after 2007 inspections tended to focus on clinics' quality management systems and processes. Figure 4 shows that while there were frequent recommendations for improvement with respect to clinics' QMS, non compliances tended to be less serious with more 'other' recommendations than critical or major. Because of the pivotal role of the QMS in ensuring quality of care, we will continue to focus on this aspect of practice but since April 2015 we have refreshed our approach to consider the impact and effectiveness of clinics' audits of practice. It is likely that we will continue to make recommendations for improvement as we try to raise the bar on quality.

4.4. Consent is at the heart of our regulatory regime and consent failure is considered to be one of the two most significant risks of fertility treatment. Consent requirements are very complex and were changed significantly in 2009. As a result we continue to scrutinise clinics' procedures for taking consent and we continue to recommend improvements. Commonly we make recommendations with respect to the storage of gametes and embryos after the gamete provider's consent to storage has expired – while it is critical that clinics' store in line with consent this particular non compliance has fewer associated risks than other consent failures. Notably the absolute number of samples stored beyond the consented period has reduced significantly. More significant are problems with reporting of consent to disclosure intentions and in relation to legal parenthood. The observation of these anomalies (accounting for 6 of 22 critical non-compliances observed –see Figure 4) has had a wider impact beyond regulatory action and we held consent workshops across the country in 2014 and at the 2015 annual conference. We also implemented changes to disclosure consent forms and initiated sector wide regulatory action with respect to consent to parenthood.

4.5. Non-compliances related to equipment and materials commonly include failing to validate new and/or repaired equipment and using non-CE marked medical devices. The requirements related to CE marking were poorly understood by the sector but collaborative working with the Medicines & Healthcare products Regulatory Agency has clarified requirements in the last year, We also had a workshop on CE-marking at the HFEA annual conference in 2015. Clinics are still working through the implementations of these requirements – hence the frequency of recommendations for improvement.

4.6. In relation to procuring, processing and transporting gametes and embryos, common non-compliances include inadequacy of process validation and poor practice around the screening of gamete providers. As noted above, validation requirements were poorly understood when introduced in 2007 and we continue to try to raise the bar and encourage clinics to ensure not only that they 'tick the

boxes' with respect to validation documentation, but that they are able to demonstrate the effectiveness of their validation in leading to improvements in the quality of their services. With respect to viral screening the frequency of this non compliance has arisen as a result of changes in guidance. In response to observation of this non compliance we sought expert opinion and then issued updated guidance following consultation with the Licensed Centres Panel.

4.7. Risk of misidentification is (with consent) the most significant risk of fertility treatment and effective witnessing is key to minimising it. As a result we scrutinise this area of practice closely. Clinics all have good procedures in place to minimise these risks and common non-compliances (the absence of witnessing at the disposal of sperm after treatment and errors in the documentation of witnessing) generally carry an extremely low level of risk. Although this is a common no-compliance, there were no critical witnessing non-compliances and seven of the 16 non-compliances were low risk and classified as "other" (see Figure 4).

4.8. In relation to traceability, the most common non-compliances observed were failure to label tubes used during egg collection –as clinics generally only carry out one egg collection at a time there are no significant opportunities for misidentification, but because of the potential impact we continue to prompt clinics to be robust in the documentation of the measures they take to minimise all possible risks in respect of this non-compliance.

5. Changes in the prevalence of non-compliance, 2013/14 and 2014/15

5.1. We also looked at which critical and major non-compliance were identified more frequently in 2014/15 when compared to 2013/14 (Table E, Annex 1).

5.2. Increases were noted between 2013/14 and 2014/15 in non-compliances related to consent, data submission, equipment and materials, QMS, traceability, witnessing and procuring, processing and transporting gametes and embryos. These non-compliance types have already been identified as focus areas in this analysis.

5.3. Non-compliances related to premises and facilities and staffing also increased to a notable level in certain clinic types such that they were relatively prevalent as non-compliances in 2014/15. Our revised interim inspection methodology already focusses on these areas.

5.4. Increases were also noted with respect of non-compliances related to: counselling, donor selection, egg sharing, information provision, record keeping and document control, but these areas of non-compliance were still not notably prevalent in 2014/15 relative to other areas. They may however represent areas of potential regulatory concern in the future.

5.5. 'Suitable practices' was the seventh most prevalent critical or major non-compliance type in all inspections in 2014/15 (see Table E in Annex 1. As noted above 'Suitable practices' non-compliances are commonly cited where clinics are failing to meet the 10% target for multiple births or when poor practice is found relevant to findings of inspection of the extended clinical practices. The HFEA continues to engage with the sector with respect to compliance with the multiple births target and we have already provided clarification of requirements around the new areas of clinical practice being inspected – particularly medicines management.

6. Implementation of recommendations to resolve non-compliance

6.1. Ninety percent (436 of 484) of the recommendations for improvement made following inspection in 2013/14 were implemented within the prescribed timescales. It is likely that a small number may not have been recorded as complete in our monitoring system although they are complete and, occasionally, Persons Responsible (PRs) do not provide evidence of compliance. Where outstanding non compliance poses a risk we generally invoke the Compliance and Enforcement policy and take appropriate action if the PR does not provide evidence of improvement. So far in respect of recommendations made following inspection in 2014/15 only 78% (251 of 323) have been implemented. This is because the deadline for completing some recommendations made in 2014/15 has not yet been reached.

7. Clinic feedback regarding inspections

7.1. We ask PRs to provide feedback to the HFEA regarding the inspection process via a questionnaire on our website.

7.2. Feedback has been provided with respect to 42 renewal inspections and 36 interim inspections carried out between 2013 and 2015. Seventy two of the 78 respondents (92%) considered that their inspection visit had promoted improvement to the way the clinic carries out its work and >95% of the 78 respondents were satisfied with their inspection report and with the recommendations and timescales for implementation within it.

7.3. There was a small proportion of negative feedback. Two of 42 respondents who experienced renewal inspections and three of 29 who experienced interim inspections did not agree that patients were not inconvenienced and/or their care was not jeopardised by the inspection. Furthermore, five of 29 respondents who had experienced an unannounced interim inspection did not agree that staff were able to take the inspection in their stride and carry on with their work while the inspection took place. These respondents are in a minority however the

inspection team are mindful of this feedback and continue to endeavour to minimise any negative impact of the inspection visit on patient treatment.

7.4. Of 78 respondents, three said that they did not have enough time to discuss the inspection findings on inspection and two felt they did not understand an issue of non-compliance. It is noted that inspection team leaders telephone clinics, where required, after an inspection and all but one respondent was satisfied with this interaction.

8. Conclusions

8.1. The sector remains largely compliant and the non-compliances identified during inspection relate to either high risk or complex areas of practice.

8.2. Inspections continue to adapt to the regulatory landscape and aim to raise the bar and clinics are clearly making improvements prompted by our regulatory activities. Post inspection feedback supports a conclusion that inspection visits lead to improvements in service delivery and patient care.

Annex 1: Analysis of data on inspection findings

Table A: The numbers of renewal and interim inspections performed in 2013/14 and 2014/15, by clinic size[6] and activity[7]

Centre size/activity	2013/14			2014/15		
	Renewal	Interim	Total inspections	Renewal	Interim	Total inspections
Large IVF	7	6	13	3	9	12
Medium IVF	12	7	19	8	2	10
Small IVF	9	6	15	7	2	9
IUI/DI+IUI	7	13	20	3	1	4
Storage only	2	2	4	3	0	3
Total	37	34	71	24	14	38

[6] A clinic that provides treatments to less than 500 patients per year is categorised as small; 501–999, medium and 1000+ large.

[7] Clinics with treatment and storage licences can provide a full in vitro fertilisation service (IVF), or storage facilities allowing insemination with stored donor sperm or partner sperm (DI+IUI). Other clinics have a treatment only licence and provide insemination with partner sperm (IUI) or a storage only licence and provide facilities for gamete and embryo storage only (Storage only). In this analysis DI+IUI and IUI clinics have been amalgamated due to the low numbers in each group and the common activities between them.

Figure 1

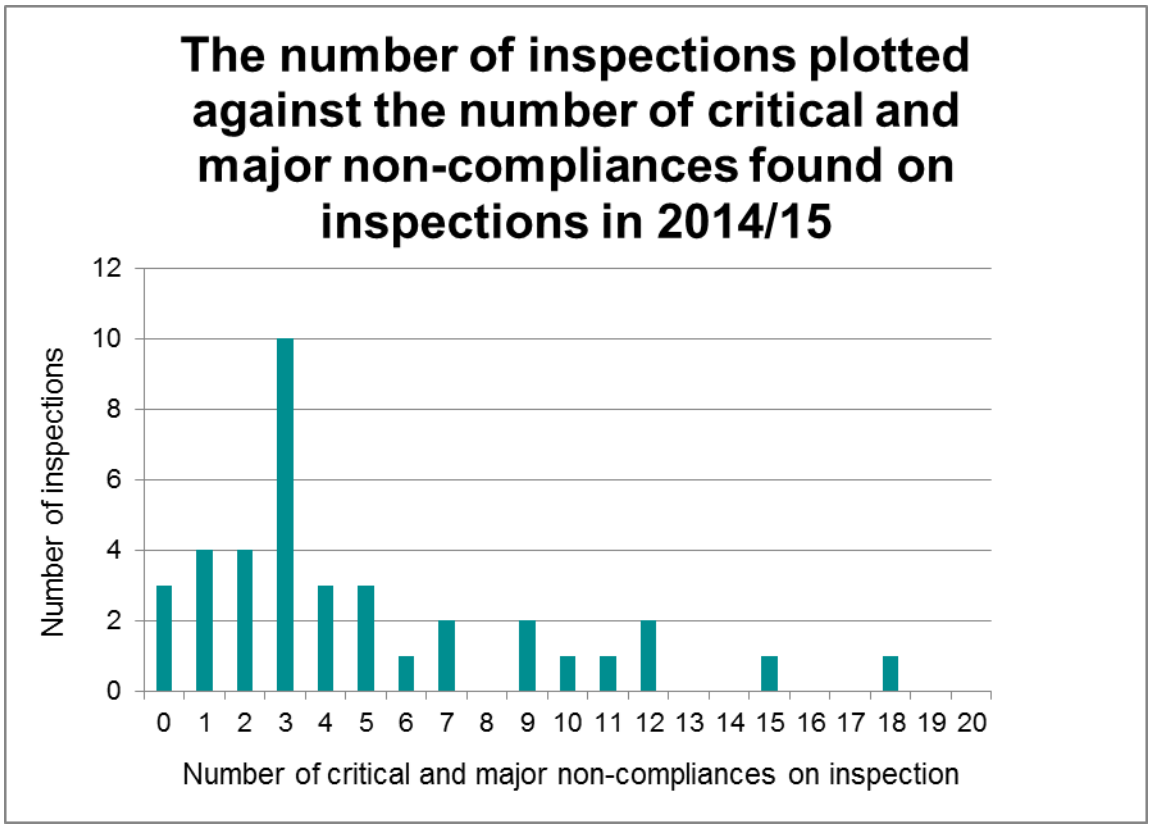
The number of inspections plotted against the number of critical and major non-compliances found on inspections in 2014/15
Number of inspections
0
2
4
6
8
10
12
0 1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20
Number of critical and major non-compliances on inspection

Table B: 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 2013/14 and 2014/15. The corresponding detection rates per inspection are also shown. Increases (Red) and decreases (Green) in non-compliance detection rates in 2014/15 versus 2013/14 are highlighted to show at which types of clinic non-compliances and their severity is changing.

2013/14									
	Non-compliances found					Number per inspection			
Inspection type	C	M	O	All	Inspections	C	M	O	All
Renewal	5	118	233	356	37	0.1	3.2	6.3	9.6
Interim	3	57	68	128	34	0.1	1.7	2.0	3.8
Clinic size/activity									
Large	5	39	82	126	13	0.4	3.0	6.3	9.7
Medium	2	54	98	154	19	0.1	2.8	5.2	8.1
Small	0	43	67	110	15	0.0	2.9	4.5	7.3
DI/IUI + IUI	0	34	50	84	20	0.0	1.7	2.5	4.2
Storage only	1	5	4	10	4	0.3	1.3	1.0	2.5
Grand Total	8	175	301	484	71	0.1	2.5	4.2	6.8
2014/15									
	Non-compliance found					Number per inspection			
Inspection type	C	M	O	All	Inspections	C	M	O	All
Renewal	14	123	118	255	24	0.6	5.1	4.9	10.6
Interim	8	40	20	68	14	0.6	2.9	1.4	4.9
Clinic size/activity									
Large	4	32	40	76	12	0.3	2.7	3.3	6.3
Medium	4	50	42	96	10	0.4	5.0	4.2	9.6
Small	12	62	40	114	9	1.3	6.9	4.4	12.7
DI/IUI + IUI	2	13	11	26	4	0.5	3.3	2.8	6.5
Storage only		6	5	11	3	0.0	2.0	1.7	3.7
Grand Total	22	163	138	323	38	0.6	4.3	3.6	8.5

Figure 2: The number per inspection in 2014/15 of non-compliances of differing severity by clinic type and size

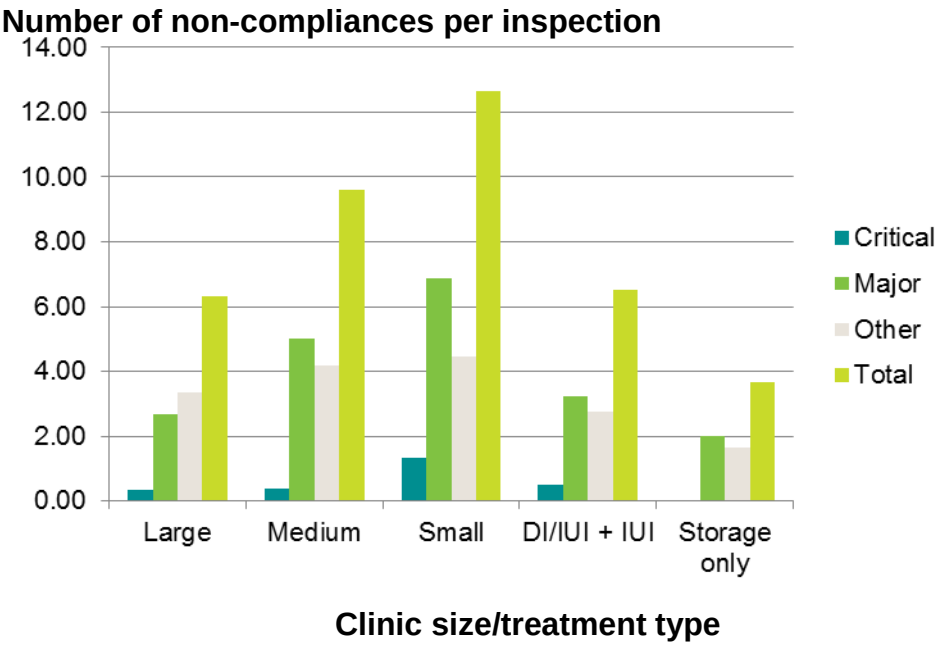

Figure 3: Five most frequently observed non-compliances by clinic size and type

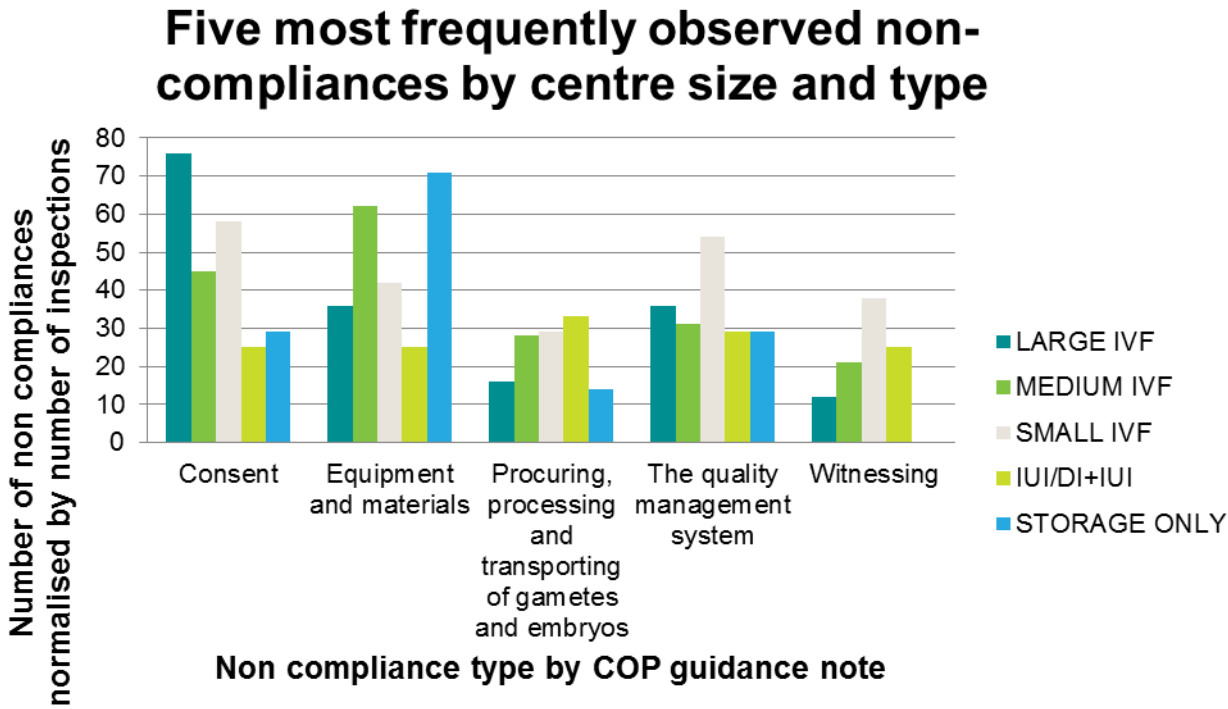

Table C: The detection prevalence per 100 inspections in 2013/15 of all non-compliances, by type, as a function of inspection type (All; renewal; interim) and clinic size and activities (Large IVF clinic; medium size IVF clinic; small IVF clinic; IUI/DI+IUI; storage only). The top six non-compliance types in each class are highlighted in pink.

	Detection rate/100 inspections in 2013-15							
Non-compliance type	**ALL**	**RENEWAL**	**INTERIM**	**LARGE IVF**	**MEDIUM IVF**	**SMALL IVF**	**IUI/DI+IUI**	**STORAGE ONLY**
Confidentiality and privacy	19	20	18	32	14	25	13	0
Consent	84	77	92	112	93	108	38	29
Counselling	12	20	2	12	7	33	0	0
Data submission	36	39	31	56	55	29	8	0
Donor payment	6	10	0	0	14	8	0	0
Donor selection	30	43	14	32	38	54	0	14
Egg sharing	6	10	0	4	14	4	0	0
Embryo testing	3	5	0	12	0	0	0	0
Equipment and materials	62	93	22	56	86	63	38	71
ICSI	2	2	2	0	3	4	0	0
Import and export	9	15	2	12	7	21	0	0
Incidents and complaints	6	11	0	8	3	13	4	0
Information provision	26	39	8	20	38	33	17	0
Multiple births	18	21	14	20	34	21	0	0
Payment of HFEA fees	4	3	4	0	14	0	0	0
Premises and facilities	31	43	16	32	31	54	13	14
Procuring, processing and transporting of gametes and embryos	53	85	12	48	45	71	63	14
Record keeping and document control	22	34	6	28	17	25	25	0
Research and training	11	18	2	20	17	8	0	0
Staff	30	38	20	16	28	54	33	0
Storage of gametes and embryos	14	18	8	12	17	21	4	14
Suitable practices	20	30	8	16	28	29	4	29
The quality management system	86	126	35	88	76	92	96	71
Third party agreements	30	48	8	40	34	33	13	29
Traceability	45	59	27	52	62	50	21	14
Website	5	7	2	8	7	0	4	0

Welfare of the child	17	25	6	20	21	13	17	0
Witnessing	53	64	39	52	59	67	50	0

Table D: The detection prevalence per 100 inspections in 2013/15 of only critical and major non-compliances, by type, as a function of inspection type (All; renewal; interim) and clinic size and activities (Large IVF clinic; medium size IVF clinic; small IVF clinic; IUI/DI+IUI; storage only). The top six non-compliance types in each class are highlighted in pink.

Non-compliance type	ALL	RENEWAL	INTERIMS	LARGE IVF	MEDIUM IVF	SMALL IVF	IUI/DI+IUI	STORAGE ONLY
Confidentiality and privacy	7	8	6	8	10	13	0	0
Consent	50	34	67	76	45	58	25	29
Counselling	8	15	0	0	7	29	0	0
Data submission	17	13	20	28	17	17	8	0
Donor payment	0	0	0	0	0	0	0	0
Donor selection	9	13	4	8	7	25	0	0
Egg sharing	5	8	0	4	10	4	0	0
Embryo testing	0	0	0	0	0	0	0	0
Equipment and materials	44	64	18	36	62	42	25	71
ICSI	1	2	0	0	0	4	0	0
Import and export	3	5	0	4	3	4	0	0
Incidents and complaints	4	7	0	4	3	8	0	0
Information provision	7	13	0	4	14	8	4	0
Multiple births	9	7	12	4	24	8	0	0
Payment of HFEA fees	1	2	0	0	3	0	0	0
Premises and facilities	18	25	10	16	17	38	8	0
Procuring, processing and transporting of gametes and embryos	26	41	6	16	28	29	33	14
Record keeping and document control	9	15	2	12	3	17	8	0
Research and training	3	5	0	4	3	4	0	0
Staff	14	15	12	4	10	29	17	0
Storage of gametes and embryos	9	13	4	12	14	13	0	0
Suitable practices	8	8	8	0	10	21	0	14
The quality management system	37	48	22	36	31	54	29	29
Third party agreements	11	18	2	20	7	13	4	14
Traceability	8	13	2	4	17	4	8	0
Website	0	0	0	0	0	0	0	0

Welfare of the child	8	11	4	8	10	8	8	0
Witnessing	22	25	18	12	21	38	25	0

Figure 4: Number of non-compliances observed in 2014/15 by guidance note and severity.

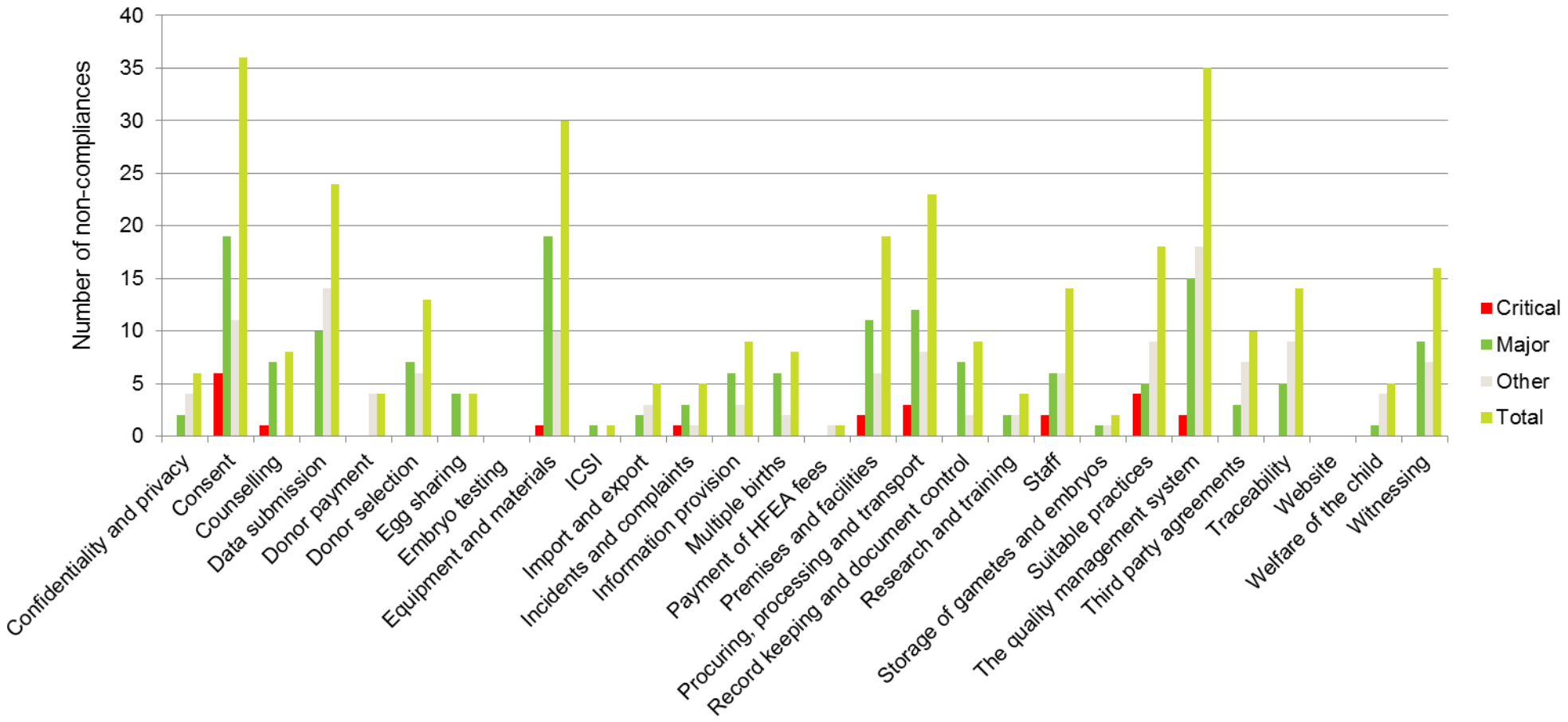

Table E: The percentage change in the prevalence of critical and major non-compliance types between 2013/14 and 2014/15, as a function of inspection type (All; renewal; interim) and clinic size and activities (Large IVF clinic; medium size IVF clinic; small IVF clinic; IUI/DI+IUI; storage only). Prevalence rate changes are proportionately colour coded from dark green at -100% (i.e. a decline to zero), to clear at 33%, to dark red at 300% and above. The prevalence rate of all non-compliance types in all inspections in 2014/15 (top 10 marked in pink) is included to show where prevalence increases may be relevant.

		As %increase between 2013/14 and 2014/15 IN RATE/100 inspections							
	Prevalence rate 2014/15	**ALL**	**RENEWAL**	**INTERIM**	**LARGE IVF**	**MEDIUM IVF**	**SMALL IVF**	**IUI/DI+IUI**	**STORAGE ONLY**
Confidentiality and privacy	16	-38	3	-100	-100	280	-100		
Consent	95	61	16	129	86	19	67	0	-100
Counselling	21	1395	1133			90			
Data submission	63	134	-8	467	171	-53	400	400	
Donor payment	11	No entries because no critical or major non-compliances were recorded in 2014/15							
Donor selection	34	336	363	143	8		233		
Egg sharing	11	647	517			280			
Embryo testing	0								
Equipment and materials	79	33	7	94	-46	138	-29	0	100
ICSI	3	No entries because no critical or major non-compliances were recorded in 2013/14							
Import and export	13	274	208				-100		
Incidents and complaints	13	No entries because no critical or major non-compliances were recorded in 2013/14							
Information provision	24	461	363				67	-100	
Multiple births	21	180		21		43			
Payment of HFEA fees	3	-100	-100			-100			
Premises and facilities	50	247	131	871	225	185	483	-100	
Procuring, processing and transporting of gametes and embryos	61	116	96	21	-64	90	900	200	
Record keeping and document control	24	336	440	-100	117		400	400	
Research and training	11	274	208		-100				
Staff	37	114	93	143	-100	-100	900	400	

Storage of gametes and embryos	5	-79	-78	-100	-100	-100	-17		
Suitable practices	47	No entries because no non-compliances were recorded in 2013/14							
The quality management system	92	38	9	102	-46	52	94	100	33
Third party agreements	26	-38	-42	-100	-100	90	233	-100	-100
Traceability	37	134	157	-100	-100	185		400	
Website	0	All non-compliances in 2014/15 were included in information provision							
Welfare of the child	13	-77	-74	-100	-100	-100	-100	400	
Witnessing	42	12	76	-70	-46	-5	33	150	

Table F: Critical, major and other non-compliances and the implementation of recommendations to address them, at clinics of varying size and activities in 2013/14 and 2014/15. The corresponding percentage of recommendations implemented is also shown.

clinic size/activity	Non-compliances found/recommendations implemented (as %)			
	Critical	Major	Other	All
2013-15				
All clinics	30/25 (83%)	338/283 (84%)	439/379 (86%)	**807/687 (85%)**
2013/14				
Large	5/5 (100%)	39/38 (97%)	82/81 (99%)	126/124 (98%)
Medium	2/2 (100%)	54/53 (98%)	98/81 (83%)	154/136 (88%)
Small	0	43/38 (88%)	67/53 (79%)	110/91 (83%)
DI/IUI + IUI	0	34/30 (88%)	50/46 (92%)	84/76 (90%)
Storage only	1/0 (0%)	5/5 (100%)	4/4 (100%)	10/9 (90%)
Grand Total	8/7 (88%)	175/164 (94%)	301/265 (88%)	**484/436 (90%)**
2014/15				
Large	4/4 (100%)	32/29 (91%)	40/36 (90%)	76/69 (91%)
Medium	4/2 (50%)	50/36 (72%)	42/39 (93%)	96/77 (80%)
Small	12/10 (83%)	62/38 (61%)	40/26 (65%)	114/74 (65%)
DI/IUI + IUI	2/2 (100%)	13/11 (85%)	11/8 (73%)	26/21 (81%)
Storage only	0	6/5 (83%)	5/5 (100%)	11/10 (91)
Grand Total	22/18 (82%)	163/119 (73%)	138/114 (83%)	**323/251 (78%)**

Compliance activities 2014/15: clinical governance learning

Strategic delivery:	☒ Setting standards	☐ Increasing and informing choice	☐ Demonstrating efficiency economy and value
Details:			
Meeting	Authority		
Agenda item	13		
Paper number	HFEA (16/09/2015) 770		
Meeting date	16 September 2015		
Author	Paula Nolan, Clinical governance lead/Inspector		
Output:			
For information or decision?	For information		
Recommendation	N/A		
Resource implications	In budget		
Implementation date	Through ongoing compliance activities		
Communication(s)	Through the annual incidents report.		
Organisational risk	☐ Low	☒ Medium	☐ High
Annexes	Annex 1: Clinic Focus articles Annex 2: Learning disseminated by other professional bodies Annex 3: Review of patient complaints Annex 4: Adverse incidents in fertility clinics: lessons to learn		

1. Background

1.1. An estimated 1% of the 60,000 cycles of IVF treatment that are carried out in the UK each year are affected by some sort of adverse incident.

1.2. The Person Responsible (PR) for an HFEA licensed clinic has a statutory duty to report and analyse the causes of incidents[1]. Similarly, the Authority has a duty[2] to investigate and take appropriate control measures in relation to reported incidents[3].

1.3. The primary reason for reporting and investigating incidents is to improve safety for patients, embryos and clinic staff. Reporting an incident is not enough on its own: to be most effective, learning should be extracted from each and every incident to minimise the risk of it happening again.

1.4. The HFEA has a national role in gathering information on incidents, identifying patterns and disseminating learning across the sector so that clinics can learn from the mistakes of others.

1.5. The PR also has a duty to implement and adhere to a complaints procedure. Every year, in addition to investigating incidents, the HFEA investigates a small number of complaints from patients unhappy about some aspect of their treatment. In 2014, for the first time we shared a summary of learning from patient complaints with the sector. As with incidents, there were common threads in the complaints made to the HFEA and the analysis was shared to help clinics deal with and learn from complaints more effectively.

2. Clinical governance developments in 2014/15

2.1. In 2013 the Authority published contextual information about incidents to promote shared learning across the sector. In July 2014, we published a summary of incidents reported by clinics between 1 January 2010 and 31 December 2012[4]. This report outlined the key features of the incidents reported by clinics and made recommendations to help clinics avoid having similar incidents. In December 2014, we published our first annual report, looking at incidents reported by clinics between 1 January 2013 and 31 December 2013[5]. The second annual report for incidents reported in 2014 (see annex 4) will be published today.

2.2. In the last year, to promote transparency and information sharing we developed a dedicated governance section on the HFEA website. This section includes links to all published A grade incident investigation reports and the

[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
[4] http://www.hfea.gov.uk/docs/Adverse_incidents_in_fertility_clinics_2010-2012_-_lessons_to_learn.pdf
[5] http://www.hfea.gov.uk/docs/INCIDENTS_REPORT.pdf

accompanying Licence Committee minutes; the risk grading matrix; relevant definitions; and descriptions of the types of incidents that fall into the different incident categories[6].

2.3. Our inspectors have adjusted the focus of inspection to look for evidence that clinics have learnt from incidents rather than focussing on clinics' processes for incident reporting. Moreover, where clinics seem to be struggling to recognise when an incident should be reported to the HFEA the Clinical Governance Lead now provides bespoke incident training sessions to individual clinics.

2.4. Clinics reporting a high number of administration incidents[7] have also been offered further focused assistance by the Clinical Governance Lead. This support has encouraged clinics to carry out in-depth analysis of the causes of incidents (root cause analysis using the "five-why" technique – the subject of a well-attended session at the 2014 HFEA annual conference). This work is in the early stages however one clinic has managed to reduce their administration incidents from nine in 2014 to two this year following a focussed site visit.

2.5. Clinic Focus (the HFEA's monthly e-mail for licensed clinics) is being used as a platform to share ad hoc lessons from incidents (see annex 1) and also to disseminate good practice advice on handling complaints (see annex 3) and learning disseminated by other professional bodies (see annex 2).

2.6. We have also re-developed the patient complaint section of the HFEA website. This section now includes advice on how to make a complaint[8].

3. What we have learnt

3.1. The number of incidents reported in 2014 is not significantly different from previous years. "A" grade incidents usually happen as the result of a unique set of circumstances and are not usually foreseeable but where apparently avoidable low risk incidents (particularly administration incidents leading to breaches in confidentiality) continue to recur we are concerned that clinics' root cause analysis may not be sufficiently robust to identify effective corrective actions. This means that some avoidable incidents may continue to recur.

3.2. The recommendations and "lessons learnt" included in the previously published incident reports may need more time to be absorbed by clinics but one explanation may be that clinics are failing to embed learning as quickly or effectively as we would like.

3.3. Recent discussions with the Patient Safety Investigation Unit at NHS England suggest that this may be reflected across the healthcare sector in general. It is a common observation that corrective actions following incidents tend to impose additional administrative burdens (checking, documenting, double and triple checking) which may be impractical to adhere to and ineffective in

[6] http://www.hfea.gov.uk/6678.html
[7] especially breaches in patient confidentiality
[8] http://www.hfea.gov.uk/1072.html

preventing reoccurrence of incidents. To combat this, we are aiming to encourage clinics to fully engage with incident investigations to identify the root causes and opportunities for improvement rather than blaming "human error". This change in focus aims to encourage and promote the continued establishment of an open and learning culture in HFEA licensed clinics.

3.4. We also aim to keep our own processes under constant review and will aim to establish collaborative working relationships with NHS Improvement[9] to ensure that wider learning from colleagues working in patient safety in a healthcare setting feeds into our own ways of working.

3.5. The Authority is asked to note this report. In summary:

- We are seeking to influence the culture in licensed clinics so they develop an embedded learning and safety culture.
- We are aiming to ensure that our work on incident oversight reads across to our inspection activities.
- We are publishing a national report on incidents in 2014[10] today.

[9] The new jointly-led Monitor and NHS Trust Development Authority will be setting up a new Independent Patient Safety Investigation Service.
[10] See annex 4

Annex 1

Incidents case study: A cautionary tale on the use of benchtop incubators

Our recently published incidents report showed that equipment failure was the most commonly reported type of incident in the 'laboratory incidents' category. In the following case study, a clinic reflects on a major incident that occurred on their premises involving benchtop incubators.

"As embryologists working in the UK, we are lucky to have a legal framework and comprehensive sets of guidelines, regulations and professional standards around which to build our practice. Working in such a carefully controlled environment significantly reduces the risk of incidents, so it is always a major shock when a serious incident occurs. However, as part of the investigative process, it is also important to share any learning points identified.

Our unit has been using a combination of large front loading and benchtop mini-incubators for several years, without any previous significant issues. The benchtop incubators were introduced into practice in 2009 as part of a drive to introduce new technology to improve embryo implantation rates, following publication of the HFEA multiple births minimisation strategy. Benchtop incubators with a minimal chamber volume reportedly allowed better control of temperature (Cook et al, 2002) and better recovery of gas concentration after opening. This was said to lead to an improved and optimal culture environment (Fujiwara et al, 2007) as well as taking a mixed gas feed, enabling the use of low oxygen, which is potentially beneficial during extended culture to the blastocyst stage (Catt et al 2000; Meintjes et al 2009).

An extensive Installation Operational Qualification (IOQ) was carried out in our laboratory and a validation over several months provided confirmatory evidence of potential improved performance compared to the traditional large incubator. The IOQ, however, identified a potential issue with independent monitoring. In the large incubators, because of large chamber size, it was possible to monitor both CO2 and temperature independently, on a 24-hour basis, with an appropriate alarm system to alert on-call staff if either factor strayed outside set limits. In the bench top incubators, it was only possible to monitor temperature, as accurate CO2 probes were too large to fit inside the chamber.

A risk assessment was carried out and as a result, extra checks put in place to counteract this potential risk, such as regular measurement of pH, daily visual checks on the gas supply and the use of pH reference dishes following services and any prolonged period of inactivity.

However, such measures cannot identify problems with CO2 levels which occur outside normal working hours and recently, following a change of the humidification set, the gas supply to the culture chambers failed overnight after two days of working adequately. There had been a leak between the filter set and the gas inlet, probably due to a misthread the connector. As the gas supply to the gas inlet had not failed, the incubator did not go into system alarm and the fault went undetected overnight, causing irreparable damage to the embryos being cultured within. This represented a major incident for the unit and the patients involved.

Small chamber incubators, with or without time lapse, are in very common use throughout the UK and worldwide, but several currently have no capability for independent monitoring, particularly of CO2. Although providing improved overall performance over a number of years, this potential design flaw also poses a risk of which all embryologists should be aware. Due to this incident we have stopped using these particular benchtop incubators for overnight culture of embryos in our unit."

Contingency planning

As part of our commitment to share learning amongst clinics based on actual experience, this month we are looking at an incident around contingency planning. We have asked two centres to offer advice on their learning based on an actual incident and what a good contingency plan should consist of.

The scenario

In this case study ongoing building works at centre A meant that the contingency arrangement with centre B was activated. It became apparent after the arrangement was activated that centre B did not have the same licence as centre A. This effectively meant that centre B was carrying out an activity that they were not licenced to perform.

The learning outcomes

Regularly review arrangements

Contingency planning is normally set out in general terms to ensure that it covers all potential emergencies, in this case, citing the reasons for invoking the contingency arrangement. There may never be a need to invoke the arrangements and therefore they may remain relatively untested until they are required.

It is therefore important to **regularly check and review the contingency plan** for any changes within the clinics which may impact the effectiveness implementing the plan. For example, changes may include modifications to the clinics' licensed activities, changes in embryology methods or changes in capacity.

Have a shared checklist

A clear, shared checklist can help both parties to review the required contingency arrangements and to identify any major differences which would prevent the transfer of some or all patients. Pre-planning and working to a checklist will ensure that the plans can be completed smoothly and efficiently for all parties involved.

In this case where patient transfer was required, speed of response is essential and the checklist can be used to allow the transferring and receiving clinic to review both short and long term requirements.

After an incident the checklist can also assist in the post-transfer review to identify any areas for improvement.

What to include in a checklist

The checklist should be tailored to the specific needs of your clinic. However the following items should be considered:

- Communications with the HFEA informing the respective Inspectors for both clinics. This will ensure that specific guidance can be provided as required.
- Review the treatment licence for both clinics to ensure that there are no gaps.
- Review capacity in both clinics to ensure that the treatments can be safely transferred and accommodated.
- How information will be communicated to patients to minimise any concerns.
- Review if any equipment, consumables or staff to be transferred to receiving clinic.
- Discuss protocols to be followed.

The suggestions listed are intended to act as a guide to help improve or refine your current and we welcome your views in on ways of working that would help your peers.

Annex 2

Off-label use of intralipid infusions

Following concerns from the President of the RCOG about the administration of intralipid infusion to women undergoing IVF and those with a history of recurrent miscarriage, you should pay particular attention to the risks when prescribing the use of medicines off label.

The use of intralipid infusion for these indications represent off-label use of the medicine. Healthcare professionals' responsibilities when prescribing a medicine off-label may be greater than when prescribing a medicine for use within the terms of its licence. If you are prescribing the use of medicines off label you should pay particular attention to the risks which may include: adverse reactions; product quality; discrepant product information or labelling (eg, the patient information leaflet may be inconsistent with the medicine's off-label use). The MHRA provides guidance on off-label use of medicines on its website.

What you should do now

If you are prescribing the use of intralipid infusion off-label you should consider the advice of the President of the RCOG in relation to the evidence base for the use of the medicine in terms of its safety and efficacy.

- Take responsibility for prescribing the medicine and for overseeing the patient's care, including monitoring and follow-up.
- Record the reasons for prescribing this medicine in the patient's records.
- Review the information that you provide to patients to make sure that you explain the reasons for prescribing this medicine off-label where there is little evidence to support its use.
- Document what information has been provided to your patients in the patient's records.

The documentation of your rationale for prescribing intralipid infusion off-label and of the information provide to patients receiving this treatment may be reviewed in the course of your HFEA inspection. This advice should be followed in all cases where you prescribe the use of medicines off-label.

Annex 3

HFEA report on patient complaints

We have carried out a review of patient complaints made to the HFEA about clinics.

Most people undergoing treatment have a positive experience. However when things do go wrong, it is important to deal with such issues in the right way so that the individual can receive justice and the organisation can learn from what went wrong.

We can only consider a complaint that indicates a potential breach of the Act, licence conditions or directions. We expect clinics to take complaints seriously, carry out an investigation into the issues raised, explain what went wrong and offer an apology (when appropriate). We also expect clinics to explain what measures have been taken to put matters right. If you do this well then patients feel they have been listened to and that their concerns have been acknowledged and taken seriously.

During calendar years 2011, 2012 and 2013, the HFEA received 133 queries from patients regarding complaints about clinics. Most complainants had not accessed the clinic's grievance procedure and simply wanted advice on whether or not they had grounds to make a complaint and if so, how to do so.

During the same three-year period, nine queries were investigated further. In seven of these the intervention was minimal and required no further action other than contacting the clinic to chase up the response or to ask the clinic to re-review their complaint response to make it clearer. One complaint resulted in a further investigation by the HFEA and one complaint resulted in a site visit and further investigation.

What bad looks like according to those surveyed:

- No formal acknowledgement of the complaint
- A lack of accuracy in the clinic's response (for example, a letter that contains wrong names or incorrect treatment dates, indicating to the complainant that the clinic has not investigated their complaint seriously).
- Apologies that feel insincere or part of a generic corporate template (for example, a complaint response that begins with "I am sorry that you felt you have cause to complain").
- Responses that ignore specific concerns or do not fully engage with the concerns raised by the complainant.
- A response that contains defensive or legalistic language.
- Late responses or no response at all.

What good looks like according to those surveyed:

- Having access to an 'intermediate' contact – perhaps a general manager – to discuss a concern before submitting a formal complaint.
- A response that addresses the initial complaint directly and accurately.
- A personalised apology.

- The offer of face-to-face meetings with plenty of time to talk through the complaint response in detail.
- A single point of contact to support the complainant and help them understand what they want to achieve through their complaint.
- Clarity at every stage of the complaint process. If a complaint is complex in nature and may take longer than usual to investigate, complainants should be kept up to date with their case.
- A final response that includes the lessons that have been learnt and what steps the clinic will take.
- Staff training on how the complaints system works and how to help patients access it.
- Training and support for staff that have had a complaint upheld about them.

You may want to review your own complaint handling procedures to make sure that this aspect of the service is as good as it can be.

Annex 4

Adverse incidents in fertility clinics: lessons to learn

To follow