

BFS Comments on the publication of HFEA Inspection Reports

In response to the HFEA consultation on the publication of inspection reports, the British Fertility Society undertook a survey of its members. Below are summarised the views on publication. The detailed comments are also included for your information. These have been anonymised.

a. Executive summary

- This report encompasses the responses from 31 Directors of Services / PR's and senior members of the infertility profession (including scientists, clinicians, counsellor and nurses)
- There is a small majority who accept this is inevitable or are positively supportive. There is a significant minority who are completely opposed.
- There are significant concerns about the detail of reports, the publication of minuted dialogue, the factual accuracy and the need for agreement of the text prior to publication.
- There is a clear theme that, if publication is to take place, the public version should be strongly edited and be a "summary" statement
- Several of the respondents suggested that a summary / report to a standard format would be useful e.g. services provided, staff, results, numbers of embryos replaced, audit, complaints etc.
- In line with other organisations reporting adverse events e.g. industry and the NPSA, adverse events should be non attributable.

b. Detailed Comments (non attributable)

Re the clinics - I have never been opposed to making inspection reports public - but after editing.

This was discussed years back at the HFEA and I thought the versions they planned then were OK, but it seems to have taken a while to get round to this.

As a Member of the HFEA I am in the difficult position that I am not able to make external comment on HFEA matters like this. However you may remember that I was concerned that PRs would be made aware as early as possible of the proposal that HFEA inspection reports would be public documents on the web. That is why I raised it at the Aberdeen meeting with senior officers of BFS. I had been keen to highlight the need for PRs to feedback to HFEA when the consultation was planned last summer. I had the impression that many PRs would be anxious about the detail in the draft public report.

This is a worthwhile coordinating initiative from BFS.

You already have my thoughts on the Inspection report. It is primarily for the HFEA Licensing committee and only secondarily for others such as Trusts, General Public and others and their interests are different. They do not need the detail that we believe should be confidential. This can be achieved in two ways;

1 A full report should go to HFEA and certain sections of it should be retained from copies sent to others.

2 A standard report, of a rather general nature and to be discussed by BFS as well as HFEA, goes to everyone and extra *tables* and *appendices* can be produced for HFEA alone such as complaints, minor breaches of the Act, near misses etc

I favour 2 because it would allow continued detailed reporting without press involvement while letting everyone have a common report.

I would be grateful for your comments on the following:

whether you are in favour of publication of reports - [Yes](#)

if yes, to what extent should the report should be made public – [should be available on the internet \(like OFSTED reports\)](#)

if yes, how much detail should the report contain – [should summarise the facilities, staffing levels, success rates \(inc multiple pregnancy rates and numbers of 3 embryo transfers\), risk management arrangements, counselling facilities, which treatments are provided \(inc unlicensed\). Licence conditions could be mentioned, but overall the report should try and remain positive.](#)

[Essentially everything that goes in the current report should be available on the web since anybody can already request a copy of the paper inspection report for any clinic. Consideration should be given to the way information is presented as well as what information is contained. Although I am in favour of openness the report should not include trivial details such as minor recommendations over wording of information leaflets and such like.](#)

Whether you are in favour of publication of reports - no as the HFEA cannot be trusted to get it right - we have experienced this recently. I have absolutely no faith or trust in the HFEA and have seen no improvement.

whether you are in favour of publication of reports: Yes - these should be in the public domain

*to what extent should the report should be made public
Full document would be best. Must ensure avoidance of identifying information on couples - for example in very rare cases people can be identified by the nature of their clinical details. Otherwise it should all go on the Web in an unedited form.*

*if yes, how much detail should the report contain
The report should be highly structured with details of all aspects of the inspection*

additional comments:

This is timely. Transparency is key here. We should have nothing to hide, and the public should be able to access this information. After all, the patients pay for it.

First of all I'll like to support the BFS attempt to scout for opinion in this way.

1. Re HFEA:

It seems to me that the consultation exercise is more in the way of information for us because there are those in HFEA who might strongly believe that patients have a right to this information under Freedom of Informations Act and that this information will be useful for them.

Accepting it therefore as an inevitable outcome I think that it is important to concentrate on ensuring that implications of this change in policy are understood by the profession, the PRs and trusts.

I think those listed below might be a few of the concerns and related questions that we should ask HFEA to respond to :

Right for information has to go hand in hand with the receiver's ability to comprehend, interpret, assess and compare.

If HFEA is going to put some information in public domain what steps is it going to take to ensure that there is sufficient background for the issues for them to be understood in the lay press?

How objective will be the published information?

Have the parameters to be reported been defined?

Are the parameters reported going to be the same for all units?

Who is responsible for defining these parameters? Does BFS or PR body have any role in stating what parameters are suitable and also unsuitable for public domain?

For subjective and objective criticisms, would HFEA also publish the evidence on which this was based and state how this variation has occurred form recommended practice?

There is a high risk that for some units at the receiving end of a negative report, there may be local unrest, patient distress, financial hardship and there may even be retrospective legal actions against PRs and Units.

If any unit or an individual is inappropriately or unfairly represented would HFEA be answerable too?

Has the impact of this to the NHS indemnity costs been assessed?

The inspection process for benefit, one hopes is less confrontational, more professional and positive where everybody starts from the premise that all parties are working to the same goal. HFEA have made improvements in that direction.

How would the threat of inappropriate inspection report affect this process?

HFEA inspectors may become more liable/vulnerable and may be less/more likely to rebound action by units. Are they indemnified?

Do the units (private especially) need indemnity against the impact of an adverse HFEA report?

Personally I am not in favour of making reports public - I appreciate that this is the way things are going, but it is an enormous fuss for very few people actually interested to read them. There is also the difficulty of making them accessible for non-clinical audience.

Whether you are in favour of publication of reports

No. The reports are supposed to guide units and help improve quality. As a public disclosure they risk discrediting the HFEA. Units will not stand by so passively when critical comment is made if it is public criticism. There will be more appeals more conflict and more legal challenges. When the HFEA loses these challenges there will be bids for compensation. Currently the reports are inconsistent, often illogical and invariably subjective. Most of us tolerate the inconsistencies as the general gist of the reports are constructive and helpful and we can use them to improve services. However those inconsistencies will be intolerable in the public domain and will result in conflict. I don't know whose idea this is but it smacks of the same blinkered ideology as the confidentiality issues with donors. I could continue if you want but suspect it's not what you want to hear.

whether you are in favour of publication of reports: Yes

if yes, to what extent should the report should be made public

It should be edited to make it readable by the lay person and should not be made available until the content has been agreed by the Clinic

if yes, how much detail should the report contain:

very little; there can be little interest in the general discussions

additional comments:

The HFEA must take on board that any details enclosed must be verifiable and there must be an independent ombudsman scheme that a clinic can go to if they feel they have been unfairly treated

In answer to your questions:

1a) I am not in favour of reports being made public but feel that it is likely that we will have to bow to the inevitable.

1b) I presume that there can be no restriction on access if the report is to be considered "public". I would however hope that no report is published until the content has been agreed with the unit concerned

1c) I do feel that if we go down this line then the reports should follow a generic format. There has to be concern that constructive criticism would be lost from the process if the HFEA become concerned that they may face legal challenge on the report. If the report is reduced to generalisations or a crude grading system then this will surely reduce the effectiveness of the process. One point I would be most anxious to avoid would be references to named individuals, as has happened to our unit in the past.

At present I am not in favour as there are too many mistakes and problems with inspections that full of opinions rather than facts. Rather than bore you with many details I will give you 2 examples from visits here. We were attacked about a form we use for consent which was a copy of HFEA form by a clinical Inspector! We were also criticised for not having a oxygen monitor when one not only exists but is an seriously expensive kit working well and linked to switch board. Until HFEA standardises their inspection and gets rid off inspectors you do not make the mark (or even know what HFEA provides e.g. forms etc) then we will get very biased forms.

whether you are in favour of publication of reports

If it was in an agreed draft by the clinic and the HFEA.

if yes, to what extent should the report should be made public

Only agreed draft.

In answer to your questions:

1a I am not in favour of report publication.

1b n/a

1c n/a

whether you are in favour of publication of reports - No

Please also provide any additional comments

I think it would be very damaging to units to publish reports as sometimes, recommendations that are fairly minimal may be seen by a member of the public to be much more important. For instance if an inspection team found a mistakes on consent form, this needs a tightening up of the admin system but maybe a one off and yet a comment is still made. This may be seen as quite damaging by a member of the public

In education, league tables never give a true picture and inspection reports may not always reflect fully how well a unit is operating as by definition they really only comment where changes need to be made

I believe that a short summary of the inspection should be publically available, jointly agreed by the HFEA and relevant unit.

whether you are in favour of publication of reports

A concise version should be published i.e. whether the clinic satisfies the requirements.

to what extent should the report should be made public

There is not much consistency with different inspection teams. The reports depend on the HFEA inspectors that you get! It is difficult to envisage a perfect clinic and any negative comments in the published report may damage the reputation of the clinic.

if yes, how much detail should the report contain

I think the HFEA should condense the report into for e.g. IVF -satisfies requirements, concerns rather than a rambling dissertation.

In my opinion the HFEA needs to exercise great care in making inspection reports available to the public. Whilst I am all in favour of openness and transparency I would be concerned that the highly complex nature of the work that we do (particularly in the lab) may be all too easily misunderstood by the public. Particularly where adverse clinical events are concerned etc.

whether you are in favour of publication of reports

Yes

if yes, to what extent should the report should be made public

Made available on clinic and HFEA web sites

how much detail should the report contain

Clinical services offered, sufficient background information to support summaries of main areas inspected, centre's data, any commendations, recommendations or conditions on licence.

whether you are in favour of publication of reports **YES**

to what extent should the report should be made public **The full report**

if yes, how much detail should the report contain **As much as possible**

Re Public access to HFEA inspection reports.

This is a hot topic locally as the HFEA sent me an e-mail through my office at home, with less than 24 hours notice, of their intention to send out a report on our last inspection. The report was inaccurate and included misleading information which suggested we had no accredited scientist in our fertility team. In truth, we had lost our senior scientist in the seminology department of our haematology laboratory and were in the process of reappointing. The report also suggested we had not undertaken an audit of stored sperm within the preceding year, which was untrue. The HFEA had received the report and a further copy within the previous 8 months. Due to staff changes at the Authority they had lost both copies! I then had to locate a further copy of the report and all covering correspondence within 24 hours to prevent them sending out a factually incorrect document. The onus was on me to prove them wrong!

After speaking to our legal department at North Bristol Trust, I advised the HFEA that we would institute legal action against them if the incorrect report was issued. There was no apology from the HFEA but they did not send out the document to the person who had requested it.

In addition to the copy of their proposed "Public Report" the HFEA also sent me minutes of the licence Committee meeting where our licence renewal had been considered. They were also intending to send this out to a member of the public (who could easily have been an investigative journalist as there is no protection against this). This contained a lot of information which had not been passed on to us and had not been included in the information we had received with our draft licence. This included recommendations for review topics at our next inspection which we would otherwise have been totally unaware of.

Whilst I was in favour of openness and public access to inspection reports, this experience has totally changed my view. I believe that no report should be issued without adequate time for the Centre concerned to review the content and agree its accuracy. In the case of a dispute or disagreement I do NOT believe any report should be issued. A minimum of 3 weeks should be allowed for a clinic to comment on any information before it is released. This would allow time if the PR is away on holiday at the time.

Our legal department inform me that the Information Act does not actually come into force until next year. Why are the HFEA so determined to act so far in advance. Does Suzie Leather want to impress someone?

If the Authority are wanting to behave in a dictatorial way on this matter it is inevitable that they will alienate Centres and also run the risk of legal action against themselves. There needs to be more consultation and reassurance that the information they give out will be correct. With those reassurances I would be happy for them to release whatever information they want, including what the inspection team had for lunch!

whether you are in favour of publication of reports

No. But if to be made public then the comments/reply of the centre should be included at the same time.

how much detail should the report contain

All, if centre can also respond.

Please also provide any additional comments

would be keen to know what the consensus response from the BFS is.

a) I think it puts us in a good light if we are at least open about the fact that we do have regular inspections and that the dates of these inspections should be published. Information about patient care is always difficult because even without patient identifying information it might be possible for a well informed outsider to work out the identify of a patient or couple. If details are to be published then we would all want to have editorial control as to what was said. Of course we are very happy to publish favourable comments into eh HFEA but are nervous about any unfavourable comments being published. Some sort of agreed template about the information that is published might be a way around this. I am sure some clinics would want to have Lawyers approve the final working.

b) I am sure the HFEA would want the reports to be freely accessible on the HFEA website, as I am sure their intention is to be as open as possible with the general public.

c) I would be happy for reports to contain details about success rates and include generalised statements about what the HFEA inspectors liked or disliked about a centre. However, I would advise against any comments that referred to specific couples for the reasons mentioned above.

whether you are in favour of publication of reports [Yes](#)

to what extent should the report should be made public [Summary of the report](#)

if yes, how much detail should the report contain

[Including conditions but excluding recommendations](#)

I suspect Richard is focusing on the consultants who have completed the job plan diaries and have thus documented the time they spend. This seems universally to have been much greater than when we estimate how much time we spend doing things, for instance I know one reliable diary showed over 18 hours on PR / clinical director work per week. Averaging over a year I think 8 hours would be conservative estimate, and if less than this I would query if the PR was doing the job properly. I am pretty sure you spend much more than 8 hours per week

Regards,

Publication of reports I am not in favour of, however the politics of the day and "transparency" will ensure that they are. Thus I would make the following recommendations:

1. Each unit be required to produce an annual report to a template agreed between the HFEA, National Patient groups, the DoH and the

Professional Bodies. These reports would be in the public domain and form part of the documentation received by the HFEA for the licensing / renewal process. As they are produced by the individual clinics - they will feel "ownership" and some editorial control.

2. Inspection reports can then very simply focus on:
 - a. Is the clinic compliant
 - b. If not what actions are being taken
 - c. Is the lab accredited (when that inevitably comes into being)
 - d. What conditions are placed on the license

I have absolutely no problems with this. I think we should open ourselves to scrutiny warts and all.

I have no specific objection to the HFEA's proposal to publish reports - providing they use inspection teams whose members do not come from other units. At the present time, the inspection process is flawed because some members of inspection teams have an interest. This cannot be right and until the HFEA provide a fully independent inspection body the whole process is inevitably open to criticism.

Publishing the HFEA inspection report has the potential of being a constructive move provided that the inspection report is made clear, objective and unambiguous. In my opinion it should clearly specify whether there is any breach of the Act (and perhaps the nature of that breach) and whether there is any breach of the Code of practice (and perhaps the nature of that breach).

The area that has the potential of being subjective and may be controversial is whether a unit is following 'suitable practices' as this could be subject to interpretation, bias, and sometimes facilities, resources and other issues that could be beyond the PR power to implement. Additionally, this issue could potentially confuse the public.

The material published in the inspection report should be sensitive to the "media interest" in matters related to IVF and the tendency to sensationalise and jumping into premature conclusions that could be damaging to all involved not least the patients.

Publication is inevitable but summary only. It should be supported in the spirit of openness.

In answer to your questions:

- a. I would be in favour of the publication of reports
- b. I think they should be kept confidential to PR only on a non identifiable basis
- c. An executive summary so that other centre may benefit

CRK/ 15th May 2004