

HFEA
Annual Conference
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Introductory Speech

Paul Corrigan

Facilitator

I. Preamble

The purpose of this day, as you will see and hopefully experience, is intensely interactive. It is trying to get you to think about what you are doing, talk to each other, talk to HFEA staff, and listen to things. Actually doing these interactive days is difficult, we would like to know what it felt like, what you want more of, what you want less of. The reason for this is that most conferences do not work well in terms of interaction. We want to make this work much better.

It is a really interactive day; there will be a lot of questions from us to you. You have a traffic light set of cards, for you to answer questions *en masse*. There will also be interactions where you are asking questions of us. It is important that there will be things that will occur to you during the day, and there are questions cards which can be filled in, and HFEA will get a question to everybody on every question by the end of the month.

Additionally, there is a comments wall outside which will be answered within the same timeframe. There are a series of one-to-one sessions that can be signed up for at the registration desk, there are also stalls, and HFEA staff that can be talked to.

II. Are You Ready?

The slogan of the day is 'are you ready?' a lot of the discussions today will be about the nuts and bolts of being ready for the act, registration and for a whole set of new regulations. More significant than that is something that we can lose the purpose of a lot of what we are about.

We are not simply about regulating people. What we are about is you in this room are responsible for one of the rare occasions in which people can see the way in which science and the application of science can completely transform people's lives. What we are looking at today is the registration of a move forward in the application of that science. It is about the moving forward of what science can do for people in our society. That is a very complex thing, and a lot of people are quite anxious about it. The way society makes the move forward is the thing that the whole of society, as well as people in the room, have to be ready for. The point we have reached in the debate in our society is that we are ready for another step forward, and in a few years time it will be ready for another step forward, because that is the relationship between science and our society in our life.

There is something big and exciting going on, as well as something quite detailed about the nature of regulation.

It is a step change for the whole of our nation, and the whole of our society – not just for people in this room. The way in which the society chooses to deal with that is to have parliament and other organisations regulating it. The ‘are you ready?’ is about the nature of the world out and the world in here.

Are you ready? At the end of the day I am going to ask you the same question.

It looks as if the majority is amber. At the moment we are amber, and the purpose of today is to move that forward a bit. However, a day’s interaction is not going to make an enormous difference, the purpose is not just the day’s interaction, but for you to recognise that those of you that are amber, can talk to the HFEA, find support, ask questions, and move forward.

Keynote Speech

Lisa Jardine

Chair, HFEA

I. Introduction

I was just talking to one of my members, who fortunately is a councillor, because she reminded me that last year on this podium I said that I had not slept all night because I had been so nervous. It is extraordinary as I do an enormous amount of public speaking, this is the only occasion on which I get seriously nervous. I had to tell her that I slept last night, but had the weirdest dream. By the end of today she is going to tell me the deep and sinister meaning behind the dream.

II. The New Regulations

Thank you for coming today, most of you are associate with treatment or clinics. To begin with the important heart of the matter, we at the HFEA we are full of gratitude for your work in the run up to the new legislation. It is absolutely clear to us that the world outside has no conception of what it takes to become ready for the new regulations. I am glad you all put up amber about whether you were ready, because I respected it because we are all at that stage of absolutely being on tenterhooks about the implications. None of us know what is round the corner, in terms of spin-off or was in thrown up unexpectedly by new legislation – however well-intentioned it is. There will be anomalies and curious corners, and we will all have to deal with them.

You in the clinics will have to deal with them on the hoof; you will find a patient in front of you asking a question to which none of us has considered the answer, this means so much respect is due to you, and confidence is so important in this process. This process of life and death between science and society in which you are all engaged. You will have to behave as if it is clear to you what the answer is. Then we will have to unpack the consequences.

I am thanking you in advance of those situations, but I am thanking you enormously for where you have moved in the process of exchange between us at the HFEA and you in the run up to today. Additionally, I hope that you feel, as we were beginning to feel last year; I myself feel with greater confidence this year, that we are in a partnership. I am going to come on to why the world may not think this is a good idea, but I am adamant and passionate about the fact that as regulators in this life or death area, we are not Ofcom or Ofgem. We are not regulating finance, we are regulating life and death.

We have the lives and futures of patients, children and future generations in our hands. We do not regulate by policing, we regulate in partnership. Every time we drive you crazy and ask for some ridiculous form we have invented to cover our backs just remember that we are not trying to drive a wedge between us, we are trying to move the human race forward in the British Isles, in a way that I think we can stand up to the rest of the world and demonstrate that we are uniquely in partnership and competent.

III. News Coverage

1. The Report

We have rarely been out of the news this year. I want to talk about a couple of stories that have been reported for you to see the dilemma or difficulty for us in the press. I was recently asked for an interview for a Radio 4 programme called *The Report*. It went out at the end of August, and was a rapidly put together, low budget BBC programme. When it went out it fired off in all directions under the banner of investigative journalism, but broadly it wagged a stern finger at us for not being tough enough.

A number of issues raised by this programme are relevant to us in this room today – HFEA staff and clinic members. Firstly, the study of IVF and other infertility techniques is of profound interest to many if not all. One of my close friends is an editor of a national newspaper: ‘IVF’ in a story will actually guarantee a certain number of extra sales and hits. While the subject is of profound interest there is widespread ignorance of the science – of the delicacy of clinical practice, the implications for patients. Of what patients go through – as your lay Chair, with a moral agenda, the ignorance of the public at large about this, in terms of invasive techniques and the emotional rollercoaster, the hormonal treatments, the disappointments, the highs and lows, and as we know only one in three will walk away from a clinic with a child in their arms. There is a combination of public fascination with our area, and a plain need for people to be better informed.

2. Arguments

That is what we at the HFEA want to focus on, but the BBC programme focused on why we are not tough enough, that mistakes happen and we do not care, mistakes happen and we do not rap people over the knuckles – which is a very simplistic argument, it was about how the regulation was not closing clinics, stopping treatments, or preventing people from storing. The programme, as ever, triggered an avalanche of press coverage.

There were three arguments. The regulator is not doing enough to prevent human error. The regulator is not tough enough with units where incidents happen, and finally if we were tougher there would be fewer incidents. Each of those arguments is as wrong as it is simplistic. I am prepared to say they are wrong because all the evidence points in the other direction. They are

simplistic because they do not stem from broad analysis of sector experience, but from an under-informed, partisan, knee-jerk response to specific incidents. I write journalism, some people will say 'what do you expect from journalists?' That is not good enough, that is not what respectable journalists do, or how investigative journalism tackles issues.

This morning the investigation of BAE by the SFO has been a media brick on brick on story, where people have lovingly continued to explore the issue; long after the public forgot the headlines which said there was nothing to investigate.

3. The Evidence

In industries where mistakes can have catastrophic consequences it is now clear and evidence-based that threatening punishment has the opposite affect to reducing the number of incidents. It discourages honest examination of mistakes and the looking at near misses. It drives learning underground for all of us. Regulation is not a virility test, it is not a test of how tough we can be. Regulation in this sector lies in creating an environment where failures are not tolerated, but seen as the point from which centres will improve and our methods of regulating will improve also.

I want to hear from you today, if any of you believe that harsher sanctions, more swiftly applied would lead you to improve your services, or more importantly prevent mistakes.

4. Other Observations

The second observation I want to make is that the criticisms from this programme about us not being tough enough largely come from people who have little or no understanding of how regulation in this sector works. In a part of the interview they did not use they asked 'why don't you?' and gave a list of things that we might do. I said 'we can't do that in law, we can only shut the clinic'. That was not a very good start, that all they wanted us to do were things we were not legally allowed to. This included exacting financial penalties.

5. Responsibility

I am a senior academic, a professor, with a strong sense of the responsibilities of wearing that title. I do not use it for my journalism, because you do not have to believe every word I say in journalism – I may be just putting across my opinion. If I put professor in front of my name, I mean it is a kitemark that tells you that I have analysed the problem, looked at the evidence on the issue, and that this is my considered professional opinion. We have, as professors, professional responsibility as sifters and transmitters of reliable information in all areas, and therefore this area in particular. I despair when academics using that title are prepared to voice strong opinions without checking sources, coming to talk to us or see what we do, believing what they are told is true, and taking it on trust on the basis of snippets of press cuttings. In other words without observing the basic protocols for examining data in our profession.

If ever I say anything about this sector, if ever I criticise any of you, and use that title, it will be on the basis of me believing that there is no question that what I am saying is worthy of your serious attention and consideration. Now, you might think I am sounding oversensitive, and perhaps I am, but there is nowhere else I can say this. The decision to air these points was taken by myself and the Chief Executive, because there will be as many under-researched stories going forward as there have been in the past.

IV. Problems of Poor Reporting

As a regulator we expect others to have strong views about our work, and expect others to criticise us. That was one of the things I was asked at my interview for the job, and two year's on I feel I may have been a little light-hearted in my responses. Being able to take it on the chin is part of mine and Alan Doran's jobs. You expect people to criticise you. I welcome the fact that we deal with important and highly-charged issues, but ill-informed and poorly researched journalism misleads all of us, and above all it confuses patients.

An example of this is that the BBC ran a story on its website based on an investigative radio programme about women so desperate to have a baby that they use internet sites to have fresh sperm delivered. There are men, the programme showed, with a titillated interest, who are prepared to supply their own sperm as many times and to as many purchasers as choose to ask. No checks, no tests, just pay money and wait for the postman.

The story was breathtakingly irresponsible, the journalists had made no effort to understand the gravity involved. The risks were either ignored, or shrugged off, it was seen as such interesting story on the self-indulgence of the sperm donors, but nevertheless it was advertising the availability of the service. Getting fresh sperm, from an unknown source, with no reliable way of knowing it was tested or traceable, was described as a harmless, personal choice.

V. New Publication Initiative

The HFEA works hard to explain to the wider public the advantages of regulating access to sperm and eggs for patient safety, an ill-informed, sensationalist story undermines that strategy. The BBC should know better. getting information out there and increasing understanding and awareness is at the top of my agenda for the HFEA, the more understanding there is about what those in clinics do and what we do to monitor and regulate it the better it is for all of us.

Therefore I am now going to make an announcement on a new initiative we, at the HFEA, are taking from today. For some years we have followed the practice of not publishing incident inspection reports or licence committee minutes relating to such reports. There was a good reason for this when it was adopted; we wanted to build trust to assure centres that our aim was to learn and promote higher standards, and we did not want to punish human error. We did not want to alarm or discomfort patients having treatment at particular clinics, for whom this was a statistical relevancy, but which would upset them.

I am convinced we now have a solid foundation, we have laid the groundwork for a culture of learning and improvement, a joined up programme of regulation, the sector is far more mature, and from today we will be transparent about all grade A incidents that occur going forward. Incident inspection reports will be published on our websites, so will the associated licence committee reports. This is part of our drive to ensure greater transparency in our work as regulator.

Since December last year we have introduced a series of measures designed to make more of our work accessible on our website, this was the logical next step, and it is about saying 'yes, this happens, we went in, we all talked about it. We tried to make sure it would never happen again, you can all look at it, and there is nothing here that we need to hide. We do not want to hide it and do not want you to believe that we are hiding it'.

VI. The New Act

The new legislation that came into force today is the single most extensive change in our sector since the legislation of 1991, hence my heartfelt thanks to everyone in this room about the work that has gone in to coming to this day. The new act brings onto the statute books many things that have been a matter of HFEA policy until now. A ban on social sex selection, the licensing of PGD, and of human and mixed embryos for research are all examples of this.

However, more important are the broader social changes that have happened since 1991, and the new act formalises recognises these. I think these will be the changes that you experience in your clinics. In terms of who come to you, what they ask for, and the decisions that you have to make about treatment. This includes the ability for both members of same sex couples to have a recognised legal relationship with their child. The fact that clinics no longer have to consider the child's need for a father as part of welfare of the child assessment, the new rights of access to our register of information for donor conceived people, their parents and donors. Our new ability to release information from the register for studies which researchers have been crying out for.

These will be studies which advance our understanding in this fast-moving, but new area of medicine. Therefore, this is heartfelt, I want to thank the minister, Gillian Merron, on what is a progressive piece of legislation. It recognises that society and the families we form are changing and that patients have different expectations of fertility treatment today. The reason I name the minister is that she and I had conversations at great speed and one-to-one about the cases of transitional arrangements for embryos storage, and she responded along my lines – which would be absolute concern for the patients involved, and clarity of thinking about what it meant for individual human beings.

You already know from last year's speech that Dawn Primarolo and I had a terrific relationship, arms length – if there were another party's minister there I would be more than happy to collaborate with them.

Of course you in the clinics have been dealing with changing attitudes and expectations for years, but the new act means the law has caught up, and that you have had further to modify your processes and practices as a result. We know it has been hard work preparing for the act, we know the requirements of the new act are shortly after the requirements of the European Union tissues and cells directive. It has been a tough couple of years. If there is only one thing you take home from this conference it should be the knowledge that I, all HFEA staff, and all of my members on the authority are grateful for the sheer hard work you have all done to get ready for today. I know that work is not over, that there will be a period of bedding down and getting ready for the provisions; we will continue to help you with that.

VII. What Next?

We are extremely clear that with the rapid pace of change we do not want to introduce anything further unless we have to. We will not be making substantial changes, and I hope you will not have to make substantial changes in your practice for some time to come. Our priority over the next six months – and it could be more like a year – is to help you get used to the new requirements of the act, and settle down, particularly into our new style of inspections. We are very proud of these, and we will be rolling those out.

Looking to the future, the regulation of IVF and embryo testing in the UK is built, as has already been said today, as a compact between science and society. I am an arts/science person, and I think this is the most brilliant place for interaction between arts and sciences. If anybody ever tells you that the arts can solve problems without science, here is a problem where the two together are solving all the problems.

The new act is in effect a reshaping of the compact between science and society, to cope with changes in the science and shifts in public attitudes, as well as actual changes in our social structure. Changes in the nature of the family – these have happened since 1990 and are now recognised in the act. People are much more relaxed about discussing IVF than before, discussions about genetic inheritance are commonplace, our sector is moving forward.

This is something to celebrate, unless you are sitting at dinner, where with my professorial hat on I can tell you that there is not a family in the land that does not have an IVF story in their family history.

VIII. Changes to HFEA Policy

1. Transparency

The authority's top agenda items for the next 18 months, the first is to ensure the new act and guidance are working well, and you will tell us if anything is not clear. We may have to make minor amendments. Secondly transparency about being more open with the information held. Today we open the HFEA register of data, the longest running and most comprehensive set of information about fertility treatment in the world. Donor-conceived people and donors will have new access rights to the information we hold, and in spring 2010 we will be setting up a voluntary sibling contact register to allow donor-conceived adults to trace their siblings on the basis of mutual consent. This will be a significant step in the normalisation of assisted reproduction. It will allow us to talk about these things, and for families to be comfortable, and where donor-conceived people feel easy about their inheritance.

2. Open for Research

From today our register is also increasingly open to researchers, which will mean the practice of clinics and the understanding of the whole process for the public and us at the HFEA will be rapidly improved by the studies based on the data. If we are to make progress in this area we need centres to explain the benefits of that research to patients when they are asked to give consent.

For the counsellors and nurses who will be dealing with forms, it is relevant to the future of the sector that you encourage patients to give their consent to research using their data. It is not part of the priority of getting pregnant, but in the longer term it is vital to clinical success rates. We will be making an anonymised version of our register open to researchers from later this month, and in November we will be publishing a detailed statistical analysis of treatment data for 2006, the first of a regular series we intend going forward. We do not regard openness as coming at the expense of confidentiality, consent is absolutely vital, the penalty for revealing anybody's identity without their consent remains severe, but increased transparency results in real benefits to donor-conceived people, donors, parents, researchers and clinical practice. I hope you will give these initiatives your full support.

3. One at a Time Strategy

As you know we set a target of 24% maximum for multiple births, a requirement that clinics have a minimisation strategy in place by January 2009, I am pleased to say that all clinics have this strategy, and our new 'choose a fertility clinic' website launching today will for the first time place the proportion of single live births in that new context.

Look at the website, there are people in the room who have been working late nights and weekends for months to put the data in a user-friendly format on the web. Now we need to go further, and work with you towards an overall aim of reducing the incidents of multiple births to 10%. Over the next three months we will be analysing the evidence of how our minimisation strategies are working. We aim to announce the next multiple birth target in January 2010, and have it come into force in April.

Any target we, and the stakeholder group, agree on will have at its core a balance between minimising the risk of multiple births, and any impact that might have on the live birth rate. Let us be clear, we can do better than 24%.

4. Donations

Following the removal of donor anonymity in 2005, the HFEA undertook a major policy review of sperm, egg and embryo donation. This was known as the seed review, and its policies were implemented in 2006. Over the coming months we are going to evaluate the success of these policies, we know that some are working well and that some are not. The authority will be setting the broad direction of the review at its next public meeting in Newcastle in December.

IX. Ethical Topics

1. Regulation and Compensation Issues

These issues are payment or compensation for donors, and intergenerational and interfamily donation. We know there are not enough donors, the removal of anonymity may have been part of the story. From a professorial point of view I am not convinced of that, but there can be no going back on that given what we know about the legitimate desire for donor-conceived people to understand their origins. We owe it to the donor-conceived that if they wish they be able, like adopted children, to be able to find out their origins.

Might our particular interpretation of the rules of compensation allowed by the European Union tissue directive play its part? Countries such as Spain reimburse their donors more generously than we do, and they appear to have a greater supply of donor gametes. I do not know whether the two facts are related, what I do know is that we should be talking about this issue.

The new storage regulations brought in by the act will make it much easier for people to store gametes for use across generations. Clinicians have already used gametes across generations, and the ones I spoke to are perfectly relaxed about that. What are the ethical tensions of donations across generations within families? As an historian of the family I am concerned about this, and think it should be talked about.

The authority is uniquely positioned to lead the public conversation, that is one of the reasons we were set up, and I hope that all of you in the sector who deal with these dilemmas regularly, you have the information. I hope you will join in the conversation too.

2. HFEA New Arrivals

We were not sure I would be able to do this today, but I can. I can announce that we have three new members of the HFEA authority as of yesterday night. Firstly, I want to say there are a number of members in the room, the members of the authority are an astonishingly distinguished, experienced and thoughtful group. I have never chaired anything like it; this is the best job I have ever done. They put in enormous amounts of work, and I want you to talk to them, and know that they are not people with axes to grind, they are sincerely struggling with the same issues as you, and are trying to move things forward.

The three new people joining are a clinical embryologist, Dr Alan Thornhill, who works on reproductive biology. Many of you have told us that we needed a clinical embryologist, I am thrilled that he is joining us. Dr Andrew Greenfield is a biologist joining us, he works at Harwell and works on mouse testes. We are looking forward to him joining the research licence committee to help us with difficult scientific decisions. Finally, we have the Reverend Ermal Kirby who is the Chair of the London District Methodist Church. A very distinguished faith member, his job is to replace the former bishop, Richard Harries, Lord Harries, who steps down from the authority in November. Nobody can replace Lord Harries, as anyone who listens to *Thought for the Day* will be clear. I think that if anybody can, Dr Ermal Kirby can.

X. Conclusions

Today is where it all begins: a new act, new code and new compliance cycle are the beginning of a dialogue, not the end. The way we go forward from today will reflect that approach, we have never held an annual conference like this before. It is supposed to make you feel that we are participating together, look at the glamour of the venue – it did not cost a lot for those who are worried. It gives us a sense of excitement, that something special is happening, that we are moving it forward; it is symbolic of our new way of working with you.

We want to be sure that you are ready for this new era, and desperately want to listen to what you have to say. We are going to be listening, you are going to have plenty of opportunities to ask questions. We do not only want praise, we want to know where it looks as if we will have difficulties. You can even vent your spleen on things we have done in the past.

Our breakout sessions will provide you with the opportunity to discuss and take part in the development of policies – which is important for you to see where we are moving forward. I want you to enjoy the day, we are here to talk to you, I am here because I think this is the most important job there is to do at this level, in this country today. I am here to help you improve your sector and for us all to move forward together to do it. Thank you very much.

Interview

Paul Corrigan

We have just heard from Lisa about the importance of this particular day, and how this fits in with quite a large historical set of changes in our society. What happens after today?

Alan Doran, Chief Executive, HFEA

Thank you Paul, I think the first thing to say is that I really do not like toadies, the second is that I agreed with everything Lisa said. What is going to happen during today will help us formulate our answer. What you have just heard from Lisa is important to me, you cannot regulate any sector without knowing what it feels like to be regulated. We will be picking up from you how you feel about us, if you have views on what the HFEA should be doing next today is the day to give us them. We will definitely be following up on this conference in about a fortnight, and will provide the key messages for everybody. Then there is a specific set of changes, you have the most interface with us through the inspections and our visits. We know how grateful you are for these visits.

Over the next six months we will transform that whole set of processes, from the start of the self-assessment questionnaire, through a risk assessment, through the inspection, a new style of inspection report, and a new way of handling licensing – with an executive licensing panel. You will feel the difference in the inspections, and it will feel into the work that Lisa has said the authority will be doing to say to ourselves, ‘is the new act bedding down? Do we have the style of regulation that we want to have?’ They style of regulation that we want to have is relatively simple, we want to be approachable, that you can feel you can engage with us, but we also want you to feel that we are authoritative. I am not promising you that we will always make the decision that you want us to make, but I promise you will understand how and why we make it.

Paul Corrigan

It seems that you are saying that you are looking forward to a very different process of inspection, which sounds as if it contains much more dialogue. How might that happen?

Alan Doran

As we have built up to today, and had consultations, people in centres have said that they feel sometimes we are not consistent when we expect, and sometimes we might even go looking to find fault when there is not much to find. What we are going to do is develop the approach that we have set out, which is based on the assumption that you already wish to show that you comply. We are going to use the inspection as the occasion on which you can demonstrate that you comply. No one, including the HFEA, is incapable of improvement, the reality is that the inspectors will find things. Our members are a joy to work with, and we have a really impressive group of inspectors.

What they see themselves doing is working with you to help improve standards. What we want to do over the next six months is learn, by working and developing the processes – what matters is the outcome, how can we use the regulation that we undertake to help you improve services. That is what we want to do.

Paul Corrigan

It seems that there are two sorts of things going on here, one is that regulation and inspection is looking at the minimum, but equally what you want it to do is actually give advice and discussion about improvement above that.

Alan Doran

Exactly, one of the things that impressed me when I first came to the HFEA was that our new code of practice, the eighth version, which was enforced today is a slimmer volume than the seventh, but it is still weighty. If you want regulation or rules we have got them, but they only take you so far. The key is understanding what is happening in the clinical process and how that might be improved, and understanding what it feels like to be a patient in a particular centre. That is what our inspectors are trying to do, measuring compliance is our term for it. We genuinely believe that centres set out to comply.

If we find that you set out not to comply we will be slightly less cuddly. The basic assumption is that you want to offer the best service you can, and our aim is to work with you to do that. As Paul has said it will vary from centre to centre, but how can we help spread best practice, as well as record breaches and other aspects? It is essential that you know that we are coming to do that. The value that you and patients will get from an inspection visit is if it helps you improve your services.

Paul Corrigan

Thank you Alan, we will come back to these issues throughout the day.

[Video shown]

We are now going to go into the breakout sessions.

[Adjournment]

Feedback from Breakout Sessions

Paul Corrigan

The first thing to say about the sessions you have just been in - and Alan and I are going to talk a bit about them now and some of the feedback - is that everything was being captured by note takers and will be written up and produced as part of a report which will reach you within a couple of weeks. I will give you the date at the very end of the session, so that is the promise of when you are going to receive the break-out sessions. Also, if the notes from the break-out sessions have issues that we are not dealing with in this session, we will get back to you in writing after the end of the session.

It seemed to me, Alan, that one point that I was hearing arise in two or three sessions was a wish, and an anxiety at the same time, about how an organisation which has regulation as part of its core business is also going to be dealing with a second part of its core business, about improving quality above the regulated level. Lots of people said: 'The inspectors and the HFEA are able to see

everybody. We only work on our own. We feel quite isolated. How could you share that with us?' Then, almost in the second paragraph, there was, 'If you share that with us as a piece of extra regulation, we are not sure we want it.' It is, then, about how you do two things and seem to have different things. Your inspectors will have, at the end of a year, a picture which is much bigger than anyone else will have and it is how that is shared in a non-regulatory way.

Alan Doran

The way I think these two dimensions of what we do fit together is that we are first and foremost a regulator, in the sense that the law says there are certain things that you cannot do unless you have a licence. That is first point. The only place you can get a licence is the HFEA. That is the second point. The HFEA is charged to consider the outcome of an inspection before considering your licence application in its licence committee. That is core to what we do.

When Lisa and I say we want to engage and have a dialogue with you, we mean how can we use that function of inspecting you against the standards and requirements that are set out in the code and in the licence conditions and in other places? How can we use those processes in such a way that they do contribute to raising standards? I am not responsible for an individual clinic; just as well for the British public, I think. The Person Responsible (PR) and his or her staff are responsible and they have their personal and professional dedication to those standards.

We want, with you, to better understand how the way we carry out inspections, report on them and engage with you can contribute to raising your standards. We are not going to have a single answer. It is a process of engagement over a process of time. I know from our inspectors, and this may cause a silver tear on one or two cheeks, that they feel as frustrated as you at times by the process they have to follow. They do not see their role as negative; as simply finding out where you are going wrong. They want to contribute to a raising of standards; that is what they believe they are doing. We are under no illusion about where the raising of standards is going to occur and where we are going to find value. It is in individual centres.

However, I accept that, where we pick up patterns or themes, we may not as an HFEA in the past have been particularly good at communicating that, not necessarily with the consequence of 'we have looked at this area of your work and we are setting a new requirement', or 'we are expecting you to do better'. It might be a different kind of dialogue. We need to think through how we can communicate and generalise. No inspection is ever the same in any two places, but how can we generalise those? That is an area, I think, that we need to think through.

Paul Corrigan

This will only work as a genuine shift in a genuine relationship; i.e. on both sides. It seems to me, as you said in the first part of your answer, that the core business of the HFEA and of the inspector is to provide and assure a licence, and to make sure it is there. There is a secondary business which is about advice and best practice. If that is experienced by you as simply laying down more law, it is not going to be at all helpful.

Alan Doran

No.

Paul Corrigan

This may sound like a very odd way of explaining it, but I am working with a lot of other regulators, all of which suffer this problem in a wide variety of different areas where there is a minimum standard and an attempt to improve practice. I have ended up saying you need a different type face: 'This is the way in which we are going to express to you what our minimum standards are in relation to this and is the way in which we are going to express to you something around best standards'. I have referred to it in other ways: you take your tie off when you are doing the second and you keep your jacket on when you are doing the first.

One way or another, we have to recognise that both are a really important part of the relationship, but if clinics feel that, when an inspector comes along and says, 'Look, I have seen this really interesting idea' that it is being enforced, it will not work. This may sound like a very strange sentence, but another point I heard in the group was, 'Would it not be good if the inspectors came around on another occasion, not in their inspector capacity, and just talked about inspection, about what it is like and what happens? How can you prepare us for inspection by walking through it?' There were a number of ideas that arose about that.

Alan Doran

Do any of you think that the HFEA should just, to use an American term, 'butt out' – have nothing to do with quality? That is the first time anybody has ever agreed with me to this extent.

Participant

What about the opposite question: have only to do with quality?

Alan Doran

Starting from there, it does seem to me that, to do our job well and responsibly, we need to take the right kind of interest in quality and be clear about what we can do to contribute to that. In addition to the suggestion you have just floated, Paul, there is also the idea of whether the HFEA should work with the BFS (British Fertility Society) and ACE (Association of Clinical Embryologists), as we have done on multiple births, which is a specific policy area. Should we work with them, or through them, to help them set up, for example, action learning sets on quality across the sector; not HFEA-badged ones, necessarily, but work through and with the professional associations? Where are the ideas? What would you have us do?

Paul Corrigan

In one of the groups I was in, it certainly seemed that people were quite clear that it is the job of the professional associations to really delve into the detail of clinical improvement and improving quality. However, it does seem that the HFEA gathers a lot of experience through its core practice that needs to feed into those discussions. What is the nature of that joint learning? I think the point of action learning sets is that people turn up with a problem from a variety of different settings, and work through what the detail of that problem is over a period of months. I think the HFEA could provide information for that, but the work could be primarily carried out for clinics.

It is very interesting for me, hearing the points raised, because there is a feeling of quite extreme isolation between clinics, some of which was expressed because of the nature of competition. There is an almost inevitable problem about how you cooperate as a competitive sector as well as how you compete. Again, it is interesting how, in other markets in our society, all sorts of organisations have found ways of doing that. In the grocery retail trade, there is enormous conflict and struggle in the media all the time between various supermarkets, but they have a very good trade association, the Institute of Grocers, which improves quality for all of them, and they all give credibility to that, as well as competing. In a market which is competitive, how do you arrive at shared practice?

Alan Doran

Can I ask a question of the majority of you who are in centres? You might not want to see a grown man cry, but I want an honest answer. Do our inspections help you to improve the quality in your unit or centre? Hold up a green or red card; no 'ifs' and 'buts', please.

[Show of cards]

Paul Corrigan

That is a majority green.

Alan Doran

That is a majority green, but a lot of red.

Paul Corrigan

About 60%, 20%, 20%.

Alan Doran

It seems to me that we need, both today and in following up this conference, to ask ourselves that question. There are clearly some of you who are receiving value. We need to capture that and build on it. There are some of you who do not feel that you are receiving value and a contribution to improve quality from your inspections. Again, we need to hear from you. You will have the time during the day. There are lots of HFEA staff here. Please talk to us and let us know. We will set out to try to develop our thinking in this area. That is one aspect. Paul and I have floated some ideas, like working with the professional associations. Do any of you have a really good idea that you are just burning to put your hand up and tell us about and let us hear?

Sam[?]

I am speaking as a PR rather than a member of the authority. I have always considered that inspection helps to improve quality. However, your job is to licence what is possible to licence and important. When you go to the public in your report and judge clinics on their quality as well, and you are not, primarily, a quality inspector, it becomes a very difficult thing for clinics. People who really come and inspect for quality carry out pre-inspection visits. They look at things that need to

be improved and advise people about them, and those people try to improve on them. Then they have the visits. Your inspectors come with dual hats. One of them is to inspect the legal aspects of our activity and the extent to which we are abiding. They also come to improve our quality. For both of them to feature in the same report can be less appropriate. We have to find a way to help that.

Alan Doran

Obviously, there would be quality points coming from an inspection. Are you saying that we separate out much more clearly, as a separate stream of activity, our work with you and others on quality? We do not link it so explicitly with a judgement about compliance - is that the feeling?

Alison[?]

Coming back to your point earlier, Alan, about working with the BFS in particular, I think we have taken a lead in the quality aspect through the BFS. We have worked quite closely with the HFEA. Deborah and I were both on the same table so I think that is quite a good sign. We facilitate the workshops and we do try to focus on the quality aspects through the quality workshops, which has to marry in, a little bit, with the code of practice. I think, from the professional side, we have shown we are willing to go down that route, while keeping it within the professional side as well.

Sam

A quick reply, Alan, to what you said. The answer is: be more interactive. A lot of reports are published with what the inspector wrote rather than the ultimate result of the interactive process. When the public see the report, they see what the inspector thought of the place, not after the interactive process and the improvements and everything else have happened. That has to change.

Alan Doran

I must say, I think that is absolutely right, Sam. There are inspectors in the room and I am sure that they agree that you arrive at the considered judgement that is embodied in an inspection as a result of the process of visiting and inspecting, as well as the discussion that you have with the PR and others about what the inspectors found. We are looking at our processes with precisely that in mind.

One of the points you mentioned certainly arose in a good workshop that I have attended. It is an issue of publication and the kind of environment we are in. Paul knows more about other sectors than I do, but in the health care sector, which is the one we are in, there is intense public interest. There is not only a Freedom of Information Act, which is established as a very real set of legal obligations on us and on others, but there is a growing public expectation, and it is not going to diminish, about transparency, as it is called in the regulation jargon. It is about being open and honest and people being able to see things. That is not going to go away. There is a sense from some that it is so easy for the irresponsible to say 'we are hiding things'. I do not think that we have anything to hide in the sector. You can take it from me that the pressure from parliament and others to be more open is real and palpable, is it not Paul?

Paul Corrigan

Absolutely, and, in a sense, given what we were saying in the first session, that the nature of regulation of this sector is the result of a compact in society between the public, science and all sorts of fears around that, transparency is absolutely essential.

I think the interesting point that I take from what is being said here though is, if the only thing being published is an inspection report, that is the only thing that the public see. It seems to me that not just the HFEA, but also the professional associations, have to find a way of being able to publish other documents that are not simply an inspection report, but keep them separate from that. What comments can be made about best practice in a range of areas that can be published and will say 'this is really good', while ensuring that other documents are being published, apart from just the inspection report?

I think, given the nature of the media that Lisa was talking about, there will be people combing over everything all the time. One of the ways in which we have learnt to not deal with it over the last 10 years is to try to keep things secret. One of the ways of dealing with it is to publish everything, around all sorts of areas, of which the inspection report is a part.

Alan Doran

That is correct.

Paul Corrigan

In fact, then, there is a lot of material out there in the public domain which you can all be very proud of, as well as inspection reports.

Alan Doran

One of the connections I would make is that what is unusual or not typical about the HFEA as a public body, or 'quango', as we are so delightfully and accurately described, is we that quite rightly have a very strong obligation to maintain confidentiality of patient details. In a wider public environment where there is frank mistrust of public bodies anyway, and many voters believe they have to be made to tell you the minimum, we operate, at the same time, with this real issue of patient confidentiality.

One of the senses I have, and I may be wrong, is that I would like to ask you, again, in centres: do you really have the kind of understanding you think you ought to have of public obligations around publishing documents, the Freedom of Information Act and that kind of thing? Should the HFEA do more, simply to inform you about how those expectations are changing and what the very real legal situation is? If you think you understand it, and you could give me a master class, that would be great; hold your green card up. If you think you are not really sure, hold up a red card.

[Show of cards]

Paul Corrigan

That is very significant. If we are right about where we were between 10.00 and 11.00 - that what is going on today with regard to new forms of regulation is part of a compact between the public, parliament, science and society - then public information is as much a part of this whole enterprise as is the whole regulation of it. If we, as an industry - if I can call it that for a moment - regulator, professional associations and clinics are not able to think how we should get this message across, we leave it to the people that Lisa was so delightfully criticising earlier on.

Lisa Jardine

Since so many of you did hold up a red card there, I just have this gut feeling that it is one of the snagging points in terms of the understanding between you and the HFEA. It is worth me just saying with my professorial hat on – that means believe what I say – what the issue is for the HFEA. It is that, as a public body on any given day, and it happens every day, anyone at all in the UK can ask us for information that we hold, as long as it is not confidential to persons and does not identify persons, without even telling us why they want it. Therefore, now it is the blunt instrument of journalism to ask for everything on a particular clinic dating back to 1992.

The only thing we are allowed to say is that the burden of finding the information is too costly and too time consuming but, for the most part, we have to comply. That is because we are a public body. In the private sector you are not bound by the Freedom of Information Act, but any exchanges of any kind you have with us come under freedom of information: any email, document or letter you send us; and, technically, any phone call if there is a record of it. I just want you to understand that.

When we talk about putting more up on the website, much of that has come as a result of internal discussion, not least with our legal advisor, where, since it is going to be freely called for on any day of the week by anybody who wants to know, we feel it may as well go up there. You may feel that we might be over doing it but, believe me, it is better for us and for you to understand that that material is public. We may have conducted it in private but it is public. I happen to be someone who believes in freedom of information. I think we live in a wonderfully advanced democracy where people can have access to information; things are not hidden. This is, however, a huge burden. It is also something that I just feel that you should be aware of because you do not have to respond to those requests yourselves but you are implicated in them by what you have sent to us. I think it is something that we might want to discuss. I have had so much experience of it in the last 18 months. Anybody who wants to come and talk to me about it, I would be very happy to have a dialogue with you.

Paul Corrigan

I think what that means in the forest of red cards, in a sense, is that one of the outcomes of today is that there needs to be a systematic approach to what giving information means to a public body. You need to understand what that Freedom of Information Act means. There is certain information, therefore, which, the moment it crosses the threshold, becomes public. The response of many public bodies to that is that, since it can be made public by someone coming and extracting it from you, and the law is on their side in that, you might as well make it public. What you will see, not just in this field but in all sorts of fields, is much more information being routinely made public.

Part of the compact that you have with the public body is that the public body has no choice over that. I think we all need to be clear about what that is, what it means and where that leaves information.

I think the red cards mean something more than that as well, which is, as an individual set of services, because of competition, it is in your interests to inform the public about your services. As a profession and a set of services, however, I think you need to be much more active in talking to the media about the nature of the services, so that the things that Lisa was talking about at the beginning are not the only things.

When we sit here and watch these videos, they are stunning stories. Your work provides a lot of joy, all the time, in really good stories. The only things that the media portray are problems. That seems to me to suggest that, somehow or other, we are not engaging as we should be here. I think the forest of red cards is something specific about the Freedom of Information Act, but something much more general about how you need to give information to the public.

We are now coming up to lunch. You go into breakout groups again between 14.00 and 15.00, and we come back here at 15.00. Thank you.

[Adjournment]

Feedback from Breakout Sessions, Continued

Paul Corrigan

We are now going to do the feedback from the last two groups, on information and patient feedback, and consent disclosure. As I said this morning, all the feedback on all the groups will be sent to you. One of the interesting discussions that I have had is something that has been happening increasingly in the public sector for the last 15 years or so: organisations that have not had organised patient feedback are now starting to get organised patient feedback. Generally everyone thinks generic feedback is a good thing, but if you criticise the way in which I have done this today, I will be really hurt. Specifically, it is very difficult, but it is still very important. There is no way any industry or service can escape more feedback in the current period of time and the near future.

In other aspects of the health service, there have been all sorts of attempts by the Department of Health (DH) to construct quite heavyweight and clunky websites. There is one called NHS Choices that is worth looking at which contains all sorts of feedback and is very interesting. Much more interesting is to go to a thing called Patient Concern, which is run by a GP in Sheffield, or a website called Iwantgreatcare.com. Those both contain anecdotes from patients; the one in Yorkshire is used by quite a lot of patients, and this week people have gone on a few times and said 'the nurses in my hospital do not smile.' You can ignore that – not very good – or you can think 'What is going on here?' Iwantgreatcare.com is run by young, entrepreneurial doctor and because he has the names of all the doctors in the country – which are public property – it is encouraging people to talk about their doctor.

There is nothing really that is going to stop this. The Chinese government tried to stop the internet and the internet won. What we do need to do is organise it. We need to find a way, both as individual organisations and as a service for the Human Fertilisation and Embryology Authority (HFEA) to organise these relationships so they are really helpful, both for other patients and the

providers. With patient feedback, how do we organise a set of relationships which are organically part of what we do every day? I have worked with people running maternity wards and they ask what patient feedback is; I say 'As people leave, you say "How was it?"' They say 'That sounds quite easy,' and it is quite easy, but you then need to do something with the answer.

I think it is something which quite likely causes a lot of anxiety at a personal level, as well as what it means for the business. Actually, major businesses in almost every area of life have been doing it for some period of time, and improving because of it; Tesco, Marks & Spencer, etc, have built a business on that sort of feedback. It is a difficult time when it is introduced, but we need to find a way of organising and learning from it.

Alan Doran

I would like feedback about the HFEA. No doubt there are some of you only too willing to give it; as Paul says, that applies to us all. I think the really hard part about it is identifying the real lessons; if the nurses are not smiling, what can you do about it? Picking out from what could be quite an undifferentiated set of feedback, where are the three or four things that if we pick them up our centre will raise its standards? For the HFEA, where are the two or three things that if we put a bit of effort in we will get a real payoff? The hard part really is not getting the feedback, because people will give it to you and expect to be able to give it to you. It is assessing, prioritising and making good use of it that is the hard part.

Paul Corrigan

With regard to consent for disclosure for research, the reality is that this whole service and part of the health care industry is constructed because of research at some stage in the past. If people had not given such consent there would probably be some real problems about moving science forward. What is certain is that science will move into the future on the basis of research, so in a sense there is a real self-interest. However, all your services have been founded on a really important principle of confidentiality, and I think that explaining all this to the public is a new set of tasks. It is important to play out the role of research, but the public have a very strong expectation around confidentiality. In the NHS, we have increased the numbers of cancer patients engaged in research enormously in the last few years by explaining the nature of it, but at every stage it is quite tricky, and numbers of people want to opt out.

Alan Doran

Some time ago, I was working at the NHS in Warrington when Frank Dobson was Secretary of State. He had this hare-brained idea that people could have a post card and write in about the three things they would like the NHS to do. We were instructed, as the health authority, to have a consultation about it, to talk to the public. We thought we would be pretty zingy and we went on Wire FM in Warrington to advertise a public meeting, and invited people to come and tell us. We got there, and nobody came. We were just about to close up and a woman came in. I went to chat to her, and she said she was glad we were having the meeting because she wanted to complain about Warrington Hospital.

She had been in the emergency medical admissions ward the previous week; the nurses were all angels and the doctors all looked like George Clooney, and I was beginning to wonder what the problem was. She said she had been there three hours when another person came in, and this person was a gentleman. He had clearly spent a bit of time before admission in the Three Ferrets,

and the natural consequence was that he was getting up and going to the loo. I was still looking for what the point was when she looked me quite fiercely in the eye and said ‘And every time he got up, I could see his bottom.’

To begin with, I thought this was flippant, but I learned that it was not. She had every right to be treated with dignity and respect in that hospital. Finding the pearls in this feedback is the hard part; being willing to listen to it and thinking what it means.

Lisa Jardine

A side of the HFEA that does not concern you but that you have to understand is our concern is the licensing of research. Throughout today, what I have really been feeling – and it is a good feeling – is that much of what most of you do, and we inspect and regulate, is becoming increasingly routine. There are even people who wonder why we are going to go on regulating the routine. The answer is that the creation of life for many people is never routine, so we will go on regulating. However, we will try and find simplified methods for doing it so that we are not taking up inordinate amounts of people’s time when what is being done is increasingly being seen as an ordinary fact of life. While you are not looking, we also regulate areas of embryonic stem cell research which are moving forward at a terrifying pace. We try to keep abreast of the changes, what is going on and what we ought to be paying attention to, but when I have my sleepless nights about the HFEA, it is most often about that work rather than yours. Therefore one of things you have to realise is that though we may seem to be here to keep a check on everything, we will increasingly be looking past you at other areas, as well as the growing field of patient uptake and outcomes.

The two connect up, because I truly believe in scientific progress and research, particularly research into these areas revolving around the creation of life and the curing of terrible diseases that threaten most of us, like Alzheimer’s and Parkinson’s. We will be paying more and more attention to that; you will be part of the whole arena of things that we deal with, but you will be the cosy cousin to some of the work that we are regulating. We have to do those things together; we need to be able to see it in the round. One has a sense that we are only discussing clinics here – is that fair?

Paul Corrigan

Yes – and that leads us into the future.

Alan Doran

Picking up on or two of the themes coming from the sessions today, the first is, there has been a recent and welcome greater willingness on the part of the NHS to fund IVF treatment. Everybody knows what the state of public finances is, and there is understandable concern; also, in relation to a possible consequence that as funding might be more constrained in future than it is now, more people might feel that they need to go abroad. We are in a well-regulated but closely regulated sector in the UK, and some of you know better than I the circumstances in other sectors. There was a real feeling in the sessions we had about patient expectation, that people might place undue reliance on freezing eggs; that although techniques will continue to improve, seeing frozen eggs as a guarantee or insurance itself may not be the best course for individuals.

Who is best placed to help people understand? There is a ‘Tomorrow’s World’ view of the technology; as Lisa says, it does develop at a frightening rate, but nevertheless it is not a perfect answer. Is it part of the HFEA’s role to do that? Is the HFEA competent to do that? That also led

us to a discussion about ‘mission creep;’ has the HFEA allowed a legitimate ability to interpret our role to go a bit too far, so you have maybe a broader and fuzzier role for the HFEA? Should we be more tightly focused on compliance, for example? There seemed to be a thread of issues that you can read into each other for looking forward. Strong, clear views; suggestions from those in the room – what do you think the HFEA should be focusing on over the next 18 months to two years?

[Video shown]

Paul Corrigan

We will now put some questions you have asked to the panel, but we also have microphones in the audience to supplement those, so think of things you’d like to ask the senior management team of the HFEA. After that, I am going to ask you some questions about some scenarios, so we will have questions and answers going both ways.

The first question, from one of the sessions I was in, asks ‘why does the HFEA inspect quality management systems in centres if the centre holds an ISO or equivalent?’

Trish Davies

It is a statutory license condition that every clinic should have a quality management system. It was introduced as part of the European Union Tissues and Cells Directives, and so we have to be satisfied that you have one, that it is effective and that you are following it. Those clinics that do have an ISO system in place should find it even easier to demonstrate compliance with that condition.

Paul Corrigan

That seems to be noting rather than inspecting. ‘Is it there? Yes.’

Trish Davies

We will not just say ‘Is it there?’ We will look at how it is functioning. It has got to be effective.

Participant

With regard to quality management, there were three different tables and we almost all came to one conclusion in that session, which was that it would be 10 times better if the authority develops a quality manual template upon which clinics can work, rather than us going to ISO and to you. In that scenario, you are not inspecting against it, but at least you are providing what you believe is a proper quality system for the sector. The sector can then work around it and you can inspect for it.

Trish Davies

That kind of issue also came up in our discussion on the compliance cycle, and the request that the authority should develop templates. I think there is a dilemma around that; the regulation agenda is about throwing responsibility back to clinics, not being prescriptive, saying ‘you must have one of these and 10 of those,’ so we have to manage the tension between clinics who want us to be prescriptive so they do not have to reinvent the wheel, that they can be confident that what they are

doing is going to meet our expectations, as opposed to us being told that we have to distance ourselves a little bit, throw the responsibility back to clinics and being prepared to let a thousand flowers bloom, if you like. There will be more than one way of operating quality management systems, protocols or whatever. We do not operate your clinics, so there is a tension around that. I think we can work together in various forums, as we are doing around the cost of treatment plans, to look at what we might expect to see and reach some kind of consensus in order to demonstrate compliance with certain requirements.

Participant

We have had a quality system in place since 1992 and the remit is that we are supposed to have one in place. We are externally inspected and have audits twice a year by BSI; I feel the duty of the HFEA is to see that we have got the system in place and trust the external experts we have auditing our system, rather than try and do it themselves.

Alan Doran

We do need to avoid duplication, of having one layer of inspection on top of another. What Trish was saying is that we were trying to design our approach to inspection in such a way as to be more amenable and tailored more to the individual circumstances of clinics. I have a lot of sympathy with your point of view. If you are observing ISO or the BSI, and you can demonstrate it, we should be more than happy not to go into those areas. The system that Trish and her team are working on is to try to refine an approach to inspection that does pick up individual characteristics in centres such as this.

Participant

These external inspectors are experts in that field, whereas the HFEA is not.

Alan Doran

Exactly.

Paul Corrigan

‘Why do we hear about serious grade A incidents months after their occurrence in the popular press, and not by the alert system?’

Alan Doran

This is a really good question, and a really good challenge for the HFEA. I think we do need to look again at our alert system, from the point of view of the discussions we were having this morning, about seeing it not just as a list of things that have gone wrong but as part of a proactive approach to helping share good practice. Trisha’s team is working on exactly that kind of approach. One part of my answer is that I think we can make more use of the alert system. The second part is that when we speak about the Freedom of Information (FOI) Act and the publication of reports, there is no doubt that we do not deserve the suggestion that the sector is burying poor practice, and is not facing up to it. That is not my experience of the sector, and we should have confidence in ourselves. Providing that we manage the investigation of incidents well, working closely with the

units in question, and the unit shows what it has done, as you do, to improve, making known to the public what happened, what the analysis and consequential action was, is part of what we want to do when we work towards publicising these incidents. This is where we need to be: we must not allow ourselves, because it is not true or fair, to be accused of keeping away from the public what they should know about our safety record. We need to be on the front foot on this.

Paul Corrigan

One of the problems is the way in which the media can do things quite immediately, without reference to any evidence. That seems to be against the rather clunky long-term way that we have to deal with things. Does it have to take that long? It is not just in this but in all sorts of areas of public life that those people doing things properly with due process lose out because the speed at which the other side can do things without due process means we are two years later after the fuss has died down.

Trish Davies

To add to that, the issues that were disclosed in the popular press related to witnessing; to my knowledge we have issued three alerts on witnessing over the past few years. One of the things we have to think about is if there is any additional learning that may have come out of particular incidents to add to the alerts already issued. We sometimes get to the point where we think 'How many times do we have to say the same sorts of things to the sector?' What we are looking for is what the new learning that has come out of a particular incident that you need to know about in order to safeguard against something like that happening again.

Alan Doran

Is our alert system more helpful and informative than not?

[Vote]

I am glad I asked that question.

Lisa Jardine

You also have to remember that one of the reasons that you read in the press about things that are happening in a clinic not your own is exactly because we treat that clinic exactly as you would hope we treat you, which is to say that if there is an ongoing investigation, we will not talk to the press. That is tricky, because it means that they can say what they have been told. Since I have been at the HFEA, the incidents that have been in the press are sincerely ones where we have been well on top of it, well down the road on investigations and suddenly a paper says 'the HFEA does not seem to have realised that a baby was nearly born with three heads.' As well as the problem of information dissemination, the other thing to remember is that the popular press loves to be able to say 'Nearly Had an Embryo Put Back in the Wrong Woman,' – the great 'Oh my god!' headline – as we love to refer stories back to ourselves; 'What if it happened to us?' Like everybody else in the public, you read about a grade A alert in the terms it is being produced for the general public, and not in the terms you would expect to see it.

Paul Corrigan

That comes back to the point we were making about speed compared with, say, the oil industry. If something happens in the oil industry there is an immediate investigation.

Participant

My background is in the oil industry, as some of you know, with 16 years in a multinational. If there was a fatality onsite in a subsidiary of a group company, the managing director would be on a plane within 48 hours with an explanation of what had happened and what he was proposing to do about it to the group managing directors, who sit in the head office. This was done not to start a blame game but to actually make sure that lessons were learned as quickly as possible.

Carmel Dodson-Brown

Is the timeframe for investigating and being onsite for a grade A incident as Mark described it? The rest of the timeframe around investigating and the process is in the compliance and enforcement policy, which was authorised in December 2008. The steps are clearly laid out for how long the centre has to respond when they are writing an investigation report, and how long we have to write the report.

Paul Corrigan

How long does that all add up to?

Carmel Dodson-Brown

The centre has 40 working days, and we have 60 working days. If you are looking across the NHS, oil industries and other industries, a root cause analysis of 60 working days is pretty reasonable.

Alan Doran

The total then is 100 working days.

Carmel Dodson-Brown

Not always.

Alan Doran

That is what we allow.

Carmel Dodson-Brown

Yes, depending on the complexity and where you have got to get the information from.

Paul Corrigan

Consent to research – ‘why is the patient’s name useful in any use of data, and what would it be used for?’

Panellist

The patient’s name might not be useful; the key thing is that it is a question of identifiers. It might not be the patient’s name; it could be a date of birth or something else, it will depend on the research. It is nearly always a question of what is called linkage research, so there might some subset of our data linked to a cancer data, say, or some other kind of data set. A researcher will try to take a particular sub-category of people on our data centre, link it to the other data set and see to what extent you can then extrapolate from that linkage. The name is not always useful, but what is useful is any kind of linkage.

It could be used for a whole range of things. IVF is over 30 years old, but we know remarkably little about its long-term effects, whether on the health of the children born or that of the mother. There could be a whole range of really quite useful studies, and we have made this plea about research a number of times. For good or ill, when the first act came in there was, if not a blanket ban, such restrictions on confidentiality that despite sitting on an enormous mountain of data, there was very little that researchers could do with it. The new act changes that quite fundamentally.

Parliament came to a conclusion that, in that balance between the greater benefits that might accrue from greater access to our data and the concerns about confidentiality, with the right kinds of safeguards the benefits outweighed the concerns. The process we are designing, and that DH is still consulting on – we will be going out to consultation on the regulations soon – sets quite a high hurdle to get access to your data, if that is any consolation. The researcher will have to be linked to a recognised institution, they will need ethics committee approval; the application itself will be sent off to the National Information Governance Board (NIGB), who look at a whole raft of other access to medical data and are used to handling that kind of sensitive material. By the time the researcher might actually get access to our data, any particular project will be very tightly circumscribed with a set of rules. They will only get access to the kind of identifiers they might need, not just blanket access, and they will have to use our data set in our offices. We then break the link when they leave, so they leave with data that is properly connected but not necessarily with patient identifiers.

A lot of that sounded like gobbledegook and jargon. What am I trying to say is that the circumstances surrounding this new consent on identifying information will be very rigorous indeed. I think that Parliament took the view that the benefits outweighed any remaining concerns there might be around confidentiality.

Participant

Would you not be able to produce a leaflet along the lines of that answer that we could hand out to patients? It would save us an enormous amount of work.

Panellist

We have got quite a bit of information on the website around this. If, having had a look at that, you do not feel that covers all that, please do say, and we will happily amplify that. I realise that this is a difficult story to tell in a number of respects.

Participant

We can recount that to the patient, but it would be easier if they could read it themselves.

Panellist

I am sure we could do something.

Paul Corrigan

I think the answer to the question is 'yes'.

The next question is 'How are whistleblowers protected in relation to FOI?'

Panellist

We are getting a real concern from you today about the way you deal with requests for information arising from your centres. We deal with each question and request for information on a case-by-case basis. It is our custom and practice, where information is requested that relates to your centre, to contact the PR to give them a copy of the request and ask them if they have any comments about disclosure of that information. The decision on disclosure is ours; we are a public body, and we have to comply with the FOI act. The act provides a number of exceptions; some are absolute exceptions, so the information is not disclosed. Some are qualified exemptions, and that means we have to do a balancing exercise between the public interest in disclosing the information against the interest of the person requesting the information and any other interests.

Whistleblowing is an awkward one. Dealing with the concerns behind the question, if you are a whistle blower and your disclosure is a protected disclosure., that is it falls within criteria set out in the Public Interest Disclosure Act 1998 relating to the information you are disclosing, the reasons that you are disclosing and the reasonableness of your belief, you have a whole set of statutory protections relating to your employment against victimisation and unfair dismissal. Where a whistleblower has contacted us, there are a number of exceptions that might apply, for example data protection relating to the name or address of the whistleblower; where the whistleblower provided information which led to an investigation, there are exemptions under section 31 of the FOI Act, which prohibits disclosure of information related to ongoing investigations.

Difficulties arise after the investigation is concluded, or if a matter has gone to a license committee, after the license committee has made its decision. The learning coming out of the cases from the information tribunal and the information commission's guidance is that the decision whether or not to disclose information is time sensitive. The longer a period of time since the information was provided, the less strong the case for disclosure. We cannot say, hand on heart, that any information you give to us we would not be able to disclose. Certainly, we may not be able to disclose it forever. Obviously, with the caveat that all lawyers use, if you are thinking of making a whistleblowing disclosure, do seek legal advice.

Paul Corrigan

One of the things that I have got out of today is that it is going to be necessary for the HFEA to actually do quite a bit of work with you about FOI, so that we all know what the nature of the disclosure would be on a whole range of different parts of information, of which this is one. Since

information is really one of the main things that flows between your organisations and the HFEA, actually the nature of that disclosure needs some quite good guidance.

Unless there are any more questions from the floor, it is now questions to the floor. This is to test your knowledge, but it is not about how well you do. We have a series of scenarios, and the answers are green, amber and red.

‘You are about to have a consultation with a married couple who wish to enter a surrogacy arrangement with a surrogate who is herself married. They are planning to use their own eggs and sperm. Will the couple automatically be the legal parents of the child when it is born?’

The answers are ‘No, but the man will be; No, neither of them will be; No, but the woman will be.’
Red, amber, green.

[Vote]

We have got a majority of ambers and a few more reds than greens. The answer is ‘amber’, neither of them would be, they would need to apply for a parenting order. There is an additional activity they need to engage in. Again, the purpose of this is to show that there are new sets of arrangements that you will have to get used to, and as we have said throughout the day, if in doubt, ask the HFEA.

The second scenario: ‘Mr and Mrs Cartwright are treated in November 2009 because Mr Cartwright is prematurely infertile. He consents to surplus embryos being stored up for up to 55 years, and, in the event of his death, to the continued storage of the embryos and the use of them in the treatment of his wife. The embryos have been in storage for 19 years; Mr Cartwright has died, and his wife wishes to extend the storage for a further 10 years so that she may use the embryos in the future. Can the storage be extended?’

‘No; yes, for a further 10 years, up to 55 years in total; yes, until Mrs Cartwright is 55.’

[Vote]

That is quite mixed; mostly amber, and more green than red.

It is green, and the answer is because Mrs Cartwright is not prematurely infertile.

There seems to be some disagreement here – Juliet, can you explain the answer, please?

Juliet Tizzard

In order to qualify for extended storage under the 2009 regulations, the person who provided the gametes, or the person to whom those gametes have been allocated, needs to pass the test, which is that they are prematurely infertile. Because by implication Mrs Cartwright is not prematurely infertile – it was him that had been the cause of the treatment in the first place – and because those gametes have been allocated to her because of his death, she is not able to extend those gametes any further.

Paul Corrigan

I think the answer is that there is no evidence that she is, so using that as a reason, there is no evidence there that you could use that as a reason.

Scenario three. 'You are talking with a lesbian couple who are civil partners about the implications of their treatment. How can they both become legal parents?'

'They both need to fill in consent to parenthood forms; the law makes them legal parents automatically, though it is advisable for the person not receiving treatment to complete a parenthood consent form; they cannot both be legal parents.' Green, amber, red.

[Vote]

Again, quite a mixture, but the majority amber. Amber was correct: the law makes them legal parents automatically, though it is advisable for the person not receiving treatment to complete a parenthood consent form.

This is the last scenario. 'A married couple received treatment together in November 2009 and consent to the storage of their surplus embryos. In April 2019 the wife writes to your centre to withdraw her consent to storage. You contact the husband but he would like to keep the embryos in storage. How long does the couple have to resolve their dispute before the embryos must be destroyed?'

'12 months; now; or five months.'

We have got a complete majority for 12 months. Oh dear. Since they got it wrong, they are going to need another explanation.

Juliet Tizzard

The correct answer is five months, because there is a new provision that came into force today, whereby a couple who have embryos in storage where one member of that couple withdraws their consent to storage and there is therefore disagreement between them have a 12-month period within which those embryos can continue to be stored in the hope that they will resolve their dispute. If they have not, those embryos have to be destroyed after the 12 months. However, those 12 months cannot be used to extend the statutory storage period within which they were stored originally. It is a trick question, sorry. They can continue to be stored as apart of the cooling off period, but only until the original storage period has expired. Then they cannot be stored for any longer.

Paul Corrigan

Are there any questions arising from that? These are genuine issues, not meant to just trick you. The whole point of today is about asking for support and assistance, and this is to try to replicate that.

[Video]

Closing

Paul Corrigan

Going back to the first question, we asked this morning 'are you ready?', and we are going to ask you again now: how ready are you now? Green for ready, amber for not so sure and red for not ready.

There seems to be slightly more amber than there was this morning, but some enthusiastically waved greens. I think what is interesting about days like this is that in truth what happens is you know there is always more to know; a day like today increases the amount that you know there is to know. I hope it also increase the fact that there are people who can help you do that knowing, and that you do not confront this amber feeling on your own. It is the job of the HFEA not just to help you out but to increase and complete that knowledge.

To reiterate something I said at the start, it has only been one day. All of this will be on the web, if you want to look at it or get your staff to look at it, and by the end of the month there will be a response to every single question that has been asked. It sounds like a cliché, but although we are coming to the end of a day, it is actually the start of a process of learning and developing. If you feel you are in an amber condition, that is understandable given the amount we have talked about.

Lisa Jardine

I love this job. It makes my Chief Executive laugh that I say that, but the reason I say that to you in this room, who work in clinics, is that I actually know that you all love yours. One of the things about being in this sector is that what you do is strive to give joy to people who are in despair, not to put too strong a point on it. We have our ups and downs, of course, but it is an extraordinary scenario in which to work. I do believe that as a regulator we are striving for a kind of relationship with you that will allow us all to do our best in this extraordinary field, which will allow us to do our best for the patients, the children produced in treatment and all those who surround them. I think it's a very special job, I love it and I am proud to do it.

However, Josephine Quintavalle said to me earlier 'You know, you have got a job to do as the regulator. I am worried you are getting too friendly, that you are not tough enough.' My very last word to you, therefore, is that we are all grown ups here together. We are tough. You know very well that if anything were to happen in your clinic deliberately, if there were any flouting of regulations, if any illegal matter happened, we would be there. It would not take us 100 days to be there. We would exact the penalties we are allowed to exact by law. You need to know that, we need to know that, because that is what makes us able to operate the way we really do all the rest of the time; we try to guard against mistakes, we hope that patients will leave the clinics happy, we hope that licenses will be awarded speedily, and that our paperwork will be as good as yours. We all work on that assumption, and we all work on it together. I hope that by the time we all come together next year, we will all be able to say that in this era of real new legislation, with the field becoming ever more interesting and exciting, we are moving on together and remain in that partnership that I strive for. Thank you very much.