## Strategic delivery:
- ☒ Setting standards
- ☒ Increasing and informing choice
- ☒ Demonstrating efficiency, economy and value

## Details:

<table>
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<th>Meeting Authority</th>
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<td>Agenda item</td>
<td>8</td>
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<tr>
<td>Paper number</td>
<td>HFEA (14/09/2016) 808</td>
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<tr>
<td>Meeting date</td>
<td>14 September 2016</td>
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</table>
| Author            | Paula Robinson, Head of Business Planning  
|                   | Juliet Tizzard, Director of Strategy and Corporate Affairs |

## Output:

<table>
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<tr>
<th>For information or decision?</th>
<th>For decision</th>
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<tr>
<td>Recommendation</td>
<td>To approve the outline strategy, prior to discussion with stakeholders in the autumn.</td>
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<td>Resource implications</td>
<td>Within budget.</td>
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<td>Implementation date</td>
<td>1 April 2017 onwards</td>
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<tr>
<td>Communication(s)</td>
<td>Publication on website.</td>
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| Organisational risk          | ☐ Low  
|                              | ☒ Medium  
|                              | ☐ High |
| Annexes                      | A: Draft Strategy 2017-20 |
1. **Background**

1.1. Earlier this year, the Authority started to consider the next phase of its strategy, which will run from 2017 to 2020. We have prepared an early outline of the strategy (annex A), informed by workshops and discussions with Authority members and staff. This paper presents a draft strategy to be opened up for feedback and comments during the autumn.

1.2. Our existing strategy – the first for some years – has brought us a long way towards achieving our vision of high quality care for everyone affected by assisted reproduction. By April 2017, we will have a promising range of assets and capabilities at our disposal, some of them new:

- Good stakeholder networks and more patient input
- A good understanding of what various users want and need
- New information for patients, published primarily through our website
- A redesigned Choose a Fertility Clinic service, making clear to patients what high quality means in a clinic
- A new Register database, enabling greater analysis
- A new clinic portal and data submission system
- An established process for assessing the safety and efficacy of existing and new treatments
- Effective regulatory tools (Code of Practice, inspection approaches) and methods for helping the sector learn and improve
- Inspection and monitoring information about clinics, and potential to analyse this more deeply
- A warmer tone and refreshed brand
- New communications strategy incorporating social media
- The funding we need to operate
- A dedicated and talented workforce.

1.3. These assets put us in a great position to take the next step in our ambitions for high quality care. We will need to develop new approaches and processes in the next three years. But what we have done in 2014-17 will enable us to work with patients and with clinics to improve services and, crucially, the experience of care.

2. **Strategy 2017-2020**

2.1. At the centre of the new strategy is our ongoing vision for high quality care for everyone affected by assisted reproduction. Based on our research during the current strategy, we have identified stages along the patient and donor pathway and set out their needs at each stage. We have also developed three
main areas of strategic focus, based on the ‘quality’ diagram discussed in earlier workshops:

- Consistent support and outcomes for patients
- Safe, ethical, effective, proven treatment
- Improving standards through intelligence.

**Audience**

2.2. Based on earlier discussions, we have focused on existing and prospective patients, donors and donor conceived people. Although we also want to reach the general public (and future fertility patients and donors), there is still much to do with ‘our’ public, so our strategic aims and benefits start with our main audiences.

**Donor conception**

2.3. We have situated our ambitions for donor conception patients and for donors within the strands of the strategy relating to support throughout treatment, good experience of care and evidence-based, effective treatments. This will enable us to stay focused on high quality care for everyone.

2.4. When we started work on our donation strategy back in 2012, we needed a separate campaign (which became known as Lifecycle) because we were seeking to reach new audiences (such as those thinking about going abroad for treatment). However, with our new website and tone of voice, and a willingness to reach that wider patient audience, there is much less justification for a dedicated donation campaign and the resources to support it.

2.5. Re-registration of donors is an important area, and an option that we will highlight on our website and through other channels. Doing more on improving re-registration rates, such as reaching past donors who have moved on and no longer follow the fertility sector, would require a sustained effort with significant advertising and PR costs (£50,000 plus), and we have therefore decided this would not be practical, for resource reasons.

**Our own role**

2.6. As a regulator, our role should be both to raise the bar and to push the bar for clinics. We can raise the bar by driving up sector standards to encourage greater consistency and excellence between and within clinics, being directive and challenging when it is necessary and proportionate to do so. We will also sometimes need to push the bar, setting new standards and expectations where there were none before.

3. **Engagement and next steps**

3.1. When we developed our current strategy, we put it out to consultation. Given that the Authority has decided to retain the vision for the next phase of the
strategy and that it builds on what we have achieved so far, we don’t think there is a need to have such a wide consultation and research exercise this time.

3.2. Instead, we will discuss the developing new strategy with stakeholders at meetings in the autumn and winter, and we will continue the strategy conversation with staff. We also plan to arrange some focus groups with patients in the winter.

3.3. In November, we will bring you the feedback gathered so far, for discussion. This will help us to shape a final draft, ready for sign off at the January Authority meeting. We will also bring a draft business plan for 2017-18 and an outline of the work for the following two years.

3.4. Our plan is to publish the strategy on 1 April, with a launch slightly earlier at our annual conference. It is anticipated that we will be able to make the finished document shorter and more concise than the attached annex, once we have obtained the stakeholder input, in keeping with the general design of the current strategy.

4. Questions for the Authority

4.1. We are not, at this stage, asking members to sign off a final strategy. Rather, we are asking that you approve it as a draft outline strategy that we can discuss with stakeholders during the autumn.

4.2. At this stage, we would, in particular, welcome thoughts on the following areas:

- Do you think we have taken the right approach in setting the strategy around the different needs of patients and donors through the various stages of treatment and donation?
- Do you think we have taken the right approach around data and embryo research? Should we be focusing on facilitating patient choice in this area or promoting research and innovation and increasing consent rates?
- Are you happy with our approach of including donor conception issues in all fertility treatment? And do you agree that the Lifecycle campaign should come to an end (bearing in mind that we will of course continue to use the good work that the campaign has produced)?
Annex A: Draft strategy 2017-20

Our vision

In 2017-2020 we will retain the same strong vision:

High quality care for everyone affected by assisted reproduction

Our strategy over the past three years has focused on developing new information systems and services to further our vision for high quality care. We now have:

- New information for patients and donors to help them understand their options, research treatments and find the clinic that is best for them
- Easy-to-understand measures of quality in clinic services
- A patient ratings system for clinics, encouraging better support through treatment
- A new, simpler data submission and clinic performance system, allowing clinics better oversight of their data and their outcomes
- A new HFEA register of treatments, enabling better analysis of treatments, outcomes and trends in clinical practice.

Through our 2017-2020 strategy, we will capitalise on these new services to reap the benefits for patients, donors and for clinics. We will make sure that patients get access to the right information, at each stage of their fertility journey and that they have a good experience of treatment, whatever the outcome. And we want to ensure that the clinical service they receive is consistent, evidence based, effective and represents good value for money. Our role as the regulator is to drive up sector standards, identifying areas that require some improvement, drawing on our data and our regulatory intelligence.

The following drivers inform our new strategy:

- Although standards have improved over recent years, clinics still need to be more consistent within the areas they offer, and to improve in some particular areas of service, for example consent taking and support for patients and donors.
- Not all treatments offered are safe, effective, ethical and proven.
- Patients sometimes struggle to find accurate, good quality information, at various points in their research and treatment.
- The improvements we have made to our data systems and information services make it possible for us to do more to meet patients’ needs and to focus on areas for improvement in clinics.

What do we want for patients, donors and donor-conceived people?

Patients, donors and donor-conceived people are at the heart of our strategy, and our work. Having completed extensive user research with our audiences whilst developing our new services, we know that patients and donors go through a number of stages in their journey through fertility services, and
may interact with us, as well as with clinics, at each stage. In deciding what objectives and actions will improve the quality of care, we will focus on the varying needs people have as they go through each stage.

**Early research on fertility and IVF or donation**

Prospective patients and donors, and their partners/families, need to be able to find information to help them understand their options, where to go for further advice and what steps to take next.

**Our goals:**

- Those in need of information can easily find and use our website, can learn about us and our role, and can readily find information that is useful and relevant and that informs their next steps.
- Prospective patients realise that they should seek an assessment and diagnosis first, before commencing IVF or other treatment (in case this is not the right option for them), and feel equipped to obtain this assessment.
- Patients start treatment with a realistic idea of their chances of success.

**Contact with a clinic and making initial treatment or donation decisions**

People who have decided that they will seek treatment (or become a donor) and have contacted a clinic, need more detailed information to help them make choices and be prepared for treatment or donation.

**Our goals:**

- When patients or donors first walk into a clinic, they know what they should expect, what questions to ask, and what initial decisions they may need to make. They feel prepared and are able to get more out of the initial conversation as a result.
- Patients know that whichever clinic they go to, it will be well-regulated, safe, appropriately licensed and working constructively with its regulator to address any problems.
- Patients understand in advance what the price of a treatment at a given clinic will be, and whether or not they can get any NHS funding.
- Patients understand the risks of having a multiple birth and the advantages of having a single embryo transfer if possible, subject to individual considerations with their doctor.

**Having treatment or being a donor**

People who are in treatment, or are donating, need a deeper understanding of particular topics (eg, additional treatments they are offered, consent, donating spare embryos) and need good support through treatment to know how to ask a question or raise an issue regarding their care.

**Our goals:**

- Patients and donors have a consistently positive and safe experience of care, including properly taken consents (eg, for treatment, legal parenthood, storage of gametes or embryos, use of data for research) and experience wrap-around support from the clinic at all stages, regardless of outcome.
- Patients (and also clinicians, researchers and others) turn first to the HFEA for a clear, unbiased and authoritative explanation of scientific developments and current treatment types, and can clearly see whether or not there is established evidence of the efficacy and safety of a given treatment.
- People are able to make informed choices and challenge or question if they are offered an unproven treatment.
- Patients know that they can take part in research (whether embryo research or research using their data) what they need to consider before doing so and how it might benefit future patients.

**Treatment / donation outcomes and longer term needs**

People who have completed at least one treatment cycle, whether successful or not, or who have donated, may require further information, emotional support, and in the event of an unsuccessful outcome they will have ‘what next’ questions and decisions to make.

**Our goals:**

- At the end of their treatment, patients will have paid what they expected to pay.
- Regardless of the outcome of their treatment, but especially if it was unsuccessful, patients know they should expect appropriate care and support from the clinic beyond their final treatment cycle.
- Donors, parents and donor-conceived people understand how and where their information has been stored, the responsibilities of the clinic and the HFEA, what their rights are, and how to apply to access information from the Register.
- Patients, donors and donor-conceived people can have confidence that their clinic has fully understood the importance of their life-long role as an information guardian and information provider, and that the clinic staff are rigorous in meeting their responsibilities through excellent and timely records management and data submission practices to the HFEA Register.
Elements of quality

Based first and foremost on the above patient-focused considerations, this diagram summarises the issues that we believe our new strategy should include in order to achieve our quality goals.
### Consistent support and outcomes for patients and donors

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<th>Patient needs</th>
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<th>How should we approach this?</th>
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| **Effective treatment**  | Birth rates are, and will remain, an obvious prime concern for patients. Our aim should be to increase birth rates if this is possible, and to ensure that other outcomes (including multiple births) are addressed within our thinking. Using the new data presentation on our website as the starting point, we will work with our professional stakeholders to uncover, with the help of our data, any areas where there is scope for improving success rates further without driving up multiple births or having any other adverse effects. | Making headway in this area will be challenging, and will require a lot of thought, including consideration of the various available statistics and their meaning. Our main tactics will be:  
  - Look at this topic afresh, and with the help of our professional stakeholders.  
  - More sector-wide analysis, such as the impact of emerging treatments on birth rates.  
  - Analysing and exploring the data for different factors such as patient age.  
  - Identify areas where there is genuine scope to improve success rates and make them more consistent without driving up multiple births.  
  - By publishing open and transparent comparative information, empower patients to drive clinic improvements - to the extent that these are needed/possible. | Patients start treatment with a realistic idea of their chances of success.  
Patients understand the risks of having a multiple birth and the advantages of having a single embryo transfer if possible, subject to individual considerations with their doctor.  
Measures:  
To be able to define success and what affects it.  
To have reconfigured the debate about ‘success’ according to our new understanding of it, including multiple births.  
To be able to actively promote a set of substantiated success factors. |
| **Value for money**       | Patients often raise concerns about the cost of treatment. We would like to see informed and discerning patients, expecting the price quoted to be the price paid, and for these charges to represent good value in return | A benchmarking exercise for treatment costs in IVF is underway and this will provide some initial transparency as a starting point. Our main tactics will be: | Patients understand in advance what the price of a treatment at a given clinic will be, and whether or not they can get any NHS funding.  
At the end of their treatment, patients will have paid what they expected to pay. |
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<td><strong>for effective and proven treatments and services.</strong>&lt;br&gt;Patients should be able to compare treatment costs and payment packages with each other and between clinics, equipped with more knowledge about each of the things they might be charged for, so that people are able to negotiate or shop around. NHS commissioners should pay a fair price for fertility services.</td>
<td>- To examine the benchmarking report when it is available, and consider how we can use the information.&lt;br&gt;- To encourage further feedback from patients, especially on aspects that are common sources of concern.&lt;br&gt;- To get feedback from patients through our website as to whether they paid what they expected to pay at the outset.</td>
<td>Measures:&lt;br&gt;Patients question costs more often and behave more like consumers when discussing prices with clinics. (Survey and analysis of website feedback.) Ultimately, less variation in the price of treatment (through specific research to see whether or not this is the case).</td>
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<td><strong>Good access (to treatment and to donation)</strong>&lt;br&gt;Although the position is better in Scotland than in the rest of the UK, access to NHS cycles and to treatment using donated gametes (particularly sperm) remains inconsistent and problematic for many people seeking treatment. NHS provision is in some difficulty in places.&lt;br&gt;There is fairly good availability of donor eggs, but much less availability of donor sperm.&lt;br&gt;We also believe access to sperm donation could be improved.</td>
<td>Our main tactics will be:&lt;br&gt;- To inform those thinking about going abroad for treatment how they might get access at home.&lt;br&gt;- To encourage more and better support for people going through the donation process (both patients and donors).&lt;br&gt;- To get relevant information to the right patients, promoting it through the right channels.&lt;br&gt;- To work with clinics, sperm banks and voluntary organisations to improve the availability of donor sperm.</td>
<td>Those in need of information can easily find and use our website, can learn about us and our role, and can readily find information that is useful and relevant and that informs their next steps.&lt;br&gt;Measures:&lt;br&gt;People understand the process and the hurdles, and are prepared for treatment (measured through patient/donor surveys).&lt;br&gt;An increase in UK-based sperm donation.</td>
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| **Well supported throughout treatment**<br>We want to see more support by clinics for patients, particularly those whose treatment is unsuccessful.<br>We believe there is insufficient support and care by clinics, particularly after | Our main tactics will be:<br>- To define and promote best practice to clinics, above and beyond offering counselling, working with professional stakeholders. | Prospective patients realise that they should seek an assessment and diagnosis first, before commencing IVF or other treatment (in case this is
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| unsuccessful treatment, when patients tell us that the final bill is also the final contact from the clinic. We also believe that ‘support’ includes facilitating easy access to high quality counselling, making time to explain treatment recommendations and other advice in depth, or helping people to understand consent requirements, storage limits, data held and its future importance, depending on the patient’s needs and situation. People’s emotional experience of care in clinics can be improved. We could help clinics to recognise what should constitute best practice in this area. Donors need better support in preparation for donation and in giving information about themselves to be share with donor conception parents and donor-conceived children. | • To ensure best practice is applied to donors and donor-conceived people as well as to patients.  
• To be clear with clinics that good support includes both post-treatment care and information for donor conceived people in the future; and that ‘treatment’ has a much longer duration and impact than just the clinical period of time when a patient is attempting to get pregnant.  
• To highlight and promote particular issues we believe are relevant.  
• To make excellent support for patients a core message.  
• To continue to focus on this – including at inspection. | not the right option for them), and feel equipped to obtain this assessment.  
Patients and donors have a consistently positive and safe experience of care, including properly taken consents (eg, for treatment, legal parenthood, storage of gametes or embryos, use of data for research) and experience wrap-around support from the clinic at all stages, regardless of outcome.  
When patients or donors first walk into a clinic, they know what they should expect, what questions to ask, and what initial decisions they may need to make. They feel prepared and are able to get more out of the initial conversation as a result.  
Regardless of the outcome of their treatment, but especially if it was unsuccessful, patients know they should expect appropriate care and support from the clinic beyond their final treatment cycle.  
Measure:  
Patient and donor feedback through website and surveys.  
Inspection focus (once best practice is agreed and shared), with tracking of findings over time (including patient feedback obtained on or before inspection) to see if support is improving. |
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<td>Safe, regulated care, with consistent standards</td>
<td>We want patients to be offered high quality treatment at the right stage in their pathway. This includes advising patients on initial contact about the need to seek an assessment and diagnosis before setting out on a particular course of action. Our inspection regime ensures continuous good regulation, but we know that there is still scope for improvement in clinics in a number of areas, particularly consent. We want to encourage an increase in the quality and consistency of the service provided between inspections. We will have easier access to a range of data following IfQ, some of which will prospectively enable us to make more targeted regulatory interventions and provide more frequent information to clinics on some aspects of their compliance (such as timely data submission to the HFEA).</td>
<td>In recent years, we have worked hard to become more consistent, clearer and more transparent in our regulatory approach. We include success rates, multiple births data and information about incidents and alerts in our inspection reports. However, multiple non-compliances are still too common on inspection. Our main tactics will be: - To develop a more strategic view of how much a clinic needs to do to meet (or get up to) key performance benchmarks. - To work out constructive ways of using our data and the skills of our inspectorate to help clinics to be more compliant, more of the time. - To persuade, encourage, and regulate clinics in the interests of consistency.</td>
<td>Patients know that whichever clinic they go to, it will be well-regulated, safe, appropriately licensed, and working constructively with its regulator to address any problems. Measures: Reduction in average/median number of critical, major and other compliances, over time. Reduction in number of clinic incidents over time, owing to increased compliance.</td>
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### Safe, ethical, effective, proven treatment

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| New and emerging treatments/developments | Scientific stories are frequently poorly reported or sensationalised, giving patients and others an incorrect impression of what is possible and what the evidence is saying. The evidence itself (published research) is written by expert scientists and is often not readily available outside academia, or an accessible read for those without scientific training. We want to increase patients’ insight into subjects they may be researching, like potential new treatments, and we want to ensure they do not have unrealistic expectations about these. We want to ensure that patients have the right treatment for them, at the right time (i.e., they are not offered IVF too soon and they are not offered more high-tech interventions than they need). We also want to ensure that when patients are offered treatment ‘add-ons’, they can obtain information as to the efficacy and safety of such treatments, which will normally have an associated additional cost. | Our new website has clear and impartial material to help patients and others make sense of complex scientific information. We also have a respected scientific committee to assess the evidence and to help develop information on established and emerging treatments. We are able to monitor outcome data on existing treatments. To gain further traction on this issue, our main tactics will be:  
- To be an up to date information provider, with regularly updated accessible factual information about new and emerging topics (e.g., gene editing in research).  
- To refine the statistical and scientific data we present so that it is as easy as possible to understand.  
- To establish a myth-busting or rapid intervention function within the HFEA to correct misperceptions or incorrect reporting.  
- To use our channels including social media to inform patients and the wider public.  
- To define for clinics, in guidance, what good quality treatment is – what works, what doesn’t. | Patients (and also clinicians, researchers and others) turn first to the HFEA for a clear, unbiased and authoritative explanation of scientific developments and current treatment types, and can clearly see whether or not there is established evidence of the efficacy and safety of a given treatment. People are able to make informed choices and challenge or question if they are offered an unproven treatment. Measures:  
Surveying patients to check that they can find and understand the written information we provide, and that they can make intelligent choices or challenge clinic staff if they are offered a dubious treatment add-on. Guidance being completed and in place for clinics. Clear and up to date information on our website about treatment types, new treatments, emerging science, developments in genetics and genomics, and treatment add-ons. |
| Evidence based treatments | | | |

*Evidence based treatments*
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| High quality research (data and embryo) | Both forms of research are supported through our research regulation function and our Register data research panel. Some inspections uncover examples of consent to the use of data for research being incorrectly reported to the HFEA, or not being properly sought, which could have serious consequences. We want to see an increase in patient consent rates for research (where they wish to), and for those consents to be fully informed and recorded properly so that patients can be confident their personal data or embryos will only be used in ways they have consented to. We want data researchers and embryo researchers to be able to access the data and the embryos that they need for their work. | A policy project in the second half of the 2016/17 business year will review our embryo research policies, and this work will inform our approach. Our main tactics will be:  
- To promote and explain research findings and research in progress (both licensed research and data research).  
- To encourage more patients to participate in both data research and donating embryos for research. (More to be developed stemming from this year’s policy project.) | Patients know that they can take part in research (whether embryo research or research using their data), what they need to consider before doing so and how it might benefit future patients.  
Measures:  
That patients can easily donate embryos to research where they want to and research centres can gain access to donated embryos for their projects.  
Higher rate of consent to research from patients. |
## Improving standards through intelligence

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<td>Use treatment data in our Register and our inspection intelligence to drive improvements in treatment standards and outcomes.</td>
<td>Our new data systems allow us to make better use of treatment data. We want to turn this, and our inspection intelligence, into useful and reliable information, that can be analysed and published more easily and quickly, and that can drive various quality improvements for patients.</td>
<td>To make full use of our treatment data, we will need to adopt the following main tactics: - To produce an information strategy setting out how we will use our data, with what tools, to what ends and with what outputs. - To ensure that we have enough analytical capability and capacity to get more value from the data we hold. - To use our improved data, together with our scientific sources, to radically improve the range and quality of information available to patients and others. - To use our data to improve the quality of NHS commissioning decisions, and therefore the quality and standard of care received by patients.</td>
<td>Donors, parents and donor-conceived people understand how and where their information has been stored, the responsibilities of the clinic and the HFEA, what their rights are, and how to apply to access information from the Register. Patients can have confidence that their clinic has fully understood the importance of their life-long role as an information guardian and information provider, and that the clinic staff are rigorous in meeting their responsibilities through excellent and timely records management and data submission practices to the HFEA Register. Measures: Information strategy sets out our plans in this area. Further work to be determined based on the information strategy.</td>
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<td>Continually able to receive, use and act upon patient feedback</td>
<td>We want to use the new patient rating service on Choose a Fertility Clinic to understand patient experience in clinics and encourage clinics to act on patient concerns. We also want to promote good practice across the sector, based on positive feedback.</td>
<td>With the new information systems and services we have built, our main tactics will be: - To collect more patient feedback through new routes; and to analyse it and feed it back into the system as intelligence to inform our activities.</td>
<td>Measures: Improvement in the quality of services and patient/donor support as a result of patient ratings and other feedback. Quantifiable increase in the amount and frequency of patient feedback available</td>
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<td>We want to use additional feedback sent to inspectors to improve standards in clinics and make it clearer in inspection reports. We commissioned extensive user research in order to shape our IfQ website information. However, we have not engaged with patients directly on our other services. We will make good use of new channels and opportunities available through which to engage with patients on what matters to them.</td>
<td>• To establish what ongoing input we will collect from patients, through which routes and methods, and with what outputs. • To establish how we will analyse and use patient feedback to improve both the quality of our service and the quality of care. • To share the feedback we receive with professional stakeholders. • To use patient feedback to focus inspections.</td>
<td>to the HFEA and our professional stakeholders.</td>
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<td>Regulatory performance</td>
<td>Our existing regulatory regime and compliance and enforcement policy are performing well. But we would like to be able to use our data, as described earlier, to make more targeted and responsive regulatory interventions in the interests of both quality and consistency.</td>
<td>In addition to work described elsewhere in this strategy, our main tactic will be: • To work out how we can use the intelligence available to us from clinics, patients and our data to improve the quality and consistency of regulatory performance across the sector.</td>
<td>Measure: Ability to make earlier and more responsive regulatory interventions, rather than awaiting the next renewal or interim inspection point.</td>
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<td>A lean and efficient regulator</td>
<td>Over the past six years, the HFEA has significantly reduced its size and costs. Part of the purpose of the IfQ Programme has been to enable us to work more smartly with the resources we have. To capitalise fully on the changes brought about from IfQ, we will need to re-shape our organisation so as to enhance our efficiency and effectiveness.</td>
<td>Our main tactics will be: • To identify the capabilities we will need in order to make the best use of our new website and Register, re-shaping our organisation in the process. • To continue to demonstrate that we are a good value regulator.</td>
<td>Measure: Organisational re-shaping achieved and the right capabilities and capacity in place. Stakeholder feedback/survey.</td>
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