

Authority meeting held by teleconference

Date - 17 August 2020

Venue - Online

Agenda item	Time
1. Welcome, apologies and declarations of interest	3:00pm
2. Minutes of the Authority meeting held 2 July 2020	3:05pm
3. Covid-19 updates	3:10pm
4. Resuming inspections	3:40pm
5. Any Other Business	4:20pm
6. Close	4:25pm

Minutes of Authority meeting held 2 July 2020

Details:

Area(s) of strategy this paper relates to:	Safe, ethical effective treatment/Consistent outcomes and support/Improving standards through intelligence
Agenda item	2
Meeting date	17 August 2020
Author	Debbie Okutubo, Governance Manager

Output:

For information or decision?	For decision
Recommendation	Members are asked to confirm the minutes of the Authority meeting held on 2 July 2020 as a true record of the meeting
Resource implications	
Implementation date	
Communication(s)	
Organisational risk	<input checked="" type="checkbox"/> Low <input type="checkbox"/> Medium <input type="checkbox"/> High
Annexes	

Minutes of the Authority meeting on 2 July 2020 held via teleconference

Members present	Sally Cheshire Margaret Gilmore Anita Bharucha Anthony Rutherford Emma Cave Anne Lampe	Gudrun Moore Ruth Wilde Yacoub Khalaf Ermal Kirby Kate Brian
Apologies	Jonathan Herring	
Observers	Steve Pugh (Department of Health and Social Care - DHSC)	
Staff in attendance	Peter Thompson Clare Ettinghausen Richard Sydee Rachel Cutting	Nora Cooke-O'Dowd Helen Crutcher Paula Robinson Debbie Okutubo

Members

There were 11 members at the meeting – seven lay members and four professional members.

1. Welcome, apologies and declarations of interest

- 1.1. The Chair opened the meeting by welcoming Authority members, the public and staff present online. She stated that the meeting was audio recorded in line with previous meetings and the recording would be made available on our website to allow members of the public who were not able to listen in during deliberations to hear it afterwards.
- 1.2. Jonathan Herring gave his apologies.
- 1.3. Declarations of interest were made by:
 - Yacoub Khalaf (PR at a licensed clinic)
 - Anthony Rutherford (clinician at a licensed clinic)
 - Ruth Wilde (counsellor at licensed clinics).

2. Minutes of the Authority meeting held on 1 June 2020

- 2.1. Members agreed that the minutes of the meeting held on 1 June 2020 were a true record and be signed by the Chair.

3. General updates

- 3.1. The Chair invited the Chief Executive (CE) to present this item.
- 3.2. The CE updated members on four areas: equality and diversity, human resources issues, PRISM and new Authority member appointments.

Equality and diversity

- 3.3.** The HFEA has long had a range of policies on equality and diversity but it was vital that the organisation reflected on this issue in light of the recent Black Lives Matter (BLM) campaign. As a consequence, the organisation has begun a process to look at ourselves and what is important. We spoke to staff in early June and put a statement on our intranet but we recognise that we need to do more. We will need to be asking questions about whether we are a fair employer and how we can be better colleagues. The HFEA has a predominantly female staff (80%), and about a quarter of staff are from a black and minority ethnic (BAME) background and 7% report a disability. The HFEA Board replicates that pattern with about two-thirds female and a quarter from a BAME background.
- 3.4.** The Head of HR has been talking to BAME staff and we will look again at the policies we have and whether they are adequate and meet our current expectations. The Chair has also had conversations with Board members about embedding equality and diversity with champions from Board. A working group is being set up to see what can be taken forward.
- 3.5.** The HFEA considers this to be an important moment and we are determined to move beyond making statements to looking at ourselves and see how we measure up. We will report back to the Board about how we are doing on this on a regular basis.
- 3.6.** Members asked how BAME colleagues were feeling during this pandemic time in particular as everyone was working from home and in light of the concerns raised by BLM.
- 3.7.** The CE responded that there was a support group for staff, established as a response to recent events.
- 3.8.** It was noted that even though the new premises would be available from mid-October, staff had been advised that we would only return to the office when it was safe to do so. Also, that safety arrangements were being put in place for when colleagues go out on inspections, and this included BAME colleagues.

Human resource (HR) issues

- 3.9.** The CE commented that due to the current situation where all staff continued to work from home, we were putting in place informal support arrangements for all colleagues online. These included daily or weekly team catch-ups, support from staff mental health first aiders and other activities such as 'lunch and learns' and weekly quizzes.
- 3.10.** Members were advised that we recently had a full staff survey and the headline results were positive. Once the results had been analysed, the CE would share any key findings.
- 3.11.** The CE commented that the recent report on HR matters that went to the Audit and Governance Committee (AGC) would also be sent to Authority members for information.

PRISM

- 3.12.** The CE provided a brief overview of PRISM. Continuing, he reminded members that all licensed clinics had a statutory duty to provide us with data and that we were building a new mechanism to store this data. It was noted that AGC provided oversight of the PRISM work.

- 3.13.** We were now at the testing stage and the CE had recently written to advise licensed clinics that we were tentatively looking at a launch window of between September and October. Due to practical considerations relating to the pandemic, this would be a staggered launch.
- 3.14.** It was noted that the feedback from clinics that had responded to date indicated that they could adopt the new system during the timescale specified. Training materials was also being developed and would be available when we launched PRISM.
- 3.15.** Since we would be moving offices in the Autumn, the PRISM launch would have to be coordinated with the move.

New appointments

- 3.16.** Four Authority member places had now been advertised and the recruitment campaign was being run by the Department of Health and Social Care (DHSC). The campaign was for two professional and two lay members.

Director updates

- 3.17.** The Director of Strategy and Corporate Affairs commented that her teams were working very hard especially during these difficult times and had not only carried on with their activities but made significant improvements to our work. An example of this was the new style Fertility Trends report that had been published on 30 June.
- 3.18.** The planned stakeholder group meetings had been cancelled earlier in the year at the start of lockdown and would now be taking place remotely. The patient facing group (AFPO) meeting had taken place in June which was helpful and the professional group (PSG) would be meeting later in July.
- 3.19.** The work with the Competitions and Market Authority (CMA) was ongoing and they are looking to engage staff in clinics later in the year, which was postponed from April due to Covid-19.
- 3.20.** We had also been speaking to other regulators to gauge how their work has changed as a result of the pandemic, any shared lessons on the way we regulate and also on the home working of staff.
- 3.21.** A member commented that the increase in the number of people visiting our website during the pandemic was positive and it should be used to build further engagement with patients.
- 3.22.** The Director of Compliance and Information presented to members and commented that her team were working hard on individual projects that they would normally not have the time to do, as there were currently no physical inspections.
- 3.23.** Although, we have a statutory duty to inspect licenced premises she reminded members that in March the inspection of clinics stopped due to the Covid-19 public health emergency. A risk-based approach was used to identify those centres (who were due a renewal inspection) where it was deemed appropriate to extend the licence to 5 years. A decision was made not to conduct interim inspections for centres where there were no concerns. A desk-based analysis was conducted for any centre where concerns were raised and highlighted for a targeted inspection once restrictions are eased and inspections recommence.
- 3.24.** She commented that we were now at a point where we needed a strategy for resuming physical inspections at licensed clinics.

- 3.25.** Members were reminded that although the opening the register (OTR) service was suspended it was being considered how and when it would be practical to re-open the service.
- 3.26.** Members were advised that we had recruited to the Donor Information Manager post. This was an internal promotion and we had now also successfully recruited to the vacated Donor Information Officer position. Training was given to all new staff.
- 3.27.** Members asked about the clinics where there were previous concerns that they were overcharging for personal protective equipment (PPE). Members heard that the CE had sent a letter to licensed clinics about this. Since the letter went out no further complaints had been received.
- 3.28.** Members asked about the position of the HFEA in relation to patients who were initially told to shield and if clinics were now in a position to make clinical decisions to treat them. Staff responded that it was up to clinics to take a responsible and informed position on this as long as it was in line with the government's guidance.
- 3.29.** The Director of Finance and Resources presented to the Authority.
- 3.30.** It was noted that the office move was on track and there were indications that it could now happen in October which was sooner than we expected. He further commented that staff had been advised that we would not be moving back to Spring Gardens and this was welcomed by the majority of staff.
- 3.31.** Regarding our finances, it was noted that we had received informal assurance from the DHSC that we would be funded this year. Members were reminded that 80% of our income came from regulatory charges for licensed activity but as the majority of clinics had to cease operations for a period, the funding for this year would be significantly reduced.
- 3.32.** Lastly, the fee project was in progress, even though commencing this work had been complicated by Covid-19.

Decision

- 3.33.** Members noted the general updates.

4. Covid-19 updates

- 4.1.** The Director of Compliance and Information gave an update. It was noted that weekly sector updates are sent to Authority members.
- 4.2.** Members were advised that eight licensed centres were yet to reopen. Of these, two centres decided to revoke their licence (but not due to the Covid-19 situation). Some centres had been given permission to reopen but had not yet started actual treatments.
- 4.3.** The Director of Compliance and Information stated that many centres had started with frozen embryo cycles. Such treatments required fewer monitoring visits, less theatre time and no anaesthetist. However, treatment activity in the NHS units remained low compared to the private sector.
- 4.4.** The feedback on the new ways of working was that every aspect of services in units had been risk assessed to ensure that the spread of Covid-19 was minimised.

- 4.5.** The results of the British Infertility Counselling Association (BICA) survey was shared with members. 89% of respondents had remarked that they had undertaken counselling even though counselling services have had to adapt to new ways of working.
- 4.6.** Regarding immunosuppressants, it was noted that some centres continued to use reproductive immunotherapies such intralipid therapy and further advice was being sought as the current professional advice was that these therapies may lead to patients having an increased risk from Covid-19.
- 4.7.** Members commented that the professional guidance was that immunosuppressants should be avoided at this time. Some members felt that patients should be made aware of all potential risks so that they could make an informed choice.
- 4.8.** There was a further suggestion, that if this issue was on-going, it could be discussed with the General Medical Council (GMC) and that we should ask why professionals were not following the BFS/ARCS guideline which states that empirical immunosuppressive treatments should be avoided.
- 4.9.** Regarding telling patients to self-isolate for so long before commencing treatment, some members felt that this could be difficult as not all patients disclosed to their employers that they were receiving fertility treatment.
- 4.10.** In terms of regional lockdowns, it was noted that the city of Leicester had been put on a further localised lockdown, and therefore frequently asked questions (FAQs) had been updated to reflect potential local changes in circumstances of clinics.
- 4.11.** Members asked if partners could link up via video platforms as partners were not able to attend clinic appointments with patients. It is understood that some clinics are offering this.
- 4.12.** Members commented that the NHS backlog could have a negative impact on women reaching their cut-off ages.
- 4.13.** The Director of Strategy and Corporate Affairs gave an update on public enquiries.
- 4.14.** It was noted that Covid-19 related questions and media enquiries had reduced, and we were now returning to more standard enquiries. The questions that came in relating to Covid-19 included immunosuppressive treatment and treating patients with comorbidities, among other areas.
- 4.15.** The Chair thanked all staff including the Senior Management Team (SMT) and all those working in the sector that enabled most clinics to reopen so promptly.

Decision

- 4.16.** Members noted the Covid-19 updates.

5. Performance report

- 5.1.** The CE introduced the report. It was noted that in May performance was generally good.
- 5.2.** Regarding debtor days, which was the average days debts remained outstanding, it was noted that the target was 30 working days or less. In May, performance was listed as 437 days and the Chair requested that this be verified. The Director of Finance and Resources responded that debtor days was the debt owed to us but he would check the data and if necessary correct the figure.

- 5.3.** In relation to the efficiency of end-to-end licensing processes, the Chair of the Statutory Approvals Committee (SAC) asked why this was in red as the team supporting the process worked closely with her and targets were met. The CE explained that other factors during the preparation of reports for committee also affect this performance indicator.
- 5.4.** Members noted the performance to May 2020.

6. Fertility trends

- 6.1.** The Head of Research and Intelligence outlined the Fertility Trends 2018 that was launched on 30 June 2020.
- 6.2.** It was noted that there were some new features this year including HTML presentation and larger underlying data tables.
- 6.3.** The team had spent some time considering expanding the information we published to cover enquiries received and what patients and the sector had said that they wanted to see.
- 6.4.** In terms of key findings, it was noted that:
- Birth rates increased for patients under 43 but remained above 25% for all ages where donor eggs were used (donor eggs were mostly used by patients over the age of 44).
 - Multiple birth rate decreased further to 8% across all age groups
 - Regarding sector activity, storage and frozen embryo cycles increased and were the fastest growing activities. Embryo storage increased by 700% and egg storage by 240%.
 - It was also noted that NHS funding of IVF cycles in some English regions had reduced significantly.
- 6.5.** In response to a question on why we were using the 2018 figures and not more recent ones. Staff responded that outcomes for treatment received in 2018 manifested in 2019, owing to the duration of pregnancy. Hence, there would always be a lag in the data reported.

Decision

- 6.6.** Members noted the Fertility trends report.

7. New strategy revisited

- 7.1.** The Head of Planning and Governance presented this item. Members were reminded that at a previous meeting they had agreed to postpone the publication of our strategy and business plan owing to the Covid-19 pandemic until October this year. Also, it was agreed to extend the strategy by one year, to 2024.
- 7.2.** Members were asked some key questions:
- Had Covid-19, and our response to it, altered our relationship with patients, the public, and the sector?
 - If so, how this affected our approach to delivering our strategy, particularly in relation to collaborative working, or the timing of some of the objectives between later this year and March 2024?
 - Were our strategic goals still the right ones?

- Should the 'shaping the future' area of the strategy now come into focus sooner, rather than later?
- 7.3.** The Head of Planning and Governance commented that there was a corporate management group (CMG) business planning meeting in August and a steer from the Authority would help to identify the right priorities for each year of strategic delivery.
- 7.4.** Members commented that the strategic goals remained the right ones and approved the strategy for later publication.
- 7.5.** This strategy would bring a continuation of our emphasis on best patient care, as we mark the 30th anniversary of the Act (2020) and the HFEA (2021). Although it was unlikely that the Act would be re-opened in the near future, members commented that in thinking about future challenges it would be important to give early consideration to what needed to change or be updated.
- 7.6.** Members commented that accurate and useful information provided at the right time remained important and could be achieved in part via education of both GPs and patients.
- 7.7.** Other key priorities identified by members included consent, add-ons and the current ongoing work with the CMA, clinic leadership, equality of access and funding, the emotional care of patients, and research.
- 7.8.** To summarise, the Chair commented that we would prioritise information provision, and that shaping the future had become more important than ever and should be brought forward. It was agreed that the delivery plan for the strategy would be brought back to the September Authority meeting.
- 7.9.** The CE thanked Authority members and noted that the strategy was in the right place and that staff would continue to endeavour to match the collective ambition of Authority members. The CMG would consider scheduling and resourcing in August.

Decision

- 7.10.** That the delivery plan for the strategy be brought back to the September meeting.
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8. Any other business

- 8.1.** The Chair reminded Authority members that they would be contacted about the date of the next meeting in August.
- 8.2.** The DHSC representative thanked the CE and his colleagues for their support in particular during this period.
- 8.3.** The Chair thanked the DHSC representative and his colleagues in the department.
- 8.4.** The Chair extended her appreciation to staff and commented that HFEA received due credit from the Secretary of State for Health for re-opening the sector.
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Chair's signature

I confirm this is a true and accurate record of the meeting.

Signature

Chair: Sally Cheshire

Date: 17 August 2020

Resuming Inspections

Details about this paper

Area(s) of strategy this paper relates to:	Compliance
Meeting:	Authority
Agenda item:	2
Meeting date:	17 August 2020
Author:	Rachel Cutting, Director of Compliance and Information
Annexes	

Output from this paper

For information or decision?	For decision
Recommendation:	That members consider the criteria set out in section 3 and the discussion points in section 4. If approved, inspections would restart from November 2020.
Resource implications:	N/a
Implementation date:	August 2020
Communication(s):	Letter to all PRs detailing transitional approach for prioritising inspections
Organisational risk:	High

1. Introduction

- 1.1.** In response to the Covid-19 public health emergency the Authority decided on 18 March that the inspection schedule should be suspended until September 2020 at the earliest. This paper seeks Authority approval to the criteria that would guide any decision to resume inspections.
- 1.2.** The HFEA has a statutory duty to inspect licensed clinics every two years, and moreover that the inspection should involve a visit to the licensed premises. However, given the extraordinary situation posed by the pandemic our decision to cease onsite inspections was clearly justified. Licensed clinics were required to cease almost all treatment from 15 April and many clinics furloughed staff leaving only a skeleton team in place. It would have been wholly inappropriate to inspect clinics during this time.
- 1.3.** Now that treatment is resuming (GD0014 version 2 came into force on 11 May 2020 allowing clinics to reopen following the approval of the clinic's inspector) and Government restrictions are generally easing, it is appropriate to consider when and how we recommence inspections.
- 1.4.** Section 2 of this paper sets out how inspections were conducted pre Covid-19 and during lockdown.
- 1.5.** Section 3 of this paper sets out the proposed criteria against which the decision to restart inspections should be assessed. Section 4 sets out the key changes proposed in the inspection process to mitigate the risks of Covid-19. Next steps are outlined in section 5.

2. How inspections were conducted pre-Covid-19 and during lockdown

- 2.1.** In considering how to move forward it is helpful to remind ourselves of how inspections are conducted under normal circumstances and how we modified the process during lockdown to maintain compliance oversight of the sector and to ensure clinics maintained their licence.
- 2.2.** The inspection cycle involves three types of inspection: initial, interim and renewal. Most clinics are usually issued with a four year licence, although the Act allows for a licence of up to five years. Clinics where significant concerns are raised have more targeted and focussed inspections and may receive a licence for a period shorter than four years if significant problems are identified at a renewal inspection. As noted above the law requires an inspection of the licensed premises every two years.
- 2.3.** The initial and renewal inspection involves a review of compliance against all requirements of the Human Fertilisation and Embryology Act 1990 (as amended) as set out in Licence Conditions, Directions, the Code of Practice and all applicable statutory provisions. An initial inspection to determine if a centre should receive a licence involves 2-3 inspectors for one day, while a licence renewal inspection involves 2-3 inspectors over two days. Less time is required on site for an initial inspection because treatment has not yet started, and more information can be reviewed in the pre-inspection period.

- 2.4.** An interim inspection is normally conducted at the half-way point of a licence, which in the case of a four year licence is after two years. These types of inspection are typically unannounced and focused on certain elements of the regulatory requirements, involving two inspectors for one day.
- 2.5.** Having decided to suspend inspections a risk-based approach was developed for inspections which were due between 18 March and 31 August 2020. This included the fact that the law, the Human Fertilisation and Embryology Act 1990 (as amended), allows a licence of up to five years so we could ensure that no clinic was unlicensed.
- **Renewal Inspections:** for centres with a four year licence with no concerns, the recommendation to the licensing committee was that the licence be extended by 1 year. For centres with a four year licence with significant concerns, or with a licence for less than four years, a desk-based analysis (DBA) was undertaken to review the risks of extending the licence by a further year. If extension was deemed inappropriate, it was noted that an inspection should be scheduled when inspections recommence.
 - **Interim Inspections:** no interim inspections were to be conducted at clinics with a four year licence and no concerns. A clinic where inspectors had concerns, the recommendation was for an inspection to be scheduled at the earliest opportunity when inspections are safe to resume.
 - **Initial Inspections:** if appropriate a DBA of the licence application and virtual inspection were conducted.

3. Criteria to inform a decision to resume inspection of licenced premises

- 3.1.** As fertility services have now restarted and lockdown restrictions are easing generally, consideration is now required to how and when inspections can resume. The decision to extend the licences of clinics that were coming up for renewal (see section 2 above) is clearly time limited and we cannot leave clinics without a licence in the future. Any decision to resume inspections is best considered against criteria which considers HFEA statutory duties, Government and public health advice, as well as our commitment to keep patients, clinic staff and HFEA inspectors safe. The proposed criteria are set out below:

1: That an inspection resumption strategy is in place

- The draft inspection resumption strategy has been agreed with SMT and the compliance directorate. The strategy is a detailed operational document which sets out how inspections can be conducted in a manner which minimises the risk of Covid-19 to HFEA inspectors, clinic staff and patients.
- The strategy is based on a Covid-19 inspection risk assessment, which assesses the different elements of the inspection process highlighting where activities should not be undertaken or where they can be undertaken using extra precautionary measures, such as the use of PPE, social distancing, hand hygiene and access to testing. The strategy also specifies that an inspector will work alongside the same inspector wherever possible, to mitigate risks of Covid-19 infection between licenced premises.
- All inspectors will be provided with this document and receive training on precautionary measures prior to inspections recommencing.
- As part of the strategy a risk-based approach to the inspection methodology and resources will be used. Utilising a pre-inspection DBA this approach will ensure those centres with concerns are prioritised for an onsite inspection with appropriate levels of inspector resource, whereas if a DBA

indicates a centre is at low risk for non-compliance, the time and resources used for on-site inspection can be reduced.

2: That risk assessments have been conducted for individual inspectors and on each clinic to be inspected

- Public Health England (PHE) advice regarding the health and wellbeing of colleagues who are BAME, those with chronic long term health conditions, those shielding and older colleagues, is that managers should undertake a risk assessment to ensure work activities undertaken do not expose those colleagues to unacceptable levels of risk. The main objective is to minimise their exposure to and risk from Covid-19, and where possible to enable them to continue undertaking a full range of activities.
- Where a significant risk is identified and inspectors cannot undertake the full normal range of activities, they will be deployed to other meaningful work which presents an acceptable level of risk.
- Prior to any inspection taking place an inspection risk assessment will be completed to identify the additional risk controls that may be required for a specific clinic for the duration of the national pandemic emergency response. This risk assessment acts as a first filter which enables us to understand whether an individual inspector can undertake an onsite inspection without increased risk.
- If an inspection is to proceed the inspection risk assessment should be tailored to reflect the activities to be undertaken and the control measures to mitigate any risks prior to each inspection
- The fundamental principle of the inspection risk assessment is to determine whether a visit in person is justified and that all alternatives such as DBA, telephone conversation, video conferencing have been explored and deemed inappropriate. The statutory duty to inspect licenced premises every 2 years must be considered and if an onsite visit cannot be conducted justification must be documented within the inspection risk assessment.
- As clinics will have their own procedures in place to mitigate Covid-19 risks inspectors will contact the centre prior to the inspection to ensure compliance with the clinic's requirements such as testing or completion of a screening questionnaire. Members should note that it is therefore not appropriate that interim inspections are conducted as unannounced inspections during the Covid-19 pandemic (some notice of inspection will be given).
- Whilst on inspection inspectors should exercise caution and assume everyone has the potential to be infected and act accordingly using social distancing, rigorous handwashing and relevant PPE.

3: That Government restrictions on social contact and travel are lifted

- The Government set out its plan on the 4 July with the aim to return to as near normal as we can whilst protecting communities and the NHS.
- The guidance on 'staying alert' and 'staying safe outside your home' states that people who can work from home should continue doing so, but where work can only be done in the workplace there are tailored guidelines for employers to help protect their workforce and others and give staff confidence to return to work.
- The safer travel guidance for passengers sets out the guidance for using public transport such as the legal requirement to wear a face covering. The recommendation remains to avoid using public transport wherever possible so we will reallocate clinic inspections to inspectors based on geographical location to reduce travel time, the need to use public transport and minimise the need for overnight hotel stays. Where this is impossible, such as the clinics in Scotland, a DBA will

allow the inspection specific risk assessment to balance the need to inspect (i.e. the risks of potential non compliance determined by DBA) against the increased risks to the inspection team, patients and centre staff of travel, accommodation and onsite inspection. This risk assessment will allow onsite inspection to progress safely or provide the rationale for not progressing the inspection, justifying why our statutory requirements can't be met.

- Local lockdowns would need to be monitored as it may be inappropriate to visit a clinic in an area with enhanced restrictions (such factors would be considered in the inspection specific risk assessment).

4: That the inspection process has been modified to minimise onsite inspection time whilst maintaining a robust and effective inspection process

- Part of the inspection process requires significant review of clinic documentation including standard operating procedures, policies, competency assessments and audits. It is proposed that many of these documents should be assessed by a DBA as a first component to inspection
- A modified inspection notebook will be sent to clinics 12 weeks prior to the inspection. All information requested can be sent electronically to inspectors for review against the requirements specified in the notebook. A DBA will then highlight areas of compliance as well as the risks to compliance. The need to further investigate these risk areas will dictate the inspector resources allocated to onsite inspection. Those resources and the approaches to be used will also be controlled through the inspection specific risk assessment.
- Wherever possible video conferencing will be used to assess compliance with licence conditions or to determine, for example, whether a clinic is well led and if a PR is fulfilling his or her duties.
- As an interim measure, as an agreed action from the PR event in 2019, each inspector will organise an annual PR review conversation to ensure the requirements of the revised G0014 v2 are being continually reviewed and met.

4. For discussion

4.1. Members are asked to consider the four criteria set out in section 3 above. In particular, members should note that these criteria propose a move away from how we normally carry out inspections, involving:

- A greater use of DBA and other tools to allow for off-site review of compliance.
- A more focussed and shorter time spent at the licensed premises, with prioritisation given to those clinics with the greater risk of non-compliance.
- Individual risk assessments of inspectors and clinics, with inspections being geographically distributed between inspectors to reduce travel distance.
- A cancellation of unannounced interim inspections (interim inspections to continue with notice given)
- An annual review conversation between the inspector and the PR to ensure that safe practices are being followed while the Covid-19 pandemic is ongoing.

4.2. Our primary aim must be to ensure that our statutory duties are met, that no clinics are left without a licence and that inspections meet the necessary requirements. However, we must also consider the impact of the Covid-19 public health emergency and prioritise the safety of patients, clinic staff

and inspectors. At times, the constraints imposed by the pandemic will require us to try to meet our statutory duties in different ways.

5. Next steps

- 5.1.** To agree a safe and effective transitional approach for HFEA inspections from November 2020.
- 5.2.** To ensure effective communication is issued to the sector to fully inform PRs of the new approach to inspection in the Covid-19 public health emergency and the requirements to provide information in evidence of the compliance of their centres ahead of the inspection date.
- 5.3.** Looking further ahead, we will review the measures taken during this period to see whether they should shape the inspection process when circumstances return to normal.