Review of Assisted Reproduction Unit at University Hospital of Hartlepool

June 2016
# Contents

<table>
<thead>
<tr>
<th></th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td>Introduction and Background</td>
</tr>
<tr>
<td>2.</td>
<td>Terms of Reference</td>
</tr>
<tr>
<td>3.</td>
<td>Methodology</td>
</tr>
<tr>
<td>4.</td>
<td>What the panel heard</td>
</tr>
<tr>
<td>4.1</td>
<td>North Tees and Hartlepool NHS Foundation Trust</td>
</tr>
<tr>
<td>4.2</td>
<td>Hartlepool and Stockton-on-Tees CCG</td>
</tr>
<tr>
<td>4.3</td>
<td>Local Authorities</td>
</tr>
<tr>
<td>4.4</td>
<td>Person Responsible</td>
</tr>
<tr>
<td>5.</td>
<td>Findings of the Panel</td>
</tr>
<tr>
<td>5.1</td>
<td>Clinical Safety</td>
</tr>
<tr>
<td>5.2</td>
<td>Proposed Future Service</td>
</tr>
<tr>
<td>5.2.1</td>
<td>Option 1</td>
</tr>
<tr>
<td>5.2.2</td>
<td>Option 2</td>
</tr>
<tr>
<td>5.2.3</td>
<td>Option 3</td>
</tr>
<tr>
<td>6.</td>
<td>Summary</td>
</tr>
</tbody>
</table>

Appendix A | Biographies of panel members | 9 |
Appendix B | Terms of Reference | 11 |
Appendix C | List of documentation distributed in advance of review panel meeting | 16 |
Appendix D | Agenda | 17 |
Appendix E | Attendees in each session | 19 |
1. Introduction and Background

In early January, 2016, NHS Hartlepool and Stockton-on-Tees Clinical Commissioning Group (CCG) approached the Northern England Clinical Senate to ask the Senate to undertake a clinical review of the Assisted Reproduction Unit (ARU) at the University Hospital of Hartlepool (UHH). This request followed an apparent decision by the provider of the service, North Tees and Hartlepool NHS Foundation Trust (NTHFT), to cease providing the service themselves, leading to negative publicity in the local press.

The Associate Director for the Northern England Clinical Networks and Senate subsequently attended a meeting of the Health Scrutiny Joint Committee and the Audit and Governance Committee in Hartlepool on 15th March 2016 and gave details of how such a review might be undertaken and the likely timescales which would be involved.

Agreement was reached to convene a panel of independent clinical experts to undertake the review on behalf of the Clinical Senate; it was considered important to go outside the Northern England boundaries for this expertise to ensure absolute independence. The three clinical members of the panel were

<table>
<thead>
<tr>
<th>Member</th>
<th>Role</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mrs Jane Blower (Chair)</td>
<td>Consultant Embryologist, Leicester Fertility Centre, Leicester Royal Infirmary and HFEA Person Responsible</td>
</tr>
<tr>
<td>Prof Daniel Brison</td>
<td>Consultant Embryologist, Department of Reproductive Medicine, Central Manchester University Hospitals NHS Foundation Trust, St. Mary’s Hospital, Manchester.</td>
</tr>
<tr>
<td>Dr Cheryl Fitzgerald</td>
<td>Consultant in Reproductive Medicine, Central Manchester University Hospitals NHS Foundation Trust, St. Mary’s Hospital, Manchester.</td>
</tr>
</tbody>
</table>

Biographies for the panel members are included as Appendix A.

The panel was supported managerially by Roy McLachlan, Associate Director of Clinical Networks and Senate and by two members of his support team, Michelle Wren and Denise Preston. Terms of Reference for the review were agreed with the CCG; an extract is given in section 2 below and the full Terms of Reference are given as Appendix B.

The date for the review was established as Tuesday, 7th June 2016 and it was agreed it would take place at University Hospital Hartlepool (UHH) so that an opportunity could be taken to visit the ARU during the course of the day. The date of the visit was also scheduled to fit in with the planned public consultation on the future options for provision of the service. It was hoped that this report would be available during week commencing 20th June, 2016 so that its contents could be considered alongside the formal consultation document.

2. Terms of Reference

An extract from the Terms of Reference is given below, summarising the main issues to be considered by the review panel.
Undertake a critical review and clinical analysis of the proposed service change in relation to the Assisted Reproduction Unit (ARU) provided by North Tees and Hartlepool Foundation Trust (NTHFT) to:

- Review clinical safety of current service delivery and workforce which takes account of the work undertaken by NTHFT in identifying the mitigating clinical risk.
- Review proposed future service model to ensure the commissioning of a sustainable future service including, efficiency, workforce, clinical safety, patient experience, current and future demand.
- Provide assurance of the option proposed or provide recommendations that will result in the commissioning of safe services for local people which has sustainability.

The full Terms of Reference are given as Appendix B to this report. The following timeline was established for the production of this report:

- First draft available to CCG for accuracy check in early week commencing 13th June 2016
- Final version available week commencing 20th June 2016

It was recognised by all concerned that this timeline was much tighter than usually expected for a Clinical Senate report.

3. Methodology

A range of documentation was made available to the Senate Review Team by the CCG in advance of the review visit and was presented via email over a period of weeks. A list of documents provided is detailed in Appendix C.

Some further information from North Tees and Hartlepool Foundation Trust was presented at the request of members of the review team.

The agenda for the day was designed carefully to allow 90 minutes each with representatives of the following organisations:

- North Tees and Hartlepool NHS Foundation Trust
- NHS Hartlepool and Stockton-on-Tees CCG
- Local Authorities – Hartlepool, Stockton, Middlesbrough, Redcar and Cleveland and Durham.

Time was also built in to visit the ARU which gave the review panel an opportunity to talk to staff. The panel noted the absence of the Person Responsible and made enquiries as to his availability.

During the early afternoon of the visit, arrangements were made for the Person Responsible, Mr Hany Mostafa, to meet with the panel as he had been in Newcastle on a professional appointment during the morning. The panel met with Mr Mostafa for half an hour after meeting representatives from the Local Authorities.

The planned agenda for the day is included as Appendix D and a list of attendees for each session as Appendix E.
The review panel had several opportunities to deliberate on discussions throughout the day and had a final session to discuss the possible contents of this report before the end of the visit.

4. What the panel heard

The following sections outline the key messages heard in each of the sessions outlined in the methodology section.

4.1 North Tees and Hartlepool NHS Foundation Trust

The key issues highlighted to the panel by the Trust were:

- that the ARU is a small unit which has encountered difficulties in recruiting into Embryology posts
- that by the end of 2015 the Trust had serious concerns over the viability of continuing with the service safely and did not wish to compromise their ability to offer high quality services to patients
- that the CCG and Local Authorities had been made aware of the difficulties during the course of 2014 and 2015.

4.2 Hartlepool and Stockton-on-Tees CCG

The key issues highlighted to the panel by the CCG were:

- the CCG did not initiate the proposed changes to the ARU but wanted their residents to have access to a sustainable good quality service which was also economically viable
- that the CCG was representing other CCG’s whose residents used the service at UHH
- the CCG welcomed advice from the independent panel on the options set out in the public consultation document.

4.3 Local Authorities

The key issues highlighted to the panel by the representations of the Local Authorities were:

- that there was a strong disappointment with the Trust for not engaging with the local Audit and Governance Group or the Health Scrutiny Joint Committee
- that on behalf of local residents they wanted to keep as many services as possible provided at UHH but there was a feeling that the Trust wanted increasingly to centralise services at Stockton
- that the Trust had not exhausted all possible recruitment routes to get their Embryology posts filled.

4.4 Person Responsible

The key issues highlighted to the panel by the Person Responsible (PR) were:
• that the ARU at UHH was a mature service with good standing and a strong regional position that had encountered difficulties in recruiting to vacant Embryologist posts
• that there had been a trend for merging of smaller units but not a move to close them completely
• that issues identified in the HFEA inspection had been satisfactorily addressed.

Overall the panel were impressed by the desire of all the people they met to be able to offer a sustainable safe service for patients.

5. Findings of the panel

It is intended to give only a summary of the findings of the review panel against each of the three main elements of the Terms of Reference as set out below.

5.1 Clinical Safety

The main factor given by NTHFT behind the cessation of (and intention to close) ARU services in Hartlepool was the inability to fill the staffing establishment for the unit. Based on the accounts and evidence provided regarding the recent workforce issues it was clear that:

• there had been difficulties with recruitment to Embryology posts over an extended period,
• succession planning around the retirement of long term staff had not proved successful
• the ARU did not train its own embryologists (which improves a unit’s ability to recruit and retain staff)
• there has been recent instances of long/medium term sickness amongst medical and nursing staff within the ARU
• there had been a sudden departure of a substantive consultant appointment after only 3 months in post.

The approach to recruitment adopted by NTHFT had not managed to address these workforce shortages despite short-term measures being adopted. For example, a flexi-retired member of staff was retained and then supplemented with locum arrangements, some of which cost £750 per day. The equivalent per annum rate of this arrangement is £200,000 per year, an amount which is not financially sustainable in the medium- to long- term.

The Trust was, therefore, by the end of 2015, running at 25% Embryologist capacity against establishment for the unit (i.e. funding in place for 2.5 wte but with only 0.6 wte available). This situation was exacerbated by the absence of 1 Associate Specialist due to long-term sickness and one nurse on long term sickness a reduction in available nursing workforce of 25%.

Panel Findings

Based on the assessment of this workforce situation, the Expert Panel feel that the ARU could not provide a clinically safe environment for patients and that on balance NTHFT were right in giving serious consideration to no longer providing the service in the short-term. Given the unsuccessful attempts to address the workforce issues,
the Expert Panel also feel that the CCG are right in considering a range of options for a sustainable service for the medium- to long-term.

5.2 Proposed Future Service Models

The session with the CCG gave an opportunity to consider jointly the options set out in the consultation document. Colleagues from the CCG were keen to hear the panel’s views on the advantages, risks and challenges of each option with a view as to how the CCG ensured a sustainable future service to meet patient’s needs.

Hartlepool currently provides (on average) 250 cycles per year undertaken on the basis of patients choosing to select Hartlepool ARU as their unit of choice (from the range of reproduction units across the North East / England). The facilities provided in the UHH ARU are also generally excellent although there is a likely requirement for modification to the current laboratory space which would require additional investment (a consideration that would need to be taken into account when making a final decision on future models).

The Expert Panel suggested that for a licenced fertility provision to be clinically and sustainable and financially viable, clinics usually need to deal with between 400 and 500 IVF cycles a year.

Based on the necessity for a range of clinical skills i.e. Nurse Specialists, embryologists, consultants, to be available each day within an ARU, the number of cycles overseen by a unit in a year is highly correlated to its ability to recruit the appropriate workforce and be financially viable.

The CCG had identified three main options for new service models which the Expert Panel were asked to comment on. These are:

- **Option 1**: A comprehensive assisted reproductive service including HFEA Licensed and unlicensed provision remains at Hartlepool delivered by an alternative provider.
- **Option 2**: Unlicensed assisted reproductive services continue to be delivered at Hartlepool and patients requiring licenced provision go to an alternative site e.g. James Cook University Hospital, Queen Elizabeth University Hospital, Gateshead and Newcastle Fertility Centre at the Centre for Life.
- **Option 3**: A comprehensive assisted reproductive service including HFEA Licensed and unlicensed provision will no longer be available at Hartlepool but will be delivered at other sites in the region.

5.2.1 Option 1

<table>
<thead>
<tr>
<th>Service Option 1</th>
</tr>
</thead>
<tbody>
<tr>
<td>A comprehensive assisted reproductive service including HFEA Licensed and unlicensed provision remains at Hartlepool delivered by an alternative provider.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Risks</th>
</tr>
</thead>
<tbody>
<tr>
<td>• The CCG is unable to secure and commission an alternative provider to deliver at Hartlepool site.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Benefits</th>
</tr>
</thead>
</table>
Existing provision will be maintained and patients will not see any changes.
Patients will receive all treatment in Hartlepool.

Patients Potentially Impacted
0 (nil)

Advantages identified by the Expert Panel:
- Maintains a local service, for both licensed and unlicensed treatments
- Provides stability for current staff and patients
- Potentially sustainable from a service perspective (but only if greater numbers of patients chose to utilise Hartlepool for their treatment and current workforce challenges overcome)

Risks/challenges identified by the Expert Panel:
- The service sustainability does not necessarily mean financial viability (which would in all probability be dependent on the ARU undertaking fee paying and private work).
- This option would in all likelihood be very expensive for a new provider to take on as it would need to replicate a full range of staffing and laboratory services over multiple sites, reducing potential economies of scale.
- Would require increased staffing levels to sustain a future service which has so far proved difficult to attract and retain.

5.2.2 Option 2

Service Option 2
Unlicensed assisted reproductive services continue to be delivered at Hartlepool and patients requiring licenced provision choose to go to an alternative site e.g. James Cook University Hospital, Queen Elizabeth University Hospital, Gateshead and Newcastle Fertility Centre at the Centre for Life.

Risks
- Patient experience, as patients may not be aware when starting unlicensed treatments that they may not be able to receive all of their treatments from the one site if they progress to licensed treatments.
- Ensuring referrers are aware of the changes before referring.
- Capacity assessment required for other providers to ensure that they have the capacity to manage additional patients.

Benefits
- Assisted reproductive services for the majority of patients will continue to be provided at Hartlepool site.

Patients Potentially Impacted
116 (Based on the average number of cycles of 1.2 per patient and 2015/16 activity)
Advantages identified by the panel:

- Keeps a limited local service (likely to be about 20% of referrals would undergo treatment locally with the remaining 80% either not undergoing treatment or being referred to a tertiary unit for assisted conception).

Risks/challenges identified by the panel:

- Patients under the care of two providers with potentially poorer patient experience (e.g. patients needing to change pathways for licensed treatments)
- Duplication of investigations unless a robust single pathway is developed
- Travel to other hospital sites for 80% of patients
- With this option it was noted that stored gametes and embryos would need to be transferred to another provider site. This has risks in terms of transporting embryos in tanks of liquid or vapour phase nitrogen and also in maintaining administrative records of patients consent to storage, expiring deadlines for storage and systems for contacting patients.

The Expert Panel feel that the fewer service providers involved in delivering the different elements of the overall fertility service (with an ideal of one - but mindful of procurement restrictions), the stronger the clinical governance and clearer the care pathway would be within a larger, overall service utilising more streamlined processes.

5.2.3 Option 3

<table>
<thead>
<tr>
<th>Service Option 3</th>
</tr>
</thead>
<tbody>
<tr>
<td>A comprehensive assisted reproductive service including HFEA Licensed and unlicensed provision will no longer be available at Hartlepool but will be delivered at other sites in the region.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Risks</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patients already referred to the service will need to be transferred to another provider.</td>
</tr>
<tr>
<td>Capacity assessment required for other providers to ensure that they have the capacity to manage additional patients.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Benefits</th>
</tr>
</thead>
<tbody>
<tr>
<td>Service will be commissioned from a smaller number of providers which can attract clinical staff due to the specialist nature of the provision.</td>
</tr>
<tr>
<td>Increased volumes of activity at other sites will improve the financial viability of services ensuring continues delivery of services in the future.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Patients Potentially Impacted</th>
</tr>
</thead>
<tbody>
<tr>
<td>A maximum of 600 of which 116 relate to licensed provision.</td>
</tr>
</tbody>
</table>

Advantages identified by the panel:

- May make other nearby units more sustainable in the medium- to long-term thereby securing viability.
May enable seven-day working in nearby units.

Risks/challenges identified by the panel:

- This would be a loss of local service and therefore, consideration of this option should include the views of the public over the degree of willingness to travel and how far, to access a new service.
- With this option it was noted that stored gametes and embryos would need to be transferred to another provider site.

Overall, the Expert Panel were not able to identify any other alternative options.

6. Summary

Throughout the review, the Expert Panel was struck by the strength of feeling of local councillors and others for keeping services local and of commissioners and providers of ensuring services were of a high level of quality and sustainable into the future.

The main findings of the Expert Panel are that:

- The Trust was right to consider the clinical safety of the ARU to be compromised in December 2015.
- There are benefits and risks associated with each of the options identified by the CCG as the sustainable model for the future.
- Generally larger units seeing more NHS funded cycles (or supplementing NHS funded cycles with privately funded work) find it easier to recruit and retain staff in a clinically sustainable and financially viable service. They are also more likely to attract other national funding (e.g. for the development of a training scheme locally for embryologists, such as those which exist in Newcastle, Manchester and other centres throughout the UK).
- Adopting a more nuanced form of recruitment (e.g. use of specialist media) may have a greater chance of identifying new members of staff to any future service.
- Whilst being mindful of procurement regulations and the wishes of neighbouring commissioners and providers, there may be benefit in looking for greater collaboration with neighbouring ARUs within the options for new service models.

On behalf of the Northern England Clinical Senate the Expert Panel would like to thank everyone who contributed to the discussions.
Appendix A

Biographies

Jane Blower
Consultant Embryologist and Human Fertilisation and Embryology Authority (HFEA) Person Responsible Leicester Fertility Centre University Hospitals of Leicester NHS Trust

Jane graduated from Nottingham University with the first UK Masters in Assisted Reproductive Technology. In her substantive role as a consultant embryologist she is responsible for directing and managing the scientific service for the diagnosis, management and treatment of infertility patients at the Leicester Fertility Centre. She is also the HFEA Person Responsible; she was part of the original team who opened the Leicester Fertility Centre in 1989. Jane is a founder member of the Association of Clinical Embryologists (ACE) and sat on the ACE Executive committee for 6 years. Jane is a member of the quality Improvement group for the IQIPS Improving Quality in Physiological Services accreditation programme at the Royal college of Physicians and has a strong belief in the role of accreditation to improve the quality of diagnostic services. She was a member of the NICE evidence update review on fertility group and is a Health & Care Professions Council (HCPC) partner. She is also a scientific advisor to the HFEA and a member of the East Midlands Clinical Senate Assembly. In October 2010 Jane was appointed as Scientific Director to the NHS East Midlands as a part time secondment, offering scientific advice to the Strategic Health Authority (SHA), and subsequently Healthcare Science workforce advisor to Health Education East Midlands, whilst providing leadership, strategic direction, and influence for healthcare sciences and scientists across the region. Jane undertakes a part time role providing scientific advice to the East Midlands Academic Health Science Network (EMAHSN) and supporting their affiliated projects, including the Medical Research Council (MRC) nodes. In April 2014 Jane was seconded to a national role as Deputy CSO for 12 months, and subsequently as Clinical Associate with the CSO team. In this role she worked closely with the Chief Scientific Officer (CSO) and senior colleagues at NHS England and continues to be actively involved in the CSO work programme supporting accreditation of scientific and diagnostic services focusing on leadership, quality, and innovation and commissioning of diagnostics as well as the delivery of seven day scientific services. Her research interests include male factor infertility.

Professor Daniel R Brison
PhD, FRCPath

Professor of Clinical Embryology and Stem Cell biology; Scientific Director of the Department of Reproductive Medicine, Co-Director NW Embryonic Stem Cell Centre. Department of Reproductive Medicine, St Mary’s Hospital, Central Manchester and Manchester University Hospitals NHS Foundation Trust.

Professor Daniel Brison is a Consultant Embryologist at St Mary’s Hospital, Manchester and Person Responsible to the HFEA for licenses in embryo research and embryonic stem cells. He is a member of the HFEA's Scientific and Clinical Advances Advisory Committee, the UK Association of Clinical Embryologists Scientific Advisory Committee, Clinical lead for the UK national MSc in Reproductive
Sciences and an examiner for the Royal College of Pathologists. His clinical and research interests include: improving the effectiveness and safety of clinical assisted reproductive technologies (ART), the characterization of early human development at the molecular level, the regulation of pluripotency in embryos and embryonic stem cells and the derivation and use of clinical grade embryonic stem cells for the treatment of disease, and the impact of environmental factors and ART on embryonic and child health.

Cheryl T. Fitzgerald  M.B. Ch.B.,  M.R.C.O.G.,  M.D.
Consultant in Reproductive Medicine
Old St Mary’s Hospital, Manchester

Cheryl graduated from The University of Manchester in 1986. Her current role is full time NHS Consultant in Reproductive Medicine, and she has a commitment to the general gynaecology on-call rota and the Termination of Pregnancy service.

From 2006 – 2010 was the person responsible to HFEA. 2010 – 2014 saw her as Clinical Lead for IVF and ICSI. Cheryl is the clinical lead for the fertility preservation service and is also the Associate Dean of Undergraduate studies for St Mary’s hospital, and, Clinical Lead for the Gynaecology Quality Improvement Programme

Cheryl has been actively involved in the production of several clinical publications – peer reviewed.
SENATE CLINICAL REVIEW

TERMS OF REFERENCE

Title: Assisted Reproduction Unit, University Hospital of Hartlepool

Sponsoring Organisation: Hartlepool and Stockton-on-Tees Clinical Commissioning Group (CCG)

Clinical Senate: Northern

NHS England regional or area team: NHS Cumbria and the North East

Terms of reference agreed by:

Roy McLachlan
on behalf Northern England Clinical Senate and

(Name)
on behalf of Hartlepool and Stockton-on-Tees CCG

Date: 7 June 2016

Senate Clinical Review Team Members

Chair: Mrs Jane Blower, Consultant Embryologist & HFEA Person Responsible.

Professor Daniel Brison, Consultant Embryologist, Department of Reproductive Medicine, Central Manchester University Hospitals NHS Foundation Trust, St Mary’s Hospital, Manchester.

Dr Cheryl Fitzgerald, Consultant in Reproductive Medicine, Central Manchester Foundation Trust.
Scope of the Review

To undertake a critical review and clinical analysis of the proposed service change in relation to the Assisted Reproductive Unit (ARU) provided by North Tees and Hartlepool Foundation Trust to;

- Review clinical safety of current service delivery and workforce which takes account of the work undertaken by NTHFT in identifying the mitigating clinical risk.
- Review proposed future service model to ensure the commissioning of a sustainable future service including; efficacy, workforce, clinical safety, patient experience, current and future demand.
- Provide assurance of the options proposed or provide recommendations that will result in the commissioning of safe services for local people which has sustainability.

Timeline

June 2016.

Reporting Arrangements

The clinical review team will report to the clinical senate council which will agree the report and be accountable for the advice contained in the final report. Clinical senate council will submit the report to the sponsoring organisation and this clinical advice will be considered as part of the NHS England assurance process for service change proposals.

Methodology

The review team will look over the information provided by the CCG (This can be circulated via secure email) then the review team will come together for a one day face to face meeting to discuss the information received as a group and meet with teams from North Tees and Hartlepool NHS Foundation Trust, Hartlepool Borough Council, and Hartlepool and Stock-on-Tees CCG to clinically test out the proposal. The timeframe would be for CCG information to be circulated in May 2016 with the face to face meeting on Tuesday 7 June 2016.
Report

A draft clinical senate assurance report will be circulated within five working days from the face to face meeting by the review team to the sponsoring organisation for factual accuracy.

Comments/correction must be received within five working days.

The final report will be submitted to the sponsoring organisation during week commencing 20 June 2016 and will be endorsed at the Northern England Senate Council meeting in July 2016.

Communication and Media Handling

The arrangements for any publication and dissemination of the clinical senate assurance report and associated information will be decided by the sponsoring organisation.

Resources

The Northern England Clinical Senate will provide administrative support to the review team, including setting up the meetings and other duties as appropriate.

The clinical review team will request any additional resources, including the commissioning of any further work, from the sponsoring organisation.

Accountability and Governance

The clinical review team is part of the Northern England Clinical Senate accountability and governance structure.

The Northern England Clinical Senate is a non-statutory advisory body and will submit the report to the sponsoring organisation.

The sponsoring organisation remains accountable for decision making but the review report may wish to draw attention to any risks that the sponsoring organisation may wish to fully consider and address before progressing their proposals.

Functions, Responsibilities and Roles

The sponsoring organisation will
i. provide the clinical review panel with the agreed information pack, including the formal consultation document. Background information may include, among other things, relevant data and activity, internal and external reviews and audits, impact assessments, relevant workforce information and population projection, evidence of alignment with national, regional and local strategies and guidance. The sponsoring organisation will provide any other additional background information requested by the clinical review team.

ii. respond within the agreed timescale to the draft report on matter of factual inaccuracy.

iii. undertake not to attempt to unduly influence any members of the clinical review team during the review.

iv. submit the final report to NHS England for inclusion in its formal service change assurance process.

Clinical Senate Council and the sponsoring organisation will

i. agree the terms of reference for the clinical review, including scope, timelines, methodology and reporting arrangements.

Clinical Senate Council will

i. appoint a clinical review team, this may be formed by members of the senate, external experts, and / or others with relevant expertise. It will appoint a chair or lead member.

ii. endorse the terms of reference, timetable and methodology for the review

iii. consider the review recommendations and report (and may wish to make further recommendations)

iv. provide suitable support to the team and

v. submit the final report to the sponsoring organisation

Clinical Review team will

i. undertake its review in line with the methodology agreed in the terms of reference

ii. follow the report template and provide the sponsoring organisation with a draft report to check for factual inaccuracies.

iii. submit the draft report to clinical senate council for comments and will consider any such comments and incorporate relevant amendments to the
report. The team will subsequently submit final draft of the report to the Clinical Senate Council.

iv. keep accurate notes of meetings.

**Clinical Review team members** will undertake to

i. commit fully to the review and attend all briefings, meetings, interviews, panels etc. that are part of the review (as defined in methodology).

ii. contribute fully to the process and review report

iii. ensure that the report accurately represents the consensus of opinion of the clinical review team

iv. comply with a confidentiality agreement and not discuss the scope of the review nor the content of the draft or final report with anyone not immediately involved in it. Additionally they will declare, to the chair or lead member of the clinical review team and the clinical senate manager, any conflict of interest prior to the start of the review and/or materialise during the review.

END
Appendix C

Documentation provided by CCG in advance of review panel meeting

- Human Fertilisation Embryology Authority - Executive Licensing Panel minutes – Interim Inspection Report
- Terms of Reference
- ARU paper to Audit and Governance Committee January 2016
- Letter to Secretary of State 15 April 2016
- CCG Letter to Audit and Governance Committee 19 April 2016
- Notes from Hartlepool ARU Teleconference 27 April 2016
- Unison Report
- Contract Information – there is not a separate specification for this service there is only a reference to the service in women and children's overarching specification
- Activity Levels
- Engagement and Consultation document
- Timeline
# Hartlepool ARU Meeting
## Agenda

**Date:** Tuesday 7 June 2016  
**Time:** 08:30 – 16:00

### Location:
University Hospital of Hartlepool, Holdforth Road, Hartlepool TS24 9AH  
Board Room

### Chair:
Mrs Jane Blower

### Panel Members:
Professor Daniel Brison, Dr Cheryl Fitzgerald, Roy McLachlan

### Time:

<table>
<thead>
<tr>
<th>Time</th>
<th>Event</th>
</tr>
</thead>
<tbody>
<tr>
<td>08:30</td>
<td>Panel Meet</td>
</tr>
<tr>
<td>09:15</td>
<td>Visit to ARU</td>
</tr>
<tr>
<td>09:45</td>
<td>Panel Reconvene</td>
</tr>
<tr>
<td>10:00</td>
<td>Meeting with North Tees and Hartlepool NHS Foundation Trust</td>
</tr>
<tr>
<td></td>
<td>Chief Operating Officer &amp; Deputy</td>
</tr>
<tr>
<td></td>
<td>Chief Executive – Julie Gillon</td>
</tr>
<tr>
<td></td>
<td>Medical Director – David Emerton or Deepak Dwarkanath</td>
</tr>
<tr>
<td></td>
<td>Clinical Director – Elaine Gouk</td>
</tr>
<tr>
<td></td>
<td>Associate Director – Lynne Kirby</td>
</tr>
<tr>
<td></td>
<td>General Manager – Jane Barker</td>
</tr>
<tr>
<td></td>
<td>HR Business Partner – Catherine Connor</td>
</tr>
<tr>
<td>11:30</td>
<td>Break</td>
</tr>
<tr>
<td>11:45</td>
<td>Meeting with Hartlepool and Stockton on Tees CCG – Working Lunch</td>
</tr>
<tr>
<td></td>
<td>Ali Wilson – Chief Officer (TBC)</td>
</tr>
<tr>
<td></td>
<td>Karen Hawkins – Associate Director Commissioning</td>
</tr>
<tr>
<td></td>
<td>Carl Parker – Clinical Lead IHC</td>
</tr>
<tr>
<td></td>
<td>Paul Pagni – GP Lead</td>
</tr>
<tr>
<td></td>
<td>Trish Hirst – Senior Contract Manager</td>
</tr>
<tr>
<td>13:15</td>
<td>Break</td>
</tr>
<tr>
<td>13:30</td>
<td>Meeting with Local Authorities</td>
</tr>
<tr>
<td></td>
<td>Hartlepool</td>
</tr>
<tr>
<td></td>
<td>Joan Stevens – Scrutiny Officer</td>
</tr>
<tr>
<td></td>
<td>Ray Martin Wells – Chair, Audit and Governance Committee</td>
</tr>
<tr>
<td></td>
<td>Stockton-on-Tees</td>
</tr>
<tr>
<td></td>
<td>Peter Kelly – Director Public Health</td>
</tr>
<tr>
<td></td>
<td>Jim Beal – Councillor (Chair, Health &amp; Wellbeing)</td>
</tr>
<tr>
<td></td>
<td>Middlesbrough</td>
</tr>
<tr>
<td></td>
<td>Julie McGee – Councillor</td>
</tr>
<tr>
<td></td>
<td>Julie <a href="mailto:McGee@middlesbrough.gov.uk">McGee@middlesbrough.gov.uk</a></td>
</tr>
<tr>
<td>Time</td>
<td>Event</td>
</tr>
<tr>
<td>--------</td>
<td>----------------------------</td>
</tr>
<tr>
<td>15:00</td>
<td>Panel Review and Report Writing</td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td>16:00</td>
<td>Close</td>
</tr>
</tbody>
</table>
### Appendix E

#### Attendees at each session

<table>
<thead>
<tr>
<th>Time</th>
<th>Panel Meeting</th>
<th>Attendees</th>
</tr>
</thead>
<tbody>
<tr>
<td>8.30am</td>
<td></td>
<td>Jane Blower, Cheryl Fitzgerald, Daniel Brison, Roy McLachlan, Karen Hawkins (part)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Time</th>
<th>Visit to ARU</th>
<th>Attendees</th>
</tr>
</thead>
<tbody>
<tr>
<td>09.15am</td>
<td></td>
<td>Jane Blower, Cheryl Fitzgerald, Daniel Brison, Roy McLachlan, Michelle Wren, Denise Preston</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Time</th>
<th>Meeting with North Tees and Hartlepool NHS Foundation Trust</th>
<th>Attendees</th>
</tr>
</thead>
<tbody>
<tr>
<td>10.00am</td>
<td></td>
<td>Jane Blower, Cheryl Fitzgerald, Daniel Brison, Roy McLachlan, Michelle Wren, Denise Preston</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Time</th>
<th>Meeting with Hartlepool and Stockton on Tees CCG</th>
<th>Attendees</th>
</tr>
</thead>
<tbody>
<tr>
<td>11.45am</td>
<td></td>
<td>Jane Blower, Cheryl Fitzgerald, Daniel Brison, Roy McLachlan, Michelle Wren, Denise Preston</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Time</th>
<th>Meeting with Local Authorities Hartlepool</th>
<th>Attendees</th>
</tr>
</thead>
<tbody>
<tr>
<td>13.30pm</td>
<td></td>
<td>Jane Blower, Cheryl Fitzgerald, Daniel Brison, Roy McLachlan, Michelle Wren, Denise Preston</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Time</th>
<th>Redcar and Cleveland</th>
<th>Attendees</th>
</tr>
</thead>
<tbody>
<tr>
<td>13.30pm</td>
<td></td>
<td>Jane Blower, Cheryl Fitzgerald, Daniel Brison, Roy McLachlan, Michelle Wren, Denise Preston</td>
</tr>
</tbody>
</table>