

AUDIT AND GOVERNANCE COMMITTEE AGENDA



Wednesday 8 February 2017

11.00 am

**Council Chamber, Civic Centre
Hartlepool**

MEMBERS: AUDIT AND GOVERNANCE COMMITTEE

Councillors S Akers-Belcher, Belcher, Cook, Hamilton, Harrison, Martin-Wells and Tennant

Standards Co-opted Members: Mr Norman Rollo and Ms Clare Wilson

1. **APOLOGIES FOR ABSENCE**
2. **TO RECEIVE ANY DECLARATIONS OF INTEREST BY MEMBERS**
3. **MINUTES**
 - 3.1 Minutes of the meeting held on 19 January 2017 *(to follow)*.
4. **AUDIT ITEMS**

No items.
5. **STANDARDS ITEMS**

No items.



6. STATUTORY SCRUTINY ITEMS

6.1 Assisted Reproduction Unit at the University Hospital of Hartlepool:-

- (a) Covering Report – *Scrutiny Manager*
- (b) Requested Information – *Representatives from Hartlepool and Stockton-on-Tees Clinical Commissioning Group (to follow)*

7. MINUTES FROM THE RECENT MEETING OF THE HEALTH AND WELLBEING BOARD

No items.

8. MINUTES FROM THE RECENT MEETING OF THE FINANCE AND POLICY COMMITTEE RELATING TO PUBLIC HEALTH

No items.

9. MINUTES FROM RECENT MEETING OF TEES VALLEY HEALTH SCRUTINY JOINT COMMITTEE

No items.

10. MINUTES FROM RECENT MEETING OF SAFER HARTLEPOOL PARTNERSHIP

No items.

11. REGIONAL HEALTH SCRUTINY UPDATE

No Items.

12. ANY OTHER BUSINESS WHICH THE CHAIR CONSIDERS URGENT

For information:

The next meeting of the Audit and Governance Committee will be held on Thursday 16 February 2017 at 10.00am in the Civic Centre, Hartlepool.



AUDIT AND GOVERNANCE COMMITTEE

MINUTES AND DECISION RECORD

19 JANUARY 2017

The meeting commenced at 10.00 am in the Civic Centre, Hartlepool.

Present:

Councillor: Ray Martin-Wells (In the Chair).

Councillors: S Akers-Belcher, Belcher, Cook (Vice-Chair), Hamilton, Harrison and Tennant.

Also Present: Mr Norman Rollo, Standards Co-opted Member.

Professor Jane Metcalf, Deputy Medical Director, North Tees and Hartlepool NHS Trust
Keith Wheldon, Safety and Quality Performance Manager, North Tees and Hartlepool NHS Trust
Karen Hawkins, Director of Commissioning and Transformation, Stockton and Hartlepool Clinical Commissioning Group

Officers: Sally Robinson, Director of Child and Adult Services
Peter Devlin, Chief Solicitor
Joan Stevens, Scrutiny Manager
David Cosgrove, Democratic Services Team

105. Apologies for Absence

None.

106. Declarations of Interest

None at the commencement of the meeting.

Councillor Ray Martin-Wells declared a personal interest during the consideration of Minute No. 116 'Consideration of Investigation Report – SC03/2016'.

107. Minutes of the meeting held on 8 December, 2016

Confirmed.

108. Health and Wellbeing Board Referral - Reporting Arrangements for Delayed Transfers of Care (*Scrutiny Manager*)

The Director of Child and Adult Services referred to the discussion at the previous meeting of the Committee on 8 December, 2016 (minute no. 99 refers) when Members received an update on the referral from the Health and Wellbeing Board in relation to the arrangements for the delayed transfer of care between hospital and social care. The Committee had noted the update and indicated that the referral be reported back to the Health and Wellbeing Board. The Director reported that when the Board had discussed the issue at its 16 January meeting it was highlighted that some issues remained outstanding and this Committee was asked to retain the referral at this time. The Director indicated that at a meeting with the Trust and officers from both Hartlepool and Stockton Borough Councils last year, a series of actions had been agreed. A number of these actions remained outstanding and therefore the matter is not yet fully resolved. Work had commenced on identifying what would constitute a reasonable placement choice to encourage people to consider homes outside of Hartlepool, however there were still delays arising from individuals who have expressed a choice not to be placed in an out of borough setting. There would be a further report to Members once the work on the agreed actions had been completed.

Members referred to their long-standing concerns at the lack of care home places available in the town, particularly nursing beds. Members highlighted the news that the former Manor Park home was to be reopened. There was also the former Admiral Court site in the north of the town that was undergoing extensive renovations which would bring further new residential places. Members understood that these two properties would require appropriate registration but asked the Director if there was any indication of when they would be open to new residents. The Director commented that the Council and the Clinical Commissioning Group (CCG) were speaking to new providers and had hopefully negotiated a mix of residential and nursing home beds at the two sites which reflected the need in the town. It was anticipated, though not confirmed, that the former Manor Court site may be available from the late spring and the former Admiral Court site in the autumn. The Director confirmed that the authority was working with the two providers and the Care Quality Commission (CQC) on their registration process, which the Director reminded Members could take some ten weeks to complete.

Members welcomed the Director's comment and indicated that they understood the registration was very process driven and would therefore take the requisite time to complete. When these two properties had closed it had been very distressing for the residents that had to be re-homed. A number had had to accept residential placements outside the town and Members questioned if these residents would be given any priority so they could return to the town. The Director indicated that there was a need to be

mindful of the capacity available within the town. Some residents had had to move out of the town arising from both the closure of homes as well as when there has been no available provision within the town, however decision making also needed to take into account those waiting to be discharged from hospital. Staff would look to doing as much as they could to meet peoples care choices within the available provision. The Chair stated that the Committee would wish to see some priority being given to those wishing to return to the town after being moved out following the previous closures of the two sites.

Recommended

That the report be noted and a further update report be submitted to the Committee in March.

109. Investigation into Mortality Rates (*Scrutiny Manager*)

The Scrutiny Manager introduced the representatives from the North Tees and Hartlepool NHS Trust who, as part of the Committee's investigation into mortality rates, had been invited to the meeting to give a presentation to the Committee setting out the Trust's current performance on measured mortality statistics.

Professor Jane Metcalf, Deputy Medical Director, and Keith Wheldon, Safety and Quality Performance Manager, North Tees and Hartlepool NHS Trust outlined the following key points in their presentation: -

- Professor Metcalf commented that the statistical figures and calculations behind both HSMR and SHMI were extremely complex and both statistics related to the Trust area and could not be broken down into geographical areas.
- The Trust is now in the 'as expected' range for both the HSMR and SHMI modules. SHMI this is the first time since April 2012 – March 2013
- HSMR (Hospital Standardised Mortality Ratio)
- SHMI (Summary Hospital-Level Mortality Indicator)
- All Trusts upload their patient activity data to the Secondary User Service (SUS) on a monthly basis
- SUS is the single, comprehensive repository for healthcare data in England which enables a range of reporting and analyses to support the NHS in the delivery of healthcare services
- The data is provided to us, the Trust does not calculate the HSMR and SHMI.
- The HSMR is a ratio of the observed number of in-hospital deaths at the end of a continuous inpatient spell to the expected number of in-hospital deaths (multiplied by 100) for 56 specific Clinical Classification System (CCS) groups; in a specified patient group
- Latest HSMR – 105.29 (September 2015 to August 2016). The Trust

currently has the 41st highest value (from the 137 Trusts), the Trust did have the highest value in the country for a period of time. In the 2015/16 Quality Accounts, the HSMR was 111.94. The highest value had been 128.08 April 2014 to March 2015. Detailed comparators both nationally and locally were displayed.

- The Trust's HSMR was now defined as being 'As Expected' and had been so for the past 8 months.
- The SHMI is a ratio of the observed number of deaths to the expected number of deaths for a trust (provider). The observed number of deaths is the total number of finished provider spells for the trust which resulted in a death either in-hospital or within 30 days (inclusive) of discharge from the trust. If the patient is treated by another trust within 30 days of discharge, their death is attributed to the last non-specialist acute trust to treat them.
- Latest SHMI – 111.84 (July 2015 to June 2016). The Trust currently has the 12th highest value (from the 137 Trusts); the Trust did have the highest value in the country for a period of time. In 2015/2016 Quality Accounts SHMI reporting 117.74 (October 2014 to September 2015). The highest SHMI value was 124.53 (June 2014 to May 2015).
- The Trust SHMI is now defined as being 'As Expected'; this is the first time since April 2012 – March 2013. Detailed comparators both nationally and locally were displayed.
- External assurances on the Trust's performance was gained from sharing and monitoring statistics with; North East Quality Observatory System (NEQOS), Advancing Quality Alliance (AQuA), NHS England, Care Quality Commission (CQC) and Clinical Commissioning Groups (CCGs).
- The Trust would continue to monitor both statistics and work with a range of local, regional and national bodies. There would be continued participation with the Regional Mortality Group, continued collaboration with NEQOS (North East Quality Observatory System), continued inclusion with the Clarity work for Pneumonia and UTI, the proactive review of deaths based on up to date HSMR data and Engagement with other Health Care providers, GPs, Care homes, and other Trust's.
- As part of this work the Trust had established a Keogh Delivery Group. This group delivered key ambitions that were raised in the Sir Bruce Keogh report. This Group became the Trust Outcome Performance Delivery Operational Group (TOPDOG) to provide support to deliver on dedicated projects.
- Within the Trust there were; Weekly Mortality Reviews, Monthly Mortality workshops for consultants and Junior Doctors, Improved Adult Core Admission and Ward round documentation, Family engagement via a bereavement survey, Ambulatory Care data to bring in line with other trusts, on-going Palliative care training for consultants, and improved Specialist Palliative Care processes, increasing patients seen by the SPC team.

The Chair commented on the complexity of the two measures which made them particularly difficult for the public to understand. The Chair commented that he did note that when the last two Quality Accounts had

been reported to the Committee, the statistics had been referred to 'as above average' and not among the highest in the country. Both figures were still, technically, high but it was welcome that both had improved.

Members echoed the Chair's comments on the complexity of the two statistics and indicated that for them and the public, all they wanted to see was whether changes to the provision of services in Hartlepool had had an effect on mortality rates. The Trust representatives stated that they didn't get figures separated by postcode, though figures by electoral ward were supplied to Councillors, though not the Trust.

Members questioned if there were any specific issues behind the fall in the statistical rates recorded by HSMR and SHMI. Professor Metcalf commented that, from the Trust's understanding, there was no one specific thing. For example, the bad winter of 2014 had led to an increase in pneumonia deaths. These deaths had been examined in detail and it was noted that there were some coding issues around the recorded cause of death which may have had an adverse effect on the statistics. There were also significant co-morbidity issues with many people having on average four and a half other serious health issues.

The Chair commented on the recent discussion at the Committee on the stroke statistics and the rating that North Tees and Hartlepool Trust was one of the worst performing in the country in this regard. Professor Metcalf indicated that the Trust received statistical data on strokes every four months. The most recent figures did show improvement, particularly on the delay in receiving CT scans, and they were not now seen as a concern. Members expressed their concern at the recent stroke statistics and questioned if a shortage of CT scanning equipment had been an issue. It was indicated that this was not an issue.

The Vice-Chair commented on the complexity of the statistics and indicated that it was refreshing to hear a health representative say they were unduly complicated and difficult to understand. The differences caused in the statistical comparisons with some areas that undertook more elective surgery were understood but people in Hartlepool were more concerned with why people were dying, or more likely to die, from specific ailments than they were in other areas. Professor Metcalf indicated that from these statistics it was difficult to determine that; even those at the centre considered that the HSMR and SHMI indicators were not a good comparison.

A Councillor referred to their own experience of getting a stroke victim to hospital and then the wait for a CT scan which ended up being some five hours after arriving at A&E. The Councillor questioned if the Trust had its own performance measures for dealing with stroke victims. Professor Metcalf stated that a CT scan was usually undertaken within an hour of arriving at A&E. The Trust also had some of the lowest waiting times for ambulances at A&E.

There was general discontent at the complexity of the statistics and the unavailability of more local information. Members did welcome the improvement in the statistics reported as they appeared to show an improvement in mortality rates across the two hospitals. A Member of the public commented on the complexity of the statistics returned from the central service and the unavailability of simple local statistics that could easily be measured. The Trust representatives did state that all the statistical information was available on the NHS Digital website but it was difficult to recreate the HSMR and SHMI figures from those figures. It was, however, the Secondary User Service that compiled and produced the two measures and they were nationally reported; these were not some kind of massaged figures to show the Trust in a good light.

The Chair thanked the two Trust representatives for their attendance at the meeting and their frank responses to Members questions. The Chair welcomed the improving statistics for HSMR and SHMI but had been concerned that in the past Quality Accounts reported to this Committee the real situation on the figures had not been fully reflected.

The Chair indicated that the information provided had addressed the concerns raised as the foundation for a specific investigation in to mortality figures. The Chair indicated that the information provided concluded the Committees mortality investigation and that the rates would continue to be monitored through the Quality Account, whilst retaining the ability to look at again in more detail, should rates worsen at any time.

Recommended

1. That the presentation and comments be noted.
2. That the information provided concluded the Committees mortality investigation and that rates continue to be monitored through the Quality Account, with the ability to look in more detail, should rates worsen at any time.

110. Urgent and Emergency Care – Update *(Representatives from Hartlepool and Stockton-on-Tees Clinical Commissioning Group)*

The Director of Commissioning and Transformation, Stockton and Hartlepool and Darlington Clinical Commissioning Groups, reported that the same pressures on urgent and emergency care that were being reported nationally were being experienced within the Hartlepool and North Tees Trust area. The Trust did, however, regularly maintain the 'four-hour' waiting time measure. Non-elective admissions – those that presented at A&E and were subsequently admitted were generally reflective of the national picture as were the discharge procedures – which had been discussed earlier in the meeting. In a presentation to the Committee, the Director of Commissioning highlighted the following key points -

- The Trust had instigated a series of projects to address some of the issues caused by the additional pressures and these included –
 - Better Care Fund projects such as the clinical SPA (Service Provider Agreement), re-ablement and Early Intervention Services
 - Regional vanguard developments such as NHS 111 initiatives – clinical hub
 - Tackling GP variation, development of the frailty register
 - Care-coordinators commissioned to ensure the top 2% at risk patient group have a co-ordinated approach across health & social care
 - Working with the Voluntary and Community Social Enterprise sector to enhance community response.
- The current urgent care arrangements which were commissioned from a number of providers and had differing opening hours.
- The new integrated urgent care service model to be delivered by NHS North Tees and Hartlepool Foundation Trust collaborating with Hartlepool and Stockton Health (HASH) and NEAS would be delivered across two sites - University Hospital North Tees and University Hospital Hartlepool. The new service would meet the new national requirements for urgent care standards recently released putting the area ahead of most others in the country.
- The new service would be a GP led urgent care service provision 24 hours a day, 7 days a week, 365 days a year providing walk in and bookable appointments for; clinical assessment, face to face consultation, home visiting (OOH), and a prison visiting service (OOH). (OOH – Out of hours.) The service would provide timely assessment and referral to appropriate mental health services together with diagnostics and appropriate referrals.
- The principle benefits of the service would be: -
 - GP led,
 - A single call to get an appointment out-of-hours (OOHs),
 - Data can be sent between providers,
 - The capacity for NHS 111 and OOHs is jointly planned,
 - The summary care record is available in the clinical hub and elsewhere,
 - Care plans and patient notes are shared between providers,
 - Appointments can be made to in-hours GPs,
 - There is joint governance across local urgent and emergency care providers,
 - There is a clinical hub containing (physically or virtually) GPs and other health care professionals,
- The service was being introduced in three phases – Phase 1 on partner and stakeholder engagement was now completed. Phase two would run up to the launch of the new service in April and would involve raising public awareness of the changes. Phase 3 would run between April and June and would involve explaining the new services to local people and how they could access them.

The Chair welcomed the proposed new services. The simple message for the public was if a situation was life threatening, then call 999; for

everything else call 111 or attend this service. The only concerns that the Chair had related to the Trust's ability to get the message out to the public about the new services. Past public messages from the Trust had been poorly conveyed; the One Life Centre being a key example. Signage needed to be clear and had to give an indication of what services were provided, not what wasn't. The Chair also suggested that information in the printed press shouldn't be a once only event and indicated that it may be useful for something to be in Hartbeat for a full calendar year with an initial information pull-out or wrap-around.

The Chair commented that the CCG had to be congratulated on listening to the public on service provision. A Member supported the comments but reiterated the Chair's comments in relation to the poor publicity around the previous changes to services. Some form of town-wide leaflet was promised last time but a lot of homes never received them. Social media should also be used to a much greater extent to get the messages out to the public. The Director of Commissioning and Transformation indicated that similar comments had been made at the Health and Wellbeing Board and the Trust and the CCG would liaise with the Council's Public Relations Team on publicity. Preliminary discussions had been held on the potential of an information pull-out in the March edition of Hartbeat. The use of social media was also something that would be utilised as far as possible.

A Member commented that while these services were welcome, they were not the return of A&E services that the public wanted. The Vice-Chair questioned the service being GP led and asked if that would mean a GP being available at all times at the two locations. The Vice-Chair also referred to the comment in the presentation that there would be other professionals available at the centres; did this mean people attending would be triaged. The Director of Commissioning and Transformation stated that there would be a GP at both sites and both sites would operate with a 'clinical streamer' that would direct people to the appropriate medical professional. This included getting x-rays done first if these were needed for example. Any onward referrals could be done direct from the clinic, whether that was to an individual's own GP or a hospital specialist. Emergencies would need to be 'blue lighted' to A&E. In response to the comments on returning A&E services to Hartlepool, the Chair indicated that even when they were at Hartlepool Hospital, many patients found themselves being transferred to other hospitals for specialist services.

Members and members of the public sought some clarity on particular elements of the service from the Director of Commissioning and Transformation around staffing and the treatment specific injuries.

In concluding the debate the Chair re-stated his comments in relation to publicity and stated that this would be the key element to the success of the new services.

Recommended

1. That the update be noted.
2. That the CCG be congratulated on their decision.
3. That Public Relations teams from the Local Authority and CCG work closely to develop and implement effective communication of the changes to Urgent Care services.
4. That the Audit and Governance Committee be involved in the development of communications proposals.

111. Adult Services Committee's Response to the Investigation into Access to Transport for People with a Disability (*Adult Services Committee*)

The Scrutiny Manager reported that the Adult Services Committee considered the Final Report into Access to Transport for People with a Disability. The report set out the feedback from the Adult Services Committee's consideration of, and decisions in relation to the recommendations. Following on from this report, progress towards completion of the actions contained within the Action Plan would be monitored through Covalent; the Council's Performance Management System; with standardised six monthly monitoring reports to be presented to the Committee.

Recommended

That the proposed actions detailed within the Action Plan be noted.

112. Minutes from the Finance and Policy Committee meetings held on 31 October 2016 and 2 December 2016

Noted.

113. Any Other Items which the Chairman Considers are Urgent

The Chairman ruled that the following items of business should be considered by the Committee as a matter of urgency in accordance with the provisions of Section 100(B)(4)(b) of the Local Government Act 1972 in order that the matter could be dealt with without delay.

114. Care Quality Commission – Consultation on the Next Phase of Regulation *(Scrutiny Manager)*

The Scrutiny Manager had circulated to Members in advance of the meeting a consultation document issued by the Care Quality Commission (CQC) 'Our next phase of regulation: A more targeted, responsive and collaborative approach'. The deadline for responses to the consultation was 14 February, 2017, ahead of the next scheduled meeting of the Committee. Alongside the consultation, the CQC were also consulting jointly with NHS Improvement on their approach to leadership and the use of resources in NHS Trusts. Copies of both documents were submitted for Members information.

In light of the tight timescales on the two consultation documents, the Scrutiny Manager requested that Members consider the two documents and any comments they wished to make should be referred to the Scrutiny Team in time for a response to be submitted to the CQC.

Recommended

That the consultation documents be noted.

115. Local Government (Access to Information) (Variation Order) 2006

Under Section 100(A)(4) of the Local Government Act 1972, the press and public were excluded from the meeting for the following items of business on the grounds that they involved the likely disclosure of exempt information as defined in the paragraphs referred to below of Part 1 of Schedule 12A of the Local Government Act 1972 as amended by the Local Government (Access to Information) (Variation) Order 2006.

Minute 116 – Consideration of Investigation Report – SC03/2016 –
Chief Solicitor and Monitoring Officer This item contains exempt information under Schedule 12A Local Government Act 1972 as amended by the Local Government (Access to Information) (Variation) Order 2006 namely information relating to an individual (para1).

116. Consideration of Investigation Report – SC03/2016 *(Chief Solicitor and Monitoring Officer)* This item contains exempt information under Schedule 12A Local Government Act 1972 as amended by the Local Government (Access to Information) (Variation) Order 2006 namely information relating to an individual (para1).

At this point in the meeting, the Chair declared a personal interest in the report and sought the Committee's agreement to his remaining in the Chair. This was agreed by Members.

The Chief Solicitor and Monitoring Officer reported to the Committee further following the consideration of the investigation report at the meeting on 8 December, 2016. Further details are set out in the exempt section of the minutes.

Recommended

Details of the decision are set out in the exempt section of the minutes..

The meeting concluded at 12.20 pm.

CHAIR

AUDIT AND GOVERNANCE COMMITTEE

8 February 2017



Report of: Scrutiny Manager

Subject: ASSISTED REPRODUCTION UNIT AT THE
UNIVERSITY HOSPITAL OF HARTLEPOOL –
COVERING REPORT

1. PURPOSE OF REPORT

- 1.1 To introduce representatives from Hartlepool and Stockton-on-Tees Clinical Commissioning Group (CCG) who will be in attendance at today's meeting to discuss their recent announcement regarding the Assisted Reproduction Unit at the University Hospital of Hartlepool (**Appendix A**).

2. BACKGROUND INFORMATION

- 2.1 On the 10 January 2017, Hartlepool Borough Council received formal notification that the CCG had been unable to secure a provider to offer both licensed and unlicensed fertility services at the University Hospital of Hartlepool. This notification indicated that the future provision of fertility services would be as follows;

- To work with existing NHS commissioned providers in the region to continue the delivery of unlicensed services only from the Hartlepool site.
- To remove licensed fertility services from the Hartlepool Assisted Reproduction Unit.
- That all patients who, following tests, require licensed fertility services (e.g. IVF, ICSI) will be required to travel out of Hartlepool to the base site of their chosen provider.

- 2.2 On 13 January 2017, the Chair of the Committee wrote to the CCG (**Appendix B**), requesting, on behalf of the Committee the following information:-

The Tender;

- The tender process undertaken (including chronology).
- The tender specification.

- The information made available to enable tenderers to make an informed decision (i.e. service data / associated costs etc.).
- Any points of clarification raised and issues covered.
- The number of expressions of interest received from prospective tenderers and at what stage they withdrew or where otherwise excluded from the process.
- The reasons for the rejection of any tenders that may have been submitted.

2) Proposals;

- Your proposed service changes for the future provision of fertility services from the ARU in Hartlepool.
- Clarification of the process, and timetable, for implementation of your proposed service changes.
- Clarification of the interim arrangements for the continuation of services from the ARU in Hartlepool.

3) Communications;

- In conjunction with your press statements, the process and timetable for communication with patients and details of arrangements for the movement of embryos.

2.3 Representatives from the CCG will be in attendance at today's meeting to assist the Committee in its scrutiny and review of:

- The tender process;
- Any decision upon formal consultation, following the outcome of this present tender process, and
- The arrangements for both licensed and unlicensed services contingent upon the above.

3. RECOMMENDATIONS

3.1 That the Audit and Governance Committee:-

- i) Receives the information provided by the CCG and reviews:
 - The tender process;
 - Any decision upon formal consultation following the outcome of this present tender process; and
 - The arrangements for both licensed and unlicensed services contingent upon the above.
- ii) Seeks confirmation that no precipitative action has or will be taken, that would lead to the cessation of licensed and unlicensed fertility services at the University Hospital of Hartlepool, pending the Audit and Governance Committee's scrutiny of this matter.

- iii) Consider if the announcements made by the CCG constitutes a substantial variation from the model for service delivery agreed, and tendered for, following the consultation previously undertaken.
- iv) Consider what, if any, further action could be taken.

Contact Officer:- Joan Stevens, Scrutiny Manager
Chief Executive's Department – Legal Services
Hartlepool Borough Council
Tel: 01429 284142
Email: joan.stevens@hartlepool.gov.uk

BACKGROUND PAPERS

No background papers were used in the preparation of this report.

Hartlepool and Stockton-on-Tees Clinical Commissioning Group

Press Statement

6 January 2017

Embargoed 5.00pm 06/01/2017

Assisted Reproduction Services in Hartlepool

Following North Tees and Hartlepool NHS Foundation Trust advising the CCG that they could no longer deliver a safe and clinically effective assisted reproduction service (IVF, IUI) at University Hospital of Hartlepool we, along with NHS Durham Dales, Easington and Sedgfield CCG, NHS Darlington CCG and NHS South Tees CCG undertook a formal public consultation between 31st May and 15th July 2016.

The findings of the consultation were received by the CCGs Governing Body on 22nd July 2016. Governing Body convened on 26th July 2016 and agreed to progress the recommended option which was option 1; to procure a comprehensive assisted reproductive service including HFEA (Human Fertilisation and Embryology Authority) licensed and unlicensed provision at Hartlepool delivered by an alternative provider.

The risk of this option (highlighted in the consultation document) was that the CCG may be unable to secure and commission an alternative provider to deliver a full service from the University Hospital of Hartlepool site.

Unfortunately, due to a limited response from the provider market and the bids received not meeting the required quality standards, we have not been successful in securing a provider that can offer both licensed and unlicensed fertility services at Hartlepool.

The priority of the CCGs is to ensure that patients can continue to have as much of their care delivered locally at the Hartlepool site and on this basis we are working closely with existing NHS commissioned providers in the region to deliver unlicensed services at the Hartlepool site. This will mean that patients have an increased choice of Providers at the Hartlepool site than was previously available. Any patient who following tests require licensed fertility services (e.g. IVF, ICSI) will then be offered this at the base site of their chosen provider.

Issued by the Communication and Engagement Team for the North of England Commissioning Support Unit (NECS) on behalf of Hartlepool and Stockton-on-Tees Clinical Commissioning Group.

For information, photographs and interviews, please contact **Judith McGuinness**,
Senior Communication Officer
on **01642 745019** or by e-mail: **judith.mcguinness@nhs.net**

Teesdale House, Westpoint Road, Thornaby, Stockton TS17 6BL

We are disappointed that we have not been able to secure a provider but as commissioners our priority is to ensure any service we commission is safe, clinically effective and of the highest quality. Although patients told us during the consultation that they would be prepared to travel for fertility treatment we do know that this will be difficult for some and we will work with providers to minimise the impact of these changes as much as possible.

North Tees and Hartlepool Foundation Trust will be contacting all patients who have embryos in storage at their site to ask them to choose which HfEA licenced provider in the region they would like their embryos to transfer to for continued storage and any subsequent treatments.

We understand that this will cause distress to patients who have really valued the full service delivered at Hartlepool.

Ends.

Issued by the Communication and Engagement Team for the North of England Commissioning Support Unit (NECS)
on behalf of Hartlepool and Stockton-on-Tees Clinical Commissioning Group.

For information, photographs and interviews, please contact **Judith McGuinness**,
Senior Communication Officer
on **01642 745019** or by e-mail: **judith.mcguinness@nhs.net**

Teesdale House, Westpoint Road, Thornaby, Stockton TS17 6BL

Councillor Ray Martin-Wells
Chair, Audit and Governance Committee
C/o Civic Centre
Hartlepool
TS24 8AY



Ali Wilson
Chief Officer
NHS Hartlepool & Stockton-on-Tees Clinical Commissioning Group
Billingham Health Centre
Queensway
Billingham
TS23 2LA

13th January 2017

Dear Ali

ASSISTED REPRODUCTION UNIT AT THE UNIVERSITY HOSPITAL OF HARTLEPOOL

On the 10th January 2017, Hartlepool Borough Council received formal notification that you have been unable to secure a provider to offer both licensed and unlicensed fertility services at the University Hospital of Hartlepool. This notification indicated that the future provision of fertility services would be as follows;

- To work with existing NHS commissioned providers in the region to continue the delivery of unlicensed services only from the Hartlepool site.
- To remove licensed fertility services from the Hartlepool Assisted Reproduction Unit.
- That all patients who, following tests, require licensed fertility services (e.g. IVF, ICSI) will be required to travel out of Hartlepool to the base site of their chosen provider.

In light of evidence previously considered by the Audit and Governance Committee (acting in their statutory scrutiny capacity), which highlighted the existence of potential tenderers, we were exceptionally disappointed, and surprised, to learn that you had been unable to secure a provider.

Given our responsibilities under the Local Authority (Public Health, Health, Health and Wellbeing Boards and Health Scrutiny) Regulations 2013, we feel that it is incumbent upon us to obtain a clear understanding of the background to this development, the overall tender process and the proposed service changes. In order to facilitate this, under Regulation 21 of the above (namely the review and scrutiny of 'any matter relating to the planning, provision and operation of the health services' in the Authority's area), I request on behalf of the Committee the following information:-

1) The Tender;

- The tender process undertaken (including chronology).
- The tender specification.
- The information made available to enable tenderers to make an informed decision (i.e. service data / associated costs etc.).
- Any points of clarification raised and issues covered.
- The number of expressions of interest received from prospective tenderers and at what stage they withdrew or where otherwise excluded from the process.
- The reasons for the rejection of any tenders that may have been submitted.

2) Proposals;

- Your proposed service changes for the future provision of fertility services from the ARU in Hartlepool.
- Clarification of the process, and timetable, for implementation of your proposed service changes.
- Clarification of the interim arrangements for the continuation of services from the ARU in Hartlepool.

3) Communications;

- In conjunction with your press statements, the process and timetable for communication with patients and details of arrangements for the movement of embryos.

Pending receipt of this information, and the convening of a meeting of the Committee to review the tender process and any decision upon formal consultation following the outcome of this present tender process, it is requested that you do not take any precipitative action, which would lead to the cessation of licensed and unlicensed fertility services at Hartlepool.

It is appreciated the 'distress and disruption' (Hartlepool Mail comment) occasioned by your press statement and it is in all parties interests if you could respond with the necessary assurances requested in this correspondence at your very earliest opportunity and allow the Committee to be convened as soon as possible with the attendance of CCG representatives, at a mutually convenient time.

Yours faithfully



COUNCILLOR RAY MARTIN-WELLS
CHAIR OF THE AUDIT AND GOVERNANCE COMMITTEE

Copies to:-

Gill Alexander, Chief Executive, Hartlepool Borough Council
Louise Wallace, Director of Public Health, Hartlepool Borough Council
Councillor Christopher Akers-Belcher, Leader of Hartlepool Borough Council
All members of the Audit and Governance Committee

AUDIT AND GOVERNANCE COMMITTEE

8 February 2017



Report of: NHS Hartlepool and Stockton-on-Tees Clinical
Commissioning Group

Subject: ARU PROCUREMENT OUTCOME REPORT

1. PURPOSE OF REPORT

1.1 The purpose of this report is to provide the Audit and Governance Committee an update, this update is following the procurement exercise undertaken in relation to Assisted Reproductive Services delivered from the University Hospital of Hartlepool (UHH) and provided by North Tees and Hartlepool Foundation Trust (NTHFT). The report also provides the Audit and Governance Committee Chair a response to the correspondence issued to the Clinical Commissioning Group (CCG) dated 13th January as set out in Appendix A.

1.2.1 The report addresses from this correspondence the following areas;

- Procurement process (chronology, specification, information, clarification and outcome)
- Proposals for future service delivery
- Communication

2. BACKGROUND

2.1 Following receipt of notice from the current provider of Assisted Reproductive Services informing the CCG that they were unable to sustain future service delivery a formal consultation was undertaken in advance of determining future options for service delivery

2.2 NHS Hartlepool and Stockton-on-Tees Clinical Commissioning Group (CCG) working on behalf of NHS Durham Dales Easington & Sedgfield (DDES), NHS Darlington and NHS South Tees Clinical Commissioning (STCCG) Groups on 26th July 2016 presented a consultation outcome report and presentation to the CCG Governing Body (GB). Following the presentation of the consultation outcome a decision was taken by the GB to proceed to procurement based on option 1, for a comprehensive assisted reproductive

service including Human Fertilisation and Embryology Authority (HFEA) licensed and unlicensed provision at the University Hospital of Hartlepool.

- 2.3 The outcome of the GB decision was presented to Audit and Governance Committee on 28 July 2016. The Committee requested that they were kept fully informed of the procurement process.

3. PROCESS

- 3.1 The procurement process in its entirety was undertaken in line with the regulations to ensure the CCG fulfilled its statutory duties.
- 3.2 A Prior Information Notice (PIN) (Appendix B) was issued on 26 August 2016 in the Official Journal of the European Union (OJEU) and on Contracts Finder (<https://www.gov.uk/contracts-finder>) as a call for competition and to identify the potential level of interest from the market. This resulted in a response of receipt with 9 expressions of interest.
- 3.3 In order to develop the service specification and to establish the best method for securing future services, an oversight project group which was established throughout the consultation made up of the relevant subject matter experts continued to oversee the project to ensure delivery of the procurement timelines. This group included:
- Associate Director of Commissioning & Delivery – NHS Hartlepool and Stockton-on-Tees CCG
 - Commissioning and Delivery Manager – NHS Hartlepool and Stockton-on-Tees CCG
 - Clinical Lead – NHS Hartlepool and Stockton-on-Tees CCG
 - Senior Commissioning Manager- Commissioning (North of England Commissioning Support (NECS on behalf of the CCG) Provider Management)
 - Procurement Officer (NECS Healthcare Procurement & Market Management)
 - Senior Commissioning Support Officer (NECS Service, Planning and Reform)
 - Senior Finance Manager (NECS Commissioning Finance)
- 3.4 A Procurement and Evaluation Strategy (PES) (Appendix C) was developed in compliance with the Public Contract Regulations 2015, the Public Services (Social Value) Act 2012, the NHS (Procurement, Patient Choice and Competition) (No.2) Regulations 2013, and the CCGs Detailed Financial Policies.
- 3.5 The PES report and associated ITT documentation was presented to the CCG DT (who had delegated responsibility from the CCG GB) on 18 October 2016, and approval was obtained to proceed to procurement based on the approach detailed in the PES. The report was then provided to the CCG GB on 29 November 2016 for information.

3.6 The timetable for tender is as set out below in Table 1.

Table 1 Tender Timetable

Activity	Date
Date Advert Published	19/10/2016
Deadline for receipt of final ITT clarifications from bidders	31/10/2016
Deadline for issue of final ITT clarifications to all bidders	09/11/2016
Tender submission deadline	16/11/2016
Evaluation of tender submissions	17/11/2016 – 20/12/2016
Issue Intent to award notification and provide feedback	21/12/2016
Standstill period begins	21/12/2016
Standstill period ends	06/01/2017
Issue Contract Award Notice	07/01/2017
Mobilisation period begins	07/01/2017
Service commencement	01/04/2017 (Earlier if possible)

3.7. The procurement was then advertised on 19 October 2016 through both OJEU and Contracts Finder and as such was available to any interested parties. The advert directed interested parties to a free to register procurement portal to download the procurement documentation.

3.8 A copy of the service specification and supporting procurement documents to enable bidders to make an informed decision are described below and set out in (Appendix D). These were issued to bidders in line with the timetable described above

- ITT Document 5 NHS Standard Contract
- ITT Document 9a ARU Heads of Terms for Trust
- ITT Document 9b UHH Maternity ARU lease plan
- ITT Document 9c Trust policies and procedures
- ITT Document 9d Trust ARU Equipment List

3.9 A site visit was scheduled on the 24 October 2016 and 3 potential bidders attended the site visit facilitated by NECS working on behalf of the CCG and the NTHFT staff.

3.10 The deadline for bidder clarifications was the 31 October 2016 and 20 clarification questions were submitted by potential bidders via the procurement portal (Appendix E). Responses were provided to all clarification questions by 07 November 2016 ahead of the published timeframe of 09

November 2016, thus offering full compliance with the Public Contract Regulations 2015 and advertised process.

- 3.11 Following closure of the clarification query timescale, the CCG received subsequent contact from interested bidders (3) between the on the 3rd and 16th November advising they had withdrawn from the procurement process on the basis that although interested in providing a service, following review of the model and premises they did not believe option 1 was a viable model. It was suggested from correspondence that using a “satellite” model would have been the preferred approach.
- 3.12. On the 11 November 2016 the CCG received correspondence from the Chair of Audit and Governance Committee (Appendix F) raising concerns and advising that he had been contacted directly as ‘a number of parties were finding it difficult to obtain information’ in relation to the procurement.
- 3.13 The CCG responded immediately upon receipt of the letter, advising the Scrutiny Officer although a formal response would be issued, the CCG would undertake an investigation. This investigation would be to seek assurance that all parties (CCG, Provider and Bidders) had complied in accordance with the ITT requirements.
- 3.14 Following investigation a formal response (Appendix G) was then issued to the Chair of Audit and Governance Committee on the 18 November 2016. This outlined from the investigation undertaken the CCG had complied with the requirements and all applicable regulations, identifying no clarification questions issued in line with the guidance had been left unanswered and these were answered in advance of the timetable as set out in 3.10.

4. EVALUATION

- 4.1 Upon closure of the process and at the tender submission deadline of 12 noon on 16 November 2016 1 bid was submitted. This was opened in line with the approval gained within the PES by a nominated director within NECS. No bids were rejected or excluded from the procurement process.
- 4.2 This submission was then evaluated by individual subject matter experts (see 3.3) in line with the regulatory requirements and included additional expertise in the areas of clinical governance, information governance, ICT and communications.
- 4.3 A consensus was conducted by the subject matter experts on 02 December 2016, this identified the bidder had failed to deliver the requirements of the minimum 50% with respect to Quality as described in the PES and ITT documents. This consensus identified the bidder within this had failed 2 red flag questions and overall the bid achieved a score of 38.25%.
- 4.4 A Procurement Outcome report (Appendix H) was presented to the CCG GB on 20 December 2016. This report set out options and recommendations for

the GB to consider with a planned meeting to be held on the 4 January 2017 to agree next steps and the recommendation.

- 4.5 Following the meeting on the 4 January 2017 CCG GB agreed to explore the options 3 and 4 from the Procurement Outcome report was approved to ensure service delivery could be maintained within Hartlepool.
- 4.6 On 5 January 2017 an outcome letter was issued to the unsuccessful provider in line with the regulations.

5. PROPOSALS

- 5.1 The preferred option based on the original consultation (option 1) and the decision from GB was that all fertility services should continue to be delivered from UHH.
- 5.2 Following a robust procurement process as outlined in the report the CCG has been unable to secure a viable provider for this option, market feedback has also identified this option is unlikely to be a viable sustainable option in the longer term.
- 5.3 In order to ensure a service remains in Hartlepool alternative options had to be considered which could be implemented immediately due to the fragility of the existing service provision. The option needed to be one which would prevent a break in service if possible, minimise disruption to patients and staff and offer the best alternative to closure with the flexibility to allow for any future service to be scoped, developed and redesigned.
- 5.4 As the CCG currently has commissioned and contracted arrangements with a number of Providers of both unlicensed and licenced services discussions have been held to ascertain the options that could be implemented immediately, this would retain the majority of service provision in Hartlepool and ensures patients are still offered choice of Provider. This was in line with the GB recommendation. The options considered were;

Option 1 - shared care model: NTHFT will continue to deliver unlicensed services; patients will choose a provider for licensed treatment (Gateshead Health Foundation Trust and Newcastle Upon Tyne Hospitals Foundation Trust) with the majority of treatment and work up undertaken in Hartlepool through shared care arrangements with the licensed provider of choice.

Option 2 – NTHFT continue to deliver unlicensed services at UHH and HFEA Licensed provision will be delivered at other sites in the region based on patient choice





6. COMMUNICATIONS










- 6.1 Communications is being managed through the current provider NTHFT as they are working in accordance with HFEA regulations to manage the communication and process for patients with stored embryos, gametes and sperm (Appendix I).

7. RECOMMENDATIONS

- 7.1 The CCG recommendation to ensure continuation of delivery of services is to immediately progress with Option 1 (5.4) – a shared care model with all unlicensed treatments and the preparation of patients for licensed treatments in line with the agreed protocols for the licenced cycle delivered by NTHFT at UHH. Patients will have a choice of provider of licensed services following this pathway; this could be implemented immediately for Gateshead/Newcastle Trusts reducing the additional travel time for the majority of appointments/treatments for those patients wishing to choose either of these providers.
- 7.2 Those patients accessing NTHFT for unlicensed treatment, who are then identified as requiring licensed Assisted Reproductive Services, and who choose STHFT as a provider would immediately commence their pathway at STHFT. This would mean a patient having all appointments and treatments for their licenced care provided at the James Cook site.
- 7.3 Longer term future service pathway to be re-scoped following review of the immediate solution.

8. BACKGROUND PAPERS

Paper	Appendix	Attachments
Audit and Governance correspondence 13 th January 2017 – procurement process	A	 Appendix A - Cll Martin-Wells - Letter 1
Prior Information Notice	B	 Appendix B - HaST ARU PIN NOTICE.doc
Procurement and Evaluation Strategy	C	 Appendix C - NECS255 Procurement
Invitation to Tender documentation	D	 Appendix D - ITT Document 5 - NHS St

		 Appendix D - ITT Document 9a ARU He  Appendix D - ITT Document 9b UHH_Mi  Appendix D - ITT Document 9c Trust pc  Appendix D - ITT Document 9d - Trust ,
Clarification Log and responses	E	 Appendix E Clarification Log and r
Audit and Governance correspondence 13 th November 2016 – information queries	F	 Appendix F - Audit and Governance corri
CCG response to Audit and Governance – information queries	G	 Appendix G - CCG response to Audit and
Procurement Outcome Report	H	 Appendix H - Procurement Outcom
Trust communication correspondence	I	 Appendix I - letter to patients with Embryc

9. CONTACT OFFICER

Karen Hawkins
Director of Commissioning & Transformation
NHS Hartlepool and Stockton-on-Tees Clinical Commissioning Group
01642 745126



**Councillor Ray Martin-Wells
Chair, Audit and Governance Committee
C/o Civic Centre
Hartlepool
TS24 8AY**

Ali Wilson
Chief Officer
NHS Hartlepool & Stockton-on-Tees Clinical Commissioning Group
Billingham Health Centre
Queensway
Billingham
TS23 2LA

13th January 2017

Dear Ali

ASSISTED REPRODUCTION UNIT AT THE UNIVERSITY HOSPITAL OF HARTLEPOOL

On the 10th January 2017, Hartlepool Borough Council received formal notification that you have been unable to secure a provider to offer both licensed and unlicensed fertility services at the University Hospital of Hartlepool. This notification indicated that the future provision of fertility services would be as follows;

- To work with existing NHS commissioned providers in the region to continue the delivery of unlicensed services only from the Hartlepool site.
- To remove licensed fertility services from the Hartlepool Assisted Reproduction Unit.
- That all patients who, following tests, require licensed fertility services (e.g. IVF, ICSI) will be required to travel out of Hartlepool to the base site of their chosen provider.

In light of evidence previously considered by the Audit and Governance Committee (acting in their statutory scrutiny capacity), which highlighted the existence of potential tenderers, we were exceptionally disappointed, and surprised, to learn that you had been unable to secure a provider.

Given our responsibilities under the Local Authority (Public Health, Health, Health and Wellbeing Boards and Health Scrutiny) Regulations 2013, we feel that it is incumbent upon us to obtain a clear understanding of the background to this development, the overall tender process and the proposed service changes. In order to facilitate this, under Regulation 21 of the above (namely the review and scrutiny of 'any matter relating to the planning, provision and operation of the health services' in the Authority's area), I request on behalf of the Committee the following information:-

1) The Tender;

- The tender process undertaken (including chronology).
- The tender specification.
- The information made available to enable tenderers to make an informed decision (i.e. service data / associated costs etc.).
- Any points of clarification raised and issues covered.
- The number of expressions of interest received from prospective tenderers and at what stage they withdrew or where otherwise excluded from the process.
- The reasons for the rejection of any tenders that may have been submitted.

2) Proposals;

- Your proposed service changes for the future provision of fertility services from the ARU in Hartlepool.
- Clarification of the process, and timetable, for implementation of your proposed service changes.
- Clarification of the interim arrangements for the continuation of services from the ARU in Hartlepool.

3) Communications;

- In conjunction with your press statements, the process and timetable for communication with patients and details of arrangements for the movement of embryos.

Pending receipt of this information, and the convening of a meeting of the Committee to review the tender process and any decision upon formal consultation following the outcome of this present tender process, it is requested that you do not take any precipitative action, which would lead to the cessation of licensed and unlicensed fertility services at Hartlepool.

It is appreciated the 'distress and disruption' (Hartlepool Mail comment) occasioned by your press statement and it is in all parties interests if you could respond with the necessary assurances requested in this correspondence at your very earliest opportunity and allow the Committee to be convened as soon as possible with the attendance of CCG representatives, at a mutually convenient time.

Yours faithfully



COUNCILLOR RAY MARTIN-WELLS
CHAIR OF THE AUDIT AND GOVERNANCE COMMITTEE

Copies to:-

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Councillor Christopher Akers-Belcher, Leader of Hartlepool Borough Council
All members of the Audit and Governance Committee

6.1 Appendix B

North of England Commissioning Support (NECS) are working for and on behalf of NHS Hartlepool and Stockton, NHS Durham Dales Easington & Sedgefield, NHS Darlington and NHS South Tees Clinical Commissioning Groups (the CCGs) who wish to invite expressions of interest from providers who could provide unlicensed and HFEA (Human Fertilisation and Embryology Authority) licensed fertility services from University Hospital of Hartlepool to achieve the following aims and objectives for the CCGs population.

- To meet the requirements of the Human Embryology and Fertility Authority to provide licensed fertility services.
- To provide investigations to determine the cause of subfertility
- To offer assessment and treatment for patients suffering from subfertility.
- To help couples suffering from subfertility to achieve a successful pregnancy
- To provide a quality, safe, cost effective HFEA licensed services ensuring that the risk of infection and other complications to service users is minimised
- To provide a personal service sensitive to the physical, psychological and emotional needs of service users
- To offer unlicensed and HFEA licensed services which are safe, effective, appropriate, accessible and acceptable to Service users, and represent good value for money
- To offer Assisted Conception treatment in line with the IVF and ICSI Clinical Commissioning Policy

To note that following public consultation the CCG is very clear that the services need to be delivered from the University Hospital of Hartlepool site and would request that only those bidders who would be willing to deliver the full service from that site submit an expression of interest.

NECS is utilising an electronic tendering tool to manage this procurement and communicate with potential providers. Accordingly, there will be no hard copy documents issued to potential providers and all communications with NECS, including your submission, will be conducted via the portal <https://www.proactisplaza.com/SupplierPortal/?CID=NECS> hosted by Proactis, the managed service provider for the NECS e-tendering system.

It is free to register on the portal, and it can be accessed at any time of day providing you have a working internet connection. Should bidders have any queries, or are having problems registering on the portal, they should contact the eTendering provider by Email: Suppliersupport@proactis.com or Website: <http://proactis.kayako.com/suppliernetwork/Core/Default/Index> (Monday to Friday 8:30am to 5.00pm).

Please could any expressions of interest be submitted as per the instructions on the e-tendering portal by 16 September 2016.

Procurement and Evaluation Strategy

Assisted Reproductive Unit Service

*For and on behalf of: NHS Hartlepool and
Stockton-On-Tees Clinical Commissioning
Group*

*Michael Robson
Procurement Officer*



1. Purpose

The purpose of this paper is to:

- 1.1. Inform NHS Hartlepool and Stockton on Tees Clinical Commissioning Group (HaST CCG) Delivery Team (DT) of the proposed procurement and evaluation strategy to be used in the procurement of the Assisted Reproductive Unit service
- 1.2. Request approval of the proposed procurement and evaluation strategy, procurement timetable, financial threshold, contract term and to note any risks identified.
- 1.3. Request approval for the use of electronic tendering systems and approval for an authorised representative from North of England Commissioning Support (NECS) to open the bids on behalf of HAST CCG.
- 1.4. Request that the date of the recommended bidder report is noted and this item is added to the agenda for the Governing Body development session on 20th December 2016
- 1.5. Request that the minutes of this meeting for this agenda item are forwarded to NECS for audit purposes via necsu.neprocurement@nhs.net

2. Background

- 2.1. The Assisted Reproduction Unit (ARU) at the University Hospital of Hartlepool (UHH) undertakes non licensed and licensed fertility treatments. Licensed treatments are those regulated by the Human Fertilisation and Embryology Authority (HFEA) and require the specialised skills of an Embryologist.
- 2.2. NHS Hartlepool and Stockton-on-Tees Clinical Commissioning Group (CCG) commission both unlicensed and licensed fertility treatments from North Tees and Hartlepool NHS Foundation Trust (NTHFT) as part of an annual contract.
- 2.3. In January 2016 NTHFT informed the CCG as the commissioner of the service and at the same time Hartlepool Borough Council (the Council) (due to the service location being in Hartlepool Hospital) of its decision to no longer provide licenced treatments from UHH but that it would continue to provide general infertility treatment.
- 2.4. In accordance with regulations the Audit and Governance Committee of the Council requested attendance of the CCG and NTHFT at a committee meeting to enable the committee to scrutinise matters relating to the planning, provision and decision making of this matter.
- 2.5. In early January, 2016, the CCG approached the Northern England Clinical Senate to ask the Senate to undertake a clinical review of the ARU at the UHH.
- 2.6. The Audit and Governance committee referred the matter to full council with a recommendation to undertake a judicial review and papers were submitted to the High Court on the 4th March. This review was requested on the grounds that the council determined the decision to no longer provide licenced fertility treatment from UHH was taken without any consultation with Hartlepool Borough Council and other

key partners (Hartlepool and Stockton on Tees Clinical Commissioning Group, Stockton on Tees Borough Council, Durham County Council).

- 2.7. A copy of the court order was subsequently received by the CCG on 10th March with a date set for this to be heard at High Court on the 5th April.
- 2.8. A consent order was issued following the 5th April on 16th April outlining that:
 - 2.8.1. The Defendant will enter into user engagement around the future of the licensed fertility treatment at the Assisted Reproduction Unit (ARU) at the University Hospital of Hartlepool, which it proposes to do alongside the NHS Hartlepool & Stockton on Tees Clinical Commissioning Group (CCG).
 - 2.8.2. The Defendant will consult with the Claimant individually and/or a joint committee of the Claimant and Stockton-on-Tees Borough Council and Durham County Council (if the latter two authorities wish to participate in a joint committee) as to the proposals around the ARU. If possible, the Defendant will carry out this consultation alongside the CCG.
- 2.9. Until the conclusion of the aforesaid consultation, and until a decision is taken on the proposal set out above, the Defendant shall:
 - 2.9.1. take no step intended to facilitate the closure of the ARU, and
 - 2.9.2. use its best endeavours to continue to provide licensed treatment services at the ARU.
 - 2.9.3. The Trust and the Council will use their best endeavours, alongside the CCG, to ensure that consultation and engagement is completed and a final decision about the future of the ARU taken, by 31 July 2016.
- 2.10. Following the consultation process closure, a decision was taken by HaST Governing Body to proceed with option 1 presented in the consultation process.
- 2.11. Option 1 consisted of the following: A comprehensive assisted reproductive service including HFEA licensed and unlicensed provision remains at Hartlepool delivered by an alternative provider
 - Existing provision will be maintained and patients will unlikely see any changes
 - Patients will receive all treatment in Hartlepool
 - There would be no (nil) patients potentially impacted
- 2.12. In order to develop the Service Specification and establish the best method for securing services an Oversight Project Group was established made up of the relevant subject matter experts which included:
 - Senior Manager- Commissioning (NECS Provider Management)
 - Procurement Officer (NECS Healthcare Procurement & Market Management)
 - Senior Commissioning Support Officer (NECS Service, Planning and Reform)
 - Senior Finance Manager (NECS Commissioning Finance)
 - Commissioning Manager (HaST CCG)

- Associate Director Commissioning & Delivery (HaST CCG)

2.13. In addition, Clinical input has been provided towards the development of the service specification and the evaluation criteria from a number of GP Leads across the participating CCGs.

3. Procurement Objectives

3.1 The procurement strategy is in place to ensure, in line with the National Health Service (Procurement, Patient Choice and Competition) (No. 2) Regulations 2013 that the following objectives will be met:

3.1.1 Regulation 2 (a): securing the needs of the people who use the services;

Through the public consultation process it has been highlighted that a local service within the boundaries of Hartlepool and Stockton on Tees is of high priority to local users of the service. By allowing providers the opportunity to deliver this service from the premises of University Hospital of Hartlepool we will meet this need of the people requiring the ARU service. Without this procurement the service would be at risk of ending due to the current situation of the incumbent provider.

3.1.2 Regulation 2 (b): improving the quality of the services;

The Assisted Reproductive Services offered will be safe, effective, appropriate, accessible and acceptable to Service users and represent good value for money. The Provider will be required to co-ordinate inpatient, day care and outpatient services to ensure continuity of care. The key objectives to improving the quality are:

- To offer Assisted Reproductive Services which are safe, effective, appropriate, accessible and acceptable to Service users, and represent good value for money
- To offer Assisted Reproductive Services treatment in line with the care pathway agreed by Hartlepool and Stockton Clinical Commissioning Group
- To offer Service users consistent, appropriate and suitable information in a format that they can understand.

3.1.3 Regulation 2 (c): improving efficiency in the provision of the services;

The new specification has a strong focus on interoperability with a view of further integrated working amongst other health and social services. The service is also taking the approach of bundling both licensed and non-licensed treatments into the specification. This is to make the package more attractive to providers and to drive efficiency for the CCG.

4. Compliance with the Public Services (Social Value) Act 2012

4.1 Under the Public Services (Social Value) Act 2012 the Contracting Authority must consider;

- How the proposed service to be procured may improve the economic, social and environmental well-being of Hartlepool and Stockton on Tees; and
- How, in conducting the process of procurement, it might act with a view to securing the improvement.

4.2 Areas of Social Value which potential providers will be encouraged to address include: -

- Improved social inclusion for residents i.e. improved community access;
- Improved local training or job opportunities including creating local jobs for local people and retaining local people within the existing workforce;
- Greater participation with third sector organisations in the community; and
- Encouraging and supporting on-going local business growth and development – the tender process does not prohibit any potential provider from being involved in the process.

4.3 This will then be evaluated in the technical response as per the evaluation criteria detailed in this report.

5. Procurement Methodology

5.1 There are a number of procurement processes available to the CCG as detailed in the table 1. It should be noted that some procurement procedures are more appropriate to the nature of this service requirement than others. This report makes a recommendation on the project groups preferred option to achieve the desired outcomes.

Table 1

Procurement Process	Description	Consideration
Not to procure	Allow the current provision to expire	This option would leave a gap in service provision and would mean that the CCG was failing to meet the needs of the population.
Open Procedure Through adoption of the Light Touch Regime (LTR) as set out in Regulations 74 to 77	This allows an unlimited number of interested providers to tender against defined parameters. This procedure is open and transparent and is the recommended procedure if low numbers of interested providers are known.	Knowledge of the market has identified that there are a low number of providers who may be interested in this service provision.

Procurement Process	Description	Consideration
Restricted Procedure	<p>This is a two-stage procedure. The first stage allows an unlimited number of interested providers to tender but allows the contracting authority to set the minimum criteria relating to technical, economic and financial capabilities that the suppliers have to satisfy.</p> <p>Following evaluation and short-listing, a minimum of five suppliers (unless fewer qualify) are invited to tender in the second stage.</p>	<p>There are a finite number of providers in the market that can deliver the service.</p> <p>This process is longer than the Open route.</p>
Competitive Procedure with Negotiation	<p>This procedure is appropriate for complex contracts where contracting authorities are able to define some of the technical means capable of satisfying their needs or objectives but which could be negotiated following receipt of tenders. The contracting authority may enter into negotiation with bidders following assessment of their initial tender to identify and define the means best suited to satisfying their needs but must ensure that the minimum requirements for service delivery are not amended and that all bidders are treated equally.</p>	<p>There is a known service specification and financial envelope for the service and this is not a complex service.</p>
Competitive Dialogue	<p>This procedure is appropriate for complex contracts where contracting authorities are not objectively able to define the technical means capable of satisfying their needs or objectives, and/or are not objectively able to specify the legal and/or financial make-up of a project. A pre-qualification questionnaire should be completed to select the candidates to participate in the</p>	<p>As above</p>

Procurement Process	Description	Consideration
	dialogue. The contracting authority enters into a dialogue with bidders to identify and define the means best suited to satisfying their needs. The dialogue may be conducted in successive stages with the remaining bidders being invited to tender.	
Innovation Partnership	This procedure is appropriate for the requirement of an innovative product, service or works that cannot be met by purchasing products, services or works already available on the market.	The service is not a new or innovative service.
Negotiated Procedure without prior publication <i>(also known as Single Tender Action)</i>	A single tender action is the process where a contract is awarded to a provider without competition. Although it is not a term that is defined in the EU Directives or UK Regulations, Regulation 32 of <u>The Public Contracts Regulations 2015</u> refers to the “negotiated procedure without prior publication of a contract notice”. This allows a contracting authority to depart from the Regulations’ usual obligations on open competition and transparency and negotiate a contract directly with one or more providers. Its use is limited to a few defined circumstances in which it is considered strictly necessary. If the negotiation is being conducted with one provider then this is in effect a single tender action. Evidence is critical for audit purposes and to overcome challenges that there are no other providers within the market with capability and capacity to provide the required service. Market engagement and analysis will enable the evidence required.	There is more than one capable provider that can deliver this service.

- 5.2 Due to the value of the contract and in line with the CCGs Detailed Financial Policies (DFPs), a process which reflects the Open procurement route is considered the preferred route to market. This would be proportionate and relevant to the nature of the service requirement, whilst also presenting a lower degree of the risk of challenge to the CCGs (in contrast to other routes to market, which inherently present a greater degree of risk of challenge to the CCGs on the basis of utilising a disproportionate procedure). The route also provides a contract award in line with the time constraints of a service commencement 1st April 2017
- 5.3 The procurement will be advertised in the Official Journal of the European Union (OJEU) and on Contracts Finder and governed by the Public Contract Regulations 2015), the Public Services (Social Value) Act 2012, the NHS (Procurement, Patient Choice and Competition) (No.2) Regulations 2013, and HaST CCG Detailed Financial Policies.

6. ETendering

- 6.1 The Invitation to Tender and supporting documents will be available to download via a dedicated NECS eTendering portal.
- 6.2 NECS utilise a secure electronic tendering system. Online tenders are published and received into a secure online eTendering portal. The bids can only be accessed by specified representatives on the pre-determined tender closing date. NECS is proposing that an authorised representative is given approval to open bids on behalf of HaST CCG for this procurement. This will ensure that bids are opened in the agreed timeframe.

7. Procurement Timetable

- 7.1 Table 2 shows the key milestones and timescales for the proposed procurement process.

Table 2

Milestone	Description	Date
Procurement and Evaluation Strategy approval	Strategy approved by CCG DT	18/10/2016
	Strategy presented to CCG Governing Body (for information only)	29/11/2016
Advert	Date advert published on Contract Finder	18/10/2016
Bidder event/Site Visit	Event to explain procurement process and documents	24/10/2016
Tender deadline	Date by which bids need to be submitted	16/11/2016
Consensus scoring	Evaluator panel meeting to agree scores	30/11/2016 – 01/12/2016

Milestone	Description	Date
Recommended bidder report	Report presented to CCG DT to review successful bidder	13/12/2016
	Report presented to CCG Governing Body for approval	20/12/2016
Standstill period	Notification to bidders of outcome, allowing 10 days for any challenges to be raised	21/08/2016 – 06/01/2017
Contract award	Official offer of contract sent to successful bidder	07/01/2017
Contract signature and mobilisation	Mobilisation of contract	07/01/2017 – 01/04/2017
Service commencement	Service start date	01/04/2017

8. Evaluation Strategy

- 8.1 The evaluation model proposed seeks to identify the Most Economically Advantageous Tender (MEAT), which is interpreted as affordable Value for Money (VfM), the evaluation criteria are outlined in Table 3:

Table 3

	Section	Question Ref.	Red Flag Question	Micro Weighting %	Macro Weighting %
Quality	Section 1 Operational	OP01		7	35
		OP02		10	
		OP03		8	
		OP04	Red Flag	10	
	Section 2 Mobilisation	MOB01		20	20
	Section 3 IM&T	IT01		4	10
		IT02		3	
		IT03		3	
	Section 4 Resources	RES01	Red Flag	15	15
	Section 5 Facilities	FAC01		5	5
	Section 6 Communications	COMM01		10	10
	Section 7 Social Value	SV01		5	5
	Sub-total for Quality				100
Finance		Bid Price		PASS/FAIL	N/A
Sub-total for Finance					0
Grand Total					100

8.2 The evaluation process is made up of three stages as detailed below.

8.2.1 Stage 1 – Compliance

The information supplied in the bid response by each bidder will be checked for completeness and compliance with the requirements of the ITT before responses are evaluated. The preliminary compliance review will check that submissions:

- have answered all questions (or explained satisfactorily if considered not applicable); and
- have included all documents as requested.

8.2.2 Stage 2 – Capability and Capacity

To assess whether the potential bidder and its relevant organisations:

- are eligible to be awarded a public contract, as detailed in Regulation 57 of the Public Contracts Regulation 2015;
- are in a sound economic and financial position to participate in the procurement and is within the affordability limit of £1,196,907 per annum including CQUIN (£5,984,535 for the contract term including CQUIN);
- have the necessary resources and core competencies available to them.

8.2.3 Stage 3 – Technical Evaluation

This stage of the evaluation is to assess the detailed bidder solutions to the service-specific questions and must:

- achieve a minimum score of 50% on all Red Flag questions*;
- achieve a minimum of 50% for all non-finance related criteria (quality).

* Red Flag questions are those that have been identified as crucial for all bidders to achieve a minimum score. If a bidder does not achieve a minimum score of 50% for the red flag questions further evaluation of the ITT will not be undertaken and the bidder will not be taken any further in the procurement of the service.

If a bidder does not achieve the required level of scoring, the bidder may be disqualified.

Following the evaluation process of stages 1, 2 and 3 which will be carried out by a team of subject matter experts, a consensus score will be agreed.

8.3 Following the evaluation process, which is carried out by a team of clinical and subject matter experts, a consensus score is agreed and the bidder who has passed each stage of the process and scored the highest consensus mark will be reported to the CCG board as the recommended bidder.

9. Recommended Bidder

- 9.1 The recommended bidder will be the bidder who has met the requirements of the evaluation criteria and has submitted the Most Economically Advantageous Tender (MEAT) by scoring the highest marks. This will have been evaluated against the published evaluation criteria.

In the event that two or more bidders achieve the same score, the bidder with the highest overall score in the operational section of the quality evaluation will be awarded the contract. In the event that two or more bidders still score the same marks the rule will be applied in the following order:

- Resources;
- Mobilisation;
- IM&T
- Communications;
- Facilities

10. Financial Threshold

- 10.1 The financial threshold for this procurement is £5,984,535 including CQUIN. The contract is for 5 years. The maximum agreed budget is £1,196,907 per annum including CQUIN. The CQUIN element equates to an additional 2.5% per annum will be provided and has been including within the total envelope available.
- 10.2 The financial threshold has been agreed based upon 2015/16 usage volumes of the service against the national and local tariffs proposed in this procurement. Contributions have been made by all participating CCGs and are demonstrated in the table below:

Clinical Commissioning Group	Annual Cost *	5 year cost
NHS Darlington CCG	77,269	386,345
NHS Durham Dales, Easington and Sedgefield CCG	279,850	1,399,250
NHS Hartlepool and Stockton-on-Tees CCG	777,838	3,889,190
NHS North Durham CCG	-	-
NHS South Tees CCG	61,950	309,750
Total cost	1,196,907	5,984,535
* incl CQUIN and licenced IVF drug costs		

- 10.3 Delegated authority has been obtained from NHS Darlington CCG, NHS Durham Dales, Easington and Sedgefield CCG, NHS North Durham and NHS South Tees Clinical Commissioning Groups for their participation in this procurement.
- 10.4 The payment methodology proposed is a tariff based model utilising nationally prescribed and locally defined prices. The list of tariffs proposed are available in the table below. These are maximum values and no bid will be accepted exceeding any individual tariff.

Licenced Services	ICSI Cycle		3,271.00
	INTER UTERINE INSEMINATION		286.00
	IVF - FRESH		2,139.00
	FROZEN CYCLE - ICSI/IVF		593.00
	EMBRYO FREEZING & STORAGE (PER YEAR)		334.00
	ABANDONED CYCLE		1,490.00
Non Licenced Services	Minor Therapeutic or Diagnostic General Abdominal Procedures, 19 years and over		865.00
	Intermediate Therapeutic General Abdominal Procedures, 19 years and over with Major CC		2,017.00
	Intermediate Therapeutic General Abdominal Procedures, 19 years and over without CC		1,367.00
	Major Laparoscopic or Endoscopic, Upper Genital Tract Procedures		2,260.00
	Minor Laparoscopic or Endoscopic, Upper Genital Tract Procedures		992.00
	Resection or Ablation Procedures for Intra-uterine Lesions		927.00
	Minor Lower Genital Tract Procedures Category 1		817.00
	Medical Termination of Pregnancy, less than 14 weeks gestation		407.00
	Diagnostic Hysteroscopy		293.00
	Minor Upper Genital Tract Procedures Category 1		904.00
	Minor Upper Genital Tract Procedures Category 2		614.00
	Other Gynaecological Conditions		1,066.00
	Resection or Ablation Procedures for Intra-uterine Lesions		927.00
	Minor Lower Genital Tract Procedures Category 1		827.00
	Major Female Pelvic Peritoneum Adhesion Procedures		1,715.00
	Outpatients - new		140.00
	Outpatients - review		90.00
	Minor Upper Genital Tract Procedures Category 2		129.00
	Minor Upper Genital Tract Procedures Category 2		129.00
	Minor Lower Genital Tract Procedures Category 2		137.00
Unbundled Radiology	MRI Pelvis Gynaecological		126.05
	Hysterosalpingogram		116.82
	US Abdomen		44.07
	US Pelvis		44.07
	US Pelvis (Transvaginal)		44.07
	US Testes		44.07
	US Urinary Tract		44.07
	US Pelvis (Transabdominal/vaginal)		56.36

10.5 There is no weighting attached to the financial threshold and bids will be scored on a pass or fail basis. Any bid exceeding the maximum financial affordability limit will be deemed not to be viable and the bid will not be taken any further in the evaluation process.

11. Potential Procurement Risks and Mitigation

11.1 Bids submitted exceed the affordability thresholds:

- Bidders will be notified of affordability thresholds within the ITT documentation and the subsequent process for those bids which exceed the threshold, i.e. those bids which exceed the affordability threshold will not be taken forward in the procurement process.

11.2 Limited interest from potential bidders:

- A PIN was released 26th August and received 10 expressions of interest, demonstrating a strong potential market; and
- The ITT documentation has been streamlined and reduced in complexity via lessons learnt from prior procurement activity (both from NECS and the CCG).

11.3 Submissions received do not meet the minimum quality thresholds outlined in the evaluation criteria:

- The ITT documentation contains instructions on how to ensure bids are compliant with the quality thresholds;
- The service specification included in the ITT pack contains instructions on the minimum requirement of any provider delivering the service; and
- A bidder event will be held to explain the documentation, eTendering system and procurement process to those who have expressed an interest in the procurement opportunity.

12. Contract Term

12.3 The proposed contract is for 5 years with effect from 1st April 2017 to 31st March 2022.

13. Recommendations

13.1 It is requested that NHS Hartlepool and Stockton on Tees CCG Governing Body:

13.2 Approves the procurement and evaluation strategy, procurement timetables, financial thresholds and the contract term for the Assisted Reproductive Unit service;

13.3 Approves the opening of the tenders by an authorised representative of NECS;

13.4 Notes the date for the recommended bidder report and this item is added to the meeting agenda; and

13.5 Forwards the minutes of this agenda item to NECS for audit purposes via email (necsu.neprocurement@nhs.net)

Michael Robson

NECS Procurement Officer

Appendix 1

Bidder Questions

Hartlepool Assisted Reproductive Services

OP1	<p>Bidders should outline the previous experience which they have of providing NHS licensed and unlicensed fertility service.</p> <p>Responses should include as a minimum current activity levels provided, success rates and locations of delivery.</p> <p><i>Word Count 750</i></p>
OP2	<p>Bidders must provide an overview of your proposed service delivery model and demonstrate how the aims and objectives will be achieved as outlined in the service specification for :</p> <p>(a) Unlicensed fertility services</p> <p>(b) Licensed fertility services</p> <p>Responses should include as a minimum how the provider will deliver all elements of the service specification.</p> <p><i>Word Count 1000</i></p>
OP3	<p>Bidders are asked to provide an overview of the arrangements which will be put in place for the safe transfer of frozen embryos from the existing provider to the new provider to comply with the requirements of HFEA.</p> <p><i>Word Count 500</i></p>
OP4	<p>Bidders must describe their plans and timescales for achievement of a Human Fertilisation and Embryology Authority license for the provision of Fertility Services at the Hartlepool site.</p> <p><i>Word Count 500</i></p>
MOB1	<p>Please provide a detailed Mobilisation Plan to demonstrate timelines and actions associated with mobilising the service and summarise how the Mobilisation plan which will be implemented highlighting any key stages and actions proposed.</p> <p>Your response should reference, but not be limited to, the following considerations:-</p>

	<ul style="list-style-type: none"> • Contract Award to Service Commencement (within a maximum six month period); • Transition plan; Service commencement to full service delivery; • Full Recruitment Strategy and Timeline; • Major Deadlines; • Equipment and Resource Planning; • Exit Strategy; • Transfer of Undertakings (Protection of Employment) (TUPE), including liabilities under the New Fair Deal legislation; • Due diligence of the transferring of workforce; • Meeting project deadlines and commencement of operational service; • Embedding business change into 'business-as-usual'; • Operational review and benefits realisation. <p><i>Word Count: 1000</i></p>
IT1	<p>With reference to the tender documentation, please detail the IM&T technical infrastructure and systems you intend to use to support the administrative and clinical systems to deliver the Service.</p> <p>Response should include but not be limited to the details of:</p> <ul style="list-style-type: none"> • Identification of systems; • Interfaces and interoperability with relevant systems; e.g. PAS, Choose & Book, Summary Care Record; • Disaster Recovery & Business Continuity Plans; • Expected system availability; • Service Level Agreements to meet availability; • Back-ups; • Infrastructure security; and • Desktop and laptop data loss prevention. <p>System Functions:</p> <ul style="list-style-type: none"> • Appointment bookings/scheduling etc.; • Activity/audit information; • Use of NHS number as the key identifier for patients; • Clinical coding; and • Processing referrals to secondary, primary care and social care Data export options.

	<i>Word Count: 1000</i>
IT2	<p>With reference to the tender documentation, bidders are requested to describe their approach to information governance, confidentiality and data protection assurance.</p> <p>Your response should include but not be limited to:</p> <ul style="list-style-type: none"> • Confidentiality and data protection assurance; • Information security assurance; • Clinical information assurance; • Records management; • Data quality; • Information incident management; and • Information risk management. <p><i>Word Count 750</i></p>
IT3	<p>To deliver this service bidders must achieve a minimum score of IG Toolkit Level 2 (Satisfactory). Therefore, please provide evidence of the following:</p> <p>(i) An action plan which clearly describes how your organisation will attain IG Toolkit Level 2 prior to the service commencement date to include details of any gaps against requirements which do not meet Level 2 and how these gaps will be addressed.</p> <p>Please refer to https://nwww.igt.hscic.gov.uk/ for more information regarding the IG Toolkit.</p> <p>(ii) Evidence of appropriate ICO Data Protection Registration, including the ICO registration number for checking purposes. If your organisation currently provides NHS services this must include registration for freedom of information.</p> <p>OR</p> <p>If ICO Data Protection Registration does not include Freedom of Information (FOI) it is expected that this registration will be obtained prior to the service commencement.</p>

	<p>Please refer to http://ico.org.uk/for_organisations/data_protection for more information regarding ICO Data Protection Registration.</p> <p><i>Word Count: 500</i></p>
RES01	<p>Please outline the staffing plan you intend to put in place to adequately deliver and maintain a safe, consistent and efficient service that provides optimal value for money, whilst remaining robust and sustainable.</p> <p>Your response should reference, but not be limited to, the following considerations:-</p> <ul style="list-style-type: none"> • Staffing structure (including sub-contractors/collaborative providers), including WTE/Job Titles/professional grades/skill mix (in relation to this service only); • Working hours (including flexible working arrangements); • Operational management, including work allocation and staff deployment; • Staff management, leadership and accountability lines; • Workforce governance, including professional discipline, complaints, allegations and investigations; • TUPE arrangements for eligible staff; • Assurances regarding sub-contracted staff/collaborative providers and the relevant staff regarding professional registration, professional indemnity and mandatory regulatory requirements. <p><i>Word Count 1500</i></p>
FAC1	<p>Please provide details on how you will ensure that the premises and facilities will be suitably equipped to deliver this service.</p> <p>Your answer should include, but not be limited to, the following considerations: -</p> <ul style="list-style-type: none"> • Equipment to be used and installed within each facility/premises; • Facilities management arrangements (if applicable); • Supply-chain management and ongoing storage/management of low level appliances for patients; • Suitability of trained staff for prescribing/dispensing low level appliances; <p><i>Word Count 750</i></p>

COMM1	<p>Please outline a communications plan which ensures that efficient communication is in place between the provider and the various service stakeholders, throughout both the contract mobilisation period and service delivery.</p> <p>Your answer should include, but not be limited to, the following considerations: -</p> <ul style="list-style-type: none"> • Details of the various stakeholder groups for this service provision; • The coverage of the information being communicated (both during contract mobilisation and upon/during service commencement); • Addressing the communication needs of the various stakeholder groups; • Evidence of a continuous improvement approach in respect of communication activity; • Integration and engagement with Secondary Care providers (including Acute Services); • Engagement with the CCG. <p><i>Word Count 1000</i></p>
SV1	<p>The Social Value Act (2012) states that if a relevant authority proposes to procure or make arrangements for procuring the provision of services by entering into a public services contract, the authority must consider how what is proposed to be procured might improve the economic, social and environmental well-being of the relevant area, and how, in conducting the process of procurement, it might act with a view to securing that improvement.</p> <p>Please detail how you will ensure that the proposed service delivery model will ensure that the South Tyneside area will achieve the following:</p> <ul style="list-style-type: none"> • Social benefits: • Economic benefits; and • Environmental Benefits <p><i>Word Count: 500</i></p>



NHS Standard Contract 2016/17 Particulars (Full Length)

**Contract title: Hartlepool Assisted
Reproduction Unit**

**NHS Standard Contract
2016/17 Particulars**

First published: March 2016
Republished: 6 April 2016
Republished: 13 April 2016

Prepared by: NHS Standard Contract Team
nhscb.contractshelp@nhs.net

The updated version published on 6 April 2016, makes minor corrections for consistency, at Schedule 2A 5.1 and 5.2 and Schedule 4A E.B.15.i.

The updated version published on 13 April 2016 updates the hyperlink in Schedule 4F and the reporting frequency of item 11 in Schedule 6A. .

Publications Gateway Reference: 04973
Document Classification: Official

Contract Reference	
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DATE OF CONTRACT	1 April, 2017 (or earlier subject to negotiation and achievement of HFEA licence)
SERVICE COMMENCEMENT DATE	1 April, 2017 (or earlier subject to negotiation and achievement of HFEA licence)
CONTRACT TERM	5 years
COMMISSIONERS	Hartlepool & Stockton CCG (00K) South Tees CCG (00M) Durham, Dales, Easington and Sedgefield CCG (00D) North Durham CCG (00J) Darlington CCG (00C)
CO-ORDINATING COMMISSIONER	Hartlepool & Stockton CCG (00K)
PROVIDER	[] (ODS []) Principal and/or registered office address: [] [Company number: []]

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CONTRACT

This Contract records the agreement between the Commissioners and the Provider and comprises

1. these **Particulars**;
2. the **Service Conditions (Full Length)**;
3. the **General Conditions (Full Length)**,

as completed and agreed by the Parties and as varied from time to time in accordance with GC13 (*Variations*).

IN WITNESS OF WHICH the Parties have signed this Contract on the date(s) shown below

SIGNED by

.....
Signature

**[INSERT AUTHORISED
SIGNATORY'S
NAME] for
and on behalf of
Hartlepool & Stockton Clinical
Commissioning Group**

.....
Title
.....
Date

**[INSERT AS ABOVE FOR
EACH COMMISSIONER]**

SIGNED by

.....
Signature

**[INSERT AUTHORISED
SIGNATORY'S
NAME] for
and on behalf of
[INSERT PROVIDER NAME]**

.....
Title
.....
Date

SERVICE COMMENCEMENT AND CONTRACT TERM	
Effective Date	1 April, 2017 (or earlier subject to negotiation and achievement of HFEA licence)
Expected Service Commencement Date	1 April, 2017 (or earlier subject to negotiation and achievement of HFEA licence)
Longstop Date	1 April, 2017
Service Commencement Date	1 April, 2017 (or earlier subject to negotiation and achievement of HFEA licence)
Contract Term	5 years
Option to extend Contract Term	YES By 2 years
Commissioner Notice Period (for termination under GC 17.2)	12 months
Commissioner Earliest Termination Date	12 months after the Service Commencement Date
Provider Notice Period (for termination under GC17.3)	12 months
Provider Earliest Termination Date	12 months after the Service Commencement Date]

SERVICES	
Service Categories	Indicate <u>all</u> that apply
Accident and Emergency (A+E)	
Acute Services (A)	YES
Ambulance Services (AM)	
Cancer Services (CR)	
Continuing Healthcare Services (CHC)	
Community Services (CS)	
Diagnostic, Screening and/or Pathology Services (D)	
End of Life Care Services (ELC)	
Mental Health and Learning Disability Services (MH)	
Mental Health and Learning Disability Secure Services (MHSS)	
NHS 111 Services (111)	
Patient Transport Services (PT)	
Radiotherapy Services (R)	
Urgent Care/Walk-in Centre Services/Minor Injuries Unit (U)	
Specialised Services and other services directly commissioned by NHS England	
Services comprise or include Specialised Services and/or other services directly commissioned by NHS England	NO
Service Requirements	
Indicative Activity Plan	NO
Activity Planning Assumptions	NO
Essential Services (NHS Trusts only)	NO
Services to which 18 Weeks applies	YES

PAYMENT	
Expected Annual Contract Value Agreed	YES
Must data be submitted by SUS for any of the Services?	YES
QUALITY	
Provider type	
Clostridium Difficile Baseline Threshold (Acute Services only)	
GOVERNANCE AND REGULATORY	
Nominated Mediation Body	CEDR/Other – []
Provider's Nominated Individual	[] Email: [] Tel: []
Provider's Information Governance Lead	[] Email: [] Tel: []
Provider's Caldicott Guardian	[] Email: [] Tel: []
Provider's Senior Information Risk Owner	[] Email: [] Tel: []
Provider's Accountable Emergency Officer	[] Email: [] Tel: []
Provider's Safeguarding Lead	[] Email: [] Tel: []
Provider's Child Sexual Exploitation Lead	[] Email: [] Tel: []
Provider's Mental Capacity and Deprivation of Liberty Lead	[] Email: [] Tel: []
Provider's Prevent Lead	[] Email: [] Tel: []
Provider's Freedom To Speak Up Guardian	[] Email: [] Tel: []

CONTRACT MANAGEMENT	
Addresses for service of Notices	<p>Co-ordinating Commissioner: Hartlepool & Stockton CCG Address: Billingham Health Centre, Queensway, Billingham, Ts23 2LA Email: k.hawkins@nhs.net</p> <p>Commissioner: South Tees CCG Address: 14 Trinity Mews, Middlesbrough, TS3 6AL Email: craig.blair@nhs.net</p> <p>Commissioner: Darlington CCG Address: Dr Piper House, King Street, Darlington, DL3 6JL Email: awilson18@nhs.net</p> <p>Commissioner: Durham Dales, Easington & Sedgefield CCG Address: Sedgefield Community Hospital, Salters Lane, Sedgefield, TS21 3EE Email: mark.pickering@nhs.net</p> <p>Commissioner: North Durham CCG Address: The Rivergreen Centre, Durham, DH1 5TS Email: richardhenderson1@nhs.net</p> <p>Provider: [] Address: [] Email: []</p>
Frequency of Review Meetings	Monthly
Commissioner Representative(s)	<p>Trish Hirst, Senior Manager North of England Commissioning Support Unit Email: trish.hirst@nhs.net</p>
Provider Representative	<p>[] Address: [] Email: [] Tel: []</p>

SCHEDULE 1 – SERVICE COMMENCEMENT AND CONTRACT TERM

A. Conditions Precedent

The Provider must provide the Co-ordinating Commissioner with the following documents:

1. Evidence of appropriate Indemnity Arrangements
2. Evidence of CQC registration in respect of Provider and Material Sub-Contractors
3. Evidence of Monitor's Licence in respect of Provider and Material Sub-Contractors (where required)
4. Copies of all Mandatory Material Sub-Contracts, signed and dated and in a form approved by the Co-ordinating Commissioner
5. Copies of the following Permitted Material Sub-Contracts, signed and dated and in a form approved by the Co-ordinating Commissioner:
6. A copy of Human Embryology and Fertilisation Authority Licence for the services detailed within the service specification for the Hartlepool site.

The Provider must complete the following actions:

--

SCHEDULE 1 – SERVICE COMMENCEMENT AND CONTRACT TERM

B. Commissioner Documents

Date	Document	Description
N/A		

SCHEDULE 1 – SERVICE COMMENCEMENT AND CONTRACT TERM

C. Extension of Contract Term

To be included only in accordance with NHS Standard Contract Technical Guidance.

1. As advertised to all prospective providers before the award of this Contract, the Commissioners may opt to extend the Contract Term by two year(s).
2. If the Commissioners wish to exercise the option to extend the Contract Term, the Co-ordinating Commissioner must give written notice to that effect to the Provider no later than 6 months before the original Expiry Date.
3. The option to extend the Contract Term may be exercised:
 - 3.1 only once, and only on or before the date referred to in paragraph 2 above;
 - 3.2 only by all Commissioners; and
 - 3.3 only in respect of all Services
4. If the Co-ordinating Commissioner gives notice to extend the Contract Term in accordance with paragraph 2 above, the Contract Term will be extended by the period specified in that notice and the Expiry Date will be deemed to be the date of expiry of that period.

SCHEDULE 2 – THE SERVICES

A. Service Specifications

Service Specification No.	
Service	Assisted Reproductive Services
Commissioner Lead	HAST CCG
Provider Lead	
Period	5 years (with an option to extend for a further 2 years)
Date of Review	

1. Population Needs

1.1 National/local context and evidence base

Fertility problems exist when a woman cannot conceive (get pregnant) despite having regular unprotected vaginal intercourse, or artificial insemination, at and around the time of ovulation. Usually over 80% of couples in the general population will conceive within 1 year if; the woman is aged under 40 years and they do not use contraception and have regular sexual intercourse (every 2 – 3 days).

Of those who do not conceive in the first year, about half will do so in the second year (cumulative pregnancy rate over 90%). [NICE, 2013].

It is estimated that infertility affects 1 in 7 heterosexual couples in the UK. Since the original NICE guideline on fertility published in 2004 there has been a small increase in the prevalence of fertility problems, and a greater proportion of people now seeking help for such problems.

The main causes of infertility in the UK are (percent figures indicate approximate prevalence):

- unexplained infertility (no identified male or female cause) (25%)
- ovulatory disorders (25%)
- tubal damage (20%)
- factors in the male causing infertility (30%)
- uterine or peritoneal disorders (10%).

In about 40% of cases disorders are found in both the man and the woman. Uterine or endometrial factors, gamete or embryo defects, and pelvic conditions such as endometriosis may also play a role.

NICE's guideline on fertility recommends that in practice healthcare professionals should define infertility in terms of the period of time people have been trying to conceive without success after which formal investigation is justified and possible treatment implemented.

1.2 Evidence Base

This specification is designed to sit alongside the legislative provisions of Infertility treatment and the Care Standards Act, and is not designed to replicate these provisions, or to duplicate, replicate or supersede the following policies and guidelines, which may change over time:

- The Human Fertilisation and Embryology Act; 1990

- The National Institute for Clinical Excellence CG156 Infertility guidance; 2013
- North East Value Based Clinical Commissioning Policy - Invitro Fertilisation (IVF) and Intracytoplasmic Sperm Injection (ICSI) 2016
- North East Value Based Clinical Commissioning Policy - Fertility Preservation for Cancer Patients 2016
- National Minimum Standards for Independent Healthcare; 2000
- Any Quality standard as determined by the Care Quality Commission
- Any Quality standard required under the terms of the Care Standards Act; 2000
- Ethnicity
- Disability Discrimination Act; 2005
- Equality Act 2010

2. Outcomes

2.1 NHS Outcomes Framework Domains & Indicators

Domain 1	Preventing people from dying prematurely	
Domain 2	Enhancing quality of life for people with long-term conditions	
Domain 3	Helping people to recover from episodes of ill-health or following injury	x
Domain 4	Ensuring people have a positive experience of care	x
Domain 5	Treating and caring for people in safe environment and protecting them from avoidable harm	x

2.2 Local defined outcomes

- We expect the provider to achieve live birth rates and outcomes consistent with national averages

3. Scope

3.1 Aims of service

- To meet the requirements of the Human Embryology and Fertility Authority to provide licensed fertility services.
- To provide investigations to determine the cause of subfertility
- To offer assessment and treatment for patients suffering from subfertility
- To help couples suffering from subfertility to achieve a successful pregnancy
- To provide a quality, safe, cost effective Assisted Reproductive services ensuring that the risk of infection and other complications to service users is minimised.
- To provide a personal service sensitive to the physical, psychological and emotional needs of service users.
- To ensure effective communications between service users and the service providers.
- To ensure effective communication between commissioners and the service providers.

3.2 Objectives service

- To offer Assisted Reproductive Services which are safe, effective, appropriate, accessible and acceptable to Service users, and represent good value for money
- To offer Assisted Reproductive treatment in line with the care pathway agreed by Hartlepool and Stockton Clinical Commissioning Group
- To offer Service users consistent, appropriate and suitable information in a format that they can understand.

- To offer Assisted Conception treatment in line with the IVF and ICSI Clinical Commissioning Policy see Appendix 1 (that is subject to annual review).

3.3 Service description/care pathway

The Assisted Reproductive services to be provided to patients fulfilling the eligibility criteria include:

Investigations and treatments of subfertility:

- Blood tests – Ovarian Reserve Testing
- Tubal Patency
- Semen Analysis and appropriate investigations where abnormal
- Ovulation induction
- Medical management for diagnosed male infertility
- Surgical treatments

Assisted Conception services:

- In Vitro Fertilisation (IVF)
- Intra-Cytoplasmic Injection (ICSI)
- Intra Uterine Insemination (IUI – Unstimulated)
- Intra Uterine Insemination (IUI – Stimulated – Funded on an exceptional basis subject to CCG policy)
- Surgical sperm retrieval methods (testicular sperm extraction (TESE) and/or percutaneous epididymal sperm aspiration (PESA)
- Cryopreservation of semen, oocytes and embryos

The above services will be provided in line with NICE clinical guidelines 2013 and HFEA regulations.

The following are outside of the scope of this service specification:

- Pre-implantation Genetic Diagnosis and associated IVF/ICSI (This service is commissioned by NHS England).
- Assisted Reproductive Services for members of the Armed Forces (Commissioned separately by NHS England).
- IVF funding for egg donation and/or surrogacy is not routinely funded.

3.3.1 Principles of Care

The Assisted Reproductive Services offered will be safe, effective, appropriate, accessible and acceptable to Service users and represent good value for money.

Clinical management of eligible couples should be in line with the agreed local care pathway. This is based on the NICE clinical practice algorithm as modified by individual CCG policies. This local pathway identifies the tests and treatments to be undertaken within Primary (level 1), Assisted Reproductive Service that will provide Secondary (level 2) and Tertiary care (level 3). Within the pathway test results should be passed on and not duplicated (refer to Appendix 2).

Where clinically appropriate, waiting times should conform to the 18-week pathway, which begins when a patient is confirmed as requiring assisted reproductive services and is considered eligible based on the relevant criteria. Service users should be seen in the chronological order of admission on waiting lists and informed of their acceptance on the waiting list.

The Provider will co-ordinate inpatient, day care and outpatient services to ensure continuity

of care.

Couples should be seen together because both partners are affected by decisions about investigations and treatment and to allow them to participate in planning their care. They should be seen in a comfortable environment ensuring privacy and dignity.

Couples should be treated by a specialist team to improve the effectiveness and efficiency of treatment and outcomes. Couples should be provided with consistent, appropriate and suitable information in a format that they can understand. This information will be provided by the specialist centre.

The Provider will ensure that the Service user is afforded the right to be fully informed of their condition, if they so wish, and to ensure information is communicated in an understandable and sympathetic manner.

Couples should be offered counselling prior to, during and after assessment or treatment irrespective of the outcome of that treatment, from someone independent of the treatment team, the cost for which will be met by the Provider.

Couples should be informed that they may find it helpful to contact a fertility support group and information such as www.infertilitynetworkuk.com

3.2.2 Service Requirements

The Provider will ensure that the Fertility services, where appropriate are shaped around the preferences of service users, their families and their carers.

Service users will be treated with respect and their dignity to be safeguarded regardless of age, sex, ethnicity, religion, culture and sexuality.

Services provided should be culturally sensitive.

Where appropriate, the Provider will work in partnership with other organisations to promote the delivery of a seamless service.

All staff will respect the confidentiality of the service user as required by the NHS document: The Care Record Guarantee (Department of Health, 2007). The Provider will be responsible for asking the patient to sign a confidentiality release clause to share treatment data to the funding authority.

The Provider will offer the service user an appropriate and timely first Outpatient Appointment from the initial referral from the primary provider.

Hospitalisation will normally be dealt with on a day case basis. If, however, this requires to be extended for clinical requirements, for a maximum of 24 hours, no further charge will be raised.

Service users will be offered counselling with a Specialist Fertility Counsellor in line with the HFEA Code of Practice.

Information sheets in plain English should be available to explain the proposed investigations and treatment, including detailed information on drugs (and any possible side effects) prescribed by the centre. Information should be tested out with couples to ensure it is user-friendly and available in a range of languages.

Information relating to outcomes should be available for couples on request.

Information to service users should make it clear that if the treatment centre does not receive contact from the couple for a six month period they will be removed from the list.

It is the responsibility of the Provider to bear the cost of all ultrasound scans and any additional outpatient appointments, which may include other tests or observations, until the woman is referred by her GP to the maternity services.

Additional Requirements

In line with GMC Guidance, it is the responsibility of the Consultant leading the service to ensure that any investigations requested by the service are followed-up and dealt with by the service, including contacting the patient directly regarding results.

Where clinically appropriate, patients will be given the option of follow-up consultation, or discussion of the results of investigations, by phone rather than in person.

The Provider is expected to be aware of local lifestyle services and voluntary sector agencies and, where appropriate, signpost patients to these.

Patients without suitable discharge care **should not** undergo any procedure. Patients should be assessed, and a discharge plan established, prior to booking an appointment for a procedure. Patients should be reassessed on the day of attendance, prior to any procedure taking place, to ensure that the discharge plan is still appropriate. On discharge patients should be provided with a summary of any procedure undertaken and details of future follow-up arrangements. They should also be provided with any newly prescribed medication and instructions for on-going care. Details of the same will be provided to the referring clinician by electronic means on the day of the procedure.

The service provider must ensure that the unit and clinical staff are competent to manage patients in the event of cardiac arrest, respiratory arrest, or anaphylaxis, or any other condition that requires emergency transfer to an Emergency Department. In the event of complications or a medical emergency the service provider must demonstrate that robust processes are in place for the rapid transfer of care to other specialities or providers where the patient's condition warrants this transfer.

Following investigation or procedure any patient with suspected cancer should immediately be referred onwards by the Provider via the appropriate 2 Week Wait Pathway. The Provider must ensure robust pathways are in place between themselves and the GP to facilitate and communicate this.

The Provider must have a Business Continuity Plan in place to ensure that all services are available at their stated times, including adequate cover for planned and unplanned leave. In the event of a service being unavailable/inaccessible, the service must have documented contingency plans to ensure that patients are provided with (and advised of) alternative services.

3.3.3 Treatment Details

For continuity of care delivery, the service user will have a named Lead Clinician, who will take responsibility for the service user during this pathway of care.

Referral criteria and sources are listed in section 3.6 of this document. It is the responsibility of the commissioned provider to ensure all criteria are met, all relevant investigations are completed, and the specific number of fresh cycles and embryo transfers allowed to be funded by the referring CCG, has been applied.

Investigations of subfertility:

Female:

- Blood tests to confirm ovulation
- Laparoscopy and/or hysteroscopy and/or hysterosalpingogram or ultrasound scan where appropriate
- Rubella antibodies

- Ovulation reserve testing
- Chlamydia screening

Male:

- Preliminary Semen Analysis and appropriate investigations where abnormal

If a diagnosis of subfertility is established, 3 treatment options will be available dependent on diagnosis and NICE guidance.

Medical Management to restore fertility:

For women diagnosed with ovulatory disorders hypothalamic pituitary failure (hypothalamic amenorrhoea or hypogonadotrophic hypogonadism), hypothalamic-pituitary-ovarian dysfunction or ovarian failure. first line treatments offered will be:

- Clomifene
- Metformin
- Gonadotrophins
- Gonadotrophins-releasing hormone and dopamine agonists

For men diagnosed with hypogonadotropic hypogonadism first line treatment offered will be:

- Gonadotrophins

Surgical Treatment to restore fertility:

For men diagnosed with obstructive azoospermia will be offered surgical correction of epididymal blockage because it is likely to restore patency of the duct and improve fertility. Surgical correction should be considered as an alternative to surgical sperm recovery and IVF.

For women with tubal damage or scarring as a result of pelvic inflammatory disease, Chlamydia and Endometriosis should be offered tubal surgery to improve the chance of pregnancy.

Assisted Conception

Assisted conception is offered to women/couples who meet the criteria set out North East Value Based Clinical Commissioning Policy - Invitro Fertilisation (IVF) and Intracytoplasmic Sperm Injection (ICSI) 2016 which is subject to annual review (See Appendix 1).

For women of reproductive age who have not conceived after 2 years of regular unprotected intercourse or 12 cycles of artificial insemination using partner's sperm or 6 cycles of donor sperm (where six or more are by intrauterine insemination), will be offered **3 full cycles of IVF**, with or without ICSI. If the woman reaches the age of 40 during treatment, complete the current full cycle but do not offer further full cycles.

In women aged 40–42 years who have not conceived after 2 years of regular unprotected intercourse or 12 cycles of artificial insemination using partner's sperm or 6 cycles of donor sperm (where 6 or more are by intrauterine insemination), offer **1 full cycle of IVF**, with or without ICSI, provided all the following 4 criteria are fulfilled: (1) They have never previously had IVF treatment (2) There is evidence of good ovarian reserve as identified by a specialist clinician (3) There has been a discussion of the additional implications of IVF and pregnancy at this age (4) Specialist clinical opinion that there is no likelihood of pregnancy with expectant management e.g. confirmed tubal blockage (absolute infertility). Treatment must start before the woman's 43rd birthday.

Surgical sperm retrieval methods included for service provision are testicular sperm extraction (TESE) and percutaneous epididymal sperm aspiration (PESA). Sperm recovery techniques outlined in this section is not available to patients who have undergone a vasectomy.

For people with unexplained infertility, mild endometriosis or 'mild male factor infertility', who are having regular unprotected sexual intercourse: do not routinely offer intrauterine insemination, either with or without ovarian stimulation (exceptional circumstances include, for example, when people have social, cultural or religious objections to IVF) advise them to try to conceive for a total of 2 years before IVF will be considered.

Any previous full IVF cycles, whether self- or NHS-funded at any IVF provider including those outside the UK, will count towards the total number of full cycles that a couple may receive under NHS funding by the CCG.

A full cycle of IVF treatment, with or without intracytoplasmic sperm injection (ICSI), should comprise 1 episode of ovarian stimulation and the transfer of any resultant fresh and frozen embryo(s). This will include the storage of any frozen embryos for 1 year following egg collection. Patients should be advised at the start of treatment that this is the level of service available on the NHS and following this period continued storage must be funded by themselves.

An embryo transfer is from egg retrieval to transfer to the uterus. The fresh embryo transfer would constitute one such transfer and each subsequent transfer to the uterus of frozen embryos would constitute another transfer.

Before a new fresh cycle of IVF can be initiated any previously healthy frozen embryo(s) must be utilized. Where couples have previously self-funded a cycle, then the couples must utilise the previously frozen embryos, rather than undergo ovarian stimulation, egg retrieval and fertilisation again.

Embryo transfer strategies:

- For women less than 37 years of age only one embryo or blastocyst to be transferred in the first cycle of IVF and for subsequent cycles only one embryo/blastocyst to be transferred unless no top quality embryo/blastocyst available then no more than 2 embryos to be transferred
- For women age 37-39 years only one embryo/blastocyst to be transferred unless no top quality embryo/blastocyst available then no more than 2 embryos to be transferred.
- For women 40-42 years, double embryo transfer may be considered.

For couples where the woman is under 38 years of age, there should be a six month period between completion of the pregnancy test post embryo transfer and commencement of drugs for the next fresh cycle.

Should an attempted fresh cycle be abandoned the reason must be recorded in the context of:

- Poor/over ovarian response
- Poor fertilisation
- Poor embryo quality
- Poor Service user compliance

If any fertility treatment results in a live birth, then the couple will no longer be considered childless and will not be eligible for further NHS funded fertility treatments, including the implantation of any stored embryos. Any costs relating to the continued storage of the embryos beyond the first calendar year of the retrieval date, are the responsibility of the couple.

Treatment for assisted conception will include:

Initial consultation, follow up consultation, and counselling sessions.

All ultrasound scans and hormone assessments during the treatment cycle.

Oocyte recovery - by vaginal ultrasound guided by aspiration under sedation or local anaesthesia or laparoscopy as appropriate. General anaesthesia will be provided when necessary.

Embryo, or blastocyst transfer, into uterine cavity.

All embryology including sperm preparation and sperm retrieval (testicular sperm extraction (TESE) and percutaneous epididymal sperm aspiration (PESA) where indicated.

Embryo/blastocyst freezing and storage will be commissioned as part of the service requirement, and will be funded for up to 12 months following completion of NHS Treatment, when further discussions with the couple will need to take place.

A pregnancy test and a maximum of two scans to establish the viability of the pregnancy.

The service will no longer provide assisted conception when:

- A live baby has been born
- The couple choose not to proceed
- There is clinical evidence to show that a successful outcome will not be possible

Prescribing

The commissioned provider of the IVF service under this contract will prescribe and supply the necessary drugs.

Providers must refrain from asking patients to request prescriptions for medication that is part of the IVF treatment pathway from their GPs.

Accurate and detailed information of the drug, the dosage and the frequency and possible side effects will be given to the service user including:

- Possible drug interactions
- The risk of Ovarian Hyper Stimulation Syndrome (OHSS)
- The risks associated with multiple pregnancies
- Follow-up and monitoring arrangements, and how the consultant will monitor the woman's progress
- The circumstances under which treatment should be stopped or re-referral made to the secondary provider consultant
- The consultant will retain overall clinical responsibility

In accordance with HFEA guidelines, the provider will seek the consent of the service user to relevant information being shared with the registered GP.

Subject to the above recommendations being followed, the cost of this prescribing will be part of the contract.

In line with NHS regulations, prescribing costs for residents receiving IVF on a private basis will not be funded under the NHS.

3.4 Days and hours of operation

The Provider will offer a 5 day normal working hours service, with the ability if necessary, to provide services up to seven days, in addition to an out of hours emergency contact details.

3.5 Population covered

The service will be available to the adult population that is registered with a GP within the NHS Hartlepool and Stockton, NHS Durham Dales Easington & Sedgefield, NHS Darlington,

NHS North Durham and NHS South Tees Clinical Commissioning Groups boundaries.

3.6 Referral criteria and sources

The service will only accept women of a reproductive age who has not conceived after 1 year of unprotected vaginal sexual intercourse, in the absence of any known cause of infertility and should have had the following primary investigations:

- Confirmation of couples health status is appropriate for conception
- Confirmation of ovulation
- Semen analysis
- Lifestyle support and advice

Early referrals will be accepted for further assessment and appropriate treatment where:

- The woman is aged 36 years or over
- There is a known clinical cause of infertility or a history of predisposing factors for infertility.

Self-referrals or from any other source than those detailed above will not be accepted and the service user should be directed back to their GP.

Couples will be assessed for referral using the referral criteria set out in Appendix 1 and 2.

3.7 Response times and prioritisation

If a received referral is rejected as it falls outside of the referral criteria of this *specification* then this should be communicated to the referring clinician within 2 working days.

If, following triage by the Consultant leading the service, a received referral is deemed inappropriate to be seen in the service, this should be communicated to the referring clinician within 5 working days of receipt of referral and no less than 5 working days prior to any appointment already booked for that patient.

This communication will include:

- The reason that the referral is not appropriate
- A suggested alternative management plan

Any follow-up procedure, investigation or appointment which forms part of the management plan agreed with the patient should be scheduled with the patient as part of the consultation, or immediately following it. This should be communicated to the referring clinician at the same time.

If a patient does not attend (DNAs) their appointment the service will communicate directly with the patient and the GP, allowing the patient a 3 week window to rearrange their appointment by phone. If the patient fails to rearrange the appointment within this time, or also DNAs the rearranged appointment, then the patient will be discharged. When a patient is discharged under these circumstances this will be communicated, in writing, to the patient and their GP.

Every effort should be made to ensure DNA rates are as low as possible. This will include:

The use of technology (e.g. text messaging) where possible/appropriate to ensure that patients are reminded of appointments in a timely fashion engaging with patients following a DNA to ascertain the reason and, where possible, address this to ensure that any subsequent appointment is kept.

All communications to Primary Care clinicians referred to in this document will be made electronically using nhs.net, or an approved system integrating securely with all Hartlepool and Stockton, Durham Dales Easington & Sedgfield, North Durham, Darlington and South

Tees GP systems.

After each attendance there will be written communication, to both the patient and referring clinician, of the assessment findings and the subsequent management plan. This communication will be as timely as possible, and must be received within 5 working days of the attendance.

Dedicated phone numbers will be available for:

Appointments/booking/cancellation etc. (available to GP Practices and to patients)
Primary Care clinicians to contact the service directly

3.8 Interdependence with other services/providers

The service provider will work directly with the following professionals to ensure a seamless service and the continuity of holistic care:

- General Practitioners
- General Practitioners with Special Interest
- Clinical Commissioning Group Exceptionality Clinical Review Boards
- NHS Genetic Services
- Oncology Teams

3.9 Care Pathway

The Care pathway route is detailed in Appendix 1 and 2. Referrals that do not adhere to this pathway should not be accepted and returned to the originating referrer.

3.10 Discharge

Discharge from the Assisted Reproductive Service will occur if initial investigations, medical or surgical management or before the completion of a maximum of 2 embryo transfers or a maximum of 1 fresh cycles when either:

- A live baby has been born
- The couple choose not to proceed
- There is clinical evidence to show that a successful outcome will not be possible

Written confirmation will be sent to the referring consultant and/or GP with a copy to the Service user detailing the reasons for the above action.

Should there be an unsuccessful treatment outcome; Assisted Conception counselling will be offered at the expense of the Assisted Reproductive Service.

Should the couple have a viable pregnancy and are requiring access to maternity services the following should occur:

- A letter confirming the pregnancy and the need for an antenatal referral will be given to the patient and sent to the GP when a viable clinical pregnancy is confirmed and the patient instructed to make an appointment with their GP to arrange antenatal referral
- The GP will refer the pregnant woman to the maternity services at or around 8 weeks of pregnancy
- The woman should access the midwifery services between 8-10 weeks

4.0 Activity and financial monitoring information

The Provider will produce activity and financial summaries on a monthly basis which will give an overview of the performance of the contract for that particular month and for the year-to-date.

4.1 Monitoring of performance targets and other outcome measures

The Provider will provide regular monitoring information on a range of performance and outcome measures to be agreed with provider.

The Provider will also provide regular status reports on each couple referred for treatment, which will include details of the treatments-to-date.

5.0 Information Governance

The provider shall conform to the Data Protection Act, (Department of Health, 2006).

Ensure the IM&T technical infrastructure and system can interface and has interoperability with relevant systems e.g. PACS, Choose & Book, Summary Care Record.

5.1 Quality of information

The Provider will ensure that all data provided is complete, accurate and timely.

The Provider will ensure that it's staff do not adopt, desist from any current clinical protocol, practice or procedure, or any administrative (or coding) practice or procedure, which will either intentionally or inadvertently, maximise income to the Provider, rather than to reflect the actual necessary treatment received by a Service user, or a group of Service users.

5.2 Performance Targets

The Provider will comply with current performance targets as laid down by the Department of Health and any local additional performance targets defined by Hartlepool and Stockton CCG.

18 week pathway for Fertility services

- It will be the responsibility of the Provider to identify, in a timely fashion in advance of the occurrence, any service user where the performance targets and maximum waiting times as identified within this document cannot be met by the Provider.

The provider will then agree with the Lead Commissioner from Hartlepool and Stockton CCG, the necessary actions to remedy these breaches of the service management.

The provider will follow an elective Single Embryo Transfer (eSET) Strategy, inclusive of selection criteria, for implementation from April 2009 as per HFEA requirements, to reduce multiple births to 10%.

The provider will be expected to achieve live birth rates and outcomes consistent with national averages.

5.3 Complaints

The Provider must establish a written complaints procedure. The procedure must incorporate the following:

- A nominated person within the organisation to be responsible for handling complaints;
- Complaints must be acknowledged within 2 working days;
- A full response or holding letter, signed by the Chief Executive or equivalent, to be sent within 20 working days;
- Hartlepool and Stockton CCG may wish to conduct an Independent Review Panel Investigation if they are dissatisfied with the Provider's response.

5.4 Waiting times for Assisted Reproductive Service

Provider will comply with the requirements of 18 week referral to treatment in accordance

with the rules set out in 5.5.

5.5 Clock Stops as per the Department of Health 208 18 week pathway for fertility services i.e when the procedure starts

- Gonadotrophin stimulation of hypogonadal men
- Treatment for pituitary tumours and other medical conditions discovered
- For IUI, IVF, ICSI, PGD as above if cycle control issues take time or if the Service user is not ready the clock can be stopped. The clock stop is the first day of the menstrual cycle in which the assisted conception is to start.
- Service users waiting for egg/sperm donation: the clock stops once they are put on the waiting list (as per transplant lists)
- Post surgery in the event of a miscarriage/ectopic pregnancy
- Ovarian Hyperstimulation Syndrome (OHSS)
- Active monitoring will begin once the Service user is on a recognised local protocol.

5.6 Outcome Data

Information on the Provider's activities will be provided on a monthly basis, in accordance with contractual requirements.

Basic outcome data

- Number of couples seen
- Number of couples treated
- Live birth rates per embryo transfer treatment cycle
- Clinical pregnancy rate – singleton and multiple
- Clinical pregnancy rate – per embryo transfer

The commissioner reserves the right to audit 5 % of clinical notes at anytime to ensure appropriate referrals only are being processed by provider.

Implantation rates and live birth rates by:

- Age bands 23-24, 25-29, 30-35, 36-39, 40-42
- Diagnostic group
- GP and Patient Postcode

Complications

- Twin clinical pregnancy rate.
- Twin births per treatment cycle.
- Ectopic pregnancies per treatment cycle.
- Rate of Ovarian Hyper-stimulation Syndrome (OHSS) – severity and duration of hospitalisation
- Other adverse outcomes needing inpatient management

5.7 Facilities and Equipment

The provider will be required to show evidence that all equipment used is regularly maintained to a standard commensurate with the needs of the service and in accordance with the terms of the HFEA licence.

4. Applicable Service Standards

4.1 Applicable national standards (e.g. NICE)

- HFEA Code of Practice 8th Edition (2015)
- National Institute for Clinical Excellence CG156 - Fertility: assessment and treatment for people with fertility problems (2013)
- Standards for Better Health Framework
- National Service Frameworks

4.2 Applicable standards set out in Guidance and/or issued by a competent body (e.g. Royal Colleges)

The service provider will comply with the requirements of:

- Royal College of Surgeons
- British Association of Urological Surgeons
- Royal College of Obstetricians and Gynaecologists
- Care Quality Commission Provider Registration
- Care Quality Commission Essential Standards of Quality and Safety

4.3 Applicable local standards

The provider must be licensed by the Human Fertilisation and Embryology Authority (HFEA). Core skills and competencies of Staff are set by the HFEA as the regulatory authority for tertiary fertility services.

In addition Providers are expected to comply with relevant legislation, including Health and Safety requirements and to follow best practice guidelines.

5. Applicable quality requirements and CQUIN goals

5.1 Applicable Quality Requirements (See Schedule 4A-D)

5.2 Applicable CQUIN goals (See Schedule 4E)

6. Location of Provider Premises

The Provider's Premises are located at:

The service is to be provided from University of Hartlepool Hospital site.

7. Individual Service User Placement

Appendix 1

North East Value Based Clinical Commissioning Policy - Invitro Fertilisation (IVF) and Intracytoplasmic Sperm Injection (ICSI) 2016

This policy describes the eligibility criteria for NHS funded infertility treatment including:

- In vitro fertilisation (IVF)
- Intracytoplasmic sperm injection (ICSI)

This policy does not apply to the investigation and assessment of infertility in general.

Background: The Clinical Guideline on *fertility assessment and treatment* was published by NICE in February 2013 (NICE CG156, 2013) and covers all clinical procedures/pathways relating to fertility assessment and treatment.

This document provides a single infertility specific commissioning policy for the NHS with the aim to ensure consistency in the application of the guideline across the North East region. Over 80% of couples in the general population will conceive within 1 year if:

- the woman is aged under 40 years

AND

- they do not use contraception and have regular sexual intercourse (every 2 – 3 days).

Of those who do not conceive in the first year, about half will do so in the second year (cumulative pregnancy rate over 90%). [NICE 2004, amended 2013].

The estimated prevalence of infertility is one in seven couples in the UK. A typical Clinical Commissioning Group can expect about 230 new consultant referrals (couples) per 250,000 head of population per year (NICE CG11, 2004).

All couples are eligible for consultation and advice from the specialist service.

Definition of infertility: A woman of reproductive age who has not conceived after 1 year of unprotected vaginal sexual intercourse, in the absence of any known cause of infertility, should be offered further clinical assessment and investigation along with her partner. IVF will only be funded after at least 2 years of unexplained infertility.

Offer an earlier referral for specialist consultation to discuss the options for attempting conception, further assessment and appropriate treatment where:

- the woman is aged 36 years or over
- there is a known clinical cause of infertility or a history of predisposing factors for infertility.

Definition of a full cycle: This term is used to define a full IVF treatment, which should include 1 episode of ovarian stimulation and the transfer of any resultant fresh and frozen embryo(s).

Policy: Funding for egg donation and/or surrogacy is not routinely funded. IVF treatment will be funded in accordance with the criteria specified below:

Ref	Eligibility criteria for treatment	Definition	Additional Notes
1	Female Age – under 40 years	In women aged under 40 years who have not conceived after 2 years of regular unprotected intercourse or 12 cycles of artificial insemination using partner's sperm or 6 cycles of donor sperm (where six or more are by intrauterine	3 full cycles of IVF Inform people that normally a full cycle of IVF treatment, with or without ICSI should comprise 1 episode of ovarian stimulation and the transfer of any resultant fresh and frozen embryo(s)

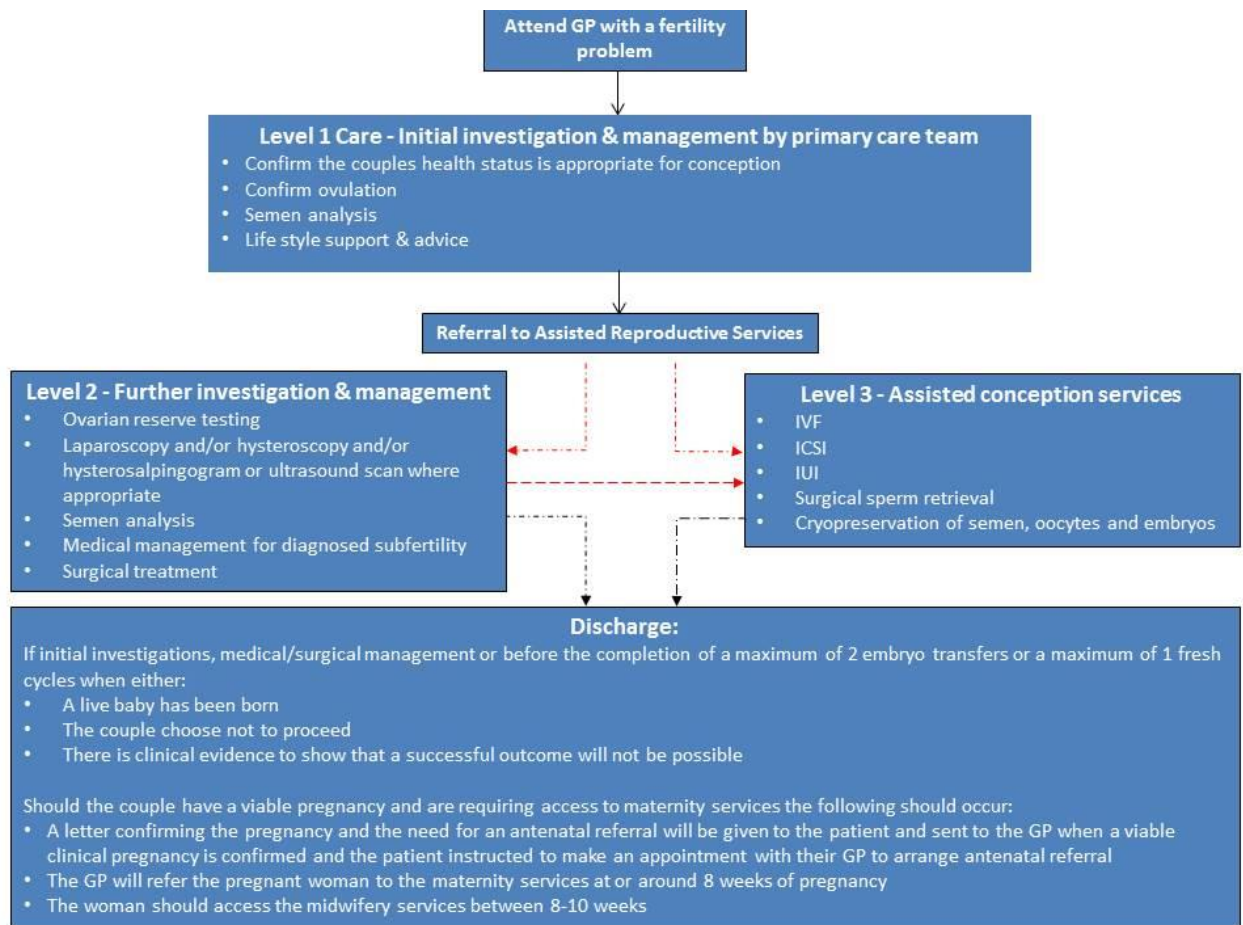
		<p>insemination), offer 3 full cycles of IVF, with or without intracytoplasmic sperm injection (ICSI). If the woman reaches the age of 40 during treatment, complete the current full cycle but do not offer further full cycles.</p> <p>For people with unexplained infertility, mild endometriosis or 'mild male factor infertility', who are having regular unprotected sexual intercourse: do not routinely offer intrauterine insemination, either with or without ovarian stimulation (exceptional circumstances include, for example, when people have social, cultural or religious objections to IVF) advise them to try to conceive for a total of 2 years before IVF will be considered.</p>	<p>The age limit also applies to all treatments including those using gonadotrophins for fertility treatment including ovulation induction and for donor insemination. Access to three cycles is not an automatic right – the outcome of any previous cycle will be taken into account. Treatment must be medically indicated at the start of each cycle. As IVF success rates decline significantly after 3 cycles, previous cycles received irrespective as to whether they were funded by the NHS or privately will be taken into account. If patients have funded 3 or more IVF cycles privately they will not be entitled to any NHS funded cycles. If patients have funded 2 cycles privately they will be entitled to 1 NHS cycle. If patients have funded 1 cycle privately they will be entitled to 2 NHS cycles</p>
2	Female Age – 40 to 42 years	<p>In women aged 40–42 years who have not conceived after 2 years of regular unprotected intercourse or 12 cycles of artificial insemination using partner's sperm or 6 cycles of donor sperm (where 6 or more are by intrauterine insemination), offer 1 full cycle of IVF, with or without ICSI, provided all the following 4 criteria are fulfilled:</p> <ul style="list-style-type: none"> • They have never previously had IVF treatment <p>AND</p> <ul style="list-style-type: none"> • There is evidence of good ovarian reserve as identified by a specialist clinician <p>AND</p> <ul style="list-style-type: none"> • There has been a discussion of the additional implications of IVF and pregnancy at this age <p>AND</p>	<p>1 full cycle of IVF (Including associated frozen/thaw transfers) provided that all other criteria are met.</p> <p>Ovarian reserve testing The aim is to select those with at least 10% chance of successful treatment. The criteria remain under review. At present use the following criteria to predict the likely ovarian response to gonadotrophin stimulation in women who are eligible for IVF treatment. -</p> <ul style="list-style-type: none"> • total antral follicle count of more than or equal to 4 <p>AND</p> <ul style="list-style-type: none"> • anti-Müllerian hormone of more than or equal to 5.4 pmol/l.

		<ul style="list-style-type: none"> Specialist clinical opinion that there is no likelihood of pregnancy with expectant management e.g. confirmed tubal blockage (absolute infertility) <p>Treatment must start before the woman's 43rd birthday</p>	
3	Minimum length of unexplained infertility	2 years of regular unprotected intercourse and unexplained infertility at time of treatment.	Unexplained infertility is a diagnosis made by exclusion in couples who have not conceived and in whom standard investigations including semen analysis, tubal patency tests and assessment of ovulation have not detected any abnormality.
4	Female Body Mass Index (BMI)	<p>BMI greater than 19.0 and lower than or equal to 30.0 at the start of treatment. This applies to all treatments including those using gonadotrophins for fertility treatment including ovulation induction and for donor insemination.</p>	<p>This criterion reflects the increased efficacy of infertility treatment in this weight range. Women with a BMI of 30 or above should be informed that:</p> <ul style="list-style-type: none"> They are likely to take longer to conceive If they are not ovulating then losing weight is likely to increase their chance of conception <p>Women who have a BMI less than 19 and who have irregular menstruation or are not menstruating should be advised that increasing body weight is likely to improve their chance of conception</p>
5	Male Body Mass Index (BMI)	If the male partner has mild male factor infertility which, after clinical assessment could be improved should weight be reduced, then the male partner should be re-assessed for fertility once weight has reduced to a BMI of 30 or below	Men who have a BMI of 30 or over should be informed that they are likely to have reduced fertility
6	Existing children	<p>Treatment will only be offered to couples where neither partner has any living children from current or previous relationship</p> <p>This applies to all treatments including those using</p>	This criterion includes adopted children, but excludes fostered children.

		gonadotrophins for fertility treatment including ovulation induction and for donor insemination.	
7	Smoking Status	Both partners should be non-smokers when referred for IVF. This is part of primary care general assessment procedures. Assessment of smoking status will be through the use of carbon monoxide monitors in primary care or stop smoking services. This applies to all treatments including those using gonadotrophins for fertility treatment including ovulation induction and for donor insemination.	Women who smoke should be informed that this is likely to reduce their fertility Women who smoke should be offered a referral to a smoking cessation programme to support their efforts to stop smoking Women should be informed that passive smoking is likely to affect their chance of conceiving Men who smoke should be informed that there is an association between smoking and reduced semen quality
8	Same sex couples and single women	Treatment will only be offered where the partner wishing to become pregnant is sub-fertile Documentary evidence for subfertility is either no live birth following donor insemination from an accredited sperm bank for at least six cycles over two years or absolute infertility documented after clinical investigation.	Treatment is offered to couples irrespective of sexual orientation. The NHS does not fund donor insemination to establish fertility in same sex couples.
9	Previous Sterilisation	No previous sterilisation history in either partner. This applies to all treatments including those using gonadotrophins for fertility treatment including ovulation induction and induction of spermatogenesis, and for donor insemination.	
10	Length of time resident in catchment area	Both partners should be patients registered for one year with a GP practice that is itself a member of one of the Clinical Commissioning Groups subscribing to these policies This applies to all treatments including those using gonadotrophins for fertility treatment including ovulation induction and for donor insemination.	This excludes short term students who are otherwise eligible for NHS treatment.
11	Residence in UK	Must be eligible for free hospital treatment in line with the Overseas Visitors Charging Regulations. This applies to all treatments including those using	

		gonadotrophins for fertility treatment including ovulation induction and for donor insemination.	
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Appendix 2



A.1 Specialised Services – Derogations from National Service Specifications

Not Applicable

SCHEDULE 2 – THE SERVICES

B. Indicative Activity Plan

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SCHEDULE 2 – THE SERVICES

C. Activity Planning Assumptions

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SCHEDULE 2 – THE SERVICES

D. Essential Services (NHS Trusts only)

Not Applicable

SCHEDULE 2 – THE SERVICES

E. Essential Services Continuity Plan (NHS Trusts only)

Not Applicable

SCHEDULE 2 – THE SERVICES

F. Clinical Networks

Not Applicable

SCHEDULE 2 – THE SERVICES

G. Other Local Agreements, Policies and Procedures

Policy	Date	Weblink

SCHEDULE 2 – THE SERVICES

H. Transition Arrangements

To be populated upon contract award

SCHEDULE 2 – THE SERVICES

I. Exit Arrangements

Upon termination of the contract it is a requirement of the provider to work collaboratively with the commissioner to ensure the safe exit from the service to ensure patient safety, in line with the terms and conditions of the contract.

SCHEDULE 2 – THE SERVICES

J. Transfer of and Discharge from Care Protocols

To be populated upon contract award

SCHEDULE 2 – THE SERVICES

K. Safeguarding Policies and Mental Capacity Act Policies

To be populated upon contract award

SCHEDULE 2 – THE SERVICES

L. Provisions Applicable to Primary Care Services

Not Applicable

SCHEDULE 3 – PAYMENT

A. Local Prices

Enter text below which, for each separately priced Service:

- *identifies the Service;*
- *describes any agreement to depart from an applicable national currency (in respect of which the appropriate summary template (available at: <http://www.monitor.gov.uk/locallydeterminedprices>) should be copied or attached)*
- *describes any currencies (including national currencies) to be used to measure activity*
- *describes the basis on which payment is to be made (that is, whether dependent on activity, quality or outcomes (and if so how), a block payment, or made on any other basis)*
- *sets out any agreed regime for adjustment of prices for the second and any subsequent Contract Year(s).*

To be populated upon contract award.

Maximum tariff is included within the bid Financial Model Template

SCHEDULE 3 – PAYMENT

B. Local Variations

For each Local Variation which has been agreed for this Contract, copy or attach the completed publication template required by Monitor (available at: <http://www.monitor.gov.uk/locallydeterminedprices>) – or state Not Applicable. Additional locally-agreed detail may be included as necessary by attaching further documents or spreadsheets.

Not Applicable

SCHEDULE 3 – PAYMENT

C. Local Modifications

For each Local Modification Agreement (as defined in the National Tariff) which applies to this Contract, copy or attach the completed submission template required by Monitor (available at: <http://www.monitor.gov.uk/locallydeterminedprices>). For each Local Modification application granted by Monitor, copy or attach the decision notice published by Monitor. Additional locally-agreed detail may be included as necessary by attaching further documents or spreadsheets.

Not Applicable

SCHEDULE 3 – PAYMENT

D. Marginal Rate Emergency Rule: Agreed Baseline Value

Not Applicable

SCHEDULE 3 – PAYMENT

E. Emergency Re-admissions Within 30 Days: Agreed Threshold

Not Applicable

SCHEDULE 3 – PAYMENT

F. Expected Annual Contract Values

Commissioner	To be populated upon contract award
Total	

SCHEDULE 3 – PAYMENT

G. Timing and Amounts of Payments in First and/or Final Contract Year

To be populated upon contract award

SCHEDULE 4 – QUALITY REQUIREMENTS

A. Operational Standards (Shaded out denotes not applicable to this service)

Ref	Operational Standards	Threshold (2016/17)	Method of Measurement (2016/17)	Consequence of breach	Timing of application of consequence	Application
	RTT waiting times for non-urgent consultant-led treatment					
E.B.3	<i>Percentage of Service Users on incomplete RTT pathways (yet to start treatment) waiting no more than 18 weeks from Referral*</i>	<i>Operating standard of 92% at specialty level (as reported on Unify)</i>	<i>Review of Service Quality Performance Reports</i>	<i>Where the number of Service Users waiting more than 18 weeks at the end of the month exceeds the tolerance permitted by the threshold, £300 in respect of each such Service User above that threshold</i>	<i>Monthly</i>	<i>Services to which 18 Weeks applies</i>
	Diagnostic test waiting times					
E.B.4	<i>Percentage of Service Users waiting 6 weeks or more from Referral for a diagnostic test*</i>	<i>Operating standard of no more than 1%</i>	<i>Review of Service Quality Performance Reports</i>	<i>Where the number of Service Users waiting 6 weeks or more at the end of the month exceeds the tolerance permitted by the threshold, £200 in respect of each such Service User above that threshold</i>	<i>Monthly</i>	<i>A CS CR D</i>

Ref	Operational Standards	Threshold (2016/17)	Method of Measurement (2016/17)	Consequence of breach	Timing of application of consequence	Application
	A&E waits					
E.B.5	Percentage of A & E attendances where the Service User was admitted, transferred or discharged within 4 hours of their arrival at an A&E department*	Operating standard of 95%	Review of Service Quality Performance Reports	Where the number of Service Users in the month not admitted, transferred or discharged within 4 hours exceeds the tolerance permitted by the threshold, £120 in respect of each such Service User above that threshold. To the extent that the number of such Service Users exceeds 15% of A&E attendances in the relevant month, no further consequence will be applied in respect of the month	Monthly	A+E U
	Cancer waits - 2 week wait					
E.B.6	Percentage of Service Users referred urgently with suspected cancer by a GP waiting no more than two weeks for first outpatient appointment*	Operating standard of 93%	Review of Service Quality Performance Reports	Where the number of Service Users who have waited more than two weeks during the Quarter exceeds the tolerance permitted by the threshold, £200 in respect of each such Service User above that threshold	Quarterly	A CR R

Ref	Operational Standards	Threshold (2016/17)	Method of Measurement (2016/17)	Consequence of breach	Timing of application of consequence	Application
E.B.7	Percentage of Service Users referred urgently with breast symptoms (where cancer was not initially suspected) waiting no more than two weeks for first outpatient appointment*	Operating standard of 93%	Review of Service Quality Performance Reports	Where the number of Service Users who have waited more than two weeks during the Quarter exceeds the tolerance permitted by the threshold, £200 in respect of each such Service User above that threshold	Quarterly	A CR R
	Cancer waits – 31 days					
E.B.8	Percentage of Service Users waiting no more than one month (31 days) from diagnosis to first definitive treatment for all cancers*	Operating standard of 96%	Review of Service Quality Performance Reports	Where the number of Service Users who have waited more than 31 days during the Quarter exceeds the tolerance permitted by the threshold, £1,000 in respect of each such Service User above that threshold	Quarterly	A CR R
E.B.9	Percentage of Service Users waiting no more than 31 days for subsequent treatment where that treatment is surgery*	Operating standard of 94%	Review of Service Quality Performance Reports	Where the number of Service Users who have waited more than 31 days during the Quarter exceeds the tolerance permitted by the threshold, £1,000 in respect of each such Service User above that threshold	Quarterly	A CR R

Ref	Operational Standards	Threshold (2016/17)	Method of Measurement (2016/17)	Consequence of breach	Timing of application of consequence	Application
E.B.10	Percentage of Service Users waiting no more than 31 days for subsequent treatment where that treatment is an anti-cancer drug regimen*	Operating standard of 98%	Review of Service Quality Performance Reports	Where the number of Service Users who have waited more than 31 days during the Quarter exceeds the tolerance permitted by the threshold, £1,000 in respect of each such Service User above that threshold	Quarterly	A CR R
E.B.11	Percentage of Service Users waiting no more than 31 days for subsequent treatment where the treatment is a course of radiotherapy*	Operating standard of 94%	Review of Service Quality Performance Reports	Where the number of Service Users who have waited more than 31 days during the Quarter exceeds the tolerance permitted by the threshold, £1,000 in respect of each such Service User above that threshold	Quarterly	A CR R
	Cancer waits – 62 days					
E.B.12	Percentage of Service Users waiting no more than two months (62 days) from urgent GP referral to first definitive treatment for cancer*	Operating standard of 85%	Review of Service Quality Performance Reports	Where the number of Service Users who have waited more than 62 days during the Quarter exceeds the tolerance permitted by the threshold, £1,000 in respect of each such Service User above that threshold	Quarterly	A CR R

Ref	Operational Standards	Threshold (2016/17)	Method of Measurement (2016/17)	Consequence of breach	Timing of application of consequence	Application
E.B.13	Percentage of Service Users waiting no more than 62 days from referral from an NHS screening service to first definitive treatment for all cancers*	Operating standard of 90%	Review of Service Quality Performance Reports	Where the number of Service Users in the Quarter who have waited more than 62 days during the Quarter exceeds the tolerance permitted by the threshold, £1,000 in respect of each such Service User above that threshold	Quarterly	A CR R
	Category A ambulance calls					
E.B.15.i	Percentage of Category A Red 1 ambulance calls resulting in an emergency response arriving within 8 minutes*	Operating standard of 75%	Review of Service Quality Performance Reports	Where, for the Contract Year as a whole, the number of Red 1 calls where the emergency response did not arrive within 8 minutes exceeds the tolerance permitted by the threshold, £300 in respect of each call above that threshold	Annual	AM
E.B.15.ii	Percentage of Category A Red 2 ambulance calls resulting in an emergency response arriving within 8 minutes*	Operating standard of 75%	Review of Service Quality Performance Reports	Where, for the Contract Year as a whole, the number of Red 2 calls where the emergency response did not arrive within 8 minutes exceeds the tolerance permitted by the threshold, £100 in respect of each call above that threshold**	Annual	AM

Ref	Operational Standards	Threshold (2016/17)	Method of Measurement (2016/17)	Consequence of breach	Timing of application of consequence	Application
E.B.16	Percentage of Category A calls resulting in an ambulance arriving at the scene within 19 minutes*	Operating standard of 95%	Review of Service Quality Performance Reports	Where, for the Contract Year as a whole, the number of calls where the response did not arrive within 19 minutes exceeds the tolerance permitted by the threshold, £100 in respect of each call above that threshold**	Annual	AM
	Mixed sex accommodation breaches					
E.B.S.1	Mixed sex accommodation breach*	>0	Review of Service Quality Performance Reports	£250 per day per Service User affected	Monthly	A CR MH
	Cancelled operations					
E.B.S.2	All Service Users who have operations cancelled, on or after the day of admission (including the day of surgery), for non-clinical reasons to be offered another binding date within 28 days, or the Service User's treatment to be funded at the time and hospital of the Service User's choice*	Number of Service Users who are not offered another binding date within 28 days >0	Review of Service Quality Performance Reports	Non-payment of costs associated with cancellation and non-payment or reimbursement (as applicable) of re-scheduled episode of care	Monthly	A CR

Ref	Operational Standards	Threshold (2016/17)	Method of Measurement (2016/17)	Consequence of breach	Timing of application of consequence	Application
	Mental health					
E.B.S.3	Care Programme Approach (CPA): The percentage of Service Users under adult mental illness specialties on CPA who were followed up within 7 days of discharge from psychiatric in-patient care*	Operating standard of 95%	Review of Service Quality Performance Reports	Where the number of Service Users in the Quarter not followed up within 7 days exceeds the tolerance permitted by the threshold, £200 in respect of each such Service User above that threshold	Quarterly	MH MHSS

In respect of those Operational Standards shown in ***bold italics***, the provisions of SC36.37A apply.

* (as further described in *Technical Guidance for Commissioners*, available at <https://www.england.nhs.uk/ourwork/futurenhs/deliver-forward-view/>)

** (The Co-ordinating Commissioner has discretion to vary the consequence of breach, in agreement with the Provider, where it is appropriate to do so to take account of the operation of a nationally-approved pilot project.)

SCHEDULE 4 – QUALITY REQUIREMENTS

B. National Quality Requirements

	National Quality Requirement	Threshold (2016/17)	Method of Measurement (2016/17)	Consequence of breach	Timing of application of consequence	Application
E.A.S.4	Zero tolerance methicillin-resistant <i>Staphylococcus aureus</i> *	>0	Review of Service Quality Performance Reports	£10,000 in respect of each incidence in the relevant month	Monthly	A
E.A.S.5	Minimise rates of Clostridium difficile*	[Insert Baseline Threshold identified for Provider]	Review of Service Quality Performance Reports	As set out in Schedule 4G, in accordance with applicable Guidance	Annual	A
E.B.S.4	Zero tolerance RTT waits over 52 weeks for incomplete pathways*	>0	Review of Service Quality Performance Reports	£5,000 per Service User with an incomplete RTT pathway waiting over 52 weeks at the end of the relevant month	Monthly	Services to which 18 Weeks applies
E.B.S.7a	All handovers between ambulance and A & E must take place within 15 minutes with none waiting more than 30 minutes*	>0	Review of Service Quality Performance Reports	£200 per Service User waiting over 30 minutes in the relevant month	Monthly	A+E
E.B.S.7b	All handovers between ambulance and A & E must take place within 15 minutes with none waiting more than 60 minutes*	>0	Review of Service Quality Performance Reports	£1,000 per Service User waiting over 60 minutes (in total, not aggregated with E.B.S.7a consequence) in the relevant month	Monthly	A+E
E.B.S.8a	Following handover between ambulance and	>0	Review of Service Quality Performance	£20 per event where > 30 minutes in the	Monthly	AM

	National Quality Requirement	Threshold (2016/17)	Method of Measurement (2016/17)	Consequence of breach	Timing of application of consequence	Application
	<i>A & E, ambulance crew should be ready to accept new calls within 15 minutes and no longer than 30 minutes*</i>		<i>Reports</i>	<i>relevant month</i>		
<i>E.B.S.8b</i>	<i>Following handover between ambulance and A & E, ambulance crew should be ready to accept new calls within 15 minutes and no longer than 60 minutes*</i>	<i>>0</i>	<i>Review of Service Quality Performance Reports</i>	<i>£100 per event where > 60 minutes (in total, not aggregated with E.B.S.8a consequence) in the relevant month</i>	<i>Monthly</i>	<i>AM</i>
<i>E.B.S.5</i>	<i>Trolley waits in A&E not longer than 12 hours*</i>	<i>>0</i>	<i>Review of Service Quality Performance Reports</i>	<i>£1,000 per incidence in the relevant month</i>	<i>Monthly</i>	<i>A+E</i>
E.B.S.6	No urgent operation should be cancelled for a second time*	>0	Review of Service Quality Performance Reports	£5,000 per incidence in the relevant month	Monthly	A CR
	VTE risk assessment: all inpatient Service Users undergoing risk assessment for VTE, as defined in Contract Technical Guidance	95%	Review of Service Quality Performance Reports	Issue of Contract Performance Notice and subsequent process in accordance with GC9	Quarterly	A
	Duty of candour	Each failure to notify the Relevant Person of a suspected	Review of Service Quality Performance Reports	Recovery of the cost of the episode of care, or £10,000 if the cost of the episode of care is	Monthly	All

	National Quality Requirement	Threshold (2016/17)	Method of Measurement (2016/17)	Consequence of breach	Timing of application of consequence	Application
		or actual Reportable Patient Safety Incident in accordance with Regulation 20 of the 2014 Regulations		unknown or indeterminate		
	Completion of a valid NHS Number field in mental health and acute commissioning data sets submitted via SUS, as defined in Contract Technical Guidance	99%	Review of Service Quality Performance Reports	Where the number of breaches in the month exceeds the tolerance permitted by the threshold, £10 in respect of each excess breach above that threshold	Monthly	A MH MHSS
	Completion of a valid NHS Number field in A&E commissioning data sets submitted via SUS, as defined in Contract Technical Guidance	95%	Review of Service Quality Performance Reports	Where the number of breaches in the month exceeds the tolerance permitted by the threshold, £10 in respect of each excess breach above that threshold	Monthly	A&E
	Completion of Mental Health Services Data Set ethnicity coding for all Service Users, as defined in Contract Technical Guidance	Operating standard of 90%	Review of Service Quality Performance Reports	Where the number of breaches in the month exceeds the tolerance permitted by the threshold, £10 in respect of each excess breach above that threshold	Monthly	MH MHSS

	National Quality Requirement	Threshold (2016/17)	Method of Measurement (2016/17)	Consequence of breach	Timing of application of consequence	Application
	Completion of IAPT Minimum Data Set outcome data for all appropriate Service Users, as defined in Contract Technical Guidance	Operating standard of 90%	Review of Service Quality Performance Reports	Where the number of breaches in the month exceeds the tolerance permitted by the threshold, £10 in respect of each excess breach above that threshold	Monthly	MH MHSS
E.H.4	Early Intervention in Psychosis programmes: the percentage of Service Users experiencing a first episode of psychosis who commenced a NICE-concordant package of care within two weeks of referral	Operating standard of 50%	Review of Service Quality Performance Reports	Issue of Contract Performance Notice and subsequent process in accordance with GC9	Quarterly	MH MHSS
E.H.1	Improving Access to Psychological Therapies (IAPT) programmes: the percentage of Service Users referred to an IAPT programme who are treated within six weeks of referral	Operating standard of 75%	Review of Service Quality Performance Reports	Issue of Contract Performance Notice and subsequent process in accordance with GC9	Quarterly	MH MHSS
E.H.2	Improving Access to Psychological Therapies (IAPT) programmes: the percentage of Service Users referred to an IAPT	Operating standard of 95%	Review of Service Quality Performance Reports	Issue of Contract Performance Notice and subsequent process in accordance with GC9	Quarterly	MH MHSS

	National Quality Requirement	Threshold (2016/17)	Method of Measurement (2016/17)	Consequence of breach	Timing of application of consequence	Application
	programme who are treated within 18 weeks of referral					
	Full implementation of an effective e-Prescribing system for chemotherapy across all relevant clinical teams within the Provider (other than those dealing with children, teenagers and and young adults) across all tumour sites	Failure to produce a robust implementation plan, by 30 June 2016, to achieve full implementation as described under Service Specification B15/S/a Cancer: Chemotherapy (Adult) by 31 March 2017	Review of Service Quality Performance Reports	5% of the Actual Monthly Value for the Services provided under Service Specification B15/S/a (Cancer: Chemotherapy (Adult) per month, until a robust implementation plan is produced	Monthly	Where <u>both</u> Specialised Services <u>and</u> Cancer apply
	Full implementation of an effective e-Prescribing system for chemotherapy across all relevant clinical teams within the Provider dealing with children, teenagers and young adults across all tumour sites	Failure to produce a robust implementation plan, by 30 September 2016 to achieve full implementation as described under Service Specification B15/S/b Cancer: Chemotherapy	Review of Service Quality Performance Reports	5% of the Actual Monthly Value for the Services provided under Service Specification B15/S/b Cancer: Chemotherapy (Children, Teenagers and Young Adults) per month, until a robust implementation plan is produced	Monthly	Where <u>both</u> Specialised Services <u>and</u> Cancer apply

	National Quality Requirement	Threshold (2016/17)	Method of Measurement (2016/17)	Consequence of breach	Timing of application of consequence	Application
		(Children, Teenagers and 3Young Adults) by 30 September 2017				

In respect of the National Quality Requirements shown in ***bold italics*** the provisions of SC36.37A apply.

*(as further described in *Technical Guidance for Commissioners*, available at <https://www.england.nhs.uk/ourwork/futurenhs/deliver-forward-view/>)

SCHEDULE 4 – QUALITY REQUIREMENTS

C. Local Quality Requirements

Quality Requirement	Threshold	Method of Measurement	Consequence of breach	Timing of application of consequence	Applicable Service Specification

SCHEDULE 4 – QUALITY REQUIREMENTS

D. Commissioning for Quality and Innovation (CQUIN)

CQUIN Table 1: CQUIN Schemes

Not Applicable			
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CQUIN Table 2: CQUIN Payments on Account

Commissioner	Payment	Frequency/Timing	Agreed provisions for adjustment of CQUIN Payments on Account based on performance

SCHEDULE 4 – QUALITY REQUIREMENTS

E. Local Incentive Scheme

Not Applicable

SCHEDULE 4 – QUALITY REQUIREMENTS

F. Clostridium difficile

Clostridium difficile adjustment: NHS Foundation Trust/NHS Trust (Acute Services only)

The financial adjustment (£) is the sum which is the greater of Y and Z, where:

$$Y = 0$$

$$Z = ((A - B) \times 10,000) \times C$$

where:

A = the actual number of cases of Clostridium difficile in respect of all NHS patients treated by the Provider in the Contract Year

B = the Baseline Threshold (the figure as notified to the Provider and recorded in the Particulars, being the Provider's threshold for the number of cases of Clostridium difficile for the Contract Year, in accordance with Guidance:

<https://www.england.nhs.uk/patientsafety/associated-infections/clostridium-difficile/>

C = $\frac{\text{no. of inpatient bed days in respect of Service Users in the Contract Year}}{\text{no. of inpatient bed days in respect of all NHS patients treated by the Provider in the Contract Year}}$

The financial adjustment is calculated on the basis of annual performance. For the purposes of SC36.47 (*Operational Standards, National Quality Requirements and Local Quality Requirements*), any repayment or withholding in respect of Clostridium difficile performance will be made in respect of the final quarter of the Contract Year.

Clostridium difficile adjustment: Other Providers (Acute Services only)

The financial adjustment (£) is the sum equal to A x 10,000, where:

A = the actual number of cases of Clostridium difficile in respect of Service Users in the Contract Year.

The financial adjustment is calculated on the basis of annual performance. For the purposes of SC36.47 (*Operational Standards, National Quality Requirements and Local Quality Requirements*), any repayment or withholding in respect of Clostridium difficile performance will be made in respect of the final quarter of the Contract Year.

SCHEDULE 4 – QUALITY REQUIREMENTS

G. CQUIN Variations

Not Applicable

SCHEDULE 5 – GOVERNANCE

A. Documents Relied On

Documents supplied by Provider

Date	Document

Documents supplied by Commissioners

Date	Document

SCHEDULE 5 - GOVERNANCE

B.1 Provider's Mandatory Material Sub-Contracts

Mandatory Material Sub-Contractor [Name] [Registered Office] [Company number]	Service Description	Start date/expiry date	Processing data – Yes/No

SCHEDULE 5 - GOVERNANCE

B.2 Provider's Permitted Material Sub-Contracts

Permitted Material Sub-Contractor [Name] [Registered Office] [Company number]	Service Description	Start date/expiry date	Processing data – Yes/No

SCHEDULE 5 - GOVERNANCE

C. Commissioner Roles and Responsibilities

Co-ordinating Commissioner/Commissioner	Role/Responsibility
Insert text locally	

SCHEDULE 6 – CONTRACT MANAGEMENT, REPORTING AND INFORMATION REQUIREMENTS

A. Reporting Requirements

	Reporting Period	Format of Report	Timing and Method for delivery of Report	Application
National Requirements Reported Centrally				
1. As specified in the list of omnibus, secure electronic file transfer data collections and BAAS schedule of approved collections published on the HSCIC website to be found at http://www.hscic.gov.uk/article/5073/Central-Register-of-Collections where mandated for and as applicable to the Provider and the Services	As set out in relevant Guidance	As set out in relevant Guidance	As set out in relevant Guidance	All
2. Patient Reported Outcome Measures (PROMS) http://www.hscic.gov.uk/proms	As set out in relevant Guidance	As set out in relevant Guidance	As set out in relevant Guidance	All
National Requirements Reported Locally				
1. Activity and Finance Report (note that, if appropriately designed, this report may also serve as the reconciliation account to be sent by the Provider by the First Reconciliation Date under SC36.28 or SC36.31)	Monthly	[For local agreement]	By no later than the First Reconciliation Date for the month to which it relates, consistent with data submitted to SUS, where applicable	All
2. Service Quality Performance Report, detailing performance against Operational Standards, National Quality Requirements, Local Quality Requirements, Never Events and the duty of candour, including, without limitation: <ul style="list-style-type: none"> a. details of any thresholds that have been breached and any Never Events and breaches in respect of the duty of candour that have occurred; b. details of all requirements satisfied; c. details of, and reasons for, any failure to meet requirements d. the outcome of all Root Cause Analyses and audits performed pursuant to SC22 (<i>Venous Thromboembolism</i>) 	Monthly	[For local agreement]	Within 15 Operational Days of the end of the month to which it relates.	All All All A

NHS STANDARD CONTRACT 2016/17 PARTICULARS (Full Length)

	Reporting Period	Format of Report	Timing and Method for delivery of Report	Application
e. report on performance against the HCAI Reduction Plan				A
3. CQUIN Performance Report and details of progress towards satisfying any Quality Incentive Scheme Indicators, including details of all Quality Incentive Scheme Indicators satisfied or not satisfied	[For local agreement]	[For local agreement]	[For local agreement]	All
4. NHS Safety Thermometer Report, detailing and analysing: a. data collected in relation to each relevant NHS Safety Thermometer; b. trends and progress; c. actions to be taken to improve performance.	[Monthly, or as agreed locally]	[For local agreement], according to published NHS Safety Thermometer reporting routes	[For local agreement], according to published NHS Safety Thermometer reporting routes	All (not AM, CS, D, 111, PT, U)
5. Complaints monitoring report, setting out numbers of complaints received and including analysis of key themes in content of complaints	[For local agreement]	[For local agreement]	[For local agreement]	All
6. Report against performance of Service Development and Improvement Plan (SDIP)	In accordance with relevant SDIP	In accordance with relevant SDIP	In accordance with relevant SDIP	All
7. Cancer Registration dataset reporting (ISN): report on staging data in accordance with Guidance	As set out in relevant Guidance	As set out in relevant Guidance	As set out in relevant Guidance	CR R
8. Summary report of all incidents requiring reporting	Monthly	[For local agreement]	[For local agreement]	All
9. Data Quality Improvement Plan: report of progress against milestones	In accordance with relevant DQIP	In accordance with relevant DQIP	In accordance with relevant DQIP	All
10. Report and provide monthly data and detailed information relating to violence-related injury resulting in treatment being sought from Staff in A&E departments, urgent care and walk-in centres to the local community safety partnership and the relevant police force, in accordance with applicable Guidance (Information Sharing to Tackle Violence (ISTV) Initial Standard Specification http://www.isb.nhs.uk/documents/isb-1594/amd-31-2012/index_html#Information	Monthly	As set out in relevant Guidance	As set out in relevant Guidance	A A+E U
11. Report on outcome of reviews and evaluations in	Six monthly (or more	[For local agreement]	[For local agreement]	All

NHS STANDARD CONTRACT 2016/17 PARTICULARS (Full Length)

	Reporting Period	Format of Report	Timing and Method for delivery of Report	Application
relation to Staff numbers and skill mix in accordance with GC5.2(<i>Staff</i>)	frequently if and as required by the Co-ordinating Commissioner from time to time)			
12. Report on compliance with National Workforce Race Equality Standard	Annually	[For local agreement]	[For local agreement]	All
13. Specific reports required by NHS England in relation to Specialised Services and other services directly commissioned by NHS England, as set out at http://www.england.nhs.uk/nhs-standard-contract/ss-reporting (where not otherwise required to be submitted as a national requirement reported centrally or locally)	As set out at http://www.england.nhs.uk/nhs-standard-contract/ss-reporting	As set out at http://www.england.nhs.uk/nhs-standard-contract/ss-reporting	As set out at http://www.england.nhs.uk/nhs-standard-contract/s-reporting	Specialised Services
Local Requirements Reported Locally				
Insert as agreed locally.*				

*In completing this section, the Parties should, where applicable, consider the change requirements for local commissioning patient-level data flows which will need to be implemented from 01 April 2017 when the new national Data Services for Commissioners technical solution becomes operational. These change requirements will be published within the *Data Services for Commissioners Resources* website: <https://www.england.nhs.uk/ourwork/tsd/data-services/resources>

SCHEDULE 6 – CONTRACT MANAGEMENT, REPORTING AND INFORMATION REQUIREMENTS

B. Data Quality Improvement Plans

Data Quality Indicator	Data Quality Threshold	Method of Measurement	Milestone Date	Consequence

SCHEDULE 6 – CONTRACT MANAGEMENT, REPORTING AND INFORMATION REQUIREMENTS

C. Incidents Requiring Reporting Procedure

Procedure(s) for reporting, investigating, and implementing and sharing lessons learned from: (1) Serious Incidents (2) Reportable Patient Safety Incidents (3) Other Patient Safety Incidents
Insert text locally

SCHEDULE 6 – CONTRACT MANAGEMENT, REPORTING AND INFORMATION REQUIREMENTS

D. Service Development and Improvement Plans

	Milestones	Timescales	Expected Benefit	Consequence of Achievement/ Breach
[Seven Day Services]*				
[Mental Health Access Standards]*				
[Digital Transformation]*				
[e-Referral]*				
Insert text locally				[Subject to GC9 (<i>Contract Management</i>)] or [locally agreed]

*Refer to Contract Technical Guidance for detail of requirements

SCHEDULE 6 – CONTRACT MANAGEMENT, REPORTING AND INFORMATION REQUIREMENTS

E. Surveys

Type of Survey	Frequency	Method of Reporting	Method of Publication	Application
Friends and Family Test (where required in accordance with FFT Guidance)	As required by FFT Guidance	As required by FFT Guidance	As required by FFT Guidance	All
Service User Survey [Insert further description locally]				All
Staff Survey (appropriate NHS staff surveys where required by Staff Survey Guidance) [Other] [insert further description locally]				All
Carer Survey [Insert further description locally]				All
[Other insert locally]				

SCHEDULE 7 – PENSIONS

Insert text locally (template drafting available via <http://www.england.nhs.uk/nhs-standard-contract/>) or state Not Applicable

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Full name: Heads of terms for the grant of a lease.

[ON HEADED NOTEPAPER OF [NAME OF LANDLORD]]

[DATE]

Dear [NAME OF TENANT]

FROM: North Tees and Hartlepool NHS Foundation Trust

TO: [NAME OF TENANT]

(A) North Tees and Hartlepool NHS Foundation Trust intends to grant [NAME OF TENANT] a lease on the following heads of terms. These heads of terms are not intended to create any legally binding obligations. They are subject to contract, completion of formally executed legal documentation and approval of the board of North Tees and Hartlepool Foundation Trust.

AGREED TERMS

1. LANDLORD

North Tees and Hartlepool NHS Foundation Trust

Country of incorporation/registration:

Company number:

Registered office address:

2. TENANT

[NAME OF TENANT]

[Trading as:]

Country of incorporation/registration:

Company number

Registered office address:

3. PROPERTY

3.1 DESCRIPTION.

Hartlepool site

University Hospital of Hartlepool, Holdforth Rd, Hartlepool, TS24 9AH

- 3.2 The Tenant will have the right to apply for annual permits to access the staff car parks, costs will be equivalent to those paid by North Tees and Hartlepool Trust staff. On site public parking spaces are available and subject to the reasonable parking management regulations and parking charges, determined by the Trust, company authority or body authorised or appointed by the Landlord to manage the parking spaces.

4. TERM

- 4.1 The lease will be for a term of 5 years beginning on April 2017 with an option to renew for 2 further years at the end of year 5 [the usual quarter day before completion of the lease].
- 4.2 The lease will exclude the security of tenure provisions of Part II of the Landlord and Tenant Act 1954.

5. RENT, SERVICE CHARGE AND RENT REVIEW

- 5.1 The rental and service charges are combined, cost are as follows:-
- (a) £67,500[Sixty-seven thousand, five hundred pounds], University Hospital of Hartlepool, Holdforth Rd, exclusive of VAT, rates, insurance premiums and all other outgoings.
- 5.2 In addition to rent, the Tenant must also pay VAT (including any VAT on the rent), rates, insurance premiums and all other outgoings.
- 5.3 There will be no rent-free period. The rent will be reviewed with effect from April 2017 and every year after that date. Inflation based on the Hospital Services Price Index would be added per annum for the period of the contract.
- 5.4 The facilities are offered without furnishings or equipment, existing items may be purchased from the Trust by separate agreement.

6. RENT DEPOSIT

- 6.1 The Tenant will not pay a rent deposit.

7. SERVICES AND SERVICE CHARGE

7.1 The Tenant will pay an annual service / rental charge. The amount is based on the floor area of the property calculated as a fair proportion of the total service expenditure.

7.2 Service charges to include:

- (a) estates maintenance; planned preventative maintenance and breakdown repair to Trust assets
- (b) domestic cleaning services will provide 7-day service based on National Standards of Cleanliness
- (c) clinical and domestic waste removal
- (d) telephone provision
- (e) Ad-hoc portering and security services

7.3 The service charge excludes:

- (a) Any requirements for dedicated portering and security staffing, mail services, telecom usage and I.T. services
- (b) Estate and clinical engineering maintenance does not extend to any equipment not owned by the Trust located within the department

8. INSURANCE

8.1 The Landlord will insure the estate, including the property and on demand the Tenant will refund a proportion of the total premium based on the floor area of the property.

8.2 The Landlord will extend its insurance to terrorist risk (as long as that insurance is available on reasonable terms).

8.3 The Landlord and the Tenant will be able to terminate the lease if the property is damaged or destroyed by an uninsurable risk so that the Tenant cannot occupy the property.

9. USE

9.1 The property can only be used as a health facility for the provision of primary, secondary and community healthcare services in accordance with the Tenant's service contract from their commissioner in connection to the Assisted Reproduction Service.

9.2 The Tenant will be allowed access to theatre 7 on a sessional basis to undertake activities associated with the service, the number of sessions to be agreed with the

Trust. Diagnostic services including, radiology and pathology services will be made available on request from the Trust. Such use of facilities and services will attract additional costs to be separately agreed with the Trust.

9.3 The Tenant cannot change the use of the property.

9.4 There are no restrictions on hours and days of access as the service is provided 24hrs 7 days a week.

10. ASSIGNMENTS AND UNDERLEASES

10.1 The Tenant can request that the lease be assigned, with the Landlord's prior written consent, which cannot be unreasonably withheld. This will be subject to Trust's policy and procedures. The Tenant will always be required to give an authorised guarantee agreement in respect of any assignee of the lease. This will be in connection to health related services associated with the Assisted Reproduction Service.

10.2 The Tenant can underlet the whole of the property with the Landlord's prior written consent, which cannot be unreasonably withheld. This will be subject to Trust's policy and procedures. This will be in connection to health related services associated with the Assisted Reproduction Service.

10.3 The Tenant can share occupation of the property with any company in the same group of companies as the Tenant with the Landlord's prior written consent, which cannot be unreasonably withheld. This will be subject to Trust's policy and procedures.

11. REPAIR

11.1 The lease will be a full repairing lease with the Tenant directly responsible for all internal repairs and responsible for the cost of all repairs. The Landlord shall be entitled to carryout regular inspections of the premises and require the Tenant to undertake any repairs deemed appropriate. The Landlord's prior written consent shall be required before any repair works are undertaken by 3rd party contractors.

11.2 The Tenant will be obliged to ensure the building is maintained in a good condition, subject to fair wear and tear.

11.3 The Tenant will not be obliged to repair damage caused by an uninsurable risk.

11.4 The Landlord reserves the right to undertake any repairs it deems essential and charge the Tenant accordingly.

- 11.5 The Landlord reserves the right to access the premises 24/7 to undertake any maintenance obligations.

12. ALTERATIONS

- 12.1 The Tenant cannot make any structural or external alterations to the property.
- 12.2 The Tenant can make internal alterations to the property with the Landlord's prior written consent which cannot be unreasonably withheld. This will be subject to Trust's policy and procedures.
- 12.3 The Tenant can put up signs on the outside of the property or that would be visible from the outside of the property in accordance with NHS requirements, with the Landlord's prior written consent, which cannot be unreasonably withheld. This will be subject to Trust's policy and procedures.

13. TENANT'S FITTING OUT WORKS

- 13.1 The Tenant must obtain the Landlord's written consent which cannot be unreasonably withheld or delayed before carrying out any fitting-out works to the property. The Landlord requires [3] copies of the drawings and specification showing the proposed fitting out works as soon as possible.
- 13.2 The Tenant's fitting-out works will be paid for by the Tenant and will be disregarded at rent review.

14. LANDLORD'S WORKS

The property will be let as seen.

15. CONDITIONS

The grant of the lease will be subject to [DETAILS OF CONDITION(S) e.g. SUPERIOR LANDLORD'S WRITTEN CONSENT CONTAINED IN A FORMALLY EXECUTED LICENCE].

16. TERMINATION

- 16.1 The Landlord will have rights to forfeit the Lease if:
- (a) there is a persistent and material breach by the Tenant of:
 - (i) the Service Contract; and/or

- (ii) the policies of the Landlord annexed to the Heads of Terms are to be considered as Quality Requirements as referenced in 17.10.4 of the NHS Standard Contract General Conditions (with such policies being directly relevant to the Landlord's status as a NHS Foundation Trust); and
 - (b) such breach is likely to materially and significantly harm the reputation of the Landlord; and
 - (c) the CCG has given its prior written consent (which is not to be unreasonably withheld or delayed) to the Landlord exercising its right to forfeit in such circumstances. The CCG is to join into the Lease solely for the purpose of approving the Landlord's right to forfeit (and without assuming any other liabilities under the Lease)."
- 16.2 The terms and conditions to termination will be co-terminus with the Assisted Reproduction Service Contract.

17. COSTS

- 17.1 Each party is responsible for its own legal costs in connection with this transaction.

18. CONVEYANCERS

- 18.1 The Landlord's conveyancer is DAB Beechcroft, Welbar Central, 36 Gallowgate, Newcastle upon Tyne, NE1 4TD, for the attention of Andrea Proudlock.
- 18.2 The Tenant's conveyancer is [NAME AND ADDRESS], for the attention of [NAME].

Signed by

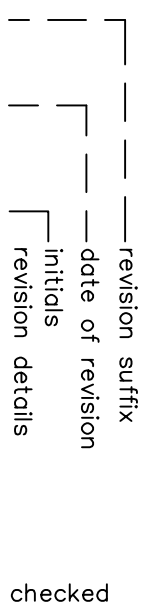
For and on behalf of [LANDLORD COMPANY]

Signed by

For and on behalf of [TENANT COMPANY]

Signed by

The information indicated on this plan is furnished as a general guide only. The plan must therefore not be regarded as authentic in every detail, nor should any annotation made thereon, when planning for, or carrying out work within the trusts without prejudice to any rights and liabilities, which might arise hereafter, limit dimensions to be checked on site prior to work commencement and any discrepancies are to be reported to the Contract Administrator.



NHS
North Tees & Hartlepool
Foundation Trust
Estates Control and Development
University Hospital of North Tees
Stockton on Tees, Cleveland TS19 8PE.
Tel : (01642) 617617.

NHS

MATERNITY BLOCK
UNIVERSITY HOSPITAL OF HARTLEPOOL

ing Title
 SUSTAINED REPRODUCTIVE UNIT (ARU) RED
 BOUNDARY OF DEPARTMENT
 BLUE LINE SHARED AREA

D Wills













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







June 2016














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








Appendix 1 – Policies







Policy Title	Reference and Version No:	Document
Antibiotic Strategy	C56 Version 4	 Antibiotic_Strategy_ C56_V4.pdf
Accidental Exposures to Bodily Fluids	C41 Version 7	 Accidental_Exposure _to_Bodily_Fluids_C4
Adult Safeguarding	C46 Version 6	 Adult_Safeguarding_ Policy_C46_v6.pdf
Anti-Fraud	F14 Version 2	 Anti_Fraud_Policy_F 14_v2.pdf
Cardiac Resuscitation	HR75 Version 12	 Cardiac_Resuscitatio n_Policy_HR75__V12
Care After Death	C82 Version 1	 Care_After_Death_P olicy_C82_v1.pdf
Central Alerting System (CAS)	EF13 Version 6	 Central_Alerting_Sys tem_(CAS)_Policy_EF
Cleaning Standards	EF16 Version 2	 Cleaning_Standards_ Policy_EF16v2_.pdf
Clinical Falls Management and Bedrails Policy ADULTS	C29 Version 10	 Clinical_Falls_Manag ement_and_Bed_Rail:
Clinical System Safety Management	C68 Version 1	 Clinical_System_Safe ty_Management_Polix
Consent to Examination or Treatment	C25 Version 9	 Consent_to_Examina tion_or_Treatment_P
Control of Clostridium difficile Infection	IC19 Version 5	 Control_of_C_Difficil e_Policy_IC19_v5.pd

Control of Substances Hazardous to Health Policy (COSHH)	RM16 Version 7	 Control_of_Substances_Hazardous_to_He
Corporate Records policy and Strategy	IG38 Version 1	 Corporate_Records_Policy_and_Strategy_
Data Breach	IG30 Version 1	 Data_Breach_Policy_IG30_v1.pdf
Data Protection, Caldicott and Disclosure	IG5 Version 8	 Data_Protection_Caldicott_and_Disclosure
Disclosure of Concerns (Whistle Blowing)	HR27 Version 6	 Disclosure_of_Concerns__Whistle_Blowing
Domestic Abuse	C81 Version 1	 Domestic_Abuse_Policy_C81_v1..pdf
Duty of Candour (incorporating Being Open)	C40 Version 7	 Duty_of_Candour_(Being_Open)_C40_v7_
Effective Management of Mandatory Training	HR45 Version 8	 Effective_Management_of_Mandatory_Training
Fire Policy	RM13 Version 1	 Fire_Policy_RM13_v10.pdf
Grievance Policy and Procedure (incorporating the prevention of Bullying and Harassment)	HR2 Version 10	 Grievance_Policy_and_Procedure_HR2_v10
Hand Hygiene	IC2 Version 10	 Hand_Hygiene_policy_IC2_V10..pdf
Health and Safety	RM10 Version 8	 Health_and_Safety_Policy_RM10_v8_(1)
Healthcare Records Keeping Policy and Strategy	IG32 Version 2	 Healthcare_Records_Keeping_Policy_and_Strategy

Healthcare Records Management Policy and Strategy	IG12 Version 10	 Healthcare_Records_Management_Policy
Incident Reporting and Investigation	RM15 Version 5	 Incident_Reporting_and_Investigation_Pc
Induction	HR17 Version 9	 Induction_Policy_HR_17_v9.pdf
Infection Prevention and control	IC3 Version 10	 Infection_Prevention_and_Control_Policy_
Infection Prevention and Control Surveillance	IC23 Version 2	 Infection_Prevention_and_Control_Surveil
Information Governance Management Framework	IG34 Version 2	 Information_Governance_Management_F
Information Governance	IG14 Version 5	 Information_Governance_policy_IG14_v5
Information Security	IG9 Version 8	 Information_Security_Policy_IG9_v8.pdf
Introduction of New Clinical Procedures or Techniques	C15 Version 6	 Introduction_of_new_clinical_procedures_
Local Decontamination of Medical Equipment Policy (Previously - Disinfection and Sterilisation Policy)	IC12 Version 6	 Local_Decontamination_of_Medical_Equip
Lockdown	RM23 Version 3	 Lockdown_Policy_RM_23_v3.pdf
Management and use of Medical Devices	RM3 Version 10	 Management_and_use_of_Medical_Device
Management of Violence and Aggression	RM7 Version 9	 Management_of_Violence_and_Aggressor

Media	IG10 Version 7	 Media_Policy_IG10_v7.pdf
Medical Appraisal (incorporating requirements of revalidation)	HR64 Version 3	 Medical_Appraisal_Policy_(incorporating_r
Mental Capacity Act	C53 Version 6	 Mental_Capacity_Act_policy_C53_v6.pdf
MRSA	IC6 Version 8	 MRSA_Policy_IC6_v8.pdf
Peripheral Cannulation	IC18 Version 6	 Peripheral_Cannulation_Policy_IC18_v6.p
Point of Care Testing (POCT)	C26 Version 4	 Point_of_Care_Testing_POCT_C26_v4.pd
Policy and Guidance for Interpreting and Translation	C44 Version 4	 Policy_and_Guidance_for_Interpreting_an
Disclosure and Baring Service (DBS) Checks	HR52 Version 6	 Policy_and_Procedure_for_use_of_DBS_d
Dealing with complaints	RM4 Version 11	 Policy_for_Dealing_with_Complaints_RM4_
Reporting and dealing with Serious Incidents; inclusive of Never Events	RM14 Version 8	 Policy_for_reporting_and_dealing_with_S
Prevention, Diagnosis and Treatment of Venous Thromboembolism	C60 Version 5	 Policy_for_the_Prevention_Diagnosis_and
Recognition and Response to Acute Illness in Adults in Hospital	C58 Version 5	 Policy_for_the_Recognition_and_Respons
Safe and Secure Handling of Medicines	C20 Version 10	 Policy_for_the_Safe_and_Secure_Handlin

Practice Relating to the Transfusion of Blood and Blood Products	C16 Version 10	 Practice_Relating_to_the_Transfusion_of_
Pressure Ulcer Prevention and Risk Assessment Policy	C13 Version 6	 Pressure_Ulcer_Prevention_and_Risk_Ass
Prevention and Management of Infant and Child Abduction	C12 Version 5	 Prevention_and_Management_of_Infant_i
Professional Registrations	HR40 Version 10	 Professional_Registrations_HR40_v10.pdf
Records Management	IG25 Version 3	 Records_Management_Policy_IG25_v3.px
Registration Authority Policy and Practice	HR73 Version 1	 Registration_Authority_Policy_and_Practic
Safe use of Potassium Chloride Formulations and Guidance on the Treatment and Prevention of Hypokalaemia	C19 Version 4	 Safe_use_of_Potassium_Chloride_Formula
Safeguarding Children	C50 Version 5	 Safeguarding_Children_C50_v5.pdf
Secure Transfer of Personal, Confidential or Sensitive Information	IG39 Version 1	 Secure_Transfer_of_Personal_Confidentia
Security Policy (includes ID Badge Policy)	RM6 Version 9	 Security_Policy_inc_ID_Badge_Policy_RM6
Smoke Free	EF12 Version 6	 Smoke-free_Policy_EF_v6.pdf
Standard Precautions	IC17 Version 7	 Standard_Precautions_Policy_IC17_v7.pdf
Tuberculosis Control Policy	IC11 Version 6	 TB_Control_policy_IC11_v6.pdf

Toy Safety	RM25 Version 2	 Toy_Safety_Policy__RM25_v2.pdf
Traffic Management Policy for Staff at North Tees and Hartlepool NHS Foundation Trust	EF3 Version 7	 Traffic_Managemnt_Policy_for_Staff_EF3
Uniform and Personal Appearance	HR18 Version 5	 Uniform_and_Personal_Appearance_Policy
Urinary Catheter Care	C67 Version 1	 Urinary_Catheter_Care_Policy_C67_v1_
Waste Disposal	EF1 Version 12	 Waste_Disposal_Policy_EF1_v12.pdf
Wound Management and Dressing Selection	C55 Version 4	 Wound_Management_and_Dressing_Select

ARU FURNITURE AND EQUIPMENT

Small Office	<ul style="list-style-type: none"> • 4 drawer filing cabinet • Computer • 2 drawer under desk cabinet • 15 drawer filing cabinet • 3 shelves • Desk • Chair • Printer • Telephone
Reception Area	<ul style="list-style-type: none"> • 2 x 15 drawer cabinet • 1 x 16 drawer cabinet • 3 x 10 drawer cabinet • Computer • 2 drawer filing cabinet • 2 drawer under desk cabinet • Filing bucket • Security monitor • Notes trolley • Telephone • Computer chair
Waiting Area	<ul style="list-style-type: none"> • TV • 6 x armchairs • 2 x 2 seater • 5 x coffee tables • Water machine • 1 x glass display cabinet
Main Office	<ul style="list-style-type: none"> • Notes trolley • Computer • 15 drawer filing cabinet • 4 drawer filing cabinet • 2 door filing cabinet • 2 drawer under desk cabinet • 2 x desks • Printer • Fax machine • 2 x telephones • 2 x shelving unit • 3 x white boards • Metal key cabinet • 2 x computer chairs
Store Room 5	<ul style="list-style-type: none"> • 4 x shelves
Store Room 6	<ul style="list-style-type: none"> • Large fax / photo copier machine • 2 x wall cabinets • Filing bucket • Shelving unit • 6 x 4 drawer filing cabinets • 1 x 2 drawer filing cabinet

	<ul style="list-style-type: none"> • 1 x 2 door filing cabinet • Leaflet rack • White board • Fridge
Store Room 7	<ul style="list-style-type: none"> • 2 door large filing cabinet • 2 x 4 drawer filing cabinets
Corridor	<ul style="list-style-type: none"> • Defibrillator • 9 x cupboard filing cabinets • Portable PC • 1 x glass display cabinet • Linen trolley
Access Lounge	<ul style="list-style-type: none"> • 4 x armchairs • 6 x bedside lockers • 2 drawer under desk filing cabinets • Filing duckett • 5 drawer mini cabinet • Desk • Linen bin • Telephone • Examination table • 4 x chairs • 2 x bins • Portable Sharps bin stand • Deck phone
Room 1	<ul style="list-style-type: none"> • 2 x armchairs • 1 x computer chair • 1 x chair • 1 x examination table • 1 x desk • 1 x computer • 2 x plastic filing drawers (desktop) • 2 x bins • Gloves and apron bucket • Wall cupboard • Telephone
Room 2	<ul style="list-style-type: none"> • 2 x armchairs • 1 x computer chair • 1 x chair • 1 x examination table • 1 x desk • 1 x computer • 2 x plastic filing drawers (desktop) • 2 x bins • Gloves and apron bucket • Wall cupboard • Telephone • Linen bin
Room 3	<ul style="list-style-type: none"> • 2 x armchairs • 1 x computer chair • 1 x chair • 1 x examination table

	<ul style="list-style-type: none"> • 1 x desk • 1 x computer • 2 x plastic filing drawers (desktop) • 2 x bins • Gloves and apron bucket • Wall cupboard • Telephone • Linen bin • 3 x chairs (no armchairs)
Clean Utility	<ul style="list-style-type: none"> • 2 x shelves • Small drug fridge • Tall storage cupboard • 3 x storage cupboards • 2 x drug cupboards • 2 x bins
Dirty Utility	<ul style="list-style-type: none"> • 3 x shelves • Sink unit with double cupboard underneath • 2 x bins • 1 x sluice master
Embryologist Office	<ul style="list-style-type: none"> • 2 x chairs • 2 x desks • Computer • 4 x under drawer cabinets • 1 x broken 2 drawer filing cabinet • 2 x shelves • Deck phone • Telephone
Partners Room	<ul style="list-style-type: none"> • 2 x bins • Chair • Side table
Toilets	<ul style="list-style-type: none"> • 2 x bins

Cryo Room	• ICSI machine intigra	£500.00	
	• Olympus microscope	£6,000.00	
	• Jencons transport incubator	£3180.00	
	• Grant water bath	200.00	
	• Camlab ultrasonic bath	200.00	
	• Mini digital scale	0.00	
	• Cryo straws sealer	0.00	
	• 2 x microscopes	£12,000.00	
	• Egg retrieval pump	0.00	
	• Transport container	0.00	
	• LN2 Dewer Lab 30	0.00	
	• LN2 Dewer MVE 20/20	0.00	
	• LN2 Dewer Biotrek 3	0.00	
	• 6 LN2 Dewers	0.00	
	• Cryo 10 freezing system	£500.00	
	• Cook power supply for	0.00	

Laboratory	pump		
	• 2 x face masks	0.00	
	• 3 pairs of Cryo gloves	0.00	
	• 2 x trolleys	0.00	
	• Jencons LN2 container	0.00	
	• 2 x table air filters	£100.00	Pair
	• Cellarsafe air monitor	0.00	
	• Dewer stand with wheels	0.00	
	• Stainless steel funnel	0.00	
	• 5 x cryo rulers	0.00	
	• LN2 Dewer 4LD	0.00	
	• 1 x small LN2 GXR2	Rented	BOC
	• 5 x alarm monitors	0.00	
	• Timelapse system (computer)	4000.00	
	• 2 x large oxygen / nitro cylinders	Rented	BOC
	• 6 x small Co2	Rented	BOC
	• Sanyo incubator	£1,500.00	
	• Telephone	n/a	
	• 3 x incubator stands	0.00	
	• Alarm system	£100.00	
	• Flow hood	£300.00	
	• Mini incubator	£3,268.03	
	• 3 x chairs	n/a	
	• Olympus microscope SXX7	£6,000.00	
	• 4 drawer trolley	n/a	
	• 6 drawer trolley	n/a	
	• 2 x change over units	0.00	
	• 3 x alarm monitors	0.00	
	• 2 x Heraeus CO2 incubator	£600.00	
	• Foster fridge	£500.00	
	• ICSI machine Eclipse Ti	£34,054.00	
	• Anti vibration table	0.00	
	• Centaur 2	0.00	
	• Olympic microscope BX45	£6,000.00	
	• Shelf		
	• Transceiver	0.00	
	• Grant water bath	0.00	
	• 2 x air filter systems	£200.00	Pair
	• 5 tier plastic trays		
	• 4 tier plastic trays		
	• 4 drawers.		
	• Cryo printer for labels	0.00	
	• Cook egg retrieval pump	£200.00	

To be kept by the Trust	• Grant tube warmer	0.00	
	• 2 x pipettes	0.00	
	• Scales		
	• Height stand		
	• BP machine		
	• Temp machine		
	• 3 x examination lamps		
	• 4 x 5 drawer equipment trolleys		
	• 4 x metal examination trolleys		
	• 3 drip stands		
	• X2 scanners		

Q No.	Date Received	Clarification	Response Due Date	Actual Date Provided	Response
1	25/10/16	Dear Sir / Madam, I would be very grateful if you could forward the following details regarding the ARU- Hartlepool tender: Break down of theatre cost Break down of the lab cost The furniture and available equipment included in the lease. Best regards,	31/10/16	25/10/16	Within the Heads Of Terms provided point 5.4 states: 5.4 "The facilities are offered without furnishings or equipment, existing items may be purchased from the Trust by separate agreement." Therefore any equipment which a provider wishes to utilise will need to be agreed with the Trust seperately. Please see attached list of current furniture and what is available for purchase from the Trust. We are informed that the residual cost for the office style furniture is £10,000. All other items have been listed with indicitive pricing for information only. Any provider will need to perform their own due dilligence and discussion with the incumbent regards which equipment they require. Indicitive figures for other associated costs are: Theatre use and communal space £70 per 4 hour session SSD costs – per tray £26.90, 4 cases on average per list (£107.60) Consumable costs – average £25 per case 4 cases on average per list (£100) As mentioned all of these costs are indicitive only and will need confirmation between the provider and the incumbent.
2	31/10/16	Can you clarify if there is shared access to allow filling of the liquid nitrogen tanks from the cryostore to outside. This is not indicated on the plans.	07/11/16	07/11/16	Shared acces is included please see attached plan showing access route from external store to the liquid nitrogen tanks.
3	31/10/16	Can you clarify the qualifactions and surgical abilities of the Gynaecology associate specialist? In particular is she MRCOG and can she perform surgical sperm retrieval,laparoscopies and hysteroscopies	07/11/16	07/11/16	The Associate Specialist holds all the relevant qualifications, this includes MRCOG and is able to carry out all the procedures listed.
4	31/10/16	Is it envisaged the provider will need to run their IT systems entirely separately from the trust or is there the possibility of utilising some of the trusts systems? If there is please confirm what it is envisaged will be available.	07/11/16	07/11/16	Access could be provided, but safeguards would need to be provided particularly around IG and data protection issues.
5	31/10/16	Is it envisaged the provider will need to run their IT systems entirely separately from the trust or is there the possibility of utilising some of the trusts systems? If there is please confirm what it is envisaged will be available.	07/11/16	07/11/16	Access could be provided, but safeguards would need to be provided particularly around IG and data protection issues.

Q No.	Date Received	Clarification	Response Due Date	Actual Date Provided	Response
6	31/10/16	Is it envisaged both licensed and non-licensed activity is submitted through SUS or just non licensed given HFEA data security requirements	07/11/16	07/11/16	The provider will only be expected to submit non licensed activity through SUS.
7	31/10/16	What is the employer NHS pension contribution %?	07/11/16	07/11/16	This Information is available from NHS Pensions (http://www.nhsbsa.nhs.uk/pensions).
8	31/10/16	Why has the NHS lead clinician not been included in the list of TUPE staff. If it is because he spends less than 50% of time on this work. Is it still envisaged he will provide services and if so what is the charging mechanism?	07/11/16	07/11/16	The lead clinician is not included in the list of TUPE staff as it is less than 50% of the agreed job plan. If the new provider wished services to be provided by a clinician employed by the Trust, negotiation would be required between the Trust, new provider and clinician
9	31/10/16	What is the maximum availability of theatre 7 and is it envisaged the non- licensed theatre activity will also be done in that.	07/11/16	07/11/16	By agreement, the availability can be increased from the current level of 3 morning sessions per week. The trust indicated theatre 7 could be a dedicated theatre to the new provider if costs were agreed.
10	31/10/16	With regards to ward and recovery facilities for the non licensed theatre activity will that be available to rent?	07/11/16	07/11/16	Yes recovery space within Daycase would be available to rent.

Q No.	Date Received	Clarification	Response Due Date	Actual Date Provided	Response
11	31/10/16	The standard contract states: For men diagnosed with obstructive azoospermia will be offered surgical correction of epididymal blockage because it is likely to restore patency of the duct and improve fertility. Surgical correction should be considered as an alternative to surgical sperm recovery and IVF. Is the provider expected to provide urological surgery services as well as gynaecological or is it anticipated that such men would be referred to the Trust for urological surgery.	07/11/16	07/11/16	Where appropriate expertise is available, men with obstructive azoospermia should be offered surgical correction of epididymal blockage because it is likely to restore patency of the duct and improve fertility. Surgical correction should be considered as an alternative to surgical sperm recovery and IVF." (NICE guidance 2013). If it is not available a pathway should be established with relevant urological services.
12	31/10/16	Medical termination of pregnancy was in the list of surgical activities - can you confirm that it is not expected that the provider will provide a TOP service.	07/11/16	07/11/16	This will not form part of the new service.
13	31/10/16	Can you clarify if SSD costs per tray and consumable costs are the same costs for all procedures - laparoscopy, hysteroscopy and TVORs?	07/11/16	07/11/16	Yes SSD costs are per procedure tray regardless of type.
14	31/10/16	Please provide clarification on the future status of the current clinics PR?	07/11/16	07/11/16	The current PR will work to an adjusted job plan within Women and Children's Directorate.
15	31/10/16	Please clarify the position of the security of funding from the CCGs for the duration of the contract	07/11/16	07/11/16	The contract is tendered for 5 years with the option to extend by 2 years on the basis of Payment by Results and will be funded based on actual activity. Following the first 12 months of service as per NHS contract terms and conditions both provider and commissioner reserves the right to provide 12 months' notice to cease the delivery of the contract.

Councillor Ray Martin-Wells (Chair, Audit and Governance Committee)
C/o Civic Centre
Hartlepool
TS24 8AY



Karen Hawkins
Associate Director of Commissioning and Delivery
NHS Hartlepool & Stockton-on-Tees Clinical Commissioning Group
Billingham Health Centre
Queensway
Billingham
TS23 2LA

Julie Gillon
Chief Operating Officer / Deputy Chief Executive
North Tees and Hartlepool NHS Foundation Trust
Hardwick Road
Stockton-On-Tees
TS19 8PE

11 November 2016

Dear Karen / Julie

**ASSISTED REPRODUCTION UNIT AT THE UNIVERSITY HOSPITAL OF
HARTLEPOOL – CONTRACT PROCESS**

It has been brought to my attention that a number of parties, who could potentially be interested in tendering for the ARU contact, are finding it difficult to obtain information from the Foundation Trust in relation to the provision of primary, secondary and tertiary services associated with the ARU. With this information required to enable an informed decision to be made on the submission of a tender, I am concerned that potential organisations may be being deterred from tendering for the contract, jeopardising the continued provision of the services from the University Hospital of Hartlepool.

In light of my concerns, could you please confirm:

- If the contract specification includes the provision of primary, secondary and tertiary services associated with the activities of the ARU?
- If there have there been any requests for information from interested parties that have been refused by the CCG / FT and if so on what grounds?
- If the contract does include the provision of primary, secondary and tertiary services, how has this information been made available or at least accessible, to interested parties?

With the deadline for tender submission approaching I would appreciate a prompt response to my queries and I fully appreciate the commercial sensitivities associated with a tender exercise and my approach is from the sole perspective of Chair to the Council's Audit & Governance Committee. I look forward to hearing from you without delay.

Yours faithfully

A handwritten signature in black ink, appearing to read 'R. Martin-Wells', with a horizontal line underneath.

COUNCILLOR RAY MARTIN-WELLS
CHAIR OF THE AUDIT AND GOVERNANCE COMMITTEE

**Hartlepool and Stockton-on-Tees
Clinical Commissioning Group**
17th November 2016

Councillor Ray Martin-Wells
Chair, Audit and Governance Committee
Hartlepool Borough Council
Civic Centre
Hartlepool
TS24 8AY

1st Floor
Billingham Health Centre
Queensway
Billingham
TS23 2LA

Tel: 01642 745982

Dear Cllr. Martin-Wells

Further to your letter dated 11th November, 2016, I write to provide clarification to you on the points which you have outlined.

The Invitation to Tender documentation (Schedule 3) outlines the process for bidders submitting requests for additional information.

BIDDER CLARIFICATION

- 4.1 *All requests for clarification about the requirements or the process of this procurement exercise shall be made in accordance with paragraph 4.3.*
- 4.2 *The Contracting Authorities will endeavour to respond to each clarification question received during the clarification stage within six working days. The Public Contract Regulations 2015 Section 5 Regulation 53 require that the Contracting Authority respond to any request for clarification at least six days before the deadline for receipt of tenders. In order to satisfy this requirement the Contracting Authorities has designated a specific window of time to deal with clarification requests (**ITT Schedule 5 Tender Timetable**).*
- 4.3 *Clarification questions in relation to the ITT must be submitted via the Messages tab within the eTendering portal. The deadline for clarification questions is stated in the **ITT Schedule 5 Tender Timetable**, and any clarifications made outside of this system (i.e. Via Telephone, Fax, Email, and Post) will not be accepted and will not be responded to. Please note that clarifications may not be accepted after the date stated in the **ITT Schedule 5 Tender Timetable**.*
- 4.4 *In order to ensure equality of treatment of bidders the Contracting Authorities intends to publish the questions and clarifications raised by bidders together with responses from the Contracting Authorities to all participants on a regular basis via the Messages tab within the eTendering portal. The source of each question or clarification will not be disclosed.*
- 4.5 *Bidders should indicate if a query is of a commercially sensitive or confidential nature - where disclosure of such query and the answer would, or would be likely to, prejudice its commercial interests, bidders must set out the reason(s) for non-disclosure to other bidders. However, if the Contracting Authorities does not either consider the query to be of a commercially sensitive or confidential nature, or one which all bidders would potentially benefit from seeing both the query and the response, they will hold at their discretion the right to refuse such a request and will inform the requesting bidder of any such decision. The bidder will then have the right to withdraw the query or clarification.*

We are satisfied that all requests for additional information that have been submitted through the correct process have been managed within a timely manner and have been made available in accordance with the above process.

The only exception to the above is in relation to TUPE information. This is covered in Section 8 of the same document.

8.1 *Bidder's attention is drawn to the provisions of the Acquired Rights Directive "Council Directive 2001/23/EC on the approximation of the laws of the Member States relating to the safeguarding of employees' rights in the event of transfer of undertakings, businesses or parts of undertakings or businesses" and Transfer of Undertakings Protection of Employment Regulations 2006 as amended by the Collective Redundancies and Transfer of Undertakings (Protection of Employment) (Amendment) Regulations 2014 (TUPE). TUPE may apply to the transfer of the contract from the present service providers to the new ones, giving the present services provider's staff (and possibly also staff employed by any present sub-contractors) the right to transfer to the employment of the successful bidder on the same terms and conditions. The above does not apply to the self-employed.*

8.2 *It is anticipated that TUPE may apply for this contract. The TUPE information obtained from the current providers can be found within the FMT (if already provided to the Commissioner at the time of publication of this ITT). Bidders are advised to form their own view on whether TUPE applies, obtaining their own legal advice and carrying out due diligence.*

To assist you with your due diligence, details of the current provider are:

*North Tees and Hartlepool NHS Foundation Trust
University Hospital of North Tees
Hardwick Road
Stockton
TS19 8PE*

The Trust has confirmed that they have not received any requests for information in accordance with above.

As I am sure you will appreciate, we are concerned that any potential bidders may have worked outside of the procurement process and therefore may have compromised their integrity in the process. We will be carrying out a full review to ensure that we do not have a scenario where a bidding provider will need to be excluded from the opportunity through breaching the process.

I trust that the above provides clarity for you.

Yours sincerely



Ali Wilson
Chief Officer

cc. Gill Alexander – Chief Executive (Hartlepool Borough Council)

Procurement Outcome Report

*Assisted Reproductive Unit
Project Reference: NECS255*

*For and on behalf of: NHS Hartlepool and
Stockton on Tees Clinical Commissioning
Group*



1. Purpose

The purpose of this paper is to:

- 1.1 Advise NHS Hartlepool and Stockton on Tees Clinical Commissioning Group Governing Body (HAST GB) of the outcome of the tender evaluations for the Assisted Reproductive Unit service.
- 1.2 Request approval of the appropriate next step recommendation noted in order to progress the Assisted Reproductive Unit service.
- 1.3 Request that the minutes of this meeting for this agenda item are forwarded to NECS for audit purposes via email necsu.neprocurement@nhs.net

2. Background

- 2.1 The Procurement and Evaluation Strategy was approved by HAST Executive Delivery Team (HAST DT) on 18th October 2016. The procurement process was completed in accordance with the timescale and objectives set out within this approved strategy.
- 2.2 There were no further amendments or changes to the procurement process following the approval of the Procurement and Evaluation Strategy.

3. Evaluation (see Appendix 1 – Summary of Evaluation)

3.1 A recommended bidder must have

- i. submitted a compliant bid;
- ii. passed all elements of the Capability and Capacity Assessment;
- iii. achieved a score of at least 50% for all Red Flag questions;
- iv. achieved a minimum of 50% from the 100% (50%) available for all non-finance related criteria (quality); and
- v. offered the most economically advantageous tender, i.e. achieve the highest combined percentage score for both quality and finance in line with the evaluation criteria.

3.2 Summary of Evaluation:

- 3.2.1 Bidder 1 submitted a complete bid. Bidder 1 passed most elements of the Capability and Capacity assessment, however noted several instances of litigation brought over the last 3 years. These instances were initially reviewed and a decision made by the CCG to continue with the evaluation, although legal support would be sought in the event of the bidder being recommended to ensure risk to the was minimised. Following moderation of the bid submission Bidder 1 failed on Red Flag question RES01 and OP04. A summary of each is provided below:

- Question RES01 covered the area of the bid around the proposed staffing plan to deliver a safe, consistent and efficient service. The

evaluators during moderation scored this as 25%. The comments from the panel indicated a lack of detail around the operational management structure and the reliance on TUPE to cover all requirements of the service. There was no contingency listed for any employee not accepting TUPE. There has been an assumption made with regards the incumbent consultant who was not included in the TUPE list. There was also no outline of line management and leadership within the response.

- OP04 covered how bidders must describe their plans and timescales for achievement of a Human Fertilisation and Embryology Authority license for the provision of Fertility Services at the Hartlepool site. Bidder 1 scored 25%. The submission references the current Person Responsible and a reliance on utilising their services even though they are not listed as a TUPE member of staff. There is limited information to offer confidence as to how this gap would be filled if potential recruitment failed and what mitigations would be put in place to continue the service long term.

In respect of Quality, Bidder 1 scored 38.25% of the available marks. Bidder 1 achieved an overall combined score of 38.25%, however due to failing 2 red flag questions; Bidder 1 took no further part in the procurement process

3.3 Only 1 bid was received from the Invitation to Tender. Following evaluation and moderation of this bid it has failed to meet the following criteria:

- pass all elements of the Capability and Capacity Assessment;
- achieved a score of at least 50% for all Red Flag questions;
- achieved a minimum of 50% from the 100% (50%) available for all non-finance related criteria (quality)

3.4 During the procurement process 3 separate informal expressions of interest were received via the eTendering portal in a 'hub and spoke' service as an alternative to the proposed specification. The feedback from those expressions was the offered specification wasn't viable for delivery with regards to the current volumes of use or levels of investment required to allow a bid for a full service from University Hospital of Hartlepool.

4. Risks

4.1 The evaluation has highlighted a risk to the service as there is no suitable bidder to deliver the Assisted Reproductive Unit specification. This could cause the service to cease. To mitigate this risk options have been provided in section 5 of this report.

4.2 A risk of challenge to the procurement process exists due to the outcome of the procurement. This has been mitigated by a robust evaluation and moderation procedure. The procurement process as a whole has been conducted in line with Public Contract Regulations 2015, the Public Services (Social Value) Act 2012 and the NHS (Procurement, Patient Choice and Competition) (No.2) Regulations 2013.

5. Next Steps

- 5.1 Given that the Invitation to Tender has not produced a viable provider following the procurement process, the CCG is required to consider the future commissioning arrangements for fertility provision in Hartlepool.

The Table 1 sets out the options available to the CCG and the associated advantages and disadvantages of each option:

Table 1:

	Option	Advantages	Disadvantages
1	Re-run the procurement process using the same service specification	Minimal risk of challenge in the process	Will take up to 3 months to complete the procurement process during which there will be a gap in service. Procurement outcome may not change.
2	Undertake a procurement process using a different service specification to attract a provider using a 'hub and spoke' model with unlicensed provision at Hartlepool and licensed provision at the providers' base site.	A number of providers have expressed an interest in providing this model of delivery therefore likely to successfully appoint a provider.	Will take up to 3 months to complete the procurement process during which there will be a gap in service.
3	Incumbent provider continue to provide unlicensed treatment at the Hartlepool site and patients are offered choice of provider for licensed activity e.g. South Tees, Gateshead or Newcastle	Existing provider therefore existing unlicensed service can be maintained.	Lack of continuity for patients on pathway between licensed and unlicensed treatments. Potential to challenge from non-contracted providers not being offered the opportunity to bid.
4	Existing service providers are offered the opportunity to run outreach clinics from Hartlepool and licensed provision from their base sites. Patients choose which provider they wish to be referred to at the beginning of	Existing acute/IVF contracts in place therefore no procurement implications. Existing providers have expressed an interest in delivering	Patients will be required to travel to South Tees, Gateshead or Newcastle for licensed treatments. Potential to challenge from non-

	the pathway	this model as part of the previous procurement process. Continuity of provider for patients between licensed and unlicensed service. Existing providers in a position to mobilise quickly and therefore no gap in services.	contracted providers not being offered the opportunity to bid.
5	No fertility services at Hartlepool with patients offered choice of South Tees, Gateshead or Newcastle	Consolidation of services at other sites resulting in greater stability of other sites.	All local patients will be required to travel to South Tees, Gateshead or Newcastle for all fertility services.

- 5.2 Following a review of these options and taking into consideration the risks associated with the current service, the project group would recommended a process following option 4 within the table.
- 5.3 This approach was offered in principle to HAST DT on 13th December 2016 and approved for recommendation to HAST GB.

6. Recommendations

Hartlepool and Stockton on Tees CCG Governing Body is asked to note the contents of this report and:

- 6.1 Approve the outcome of the procurement and allow the issue of an unsuccessful bidder letter to be issued to Bidder 1.
- 6.2 Approve a next steps option as provided within section 5 of this report and allow the project group to commence implementation.
- 6.3 That HAST GB notes the request for approvals and / or copy of minutes to be forwarded via email to: necsu.neprocurement@nhs.net



Michael Robson
NECS Procurement Officer

Summary of Evaluation – Appendix 1

Table 2 below provides a summary of the outcome of the evaluation:

Table 2

Question	Weighting (%)	Bidder 1 Score	Bidder 1 % Score
OP01	7	50	3.50
OP02	10	25	2.50
OP03	8	25	2.00
OP04*	10	25	2.50
MOB01	20	50	10.00
IT01	4	50	2.00
IT02	3	25	0.75
IT03	3	0	0.00
RES01*	15	25	3.75
FAC01	5	50	2.50
COMM01	10	50	5.00
SV01	5	75	3.75
Quality Total	100	38.25	
Finance	Pass/Fail	Pass	
Total Score	100	38.25	

* denotes a red flag question. Bidders need to achieve a minimum score of 50% to qualify against the evaluation criteria

North Tees and Hartlepool

NHS Foundation Trust

Assisted Reproduction Unit

Direct Line: 01429 522866

Direct Fax: 01429 522792

University Hospital of Hartlepool

Holdforth Road

Hartlepool

TS24 9AH

Ref:

Tel No: 01642 617617

www.nth.nhs.uk

Date of Letter:

Private and Confidential

Dear

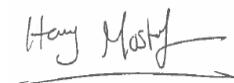
Regarding Storage of Embryos/Gametes/Sperm in the Assisted Reproduction Unit - Hartlepool

We are writing to reassure you that under the terms of our licence with the Human Fertilisation and Embryology Authority (HFEA), there are strict regulations which the Trust is required to adhere to and despite the issues with the fertility unit, all stored embryos, gametes and sperm will continue to be stored and managed by the North Tees and Hartlepool NHS Foundation Trust under the HFEA license until alternative providers are secured in the North East. The Trust is working with the CCG to identify alternative providers to take the responsibility of looking after the stored embryos/gametes/sperm and once we have concluded these discussions the Trust will contact you to discuss future storage options. We wish to assure you that in the event that a decision is taken to transfer the stored embryos/gametes/sperm to other providers, the actual transfer of stored embryos/gametes/sperm is strictly governed by HFEA regulations and the Trust will adhere to these regulations. **We will obtain your consent prior to this move; in the meantime your embryos will continue to be stored safely in the ARU Hartlepool.**

What do I need to do as a patient?

You do not need to do anything at this time, however the staff in the Assisted Reproduction Unit will be fully briefed and will continue to support you through what we appreciate is a difficult time.

Yours sincerely



Mr H Mostafa
Consultant Obstetrician and Gynaecologist
Person Responsible for ARU-Hartlepool



Jane Barker
General Manager
Women and Children's Services

Paul Garvin
Chairman

Alan Foster
Chief Executive