Guidance for Centres regarding the governance of the ANRP programme

Background

The use of Abdominal NRP (ANRP) in the UK has developed over the last decade, beginning in Cambridge and Edinburgh as research pilots before being an NHSBT sponsored service evaluation.

Following the service evaluation, and the observed positive outcomes in livers and other abdominal organs, a Business Case was developed in 2018 to further develop the service. This work was led by NHSBT in conjunction with clinicians from Cambridge and Edinburgh and DH Health Economists, with a view to securing substantive funding for a UK wide roll out. Unfortunately, the long-term funding was not agreed.

In 2020 an ANRP Steering Group was established, chaired by Chris Watson, which was responsible for the management and oversight of the safe and effective delivery of ANRP services in the UK.

The Steering group developed a revised business case which was submitted to the 4 UK Health Departments in August 2021 with a request for substantive funding. To date there has been no response despite accumulating evidence in the UK and overseas of superior results in kidney and liver transplantation from DCD donors when organs have been recovered using ANRP.

With oversight from the Steering Group, four other abdominal organ retrieval teams have successfully started an ANRP programme in their units. There are the NORS teams in the Royal Free Hospital, London; University of Wales Hospital, Cardiff; Queen Elizabeth Hospital, Birmingham and the Freeman Hospital, Newcastle.

Funding

As there is no nationally agreed substantive funding at this time, centres must agree local funding from within their own Trust to begin their programme. This should cover the costs of the additional staff required, including training of the staff and any mentoring support, as well as any capital expenditure/rental agreements for the necessary equipment.

NHSBT will continue to fund one vehicle to transport a NORS team.

Support for consumables is available from the remaining service evaluation fund held by Edinburgh. This is available until the fund has been fully utilised. It can be used to cover the following:

- Disposable perfusion circuits
- Arterial and venous cannulas
- Piccolo biochemistry cartridges (5 per case)

It is accepted that the perfusion circuit will be opened before withdrawal of treatment and will thus be used even if the potential DCD donor fails to become an actual donor. Cannulas and biochemistry cartridges cannot be claimed in this case.

Invoices from centres will be claimed monthly from Edinburgh. Once the remaining funds have been fully utilised it will fall to the individual Trust to fund the ongoing consumables.

At the start of a new programme mentoring will be required from an experienced centre. The cost of supporting this mentoring ***must be borne by the new centre***, and would be expected to include:

- Provision of transport for the mentor to and from the donor hospital
- Reimbursement of time spent mentoring. A typical rate, used previously for mentors in the DCD heart programme, is £89/hour

An agreement to financially support the provision of mentoring in this way is a condition for being reimbursed for the cost of consumables used in undertaking ANRP.

Procedure for centres wishing to start or restart ANRP

In order to ensure there is consistency of process and adequate governance regarding the use of ANRP across the UK the following framework should be followed.

Centres who are interested in developing ANRP within their Trust should consider the document in the following link. This provides a detailed overview of the responsibilities, knowledge base and competencies required by the individuals in an ANRP team.

ANRP Structure training and competency

Preliminary Meeting

Centres wishing to start/restart the use of ANRP will have an initial telcon with members of the ANRP Implementation Group, a subset of the ANRP Steering Group, to discuss and agree the steps to be taken by the centre regarding:

- Equipment to be used
- The training required for an ANRP team to start a programme
- Provision of any proctoring support that may be required to support the training of surgeons
- The governance around safe use of ANRP, including surgeon and perfusion practitioner competence sign off and any initial restrictions for teams (e.g., kidney only donors)
- The familiarisation and use of agreed national protocols for ANRP procedures, including the ongoing evaluation of the liver during ANRP

UK Protocol for Normothermic Regional Perfusion (NRP) in controlled Donation after Circulatory Determination of Death.

- The familiarisation and use of the agreed national passport to capture relevant and necessary data to accompany the organs that have been perfused during the ANRP procedure. NRP Passport

- Consent guidelines for recipients where organs have been perfused using ANRP
- NHSBT operational support regarding HUB/SNOD region training and transport
- The expectation to debrief with the ANRP implementation group after each of the early cases and a willingness to engage with the monthly national ANRP debriefs.

Following the meeting, once all criteria have been addressed, the team should contact a member of the ANRP Implementation Group to arrange a date for the ANRP assessment.

Outline of the ANRP assessment

The assessment will be a 3 hr Microsoft Teams meeting with the expectation that the complete ANRP team attends (lead surgeon, assistant surgeon, perfusion practitioner, perioperative practitioner, cold perfusionist).

The assessment will be led by Ian Currie/Chris Watson/Fiona Hunt.

Guidelines for the assessment:

- The assessment will be a series of simulated ANRP retrievals, with each team member being required to contribute. All members of the ANRP retrieval team should to be in the same room together with all the paperwork that would be taken on retrieval, including blank paperwork which you will complete as you go along. It is advisable to have several sets of the passport available to record data as the assessment progresses.

- There will not be a direct test of machine setting up and therefore no requirement for the machine to be present. Centres are expected to have rehearsed this several times already and be fully proficient.

- It is advisable to have only the core ANRP team present at the assessment to avoid any distractions.

- The roles should be allocated to the attendees – lead surgeon, assistant surgeon, perioperative practitioner, cold perfusion, ANRP practitioner. These individuals will be the focus of the assessment. The lead surgeon will retain overall responsibility for quality assurance of the team and all the paperwork

and protocols, and will be responsible for managing the donor on the pump in terms of interventions and interpretation.

The assessment will cover the full end to end ANRP pathway:

- Donor selection and considerations
- Mustering the team/SNOD info/Hub
- Equipment check and loading
- Transport arrangements
- Set-up and checklists
- Bloods and blood tests
- Blood requirements
- Key points in the brief
- Prime and sash
- Cannulation
- Managing the donor on pump
- Going cold
- Going home

The assessment will also require the team to be prepared to discuss

- Training records (of all team members)
- Competency documents (of all team members)
- Experience so far in training
- Quality considerations with blood monitoring kit
- Attendance at ANRP masterclass
- Role play scenarios of ANRP to assess knowledge base and decision making of all members of the ANRP team

Following the assessment, the team will receive feedback from the ANRP implementation group within 2 weeks. This will address any concerns and confirm an agreed start date for the new ANRP programme with the appropriate mentoring that is deemed to be required.

For example: Agreed start date of X, initially to attend kidney only donors within local area of Y, to have mentors attending in person to support.

Mentoring

Any team looking to start a new ANRP programme must have the support of their nearest established ANRP centre to provide mentoring their programme.

When a mentor attends to provide support to an ANRP Team the governance for the retrieval remains with the retrieving NORS team.

An established ANRP centre is one which has been granted established centre status by the NRP Implementation Group. At this time (2022), Cambridge and

Edinburgh are considered the only established ANRP centres in the UK by the ANRP Implementation Group.

It is acknowledged that a lack of mentor availability may impact on the number of opportunities a centre has to use ANRP. Nevertheless, it is crucial to ensure mentor support is available before proceeding to use ANRP to avoid loss of donors or organs.

Once a NORS team has a start date for ANRP, they will begin with direct mentoring and work their way through the steps of mentorship until they reach independent ANRP practice.

Step 1 – Direct Mentoring

The team being directly mentored

- Should create a WhatsApp group with teams from Edinburgh and Cambridge and all members of their team
- Should acknowledge that rota commitments in the mentoring centre (Edinburgh and Cambridge) may restrict the number of opportunities for direct mentorship to undertake an ANRP
- Should inform the mentor centre, via the WhatsApp group, of any potential ANRP case as early as possible to allow identification of potential mentor and time to travel
- Must inform the ANRP WhatsApp group if the patient has had previous abdominal or cardiothoracic surgery or any anatomical variant, as this may affect operative strategy and cannulation.
- Identify donors within the local retrieval area from which they, as a transplanting centre, have accepted at least one organ.
- Should not consider any cases with cardiothoracic involvement at this time, unless it is possible to have an experienced mentoring surgeon and perfusion practitioner to support on site in theatre. These are not ideal cases to learn on.
- May join the mentoring centre's NORS team to perform NRP. However, joining other NORS teams for this purpose is not supported.
- Should debrief with the ANRP Implementation Group representatives after each case: a representative of the team must email Sarah.Beale@nhsbt.nhs.uk with possible dates and times (Mon-Fri 0800-1800) for the team debrief at its earliest convenience post ANRP retrieval.
- Have an obligation to debrief within the team and also with the ANRP implementation group at the earliest opportunity.

The mentors

- An established ANRP centre must identify individuals with appropriate experience to mentor both surgical and perfusion aspects of ANRP.

- Should feedback to ANRP Implementation Group representatives on progress
- Make a recommendation to ANRP Implementation Group representatives when the team can move to indirect mentoring, which will be only after they are satisfied with the centre's ANRP team's abilities.

Step 2 – Indirect Mentoring

- Indirect mentoring is the virtual presence of an experienced ANRP surgeon and perfusionist to support the retrieving team.
- Indirect mentoring can only start once the ANRP Implementation group representatives have approved this in writing.

The indirectly mentored team

- Should inform WhatsApp group of the potential ANRP case as soon as possible and identify who is available to mentor remotely. ANRP should not proceed without an identified mentor agreeing to be available for supporting the whole procedure.
- Must inform the ANRP WhatsApp group if the patient has had previous abdominal or cardiothoracic surgery or any anatomical variant, as this may affect operative strategy and cannulation.
- Should not consider any cases with cardiothoracic involvement at this time unless it is possible to have an experienced ANRP surgeon and perfusion practitioner on site to support in theatre.
- Should debrief with ANRP Implementation Group representatives or on the National ANRP debriefs
- Can request to retrieve using ANRP outside of their normal retrieval areas if they are to be in receipt of one of the organs.
- May join the mentoring centre's NORS team to perform NRP. However, joining other NORS teams for this purpose is not supported.

The mentors

- An established ANRP centre must identify individuals with appropriate experience to mentor both surgical and perfusion aspects of ANRP.
- Should feedback to ANRP Implementation Group representatives on progress
- Make a recommendation to ANRP Implementation Group representatives when, in their judgement, the team no longer needs direct or indirect mentoring.

Step 3 – Independent ANRP practice

Newly independent ANRP teams

- Are encouraged to utilise experience of the WhatsApp group to discuss any complex cases which arise, such as those with previous abdominal or cardiothoracic surgery or any anatomical variant, as this may affect operative strategy and cannulation.
- Can consider attending DCD donors with cardiothoracic involvement to use ANRP, but only after experiencing at least one ANRP with DCD heart/lung case with a mentor present in theatre.
- May join any established team (currently Cambridge and Edinburgh, i.e. not just the original mentoring team) to perform NRP when the liver has been accepted by either the newly independent team or the experienced ARNP NORS team. The extent of the involvement of the visiting ANRP NORS team will be agreed between the experienced ANRP NORS surgeon (who has overall responsibility for the retrieval) and the visiting ANRP NORS surgeon, in advance of the retrieval.
- Must debrief with ANRP Implementation Group representatives or on the National ANRP debriefs when asked.
- Until a centre has established status their team would not be supported to mentor new centres starting their own ANRP programmes, run ANRP courses or undertake TANRP.
    - If a centre wishes to provide NRP courses suitable for practice in the UK, they will need to fulfil the national learning objectives and syllabus (in preparation). A centre can provide such NRP courses prior to fulfilment of these requirements if they do so in collaboration with an established centre.
- Currently TANRP is restricted to Papworth and Addenbrookes NORS teams and three specific hospitals and is not supported in any other circumstance.

Step 4 – Recognised as an established ANRP centre

An established ANRP centre is one which has been granted established centre status by the NRP Implementation Group

The ANRP Implementation Group will hold a second ANRP assessment in order to grant established ANRP centre status. This will include consideration of NRP record to date, commitment to safety, good practice and the positive reputation of NRP, mentoring feedback, participation in feedback meetings and national debriefs.

Debriefs

As mentioned above, it is expected that each new centre using ANRP will make themselves available for a debrief with the ANRP implementation group as the earliest opportunity post retrieval.

A national ANRP debrief will be held monthly, with all abdominal NORS teams invited, as an opportunity to share practice.

Due to the complexities of CT and abdominal retrievals using ANRP, debriefs are also held for any cases involving both DCD heart or lung and ANRP.

Following each debrief notes will be shared with the group, the level of mentoring will be reviewed and any changes will be communicated.

Abbreviations

ANRP: Abdominal *in situ* normothermic regional perfusion

CT: Cardiothoracic

DCD: donation after circulatory death

NORS: National Organ Retrieval Service

NRP: in situ normothermic regional perfusion

TA-NRP: thoraco-abdominal NRP