Department of Health & Social Care

Report of the ISOU Assessment and Recovery Centre (ARC) Sub-Group

Shared with Implementation Steering Group for Organ Utilisation (ISOU)
5 December 2024

Contents

Publisher's note

This Assessment and Recovery Centres (ARCs) recommendations report was presented to Department of Health and Social Care (DHSC) Ministers following agreement of the report at the Implementation Steering Group for Organ Utilisation (ISOU) meeting in December 2024.

Since then, we have entered a period of significant change, following the announcement on 13 March that the Government will be abolishing NHS England and rolling its functions into DHSC.

DHSC’s vision is to promote innovation and support the shift to roll out new technology. As such, we felt it was important to publish this report and these recommendations in their entirety given the importance of making the best use of the UK's world leading innovation in assessment, perfusion and preservation.

NHSBT have secured funding for the 2025/26 financial year to develop a programme which will initiate the development and future implementation of ARCs.

Introduction

In 2023 the Department of Health and Social Care (DHSC) established a new fixed-term Implementation Steering group for Organ Utilisation (ISOU), to drive the delivery of the 12 recommendations set out in the Organ Utilisation Group's (OUG) February 2023 report 'Honouring the gift of donation: utilising organs for transplant'.

The ISOU brings together the key organisations involved in delivering the transplant service – including NHS England (NHSE), NHS Blood and Transplant (NHSBT) and representatives from NHS Trusts – to increase collaboration and ensure that all patients have fair and equitable access to transplant services, regardless of their background, ethnicity or where they live.

There are a wide number of co-dependencies within the OUG report recommendations and cross cutting themes. This makes implementation complex, particularly when considering the wider context of other activity already underway. To aid implementation, fixed term ISOU sub-groups have been established to provide a strategic steer on some of the more complex areas of work.

OUG and Innovation in organ perfusion and preservation

The UK has a strong track record in pioneering transplant services, and this continues with the recent UK-led developments in machine perfusion to increase the number and quality of organs available for transplant.

Patient groups and clinicians expressed concern and frustration that machine perfusion was not available as standard, whereas it is now being built into regular practice in many other countries. This further embeds disparities in access due to the service only being offered in a limited number of units.

Transplant teams also provided feedback that much greater central oversight for the development and delivery of innovations in transplantation could increase the opportunities for better organ utilisation.

Implementation of recommendations 8 and 9 below are subject to securing future funding.

To address these issues, the OUG recommended:

Recommendation 8 of the OUG report stated that national multi-organ centres for organ assessment and repair prior to transplantation must be established to provide the optimum practical steps to bring new techniques into everyday clinical therapy as rapidly as

possible, to maximise the number and quality of organs available for transplant and support logistics at transplant units.

Recommendation 9 of the OUG report stated that a national oversight system must be established that makes the best use of the UK's world leading innovation in assessment, perfusion and preservation of donated organs.

Sub-group

The ARC Sub-group was established to provide strategic direction, by garnering advice from members to ensure planning is in place to take forward the OUG recommendations.

ISOU ARC Sub-group Co-chairs

John Casey, Consultant Transplant Surgeon, University of Edinburgh

Shamik Ghosh, ISOU Lay Representative – ISOU, Cardiothoracic Advisory Group and Retrieval Advisory Group

Committee members representing:

- DHSC Implementation Steering Group for Organ Utilisation & ISOU Secretariat
- DHSC (Economist)
- Scottish Government
- Welsh Government
- Northern Ireland Commissioner
- Department of Health Northern Ireland
- Health and Social Care Northern Ireland
- NHS Blood and Transplant (Medical Director)
- NHS Blood and Transplant (AMD for Retrieval)
- NHS Blood and Transplant (Programme Manager)
- British Liver Trust
- British Transplant Society
- Cardiothoracic (CT) Retrieval
- Human Tissue Authority
- NHS England

- NHS Scotland
- Donor Family Representative
- Transplant Patient Family Representative

Principles of working

The ISOU ARC Sub-group met three times prior to submitting their recommendations to ISOU. To discharge their duties, the sub-group heard from subject matter experts from various organisations including NHSBT and an expert from the University of Cambridge. They also undertook an options analysis to evaluate various approaches. A summary of the considerations from the options analysis, and resulting recommendations is provided in this report.

As with all OUG, ISOU and the recent Cardiothoracic Information Collation Exercise (CT ICE) work, the sub-group notes the importance of co-production with patients, and that the development of ARCs should continue in this principle.

A key assumption made by the group was the successful delivery of existing perfusion initiatives such as abdominal normothermic regional perfusion (A-NRP) and donation after circulatory death (DCD) heart transplantation. In making their considerations the group assumed that these therapies being effective acted as a baseline for further consideration.

Options analysis

With regards to recommendation 8 of the OUG report the sub-group undertook an options analysis to consider how national multi-organ centres for organ assessment and repair (Assessment and Recovery Centres (ARCs)) may be established in the UK. This analysis looked at the number and location of site/s and launch strategy, considering impacts on workforce, value for money, equity for patients, centre organ access and governance. Members of the sub-group provided a variety of insights and perspectives on the different options which are summarised below (see separate Annex. 1 for the discussion template).

Number of Centres

When considering the appropriate number of centres, a key limiting factor is cold ischaemia. Cold ischemia is damage that occurs to donor organs when stored in ice cold preservation fluid, the acceptable cold ischemic time (CIT) varies by organ, typically 4 to 24 hours. The travel time from the donor hospital to the ARC must therefore be less than the organ's acceptable CIT. To minimise this, the accepted workplan is that organs will be recovered at the donor hospital (placed on machines at the donor site before traveling to the ARC), depending on the organ and if the travel time is likely to be prolonged. In addition, there is a need to consider minimising air travel due to the significant expense incurred and a requirement to improve environmental sustainability.

Establishing a single centre:

- Would have simpler governance and enable production of a high-quality specialist site or 'centre of excellence'. A centre of excellence, due to its expertise, was considered to potentially encourage donor families to donate and therefore increase organ availability.

- Would have significant workforce requirements, requiring availability of sufficient and appropriately skilled workforce in the area where the centre will be established. Lack of availability of skilled workforce will result in increased workload intensity and a requirement for a workforce rota separate to those at transplant centres or NHSBT sites.

- May limit equity of access for patients, and a requirement for the centre to be in a central UK location may limit co/near location to an existing NHS facility. As a result, the disadvantages of being a standalone facility is likely to manifest (disadvantages of a standalone facility v/s co-location is discussed later in this paper).

- Would result in increased costs around transport, a separate workforce rota and the potential to build a new centre if co/near location is not feasible.

- Would result in system reliance on a single provider and associated resilience challenges.

Establishing more than one centre (geographically arranged):

- Would reduce travel time for donor organs and increase equity for patients and access to organs for centres. However, increasing centres could increase both capital expenditure and staffing costs. Modelling could be undertaken to calculate the benefits in terms of equity of access and value for money for 2 to 4 centres. Any modelling that is undertaken should be transparent and open to scrutiny.

- Would reduce the workload intensity and create equity in the innovative work career paths across the UK, both increasing staff retention. However, an excessive number of sites (more than 4) risks potentially 'thinning out' expertise, a lack of available work and opportunity and may result in staff retention issues. May make maintaining oversight and consistent standards across centres more challenging.

Launch

A pilot-style, soft-start launch, starting with one centre initially:

- Would enable the opportunity to explore logistics and workforce demands and test the ideal governance in advance of full-scale implementation.

- However, it may be challenging to run a pilot across limited areas of the UK alongside the current system and during the testing launch phase, a successful pilot would potentially result in inequity of organ access for both patients and centres across the country.

A pilot-style, soft-start launch starting with one organ initially:

- Would provide the opportunity to explore logistics and workforce demands and build technical expertise.

- Would result in inequity across patients due to reduced access for those who are not awaiting the 'pilot' organ.

- May be associated with under-utilisation of dedicated ARCs staff (who will be required to run a 24/7 service).

- Competing factors relating to which organ/s could be piloted should also be considered:

- **Lung** – UK lung utilisation is the lowest of all solid organs - just 12% of offered donation after circulatory death (DCD) lungs and 22% of donation after brain death (DBD) lungs are transplanted yet there is an urgent, keenly felt need for additional lung transplants (with 22% of patients dying on the waitlist), resulting in a clear moral argument to start the pilot with Lung. The Toronto Organ Recovery Centre model has demonstrated that marginal lung assessment, repair and preservation is feasible with current technologies and resulted in a 100% increase in lung transplant activity since launched.

- **Liver** – 11% of patients on the liver transplant waitlist die whilst awaiting an organ, and the strongest evidence base and clinical effectiveness proof is for this organ, suggesting it would be the safest organ to pilot. Evidence submitted to the OUG reported a 20% increase in organ utilisation, 54% increase in preservation time and significant improvements in patient outcomes.

- **Kidney** – The supply and demand for kidneys is the highest of all organ types in the UK. Medical management costs for patients maintained on dialysis are very high, thus the opportunity cost of not transplanting a kidney is high (kidney dialysis costs c.£30,000 per year). However, although there are devices currently in development, there is not currently a licenced device for prolonged perfusion of kidneys. Oversight of this research could work to encourage and accelerate developments in this clinical area.

- **Hear**t – UK heart utilisation is low, just 28% of offered hearts were transplanted in 2022/23. Current technology (Transmedics OCS machine) allows for hearts to be perfused for up to 12 hours at the upper limit (it is a retrieval device only). However, this technology is very expensive. Oversight of this research could work to encourage and accelerate developments in this clinical area.

A multi-organ launch would be an aspirational approach that would increase equity of access for patients and speed up the timescales for increasing overall organ utilisation and transplantation capacity. However, due to the nature of these novel centres for the UK, this approach may be impractical, with many logistics and technical processes to be established. Thus, starting concurrently across centres and/or organs could be challenging. A single organ launch, with a flight path to more, dictated by the evidence and the ease of logistics is the most feasible option. To set direction, analysis should be undertaken to evaluate which organ type would have the greatest impact in improving the UK transplant rate, patient experience and outcomes in the shortest period of time.

Site location

Standalone sites would have increased costs due to:

- Increased capital expenditure to build a new site; however, this could be built to all required, currently known specifications.

- Limited access to existing staffing from other NHS sites, resulting in a requirement for a separate workforce rota.

- Increased transport costs.

The sub-group also considered various forms of co-location (same city/site/building as a transplant centre):

- If centres are in the same city as, or co-located on the same site/building as existing transplant centres or NHSBT sites, they would have access to flexible staffing, reducing costs, however noting that flexible staffing and rotas across ARCs and transplant centres may be complex.

- There is also rationale behind co-location with a centre that has CT and abdominal retrieval and transplant on the same site or within close proximity, as the required workforce would be accessible. Other supplementary services that may be needed (imaging, blood transfusion etc.) for the ARC, will already be available.

- Consideration of impacts on already intense rotas of co-located sites would be required given co-located centres may bear unfair staffing pressures due to feeling responsible for staffing or losing workforce to the ARC. Without the proper governance in the set-up, access to organs may also not be equitable across centres and there may be issues around ownership of the space.

- In making final decisions as to where any ARC would be located, a bidding process could be used. The principles on which that bid would be decided would be experience, equity of access, addressing diversity, quality, resource implications, and plans for staffing. Bids could come from transplant centres or regionally, encouraging diversity and increasing quality. Regional staffing could also be utilised, with ARCs managed by regional teams, rather than a particular centre.

- Co-location in areas with the highest donor density and/or centres with the largest waiting lists may reduce transport costs and travel time. Noting that there may be organ specific differences and some donor types are more likely to need ARCs than others (DCD, higher risk profile donors etc.); detailed donor density modelling would therefore be necessary.

- Co-location on an existing transplant centre site/building would reduce costs however, identification of a suitable existing space that will meet the current and future needs of the ARC may be challenging.

Governance

To ensure we honour the gift of organ donation through appropriate utilisation of organs, governance will need significant attention to set up these novel centres. The group's discussions took into account:

- If ARCs will need support and governance from a national organisation to enable consistent standards, oversight and monitoring across centres to reduce inequity across the UK.

- If ARCs are co-located with a transplant or NHSBT centre, which already has local governance procedures in place, this may cause issues around who has ownership of the ARC and where the governance lies, making equity of access to organs difficult.

- With regards to the best organisation to oversee ARC governance the group noted:

    - NHSE (and relevant Devolved organisations) commission transplantation.

    - NHSBT manage organ donation, retrieval, matching and offering of organs. They also hold substantial expertise and information within the wider Organ and Tissue Donation and Transplantation (OTDT) clinical team and advisory groups in relation to ARCs. This includes the implementation roadmap co-produced with relevant small and medium-sized enterprises (SMEs) (e.g. commercial, quality, digital) which considers various options for implementation of ARCs.

Funding and Resource Issues

There is a strong business case for investment to establish ARCs, with a clear and significant benefit to patient experience and outcomes and for investing to make longer term NHS savings:

- In the UK the availability of 'ideal' organs is decreasing, and for 'marginal' organs is increasing. There is an increased organ transplant waiting list post-COVID-19, with waiting list numbers at their highest in a decade, returning to similar levels of those seen in 2014.

- As made clear in recommendation 8 of the OUG report there are proven benefits of these novel technologies with machine perfusion to increase organ utilisation, patient experience, and patient outcomes including the post-transplant outcomes of marginal organs.

- Additional transplants will reduce inequity of access for patients and provide an estimated £1.4b quality-adjusted life year (QALY) benefit to the UK economy over 10 years.

- The UK has driven much of the innovation in this area but been overtaken in its use by other countries. ARCs provide the opportunity of up to 24 hours of ex-situ preservation time for organs, reducing pressure on a stressed workforce and hospital services aligning with Government priorities to address inequities through patient-centred care and put a focus on driving innovation to modernise the NHS.

- The ability to store organs for a prolonged period of time will enable more patients to receive the organ they have been allocated, since it will afford time to optimise the patient's condition prior to surgery, thus increasing speed of recovery, and also ensuring appropriate tissue matching without paying a penalty of increasing harmful cold ischaemia. This will also reduce out of hours demand for theatre and pathology services. The anticipated increase in transplantation will also reduce pressures on the wider NHS in caring for patients with end stage organ failure.

In terms of spending, there are advantages linked to co-location, and repurposing facilities that are already available. However, aforementioned issues around ownership of the site, governance and equity of access need to be taken into account.

It is not possible to deliver the ARC programme within existing resource, and it will require additional funding to set up the ARC programme and develop the service in a sustainable fashion.

Recommendations

The ISOU Assessment and Recovery Centre Sub-group:

1. Strongly support the foundation of ARCs in the UK for the benefit **of patients, the NHS** and **the wider UK economy**, through increasing organ utilisation, reducing transplant waiting lists and reducing pressures on out of hours NHS services.

2. Agree with the OUG recommendation that **initially there should be no more than 3 centres**, noting modelling should be undertaken to calculate the benefits of additional centres in the longer term, for equity of access and value for money. The sub-group does not support a single centre in the long term,

3. Acknowledge that **a pilot centre may help in setting up the innovation in the most efficient manner**, enabling opportunity to explore logistics and workforce demands, with sequential further centres to ensure equity by geography.

4. Agree with the OUG recommendation that **centres should eventually cover all organ types**, with an **initial focus on lung and liver transplantation**. The NHSBT research board should oversee and drive further innovation which is essential to the success of ARCs. This includes creating a single national repository of ongoing research in an effort to accelerate development in all areas. This will ensure that we encourage continued world leading innovation in the UK.

5. Note that governance of ARCs needs to be clear and transparent including monitoring and innovation oversight. The sub-group recommends that **that NHSBT take responsibility for this work**, with support from NHSE and relevant Devolved Governments. Proper governance is required in the set-up, ensuring that even with a learning curve, acceleration to equity for national organ allocation should be as rapid as possible.

6. Recommend that the governance of ARCs should **take into account changes that are planned for the commissioning of transplantation**, noting that NHSBT is presently in charge of matching, offering and retrieval of organs. Consideration should also be given to a more **digital approach** to record keeping for effective data collection and sharing.

7. Noting the clear benefit to patients and a very strong argument of investing to make longer term NHS savings, the sub-group recommends **all possible methods of funding should be considered** (fully public/partly public/private) if these make the proven patient benefit more likely.

8. Given the economic benefit, the sub-group recommends **NHSBT continue to work with DHSC, NHSE and also commercial partners in order to find and discuss funding routes** for ARCs.

9. Recommends ARCs are **co-located**, noting significant advantages for co-location with a transplant centre and/ or NHSBT site. To avoid any centre bearing unfair staffing pressures, **regional staffing** should be considered.

10. Recommends decisions on ARC location have **an open and competitive tendering process**, with a call for interest/centres bidding process to host ARCs to drive quality of centres. Conflicts of interest from all those on the sub-group must also be declared and transparent. The nature of co-location (same city/site/building) will likely depend on the successful bidder.

Summary

The ARC sub-group met three times prior to submitting their recommendations to ISOU. To discharge their duties, the sub-group heard from subject matter experts from various organisations including NHSBT and an expert from the University of Cambridge.

With regards to recommendation 8 of the OUG report the sub-group undertook an options analysis to consider how national multi-organ centres for organ assessment and repair may be established in the UK. This analysis looked at the number and location of site/s and launch strategy, considering impacts on workforce, value for money, equity for patients, centre organ access and governance. Members of the sub-group provided a variety of insights and perspectives on the different options.

The sub-group made 10 recommendations that it considers would support the implementation of OUG recommendation 8 and support that a national oversight system must be established that makes the best use of the UK's world leading innovation in assessment, perfusion and preservation of donated organs (recommendation 9).

The sub-group note that establishment of ARCs faces significant challenges. Namely, securing of funding, availability of sufficient appropriately skilled workforce and a requirement for further clinical research developments. However, this technology provides the opportunity to utilise British-led innovation to increase the number of transplants per year for the significant benefit of patients, the NHS and the wider UK economy. Significant support, funding and collaboration across the transplant landscape is required to make this a reality.