NATIONAL LIVER OFFERING SCHEME (NLOS) REVIEW: REPORT & RECOMMENDATIONS

October 2025

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EXECUTIVE SUMMARY

This review of the National Liver Offering Scheme (NLOS) assessed the scheme's performance against the key objectives identified when it was introduced in March 2018: improving equity, transparency, reducing wait list mortality, and maximising survival benefit. The consultation process included regular NLOS Review Committee (NLOSRC) meetings to gather evidence, stakeholder engagement with transplant professionals, patients, patient families and carers, donor families and members of the public through meetings, focus groups and surveys.

The principal findings of the NLOSRC were:

Equity: NLOS has reduced geographic disadvantage at the point of offer through national prioritisation of patients in a standardised approach regardless of which centre they are registered in. However logistical challenges with national offering, particularly reliance on air transport, may limit access in some cases. Concerns have been raised about equity across diagnoses and for specific patient groups, particularly where data quality or model assumptions may bias prioritisation. Clinician directed recipient selection for DCD (donation after circulatory death) organs and fast track DBD (donation after brain stem death) organs has enabled access to transplantation for patient groups perceived to be disadvantaged by the algorithm directed offering process.

Transparency: While the use of a predictive statistical model (algorithm) within a standardised framework improves consistency, the algorithm is complex and poorly understood. Lack of a public-facing calculator and inconsistent terminology around "offering" versus "allocation" may lead to further confusion and misunderstanding. Most donor livers are transplanted through centre-based recipient selection with no standardised process across transplant centres for prioritising patients outside algorithm-based offering. The absence of agreed measures of success limits oversight.

Wait list mortality: Outcomes at 6 and 12 months after listing improved following NLOS introduction, with reduced mortality for newly listed patients. Improvements in outcomes for newly listed patients coincided with other system-wide changes (e.g. higher transplant activity, shorter wait list, wider use of perfusion technologies), making causality uncertain. The combination of algorithm-directed and clinician-directed recipient selection further limits interpretability of outcomes.

Survival Benefit: Three-year survival after listing improved between 2012–2015 and 2018–2021, but multiple confounding factors prevent attribution to NLOS alone.

Other Issues: Long delays in implementing IT refinements and reliance on manual workarounds; no formal appeal process for prioritisation; concern over the financial, logistical and environmental sustainability of the system, given increased reliance on air transport.

Recommendations: While implementation of NLOS in 2018 was delivered successfully and there has been improvements in outcomes against the objectives of the scheme, the NLOSRC concluded that the scheme required changes to better deliver on the intended objectives, to address areas of unresolved concern about the current scheme and to focus on additional objectives that were not considered within NLOS in its current form.

Briefly, to improve equity, transparency and consistency in liver offering, a revised system should change to a needs-based approach, using the best validated score for prioritisation. Liver offering should consider geography and waiting time where clinical priority, as predicted by the chosen scoring system, is broadly equivalent. All donor livers (DBD and DCD) should be subject to a standardised offering process, supported by clear processes for exception points, centre-based selection, and/or clinical appeals where appropriate. Operational reliability should be ensured through agile IT infrastructure and performance monitored against pre-defined key performance indicators (KPIs).

The principal recommendations of the NLOSRC are:

- Change to a needs-based offering system, meaning that a donor liver would be generally offered to the matching person on the wait list who would likely die soonest without a transplant.
- Test different ways of calculating how much each person needs a transplant so we can use the best one.
- When two or more patients need a transplant as urgently as each other, consideration would be given to the time and distance to transport the donor liver to them and how long they have waited for a transplant already.
- Use a standardised system for selecting recipients for all donor livers, including:
  - Whole livers.
  - Split livers that can go to two patients.
  - Livers from people with brain death whose breathing is carried out by machines (donation after brain death, DBD).
  - Livers from people whose heart stopped (donation after cardiac death, DCD)
- Standardise the approach to giving prioritisation points when necessary
- Create a process that enables clinicians to transplant patients by appeal for prioritisation or through standardised centre-based offering in cases where clinicians consider that the scheme does not reflect a patient's medical need.
- Simplify the system so it can be understood and changed more easily and quickly.
- Set clear standards and key performance indicators, which are measured and publicly reported regularly.

RECOMMENDATIONS IN FULL

1. What should be the preferred priority of the offering scheme?

1.1 The preferred scheme is Needs based.

1.2 Key measure of need include: risk of mortality on the wait list; quality of life particularly for those with variant syndrome and those whose risk is not fully captured in the model.

1.3 Further development and optimisation of existing Needs-based measures must occur to ensure the most accurate need prioritisation tool is used in NLOS.

1.4 Continuous monitoring of post-transplant outcomes is required to ensure utility within the scheme is not compromised.

1.5 As no tool will provide accurate prediction for all patients an appeals process, mechanism of awarding exception points and/or mechanism for centre-based recipient selection is required.

2.A. Are the current objectives of the scheme still appropriate?

2.B. Are refinements to the objectives of the scheme required?

2.1 The current objectives of Equity, Transparency and Minimising mortality before and after transplant are appropriate.

2.2 Additional objectives should include:

- Sustainability
- Agility
- Simplicity – for the purpose of transparency from a patient and clinician perspective
- The opportunity for innovation

Necessary conditions for success that should also be met are:

- KPIs for scheme defined at launch and monitored according to a pre-determined and stated strategy
- Stakeholder engagement - Ongoing structured education/feedback for professionals and stakeholders
- Access to data without restriction within the confines of UK regulation

3. Should NLOS prioritisation include age within a risk prediction model?

3.1 Age should not be used within the scheme as an unadjusted variable in the predictive model for need due to confounding from baseline mortality, comorbidity and frailty.

3.2 Age could be included if adjustment methods are applied and appropriately weighted to biases, but this is likely to be challenging.

3.3 Before deployment of the scheme it is essential to ensure an equality impact assessment is completed with modelling to assess impact on access to transplantation for different patient groups.

3.4 There should be ongoing monitoring of wait list outcomes and times across age bands with established KPIs for the scheme.

4.How can NLOS be simplified, made more agile, and transparent?

4.1 The nomenclature and definitions around offering processes needs to be clearly articulated and used consistently across NHSBT.

4.2 A tool to calculate the prioritisation score must be made widely available to stakeholders prior to the release of the scheme to support the familiarisation of stakeholders with the anticipated effects of the scheme and provide an opportunity for clinical testing by the community to ensure unintended negative consequences of the scheme are minimised.

4.3 Patients should be provided with an estimated probability of receiving a liver offer and of undergoing liver transplant within an identified period from registration based on their parameters at the time of registration. This estimate should be updated in light of any change to their condition and need score.

4.4 Agility (ease of adaptation) within the scheme is essential, and IT and NHSBT Hub expertise should be embedded in the reworking of the scheme to ensure that the approaches with the simplest and most agile digital solutions are prioritised.

4.5 Transplant registry data, including that recorded at registration and serial monitoring, should be made widely available without restriction provided GDPR guidance is met.

4.6 Existing operational “workarounds” within the scheme need to be reviewed and must be avoided in the re-design of the scheme.

4.7 A multidisciplinary team responsible for implementation should include the patient voice to ensure stakeholder scrutiny also during this phase of the project.

5.What is the appropriate level of organ distribution within NLOS?

5.1 Ideally all deceased donor organs should be distributed within a national scheme.

5.2 Within the elective tiers, geography and waiting time should be considered where patients have equivalent prioritisation scores.

5.3 Weighting for travel distance should be tailored by organ type (DBD, DCD, split livers) to reflect their distinct logistical and clinical challenges.

5.4 Measures to foreshorten cold ischemic time for livers to split through minimising travel times from donation to splitting centre should be implemented (i.e. donor livers going to the nearest centre that could be split).

6.Which organs should be included within named patient offering within NLOS?

6.1 Optimally all donated deceased donor liver allografts (whole and split) should be included in a national system of liver offering with a nationally consistent approach adopted to organ retrieval, both DBD and DCD. The phasing of this will need to be aligned and coordinated with the introduction of other national programmes.

6.2 Should inclusion of DCDs be delayed, equitable distribution of DCD offering aligned with the proportion of liver registrations should be undertaken.

6.3 Modelling must be undertaken to balance the clinical impact, logistical and financial effects of including all organs (specifically adding DCDs) in a national system.

6.4 Establish KPIs to monitor utilisation of fast-track DBD offers, DCD livers, and split grafts amongst centres to ensure patients have equitable access to liver transplantation across all regions.

6.5 Monitoring of utilisation via the fast-track scheme of organs declined by all other centres provides an insight into appetite for innovation within the scheme.

7.What proportion of organs should be placed via named patient offering in the scheme?

7.1 The aim of the scheme should be to maximise the proportion of patients transplanted via named patient offering, which necessitates a new and suitably robust tool to rank patients to facilitate offering.

7.2 Anticipating that a risk prediction tool will not accurately predict need for all patients, the practicalities of different approaches need to be considered including: a system of awarding standardised exception point for certain diagnoses (e.g. HCC, Colorectal mets, pCCA, iCCA, NET, variant syndrome), an appeal process for

patient prioritisation and/or the fallback of centre-based recipient selection and transplantation in a proportion of patients.

7.3 A process to use organs re-offered late is required, analogous to the fast-track mechanism, to ensure the utilisation of livers in such circumstances.

7.4 There should be a nationally standardised approach for prioritisation during centre-based recipient selection and transplantation to ensure transparency and consistency.

7.5 To ensure that centre-based recipient selection and transplantation is reduced to a minimum, monitoring of late declines and behaviours around centre-based recipient selection must be a KPI of the scheme.

8.Are specific changes required to offering within specific categories of patients/donors?

8.1 Paediatrics – the preferred system for paediatric offering would be via a national named patient offering scheme provided it is feasible to deliver such a scheme while maintaining the principle of NLOS.

8.2 Ongoing monitoring and oversight of this system is required, and the format should be determined by LAG in collaboration with NHSBT and align with other NHSBT processes anticipating a continual process of assessment, monitoring and updating.

8.3 Sup-populations where specific consideration is required within a revised scheme include:

- Separation of re-transplant categories e.g. ischaemic cholangiopathy and/or early HAT versus other indications for re-transplantation.
- Further analysis of categories of long waiting patients not generating any liver offers to understand those sub-groups not currently accessing donor offers.
- Offering for SLK patients to improve access to a kidney after liver offering.
- Removing or revising current weight cut offs for elective offering to ensure that weight criteria are applied only where necessary and supported by clinical evidence.
- Offering for recipients at the extremes of weight and donor recipient weight matching should be revisited.

9.Should the current offering sequence be changed?

9.1 The previously agreed adjustments in the offering tier priorities that remain to be implemented remain appropriate and should be completed.

9.2 The system should be updated in such a way as to allow for agile changes in the tiers of hierarchy. This should avoid having hard coded tiers and rather provide a hierarchy of priority groups, which could be a weighted points system, to deliver a simpler and more agile solution suitable for evolving indications and prioritisation.

9.3 There will be an ongoing requirement for the adjustment in hierarchy and communication of such changes to stakeholder groups as they occur.

10.A. What constitutes evidence a new offering scheme is operating effectively and not operating effectively and requires change?

10.B. What should be the process for changing NLOS after implementation?

10.1 There should be structured, independent monitoring of NLOS including operational aspects.

10.2 Continuous refinement to the system should be anticipated and resource to enable this should be put in place.

10.3 Monitoring should confirm the key principles of the scheme, namely meeting need, equity, transparency, simplicity, stakeholder engagement, agility and sustainability (indicative metrics have been recommended) are being met.

10.4 Refinement of the scheme is warranted if pre-specified KPIs are not being met.

10.5 The NLOSRC recognise that supply of donor organs is becoming more limited. If this situation continues it may be appropriate to review minimal listing criteria.

BACKGROUND

Review objectives

The aims of the review were set by NHSBT in the Terms of Reference produced in April 2024 describing the commissioning process.

The aims of the review were:

- To carry out a general review of the fundamentals of the scheme and assess the risk of unintended consequences.
- To review the changes previously agreed upon and re-assess the relevance and need.
    - The impact of the accumulation of changes needed include the fact we are fast-tracking more livers because of the delays in placing organs creating more work for our own staff and staff at transplant centres.
    - Additionally, we have several manual workarounds that are now required to the scheme which adds complexity and not least clinical risk. These are in place to ensure no patient is disadvantaged.
    - Other changes that are needed include for example, liver splitting criteria as this is a national offering scheme. We have reached a point of saturation for the HUB team that register recipients, offer, and allocate livers, in terms of the number of manual steps that need to be satisfied prior to allocation.
- Recommended any changes required.

In particular to:

- review the objectives of NLOS to establish their continued appropriateness.
- review the evidence that the objectives of NLOS have been met by the scheme following implementation.
- review the refinements to the scheme implemented and their role in achieving objective 2.
- review the refinements to the scheme not yet implemented to establish their ongoing requirement.
- consider the offering sequence for organs and the role of DCD offering within the scheme.
- consider all relevant aspects of the system including the sustainability, ease of implementation and refinement and operational aspects of the scheme.
- recommend refinements to the objectives and principles of NLOS if desirable.

The NLOS Review Committee

Chair – Prof Douglas Thorburn, Consultant Hepatologist, Royal Free Hospital
Deputy Chair - Mr Jim Powell, Consultant Transplant Surgeon, Edinburgh
OTDT MD (Observer) – Prof Derek Manas, Medical Director, OTDT
External reviewer – Dr Jack Lake, Past President, UNOS/OPTN; Senior Staff SRTR,
UK Clinicians – Dr Mike Allison, Consultant Hepatologist, Cambridge
Mr Ben Stuchfield, Consultant Transplant Surgeon, Edinburgh
Mr Keith Roberts, Consultant Transplant Surgeon, Birmingham*

Dr Marianne Samyn, Consultant Paediatric Hepatologist, Kings
NHSBT Statistics – Ms Lisa Mumford, Statistics, NHSBT
NHSBT Governance – Dr Richard Baker, Associate Medical Director for Governance, NHSBT
Lay Membership – Mr Andrew Madden, Lay Representative, NHSBT
Patient representative – Vanessa Hebditch, British Liver Trust
NHSBT Hub: Ms Julie Whitney, NHSBT
NHSBT IT – Mr Nick Alsop, NHSBT
Recipient Coordinators – Ms Laura Stamp, NHSBT
NHSBT Admin support – Ms Sam Tomkings

*withdrew from the review committee prior to producing the report and recommendations.

Process followed

1. The NLOSRC was established according to the Terms of Reference (TOR) (Appendix 1)
2. The NLOSRC thereafter:
    a. Reviewed and agreed the TOR.
    b. Reviewed the membership of the NLOSRC and where necessary added or removed members.
    c. Reached a common place of understanding regarding the existing NLOS including its justification, the history of its development, the consequences of its implementation.
3. To achieve 2c a list of several topics for review and consideration was created. This was reviewed, updated and refined regularly. These topics were addressed by invited speakers or discussions led by members of the NLOSRC depending on their areas of expertise.
4. Regular sense checks were undertaken with the NLOSRC to ensure topics of interest to the committee were being considered.
5. The NLOSRC considered and agreed the approach taken to stakeholder engagement and made plans for this to take place.
6. On completion of the evidence review by the NLOSRC the membership was revisited and original members who had not been able to engage with the review to this point were stood down.
7. The NLOSRC met regularly to work through the evidence and to compile opinions and recommendations.
8. Completion of draft report by the NLOSRC end of July 2025.
9. Further stakeholder engagement with professional and non-professional groups on 23rd and 24th September 2025.
10. Final review and refinement of the report by the NLOSRC.
11. Submission of the report to NHSBT.

Overview of current scheme

Liver transplantation has the potential to transform and saves lives. Each decision about who a liver is offered to and whether the transplant should go ahead is of great importance to patients, their families, and for the clinicians making these time-critical decisions. The National Liver Offering Scheme (NLOS) underpins these life-changing decisions, and its effectiveness has direct consequences for equity, transparency, and clinical outcomes. The NLOS review committee (NLOSRC) have considered the technical aspects of the scheme as well as considering the potential impact on patients and the clinical community.

Concepts discussed in this report include the Need, Utility and Benefit of liver transplantation. Need for transplantation reflects how urgently a patient requires transplantation to avoid death on the waiting list. Utility reflects how long a patient is likely to survive after a transplant, and how many life-years the transplant is likely to provide. For example, a patient who is very sick with multiple health problems in addition to their liver disease has a high Need for transplant but potentially their survival after transplant may be more limited. An otherwise healthy patient with significant but relatively mild liver disease may have a relatively low Need for transplant but high Utility. Transplant Benefit is about trying to find a balance between these two, by identifying which patients may gain the most life years from a transplant when taking into account both their risk of death before transplant and their risk of death after transplant.

NLOS was introduced in March of 2018 and was a two-step change process of moving from:
- zonal distribution to national distribution of donor organs
-prioritisation of elective wait list patients with chronic liver disease (CLD) and hepatocellular carcinoma (HCC) according to anticipated Transplant Benefit at five years estimated by the Transplant Benefit Score (TBS). The TBS is a predictive statistical model which decides the order in which people on the UK liver transplant wait list are offered a DBD liver.

UK liver distribution & offering prior to NLOS

Prior to the introduction of this scheme donor organs were distributed from hospitals locally within seven donor zones affiliated to each adult transplant centre. Decisions on recipient selection and transplantation occurred within that centre according to local prioritisation based broadly on need. The donor zones were calculated based on the proportion of elective adult liver transplant recipients registered in each centre. This percentage of national registrations were matched to the donor zone which would be expected to deliver the same percentage of national deceased brain death (DBD) donors. Donor zones were reviewed annually and were adjusted should there be a statistically significant misalignment of the percentage of national registrations and DBDs delivered from within each donor zone.

Patients were prioritised within each centre's wait list mainly based on need using a combination of the patient's UK End Stage Liver Disease (UKELD) score for those with decompensated chronic liver disease and other factors (such as presence of ascites,

encephalopathy, frailty, waiting time, blood group and donor-recipient size matching). Patients with HCC or with chronic liver disease, where centres considered the UKELD score to not appropriately reflect the need for liver transplant, were internally prioritised according to the view of the local transplant MDT and the characteristics of similar blood group / size matched patients on the list at the same time. The consequence of such a scheme was that similar patients with similar indications and disease severity may have achieved different levels of priority according to the centre at which they were registered. Although this approach was largely needs-based within each donor zone, patients in one zone may have been transplanted when sicker suitable patients existed in other zones. Furthermore, zonal distribution of donors may have resulted in differential access to donor organs amongst centres. To address this in one regional collaborative (the Northern Alliance of Edinburgh, Leeds and Newcastle) recipients with a UKELD >62, representing high urgent disease severity, were placed on a Top-Band list and were prioritised across all three centres with organ distribution and offering across the three donor zones.

The development and implementation of NLOS

NLOS was the consequence of an extended process commenced in 2007 to review and revise the UK liver offering scheme. A number of offering schemes based on need, utility and transplant benefit were proposed and discussed with stakeholders. A consensus conference was undertaken in 2012 and concluded that a needs-based approach was most appropriate but further work was required. A fixed term working group of the Liver Advisory Group (LAG) of NHSBT was established, producing a report and recommendations to LAG which was subjected to scrutiny by stakeholders including patient groups. In May 2015 LAG approved the recommendations for a system of organ offering based on transplant benefit, with proportional offering (one in 10 donors) for variant syndrome patients. In this scheme transplant benefit was defined as the difference in anticipated survival for each recipient on the wait list with a specific donor by looking at the difference in expected survival at five-years if the patient was not transplanted that day (need) and expected survival at five-years if that recipient was transplanted that day with a specific donor (utility). Between 2015 and 2018 the LAG Core Group worked on and finalised the scheme, which was launched in March of 2018 as a two-step change moving from centre based to national distribution of donor organs following donation after brainstem death (DBD) donors and the national prioritisation of elective patients with chronic liver disease and/or hepatocellular carcinoma using the transplant benefit score with patients with variant indications prioritised by waiting time. Donation after circulatory death (DCD) donors continued to be distributed, and recipients selected and transplanted on a centre basis.

NLOS objectives

The stated objectives of NLOS on its introduction were:

1. Improve equity of access and transparency
2. Reduce patient mortality on the liver transplant wait list
3. Maximise survival benefit for patient population

No specific Key Performance Indicators (KPIs) were established on the launch of the scheme.

Concerns & refinements implemented

Since its inception there has been continuous monitoring of the impact of the introduction of the scheme via a NLOS Monitoring Committee which met initially at one month then three-monthly for twenty-four months before moving to six-monthly. A report was generated for each review by NHSBT statistics providing detailed assessments of the impact of implementation of the scheme with the aim of detecting unintended consequences after its introduction. The development cohorts for the transplant benefit score were from prior to 2012 (Cancer cohort 2009-2012, Non-cancer cohort 2006 -2012) based on data at registration. Prospective data capture of patients within the transplant registry was introduced in 2013 and it was expected that the models would be regularly updated after implementation including updated parameter estimates based on extensions of the cohorts used in the models. The timeframes for these refinements were not set and routine updating of the scheme has not been undertaken.

While the objectives of the scheme were clearly established, the key performance indicators (KPIs) of the scheme were not established *a priori* and it has been an iterative process to establish whether these objectives have been met. Furthermore, there have been challenges around identifying the early signals that indicated the scheme was having deleterious consequences.

Through this monitoring process and feedback on the scheme received via the Chair of the NLOS Monitoring Committee or the LAG, several concerns were raised about the performance of the algorithm used to rank patients within NLOS. These included offering for patients with the indication of HCC and re-transplant patients. A counterintuitive effect of the diagnosis of HCC on the TBS score was seen such that for a given patient with chronic liver disease the NLOS algorithm predicted that cancer would provide a survival benefit and so reduced priority for transplantation (Attia A et al. Lancet 2023;401(10380):911-912). It was known from the modelling (with a one-year time horizon- that was performed on data from 2013) before the introduction of the scheme that there would be a shift towards transplanting older patients, and that patients with certain diagnoses such as primary sclerosing cholangitis (PSC) would wait longer for their transplants(Table 8 in LAG(14)31d). The full impact of these shifts year on year only became apparent after the inception of the scheme.

Further concerns about NLOS were raised by patients, their families and carers to NHSBT either directly to the CEO or communications department (five cases), in the form of formal complaints (15 individual patients) or enquiries (12 cases) or via members of parliament (six cases) which generated a parliamentary debate on liver offering and also in the House of Lords. There were several articles in the media, and academic journals, and NHSBT were in regular contact with the Care Quality Commission (CQC), Human Tissue Authority (HTA), the Information Commissioners Office (ICO) and a number of patient organisations. The lead for NHSBT Governance

undertook an informal thematic review of these concerns which broadly fitted into the following categories:

- Waiting times/waiting list – concerns expressed by those who continued to wait on the list without receiving suitable donor offers
- Disadvantage by age – concerns expressed about access to transplant for younger patients.
- Rare conditions – whether the modelling and predictions of the Transplant Benefit Score (TBS), used in NLOS were accurate predictors of need and utility for individual outcomes of patients with rare indications for liver transplantation.
- Re-transplant disadvantaged – concerns expressed by patients awaiting re-transplant about prolonged waiting times.
- Process to challenge decisions - there was no process for patients or centres to seek an adjustment to the level of national prioritisation for individual patients if their TBS was perceived to inadequately describe their need/utility.

In light of the lessons learned from the introduction of the scheme, together with the work of other fixed term working groups of LAG reviewing the fast-track scheme, liver splitting criteria and the establishment of a tier for patients with the indication of acute on chronic liver failure (ACLF) and nationally prioritised paediatric patients, a number of refinements to NLOS were recommended by LAG. Wherever possible these modifications were introduced in the form of operational workarounds which have added to the burden of the scheme on the NHSBT Hub team (the NHSBT operational team that manage offering prioritisation processes for NHSBT and co-ordinate the distribution and offering of donors nationally) and NHSBT statistics team. Some of these changes necessitated formal recoding of the NLOS IT system and, due to limited IT capacity and resource to support refinement of the scheme, these IT changes have not yet been implemented after more than five years (see next section in report).

Early reports identified a reduction in mortality at six and twelve months after listing for patients added to the wait list, a shift to non-zonal distribution of DBD donors (70% compared with 30% of transplants with the previous centre-based recipient selection scheme) with an increase in cold ischaemic times for DBD donors of approximately one hour overall. Outcomes of patients transplanted with DBD and DCD donors were similar to those observed at 90 days and one year after transplant prior to the introduction of the scheme.

After concerns were raised about the disproportionately low offering of donors to patients listed with an indication of HCC, a planned update of parameter estimates was combined with the work of a fixed term working group to undertake formal review of the scheme in 2020. This work was completed in 2022, having examined 17 potential updated models. TBS survival predictions are calculated for individual patients by applying the combined effects of all of the included parameter estimates to a baseline survival curve, thereby producing an individualised prediction of benefit. The revised TBS included updated parameter estimates (non-cancer 2006-2016 and cancer 2009-2016). The parameters used within the scheme only included those that had a statistically significant impact on the model. The baseline survival curves for cancer

and non-cancer indications were also revised. The revised non cancer baseline survival curves were based on published data from the UK Transplant Registry between 2003 and 2006 (Barber et al. Transplantation 2011). UK data was used to generate the baseline survival curve for the initial TBS for the HCC indication, while for the updated TBS pre-2011 Italian registry data was used, including patients with up to 3 HCCs all less than 3cm (BCLC-A) who were considered potentially suitable for transplant but not eventually transplanted (Vitale et al, Lancet Oncology 2011).

On introduction of this revised scheme and after further concerns were raised, an additional change was introduced with the removal of 'in-patient status'. 'In-patient status had the paradoxical and counterintuitive effect of deprioritising patients admitted to hospital due to worsening clinical condition by predicting they had less need for transplant. Modelling indicated 'in-patient status' could be removed without significant impact on interactions in the model and no further adjustment was required to the scheme with that change.

The scheme continues to be reviewed on a six-monthly basis by the NLOS monitoring committee, with the most recent report presented at the LAG meeting in May 2025 (LAG(25)03)). The NLOS monitoring group reported in May 2025 that since the change to the updated version of TBS:

- there has not been a change to the rate of removals for death or condition deteriorated of patients registered with HCC.
- the proportion of patients being removed for deterioration with HCC remains greater than patients registered with CLD.
- there appears to have been a reduction in offers made to patients with other CLD indications. This is particularly apparent for the "other" liver disease group, where there were no named patient offers made in the preceding six months of the report, and autoimmune liver disease.
- there remain concerns regarding equity of access to transplantation for younger patients, patients with cancer, re-transplant patients and those with rarer diseases (categorised as "other" in NHSBT reporting).

Proposed refinements still outstanding & ongoing requirement

As described, refinements to the scheme were undertaken in 2022 but in addition several requirements have been identified since 2018 based on the work of established fixed term working groups (FTWGs) and ongoing review and refinement of the scheme (LAG(25)27). Due to the process of hard coding required to make these changes, the lack of capacity within the digital team at NHSBT, and the absence of a specific revenue resource to support ongoing development of NLOS it was not possible to implement these changes, which have been curated and monitored by LAG. These have been prioritised by their clinical impact and importance and implementation of them would in many cases remove established workarounds which require time from the Hub and NHSBT statistics team with associated risks of human error.

At the NLOSRC meeting on 27th February 2025 these outstanding IT changes were reviewed by the NLOSRC to make recommendations as to whether individual

enhancements would continue to be required regardless of the outcome of the NLOS review. This process was completed, and recommendations were approved by the NLOSRC at that meeting (NLOS IT changes - with review dependencies.docx). These recommendations were thereafter sent to the Chair of LAG to establish their ongoing relevance prior to planning implementation.

Has the scheme met the intended objectives?

This has been considered at length and was the subject of a presentation at the Professional stakeholders' event in January 2025, and of specific discussions by the NLOSRC. In considering this question it is important to consider other relevant issues:

- Implementing NLOS was a two-step change with both national distribution of donor organs and prioritisation of patients within the adult elective tier by TBS (two separate models for HCC and chronic liver disease) and patients with variant syndrome prioritised by time waiting (Variant Wait list). It is impossible to disaggregate the impact of either factor on outcomes.
- Since the inception of NLOS there have been significant changes nationally regarding liver transplantation more generally. At the time NLOS was introduced in 2018 the UK liver transplant wait list was the shortest it had been since 2010, and the number of liver transplants undertaken was at the highest level recorded. Since 2020 there have been several adverse changes to UK liver transplantation including:
    - the COVID-19 pandemic
    - a reduction in donor numbers (30% reduction in DBD donors)
    - reduction in liver transplants undertaken nationally (10% reduction)
    - a shift towards DCD donation (>50% of donors now)
    - an increase in the wait list size (50% increase since 2020)
    - an increase in the number of organs retrieved but not transplanted.
- Furthermore, NLOS has been impacted by the introduction of new indications (ACLF and new cancer indications), new tiers of prioritisation (ACLF), prioritised paediatrics and patients with hepatopulmonary syndrome (HPS), evolving but still variable access to, and utilisation of, normothermic regional perfusion, new *ex vivo* perfusion technologies and live donor liver transplantation.

As a consequence of these changes, there are likely to be era effects which sit outside NLOS, and within the whole system it is very challenging to assess their respective influence on the outcomes of the national transplant programme in pre- and post-NLOS eras. Therefore, changes in outcomes cannot be definitively attributed to the introduction of NLOS *per se* and it is not possible to say whether other approaches would have produced better outcomes. Regardless, meeting the objectives of the scheme was considered:

1. **Improve equity of access and transparency**

Equity has improved in some respects in that all similar patients are nationally prioritised using objective parameters from the recipient and donor regardless of geography. However, in practice this geographical equity may have been impacted by longer travel times and a greater reliance on air transport. This may have disproportionately affected patients at certain centres more reliant on aircraft to

transport organs, especially in instances where it is not possible or practical to arrange air transport. Offering a proportion of deceased donor livers (all DBDs) nationally for elective transplantation is a considerable step forward from the previous centre-based distribution and selection of recipients. Under the previous approach, no data were available to determine whether patients with similar characteristics were prioritised differently according to their centres. In contrast, the national scheme provides a more standardised and transparent framework for access to transplantation.

There have been concerns regarding:
- fewer offers to certain patient groups such as:
    - younger patients.
    - patients with HCC.
    - patients with rarer conditions categorised in NHSBT reporting as “other”.
    - patients with Primary Sclerosing Cholangitis (PSC) and re-transplant patients.
- the complexity of the algorithm and the lack of algorithm transparency.
- the lack of a validated tool being made available to enable clinicians and patients to understand how the scheme works
- the lack of agreed KPIs for monitoring the impact of the scheme.

In addition, the concept of Transplant Benefit as a population-level measure, rather than an individual patient measure, has created challenges for patients, families/carers, and transplant clinicians. While it is generally understood that the population approach is essential for fairness and consistency, it does not address concerns in cases where it is perceived that clinically urgent patients are not given sufficient priority, especially when there is not an appeals mechanism. The key issue is not necessarily a lack of understanding of the principle of population versus individual patient benefit, but the need for recognition of the individual within the prioritisation framework. The complexity of how Need and Utility interact in the algorithm also limits the ability of clinicians to explain offering decisions in a way that addresses these concerns.

The role of the TBS algorithm within UK liver offering may not have been clearly understood by clinicians and patients, at least in part due to the terminology used to describe it. NLOS is described as an “offering scheme”. The algorithm within NLOS, the Transplant Benefit Score, functions as a tool for ranking patients with chronic liver disease and HCC based on automated survival predictions generated from donor and potential recipient data. The TBS algorithm is accountable for who receives donor liver offers (there is no formal route for appeal or clinical override within the ranking of patients or offering system).

The algorithm therefore controls access to DBD transplantation, in that patients who are not offered a liver by the algorithm will not have the opportunity for an offer of a DBD liver transplant, other than where the liver is rejected for use by all of the patients and offered the liver through the fast-track process. Clinicians retain accountability for the decision to proceed to transplantation with the donor-recipient pair that has been matched by the TBS algorithm. Ensuring transparency and appropriate safeguards at

both stages is essential to maintain trust in a system that allocates a life-saving and scarce resource. TBS is defined for the purposes of GDPR (General Data Protection Regulation) as a predictive statistical model, or algorithm, that generates a ranked list of patients and fully complies with this regulatory framework.

Geographical issues may arise if centres are unable to secure a flight to bring an organ for transplantation, either due to flight availability or airport opening times. Geographical issues may also affect organ acceptance rates, in that a team may be reluctant to accept an organ that requires a flight if it seems unlikely that the donor organ will eventually be suitable for transplantation, either due to organ quality or size. This issue also applies to split liver transplantation where challenges in transporting the liver from donor centre to the splitting centre and then on to the recipient centre could compromise patient outcomes and may result in lower organ acceptance rates. The increase in flights required for national liver offering across the elective DBD offering tier has placed considerable strain on the system which may also impact on other organ groups due to the limited availability of flights. Furthermore, the proportion of donors transplanted by centre-based recipient selection and transplantation has increased substantially from 39% in 2018/19 to 57% of transplanted organs in 2024/25 (NLOS 84-month monitoring report (LAG(25)03) tables 15 and 16). This is a consequence of DCD organs being excluded from the scheme and 30% of DBD transplants taking place via the fast-track route. This has meant that currently only the minority of livers transplanted are placed by the NLOS algorithm through a national named patient scheme.

It has not been clear to clinicians whether livers falling outside NLOS should be transplanted in line with NLOS predictions, used to target patients not prioritised by NLOS but who the team feel should be prioritised, or whether NLOS predictions should be ignored altogether. This has resulted in different approaches in different centres.

2. Reduce patient mortality on the list

Depending on the metric that is used for measurement, this objective appears to have been met, but with caveats. There was a lower mortality within six and 12 months of listing in the first 18 months after the scheme was introduced before the COVID pandemic (Allen et al. J Hepatol. 2024 Sep;81(3):471-478). However, these improvements in mortality within six months or a year of addition to the wait list coincided with other system-wide changes (e.g. higher transplant activity, shorter wait list, wider use of perfusion technologies), making causality uncertain.

Trends towards improvement in transplant rate and reduction in removal from the wait list for death/deterioration were present prior to the introduction of NLOS, suggesting overall comparison between time periods may give an incomplete picture (Figure 1). Different patient groups may have experienced different wait list outcomes in the periods pre/post NLOS. For example, Figure 2 shows divergent trends in transplant rates and wait list mortality within two years of listing for younger patients (25-39 category) and older patients (>60 years) (adapted from 84-month NLOS monitoring report).

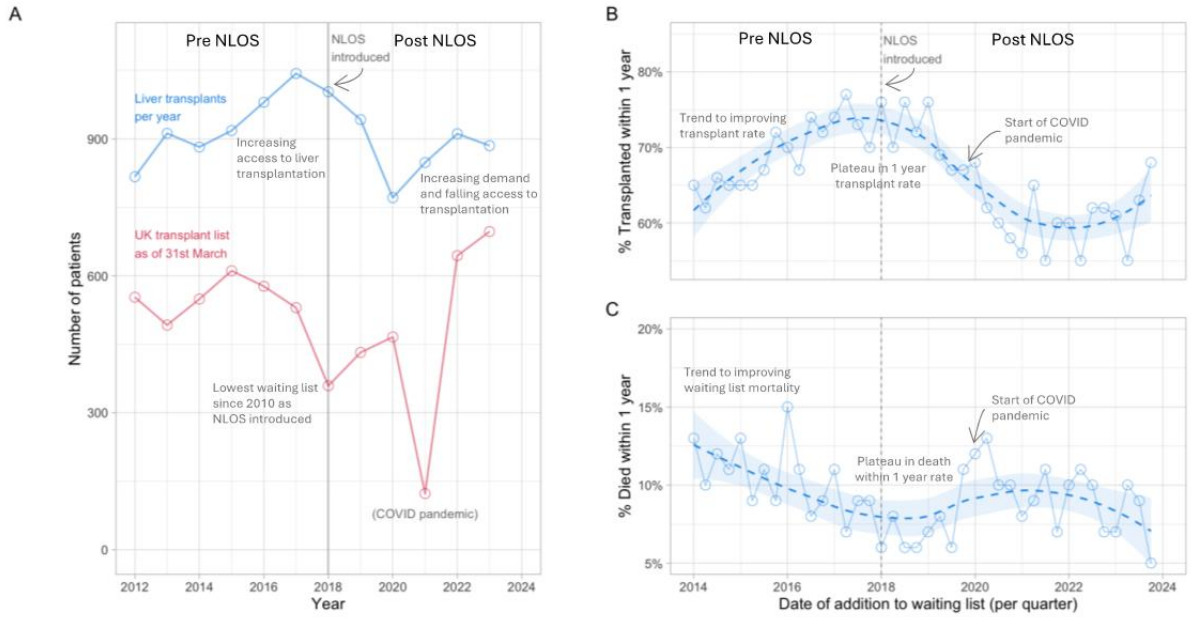


Figure 1: Run charts of UK transplant activity. A) Number of liver transplants performed in the UK per year and length of the UK liver transplant wait list as of 31st March per year between 2012 and 2023; B) Percentage of patients registered per quarter that were transplanted within 1 year of registration; C) Percentage of patients registered per quarter removed from the wait list for death or deterioration within 1 year of registration. Trends over time visualized using LOESS (locally estimated scatterplot smoothing), a nonparametric regression method. (Source: 84-month NLOS monitoring report).

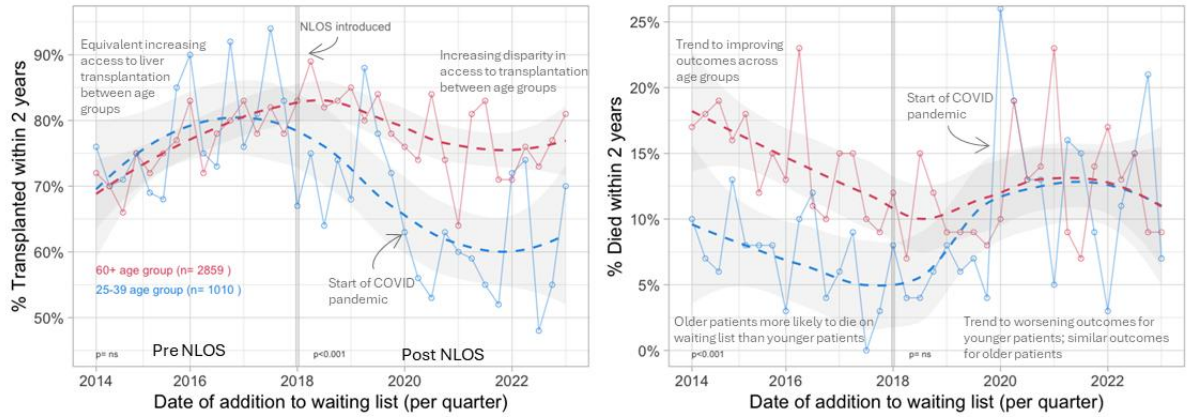
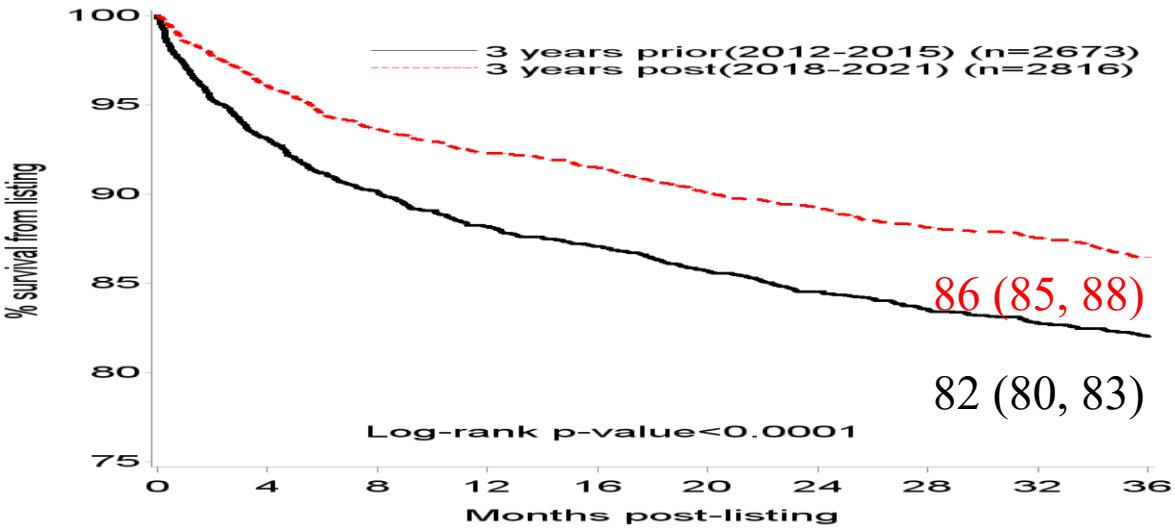


Figure 2: Access to transplantation and wait list mortality according to younger and older age groups. A) Percentage of patients aged 60+ and 25-39 transplanted within 2 years of registration per quarter between 2014 and 2023; B) Percentage of patients aged 60+ and 25-39 removed from the wait list for death/deterioration within 2 years of registration per quarter between 2014 and 2023. Note: Comparisons between pre- and post-NLOS periods were made using the Wilcoxon rank-sum test. Trends over time visualized using LOESS (locally estimated scatterplot smoothing), a nonparametric regression method (Source: 84-month NLOS monitoring report).

3. Maximise survival benefit for patient population

Whether survival benefit has been maximised is uncertain, but there is evidence to suggest survival has increased between 2018-2021 and 2012-2015 based on three-year intention to treat outcomes (evidence presented at Stakeholder event by Dr Ian Rowe)- Figure 3. This comes with the caveat that these time periods are considerably different in many respects including different transplant rates, new interventions (e.g. machine perfusion/normothermic regional perfusion), increasing dependence on transport to support utilisation, the elimination programme for hepatitis C, secular trend in healthcare outcomes and the factors that have contributed to that overall improvement in outcomes cannot be disaggregated.

Figure 3. Overall Adult Wait List Population Survival on Intention to treat basis



STATISTICAL ASSESSMENT OF THE SCHEME

The Transplant Benefit Score (TBS) is used to decide the order in which people on the UK liver transplant wait list are offered a donor liver, aiming to make offering fairer by applying the same scoring system to everyone. The score is worked out by comparing how long a patient is predicted to live with and without a transplant. However, the data behind it has important limitations.

The model makes five-year survival predictions but in reality, very few patients stay on the wait list this long as most receive a transplant much sooner. This means these long-term predictions are based on very limited information and are less reliable. TBS makes assumptions to compensate for this that may underestimate risk for certain patient groups.

TBS uses historic data from other countries to rank disease conditions (USA) and provide survival estimates for patients with cancer (Italy). It is not clear how well these datasets relate to current UK patients. Age works as a stand-in for overall health, and TBS assumes everyone's risk changes over time in the same way, which may not be true for all groups. Accuracy for different patient groups is unknown, testing uses TBS's own predictions may make it appear better than it is, and current outcome measures focus mainly on short-term results. As a result, while TBS provides a consistent approach for all patients, the reliability of its rankings is uncertain.

The statistical concerns are explored in more detail below.

Overview of the Transplant Benefit Score

The statistical methodology underpinning the development of the NLOS algorithm (TBS) is addressed in the publication by Allen et al. (Allen et al. J Hepatol. 2024 Sep;81(3):471-478). In brief, a Cox proportional hazards model is applied to a baseline survival curve to predict five-year survival both with and without transplant. Transplant benefit is then estimated by subtracting the area under the survival curve without transplant (Need) from the area under the survival after transplant (Utility) for each weight (+/-20kg) and blood group matched donor – recipient combination.

Limitations of data

Most patients on the wait list receive a liver transplant within a few years (>70%). However, TBS produces five-year survival predictions from this dataset. Where follow-up ended before five years, TBS assumes no further deaths would occur. To adjust for lack of data where patients were selected for transplantation, a technique called inverse probability of censoring weighting (IPCW) was used to estimate survival as if transplanted patients had not been transplanted. When applied to the wait list data for patients with HCC, IPCW improved predicted survival for an average patient at 2.8 years (maximum follow up) from 16% to 57%. Five-year survival was then also predicted to be 57% for these patients. More data was available for CLD patients, extending to 4.5 years (LAG (14)31c). For the revised TBS patient cohort 1% of patients with HCC remained on the list at 2.5 years, and 2% of the CLD alone patients were still active on

the list at 2.5 years (LAG(21)29). The high censoring rate (>70%), use of blood tests from listing that may not reflect status at transplant, limited follow up, unmeasured and random selection factors (e.g. clinical condition, size matching, competition from other patients on list, rate of change) may reduce reliability of the survival estimates.

These limitation in the dataset can result in counterintuitive survival predictions, such as occurred when the addition of cancer improved survival predictions for patients with chronic liver disease. For example, the current TBS predicts that a 65 year old patient with metabolic associated steatotic liver disease with a UKELD of 51 would have a five-year survival prediction of 5% without cancer (AUC 534). With the addition of a 5cm HCC and an AFP of 1000 (just inside UK transplant criteria) five-year survival prediction without transplant would increase to 23% (AUC 990). This improved survival prediction with cancer reduces predicted need for transplantation and results in a drop in TBS from 1075 to 533.

The wait list dataset reflects previous patient selection practices, making it difficult to know true wait list outcomes for groups that may have been prioritised previously. For example, TBS predicted that patients hospitalised due to deterioration in clinical condition had less need for a liver transplant and so reduced their priority. In reality, these patients were likely previously prioritised by the clinical team, so their true risk of dying without transplant cannot be seen in the data. Equally if younger, sicker patients were selected over older, fitter patients before NLOS, the risk for the younger patients may be underestimated.

Age as a proxy for health

Older people are, in general, more likely to die than younger people. TBS does not recognise that there is a difference in this baseline risk of death. Age is linked to frailty and other health problems such as heart disease. In the TBS model, age works as a stand-in for overall health, because frailty and comorbidity are not directly measured. This means the model assumes all younger patients are equally robust and all older patients are equally frail. As a result, frailty in younger patients may be overlooked, while fitter older patients may be treated as though they are more unwell than they really are. This can lead to older, but relatively healthy patients, being prioritised ahead of younger, more seriously ill patients. TBS predicts similar and sometimes higher survival after transplant (utility) for older patients. This may reflect both the capping of utility at five years and a form of survivorship bias where older patients are more highly selected, while younger patients encompass a broader clinical spectrum.

Use of historic non-UK data

TBS incorporates historic datasets from other countries, e.g. U.S. wait list data from the 1990s to rank disease conditions and Italian cancer data collected before 2011 to estimate cancer survival (see statistical development section). These datasets may not be directly relevant to the current UK population.

Proportional hazards assumption

TBS is derived from a statistical method called a Cox proportional hazards model. This method starts with a single predicted survival curve for all patients. Each patient's curve is then shifted either up or down depending on the individual risk factors. In this way every patient's survival curve is fixed in proportion to the baseline curve. For patients with chronic liver disease this survival curve is based on patients with alcohol related liver disease between 2003 and 2006, while for patients with HCC this is based on Italian data pre-2011 (Vitale et al, Lancet Oncology 2011). Patients with similar conditions may follow a similar pattern of survival. However, the transplant wait list includes a diverse mix of patients. If survival curves are not proportional, e.g. if younger patients are able to compensate for higher levels of disease prior to deterioration, then survival estimates and rankings for those groups may be inaccurate. Whether hazards are proportional across patient groups on the transplant wait list is not known.

Learning random variation

With the diverse mix of patients on the wait list, random outcome fluctuations may be misinterpreted as real differences in clinical priority, causing the model to "learn" noise. For example, in TBS version 1, patients with PSC ranked lowest for a given set of parameters but rose above three conditions in version 2, while patients with PBC saw their priority reduced. Similarly, TBS counterintuitively predicts higher survival after transplant for DCD over DBD grafts in patients with renal dysfunction, likely due to small subgroup effects.

Asymmetry in the algorithm

In TBS version 1, some important risk factors linked to higher risk of death, including ascites and encephalopathy, were only included in the post-transplant survival model, not the pre-transplant survival model. This created an imbalance where patients with these conditions were penalised for being higher risk after transplant but were not considered as factors within the pre-transplant model (M1). This could result in underreporting of conditions seen to reduce patient prioritisation.

Model performance

Operationally TBS is applied to an accuracy of five decimal places, which would equate to a sub-second difference in survival predictions over a five-year period. However, the statistical confidence in the survival predictions is low, with wide confidence intervals spanning hundreds of points. For example, in TBS version 1, the 95% confidence interval for five-year survival prediction for an average patient with cancer was 35%-95% (equivalent to a predicted survival over five years (AUC) of 950-1760 days), while for an average CLD patient 95% CI was 3%-29% (AUC of approximately 380-950 days over five years).

TBS was tested on the dataset used to develop it by selecting random pairs of patients and seeing how often TBS correctly assigned a longer survival time to the patient that, in reality, survived longer (known as the Concordance statistic). It was correct about 70% of the time for patients with CLD (Allen et al. J Hepatol. 2024 Sep;81(3):471-478). This level of discrimination is similar to published figures for the UKELD and Model for End Stage Liver Disease (MELD) Scores, although no direct comparisons have been made.

Survival after transplant predictions assigned a higher score to the patient who died sooner in approximately 60% of randomly selected pairs (50% would indicate no predictive ability at all). Testing on development data may give a more optimistic view of how well a statistical model performs. Calibration, the extent to which predicted survival matches actual survival, is not known. Accuracy in ranking patients based on 5-year benefit is not known.

Simulation testing

Simulations used to test TBS performance relied on the model's own predictions. This created a self-reinforcing effect, where patients predicted by TBS to survive without a transplant were then not transplanted in the simulation and, because the model had already assumed they would live, were also simulated not to die without a transplant. As a result, certain patient groups were predicted to receive fewer transplants while appearing to demonstrate improved survival within the simulation. This reflects the model assumptions rather than observed outcomes. For example, pre-implementation simulations predicted that patients with cancer would receive approximately a 1/3 of the number of transplants but wait list mortality would fall from 5.9% to 4.8%. Patients under 50 were predicted to receive 20% fewer transplants and mortality would improve from 4.5% to 2.9% (LAG(14)31d).

Post-implementation evaluation

Post-implementation outcome measures do not directly evaluate TBS itself. Instead, these measures reflect the combined effect of clinician and algorithm-driven selection in a national rather than centre-based system where clinicians have adapted to the way the algorithm prioritises patients. This means that clinicians compensating for perceived deficiencies in the algorithm may mask the true effects if selection was based on the algorithm alone. The focus on short-term wait list mortality limits assessment for people with slower-progressing conditions, those listed earlier in their disease course, or those able to tolerate a higher disease burden.

THE ROLE OF DCD DONATION IN NLOS

While it was initially intended that NLOS would include all deceased donors, a decision was taken shortly before deployment to include only organs offered from DBD donors. DCD donor organs continued to be offered on a centre basis, then to zonal partner centres if declined before being fast tracked to all centres nationally. Patient selection for these organs is determined within centres without national criteria and is likely to have resulted in variation according to local prioritisation of patients with variation amongst centres. This continues to be the way DCD livers are offered within the UK.

The rationale for maintaining this centre/zonal approach was for fear of negative consequences of centres transplanting DCD donor livers on a national footprint given the uncertainty around effects on cold ischaemic times when moving to national offering. Given the limited availability of, and evidence for, perfusion technologies in 2018 there was concern that a detrimental impact on patient and graft survival would be experienced, hence the proposal was DCD donors would be included within the

scheme when it had been safely implemented for DBD donors and impacts fully evaluated.

These concerns seemed to have reasonable basis given that the distribution of DBD donor organs changed markedly on the implementation of NLOS. Non-zonal distributed organs rose from 36% in 2017/18 to 83% of transplants undertaken in 2024/25 and cold ischaemic times increasing by a mean of one hour nationally. Post-transplant outcomes were not impacted by these changes. Subsequently the arrival of the pandemic, the organic implementation of various warm and cold perfusion technologies and normothermic regional perfusion (NRP) and the plans to review NLOS have prevented incorporating DCD donors within the scheme.

The exclusion of DCD organs from TBS directed named patient offering has enabled clinicians to compensate for perceived limitations of the algorithm by directing DCD organs to patients who may otherwise have been unlikely to receive a named liver offer. Figure 5 indicates differences between clinician directed DBD fast track/DCD recipient selection and transplantation and TBS (algorithm) directed patient selection and transplantation during the first 36 months of NLOS.

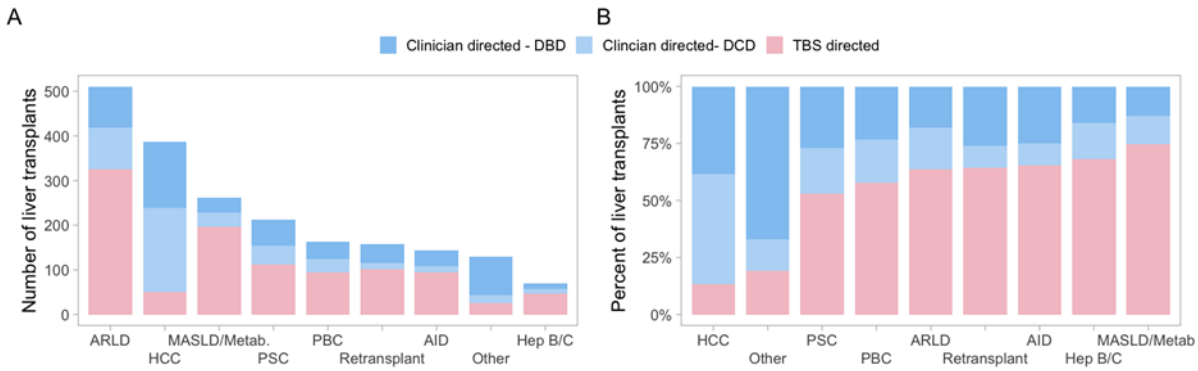


Figure 5: TBS directed, and clinician directed liver recipient selection and transplantation. A) Number of liver transplants performed either following clinician directed DBD (fast-track), clinician directed DCD, or TBS directed transplantation according to disease group; B) Percentage of liver transplants performed either following clinician directed DBD (fast-track), clinician directed DCD, or TBS directed transplantation (Source: NLOS 36-month monitoring report).

National variation in retrieval processes and use of technology exists and this is particularly the case for DCD donors. This reflects the phased introduction of novel technologies and the ongoing evolution of best practice. Normothermic regional perfusion has emerged as an effective technology and funding has been secured to enable roll out across all UK centres. Funding has also been obtained to pilot organ assessment and recovery centres which if successful may also assist with standardisation in the longer term. It should be noted that there is wide variation in liver transplant centres across the UK in terms of wait list size and staff mix. It may be that different solutions emerge at different centres.

It was the view of the NLOSRC that inclusion of DCD organs in an updated named patient offering scheme would be optimal to better understand how recipients' selection for DCD organs is occurring, to achieve better transparency and improve potential geographic inequities. National offering of DCD organs would require a standard approach to all DCD organs across the UK or require centres to retrieve DCD organs for their centre if different practices continue. A national offering approach not including geography would likely substantially increase the requirement for flights to transplant donor organs across the UK. The financial, logistical and environmental sustainability of this approach must be reviewed.

SUSTAINABILITY

This is considered as financial, logistical and environmental sustainability. Under the current system, there has been a substantial increase in the movement of donor organs by road and plane amongst the historic DBD donor zones based on differences in TBS. Patients with virtually identical predicted outcomes may be separated in the ranking, resulting in donor livers being transported by air across the country when a comparable patient's transplant centre is within road distance of the donor hospital. The recognised increase in flights includes scenarios where retrievals have had to been stood down for clinical reasons with attendant increase in environmental and fiscal impacts.

National distribution of DCD organs within an offering process akin to the current system, with no geographic consideration, would be anticipated to lead to further increases in donor organ travel times, distances and flights. In addition, due to the unpredictable nature of the DCD donation pathway, travel costs for non-progressing donation would be increased.

Sustainability was considered when NLOS was introduced, but it was decided that to improve equity only the algorithm score should be used to determine priority of national offering. Sustainability has not specifically been considered within the monitoring of the scheme and there are no established KPIs to monitor against. The Government Internal Audit Agency report published in 2020 highlighted the increasing reliance on flights within NLOS and recommended that operational monitoring be more clearly distinguished from clinical oversight of the scheme. In particular, it advised that a regular operational report, including data on flight usage and associated logistical considerations, should be shared with the Liver Advisory Group (LAG). Thereafter, a regular audit has been undertaken of flight usage within the scheme and reported on a six-monthly basis to LAG (latest paper was LAG(25)04). This has demonstrated an increase in the use of flights since the inception of the scheme.

Aligning the offering schemes to other initiatives such as the national normothermic regional perfusion (NRP) programme and the pilot implementation of organ assessment and reconditioning centres (ARCs) should create further efficiencies and improve sustainability of all of these programmes.

STAKEHOLDER FEEDBACK ON THE SCHEME

As part of the review process, it was deemed crucial by the NLOSRC to engage with professional and non-professional stakeholder groups. This concept was developed in the early stages of establishing the workplan with the full endorsement of the NLOSRC. This culminated in the following approaches:

Professional stakeholder event 23/1/25 at the London Irish Centre, Camden, London. This event was attended by invitation with broad invites sent to each adult and paediatric transplant centre, the relevant professional societies (British Transplant Society (BTS), British Society of Gastroenterology (BSG), British Association for the Study of the Liver (BASL) and British Liver Transplant Group (BLTG)), broad representation from NHSBT.

In parallel there was engagement with non-professional stakeholders which included patient groups, patients themselves, patient families, families of organ donors and members of the general public. Two approaches were planned:

i. A survey was conducted from 4th March 2025 to 21st April 2025 (Appendix 2). This was created in collaboration with the British Liver Trust (BLT) and approved by the NLOSRC. It was disseminated through the BLT and members of the UK Liver Alliance Patient Forum (UKLAPF).

ii. Three focus groups (Appendix 3) for patients and their families/carers and for donor families and members of the public.

Both approaches were developed with the support of the British Liver Trust and the UK Organ Donation and Transplant Research Network. The final format of these was approved by the NLOSRC.

Through the process of advertising the survey via patient groups, representatives of the NLOSRC were invited to participate in a webinar for PSC Support on 31st March 2025 to discuss the scheme, the review and encourage completion of the survey. This was made available online by PSC Support (https://www.youtube.com/watch?v=B1ni5zK0Kh8).

Finally, an unsolicited statement was received from several patient groups requesting specific items to be considered within the scope of the review (Appendix 4).

Professional Stakeholders

An event was held in January 2025 to assist the NLOSRC in understanding stakeholders' perspectives of the current scheme and identify any refinements to be made (Appendix 5). The morning session consisted of several presentations looking at the history of NLOS, whether the scheme is currently meeting its objectives, concerns raised around the scheme from patient and clinical perspectives, and a look at the current scheme in the United States. The afternoon session focussed on discussion among the attendees with the specific questions of; “What is working well with NLOS and needs to be saved?”, “What needs to be improved with NLOS?”, “What should the priorities be of a new NLOS Scheme?”. The event was attended by a wide range of stakeholders, including hepatologists, transplant surgeons, transplant coordinators, patient advocates, commissioners and statisticians. Attendees were present across the UK.

The questions on the day were asked using Mentimeter and responses from the stakeholders were gathered and summarised.

In terms of what is working well with the current NLOS scheme the responses could be grouped into four categories:

1. Equity and Fairness
- National (not centre-based) offering promotes equity of access.
- Sickest patients (e.g. ACLF, HPS, blood group B, small adults) have access to a national donor pool.
- Reduces regional disparities, e.g. patients in Wales/Scotland no longer disadvantaged by organ availability in London.
- Less unconscious bias and less subjectivity in allocation.
- Better equity for older patients, women, and those with variant syndromes or large paediatric needs.

2. Improved Outcomes
- Reduced mortality and wait list deaths.
- Improved organ utilisation, especially with DCD organs.
- Better prediction of need for HCC patients.
- Transparency in allocation decisions has improved.

3. Data and Monitoring
- Detailed data collection on organ acceptance, utilisation, and patient outcomes.
- Granular data enables ongoing scrutiny and monitoring.
- Ability to identify gaps (e.g. who won't get DBD) and suggest alternatives like DCD or live donation.
- Prospective quality of life data collection is being considered.

4. System Design and Functionality
- Algorithmic allocation reduces inconsistencies and centre effects.
- Named patient offers and flexibility for patients whose scores don't reflect true need.
- National network ensures broader access and coordination.
- Mitigation strategies in place for system limitations (e.g. using DBD FT and DCD organs).

In terms of what needs to be improved with the current NLOS scheme the responses could be grouped into six categories:

1. Equity and Access
- Improve access for younger patients, including those needing re-transplants and with paediatric liver diseases.
- Address age-related bias in the scoring system, which currently favours older recipients disproportionately.
- Ensure fair access for autoimmune, PSC, and regraft patients.
- Reassess donor-recipient age matching to avoid mismatches (e.g. young donors to older recipients).

2. System Design and Scoring

- Simplify the algorithm to make it easier to understand, explain, and digitally optimise.
- Rebuild the scoring model using updated data and more accurate survival predictions, especially for HCC.
- Include additional clinical factors beyond UKELD (e.g. ascites, disease severity).
- Consider a needs-based system with reduced reliance on fast-track placements and mortality-based metrics.

3. Geography and Logistics

- Incorporate geographical factors such as travel time and regional disparities.
- Address the logistical burden of flights, which can impact other organ retrievals (e.g. hearts and lungs).
- Explore regional zoning to improve allocation efficiency and reduce travel-related issues.

4. Transparency and Communication

- Improve clarity and consistency in communication with patients and clinicians.
- Develop publicly available tools (e.g. calculators or apps) to help understand scoring and allocation.
- Standardise wait-time policies across centres and improve patient-facing information.

5. Clinical Input and Flexibility

- Introduce more clinician input to balance algorithmic decisions.
- Allow flexibility for patients whose scores don't reflect true clinical need.
- Ensure consensus among clinicians and maintain centre-level discretion where appropriate.

6. Data and Monitoring

- Collecting quality of life and patient-reported outcomes.
- Update the derivation set to reflect changes in DCD, HCV outcomes, and other evolving factors.
- Include composite scores and QALYs gained in future models.

In terms of the priorities for a new scheme the responses could be grouped into six categories:

1. Equity and Access

- Ensure equitable access to both DBD and DCD donor pools across all regions.
- Develop a specific scoring system for paediatric and young adult patients, recognising their unique disease profiles and long-term potential.
- Address wait list morbidity, especially among younger patients, considering impacts on education and employment.

2. Simplification and Transparency

- Create a simplified and explainable system, with clear communication for patients and clinicians.
- Develop public tools (e.g. apps or calculators) to improve transparency and understanding of scoring.
- Ensure the system is easy to update and responsive to clinical feedback and evolving needs.

3. Utility and Outcomes

- Reassess or remove the utility element if it cannot be objectively and fairly measured.
- If retained, define utility using measurable outcomes such as quality of life (QoL), functional capacity, and long-term survival.
- Consider how utility metrics may provide reassurance to donor families about organ use.

4. Geography and Logistics

- Incorporate geographical factors (e.g. travel distance, regional access) into scoring.
- Design a sustainable system that balances clinical need with logistical feasibility and cost-effectiveness.
- Explore regional zoning within NLOS to improve allocation efficiency.

5. Clinical Flexibility and Pathways

- Retain flexibility for edge cases where scores do not reflect true clinical need.
- Unify and integrate DBD and DCD pathways, including a staged approach to incorporating DCD organs into the national pool.
- Minimise reliance on fast-track offers by improving uptake of named patient offers.

6. IT and System Responsiveness

- Build agile IT infrastructure that can adapt quickly to changes in clinical practice and policy.
- Ensure the system supports ongoing review and refinement based on real-world data and outcomes.

Summary Professional Stakeholder event (January 2025)

An interactive presentation tool (Mentimeter) enabled real time feedback through live audience polling, word clouds and open text questions. The Menti feedback highlighted both strengths and weaknesses of the current NLOS. Stakeholders valued the move to a national scheme, improved transparency in the framework of the scheme, and reduced potential for centre-level bias. However, there were strong concerns about equity of access, especially for younger patients, paediatric patients, long waiters, and other groups. Other themes included the need for simplicity, better communication, correction of exaggerated age effects, and improved handling of transport and geography. Suggested priorities for a revised scheme were new scoring systems for paediatric and young adults, inclusion of long-term quality of life outcomes, robust IT tools such as official calculators, and stronger monitoring and accountability mechanisms.

Non-professional stakeholder engagement

a. **Survey outcomes –**

A survey was designed to understand patient and public views about the National Liver Offer Scheme. The target audiences were:

patients with liver disease;
patients awaiting or post-transplant;
family members/carers of the above;

organ or tissue donor family members;
members of the public

Respondents were asked to answer from their own perspective. The survey was open for 54 days (4th March – 21st April inclusive) and shared via the associated networks of

- British Liver Trust
- UK Organ Donation and Transplantation Research Network (UKODTRN)
- National Black, Asian, Mixed Race, and Minority Ethnic Transplant Alliance (NBTA)
- UK Liver Alliance Patient Forum (UKLAPF)
- NHSBT patient groups

Ethnicity and gender questions were added into the survey questions after 271 responses to ascertain the demographics of respondents, as this was felt to be missing. Respondents were asked to rank their preference of the following 3 statements. Reponses displayed in order of preference expressed –

Preference A – patients who are most likely to die if they don't get a liver transplant soon (need).	250 respondents preferred statement A which accounted for 63% of responses
Preference C - patients predicted to have the greatest increase in the length of their life through having a liver transplant (benefit).	82 respondents preferred statement C which accounted for 21% of responses
Preference B – patients who are predicted to live the longest after a transplant (utility)	66 respondents preferred statement B which accounted for 17% of responses

Four free text questions were then posed to respondents; these were not mandatory.

1. Is there anything else you think should be an important part of deciding who should get a liver transplant first?
2. What is good about the way donor livers are offered to people now?
3. What is not good about the way donor livers are offered to people now?
4. In your opinion, what are the most important things for this review to look at?

Summary of Survey Feedback

An online survey was conducted immediately following the stakeholder event. The survey indicated that most participants found the event collaborative, inclusive, and informative. Presentations on NLOS history, objectives, patient and clinical concerns, and offering approaches were rated highly. Attendees felt they had adequate opportunities to contribute through breakout discussions and interactive tools. Concerns raised included transparency, patient information, and the need for clear

timelines and measurable next steps. Equity issues, particularly regarding age, gender, ethnicity, and socioeconomic status were frequently mentioned, alongside calls for greater urgency in change and accountability.

All responses were then manually themed for consideration (Appendix 2).

b. Patient and public focus groups

Three focus groups were held, two supported by the British Liver Trust (BLT) for patients with liver disease and their carers/family members; one supported by UK Organ Donation and Transplantation Research Network (UKODTRN) for families of deceased organ donors, and one moderated 'Ask the Expert' webinar, hosted by PSC Support.

Insights from family members of deceased organ donors were –

- There was a balanced view amongst participants of both feeling positive about a recipient having a long life and also providing a lifesaving opportunity for someone in urgent need, even if this was at the expense of a long life.
- All three principles (need, utility and benefit) were felt to be a satisfactory way of offering livers to patients, and they were happy for clinicians to lead that decision making without contesting any of the principles strongly.
- Organs are given unconditionally to strangers and families of deceased organ donors simply want the recipient to have a chance of a better life, whatever that means for them. Everyone's version of a 'good life' is different.
- In summary, the participants were reassured that a review of NLOS is being conducted and that the valuable resource of a donated organ is being carefully considered as to whom it should be offered to as a priority, but there was no strong opposition to any of the three principles of need, utility and benefit.

Insights from liver patients and their families/carers were –

- Overall, need was preferred as the most appropriate concept to underpin a liver offering scheme. There were many sensible comments demonstrating people understood the difference between the three concepts of need, utility and benefit. The only opposing view to this was a Needs-based system allowing a reasonably healthy person awaiting liver transplantation to deteriorate to a position of greater need, before they would be considered for 'rescue' by transplantation. This was rationalised with the demand for organs outweighing the supply.
- As a concept, need was closely followed by benefit, which was viewed as the next most favourable principle, and was felt to be fair but required some tweaks to the current system. Comments regarding utility was that is unhelpful given the measure of utility being capped at five years.
- Concerns were raised about the impact of the current offering scheme on recipient age, and how this impacts who is chosen to receive a donor liver. Participants didn't appear to consider it as a fair factor in an offering scheme, no matter which end of the age spectrum it favours / benefits.

- Quality of life was raised repeatedly as a factor to be considered in a future iteration of a liver offering scheme, because of how difficult it is awaiting liver transplantation, with the potential for deterioration as well as long and unpredictable waiting times being distressing.
- There were several comments about the current NLOS System not being transparent enough, and difficult to understand.
- Patients valued the opportunity to be included in such a review.

Summary of Focus groups (March 2025)
Three focus groups captured the perspectives of donor families, transplant recipients, patients, and carers. Common themes across all groups included fairness, equity, transparency, and patient experience. Donor families emphasised the wish for organs to 'do good' regardless of the length of survival. Recipients highlighted concerns about age in NLOS, with older patients receiving more transplants and younger patients experiencing longer and more traumatic waits. Patients and carers stressed the importance of quality of life, questioned the treatment of cancer patients within the system, and felt the scheme was overly complex and insufficiently transparent. Although there was broad support for the benefit principle across the groups, the need principle was favoured, alongside calls for refinement, better data, and tools that make the system clearer and more trustworthy.

Stakeholder Engagement (September 2025)
Three stakeholder engagement events were undertaken after Draft 11.2 of the NLOS Review Report was shared with those who had registered to participate. These were with:
- patient group representatives: these were invited via the British Liver Trust and UK Liver Alliance Patient Forum.
- patients, patient families and or caregivers, donor families and members of the public: invitations were shared similarly to the previous stakeholder events in the spring of 2025.
-professional stakeholders: were invited through NHSBT, LAG, professional societies (British Transplant Society, British Society of Gastroenterology, British Association for the Study of the Liver and the British Liver Transplant Group) and via transplant centres, Full details of the structure of these events is provided within Appendix 8. Details on the demography of attendees and initial feedback on the review after the webinars were collected on Mentimeter and logged in Appendix 8. An opportunity was provided to allow further written feedback via a Sharepoint link for a further 5 days after the webinar to capture anonymously peoples feedback. Everyone that had registered for one of the webinars and was in receipt of the draft report was provided with the opportunity to feedback via the Sharepoint link, regardless of whether they had been able to attend a webinar. Following the webinar a further written submission was made from PSC Support which is included in Appendix 8. All of the stakeholder feedback received was considered by the NLOS review committee in meetings undertaken on the 2nd and 9th of October 2025 and refinements to the report agrees and included in the final version (version 13.0) of this report.

SUMMARY OF THE REVIEW OF THE CURRENT SCHEME

Implementation of NLOS in 2018 was delivered successfully and there have been improvements in outcomes against the objectives of the scheme. However, the NLOSRC concluded that the scheme required refinements to better deliver on the intended objectives, address areas of unresolved concern about the current scheme, and to focus on additional objectives that were not considered within NLOS in its current form.

RECOMMENDATIONS: RATIONALE, EVIDENCE BASE AND JUSTIFICATION

1.What should be the preferred priority of the offering scheme?

Consideration was given to the following options:

a. Need – what is the best measure?
b. Utility – what is the best measure? how defined, how reliable is the prediction?
c. Transplant Benefit – incorporates the limitations and benefits of both Need and Utility
d. Waiting time credit – based on time at that disease severity?

The NLOSRC supports implementing a Needs-based offering scheme. While the current system is based on transplant benefit, it is largely driven by need although this is obscured by the complexity of the algorithm. The NLOSRC note the feedback from non-professional stakeholder groups who were keen to see quality of life using objective criteria factored into the prioritisation process but also noted the lack of such objective validated tools. The committee noted that while Utility and Transplant Benefit are attractive concepts the current method of measuring utility is censored at five years and consequently is not adequate to discriminate between patients. For example, modelling demonstrated wide variation in predicted five-year survival without transplant (Need) across populations of younger (25-49 year old) patients and older (60+) patients (IQR older: 144-473 days; younger: 448 -1164 days), yet almost identical predicted survival after transplant (IQR older: 1563-1628 days; younger: 1525-1614 days)(Attia et al, Lancet Healthy Longevity, 2024). Furthermore, pre-implementation modelling suggested only a 1% difference in patient-life years between the benefit-based approach and a need only approach from a simulation run, with identical waiting list mortality (Allen et al, Journal of Hepatology, 2024). This indicates that TBS is overwhelmingly influenced by the Need component. Patients are already selected for transplant, following detailed clinical assessment, on their likely ability to survive at least five years after transplant. In addition, discriminative ability of post-transplant survival predictions is limited (approximately 60% correct when selecting random pairs, where 50% would indicate no predictive ability at all). This limited ability is due at least in part to the many factors that are not or cannot be included in the model (e.g. comorbidity, frailty, as well as intraoperative and perioperative factors such as blood loss, cold/warm ischemic time, organ damage, sepsis, etc).

The NLOSRC expressed concerns about prioritising Utility (and hence Transplant Benefit) within the scheme due to uncertainty about the:

- accuracy of estimating utility
- preferred time horizons to represent true utility within the scheme
- robustness of models to deliver on longer time horizons

As a scheme based on Transplant Benefit is reliant on a clear agreed measure of utility which is reliably calculable, robust, transparent and possible to monitor in a timely

manner with appropriate KPIs, the NLOSRC felt that a refinement to the existing Transplant Benefit-based system was not preferred. This is aligned with the objectives and principles of the scheme as both utility and transplant benefit-based schemes are difficult to explain, understand, calculate and monitor against. Transplant teams already conduct a utility assessment based on predicted >50% five-year survival following transplantation and the post-transplant outcomes delivered prior to and since the implementation of NLOS have been the same. A needs-based model was also favoured by non-professional stakeholders as assessed within the survey and focus groups. However, it is important to note that they perceived quality of life an important factor when it came to assessing need, not just risk of death while waiting for a transplant.

In moving to a Needs-based prioritisation scheme, it will be important to determine the optimal measure of Need (risk of death without transplant) within the list using existing tools eg TBS M1, MELD Score, UKELD Score, Gender-Equity Model for Liver Allocation (GEMA Na). This will provide an opportunity to review the complexity of the model in TBS. The Need component of TBS includes 6 factors: patient age, liver disease category (three categories are allowed but only one is used for the score), and the four variables that go into the UKELD score (bilirubin, INR, creatinine, sodium). These four laboratory measures are widely used in other systems, e.g. the US and Eurotransplant regions. No other system includes age and disease group within a predictive algorithm. The suitability of including age and disease group in the UK's predictive algorithm should be reviewed as both of these variables are vulnerable to influence from confounding factors and small group effects. Understanding potential sources of bias within the dataset and in clinician selection of patients for transplantation is essential in developing the new system.

Consideration should be given to develop an updated UK risk prediction tool. This would necessitate further developmental and validation work. The TBS need component assesses survival to 5 years, but only 1 -2% of patients (HCC and CLD respectively) remain on the list at 2.5 years (LAG(21)29), meaning 5 year predictions are based on very limited data. UKELD is based on 1 year survival and MELD (including MELD 3.0) assesses survival at 90 days. The time window in which to consider need should be reviewed. To ensure patients with equivalent priority scores are identified within the scheme, it will be essential to know the confidence intervals around the preferred Need priority score which are meaningfully different can be used to distinguish between patients.

The NLOSRC recognise that while need is most easily estimated by risk of death while awaiting transplant, this does not adequately capture need for all wait list populations. In an ideal world one might apply additional objective validated measures of need out-with risk of death, such as the quality of life of patients waiting for an offer, but unfortunately such tools do not currently exist. The NLOSRC recognise that there is strong support for such a tool to be developed and included in future iterations of the scheme but recognise a number of challenges, These include
-the inherently subjectivity of quality of life

-its multidimensional nature includes many aspects such as physical health, mental well-being, social relationships, functional ability, pain levels, emotional state, and sometimes spiritual or financial concerns, so capturing all these comprehensively is challenging.
-day to day fluctuations due to symptoms, mood, treatment and/or life circumstances, make it hard to get a stable, consistent measure.
-Some patients may have difficulty expressing their feelings clearly due to language, cognitive impairments, or emotional distress.
-Cultural background influences how people perceive and report their QoL, affecting comparisons across different populations.
- the limitations of existing measures which may not fully capture what matters most to the individual or may be too generic or too disease-specific.

It will be extremely difficult to develop and validate such a measure across all wait list indications. Furthermore, should such a validated tool exist and be employed to assist with prioritisation decisions, patients' quality of life assessments could be prone to bias because of their subjective nature and potential secondary gains negating its utility to differentiate between individual patients. While attractive to stakeholders and the NLOSRC to adopt such an approach, internationally no prioritisation scheme includes a direct measure of quality of life for patients on the wait list at time of registration or subsequently. That said some schemes, such as in the USA, do prioritise patient with certain indications (the equivalent of the UK variant syndrome population) by awarding exception points as a surrogate measure of quality of life while also providing access to an appeals process for individual cases where it is considered that need is not being adequately identified. To ensure equity of access the NLOSRC proposes an appeals process for prioritisation, exception points, and/or a proportion of donors transplanted by centres-based recipient selection is required and should be developed to ensure patients whose need for transplant is not adequately represented by their risk of death on the waiting list can appropriately access transplantation.

In prioritising need within NLOS it is important to protect against loss of utility within the scheme. Thus, it will be key to monitor post-transplant and intention to treat outcomes from listing as KPIs within the scheme.

Waiting time is currently included within the variant syndrome patient cohort to determine priority of patients. It is not included in the elective chronic liver disease or HCC offering system determined by TBS. It has been demonstrated that waiting times do not necessarily correlate with wait list outcomes, but the relationship is complex The shorter time a patient spends on the list, the less exposure they have to 'death on the list'. To understand the relationship between waiting time and risk it would be important to disaggregate the factors influencing both waiting time (i.e. selection for transplantation) and risk of death and then examine their effects separately. Regardless it is not desirable for patients who have met UK criteria for liver transplantation to wait excessive periods of time to undergo liver transplant. Consideration was given as to how waiting time should be considered within an updated scheme. Options include using it as a discriminator in patients with equivalent priority scores and similar geography. Alternatively at certain trigger points waiting time could accrue prioritisation

benefit over time within the scheme. The downside of the latter being that it may create an incentive for earlier listing if additional waiting time provides prioritisation credits within the scheme. If waiting time is not considered at all in the scheme, some patients with lower priority scores will have limited prospects to receive a transplant from a deceased donor through named patient offering as they may be continually outcompeted by new additions to the list. In which case minimal listing criteria for deceased donor transplantation could be revised.

Recommendations:
1.1 The preferred scheme is Needs based
1.2 Key measure of need include: risk of mortality on the wait list; quality of life particularly for those with variant syndrome and those whose risk is not fully captured in the model.
1.3 Further development and optimisation of existing Needs-based measures must occur to ensure the most accurate need prioritisation tool is used in NLOS.
1.4 Continuous monitoring of post-transplant outcomes is required to ensure utility within the scheme is not compromised.
1.5 As no tool will provide accurate prediction for all patients an appeals process, mechanism of awarding exception points and/or mechanism for centre-based recipient selection is required.

2.A. Are the current objectives of the scheme still appropriate?
2.B. Are refinements to the objectives of the scheme required?

Consideration was given to the current objectives:
Equity
Transparency
Reducing mortality before and after transplant

Consideration was given to additional potential objectives:

- Sustainability
- Agility of digital refinement
- Simplicity
- Pre-determined KPIs
- Education/Stakeholder engagement
- Maximising utilisation and reducing variation amongst centres in the scheme
- Improving the lived experience of people before and after transplant - desirable to include measure of patient reported outcomes and/or experience within the scheme should there be accurate tools to objectively evaluate them.

Recommendations
2.1 The current objectives of Equity, Transparency and Minimising mortality before and after transplant are appropriate
2.2 Additional objectives should include:

- Sustainability
- Agility

- Simplicity – for the purpose of transparency from a patient and clinician perspective
- The opportunity for innovation

Necessary conditions for success that should also be met are:

- KPIs for scheme defined at launch and monitored according to a pre-determined and stated strategy
- Stakeholder engagement - Ongoing structured education/feedback for professionals and stakeholders
- Access to data without restriction within the confines of UK regulation

3.Should NLOS prioritisation include age within a risk prediction model?

Consideration was given to the legal framework & pros / cons of including age within a prioritisation score. Options considered were to:

a. Exclude
b. Include in calculating need
c. Include in calculating a reworked measure of utility
d. Include both aspects in a transplant benefit score
e. Age matching between donor and recipient

Age is a protected characteristic under the Equality Act 2010. Age discrimination is described as unfairly treating people differently because of their age. The act does not prevent differential treatment according to age where this can be objectively justified, for example directing organs to older patients due to a higher anticipated risk of death in older patients.

The NLOSRC concluded that age is good predictor of wait list mortality and hence may be relevant in a needs-based offering system, but there are challenges with this. It is also worth noting that Needs-based prioritisation systems for liver transplantation in other countries do not include age.

The NLOSRC noted that within NLOS there appears to be a disproportionate weight placed on age within the scheme that over-prioritises older patients, meaning sick younger patients may not be able to access to transplantation (Attia A. et al. Lancet Healthy Longev. 2024 May;5(5): e346-e355). Furthermore, there is no risk adjustment within the scheme for risk of death for older versus younger persons according to disease aetiology and associated comorbidities, and no adjustment made for older patients having a higher baseline mortality rate than younger patients. The NLOSRC concluded that age should not be included unless it is necessary to improve the accuracy of the model for need, and then only provided any age-associated confounding factors such as co-morbidity, frailty and baseline mortality rate can be reliably adjusted for. Realistically this may not be possible without creating further bias hence it may be necessary to exclude age from the revised scheme. Before the new scheme is finalised it will be essential to undertake an equality impact assessment to ensure bias is not systematically built into the scheme.

While consideration was given to some form of age matching between donor and recipient, it was not felt there was sufficient clinical evidence that this would improve outcomes equitably and might deliver unintended adverse consequences. In particular, this would prioritise Utility over Need which is not aligned with the preferred principle of the refined scheme. Rather it was felt that monitoring of the scheme against wait list outcomes and times across age bands with established KPIs should be implemented.

Recommendations:
3.1 Age should not be used within the scheme as an unadjusted variable in the predictive model for need due to confounding from baseline mortality, comorbidity and frailty.
3.2 Age should only be included where necessary to accurately assess need and if adjustment methods are applied and appropriately weighted to biases but this is likely to be challenging.
3.3 Before deployment of the scheme it is essential to ensure an equality impact assessment is completed with modelling to assess impact on access to transplantation for different patient groups.
3.4 There should be ongoing monitoring of wait list outcomes and times across age bands with established KPIs for the scheme.

4.How can NLOS be simplified, made more agile, and transparent?

Consideration was given to:
-Access to algorithm
-Access to data

Given the persisting confusion amongst clinicians, patients, carers and the public on NLOS and the need to ensure transparency, it is essential that the terminology used for the scheme is clearly defined and used consistently particularly the definitions of donor organ distribution, offering and allocation. This concern was specifically highlighted by patient groups. It was also noted that there was inconsistency within NHSBT about the use of such terminology in policy documents that describe offering schemes within liver selection and allocation policies. While this pre-existing confusion was acknowledged by NHSBT there is a commitment to ensure in future the clear, consistent and transparent definitions of each step in the process across all areas of practice to increase transparency.

Clarification was provided that, as the scheme makes named offers based on a ranked list of recipients, centres and patients were thereafter free to accept or decline these offers. The NHSBT Board, based on the advice of the Information Commissioners Office (ICO), determined that the process must be defined as an offering scheme. It is considered not to be an allocation scheme as centres and recipients are made offers which may be declined by clinicians or patients. This nomenclature was recommended by the ICO for the purposes of meeting the General Data Protection Regulation (GDPR). NHSBT are in the process of ensuring all policies and documents will conform to this nomenclature.

NLOS makes offers and does not make the final decision over who is transplanted. It does however rank patients' priority within the scheme, which informs where offers will be made to named patients. The TBS algorithm is responsible for automated generation of the ranked list based on the survival predictions that it generates. The ultimate responsibility for accepting the organ for transplantation sits with the transplant teams in collaboration with the patient. Transplant teams can accept the offer or decline if there is a specific safety or logistical concern. If a patient is not prioritised by NLOS they cannot receive a named patient offer reinforcing the importance of transparency and clarity in how the scheme operates. As the algorithm used in the scheme is classified as a medical device, it is subject to General Data Protection Regulation (GDPR) and is accountable to the Medicines and Healthcare products Regulatory Agency (MHRA). While in future the term allocate/allocation/allocated will not be used within NHSBT, NHSBT accept that they own all the steps of the process short of the transplant team accepting the organ offer or selecting the recipient if outside of the named patient offering process.

For clarity, the terminology used within this document which is supported by NHSBT is:

- Organ distribution – the geographical extent across which organs are moved to recipients for transplant. This can be centre based/zonal, regional or national.
- Recipient ranking – the process of prioritisation of patients against each other within the offering scheme which is currently and in future likely to be algorithm based with some clinical adjustment (awarding of exception points +/- prioritisation appeals process / geography / waiting time).
- Offering scheme – the process of making offers to named recipients or to transplant centres to undertake recipient selection and transplantation.
- Recipient selection and transplantation – the process by which centres choose recipients for organs that are transplanted out-with a named patient process.

Based on these definitions NHSBT own the processes for organ distribution, recipient ranking according to survival predictions generated by the TBS algorithm, and subsequent organ offering to the top seven ranked named patients. The steps owned by the transplant centre/teams include accepting or declining the named patient organ offer, and the recipient selection and decision to proceed to transplantation for when centre-based recipient selection occurs (currently fast-track DBD and DCDs).

What was clear to the NLOSRC from stakeholder feedback was that the current scheme has been poorly communicated and poorly understood. This applies to professional and non-professional groups equally and hence patients and families have been poorly supported as they navigate the transplant pathway. This lack of understanding has impaired scrutiny of the scheme. The NLOSRC were unanimous that, for the scheme to be more transparent, it must be easier to understand, communicate and to demonstrate its impact against principles and KPIs to ensure people have confidence in it. The NLOSRC recommend a needs-based system which will be simpler to explain, understand and to demonstrate its impact in a timely way. To this end, a readily available tool for use by clinicians and patients should be provided by NHSBT to ensure early familiarisation with the scoring system. Patients registered on the wait list should receive an estimated probability of receiving a liver offer within a

fixed timeframe after registration, based on the parameters at the time of registration and when they are updated. This estimate should be kept under review and updated estimates should be communicated to the patient.

When issues arise with the scheme, a clear and transparent process for raising, escalating and reviewing concerns must be in place with appropriate oversight and governance to critically appraise and resolve such issues. Thereafter, ease of adaptation (agility) of the scheme is necessary to allow simple and transparent implementation of any changes.

The NLOSRC discussed the issue of accessibility of data from the transplant registry for the purposes of experimental development and evaluation of NLOS by stakeholders and researchers not associated to NHSBT. This would provide reassurance that the scheme was transparent and open to external scrutiny and also facilitate innovation. For example, the updated score used to predict waiting list mortality in the US was developed by a team external to the governing body (OPTN). The score (MELD 3.0) was subsequently adopted for use following peer review and testing by the wider community. In the US Organ Procurement and Transplantation Network (OPTN) and the Scientific Registry of Transplant Recipients (SRTR) datasets are freely available and no conditions are placed on publication. NLOSRC agree that access to UK transplant registry data should be made as easy as possible provided GDPR requirements are met. Currently, a core dataset is available as a standard across individual organ groups, but providing more granular data is time consuming to generate hence requires specific approval by Advisory Group (AG) chairs, members of the requisite advisory group and NHSBT statistics. This standard data set does not include registration data to allow the development and evaluation of offering schemes. While not feasible at present to provide data out with this core data set without the use of workforce to prepare the data, this will change in the future to comply with the NLOSRC desire to see wide availability of data for the purposes of maximising transparency for clinicians and patients.

Simplification of the scheme and transparency of the scheme necessitates the removal of existing operational workarounds within the scheme. These are prone to human error and rely on the flexibility and availability of the NHSBT Hub and Statistics teams. These have crept in to the current version of NLOS because of the challenge of implementing IT changes. In future a zero-tolerance approach to operational workarounds is required hence the need for an agile and refinable scheme is essential.

To ensure transparency during the implementation phase of the refined scheme, patient stakeholders must be included in the implementation group. This is crucial to ensure awareness of progress and ensure accountability for delivery against timescales.

Recommendations:
4.1 The nomenclature and definitions around offering processes needs to be clearly articulated and used consistently across NHSBT.

4.2 A tool to calculate the prioritisation score must be made widely available to stakeholders prior to the release of the scheme to support the familiarisation of stakeholders with the anticipated effects of the scheme and provide an opportunity for clinical testing by the community to ensure unintended consequences of the scheme are minimised.
4.3 Patients should be provided with an estimated probability of receiving a liver offer and of undergoing liver transplant within an identified period from registration based on their parameters at the time of registration. This estimate should be updated in light of any change to their condition and need score.
4.4 Agility (ease of adaptation) within the scheme is essential, and IT and NHSBT Hub expertise should be embedded in the reworking of the scheme to ensure that the approaches with the simplest and most agile digital solutions are prioritised.
4.5 Transplant registry data, including that recorded at registration and serial monitoring, should be made widely available without restriction provided GDPR guidance is met.
4.6 Existing operational "workarounds" within the scheme need to be reviewed and must be avoided in the re-design of the scheme.
4.7 A multidisciplinary team responsible for implementation should include the patient voice to ensure full stakeholder scrutiny also during this phase of the project.

5.What is the appropriate level of organ distribution within NLOS?

Consideration was given to:

a. Nationally
b. Nationally with regional weighting
c. Regionally – how many regions?
d. Centre based

As described earlier sustainability of resource and the environment should be an objective of the scheme. Currently there is no evidence that the shift towards national organ distribution has equated to worse outcomes after transplantation. This may be different should DCD organs be included.

The NLOSRC considers that for patients within high urgency categories/tiers such as super-urgent patients, prioritised paediatric, ACLF and multi-visceral transplants national organ distribution remains appropriate.

The risk of restricting organ distribution for other categories to purely zonal or regional arrangements is that it undermines geographical equity within the scheme. Full national distribution however result in the inefficient situation that recipients with similar disease severity may receive livers from different ends of the country within a short timeframe. During stakeholder engagement, national prioritisation and organ distribution was considered a strength of the current scheme. The NLOSRC discussed the need to preserve geographical equity to ensure the objectives of the scheme are met. The NLOSRC considered that, using a validated transparent Need score, it should be feasible to determine priority scores that are not statistically different and hence would equate to a similar level of priority within the scheme. This would provide a pool

of recipients with equivalent priority where geography (and more specifically the cost and time of transport) would be included as a factor in determining the appropriate recipient. This would preserve the principles of the scheme while considering geography. The geographical threshold could be set differently for different donor types depending on the clinical and logistical issues involved across DBD, DCD and split liver grafts. This would ensure that outcomes within the scheme were not compromised whilst minimising resource utilisation.

The impact such actions would have on resource utilisation, *e.g.* flights and travel time, should be considered to ensure an acceptable balance is struck. While a formal health economic analysis has not been undertaken on development of NLOS nor as part of this review, the NLOSRC consider this important within the evaluation of the scheme and when considering future refinements. Evaluation should include ensuring availability of the necessary resources and the cost effectiveness of changes prior to the implementation.

It was considered that such an approach would be advisable within the elective tier. It would also be feasible to set a certain threshold of priority score which could be protected against this clustering approach to ensure they were determined to be of higher urgency.

Recommendations:

5.1 Ideally all deceased donor organs should be distributed within a national scheme.

5.2 Within the elective tiers, geography and waiting time should be considered where patients have equivalent prioritisation scores.

5.3 Weighting for travel distance should be tailored by organ type (DBD, DCD, split livers) to reflect their distinct logistical and clinical challenges.

5.4 Measures to foreshorten cold ischemic time for livers to split through minimising travel times from donation to splitting centre should be implemented (i.e. donor livers going to the nearest centre that could be split).

6.Which organs should be included within named patient offering within NLOS?

Consideration was given to:

a. DBDs only
b. All organs (DBD & DCD)
c. Not liver offered for splitting
d. Not livers that are split
    a. right lobes
    b. (Left lobes/paediatric donors)

Implicit is that there are insufficient donor organs in the UK to meet the needs of patients waiting for a liver transplant. While refining the offering system will deliver opportunities to maximise equity, transparency and fairness, there is a need to increase donation, maximise utilisation and to maximise the opportunities for live donation to meet the needs of patients on the list. Whilst only DBD donor organs (whole and split)

are currently in the scheme, including all organs (DCD also) in the scheme will offer an opportunity across all tiers of the offering sequence including for patients on the super-urgent wait list and national priority tiers.

The scheme was originally intended to include DBD and DCDs, but prior to implementation switched to DBD alone for fear of negative consequences of moving to national offering and the anticipated longer cold ischaemic times. LAG has accepted that the distribution of DCD donors does not align with centre registrations currently (LAG(23)34). The DCD donor zones map to the historic DBD donor zones of the adult centres based on historic registration data and associated DBD distribution prior to 2013. This disparity has become more significant with the increased reliance on DCD donation nationally exceeding 50% of donors in 24/25. There is a need to review the access to DCD donor organs to ensure equity, particularly now that there will be national support for NRP and pilot organ ARCs to support DCD donation.

The situation regarding DCD organs is complex. Historically outcomes following DCD transplantation have not been as good as following DBD transplantation, owing to longer periods of warm ischemia. Extensive research and clinical development have gone into methods to improve outcomes in DCD transplantation.

NRP is a technique where the main donor abdominal vessels are cannulated following circulatory death and the abdominal organs in isolation perfused with warmed, oxygenated blood. NRP has been shown to markedly improve outcomes following DCD transplantation and also improve organ utilisation. NRP is resource heavy, requiring a dedicated on-call perfusion practitioner and consultant level surgical team members to travel to the donor centre. Some centres have favoured ex vivo machine perfusion technologies where the donor liver is perfused by a machine outside the body to support DCD transplantation. There are different types of machine perfusion and different centres are following different approaches. Ex vivo machine perfusion can be performed at the transplant centre which can be less resource intensive than sending additional team members to the donor centre. There is also evidence to support the benefits of this approach. Funding has been awarded to expand NRP services across the UK and funding has also been awarded to support a time-limited pilot study of an ARC that would facilitate ex vivo machine perfusion of organs.

Given the different approaches to DCD organs which have developed, at least in part due to the resources available at each centre, National offering of DCD organs at the present time would be challenging and could risk the gains that have been made. Initiatives to expand availability of NRP and machine perfusion will hopefully improve standardisation across the UK and facilitate a national approach in time. Nationalising all DCD organ offers without accounting for geography would likely result in a further increase in requirement for organs travelling by air. Given the more unpredictable nature of patients progressing down the DCD pathway continuing through to organ donation (e.g. the person may not progress to death after withdrawal of life sustaining therapy within the right timeframe to enable donation) a significant proportion of organ transport distance and requirement for flights would subsequently be stood down.

The alternative to exclude these organs from a named patient offering scheme raises concerns about equity and transparency. Incorporation of DCD organs within a national organ offering scheme would require people to have confidence in the scheme. Unless they are included in a standardised process it will be more difficult to demonstrate whether the scheme is delivering on its KPIs optimally through named-patient offering or to some extent by standardising the approach to centre-based recipient selection. The geographic distribution could be created differently for DCDs than DBDs for patients with equivalent need but would only be feasible with national standardisation of DCD retrieval processes.

The offering of livers within splitting criteria may be improved with the SCORE programme (Sustainability and Certainty in Organ Retrieval programme; an initiative to generate a more sustainable, efficient and predictable organ donation service) when there may be more time to place the left lobe and hence a clearer offer of the right lobe to the adult centre in terms of timing and the nature of the graft on offer. Liver splitting is performed only at UK liver transplant centres with a paediatric liver transplant service (Leeds, Birmingham and Kings). The smaller part of the split liver (left lobe or part of) can be transplanted into a child, while the larger portion (right lobe) can be transplanted into an adult.

Donor organs travel from the donor centre to the paediatric centre to be split. If a centre other than the splitting centre has accepted the right lobe, the right lobe then travels on to the adult centre. This can create substantial logistical challenges for centres in accepting split liver offers if they are at a distance from the splitting centre. For example, if a donor liver in the North is accepted for paediatric transplantation in Birmingham and adult transplantation by a Northern centre (Newcastle or Edinburgh) the donor liver would travel to a regional airport in the North to fly to Birmingham for splitting. The right lobe would then be flown back to a Northern centre for transplantation. The right lobe would likely arrive at the implanting centre in the North with a cold ischemic time approaching or exceeding a safe time point to enable transplantation. Depending on transport logistics some combinations of donor, splitting and recipient centres are not feasible within the current system. The NLOSRC recommend the offering of livers within splitting criteria to adults including right lobes should remain within the scheme. To ensure equity of access to split liver transplants it will be essential to minimise travel distances and times on the donation and splitting side of the pathway to maximise the opportunity for patients in all centres to access the right lobe.

Patients registered at transplant centres located at greater distances from most UK donor activity face structural disadvantages in organ access. For example, within the current scheme most Scottish donors are now utilised in the Midlands or Southern England, while the majority of DBD donor livers used in Scotland originate from these same regions. Through establishing a geographic element within the scheme some of this will be mitigated. However, centres that require air transport face particular challenges in accessing fast-track DBD offers, DCD livers, and split grafts, due to time-

sensitive logistics and limited flight availability. Ensuring as many donors are offered and accepted through named patient offering may minimise the impact of some of these logistical issues. It will be key to include some metrics within the KPIs to ensure patients are not disadvantaged through the scheme over and above some of the structural aspects.

Innovation within the scheme at all centres should be encouraged and this can be achieved through utilisation of organs that are declined nationally. Patients at all centres should have equitable access to these grafts to support research and innovation. Monitoring of utilisation via the fast-track scheme of organs declined by all other centres provides an insight into appetite for innovation within the scheme.

Recommendations:
6.1 Optimally all donated deceased donor liver allografts (whole and split) should be included in a national system of liver offering with a nationally consistent approach adopted to organ retrieval, both DBD and DCD. The phasing of this will need to be aligned and coordinated with the introduction of other national programmes.
6.2 Should inclusion of DCDs be delayed, equitable distribution of DCD offering aligned with the proportion of liver registrations should be undertaken.
6.3 Modelling must be undertaken to balance the clinical impact, logistical and financial effects of including all organs (specifically adding DCDs) in a national system.
6.4 Establish KPIs to monitor utilisation of fast-track DBD offers, DCD livers, and split grafts amongst centres to ensure patients have equitable access to liver transplantation across all regions.
6.5 Monitoring of utilisation via the fast track scheme of organs declined by all other centres provides an insight into appetite for innovation within the scheme.

7.What proportion of organs should be placed via named patient offering in the scheme?

Consideration was given to

a. All organs
b. A proportion held for centre-based recipient selection and transplantation. If so;
    a. What proportion of organs overall?
    b. How is that proportion shared?

To maximise transparency and equity within the scheme, it is desirable to ensure that as many organs as possible are transplanted through named patient offering. This is dependent on a reliable and trusted system for prioritisation. Regardless, there will remain the need for a fast-track system to allow centre-based recipient selection and transplantation with organs that have failed placement through named offering or been declined late after named patient offering and are at risk of not being utilised.

The NLOSRC reviewed the approach taken in the US where the aim is to achieve <5% of offering out with the named patient scheme and all organs (DCDs/DBDs and within splitting criteria are included). This is dependent on a:

- system to award standardised exception points for given indications when prioritising patients on the wait list.
- process to allow individual appeal for prioritisation within the scheme.

In US 30% of wait list cases are awarded exception points but of these 25% are for HCC. 5% for equivalent of variant syndrome. Exception points are awarded via a national review process.

It is recognised that a risk prediction tool will not accurately predict risk for all patients given the diverse nature of the wait list and challenges with the dataset, hence some opportunity to ensure these deficiencies are mitigated through liver offering is essential. This could involve a process which will allow appeal for prioritisation or ensuring a proportion of donors are available for centre-based recipient selection and transplantation. Providing a percentage of donors for centre-based recipient selection and transplantation would require a nationally standardised system for recipient prioritisation for organs transplanted through centre-based offering. Alternatively, a nationally standardised and transparent process of appealing for exception prioritisation would be required. This would be a new process for the UK and would require consideration of the resources required to maintain such a process. It would also necessitate standardisation of who qualifies to ensure reliable and transparent decision making was supported by clinical opinion. This would require a set of principles that are adhered to such as prioritising recipients by need where additional factors would be considered, such as logistics, and decided by a local MDT decision making processes.

Recommendations

7.1 The aim of the scheme should be to maximise the proportion of patients transplanted via named patient offering, which necessitates a new and suitably robust tool to rank patients to facilitate offering.

7.2 Anticipating that a risk prediction tool will not accurately predict need for all patients, the practicalities of different approaches need to be considered including: a system of awarding standardised exception point for certain diagnoses (e.g. HCC, Colorectal mets, pCCA, iCCA, NET, variant syndrome), an appeal process for patient prioritisation and/or the fallback of centre-based recipient selection and transplantation in a proportion of patients.

7.3 A process to use organs re-offered late is required, analogous to the fast-track mechanism, to ensure the utilisation of livers in such circumstances.

7.4 There should be a nationally standardised approach for prioritisation during centre-based recipient selection and transplantation to ensure transparency and consistency.

7.5 To ensure that centre-based recipient selection and transplantation is reduced to a minimum, monitoring of late declines and behaviours around centre-based recipient selection must be a KPI of the scheme.

8.Are specific changes required to offering within specific categories of patients/donors?

Categories considered were:

a. Paediatric patients and donors
b. Acute liver failure - time
c. ACLF - time
d. Elective patients
    a. Chronic Liver Disease -
    b. HCC
    c. Variant syndrome - time
    d. New indications e.g. HPS, cancer -time such that they can be transplanted within a time window

a. Paediatric patients

The NLOSRC noted the success of prioritised paediatric programme and the plans to establish more objective and standardised criteria for elevation of patients onto this tier. The prioritised paediatric tier currently exists as a work around on the hepatoblastoma tier but with a lower level of priority than for hepatoblastoma patients. This workaround was created given the challenge of implementing the IT changes necessary to create a prioritised paediatric criteria above elective liver offering for paediatric recipients. This has created a higher level of prioritisation for paediatric recipients than intended with them sitting above candidates requiring multi-visceral transplantation. The NLOSRC felt this level of priority should be adjusted to allow multi-visceral recipients to sit above the priority paediatric category so prioritised paediatrics patients sitting just above elective paediatric offering.

Given the success of this nationally prioritised paediatric category, it prompts consideration of whether a national system of offering for elective paediatric transplantation too would be appropriate. While this would undoubtedly be most transparent and equitable it would require introduction of a system which doesn't exist in paediatric liver transplant internationally (to our knowledge). Despite this there should be re-exploration of a national system of offering for donors for elective paediatric cases too. Inclusion of a system for awarding exception points could ensure appropriate prioritisation of patients where a needs-based prediction did not generate the necessary level of priority for the recipient.

The NLOSRC noted that there are a number of refinements to paediatric offering processes which have been recommended by LAG which have not been implemented and are sitting within the backlog of IT changes.

This includes paediatric moving to

i. Establishing paediatric zones for donor distribution.
ii. Changing the offering sequence for non-zonal donors to the recent paediatric transplant activity (as opposed to the current system based on recent adult and paediatric transplant activity in each centre).
iii. Inaccuracy of the current splitting criteria and the new criteria not yet implemented. (NB As of September 2025 the new splitting criteria have been implemented)

It was felt there should a system of national offering of donors to paediatric recipients not be feasible, the earliest possible implementation of these existing recommended IT changes to support the scheme were warranted. The future scheme should be simple as possible and agile to prevent future delays in implementing necessary changes.

b. **Patients with Acute Liver Failure (ALF)**

Currently once minimal listing criteria are met for one of the existing categories candidates are nationally prioritised based on time waiting for blood group compatible offers. There is currently no prioritisation by disease severity or other measure of need beyond this. The NLOSRC discussed whether some categories with lower levels of urgency (e.g. subacute patient without hepatic encephalopathy) be placed on different priority tier from patients with greater urgency. The NLOSRC were uncertain whether such intervention was warranted based on the operation of the current system informal advice was sought out with the NLOSRC from Will Bernal & Brian Hogan (LAG meeting 26/5/25) who did not believe there was evidence that such a change was warranted. Hence the NLOSRC consider that no specific changes are required to offering for super urgent patients currently.

c. Patients with Acute on Chronic Liver Failure (ACLF)

ACLF patients are currently prioritised based on time waiting within that tier. On implementation of ACLF pilot, it was planned that they should be prioritised before elective offering for adults but after offering for splitting and multi-visceral recipients. Due to the complexity of the IT changes required to create a different tier for ACLF patients above the adult elective prioritisation this has not been implemented and currently they are prioritised as a workaround within the hepatoblastoma tier (but with lower prioritisation than hepatoblastoma and prioritised paediatrics). It is intended that they should be lower in the offering sequence and avoid the workaround that is in place which would involve prioritisation below the multi-visceral patients but above the chronic patients as was previously approved by the LAG. Thereafter, the ACLF patients could be prioritised on time waiting within that tier.

This could be achieved within a single scheme by creating exception points for priority sub-sets rather than creating a tier system to avoid the need for complex hard coding of the scheme. This is similar to the US where multi-visceral patients are prioritised by giving them exception points rather than having tiers in the US scheme bar the ALF category 1a and PNF patients which exist as a separate priority tier. This concept is attractive to ensure simplicity and agility of the scheme by avoiding having to code tiers, and is more flexible if new indications or adjustments in priority are made.

d. Patients awaiting a multi-visceral transplant

NLOSRC believe they should retain significant level of prioritisation. They should sit above paediatric prioritisation, paediatric elective, ACLF and thereafter adult elective prioritisation. Offering the prioritisation within this tier should rely on existing agreements with the MCTAG and the LAG.

e. Patients awaiting a simultaneous liver and kidney (SLK) transplant

Currently these patients are offered livers in the same way as liver alone patients. When a named-patient DBD donor offer is made the kidney is held back until for up to 60 minutes or, for a DCD donor, until both the zonal and linked centre(s) have declined to allow elective recipients who require combined liver kidney transplantation to accept one kidney to accompany the liver. Consequently, when patients requiring SLK are considered for a fast track DBD or non-regional DCD a kidney is not made available.

With the introduction of SCORE there should be more time within the offering period to ensure SLK recipients are provided the opportunity to receive a kidney as long as this will not be disadvantaging a tier A kidney or pancreas recipient. It was noted that for the Hub sequential liver then kidney transplants were difficult from operational perspective within the current system as liver and kidney schemes do not interact efficiently at present.

f. Elective patients

Chronic Liver Disease & HCC

As described above a Needs-based prioritisation system is recommended. Within this elective tier the aim is to have a single system that incorporates HCC with CLD with appropriate prioritisation for each. Thereafter, it should be feasible to reprioritise HCC (and CLD) patients according to pre-established criteria similar to the USA where it is common for patients to be provided exception points with HCC (amongst other indications) to achieve prioritisation. In this case no specific prioritisation score is required for HCC patients. Rather exception points are generated for HCC patients based on standardised objective criteria. This provides the opportunity to adjust the level of priority for subsets of HCC patients such as those where transplant is being offered as a salvage treatment when other therapies have failed.

Variant syndrome

A proportion of DBD donors (10%) within the current scheme are offered for variant syndrome patients. Prioritization currently is based on time waited. The rate of offer declines on the variant list is substantially higher than on TBS based offering. When considering variant syndrome, it was noted by the NLOSRC that the existing variant system with a separate list is not a problematic way of running the list as it is quite agile, simple to run and understand and transparent and would continue to base prioritisation by the time waited.

It was also noted within the US that patients with variant indication are awarded exception points and even within disease category may be awarded different level of exception points. An example of this would be patients with APCKD (adult polycystic kidney disease) who are waiting for a liver alone or an SLK (simultaneous liver kidney). If they are dialysis dependent different exception point are awarded. This approach is already undertaken with some categories of patients on the variant list with higher levels of urgency e.g. intrahepatic and perihepatic cholangiocarcinoma, isolated colorectal or NET (neuroendocrine tumour) liver metastases and hepatopulmonary syndrome (see below). While subjective assessment of prioritisation between different indications would be required in awarding the exception points, there should be a clear and transparent national process to achieve that.

This approach allows agility and flexibility to add new indications within the scheme and to ensure an appropriate level of prioritisation against all other categories of wait list patients. This is easier than having a separate variant category as we do at present, into which would be harder to integrate new indications into. The view of the NLOSRC is to have HCC, new cancer indications and variant indications integrated into a single system with pre-agreed levels of prioritisation on the list. This level of priority will not increase with waiting time but within any prioritisation score accrued waiting time can act to distinguish between patient with broadly equivalent prioritisation in combination with geography .

New indications e.g. HPS, cancer indications
Currently these patients are listed on the variant portion of the list and are awarded waiting time credits (equivalent of exception points) to ensure they receive a transplantable liver offer (75% chance) within a pre-determined time window. In the future, they should be awarded an exception score which would provide an appropriate level of prioritisation in order to facilitate offering a liver graft within the required timeframe. Thereafter they should be prioritised by geography and waiting time.

Re-transplant patients
Currently they are placed in a re-transplant category within the calculation of M1 and M2 of the TBS and are awarded a TBS score and prioritised against CLD and HCC. While concern has been expressed about how organs are offered to patients awaiting re-transplant, it is recognised from review through LAG that they as a group receive amongst the highest number of offers, have the lowest rate of accepted offers and there is a wide variation in the type of organs that are accepted for transplant amongst centres (e.g. some centres NRP and/or NMP DCD and LDLT versus named DBD donors only in some centres). Higher decline rates for retransplant patients likely reflect the often more challenging nature of re-transplantation. Re-transplantation may be a lengthier procedure than primary transplantation, space to accommodate the graft may be more limited and extra donor vessels of suitable quality may be required if the patient's current arterial or portal venous inflow is compromised.

Of note, currently all re-transplant patient categories are considered equivalent in terms of their level of prioritisation e.g. chronic rejection versus cholangiopathy. The NLOSRC think consideration should be given to reviewing the categories of re-transplant patients to consider whether different subsets of patients exist that could be prioritised differently according to their need. In the US for example within the re-transplant category, waitlisted patients with ischaemic cholangiopathy as the indication may be awarded an additional exception points to provide an additional level of priority. This group and patients with early hepatic artery thrombosis are the only categories of re-transplant patients where this additional level of prioritisation may be provided.

A discussion was undertaken on whether increasing priority of re-transplant patients further would be useful to encourage centres to transplant patients with more marginal grafts. However, concern was expressed this might encourage excess risk taking or a

lower rate of offer acceptance because once offering starts the expectation would be that further (better) offers will follow if an organ is declined. It was also noted that as a category re-transplant patients were already receiving amongst the highest rate of donor offers of any categories within the scheme.

Categories of patients receiving few named patient offers
This was raised as a concern at the May 25 LAG meeting in the 84-month monitoring report. There were 40 patients who received no offers in preceding six months with waiting times 400 – 2000 days+. There have been some deaths but uncertain whether these are in excess. The NLOSRC queried who this subset of patients were with questions as to whether they might include patients with portal hypertension predominant diseases e.g. Cystic Fibrosis (CF). The NLOSRC noted that in the US such patients with CF may be given exception points to ensure they can access higher levels of prioritisation within the scheme. The proposal was that long waiting patients with no offers should be monitored within the scheme with established KPIs.

Offering at the extremes of recipient weight
Currently small adults (<40 kgs) can access donors on the paediatric list in addition to being on the adult list. It was noted that in the USA it is planned that small adult recipients will be offered prioritisation points (recognising challenging of matching with donor size), but do not have access to the paediatric donor pool.

A reciprocal arrangement is in place that large paediatric recipients (>40kg) can also be dual listed. Furthermore, currently they remain on paediatric category and can access both paediatric donors and livers within splitting criteria until they are transplanted which not an option for young adult patients who are added to the list when they are above 17 years old. The NLOSRC note that this creates inequality for access to donor organs on the list in these categories of patients. This issue should be considered within the development of a national paediatric offering scheme.

NLOS has established weight cut offs for differences between donor and recipient weight built into the scheme for donor offering. This is +/-10kg for variant recipients and +/-20kg for recipients with CLD. Concerns were expressed particularly for recipients of higher weight (110kg+) within the current arrangements but equally concerns that if weight limits were reviewed it could have a detrimental impact on access to transplantation for recipients of low weight. It was noted that centres were already transplanting organs when selecting recipients on a centre-basis out with the existing weight cut offs. The NLOSRC did not feel sufficiently informed to make specific recommendations on future weight thresholds but recommend that these should be revisited to ensure low and high weight recipients are not disadvantaged which might include considerations beyond weight matching such as donor and recipient gender and height.

Recommendations:
8.1 Paediatrics – the preferred system for paediatric offering would be via a national named patient offering scheme provided it is feasible to deliver such a scheme while maintaining the principle of NLOS.

8.2 Ongoing monitoring and oversight of this system is required, and the format should be determined by LAGin collaboration with NHSBT and align with other NHSBT processes anticipating a continual process of assessment, monitoring and updating.
8.3 Sup-populations where specific consideration is required within a revised scheme include:

- Separation of re-transplant categories e.g. ischaemic cholangiopathy and/or early HAT versus other indications for re-transplantation.
- Further analysis of categories of long waiting patients not generating any liver offers to understand those sub-groups not currently accessing donor offers.
- Offering for SLK patients to improve access to a kidney after liver offering.
- Removing or revising current weight cut offs for elective offering to ensure that weight criteria are applied only where necessary and supported by clinical evidence.
- Offering for recipients at the extremes of weight and donor recipient weight matching should be revisited.

9.Should the current offering sequence be changed?

Consideration was given to the following options:|

a. Change
b. Not change

The offering sequence is the order in which the tiers of potential liver transplant recipients are considered (i.e. fulminant hepatic failure ('super urgent') sits above hepatoblastoma, and so on). The current offering sequence was noted (Figure 1 in the Liver Selection and Allocation Policy 195: https://nhsbtdbe.blob.core.windows.net/umbraco-assets-corp/32990/pol196-deceased-donor-liver-distribution-and-donation-260324.pdf).
It was noted that there are outstanding changes due to be made to the offering sequence which were agreed by LAG but haven't been implemented thus far.

Discussion took place around maintaining a hierarchy of priority within the scheme but without reliance on formally structured tiers that require hard coding and hence are not simple or agile. The same could be achieved by creating different exception points or categories. This requires clear separation within the hierarchy of categories of prioritisation groups while allowing individual patients to be prioritised against each other (eg for ACLF and SU categories on waiting time, within the elective tier by priority score, geography and waiting time in the adult elective priority group).

The NLOSRC believe this would provide a simple, agile and transparent system, but will be reliant on ongoing stakeholder engagement with professional and non-professional groups to ensure colleagues understand any adjustments, the justifications for these and the implications.

With those caveats the preferred hierarchy of offering would be:
Super urgent
Hepatoblastoma

Multi-visceral
Paediatrics (nationally prioritised paediatrics before elective paediatrics)
Adult ACLF
Adult elective and all other categories

Recommendations:
9.1 The previously agreed adjustments in the offering tier priorities that remain to be implemented remain appropriate and should be completed.
9.2 The system should be updated in such a way as to allow for agile changes in the tiers of hierarchy. This should avoid having hard coded tiers and rather provide a hierarchy of priority groups, which could be a weighted points system, to deliver a simpler and more agile solution suitable for evolving indications and prioritisation.
9.3 There will be an ongoing requirement for the adjustment in hierarchy and communication of such changes to stakeholder groups as they occur.

10.A. What constitutes evidence a new offering scheme is operating effectively and not operating effectively and requires change?
10.B. What should be the process for changing NLOS after implementation?

Consideration was given to the following aspects:

- Monitoring of updated scheme
- What are the KPIs for the scheme
- Handling counterintuitive algorithm predictions
- Recognising structural issues in algorithm
- Algorithm learning random variations in dataset
- Potential impact on patients
- Methods to recognise these
- KPIs and time frames to make changes
- Responsibility for monitoring the scheme

The NLOSRC believe there is an ongoing requirement to undertake monitoring of the scheme and the impact of any revision akin to the function of the NLOS monitoring committee. This should monitor against outcomes of the scheme but also operationalisation to determine that the requirements of agility, transparency, simplicity and sustainability are met. To achieve this requires a structure to the monitoring process and the key principles of the scheme and KPIs to measure against it to be agreed *a priori*. Furthermore, making source data on the scheme and its performance widely available to stakeholders and researchers will provide increased transparency and the opportunity for peer monitoring of the scheme.

There is the option of LAG or of an independent monitoring group (as per currently) separate to the advisory group monitoring the scheme. LAG is a properly constituted group with lay and patient representatives. For other schemes the associated advisory groups (MCTAG, KAG & PAG) monitor their own schemes. For CTAG it is undecided at present how the new national scheme will be monitored. NLOSRC recognise there is a

need to have consistency across organs. In addition, there should be a formal escalation pathway for concerns from patients, clinicians & centres to record issues with the scheme. A commitment is required to ensure that changes to the scheme that are mandated through the monitoring process are implemented speedily.

A review group that sits outside LAG may help to provide impartial scrutiny, strengthen assurance and build trust in the offering system while the approach should align with other NHSBT approaches to offering scheme monitoring.

The National Audit Office undertook a review of operational aspects of the scheme in 2020 and highlighted the need for operational monitoring of occurs through LAG core group, but this is not undertaken in a formal way. There is a need to ensure there is regular operational oversight of the scheme.

Specific KPIs should be developed once the scheme is finalised to ensure the objectives of the scheme are met. These should be against the principles of the scheme broadly as structure measures, process measures, outcome measures and balancing measures. It will be up to LAG/NHSBT to agree the specific KPIs. However, these could include:

- **Structure measures**

1. Undertaking an equality impact assessment
2.Outstanding approved modifications to the scheme not implemented
3. Existence of operational workarounds to support scheme delivery
4.The interval from a recommended change to implement these changes should be monitored against pre-specified timeframes appropriate to the severity of the impact it has on patients, staff and resource. When changes are recommended, time frames should be agreed with the Chair of the LAG and the MD of OTDT to inform prioritisation.
5. Availability of a prioritisation tool prior to release of the scheme.
6.Free availability of data that underpins the scheme from the transplant registry provided GDPR is met.
7. Timely publication of the mechanics of the proposed scheme in peer reviewed journals to document the history and evolution of UK liver offering.
8. There should be an open and transparent mechanism for formal escalation of concerns from patients, clinicians & centres to record issues with the scheme. Themes that arise from complaints and enquiries about the scheme should be monitored.
9.Consideration should be given to a survey of professional and non-professional stakeholders at an interval after the system has bedded down and centres and patients are familiar with it (after 2-3 years).
10.An established nationally standardised process for centre-based recipient selection and transplantation at inception of the scheme.
11. An established monitoring process for the scheme on inception
12.A national process for awarding standardised exception points for selected indications.
13.If agreed, a national appeals process for awarding exception points.
14.Monitor against instances when lack of resources has resulted in organ declines

- **Process Measures**

1. Number (%) organs transplanted after centre-based recipient selection.
2. Monitoring of how well the predicted outcome match the modelling.

- **Outcome Measures**

1. Non worsening of wait list mortality (from listing and overall) at early time points (3 and 6 months) from registration but also long-term wait list outcomes at 12, 24 and 36 months and overall wait list outcomes including existing patients waiting on the list.
2. Patient and graft outcomes from the point of transplant, overall and by graft type DBD, DCD, split etc.
3.Intention to treat outcomes on the wait list at 6 and 12 months and annually up to 5 years.
4. Rates and utilisation of late declines amongst centres
5.If an appeals process for prioritisation is established, then to monitor centre and patient appeals against prioritisation and outcomes.

- **Balancing Measures**

1. Post transplant patient and graft survival by graft type (DBD, DCD, split etc)
2. Monitoring the performance of the scheme against protected characteristics in particular deaths and removals (too sick).
3.Deaths and drop offs (too sick) from the list by aetiology
4.Wait time, by age and disease categories
5. Transplant rate by prioritisation score by populations to establish areas of unmet need.
6. Number of appeals, outcomes
7. Number of cases of exception points
8. Long waiting populations with few or no offers received
9. Recipient selection when centre-based recipient selection and transplantation is undertaken.
10.Total travel distances of donor organs within the scheme (road & flights) and total travel costs
11.Use of flights, frequency (use v anticipated road travel time >5 hours) and cost.

This list is not exhaustive but could provide a framework for constructing KPIs.

A limited number of predefined outcomes measures to reflect equity, transparency, sustainability and agility should be developed alongside the development of the new offering scheme. These could include composite measures such as the equity assessment utilised by OPTN (https://insights.unos.org/equity-in-access/).

A structured approach to concerns about the scheme when they are raised is required such that independent review can occur out with the scheduled review meeting structure based on the clinical impact of the concern. The scheme needs to be easily modifiable and appropriate ongoing resource needs to be planned for the scheme to support the timely refinement of the scheme when required which the complexity and

rigidity of the current team does not facilitate. Agility of the scheme to accommodate change in the future is essential.

Modelling of the impact of the scheme will be undertaken during development, iteration and in advance of implementation to the scheme to assess impact on groups and centres in the interests of transparency.

Recommendations

10.1 There should be structured, independent monitoring of NLOS including operational aspects.

10.2 Continuous refinement to the system should be anticipated and resource to enable this should be put in place.

10.3 Monitoring should confirm the key principles of the scheme, namely meeting need, equity, transparency, simplicity, stakeholder engagement, agility and sustainability (indicative metrics have been recommended) are being met.

10.4 Refinement of the scheme is warranted if pre-specified KPIs are not being met.

10.5 The NLOSRC recognise that supply of donor organs is becoming more limited. If this situation continues it may be appropriate to review minimal listing criteria.

CONCLUSION

In summary, the NLOSRC recommends changes to NLOS to improve equity, transparency and consistency in liver offering. A revised system should adopt a needs-based approach using the best validated score for prioritisation. Liver offering should consider geography and waiting time where clinical priority is broadly equivalent. All donor livers should be subject to a standardised offering process, supported by clear rules for exception points, centre-based selection, and/or clinical appeals where appropriate. Operational reliability should be ensured through agile IT infrastructure and performance monitored against pre-defined key performance indicators.

APPENDICES

Appendix 1 – Terms of Reference for the NLOS Review

Appendix 2 – Non-professional stakeholder engagement: Survey
Questionnaire
Demography of responses
Outcomes
Summary and manual theming

Appendix 3 – Non-professional stakeholder engagement: Focus Groups
Summary of 3 focus group
Thematic review of focus groups from Laura

Appendix 4 – Stakeholder input: from PSC Support and other groups and individuals
Copy of letter embedded

Appendix 5 – Professional stakeholders event January 2025
Agenda
Mentimeter summary & feedback
Written feedback after the event

Appendix 6 – Stakeholder Feedback on Draft NLOS report (V11.2 pdf): Patient Groups

Copy of pdf of v11.2 embedded

Agenda
Mentimeter
Microsoft Forms feedback

Appendix 7 - Stakeholder Feedback on Draft NLOS report (V11.2 pdf): Patients, Families, Donor Network
Agenda
Mentimeter
Microsoft Forms feedback

Appendix 8 - Stakeholder Feedback on Draft NLOS report (V11.2 pdf): Healthcare Professional Groups
Agenda
Mentimeter
Microsoft Forms feedback