



OrQA-UK Trial Organ Quality Assessment

**Organ Quality Assessment:
Novel clinical trial of an
Artificial Intelligence (AI)
enabled photograph
assessment tool to
improve organ utilisation
in the UK**

The Organ Quality Assessment (OrQA) tool

Organ transplants have greatly improved the outlook for patients with organ failure, but there are not enough organs available to meet demand. Up to 40% of donated organs are not used due to concerns about their quality.

Liver quality can be assessed by sending a small piece (biopsy) to a laboratory, but this may take too much time and prevent suitable organs from being transplanted. Surgeons make their own judgement on the quality of organs by taking out the donor organ to judge its health by how it looks and feels. Organ photographs are often used alongside the surgeon's assessment as part of this decision-making process. Organ photographs are uploaded to the TransplantPath NHS online platform, which is used for transplant administration, but image quality can vary and is open to error. As a result, transplant surgeons may choose to be cautious, meaning good quality organs may not be used.

An Artificial Intelligence (AI)-powered tool called OrQA (Organ Quality Assessment) has been created to help standardise the quality assessment of organ photographs. The tool refers to a database, which has used experienced surgeons' opinions to review liver images, to accurately assess the organ's quality and give it a quality score.

About the OrQA-UK trial

The OrQA-UK trial aims to assess whether the OrQA tool can assist transplant surgeons in evaluating the quality of donated livers and reduce the number of livers discarded for transplantation by 25%. If the OrQA tool improves the quality assessment of organs, it could lead to 60 extra liver transplants taking place per year, using current levels of donated organs.

The trial will use the TransplantPath platform, which contains information on organ donors submitted by Specialist Nurses in Organ Donation. During the liver retrieval process, surgeons assess the health of livers, and this information is

then added to the TransplantPath record alongside organ photographs taken by the Specialist Nurses.

In the OrQA-UK trial, photographs of donated livers will be automatically sent to the OrQA system, where a score reflecting the quality of the liver will be calculated. This score is then added to a secure trial database held by Newcastle University.

The donated livers will then be randomly allocated to either having an OrQA score attached to them, or not, on TransplantPath. Surgeons can then use this score as part of their decision-making process when reviewing the quality of donated organs. This will allow the research team to assess whether the OrQA tool is helpful to surgeons in evaluating the quality of donated livers, while still ensuring patient safety.

Why have I been given this information?

You have been given this information because you are currently waiting for a liver transplant. If a suitable donor liver becomes available for you, photographs of this liver may have been reviewed by the OrQA tool and the OrQA quality score may have been provided to the Transplant Surgeon to help support their review of the liver's quality. The final decision on whether to transplant a liver will always be made by the transplant surgeon.



How might the OrQA-UK trial affect patients?

The OrQA-UK trial will not change your personal care or transplant outcome. The trial has been designed to have no burden for transplant patients. Patients are not directly recruited into this trial; only donor liver photographs are analysed and randomly assigned to either having an OrQA score attached to them, or not.

Data needed for the trial will be collected directly from TransplantPath and the UK Transplant Registry (managed by NHS Blood & Transplant). This means that there are no extra steps or clinic visits in relation to this trial.

The research team will only use the collected data to analyse how helpful the OrQA tool is to surgeons.

All patients who are added to the UK liver transplant wait list are informed that it is a requirement for them to also be registered on the UK Transplant Registry and for certain personal details and clinical information to be collected. You can stop your confidential patient information being used for research by registering your decision with NHS Blood & Transplant. If you are happy with your confidential patient information being used for research, you do not need to do anything. Information about this, published by NHS Blood & Transplant for patients, can be accessed via the QR code or here: <https://www.nhsbt.nhs.uk/organ-transplantation/resources/how-we-use-your-information/>



What are the possible benefits of the trial?

The potential benefit for liver recipients is that the number of liver transplants done each year may increase and waiting times for a transplant may be reduced.

Are there any risks for recipients?

This trial does not directly recruit patients and has been designed to have no risk or burden for transplant recipients. The trial involves the use of an additional software system (OrQA). The NHS Blood & Transplant internal approval body has reviewed the trial to make sure it does not change the standard organ donation and offering pathway for recipients. The use of the OrQA tool will not change the care you will receive at your transplant centre.

Your personal information will not be shared with the OrQA tool. Only liver donor data will be shared with OrQA. Information about liver recipients that is needed for the trial will be collected from the UK Transplant Registry. Although the UK Transplant Registry includes personal data about recipients, this will not be used for the trial. At no point will any identifiable information about you (e.g. name, date of birth) be seen by the research team. If you wish to learn more about the OrQA-UK trial, you can find more information on the trial website. This includes a Frequently Asked Questions section, which can be accessed using the QR code in the Contact Us section.

How will your data be used?

The Newcastle upon Tyne Hospitals NHS Foundation Trust is the Sponsor for this trial. The research team will be using information from your transplant records to undertake this trial, and the Sponsor and NHS Blood & Transplant will act as the trial Data Controllers. This means that they are responsible for looking after your information and using it properly. Newcastle upon Tyne Hospitals NHS Foundation Trust will keep anonymised information for a minimum of 5 years after the trial has finished.

Your rights to access, change or move your information are limited, as the trial team need to manage your information in specific ways for the research to be reliable and accurate. To safeguard your rights, the trial team will use the minimum personally identifiable information possible.

You can find out more about how your information is used at:

<https://www.hra.nhs.uk/planning-and-improving-research/policies-standards-legislation/data-protection-and-information-governance/gdpr-guidance/templates/template-wording-for-generic-information-document/> (or via the QR code), by contacting OrQATrial@nhsbt.nhs.uk or via the trial website.



What will happen to the trial results?

The results of the trial will be published in scientific journals and discussed at medical conferences. A lay summary of the results will be made available for patient groups on the trial website. Your personal information will not be identifiable in any way.

What to do if you have a concern

If you have a concern or complaint relating to the OrQA-UK trial this can be reported to The NHSBT Organ and Tissue Donation and Transplantation Patient Safety Team via email (complaintsandcompliments@nhsbt.nhs.uk). You can also raise complaints with the Patient Advice and Liaison Service (PALS) office at your local hospital.

Who has reviewed the trial?

All research in the NHS is looked at by an independent group of people, called a Research Ethics Committee. This trial has been reviewed and given a favourable opinion by the Yorkshire & The Humber – Sheffield Research Ethics Committee (Ethics reference: 26/YH/0086). This trial has also been reviewed by the Medicines and Healthcare products Regulatory Agency (MHRA).

Contact Us



OrQA-UK Trial Team:
07553 525940



OrQATrial@nhsbt.nhs.uk



The OrQA-UK trial website can be accessed using the QR code or at

<https://www.nhsbt.nhs.uk/clinical-trials-unit/trials-and-studies/organ-donation-and-transplantation/orqa-uk/>

