NICE National Institute for Health and Care Excellence

NICE guidance

Ex-situ machine perfusion for extracorporeal preservation of lungs (ex-vivo lung perfusion) for transplant

HealthTech guidance
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www.nice.org.uk/guidance/htg580

Your responsibility

This guidance represents the view of NICE, arrived at after careful consideration of the evidence available. When exercising their judgement, healthcare professionals are expected to take this guidance fully into account, and specifically any special arrangements relating to the introduction of new interventional procedures. The guidance does not override the individual responsibility of healthcare professionals to make decisions appropriate to the circumstances of the individual patient, in consultation with the patient and/or guardian or carer.

All problems (adverse events) related to a medicine or medical device used for treatment or in a procedure should be reported to the Medicines and Healthcare products Regulatory Agency using the Yellow Card Scheme.

Commissioners and/or providers have a responsibility to implement the guidance, in their local context, in light of their duties to have due regard to the need to eliminate unlawful discrimination, advance equality of opportunity, and foster good relations. Nothing in this guidance should be interpreted in a way that would be inconsistent with compliance with those duties. Providers should ensure that governance structures are in place to review, authorise and monitor the introduction of new devices and procedures.

Commissioners and providers have a responsibility to promote an environmentally sustainable health and care system and should assess and reduce the environmental impact of implementing NICE recommendations wherever possible.

Contents

This guidance replaces IPG695.

1 Recommendations

1.1 Evidence on the safety and efficacy of ex-situ machine perfusion for extracorporeal preservation of lungs for transplant is adequate to support the use of this procedure provided that standard arrangements are in place for clinical governance, consent and audit. Find out what standard arrangements mean on the NICE guidance page.

1.2 Clinicians and centres doing this procedure must follow the relevant regulatory and legal requirements of the Human Tissue Authority.

1.3 Clinicians should enter details about all patients having this procedure and details about the device used into the NHS Blood and Transplant Organ Donation and Transplantation registry.

2 The condition, current treatments and procedure

The condition

2.1 Lung transplant is usually done in patients with non-malignant advanced or end-stage pulmonary diseases (such as severe pulmonary fibrosis, cystic fibrosis, pulmonary hypertension and obliterative bronchiolitis) that is minimally responsive or unresponsive to treatment and who have a life expectancy of less than a year. This improves patients' quality of life and prolongs survival.

2.2 On average, 20% of potential deceased donor lungs in the UK are used for transplant. The rest are considered unsuitable, usually because of complications associated with attempts to save the donor or injury which happens in association with death. Limited availability of deceased donor lungs that meet standard criteria for transplant results in up to 30% of patients clinically deteriorating and dying while waiting for a lung transplant.

Current treatments

2.3 Standard lung transplant protocol involves cold preservation to maintain the donor lungs. Various other strategies are used to increase the available pool of deceased donor lungs, and these include brain death donor lungs from extended criteria donors and donors after circulatory death. Living donor lobal or lung transplant is another option.

The procedure

2.4 Ex-situ machine perfusion for extracorporeal preservation of lungs (ex-vivo lung perfusion, EVLP) is a technique of lung preservation that may allow donor lungs to be preserved for longer in better physiologic conditions, and may allow

marginal donor lungs or pulmonary grafts which are working poorly to be improved and reconditioned so that they can be used in lung transplant.

2.5 Ex-situ machine perfusion for extracorporeal preservation of lungs is done once the lungs have been removed from the donor after cold pulmonary flush using surgical techniques. An adequate donor left atrial cuff and pulmonary artery are preserved to allow anastomosis to the recipients' organs.

2.6 After being transferred in cold solution and being ischemic for a period of time, the lungs are placed in a specially designed organ chamber and connected to a modified heart–lung bypass machine, a ventilator and filtration or EVLP system. A specialised nutrient solution (perfusate) is pumped from the filtration or EVLP system through a perfusion circuit (gas exchange membrane, heat exchanger and leukocyte filter) under optimal colloid pressure through the pulmonary artery to the lungs. Pulmonary effluent from the pulmonary veins drains back to the EVLP system and is recirculated. Perfusion flow is then gradually increased, pulmonary artery pressure is carefully monitored, and protective controlled mechanical lung ventilation with low tidal volume and positive end expiratory pressure is started. The lungs are gradually rewarmed to body temperature while reaching a targeted flow. EVLP is possible for a number of hours after removal from the donor. During this period, the lungs can be assessed and, if necessary, treated to remove unwanted fluid, and to re-expand areas of lung that have collapsed (atelectatic areas). If EVLP-treated lungs recover well enough, they may be considered suitable for transplant in the conventional way.

2.7 Ex-situ machine perfusion can be done using different devices or machines and protocols. The perfusate composition, perfusion and ventilation settings (target flow, temperature, pressure) may vary.

3 Committee considerations

The evidence

3.1 NICE did a rapid review of the published literature on the efficacy and safety of this procedure. This comprised a comprehensive literature search and detailed review of the evidence from 7 sources, which was discussed by the committee. The evidence included 3 meta-analyses, 3 retrospective cohort studies and 1 prospective case series. It is presented in the summary of key evidence section in the overview. Other relevant literature is in the appendix of the overview.

3.2 The professional experts and the committee considered the key efficacy outcomes to be: lung function after transplant, patient survival after transplant and quality of life.

3.3 The professional experts and the committee considered the key safety outcomes to be: primary graft dysfunction and prolonged lung recovery (for example, needing extracorporeal membrane oxygenation [ECMO]).

3.4 Patient commentary was sought but none was received.

Committee comments

3.5 The intention of the procedure is to allow better assessment of marginal lungs allowing them to be used more frequently, so increasing the number of lungs available for transplant.

Update information

Minor changes since publication

January 2026: Interventional procedures guidance 695 has been migrated to HealthTech guidance 580. The recommendations and accompanying content remain unchanged.

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Endorsing organisation

This guidance has been endorsed by Healthcare Improvement Scotland.