

## Professional Expert Questionnaire

**Technology/Procedure name & indication:** Ex-situ machine perfusion for extracorporeal preservation of lungs for transplantation

### Your information

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<b>Professional organisation or society membership/affiliation:</b>	Royal College of Surgeons(RCS), Society Cardiothoracic Surgery (SCTS, UK), European Society Cardiothoracic Surgery (EACTS), German Society Cardiothoracic Surgery, Society Heart Valve Disease
<b>Nominated/ratified by (if applicable):</b>	Click here to enter text.
<b>Registration number (e.g. GMC, NMC, HCPC)</b>	GMC 6137201

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I give my consent for the information in this questionnaire to be used and may be published on the NICE website as outlined above. If consent is NOT given, please state reasons below:

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**Please answer the following questions as fully as possible to provide further information about the procedure/technology and/or your experience**

<p><b>1</b></p>	<p>Please describe your level of experience with the procedure/technology, for example:</p> <ul style="list-style-type: none"> <li>- Are you familiar with the procedure/technology?</li> </ul> <p>Have you used it or are you currently using it?</p> <ul style="list-style-type: none"> <li>- Do you know how widely this procedure/technology is used in the NHS or what is the likely speed of uptake?</li> <li>- Is this procedure/technology performed/used by clinicians in specialities other than your own?</li> <li>- If your specialty is involved in patient selection or referral to another specialty for this procedure/technology, please indicate your experience with it.</li> </ul>	<p>We use Ex-situ machine perfusion for extracorporeal preservation of hearts and lungs for transplantation</p> <p>Yes</p> <p>Yes</p> <p>In heart and liver transplantation as well</p> <p>We use this technology in border line lungs for transplantation for assessment and optimization</p>
<p><b>2</b></p>	<ul style="list-style-type: none"> <li>- Please indicate your research experience relating to this procedure (please choose one or more if relevant):</li> </ul>	<p>I have done bibliographic research on this procedure.</p> <p>I have done research on this procedure in laboratory settings (e.g. device-related research).</p> <p>I have done clinical research on this procedure involving patients or healthy volunteers.</p>

<b>3</b>	How innovative is this procedure/technology, compared to the current standard of care? Is it a minor variation or a novel approach/concept/design?	Very innovative technology
<b>4</b>	Does this procedure/technology have the potential to replace current standard care or would it be used as an addition to existing standard care?	Technology has a potential to replace current the standard procedure

### Current management

<b>5</b>	Please describe the current standard of care that is used in the NHS.	Lungs are currently procured on ice for transfer and subsequent transplantation
<b>6</b>	Are you aware of any other competing or alternative procedure/technology available to the NHS which have a similar function/mode of action to this?  If so, how do these differ from the procedure/technology described in the briefing?	Ex-situ machine perfusion can be used as 1. an alternative transport technology or 2. for assessment and optimization of border line lungs (ex vivo lung perfusion)  Requires complex perfusion and ventilation technology

### Potential patient benefits and impact on the health system

<b>7</b>	What do you consider to be the potential benefits to patients from using this procedure/technology?	<ol style="list-style-type: none"> <li>1. potentially better outcome after lung transplantation</li> <li>2. Higher utilization rate of lungs for transplantation</li> </ol>
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8	Are there any groups of patients who would particularly benefit from using this procedure/technology?	End stage lung failure patients waiting for lung transplantation
9	Does this procedure/technology have the potential to change the current pathway or clinical outcomes to benefit the healthcare system?  Could it lead, for example, to improved outcomes, fewer hospital visits or less invasive treatment?	Yes  Improved outcome and more organs suitable for transplantation
10 - MTEP	Considering the care pathway as a whole, including initial capital and possible future costs avoided, is the procedure/technology likely to cost more or less than current standard care, or about the same? (in terms of staff, equipment, care setting etc)	Will cost considerable more
11 - MTEP	What do you consider to be the resource impact from adopting this procedure/technology (is it likely to cost more or less than standard care, or about same-in terms of staff, equipment, and care setting)?	Will cost considerable more
12	What clinical facilities (or changes to existing facilities) are needed to do this procedure/technology safely?	Highly specialized transplant centres
13	Is any specific training needed in order to use the procedure/technology with respect to efficacy or safety?	Complex training with dedicated operators

## Safety and efficacy of the procedure/technology

<p><b>14</b></p>	<p>What are the potential harms of the procedure/technology?</p> <p>Please list any adverse events and potential risks (even if uncommon) and, if possible, estimate their incidence:</p> <p>Adverse events reported in the literature (if possible, please cite literature)</p> <p>Anecdotal adverse events (known from experience)</p> <p>Theoretical adverse events</p>	<p>Damage to perfused lungs</p> <p>Oedema of the lung</p> <p>Ischemia reperfusion injury after transplantation</p> <p>Damage to left atrial cuff</p>
<p><b>15</b></p>	<p>Please list the key efficacy outcomes for this procedure/technology?</p>	<p>Better lung performance, higher organ utilization, expansion of DCD organ donation</p>
<p><b>16</b></p>	<p>Please list any uncertainties or concerns about the efficacy and safety of this procedure/?</p>	<p>Clinical efficiency, cost effectiveness,</p>
<p><b>17</b></p>	<p>Is there controversy, or important uncertainty, about any aspect of the procedure/technology?</p>	<p>Expensive technology evolving evidence about clinical potential</p>

## Abstracts and ongoing studies

<p><b>18</b></p>	<p>Please list any abstracts or conference proceedings that you are aware of that have been recently presented / published on this procedure/technology (this can include your own work).</p> <p>Please note that NICE will do a comprehensive literature search; we are only asking you for any very recent</p>	<p>Not aware about any in 2020</p>
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	abstracts or conference proceedings which might not be found using standard literature searches. You do not need to supply a comprehensive reference list but it will help us if you list any that you think are particularly important.	
19	Are there any major trials or registries of this procedure/technology currently in progress? If so, please list.	OCS™ Lung TOP Registry For Donor Lungs for Transplantation (TOP)

### Other considerations

20	Approximately how many people each year would be eligible for an intervention with this procedure/technology, (give either as an estimated number, or a proportion of the target population)?	In Harefield about 10-20% of our 50-60 lung transplants. Assume similar numbers in the entire UK
21	Are there any issues with the usability or practical aspects of the procedure/technology?	Complex technology with considerable need for qualified operators
22	Are you aware of any issues which would prevent (or have prevented) this procedure/technology being adopted in your organisation or across the wider NHS?	Costs
23	Is there any research that you feel would be needed to address uncertainties in the evidence base?	Interim analysis of OCS™ Lung TOP Registry For Donor Lungs for Transplantation (TOP)
24	Please suggest potential audit criteria for this procedure/technology. If known, please describe: <ul style="list-style-type: none"> <li>- Beneficial outcome measures. These should include short- and long-term</li> </ul>	Beneficial outcome measures:  Less complication rate, less primary graft dysfunction. Higher organ utilization

	<p>clinical outcomes, quality-of-life measures and patient-related outcomes. Please suggest the most appropriate method of measurement for each and the timescales over which these should be measured.</p> <ul style="list-style-type: none"> <li>- Adverse outcome measures. These should include early and late complications. Please state the post procedure timescales over which these should be measured:</li> </ul>	<p>Adverse outcome measures:</p> <p>Higher complication rate, higher primary graft dysfunction. Similar or Lower organ utilization</p>
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**Further comments**

<p><b>25</b></p>	<p>Please add any further comments on your particular experiences or knowledge of the procedure/technology,</p>	<p>Harefield is the worldwide leading centre in OCS for heart transplantation</p>
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**Declarations of interests**

Please state any potential conflicts of interest relevant to the procedure/technology (or competitor technologies) on which you are providing advice, or any involvements in disputes or complaints, in the previous **12 months** or likely to exist in the future. Please use the [NICE policy on declaring and managing interests](#) as a guide when declaring any interests. Further advice can be obtained from the NICE team.

Type of interest *	Description of interest	Relevant dates	
		Interest arose	Interest ceased
Choose an item.			
Choose an item.			
Choose an item.			

I confirm that the information provided above is complete and correct. I acknowledge that any changes in these declarations during the course of my work with NICE, must be notified to NICE as soon as practicable and no later than 28 days after the interest arises. I am aware that if I do not make full, accurate and timely declarations then my advice may be excluded from being considered by the NICE committee.

**Please note, all declarations of interest will be made publicly available on the NICE website.**

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