National Institute for Health and Clinical Excellence

29/2 – Extracorporeal membrane oxygenation for severe acute respiratory failure in adults

Consultation Comments table

IPAC date: Thursday 9 December 2010

Com. no.	Consultee name and organisation	Sec. no.	Comments	Response Please respond to all comments
1	Consultee 1 Senior Charge Nurse	**1**	The patients we treated in Aberdeen last winter were all in extreme hypoxaemia. Â This was due then to H1N1. Â We fully liased with the ECMO centre in Leicester and treated with ECMO. Â All survived. Â Relatives were informed of the risk, but all decided to go ahead with the treatment. It is my opinion that the patients had reached the end of our current management and we were at a stage where we could offer anything else. Â They would have died without ECMO, but they didnt.	Thank you for your comment.
2	Consultee 2 Chair Intensive Care society standard committee	**1**	The Intensive Care Society Standards Committee and Council agree with these recommendations on the proposed use of ECMO in adults	Thank you for your comment.

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3	Consultee 3 ECMO provider, Lead clinical investigator of CESAR Trial NHS Professional	**1**	Your assesment of the CESAR Trial is not reasonable. Â There was a clear treatment advantage with an NNT of 6. Â The study design was pragmatic and demonstrated that for patients in the UK with Severe but potentially reversible respiratory failure a strategy of transferring patients to a single centre for consideration of ECMO significantly improved survibval to 6 months without disability. The experience during the H1N1 epidemic confirmed these findings. This service is currently centrally commisioned by NCG and should only be provided by clinicians with specific training and governance arrangements.	Thank you for your comment. A statement regarding the CESAR trial will be added to the guidance.
4	Consultee 4 NHS Professional	**1**	I agree with all of the above especially at this moment in time. However the indications for ECMO, its cost and ease of use of the technology is not static but dynamic. Unless ECMO develops in the UK we will not be able to perform basic & outcomes research to advance this therapy for patients. Â One centre is not enough. With regards to patient information, the risks and uncertainties of mechanical ventilation rescue therapies should be included to give patients and/or relatives balanced and best information. Mechanical ventilation is not risk free and some of the rescue treatments are not based on solid foundations. Noble DW, Peek GJ. Extracorporeal membrane oxygenation for respiratory failure: past present and future.(Editorial) Anaesthesia 201065:971-4. Diaz JV, Brower R, Calfee CS, Matthay MA.(Review) Therapeutic strategies for severe acute lung injury. Crit Care Med 201038:1644–50. Soni N, Williams P. Positive pressure ventilation: what is the real cost? (Review) British Journal of Anaesthesia 2008101:446–57.	Thank you for your comment. Section 1.2 of the guidance states that ‘Whenever possible, ensure that patients and their families or carers understand the uncertainty about the procedure’s efficacy and its risks and provide them with clear written information. In addition, the use of NICE’s information for patients (‘Understanding NICE guidance’) is recommended.’

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5	Consultee 5 National Specialised Commissioning Group	**1.3**	***The following comments were made in the course of a meeting between NICE and the NSCG on 19/11/10, and are deemed by NICE to be relevant consultation comments to present to IPAC in relation to this procedure:*** The NSCG has developed 'Standards for Nationally Designated Centres for Extra-corporeal Membrane Oxygenation (ECMO) for Adults with Severe Potentially Reversible Respiratory Failure.' This is intended to limit the availability of the service to centres that meet the required standards. It would be very helpful if the guidance could reinforce this.	Thanks you for your comment. The Committee considered this comment and added a section 3.1 to the guidance.
6	Consultee 3 ECMO provider, Lead clinical investigator of CESAR Trial NHS Professional	**2.1**	Arteriovenous extracorporeal membrane carbon dioxide removal, also known as pumpless extracorporeal lung assist, can only be used to remove CO2, not to support oxygenation. Â The evidence base for efficacy of this technique is less well developed than for full flow VV ECMO. Â There is a significant (approx 10%) incidence of clinical limb ischaemia requiring intervention and sometimes amputation.	Thank you for your comment. The guidance will not be changed.
7	Consultee 6 NHS Professional	**2.1**	Is it possible to add? 2.1.4 Other modes of ventilatory support (such as High Frequency Oscillatory Veniltation (HFOV) and Airway Pressure Release Ventilation (APRV)) are available and ungoing clinical evaluation.	Thank you for your comment. The guidance will not be changed.

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8	Consultee 4 NHS Professional	**2.1**	Although, the above covers the most frequent indication it has been used for other situations too in this country and others. Partial support (CO2 removal) may prevent mechanical ventilation induced lung injury. This remains experimental at present. CO2 removal has been used to avoid invasive ventilation (pumpless assist). ECMO has been also used as bridge to transplantation without mechanical ventilation, as well as support for donor organs and as part of cardiopulmonary resuscitation. We may follow practice being pioneered in other countries presently and indications may expand in terms of different conditions. It might expand in terms of ealier use in ARDS: Averting damage done by "heroic ventilation" rather than initiation after severe damage has occurred. Gaffney AM, et al Extracorporeal life support.(Clinical Review) BMJ 2010 (6th Nov) 341:982-6. Noble DW, Peek GJ. Extracorporeal membrane oxygenation for respiratory failure: past present and future.(Editorial) Anaesthesia 201065:971-4.	Thank you for your comment. The guidance will not be changed.
9	Consultee 4 NHS Professional	**2.2**	It may be worth noting that degree of anticoagulation required usually approximates to that needed for the much commoner procedure of haemodialysis or haemofiltration within the intensive care unit.	Thank you for your comment. The guidance will not be changed.
10	Consultee 4 NHS Professional	**2.3**	Are the non-randomized trials relevant? The results from Aberdeen (n13) give an overall survival of ~60%. Â Two patients received CPR immediately prior to ECMO with one survivor. ECMO patients were far more ill than patients with ARDS who we did not consider for ECMO. I do not see how the observational studies, given their design, and much greater severity of illness of ECMO-treated patients versus the conventionally managed patients (documented in your overview) can provide useful or valid comparative information. What message can be taken from that data that will be of relevance to the reader?	Thank you for your comment. Section 2.3.2 of the guidance will be changed and a section 2.5.1 will be added to reflect the Committee's discussions on the ECMO study design.

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11	Consultee 1 Senior Charge Nurse	**2.4**	In Aberedeen we have 14 Nurses and 3 Doctors all trained in the procedure. Â All have passed to the level expected at the National centre in Leicester. Â This minimises the risk as best as we can and ensures best practice. In Aberdeen we are very enthusiastic about ECMO and have had papers published (BACCN September) reflecting on our experiences.	Thank you for your comment.
12	Consultee 3 ECMO provider, Lead clinical investigator of CESAR Trial NHS Professional	**2.4**	ECMO should only be provided in units with foramlly established ECMO programmes. Â Clinicians providing ECMO should have received specific training in an established centre. Â There should be formal clinical governance arrangements and all cases should be reportred to the ELSO registry.	Thank you for your comment. Section 1.1 of the guidance states that the procedure should only be used with special arrangements for clinical governance, consent and research. Section 1.3 states that the procedure should only be carried out by clinical teams with specific training and expertise in the procedure. Section 1.4 states that clinicians are encouraged to submit data on all adults undergoing ECMO for severe acute respiratory failure to the international Extracorporeal Life Support Organization register.
13	Consultee 4 NHS Professional	**2.4**	It is the NET benefit or detriment that is most relevant to patients and/or their relatives. The CESAR trial indicates that by the a priori defined composite end-point of survival or severe disability there is a net benefit to patients despite procedure related complications and perhaps that needs to be emphasised. In our very small series (n13) only one patient has suffered a major complication that might have been ECMO related. Bleeding has occurred in several patients but has not been clinically problematic. No patient died on ECMO.	Thank you for your comment.
14	Consultee 4 NHS Professional	**General**	I work in a general intensive care unit that has provided ECMO for patients over the last 8 years. We cared for 5 H1N1 patients with ECMO technology and all survived.	Thank you for your comment.