The Committee gives its approval for recent advice given in a letter sent to CEOs By Paul Phillips which included this briefing paper (1) regarding the use of mechanical devices in resuscitation. An excerpt of a letter from Sir Muir Gray (Director of Clinical Knowledge, Process and Safety) is also appended (2).

In summary, JRCALC

1) supports the need for research into the clinical effectiveness of these units
2) cannot recommend the introduction of further units at this time, unless to be used as part of an approved trial
3) recognises that units are already in circulation and recommends their continued use only in the context of an approved trial.

1. Briefing Paper.

Mechanical Compression: request for advice on continued but limited and centrally supervised deployment by Ambulance Trusts that are currently using LUCAS or AutoPulse Devices.

A small number of Trusts have adopted mechanical compression devices for routine management of cardiac arrest whenever a device is available on the ambulance. LUCAS has been deployed most commonly (five Trusts) but AutoPulse has also been used.

Whilst both have a CE mark and have been introduced in a small number of services in some other European countries and in parts of the United States, neither device has been shown convincingly to improve survival and as a result recommendations for use do not feature in national and international resuscitation guidelines. Anecdotal reports and one small case series (1) do suggest that in some circumstances patients may survive after lengthy periods of dependency on prolonged mechanical compression, even to the point of intervention for critical coronary disease (2), but in the absence of evidence from randomized trials the overall risk benefit ratio cannot be assessed. The only randomized study reported to date of the AutoPulse showed a trend to worse outcome than conventional CPR (3). The trial, however, had serious flaws due chiefly to cluster randomization and important mismatch of the groups. It is now being repeated with individual randomization. For the LUCAS device, a single pilot randomised trial showed no benefit over conventional chest compression but again this study had several flaws (4). An international trial of LUCAS is planned for 2007 after the completion of pilot studies carried out in at least three countries.

The University of Birmingham undertook an evaluation of the scientific evidence for the LUCAS device, and concluded that:

'Given the current evidence we can only conclude that it [the LUCAS] is still an experimental device with unknown effectiveness over manual methods of CPR' until and unless evidence can be shown for overall benefit, the ambulance service has been advised by—amongst others—Professor Roger Boyle, to discourage further use outside properly randomized trials, or in special circumstances agreed by

relevant authorities. This advice is based primarily on concerns for patient safety and good governance. Ambulance Chief Executives have accepted this advice.

Two 'special circumstances' have been suggested subject to close supervision at national level and have been agreed in principle by Professor Boyle, subject of course to approval by the Clinical/Medical Directors and by JRCALC. We will also be seeking the advice of an appropriate research ethics committee on the distinction between research and audit in this context.
The special circumstances proposed are cases for whom recovery with conventional CPR has been shown to be exceedingly low:

- Patients with asystole or PEA after bystander-witnessed (sight or sound) arrest who have received at least bystander CPR within 10 minutes of collapse and for whom transport to hospital is deemed appropriate.
- Patients with ventricular fibrillation refractory to 5 shocks (persistence or recurrence of fibrillation) in whom a decision is made to transport whilst the arrhythmia persists.

Survival for patients transported during on-going cardiac arrest has been shown to be 0 to 0.5% (4,5,6), though survivals have been recorded if mechanical compression is used (1,2).

Whilst the devices have been marketed primarily on their putative clinical benefits, also of considerable importance is the known risk of injury to ambulance personal attempting CPR in a moving vehicle (7), coupled with their reluctance to abandon a resuscitation attempt outside the provisions of ROLE for recognition of death. In this regard, mechanical CPR during transport has been advocated as an option to avoid such risks (8).

The proposed supervision would be overseen by an expert committee to be approved by the Clinical/Medical Directors and by JRCALC with on-going scrutiny of results (suggested list at the end of the document). The committee will report to the Ambulance Chief Executives, to JRCALC, and to Professor Boyle at the Department of Health at least quarterly. If the results should prove appreciably better than expected from previous experience, then a randomized trial in these groups should be considered and could be undertaken within the UK

Thus the present intention is to limit the use of mechanical devices under the conditions of the audit *only* to Trusts that already have experience of their use, and restricted to situations where survival is *extremely* unlikely with conventional methods but seemingly not rare with the current limited knowledge of mechanical devices. Thus use of compression devices would no longer be acceptable for 'routine' use outside these specified indications.

With the present state of knowledge, Services would be discouraged from making or sanctioning new purchases of compression devices. But Professor Boyle has suggested a parallel approach to NICE to establish an official view on this point and we will be writing to NICE for advice.

Limited Reference List (expanded on request).

Steen S, Sjöberg T, Olsson P, Young M. Treatment of out-of- hospital cardiac arrest with LUCAS, a new device for automatic mechanical compression and active decompression resuscitation. Resuscitation 2004;67:25-30

Wik L, Kiilb S. Use of an automatic mechanical chest compression device (LUCAS) as a bridge to establishing cardiopulmonary bypass for a patient with hypothermic cardiac arrest. Resuscitation 2005;66:391.

Hallstrom A, Rea TD, Sayre MR et al. Manual chest compression vs use of an automated chest compression device curing resuscitation following out-of-hospital cardiac arrest. A Randomized Trial. JAMA 2006;295:2620-28.

Axelsson C, Nestin J, Svensson L et al Clinical consequences of the introduction of mechanical chest compression in the EMS system for treatment of out-of-hospital cardiac arrest-a pilot study.Resuscitation 2006;71:47-55

http://www.arif.bham.ac.uk/requests/l/lucas-device-cardiac-arrest.htm

Gray WA, Capone RJ, Most AS. Unsuccessful emergency medical resuscitation—are continued efforts in the emergency department justified? New Engl J Med 1991;325:1393-8.

Kellermann AL, Hackman BB, Somes G. Predicting the outcome of unsuccessful pre-hospital advanced cardiac life support. JAMA 1993;270:1433-6.

Morrison LJ, Visentin LM, Kiss A, et al. Validation of a rule for termination of resuscitation of out-of-hospital cardiac arrest. New Engl J Med 206;355:478-87.

Jones AY, Lee RY. Cardiopulmonary resuscitation and back injury in ambulance officers. Int Arch Occup Environ Health. 2005;7:332-6.

Stapleton ER. Comparing CPR during ambulance transport. Manual vs. mechanical methods. JEMS 1991;16:63–8.

Proposed Expert Committee

Dr Tony Handley
Mr Paul Phillips for Chief Executives
Prof Douglas Chamberlain (Chairman)
Dr Mick Colquhoun for Resuscitation Council
Professor Tom Quinn
Ambulance Trust Clinical/Medical Director to be nominated
JRCALC representative Prof. C Deakin

December 2006

2. Letter from the Director of Clinical Knowledge, Process and Safety

Now that the Directors of Public Health are being appointed, we are starting a newsletter for the Directors for the public health contribution to commissioning and this will obviously focus on evidence-based topics.

I am planning, in my first letter, to highlight two particular issues which commissioners should address quickly, namely pulmonary artery catheters which have now been clearly demonstrated to do more harm than good, and mechanical devices for CPR for which there is not yet an evidence base sufficient to include them in commissioner considerations. The distinction between research and audit is clear. The aim of audit is to establish the degree to which an intervention with good evidence of doing more good than harm is included in practice; research is designed to determine the evidence. The two trials and the excellent Leader in the June 2006 Journal of the American Medical Association clearly indicate that mechanical devices for compression do not yet have an evidence base that would allow them to be considered for commissioning. I regard this as an issue which has nothing to do with resources because the evidence is simply insufficient for them even to enter debates about prioritisation.

J A Muir Gray, Kt, CBE, DSc, MD, FRCPSGlas, FCLIP
Director of Clinical Knowledge, Process and Safety.
8/11/06