4. Clinical Standards and Clinical Governance

4.1 Clinical Governance Arrangements

This section outlines suggested clinical governance for all charities and Ambulance Services providing air ambulance services, and the clinical processes that should be in place. In particular it advocates the adoption of best practice, clinical and non-clinical audit, clinical and non-clinical risk management, development of a shared model through multi-professional meetings and operational guidelines, regular peer review and clear lines of medical accountability.

The extent to which a charity will have clinical governance responsibility depends on the role of the charity. As indicated in Section 3.1 grant-giving charities will not have clinical governance responsibilities. In this case the Ambulance Service managing and providing the service will have responsibility.
For provider/operator charities:

- for charities which lease/own the aircraft and equipment but do not employ the staff, their responsibility will be to provide aircraft and equipment to a particular specification
- charities which employ clinical staff will have fuller clinical governance responsibilities.

There are two models by which Air Ambulance Units can assure clinical governance:

- the Air Ambulance Unit agrees to share the governance arrangements with one or more host NHS Ambulance Services or other suitable registered organisations. In this case the charity retains responsibility for clinical governance even though it may delegate authority
- the Air Ambulance Unit develops an autonomous governance arrangement which is recognised by the NHS Litigation Authority, and conforms to the CQC standards against which the local Ambulance Trusts are assessed.

Charities must ensure that they are clear as to the limit of their clinical governance responsibilities and that these are agreed with the Ambulance Service.

4.1.1 UK National Clinical Audit Advisory Group (NCAAG)

A National Clinical Audit Advisory Group should be instituted (to which all members report), whose membership represents all the constituent Air Ambulances Services. The Chair and Medical Director should be elected from local clinical advisory groups. The Medical Director should develop links with, or be a member of, the National Ambulance Directors of Clinical Care Group.

As part of the terms of reference, this group should oversee the development and review of nationally agreed clinical standard operating procedures.

There should be regular liaison with other organisations practising in the pre-Hospital field (CEM, Faculty of Pre-hospital Care, Royal College of Surgeons, BASICS, College of Paramedics) to ensure continuity of service and a seamless transition/provision of care. The standard operating procedures should also include best evidence-based care from pre-hospital and in-hospital sources such as NICE, SIGN, JRCALC, National Service Frameworks and other national guidance and policy.

4.1.2 Local Clinical Advisory Groups

Each service should either develop a Clinical Advisory Group or share existing clinical advisory arrangements with a defined structure, nominated chair and Medical Director. The group should meet at least twice a year and should have clear reporting lines from and to the group. The group should include (as a minimum) consultant level representation from:

- Regional Trauma Network
- Anaesthesia I Critical Care
- Emergency Medicine
- Neurosurgery
- Orthopaedics I General Surgery
- Paediatrics
- Senior HEMS crewmember.

This advisory structure is the foundation on which all clinical activities are built, and will report to the Board of Trustees and/or to the local or host Ambulance Service Trust Board as appropriate.

4.2 Risk Management, Clinical Audit and Complaints

4.2.1 Risk Management

Each service providing HEMS must have a multidisciplinary Health and Safety Committee with a defined constitution, chair and reporting structure. The committee must provide a minimum six-monthly review of incidents and occurrences and demonstrate closure of incident loops and the lessons learnt.

Each service should have a robust Clinical Occurrence Incident Reporting System which is easily accessible to staff so that any untoward incidents are recorded and the lessons learnt are communicated to all relevant staff. The system should comply with guidance from the relevant governing bodies.

4.2.2 Clinical Audit

Each Air Ambulance Service should regularly review its clinical practice and undertake an audit of all clinical documentation every three months, along with a multi-professional longitudinal audit of a series of clinical cases, reflecting representative calls attended by the Service. These sessions should be chaired by the Medical Director and the documentation should be made available to the local Clinical Advisory Group and the Board.

Each Service should hold regular events (a minimum requirement of six-monthly, but ideally monthly depending on the workload of the unit) to include an audit session comprising the number of cases attended, missions undertaken, primary and secondary workload, cancellation rate, adverse incidents reported, complaints and successes reported. A longitudinal case audit and a best practice session and safety review should be undertaken. These sessions should be chaired by the Medical Director and minutes from these meetings should be available to the Clinical Governance Committee and Trust Board / Board of Trustees.

To assist in maintaining best practice, all unit members must have access to relevant clinical journals either by hard copy or electronic means. Regular (six-monthly) journal clubs should take place and attendance at relevant national conferences and external clinical seminars should be encouraged. All operational staff should maintain a portfolio of experience and continuing professional development

and undergo regular appraisals covering both clinical and non-clinical performance.

4.2.3 Complaints

Each service should develop a system for recording and responding to enquiries and complaints. The system should follow NHS guidance and should ensure that users of the service are aware of how to register complaints. The Medical and Operations Directors should regularly review concerns expressed and demonstrate how any lessons learned are disseminated. As most Air Ambulance Services are allied to Ambulance Services it may be appropriate to share this task and the information which results.

4.2.4 Information

All Air Ambulance Services should develop a comprehensive electronic database to complement the paper-based medical records / run sheets. Medical records must be controlled in accordance with NHS guidelines and each unit will have a nominated Caldicott Guardian (normally the Medical Director).

4.2.5 Medical Indemnity Insurance

Each Service must have medical indemnity insurance for all operational staff as well as clear lines of accountability. On appointment, enhanced CRB checks must be undertaken for all members of operational staff.

4.3 Accreditation, Peer Review and Regulation

All Air Ambulance Services should undertake an annual clinical review conducted by the Medical Director of another Air Ambulance or Ambulance Service. Members should also be submitting data to the CQC as required either by their CQC Registration or by their Ambulance Service partner. This information is subject to review by the CQC.

4.4 Standard Operating Procedures

Each Air Ambulance Service should work to a core set of agreed clinical and operational procedures – see Appendix D for examples. AAA Best Practice Guidelines and Guidance Standard Operating Procedures are available to utilise and for guidance to assist in standardising best practice.

All Standard Operating Procedures should be regularly reviewed through other governance tools such as the Clinical Risk or Safety and Risk Committee and through other forms of audit.