The Scottish Critical Care Trials Group

Constitution

Revision September 2012

Aims

General

- To promote and support high quality research in to critical care in Scotland
- To work under the auspices of the Scottish Intensive Care Society (SICS) and in collaboration with the SICS Audit Group (SICSAG), and the SICS evidence-based medicine group
- To collaborate with other expert groups in carrying out high quality critical care research in Scotland
- To ensure that research is carried out in a fair and inclusive manner in the critical care community of NHS Scotland
- To ensure that relevant health care workers are kept well informed about critical care research in Scotland
- To ensure that all research meets research governance requirements

Specific

- To identify important questions relating to critical care in Scotland
- To contribute to project development, trial design and execution
- To design and execute high quality RCTs
- To support other research on different levels of scale and complexity
- To achieve funding for critical care research in Scotland, specifically by coordinating and managing grant applications for major projects
- To coordinate trials in the Scottish ICU patient base to ensure equity between different projects

Composition of the Trials Group

Executive Group

There will be an executive group that will have the following roles:

1. To ensure that the aims of the group are fulfilled
2. To lead organisation of meetings and educational activities relevant to the aims of the group
3. To support funding applications where appropriate
4. To oversee development and review of a constitution and ensure adherence to the constitution
5. To provide support in trial design
6. To disseminate relevant information to Scottish Intensive Care Society membership and relevant staff caring for critically ill patients

Executive Group Meetings

1. The Executive Group will meet at least three times each year
2. Meetings can be face-to-face or via teleconference

3. The executive group will organise an Annual General Meeting, which will take place at the combined meeting of the Scottish Critical Care Trials Group and Scottish Intensive Care Society Audit Group
4. All executive group members should attend at least 2 meetings each year
5. Failure to attend the required number of executive group meetings will result in local review by the SICS representatives to determine membership during subsequent years

Composition of the executive group
The executive group will have elected members from each of the four geographical regions delineated by the Scottish Intensive Care Society. Each geographical region will nominate three members to the executive group from within the region. Members of the executive group will be active in critical care research and will contribute positively throughout their membership of the group. A member can be a medical specialist or a non-medical allied health professional. Although the executive group may not have direct responsibility for running trials, it is anticipated that members of the group will be active in ongoing trials, will be involved in developing new trials, and have relevant experience in conducting critical care research.

In order to reflect the geographical distribution of critical care in Scotland, and the need to have research related representation from all geographical areas of Scotland, at least one representative will be sought from each of the following regions. Each region will nominate three representatives at any time.

1. NORTH: Highlands, Grampian, and Tayside.
2. EAST: Lothian, Borders and Fife.
3. WEST: Dumfries & Galloway, Ayrshire & Arran, Lanarkshire, and Forth Valley.
4. GREATER GLASGOW and CLYDE.

The minimum tenure of each member will be 3 years. All members should be in a position to undertake this tenure at the time of standing. At the end of each 3 year tenure, a new nomination for each regional representative will be sought. Re-election of individuals will be possible and no set period of duty on the group is defined.

Any member of the Scottish Intensive Care Society can stand for election to the executive group. The coordination of nomination of each regional member will be the responsibility of the regional representatives for that region on the SICS council. The method used to identify and nominate the individual will be at the discretion of the individual regions. To ensure geographical representation across ICUs only one nomination should come from each ICU.

In order to ensure that younger members are involved in the activities of the group, receive mentorship and experience, and are encouraged to become

involved in research leadership at least one member from each region should be within 5 years of appointment to a substantive post at the time of taking up their position.

The total composition of the executive group will therefore be 12 elected members, four from each region, plus any co-opted members.

Chairman: the chairman will be an SICS member, nominated by the members of the executive group. The Chairman will normally have been a member of the executive group prior to taking up the Chair, but on occasions an SICS member may be nominated who is not already a member of the group. The tenure of the Chairman will be 3 years unless extraordinary reasons necessitate resignation. This will ensure continuity. After each 3 year period the members of the executive group will nominate an individual for Chairmanship. This can include the existing Chairman, another member of the executive group, or another SICS member. The appointment will be proposed to the SICS council for ratification at the Annual General Meeting in January.

Vice Chair: the executive group will nominate a vice chair. The Vice chair will normally have been a member of the executive group prior to taking up the position. The tenure of the vice chair will be 3 years unless extraordinary reasons necessitate resignation. This will ensure continuity. After each 3 year period the members of the executive group will nominate an individual to act as vice chair. This can include the existing vice chairman, another member of the executive group, or another SICS member. The appointment will be proposed to the SICS council for ratification at the Annual General Meeting in January.

Study Group coordinator: the study group coordinator will be appointed by the executive group. He/she will be funded by the clinical trials group for an amount of time appropriate to the groups activities. There will be no stated tenure for the study office coordinator. The study group coordinator will be accountable to the Chairman. The role of the study group coordinator will be as follows:

1. To assist with organisation of executive group meetings
2. To assist with trial group meeting organisations
3. To undertake secretarial and administrative duties relevant to the running of the group
4. To assist with production of the annual report of the group activities
5. To assist with the management of the Scottish Critical Care Trial Group Finances, including production of the annual return to Companies House

Co-opted members: In addition to the members of the executive group other individuals may be co-opted on to the group. Such individuals will be invited to join the group by the chairman after overall agreement by the members of the executive group. This will be in response to specific needs for executing the aims

of the group. If an individual is co-opted on to the group it will be the responsibility of the Chairman to inform the SICS council of the identity of the co-opted member and the reason that they have been asked to join the group. There will be no limit to the number of co-opted members at any time or the duration of tenure. It will be the responsibility of the Chairman to inform SICS council whenever a co-opted member leaves the group. Co-opted members will not have voting rights in relation to decisions made by the Executive Committee

Relationship between the Executive group, the clinical trials group and individual investigators and/or trials.

It is anticipated that the clinical trials group will become associated with trials that are of differing scales, involve different numbers of sites, and address varying questions. The relationship between individual trials and the clinical trials group will therefore vary. It will be the intention of the clinical trials group to accommodate all forms of association with clinical trials as long as they are relevant to the aims of the group and function in accordance with the conditions of association laid out in this document.

Conditions for associating trials with and publishing trials on behalf of the Clinical Trials Group

1. Trials should undergo an open structured review by members of the Trials Group at one of the annual meetings
2. Trials should be run in accordance with current Research Governance guidelines.
3. Authorship for trials should be according to the Vancouver guidelines (below)
4. Trial publication should acknowledge the Clinical Trial Group in an appropriate manner (see below)
5. Results of trials should be presented to the group and disseminated to members of the group at the trials group or SICS annual meetings

Authorship

The following principles should be adhered to for trials published in association with the Clinical Trials Group:

Named authorship: Any named author on a publication should have contributed to the study in a manner in keeping with the following Vancouver guidelines:

"All persons designated as authors should qualify for authorship, and all those who qualify should be listed. Each author should have participated sufficiently in the work to take public responsibility for appropriate portions of the content. One or more authors should take responsibility for the integrity of the work as a whole, from inception to published article.
Authorship credit should be based only on

1) Substantial contributions to conception and design, or acquisition of data, or analysis and interpretation of data;
2) Drafting the article or revising it critically for important intellectual content; and
3) Final approval of the version to be published.

Conditions 1, 2, and 3 must all be met. Acquisition of funding, the collection of data, or general supervision of the research group, by themselves, do not justify authorship.

Authors should provide a description of what each contributed, and editors should publish that information. All others who contributed to the work who are not authors should be named in the Acknowledgments, and what they did should be described (see Acknowledgments).

Increasingly, authorship of multicenter trials is attributed to a group. All members of the group who are named as authors should fully meet the above criteria for authorship. Group members who do not meet these criteria should be listed, with their permission, in the Acknowledgments or in an appendix (see Acknowledgments). The order of authorship on the byline should be a joint decision of the coauthors. Authors should be prepared to explain the order in which authors are listed."

Acknowledgement of the Clinical Trials Group: All publications should acknowledge the contribution of the Scottish Critical Care Trials Group. The use of group or multiple authorship followed by: "…for the Scottish Critical Care Trials Group" is strongly encouraged.

Decisions regarding authorship: Before the outset of the trial it is recommended that the named authorship is agreed and is recorded with trial documentation. This can act as a point of reference at the publication stage, but can be changed if deemed appropriate based on work actually carried out during the trial.

Group acknowledgement: The trials group will strongly encourage acknowledgement of all significant contributors to the trials in an appendix at the end of publications and/or study reports. This should include all health care professionals who have contributed significantly to the trial.

<u>Dissemination</u>

Website: The group will establish and maintain a website that will have links to the SICS website, the EBM group website, and other relevant websites.

e-mail: The group will establish an e-mail list for all interested members of the trial group.

Meetings

The group will contribute to meetings twice each year. Meetings will be open to all members of the SICS and to other health professionals with an interest in the clinical trials group.

Combined meeting with Scottish Intensive Care Society Audit Group and Evidence Based Medicine Groups
The aim of this meeting will be

1. To provide updates on active projects and feedback to members. There will be an opportunity to address problems with ongoing work, and to discuss issue with members of the Steering Groups for active trials.
2. To update members on new developments in research funding, organisation, and governance
3. To assess in a semi-formalised and structured manner new ideas for trials (see below)

The location of this meeting will be decided by the executive group.

Scottish Intensive Care Society Annual Scientific Meeting
The aim of this meeting will be:

1. To present the results of work carried out by the group in the form of mini-lectures
2. To have a session for SpRs or other health professionals to present research project results
3. To have a poster presentation session with judging

Annual Report

The Executive group will be responsible for writing an Annual Report. This will be presented to the Clinical Trials Group and to SICS council at the SICS AGM in January. The report will include activities for the previous 12 months, but also a plan of proposed activities for the following 12 months.

Assessment of Proposed Trials

All proposed trials carried out in association with the group should undergo a structured process of peer review. The process of evaluation will be a point-by-point checklist based on the MRC guideline. The checklist will be available on the website or from the trials group office. All individuals or groups who plan to an idea to the group should submit an outline of their response to the checklist before the meeting to the Chairman of the executive group. It will be the responsibility of the executive group to decide which project ideas will be presented to the group at each meeting. This is intended to ensure that projects presented to the group have been worked up before presentation. This will enable efficient feedback by group members and allow a number of ideas to be evaluated at each meeting.

Financial Support

It is envisaged that financial support will be from several sources:

Sponsorship
Sponsorship from industry will only be accepted by the group if in the form of unrestricted educational grants. Confirmation of this status will be sought at the time of sponsorship. It will be made clear that sponsors will not directly influence the research questions addressed by the group and will have no control over data generated by trial group studies. Sponsors may be listed on the website, but will not be listed as sponsors of individual studies. Commercial sponsors should be acknowledged and declared on any relevant publications.

Grants
Grants awarded to trials carried out by the group are likely to be held in one or more University departments or NHS Trusts. The relevant host institution may be the base of the CI for the study, or several of the applicants. In these situations it is important that the host institution is agreed prior to the application. A potential function of the executive group will be to coordinate applications that involve >1 NHS Division or University department by liasing with Trust R & D Directors or relevant University departments during the application process.