

Revision of the EURO CARE Publication Policy and Data Access Guidelines

Following discussions at the EURO CARE Working Group meeting in Ragusa, Sicily, on 23 September 2004, Michel Coleman (London) was asked to revise the EURO CARE Publication Policy and the Data Access Guidelines. He submitted the revised documents on 27 September, but they were lost in a failure of the email system in Milan. As a result, they were not rapidly circulated to the Steering Committee, as intended, for approval, before being made available on the EURO CARE web-site. In view of this unfortunate delay, the documents are being posted on the web-site now, before formal approval by the Steering Committee, which will consider them at its next meeting. Michel Coleman's explanatory note (originally intended for the Steering Committee) is given below:

In making changes to drafting of the Publication Policy (version 6) and the Data Access Guidelines (version 4), as agreed by the EURO CARE plenary meeting in Ragusa on 23 September 2004, I tried to reflect not only the Working Group decisions made at the meeting, but also Franco Berrino's notes of the meeting, as well as comments hand-written on the original documents by Hans Storm and Riccardo Capocaccia, given to me afterwards, where these improved the clarity and did not alter the sense of what was agreed at the meeting itself.

In view of the general consensus in Ragusa that this was a time for renewal of EURO CARE, both in spirit and in practice, I also took the opportunity to reorganise the content of both documents for clarity and logical flow. I also moved a section from one document to the other, so the content of each document should now reflect its title more accurately. For these changes, however, I either retained the original wording, or else improved it whilst retaining its precise meaning.

The process of approval would probably become more rapid (and be more efficiently managed) if Working Group members could approve and/or comment on proposals for new analyses on-line, via the EURO CARE web-site. This would enable all Working Group members to see each others' comments and decisions, and would provide a log of such comments and decisions. This suggestion was raised in Ragusa, but it was not an explicit decision and it might require resources that are not currently available.

The only substantive change I made to the Data Access Guidelines (para 4) that was not agreed (or even discussed, I think) in Ragusa is the change from four to two weeks for the suggested response time to data requests. When revising the document, I took the view that - as a consequence of the decision in Ragusa that all data access requests must now be approved by every registry - this change might help to reduce delay in approving requests for data, and to minimise the extra administrative burden that this change will undoubtedly place on the Co-ordinating Centre in Milan. In short, if all registries must now approve all requests for new analyses of EURO CARE data, then collaborating registries should give the highest priority to speedy consideration of such requests, in order to reflect appropriately the underlying collaborative spirit of the whole enterprise. If it turns out that most Working Group members are strongly opposed to this change, however, we can revert to the original four-week period, but I hope it will be considered reasonable.

Michel Coleman

London School of Hygiene and Tropical Medicine 17 December 2004

EUROCARE Working Group publication policy

Collaboration and ownership of data

- 1 EUROCARE is a research collaboration between a number of European population-based cancer registries, designed to investigate patterns of cancer survival and of cancer treatment between European countries and over time. EUROCARE has been planned and supervised by a Steering Committee since 1990. It has been funded mainly by the European Community.
- 2 The EUROCARE Working Group is composed of representatives of cancer registries which share survival data for common analysis, and of a few other institutions involved in cancer survival studies (e.g. Istituto Superiore di Sanità, Rome; London School of Hygiene and Tropical Medicine, London).
- 3 The Epidemiology Unit in the Istituto Nazionale Tumori, Milan, Italy, is the Co-ordinating Centre, and provides the secretariat for the Working Group. The EUROCARE data base is stored at the Istituto Superiore di Sanità in Rome.
- 4 The EUROCARE data remain the property of the contributing registries, whose consent is required before they can be used for purposes other than those originally envisaged in the EUROCARE protocols. All members of the Working Group that provide data must be informed of any analysis being carried out (see *Guidelines for access to data from the EUROCARE project*), and each registry has the right to oppose the inclusion of its data in analyses with which it does not agree.
- 5 The Working Group agrees that any future developments of EUROCARE will be in line with the spirit of collaboration that has resulted in the success of previous joint undertakings in which cancer registry data have been combined. The Working Group also agrees that collaboration of EUROCARE with other projects on cancer incidence and mortality, such as EUROCIM and EUROPREVAL, is to be encouraged.

Authorship

- 6 All publications based on pooled data must mention the EUROCARE Working Group among the authors (or as the author), a suitable authorship formula being: >Authors A, B, C, ... and the EUROCARE Working Group=, with all members listed in a footnote or appendix to the article.
- 7 The first author must provide a justification to the Steering Committee for the names of all authors appearing separately in the authorship list. The list of individual authors should be kept short.
- 8 In general, the researchers who performed the analyses and wrote the paper will be first authors in the publication.
- 9 Analyses and publications can be proposed and carried out by any member of the Working Group or by other researchers not belonging to the Working Group, and will be supervised by the Steering Committee.

Role of Steering Committee

- 10 The functions of the Steering Committee are to plan and supervise analyses and publications, to ensure adherence to this publication policy and to the *Guidelines for access to data from the EURO CARE project* (q.v.), to plan the updating of the data base, and to act as Project Management Group for further common projects.
- 11 The Steering Committee is composed of members of the Working Group with expertise in survival analysis who are willing to devote time to the project.
- 12 To avoid duplication of effort or the publication of inconsistent results without appropriate comments, cancer registries participating in EURO CARE should inform the Steering Committee of any survival analysis of the same data already sent to EURO CARE.

Availability of EURO CARE publications

- 13 Publications from the EURO CARE project will be included in a numbered list of such publications on the EURO CARE web-site <http://www.eurocare.it>. Where possible, files of those publications will also be included on the web-site in a suitable format (e.g. Adobe Acrobat pdf files).

Guidelines for access to data from the EURO CARE project

- 1 EURO CARE is a research collaboration between a number of European population-based cancer registries, designed to investigate patterns of cancer survival and of cancer treatment in Europe. It is co-ordinated by the Epidemiology Unit in the Istituto Nazionale Tumori, Milan, Italy, and has been funded mainly by the European Community. The data analysed in the project remain the property of the contributing registries, whose consent is required before the data can be used for purposes other than those originally envisaged in the EURO CARE protocols.

Analyses under EURO CARE and other protocols

- 2 Basic analyses approved by the participating registries under the EURO CARE protocols are carried out either at the Co-ordinating Centre in Milan or at the Istituto Superiore di Sanità (ISS), Rome, Italy, but further analyses may also be carried out at other institutions belonging to the Working Group.
- 3 Release of EURO CARE data for other purposes requires authorisation of all the registries that have provided the data.
- 4 Any request for EURO CARE data must be submitted to the Chairman of the Steering Committee, who will circulate it to the Steering Committee and to each participating cancer registry. For requests for data from a member of the EURO CARE Working Group (internal request), registries will be expected to inform the Chairman of their approval (or alternatively of any objections they may have) within a reasonable time, say within two weeks of circulation. Requests for tabular material from scientists outside the Working Group will be treated on the same basis as internal requests. Requests from external scientists for individual tumour records, even if they can be considered as anonymised, will require explicit written authorisation for the use of its data from each registry included in the data request.
- 5 The Data Analysis Group at the Istituto Superiore di Sanità (ISS), Rome, Italy, is responsible for preparing data sets to meet such requests. Data manipulation by ISS will be limited to selection of the tumour records or tabular information specified in the data request as approved. Data files will only be released after formal authorisation from the Steering Committee.

Format of requests for data

- 6 The request must include the names and affiliations of all the individual scientists who will be responsible for the analysis and interpretation of the EURO CARE data, and who will expect to author any articles derived from the analysis; and a short protocol (1-2 pages, see Annex 1 for an example), setting out:
 - 6.1 the rationale for the study;
 - 6.2 the aims of the study;
 - 6.3 the methods of the proposed analysis;
 - 6.4 a detailed description of the EURO CARE data items requested (see Annex 2);
 - 6.5 the proposed time schedule for the study.

Protocol

- 7 The purpose of requesting a protocol is:
 - 7.1 to prevent duplication of effort and to enable the Steering Committee to bring together investigators with similar interests;
 - 7.2 to provide sufficient justification for release of the data by the Steering Committee;
 - 7.3 to enable the Committee to provide any advice that may be required on practical aspects of data preparation and on the interpretation of the data.

Conditions for release of data

- 8 The principal investigator requesting the data must sign an agreement to abide by the following conditions which apply to release of EURO CARE data:
 - 8.1 The data will only be used for the purpose(s) stated in the protocol accepted by the Steering Committee;
 - 8.2 The data will not be released to a third party;
 - 8.3 The data will be treated as confidential and will be used only for statistical purposes. Data released by the EURO CARE Working Group will in any case contain no personal identifiers, except for internal study numbers. However, because of the remote possibility that individuals might be identifiable from dates or partial dates of birth, diagnosis or death, and in order to provide suitable guarantees of confidentiality for the contributing cancer registries, the principal investigator must provide written assurance that the data will be held securely;
 - 8.4 If the data released relate to a subset of the participating registries because of refusal to release data by one or more registries, or if the protocol only envisages analysis of data from selected populations, the extent of any such restriction must be clearly set out in any resulting article;
 - 8.5 A copy of any manuscript arising from such analysis should be submitted to each Steering Committee member for review; submission for publication should only be made after the Steering Committee has responded, which will normally be within 4 weeks of receipt of the manuscript.
 - 8.6 Any publication must acknowledge the contribution of data by EURO CARE Working Group members, as set out in the EURO CARE Publication Policy.
 - 8.7 The requester must agree to provide 50 reprints or copies of any publication for distribution to Working Group members.

Agreement of Principal Investigator to abide by conditions for release of EURO CARE data

Project title submitted to EURO CARE: _____

Project accession number: _____

Undertaking by Principal Investigator

I have read and understood the guidelines and conditions for release of data from the EURO CARE project. I undertake to abide by each and every condition in this agreement.

Signature of principal investigator: _____

Name (in block capitals): _____

Position: _____

Institute address: _____

e-mail: _____

Phone and fax numbers: _____

Date: _____

Approval by EURO CARE Steering Committee

The EURO CARE Steering Committee has reviewed the protocol submitted by the principal investigator and approves it for access to the EURO CARE data requested:

Steering Committee Chairman: _____

Date: _____