EUROPEAN NETWORK OF CANCER REGISTRIES (ENCR)

Working Group on Structured Reviews of Cancer Registries

Background

The issue of reviewing cancer registries has been discussed by the ENCR Steering Committee on several occasions in the past. Specific issues discussed have included: the need for careful choice of credible reviewers based on well defined criteria; the potential high cost of the reviewing process; the source of funding for the process; the requirement for some registries to provide objective evidence of their quality in order to obtain funding; and the North American experience of an active structured reviewing and accreditation process. In addition, the results of the follow-up survey carried out among ENCR member registries in 1998 indicated an interest both in being reviewed (59% of respondents) and in acting as reviewers (32% of respondents). Responding registries identified the following main topics for inclusion in a review: registry procedures (81%); coding of morphology (71%); coding of topography (63%); coding of tumour stage (59%); coding of dates (53%); and registry publications (47%).

The new ENCR Steering Committee established in October 1999 was asked to take forward the issue of reviewing cancer registries. Terms of reference for a Working Group were drafted by the ENCR secretariat (see Annex 1). A Working Group was convened 'to establish a framework for structured review of European cancer registries by an external review team' (for membership of the Working Group, see Annex 2).

The Working Group met at IARC, Lyon on 21-22 March 2000. For the first part of the meeting, the Working Group discussed the issues identified by their draft terms of reference (see below). The remainder of the meeting was spent in constructing a draft questionnaire which would form the basis of a pilot cancer registry review.

General issues

Purpose of the structured reviews

It was recognised that registries or their sponsors may be motivated to request a review for a variety of reasons. However, the fundamental purpose of the review process would be to evaluate a registry's performance across a range of pre-determined but focused criteria, and to identify positive and negative aspects of a registry's procedures and outputs, taking account of available resources. Once piloted and if necessary amended, a standard structured review process should be applied to all registries which want to be reviewed. (This distinguishes the review process from consultation which may be focused on a specific issue). As a fundamental principle, the review should be a constructive, non-threatening experience aimed at helping registries to improve their performance, in some cases by providing independent, objective evidence of the need for additional resources. In some instances the review may be able to assist in removing legal or organisational obstacles to registration.

Initial request and negotiation process

It is anticipated that the request for a structured review would normally be made by the funding body or host institution to the ENCR Secretariat, but cancer registries could also make the request directly to the Secretariat. It is recognised that funding of the reviews may pose a problem, in particular because the registries with most incentive to be reviewed may also be the ones with least resources. Normally, the body funding the registry would be expected to fund the review, although a registry could fund the review out of its own resources, if available. Ideally, funding should not be a barrier to the process and the possibility of funding structured

reviews through the ENCR budget (as part of the contract) in certain cases should be explored.

Reviewing a fully functioning single national cancer registry would be quite different from reviewing a national registry which simply serves as a repository for data gathered by several regional registries. In the latter circumstances, a national review would require each regional registry supplying data to be reviewed separately.

The choice of reviewers is important. They must have credibility and experience based on a registry which is perceived widely to be performing well. The review team should be proposed by the ENCR Secretariat who have the personal knowledge of people in registries needed to make the appropriate choice of reviewers. Nominations for the review team should then be approved by the ENCR Steering Committee. The selection of the review team would depend on a variety of factors including: the registry to be reviewed; the country; the native language of the registry; and the job situation of potential reviewers. Reviewing 'automated/electronic' registries as opposed to 'paper-based' registries might require different types of reviewer, although the underlying principles of data processing should be the same for all registries.

Resources

The review team should consist of at least two people with, between them, knowledge of input/data flow, data processing and output/use of data. In the interests of efficient use of time, it is envisaged that the registry being reviewed would supply a pre-defined set of material well in advance of the review visit. Nevertheless, it is envisaged that a minimum of three days would be needed to complete an adequate 'on-site' assessment of a registry. The costs of the review would involve travel, per diem, and possibly a small honorarium for the reviewers. Clerical support would be provided by the ENCR Secretariat and would mainly involve producing official letters and forms, final versions of reports, accreditation certificates, and coordinating travel arrangements and accommodation. The draft and final versions of the review report would be prepared by the reviewers, with one taking the editorial lead.

Format and circulation of final report

The final review report should be an official document produced in a standard format so that a comparable process is seen to apply to all registries being reviewed. It is likely to be based on the structure of a questionnaire to be completed by the registry in advance of the visit (see separate document). A draft version of the final report should be sent to the ENCR Steering Committee for approval before being made available to the registry for comment, preferably within six weeks of the registry visit. Once amended, the final report would be sent to the ENCR Steering Committee for approval before being forwarded to the body which requested the review. Further circulation would be at the discretion of the registry. The report should be as positive as possible, and any critical comments should be constructive. The timing of the final report will depend on the speed of response of the registry but should ideally be completed within four months of the registry visit.

Listing of items comprising the standard structured review

A 'review template' will be inherent in the structure of the questionnaire to be completed by the registry in advance of the visit (see separate document).

Formal accreditation

While the value and meaning of an accreditation system is uncertain, it is recognised that an official process of accreditation might assist some registries to gain credibility and additional funding. On balance, it was agreed that an accreditation system would be feasible in Europe.

However, this would require, at least in part, a quantitative approach to the review with registries being scored against a range of pre-determined standards.

The Working Group has acquired information on the North American Association of Central Cancer Registries' (NAACCR) Registry Certification process. Essentially, this is achieved by registries submitting their data centrally for standard assessment based on a series of routinely available and measurable variables, such as the DCO percentage. In some respects, this resembles the selection process for inclusion in the IARC monograph, *Cancer Incidence in Five Continents* (Parkin *et al*, 1997). However, *Cancer Incidence in Five Continents* is not an accreditation organ and the standards to be met may vary for registries in different parts of the world.

If registries are to be subject to a process of accreditation, it may also be necessary to consider a formal process of accreditation for reviewers.

There may be merit in developing the review process in two phases, the first phase to involve the piloting of the review questionnaire (see separate document), and the second phase to involve the development of a formal accreditation process.

Registry activities to be included in the structured review

A semi-structured ENCR registry review questionnaire has been prepared (see separate document). This is intended to provide a framework for the review process and report. It should be completed in advance of the registry visit, ideally in electronic format. It should be regarded as a draft document at present to be piloted in one or more registries before being finalised (although even a final version should be flexible enough to accommodate every registry).

During the registry visit, the reviewers should have the opportunity to talk with registry staff at all levels.

The following paragraphs address the issues identified by the draft terms of reference but could form the basis of guidance notes for completion of the ENCR registry review questionnaire.

Background

Detailed information on the history and legal basis of registration is not considered necessary *per se*, but more general information on relevant legislation should be included in the final report. Rather than seeking to establish and record the details of financial resources available to the registry which would be difficult to compare across countries, the review team should assess resources in more general terms, for example, staffing complement, numbers of staff on short term contracts, etc. A brief description of the local health care system may provide important context since, to some extent, the operation of a cancer registry reflects the health care system within which it is based.

Process activities

Fundamental to this assessment will be an examination of data flows, informed, if possible, by a data flow diagram, including data sources, how sources are maintained, how discrepancies between sources are reconciled, etc. Data flows would include linkages with other registries for the purpose of maximising data quality. The reviewers should assess whether the registry data are organised and processed in a logical structure.

A suitable framework for assessment of the cancer registry's data quality can be found in the IARC Technical Report Number 19, *Comparability and Quality Control in Cancer Registration* (Parkin *et al*, 1994).

Comparability

Registries should maintain standard definitions in written form, either as part of guidelines for registry personnel, or as separate documentation. Adherence to ENCR definitions, while desirable, should not be compulsory.

Completeness

The registry should provide in advance some routinely available indicators of data quality by cancer site and sex (%DCO, %MV, M/I). In addition, the registry should be asked to provide information on incidence, mortality and survival for selected cancers - common cancers, especially those with consistent, well-defined secular trends across Europe, and less common cancers for which diagnostic accuracy may pose problems. The registry should also be asked to provide any other available assessments of completeness of case ascertainment.

Validity

Routinely available indicators of data quality are also relevant to the assessment of data validity. In addition, the registry may have evidence of data validity from specific reabstraction exercises, or from validation of registry data in the course of a research or clinical review project. While reabstraction (with or without pathology review) is the best method of assessing data validity, it may not be feasible to ask registries to perform a reabstraction exercise specifically for the purposes of the review because of the considerable resources involved. Another possibility would be to ask the registry to code a small collection of difficult cases during the course of the registry visit - the ENCR registries could be invited to submit examples of difficult coding scenarios.

Timeliness

Timeliness will be evident from annual tallies of registrations for recent years and from time trend charts (see above).

Outcome activities

The registry should provide a list (and ideally copies) of all their paper-based publications produced during the most recent three calendar year period. Information on electronic publications (diskette, CD-ROM, internet) should also be provided (including website addresses).

Information should be provided on the registry's research activities. Information on sources of funding for research, and the networks with which the registry collaborate should also be made available. Selected clinicians could be asked if and how they use the registry's data or information services.

The reviewers should seek information on the frequency of contacts with state and local health authorities, clinicians, researchers, charities and the voluntary sector, politicians, the media, patient organisations, and the lay public. Examples of *ad hoc* requests for information and the processes involved in generating the resulting output should be scrutinised during the registry visit.

Data and patient protection

Normally, a registry would be expected to have data confidentiality, protection and security guidelines which should be made available in advance to the review team. Any guidelines should reflect local legislation relevant to this issue. It will be for the review team to judge whether the written confidentiality regulations actually appear to be operative, and whether they are adequate and practical in the local context. The reviewers should also assess arrangements for regular back-up and archiving of data.

The registry should provide copies of their guidelines and form(s) relating to release of data and/or linkage to other databases. In addition, information on research permission practices (including arrangements for review by research ethics committees) should be provided.

The review process itself raises issues of confidentiality since the reviewers themselves are likely to need to view real patient data. Although this might be resolved by the reviewers signing a confidentiality statement, in reality any sanctions applied for breach of confidentiality are unlikely to apply to reviewers from another country. Registries to be reviewed must resolve this privacy issue locally prior to the review being carried out. It may, of course, be covered by existing research permission practices. If the issue cannot be resolved, the scope of the review would have to be restricted to anonymised data.

Acknowledgements

In designing the draft ENCR Registry Review Questionnaire (see separate document), the Working Group referred extensively to the Draft Registry Visit Questionnaire developed previously by the United Kingdom Association of Cancer Registries (UKACR) Quality Assurance (QA) Group. The Working Group is also grateful to the North American Association of Central Cancer Registries (NAACCR) for providing background material on their Registry Certification process - much of this material is reproduced in Annex 3 (not enclosed).

References

Parkin DM, Chen VW, Ferlay J, Galceran J, Storm HH, Whelan SL (1994). *Comparability and Quality Control in Cancer Registration*. IARC Technical Report No. 19. Lyon: International Agency for Research on Cancer.

Parkin DM, Whelan SL, Ferlay J, Raymond L, Young J (eds.) (1997). *Cancer Incidence in Five Continents*, volume VII. IARC Scientific Publications No. 143. Lyon: International Agency for Research on Cancer.

Annex 1 - Terms of Reference

To establish a framework for structured review of European cancer registries by an external review team.

1. General issues to be formulated by the Working Group

    1.1 Purpose of the reviews (Note: distinguish from consultation).
    1.2 Initial request and negotiation process for the review (usually with the host institution/funding body of the registry) including the focus of the review, the source of funding and the nomination of the review team.
    1.3 Resources: number of reviewers, clerical support, number of days to be spent on location and on preparing the report.
    1.4 Format and circulation of final review report.
    1.5 Listing of items constituting the standard review - how much detail required? This would standardise the procedures and permit reviews of selected activities.
    1.6 Formal accreditation. Is this feasible, desirable, in Europe?

2. Registry activities to be included in the review

    2.1 Background: history and legal base of registration (including confidentiality issues, ownership of data and financial and personnel resources).

    2.2 Data processing activities (refer to headings in Comparability and Quality Control in Cancer Registration, IARC Technical Report No 19)

        2.2.1 Comparability: Use of standard (ENCR) definitions
        2.2.2 Completeness: What measures used by registry to evaluate this? Results?
        2.2.3 Validity: ditto.
        2.2.4 Timeliness: ditto
        2.2.5 The review team should be able to request a sample of the registry data to be analysed (reabstracted/recoded?) prior to the review, if quality indicators are not otherwise available.

    2.3 Outcome activities

        2.3.1 Dissemination of results (incidence, prevalence, survival, mortality) Reports, scientific publications, press, Internet…
        2.3.2 Research activities (including funding and cost sharing)
        2.3.3 Relationship with state and local health authorities, clinicians, research community, media and patient organisations

    2.4 Data and patient protection

        2.4.1 Confidentiality codes and implementation
        2.4.2 Ethical review committee and research permission practices
        2.4.3 Linkages with data from other registries

Annex 2 - Membership of Working Group

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