Chapter 9. Quality and quality control

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The cancer registry, above all else, is a source of information. Since it may be argued that unreliable information is worse than no information at all, it follows that the pursuit of excellence must be high on the agenda for any registry. Quality, be it good or poor, is a property of the data and a product of the techniques used to create them. Quality control is the name given to the mechanism by which the quality of the data is measured. While it is theoretically possible to operate a registry that creates high quality data without a system of quality control, the latter is essential if the data are to be *demonstrated* to be of high quality. No large-scale data-base can be perfect. Quality control procedures are instituted to identify the areas and degree of imperfection, and thus assist in the interpretation of the data, and may indicate the need for procedural changes.

The quality of information

The quality of information is a product of the quality of the data and the quality of their presentation. It is possible to identify five main areas for consideration.

Completeness of cover

The population-based registry endeavours to register every cancer case within its defined population. While it is important to strive towards this goal, it is equally important to avoid the inadvertent duplication of patients and many registries have sophisticated techniques for ensuring that duplicates do not occur. A further source of error lies in the inclusion of patients who are ineligible for registration because their particular disease is not among those defined as registerable or because they are not truly resident within the registry's boundaries.

Completeness of detail

It is not always possible to ascertain every item of data for every patient and not all data items may be applicable to every patient. Systems should be designed such that certain items are deemed essential, for example, the diagnosis and sex of the patient, while others, such as marital status, are not (see Chapter 6). For non-essential items, it should be possible to distinguish 'Not recorded', 'Not applicable' and 'Not known'. There are also errors of commission, that is, data items being present where they

should be absent. These errors are less common than errors of omission but when they do occur, the interpretation of the data can be very difficult indeed. With errors of commission there is the feeling that the information must have come from somewhere and it may relate to another, unidentified case.

Accuracy of detail

A data item that is present is not necessarily correct. Errors of detail can arise in a multitude of ways—abstraction, transcription, coding and punching errors all introduce inaccuracy of detail. While some errors can be detected using range and consistency checks, others cannot because, though actually incorrect, the item may appear quite satisfactory.

Accuracy of reporting

Where a data-base is complex with many variables, discontinuity of coding and even different file layouts, the collation of lists and tables from the computer can be difficult tasks. In some registries, the programming of enquiries is carried out by staff who do not have first-hand knowledge of the data, from instructions given by staff who do not have first-hand knowledge of the intricacies of the computer file. Under these circumstances, reporting errors are quite likely to occur and unless they give rise to totally unexpected results, may well go undetected.

Accuracy of interpretation

To properly interpret the information coming out of a registry, it is essential to have an understanding of the data sources and how the data are collected and processed. Such knowledge can only be gained by experience and involvement at every level of the registry's activities. It also requires a knowledge of the accuracy of the data—the product of quality control.

Quality control

Quality control measures may be either a formal on-going programme which forms part of the registry's standard procedures or an occasional *ad hoc* survey to address specific questions of data quality. Less formal, but nevertheless useful, quality control occurs when the data are carefully scrutinized as they are used; indeed critical use of the data is thought by some to be one of the best forms of quality control.

Assessment of completeness

The assessment of completeness should be constantly monitored, rather than occasionally measured. One way in which this is done is by monitoring the proportions of death certificates received for which no registration has previously been made. For rapidly lethal diseases, this proportion may be quite high but for those with a longer duration it should be small, and any significant deviation from past experience should alert the registry to possible problems. These might well require rapid corrective action or registration may be permanently missed.

It is useful also to compare data from the latest incidence year with previous years. Cancer incidence rates alter relatively slowly and any marked change should be investigated at once. If possible, this type of monitoring should be on a site-specific basis since, although the overall number of registrations may be reasonably steady, a sudden drop in registrations in one of the rarer sites may go undetected. Under-registration is often site-specific, for example, because a researcher may be carrying out a study of a particular cancer and diverts hospital records away from the routine procedures.

Many of these checks can be built into the registry's computer system, since they are readily automated and can be performed at regular intervals without anyone in the registry having to initiate them specifically.

Objective measures of completeness

Various methods have been proposed to measure the completeness of registration, most commonly using death certificates (Muir *et al.*, 1987; Freedman, 1978; Benn *et al.*, 1982) or samples of hospital records (Chiazze, 1966). While these methods clearly have limitations, it is important for registries to attempt to measure their completeness from time to time. Where a registry covers a large geographical area, it is likely that standards of reporting from different institutions will vary quite considerably, even to the extent that exceeds any variations in true incidence. Where possible, incidence rates for subdivisions of the registry's geographical area should be calculated on a regular basis to identify possible areas of under-registration as rapidly as possible so that corrective action can be taken. It is also likely that the level of completeness depends upon the diagnosis; registries which routinely receive all death certificates which mention malignant disease are likely to be virtually complete with respect to the most lethal cancers, such as pancreas and lung, but may be less so for non-melanoma skin or early cervical cancers. One way of monitoring completeness for individual diseases is to sample patient attendances at specialist clinics for these diseases and subsequently check the register for their inclusion. The estimation of ascertainment rates cannot be exact but all registries should be able to quote some objective measure of this rather than relying on received wisdom and pious hope.

Completeness and accuracy of detail

Many registries adopt a procedure by which all incoming reports are checked immediately upon arrival, to ensure that at least all of the most important data items have been completed. Any errors can thus be rectified while the original hospital records are still easily available. It also gives an early warning of poor-quality abstraction. By far the best method of determining the completeness and accuracy of the detail in a record is to perform a re-abstraction and recoding of the case. This should be performed blind, that is, without reference to the original registration. When the original and reprocessed registrations are compared, every data item is checked separately to calculate error rates for each one. It is usually necessary to establish a scale of error for the item since inaccuracy is often a matter of degree. When checking site of tumour, for example, it is desirable to distinguish errors in the fourth digit of ICD from those in the first three.

In a quality control exercise of this kind, whether on-going or *ad hoc*, the sample of registrations to be checked may be weighted against the more common tumours. This avoids re-abstracting a large number of similar tumours but, by applying the appropriate weights to the sample, it is possible to reconstitute it to represent all registrations if overall error rates are to be estimated. Polissar *et al.* (1984) describe an elaborate recoding exercise and illustrate that the analysis of the results can be complex, since coding disagreement may vary by certain data items, and standardization may be necessary to control for this.

Continuous or *ad hoc* quality control

Ideally a quality control programme should be built into every registry system whereby a set percentage of registrations are re-abstracted and recoded. Duplicate coding of critical items, e.g., diagnosis, may be carried out on all cases, which also ensures consistency between coders. In this way the monitoring of data quality is a continuous process and any routine procedural errors can be corrected very quickly. An on-going programme also raises staff awareness of the need to maintain high quality, especially if the task of quality control is not delegated to a single person but is shared on a rota basis by a number of experienced staff. The only disadvantage is its cost. Unless the registry is in the unusual position of having under-employed staff, additional funding must be found and it may be easier to obtain this for occasional *ad hoc* exercises than for a permanent commitment.

Both *ad hoc* and continuous quality control measures should not only quantify the level of error but should incorporate feedback mechanisms such that the level of accuracy is constantly being improved. Should a quality control exercise reveal that a particular data item is frequently not recorded or is associated with an unacceptable error rate, consideration must be given to the advisability of removing the item from the data set. There can be little doubt that many registries continue to collect items of data which are incapable of interpretation, and there may well be significant financial savings if these items are eliminated.

Computer checks for data quality

Where the cancer registry is computerized, two important types of check can be made: validation checks and consistency checks.

Validation checks

These are carried out by the computer on each data item to ensure that no invalid codes are fed into the data-base. These may take the form of range checks—for example, that no patient's age can be less than zero or greater than, say, 105. The format of the data item can be checked, for example, to ensure that the patient's name contains only alphabetical characters and the age only numerical codes. All computerized registries should have coding control files, that is, computer files containing the valid codes for each data item. Every incoming code is checked against the control file and any invalid one rejected and reported.

Consistency checks

These checks compare the values of certain data items against others. Obvious examples are to check that testicular tumours are not recorded for women or ovarian cancers for men. Sequences of dates should be checked to ensure that the sequence date of birth, diagnosis, perhaps treatment, and death are preserved bearing in mind that tumours can be diagnosed at birth and diagnosed after death—but not by more than a few days. Naturally, the more data items that are collected, the greater the number of checks that become possible.

In some instances, attention may be drawn to possible errors and warnings issued. Cases of male breast cancer or the occurrence of carcinomas in children may be signalled, not because they are necessarily wrong, but they are unusual enough to warrant manual scrutiny. Examples of consistency checks are given in Appendix 2, and the error messages produced by the Thames Cancer Registry computer system are listed in Table 1.

Computerized data checking is extremely efficient and can be done either online (that is, at the time data are actually being entered) or offline, as part of a batch operation. In the latter case, corrective action can only be taken at the next cycle of the batch process. The system design may recognize some errors as more serious than others, and some scale reflecting the degree of error may be set up such that major errors cause rejection of a complete registration while less serious ones allow the record to be added to the data-base. Such a record should carry a flag to indicate that it contains an error. Priority is of course given to amending the most serious errors first.

Pre-requisites for quality control

Rules and documentation

It is impossible to determine which of two opinions about a data item is correct unless there are firm rules. The rules under which the data are collected must include rigid definitions of all data items and their associated terms. There will be times when subjective judgements have to be made on certain cases and these should always be taken in consultation with senior members of staff. The reasons for the decision should be documented so that similar situations in future are dealt with in the same way.

Good coding systems

A good coding system allows any appropriate term to be allocated one code only. It must be possible to code every term unambiguously. Particular attention must be given to the meanings of 'Not stated' and 'Unknown' especially the circumstances where 'Not stated' might imply 'yes' in the absence of a definitive 'no' and vice versa. Where coding systems change with respect to time, it is essential to have documented rules as to the time period under which a given set of codes operated. For example, if a registry changes its codes for surgical operations, does the time period over which the code operates relate to the time of coding, the time of the operation or the original registration?

Table 1. Error and warning messages produced by the Thames Cancer Registry computer system

Death details for live case
No death details for dead case
Duplicated section which should be unique
Date of birth after date of diagnosis
No follow-up/death date
Date of last report is before date of birth
Date of last report is before date of diagnosis
Date of hospital attendance is before date of birth
Date of hospital attendance is after death
Date of surgery is before date of birth
Date of surgery is after date of last report
Date of radiotherapy is before date of birth
Date of radiotherapy is after date of last report
Date of isotope therapy is before date of birth
Date of isotope therapy is after date of last report
Date of chemotherapy is before date of birth
Date of chemotherapy is after date of last report
Date of 'no treatment' is before date of birth
Date of 'no treatment' is after date of last report
No clinical details
Date of diagnosis in clinical details not that in identification
Post-mortem diagnosis but not dead
Post-mortem diagnosis but date of diagnosis not date of last report
No identification details
Hospital of surgery not in hospital section
Hospital of external beam not in hospital section
Hospital of isotope therapy not in hospital section
Hospital of chemotherapy not in hospital section
Hospital of death not in hospital section
Age/date of birth inconsistency
Age calculated
Sex/site of primary inconsistency
Site of other malignancy same as primary
Sex/site of other malignancy inconsistency
No site specified
Occupation filing date is wrong
Minor and occupation not 'student'
Age <16 and not single
Remarks filing date is wrong
Field clerk filing date is wrong
No occupation details
Age over 16 and occupation 'child'
Wrong sex for name
ICD-O code 195 generated
Lymphoma with 199.9 site code
Site/histology inconsistent
Benign histology at incorrect site
Male housewife
No multiple primary cross-indexing

Standards

It is important for the registry to have standards under which to operate. Maximum tolerable error rates should be set for the major data items, for example, 5% at the three-digit level of the International Classification of Diseases for Oncology (ICD-O) or 0.5% for sex. If these rates are exceeded, immediate action should be taken to reduce the errors to acceptable levels.

Further information

Quality Control for Cancer Registries (Statistical Analysis and Quality Control Center, 1985) is a comprehensive guide to quality control covering the basic principles and methods used by the Statistical Analysis and Quality Control Center. Included are a number of papers on topics related to quality control and a selection of training exercises.