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Quality assurance in medical oncology within the EORTC

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Abstract

Quality assurance (QA) lately arrived in the medical arena in comparison to other fields. EORTC focused initially its attention on the aspects related to clinical trial data handling. In the late 1980s, the EORTC appointed a Quality Control Committee (QCC) with the remit to expand the QA activities to the main disciplines involved in cancer treatment. From 1990 to 1996, two projects supported by the European Commission enabled the QCC to address, amongst others, specific questions related to medical oncology. Both projects focused on the practices of chemotherapy delivery and the quality of data reporting. Following these projects, the QCC developed standard guidelines to advise on chemotherapy delivery and also a systemic chemotherapy checklist to enable an easy collection of essential data onto the patient's files. More recently, the EORTC QA Committee proposed a minimal set of quality control procedures to be implemented by all EORTC groups.

Keywords: Chemotherapy; Quality assurance; Quality control, EORTC

1. Introduction

Since its creation in 1962, the EORTC has been interested and active in the field of quality control and quality assurance. For many years, however, initiatives taken in this area remained the prerogative of individuals working within the EORTC. In 1989, the EORTC officially appointed a Quality Control Committee under the leadership of Prof. E. van der Schueren to address this issue in the context of the various disciplines involved in clinical trials and cancer management.

In the field of medical oncology, two successive projects were conducted from 1990 to 1996. Both projects had direct impact on the management of clinical trials involving systemic therapy within the EORTC and also outside the EORTC.

Nowadays within EORTC, quality assurance processes in medical oncology are addressed by the Quality Assurance Subcommittee of each clinical group in collaboration with the Quality Assurance Unit of the EORTC Data Center.

2. Quality assurance in medical oncology (1990–1993)

The overall objective of this programme, which was integrated into a larger programme supported by the European Union (EU), was to obtain information about the organisation and quality of chemotherapy services in a variety of centres in Europe. The results could then serve to provide a framework to determine disparities between different systems of healthcare in different countries and to draw up plans of how to improve services in the future.

The programme examined the following aspects in the different EU countries:

1. Which hospitals were used for treating patients with chemotherapy?
2. What facilities existed?
3. For a variety of given malignancies, which clinicians prescribed, which persons prepared and administered anticancer agents?

To achieve these objectives, a model was developed to collect information on the procedures existing in hospitals for treatment prescription, preparation and administration, regardless of the chemotherapy regimen involved. For these general technical aspects, the institutions were asked to complete a questionnaire.

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The questionnaire was completed by the responsible physician prior to a site visit and was discussed on arrival by the site visit team who, in addition, reviewed the facilities in the hospitals. These included the pharmacy, the ward, the outpatient department and data management offices, when present. The procedure also attempted to record the actual practice in a number of individual patients entered in specific chemotherapy protocols and to check on the quality of protocol adherence and the quality of patient documentation and trial data.

A total of 32 centres were visited and the self-completed questionnaires sent to the responsible physicians prior to a site visit revealed the arrangements within the centres for the provision of chemotherapy services.

The general evaluation of the project revealed a wide variability in the degree to which centres arranged for the prescription and preparation of the correct treatment dose, for the checking of correct dosage, which were reconstituted. Although the overall quality of adherence to protocol chemotherapy was satisfactory, the recorded data demonstrated that, in many cases, treatment delays were found to have been avoidable since the major reason for the delay appeared to have been incorrect re-admission dates being given to patients by administrative personnel. The quality of the data reporting was also found to be satisfactory overall with a low percentage of incorrect data reported. However, the major problem that was highlighted in some centres was the high percentage of data that had been entered onto case report forms that could not be verified from source information in the patient hospital file.

Following the results of this project, several actions were undertaken, out of which:

1. Recommendations were given to the centres to educate local personnel in data management to improve the quality of the reporting of the data. The EORTC study group on data management also published a book containing practical information on these aspects.
2. A systemic checklist for toxicity assessment was developed to standardise and facilitate the reporting of critical data related to treatment administration by the local investigators.
3. General recommendations were given to the medical oncology community concerning chemotherapy delivery in terms of drug prescription, dose adaptation and chemotherapy administration.

3. Quality assurance in medical oncology (1994–1996)

This second project, also supported by a grant of the EU, had three main objectives. The first objective was to evaluate the impact of the previous EORTC quality control programme by revisiting the centres that were previously visited and assess the use of the systemic checklist developed by the Quality Control Committee. The second objective of this project was to obtain information about practices of chemotherapy administration in Europe outside the EORTC centres. The last objective was to include the quality assurance knowhow of the EORTC in a document for the education of oncologists.

To evaluate the impact of the previous project, 37 site visits were conducted over 21 participating institutions (previously visited) to evaluate 98 hospital records and perform source data verification for a total of 11,724 different items reported on case report forms. A detailed comparison of the data provided to the EORTC was made with the data actually available in the hospital records. The investigations included a quantitative and qualitative assessment of the use of the EORTC systemic checklist. The results of this programme showed that there was an improvement in data accuracy among centres previously visited. Moreover, the quality and the quantity of data relative to the documentation of the treatment of patients were markedly increased (Table 1). The optimal utilisation of the systemic checklist reduced the percentage of unretrievable data to a negligible amount. The use of the checklist was widely advocated within the EORTC. In some centres, the checklist has become an integral part of the dossier of any patient in the oncology department.

The second objective of the project was addressed with a questionnaire of 29 questions and 33 sub-questions relative to different aspects of chemotherapy administration that was sent to 332 European physicians known to be active in the field of oncology. 224 responses (from 14 different countries) were received, out of which 165 were completely evaluable and used for the final analysis. The results of the analysis of the questionnaires showed that there was still a large disparity of practices among physicians. Important deviations from acceptable practice were recorded in different

Table 1
Comparison of results obtained prior to the introduction of a systematic therapy checklist with those obtained after this introduction (EORTC Soft Tissue Sarcoma Group)

	1991 QA programme	1995 QA programme
Total no. of items checked	8776	8983
Correct (%)	67.9	90.8
Incorrect (%)	3.7	1.9
Missing (%)	0.1	1.2
Only on CRF[a] (%)	28.3	6.1

[a] Data coded onto the CRF and not retrievable from the patient hospital records.

areas, such as the multidisciplinary approach of cancer treatment, the calculation of dosage of chemotherapy and the documentation of the treatment procedures and follow-up in the hospital records. Important findings were as follows:

- A multidisciplinary approach to cancer treatment is actually taking place in 46.6% of the institutions, and in 20.6% of the cases one physician is deciding alone on the best treatment strategy to adopt.
- 53.3% of the chemotherapy prescriptions are always written by specialists. When chemotherapy prescriptions are written by junior doctors, each prescription is checked by a specialist in 48% of the cases. In most of the institutions, there is no general policy with regards to rounding the dosage of chemotherapeutic drugs at prescription (67%) or during the preparation of the drug (73%).
- Guidelines relative to chemotherapy administration are available to the medical staff in 56% of the institutions for standard regimen and in 90% of the institutions for specific chemotherapy regimen. When guidelines are available, 79% of them include aspects of chemotherapy preparation, 94% include aspects of chemotherapy administration and guidelines for dose adjustments and monitoring toxicity are included in 68 and 60% of the cases, respectively.
- A summary of the treatment procedures in the hospital files is available in 59% of the institutions. Chemotherapy and toxicity data can be found on a specific form in 65 and 25% of the institutions, respectively. Out-patient and in-patient chemotherapy documentation in the hospital files are localised at the same place in 61% of the institutions and at different places in the others. Finally, most physicians (82%) are using the World Health Organization (WHO) toxicity scale system to record their adverse effects and 12% do not use any established scale at all.

The complete results of this survey were presented at the 21st ESMO Congress in Vienna in 1996.

The quality assurance knowhow resulting from the two QA projects supported by the EU was then integrated in the different chapters of a reference book, *The Practical Guide to EORTC Studies*, 2nd edition. The book addresses all theoretical and practical aspects of clinical research in oncology. It was widely disseminated to the scientific community and is still regarded nowadays as an important contribution to all aspects of cancer clinical research and many aspects of cancer management.

4. Quality assurance in medical oncology after 1996

Following the completion of these two projects, the EORTC developed minimal guidelines for quality assurance to be addressed by each clinical research group as of 1998 onwards. Each clinical group now has its own Quality Assurance Subcommittee including representatives of all disciplines involved in the management of a particular type of cancer. These committees, in collaboration with the Quality Assurance Unit at the EORTC Data Center, have the responsibility to overlook the quality assurance activities of each group in the continuity of the process initiated by the EORTC Quality Assurance Committee.

Further reading

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