goals of chemotherapy in HDC patients are to obtain maximum control of symptoms, to prevent serious complications and to increase survival with an acceptable side-effect profile. The problem of toxicity has been particularly emphasised in HDC-pretreated patients. However, from the reported review of clinical trials and from our own experience, it seems that previous HDC does not significantly modify tolerability of subsequent chemotherapy. Even if most transplanted patients have already received anthracycline–taxane-containing regimens, several drugs in combination or as single agents are currently available for this purpose, including docetaxel (in patients pretreated with paclitaxel), fluorouracil, gemcitabine, vinorelbine, mitomycin c and novel oral therapies (capacitabine, vinorelbine).

Finally, patients who have failed a previous transplant would be ideal candidates for novel approaches, such as use of new agents, molecular targeted therapy, antiangiogenetic factors and gene therapy.

Z. Sirotová, A. Tartarone, M. Aieta, F. Morelli & S.S. Toma
Casa Sollievo della Sofferenza Hospital, via Cappuccini 1, 71013 San Giovanni Rotondo, FG, Italy (*E-mail: zuzka@virgilio.it)

References

4. Tartarone A, Sirotová Z, Aieta M et al. Salvage treatment with epirubicin and/or paclitaxel in metastatic breast cancer patients relapsed after high-dose chemotherapy with peripheral blood progenitor cells. Tumori 2001; 87: 134–137.

DOI: 10.1093/annonc/mdg485

Can the ISO9000 quality assessment be applied to the practice of medical oncology?

Increased safety in drug administration and continuous monitoring of the quality of clinical and research process is necessary in medical oncology, but to our knowledge no medical oncology unit in Europe has yet planned or achieved certification. In Europe, the quality accreditation system is mainly provided through ISO 9001/2000 VISION. From February 2002 to November 2002, we addressed a program to develop a management framework for the implementation of a specific quality system to retain effective management control according to ISO 9000 rules.

The Quality Management System (QMS) includes three accreditation components—besides improvement objectives—namely diagnosis and care for in-patients and out-patients, chemotherapy preparation and administration, and scientific planning.

The main improvement objectives were: reduction in the waiting time for chemotherapy administration to outpatients; decrease in the risk of errors in the administration of chemotherapy; improvement in the implementation and running of phase II–III trials; and increase in patient satisfaction. Counselling for the implementation of the quality system was provided by OPT s.r.l. directional consulting, whose activity was sponsored by a pharmaceutical company.

The QSM is guaranteed by assessment inspections, periodic meetings on quality, and corrective actions on non-conformity procedures.

Two site visits were made, with an external audit to check on other possible non-conformities of our quality system. The third-party registrar (Certiquality) assessed that our system was compliant with the ISO requests for the three above-mentioned aspects, which was followed by the Certification of the Medical Oncology Unit on 17 December 2002.

In conclusion, certification of a medical oncology unit is a goal that should be pursued to improve not only the level of clinical activity, but also the whole process of design, implementation and running of clinical trials. However, this can not be achieved without the investment of additional resources.

S. Monfardini1, A. Jirillo1, M. Boscaro2*, M. Galeazzo & O. Pitolocchi3

1Medical Oncology Unit, Padua University Hospital, Padova;
2Education and Communication Office, Cancer Center of the Veneto Region, Via Gattamelata 64, I-35128 Padova, Italy; 3OPT s.r.l., Milan, Italy (*E-mail: martina.boscaro@unipd.it)

DOI: 10.1093/annonc/mdg489