Joint Teaching Lecture

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Good clinical practice: A label of quality?

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Following the painful experience of the high incidence of birth defects caused by Thalidomide in the sixties, the US regulatory authorities and later on the European Commission, decided to set up specific regulations/guidelines to improve the protection of humans involved in biomedical research whilst generating accurate and reliable information. These set of rules are not only reinforcing the ethical principles laid down in the declaration of Helsinki but also describe in much details how a clinical trial should be conducted and reported. These guidelines were primarily written to cover the process leading to registration of a new medicinal product on the market but they apply nowadays to any type of biomedical research involving human subject. Since their official publication in 1991 in Europe, the GCP guidelines have been incorporated into most of the national regulations with however different level of interpretations left at the discretion of the different national authorities. The Pharmaceutical Industry, based its Standard Operating Procedures on the European guidelines from 1991 onwards and therefore most of the physicians participating in clinical research protocols have been confronted with these guidelines although not yet referred as regulatory obligations. For most, if not all, of them the implications of these rules have been seen as administrative constrains without any direct added value for the patient or even for the research process. This feeling is still shared by most of the physicians who play a passive role in the clinical research setting ("limited" to the management of patients recruited in trials). Those involved in research organizations and in the industry with responsibilities covering the development and the management of trials are confronted with the necessity of proving that a particular project has been conducted respecting the basic standards of conduct. These persons have witnessed the reorganization of the clinical research environment and are convinced that GCP has substantially improved our performance in conducting clinical research. However, no real attempt has so far been initiated to demonstrate this fact with solid data to provide convincing evidence to the "non-believer".

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Is our daily nursing practice Good Clinical Practice?

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Guidelines for Good Clinical Practice (GCP) are developed for trials on pharmaceutical products to establish globally applicable standards for the conducts of biomedical research on human subjects. In daily practice nurses are not aware of these guidelines, although it is important to know that innovative products are assessed on the basis of adequate pharmaceutical and biological data generated in accordance with common standards of GCP. As trial nurses work in close collaboration with the investigator they know how these guidelines can help provide guidance on protection of trial subjects, safety monitoring, record keeping and data management. Some studies suggest that cancer patients who participate in clinical trials have better survival rates than those treated outside trials. The results of a retrospective chart review by Skrutkowska et al. (1997) report differences in nursing care for patients with breast cancer enrolled in clinical trials and those not enrolled. This can partly be explained by the fact that clinical trials involve a more structured approach to the treatment of patients with cancer than the daily nursing practice. As we all know most of the daily nursing practice is based on tradition, individual knowledge and experience. Yet at the same time there is a recent evolution to more evidence based nursing. This means that nursing activities are based on scientific knowledge in stead of tradition and routine. Some of these elements are already used by individual nurses who develop a beginning of GCP. Our daily clinical practice can only become GCP if the interdisciplinary team will use evidence based practice supported by information and communication technology. Therefore methods to standardize nursing care, such as best nursing practice guidelines, developed within an interdisciplinary team, need to be reinforced. If the outcomes of the use of these guidelines are regularly evaluated in the daily nursing practice and the feedback of this evaluation change our daily nursing practices, then we develop a dynamic Good Clinical Practice.