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Globalizing quality in clinical trials: a nursing perspective on the main changes in the International conference on Harmonization Good Clinical Practice (ICH-GCP) guideline

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Events of global importance such as the thalidomide tragedy mark the history of GCP and highlight the nescessity of the protection of individuals and public. The most recent development is the globalization of GCP regulations. Since clinical trial performance needs to be regulated by the responsible authorities. in 1998 the EU directive created a legal framework for the implementation of ICH-GCP in the conduct of clinical trials. Providing quality of clinical trials the ICH-GCP Guideline is a unified standard for designing, conducting, recording and reporting clinical trials. Nurses active in the area of clinical trials need to be up to date on the historical background, the aims and the rationale of ICH-GCP and need to be familiar with the aspects relevant for nursing practice. Furthermore nurses need to explore the implications of these ICH-GCP aspects and how it is likely to work. in their practice The EORTC-ECSG Research Nurses is a group formed by the Research Nurses active in ECSG trials, founded in 1984 to give nurses involved in ECSG trials a forum to share their patient care experiences related to new drug development and the organization thereof. The group has addressed these practical aspects during. their meetings and experiences with the implementation of ICHGCP will be shared from an European perspective. Practical implications presented are a nurse led educational program to educate doctors and nurses on ICH-GCP as well as experiences with the development and implementation of standardard operating procedures (SOP's)

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The implications of GCP for the organisation of a Clinical Trial (CT)

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The GCP guidelines were instituted for the conduction of clinical trials and have two main objectives: a) protection of patients' rights and safety; b) the production of valid and credible data. Once a CT has been approved by the local ethical committee, there are many practical issues which have to be organized and implemented in order to initiate the trial and commence patient enrollment. Quality assurance mechanisms are needed to ensure that potential problems do not interfere with the progress of the study or the quality of the data generated.

The oncology research nurse, a key member of the CT team, has a very important role in trial implementation. Many responsibilities described in the GCP guidelines which are assigned to the medical investigators are, in fact, performed by nurses. Nursing implications that can be derived from these guidelines focus on the role of educator, patient advocate, direct caregiver and coordinator. Key components for the implementation of a CT include: understanding the protocol fully and anticipating any problems that may arise; coordinating between the various members of the multidisciplinary team in the research centre; introduction of the study to the nursing staff and the analysis of the impact on workload; development of tools to implement quality assurance; verification that the informed consent form is complete and adequate; the development of patient education materials.

A CT requires enormous resources in terms of time, persons and costs. If not conducted correctly, this will lead to confusion and uncertainties, and above all, will jeopardise the scientific merit of the study. Compliance with the GCP standards ensures research of the highest quality. The contribution of nurses has undoubtedly had a favourable impact on the quality of clinical research, but above all the quality of patient care provided has been enhanced.

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The ICH-GCP guideline: The patient perspective – Symposium EORTC- Oncology Nursing Study Group

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In 1996 a revision of the Good Clinical Practice (GCP) guideline was established. This revision was a result of on an initiative undertaken by Japan, North-America and Europe called the "International Conference on Harmonisation of Technical Requirements for the Registration of Pharmaceuticals for Human Use (ICH)". Goal of this initiative was to achieve a world-wide harmonisation of legislation on the subject of all aspects in pharmaceutical research.

So, what are the consequences of this renewed ICH-GCP seen from a patients perspective? And, what does it mean in practice that patients right, safety and well being are protected conformable the Declaration of Helsinki?

As oncology nurses we see patients admitted for phase I, phase II or phase III trials. Because of the fact that nurses are patients advocate we are also responsible to observe or fulfil the ICH-GCP.

Patients have a right on honest information, like: What kind of a trial I am asked for; What are the implications for my near future; What are the advantages and disadvantages to participate; How does it affect my quality of life and is that what I want? Another aspect wich can lead to ethical dilemma's is the case of what if a patient doesn't want to know. Has a patient the right of not knowing according to these revised GCP guidelines?

More and more oncology nurses are convinced that the patients perspective should be the starting point of the health care/nursing process. However, this should not only be the case with nurses, but with all health care workers. If the ICH-GCP is taken seriously into practice then maybe this could be the start of putting patients perspective as *the* central starting point of the whole health care delivery system.

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The ICH-GCP guidelines: The nursing perspective

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Cancer clinical trials are mainly conducted to evaluate the effectiveness and tolerability of new therapies and treatments and to document drug/treatment related side effects. The importance of research in cancer has been recognised by nurses for many years and the role of nurses in medically lead cancer trials is also widely acknowledged. Collaboration between all the members of the multidisciplinary team, especially doctors and nurses is pivotal for the initiation. conduct and quality of the data of the trial. Nurses involved in re search teams have many responsibilities and roles: participant in the conduct of the study, direct caregiver, patient educator, patient ally-advocate, co-ordinator of care and research, administrator of research resourses and datamanager. The main responsibility however remains the provision of the best care for the patient, which also involves the co-ordination and integration of the interventions of the team members. Many tasks and responsibilities are delegated to nurses because of their close and continuing contact with the patient, therefore quality of the data produced and collected largely depends on nurses. Good Clinical Practice (GCP) is an international ethical and scientific quality standard for designing, conducting, recording and reporting clinical trials. In order to be able to comply with GCP. nurses involved in conducting clinical trials should be qualified by education, training and experience to perform these tasks. Moreover, to conduct clinical trials properly and safe according to GCP standard, it is crucial to have an adequate organisation with sufficient allocation of resourses and facilities. The educational and organisational aspects will be discussed in the presentation.