

231: IMPLEMENTATION OF THE JACIE-STANDARDS FOR HEMATOPOIETIC STEM CELL TRANSPLANTATION AT THE UNIVERSITY HOSPITAL OF BERN, SWITZERLAND

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Objective:

The purpose of this project is the implementation of the European JACIE-Standards as a quality management system (QMS) for the hematopoietic stem cell transplantation program at our centre, and the study of their impact on the clinical activity.

Methods:

- A) Introduction: a preliminary study was performed in order to assess the feasibility of this project. Firstly, all actors involved with hematopoietic stem cell transplantation at our centre were identified. A working party was created with the responsible persons of all departments concerned. The quality management of the hospital was involved to ensure adequacy of the newly planned QMS with the centre's existing quality plan. A pre-audit by an external organisation identified the leaks that had to be filled to meet all standards requested by JACIE.
- B) Implementation: on the basis of the pre-audit, a list of missing documents was established, and a working plan with milestones was designed in order to reach the standards in a twelve-month period. The number of actors involved (several departments and laboratories), required the creation of a coordinating unit for the whole program, able to organize and control the quality of the work performed by the different departments and units. A professional data and Q manager had to be hired to fulfil this task. Documents, however, had to be written by the regular staff of the concerned clinics and laboratories. The time requested by the regular staff for this extra task was an important measure for the evaluation of our project (cost evaluation) and was continuously and strictly assessed during the monthly meetings of the working party.

Results:

Interestingly, the pre-audit revealed that the clinical activity at our centre was conforming to the JACIE-Standards, but that the documentation of this adequate activity, as well as of the communication that was taking place between the different laboratories and department involved in the transplantation program, was incomplete. A new working attitude (documentation of processes, orders and communication) had to be developed. This implicated a profound modification of the staff habits, especially on the medical level, as paramedical staff were more used to working with standardized documents. A significant amount of time and energy was required by all staff-members concerned with the stem cell transplantation program.

Conclusion:

Implementation of the JACIE-Standards in the routine activity of a university hospital is feasible, but requires an important change in medical and paramedical staff behaviour, and an important amount of administrative work. Central coordination is mandatory, and quality management at a professional level requires the adjunction of supplementary administrative staff to a transplantation centre. The impact of the implementation of the JACIE-Standards on the everyday activity can be assessed in terms of total work hours dedicated by the staff to the QMS. The impact on the quality of the hematopoietic stem cell transplant activity (clinical endpoints) will be assessed after the first year of implementation.