Abstract

Introduction: Quality is the foremost objective of healthcare organisms and it is frequently the subject of intense discourse because of not only the citizens-patients’ requirements but health administrations and professionals’ goals and aims as well.

Objectives: The aim of the present study is to show the significance of quality system ISO 13485:2003 and modern tendencies round this in the international reality and in our country.

Method: An online, systematic peer-reviewed search in Medline, Pubmed and the Cochrane Database with meta-analysis of the search results was conducted. The retrieved studies were then screened to meet certain inclusion criteria, i.e. relevance, significant meanings in correspondence with this paper’s objectives and of interest to an international health-professional readership.

Results: The present study constitutes a theoretical approach of quality in healthcare environment, as well as a presentation and description of the ways and processes for quality measurement and quality of health care services improvement. Initially, quality is conceptually determined as a general idea, but mainly focusing on health sector and the providing services. Acute importance is given on quality measurement methods and tools, as well as on the administrative processes that can be applied to continuously improve and ensure an adequate level of quality. An important part of this study is the delineation of quality system of ISO 13485:2003, as this is internationally and domestically applied in the field of Biomedical Engineering.

Conclusion: Given the need for implementation of the prevalent European and National legislation, in order to ensure the safe distribution of medical equipment and the prevention of possible adverse incidents, the present study was realized.

Keywords: Healthcare, Healthcare Quality, Biomedical Engineering, ISO 13485