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## THE ISSUE OF STANDARDIZATION OF INTERVENTIONAL MEDICAL TECHNOLOGIES IN MODERN CARDIOLOGY

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### **Abstract**

The purpose of the study was to assess the experience of implementing local protocols for the standardization of interventional medical technologies at the regional clinical hospital. There was demonstrated that the implementation of local clinical protocols can reduce the number of misdiagnoses, the total number of clinical and instrumental and clinical-laboratory studies, duration of in-hospital stay. The resynchronization of myocardial contraction by means of biventricular cardiostimulation, regulated by the clinical protocol, allows to achieve significant clinical effect on parameters such as ultimate diastolic pressure in the LV, the area of mitral regurgitation, the functional class on HYHA

**Key words: local clinical protocols, clinical guidance, cardiovascular diseases, invasive interventions**

Standardization in medical practice is currently one of the most pressing problems of modern health care. Given the changes in legal and economic realities, active reform of the industry, the issue of developing and implementing technical monitoring systems for medical care, as well as streamlining clinical algorithms used for diagnosis, prognosis, treatment and prevention of socially significant diseases, e.g. diseases of the cardiovascular system. In the conditions of the tertiary level of medical care provided by hospitals of regional and national subordination, it is important, first of all, to quantify the quality of medical care [1-4].

The Ukraine-2020 Sustainable Development Strategy, approved by the Decree of the President of Ukraine dated January 12, 2015, No. 5/2015, provides the basics for the reform of the health care system. Thus, Section 7 and Section 3 stipulate that the purpose of state policy in this area is a fundamental, systemic reform aimed at creating a patient-centered system capable of providing medical care for all Ukrainian citizens at the level of developed European states. The guideline for reform is the European Union's "European Health Strategy 2020" program [6].

In addition, the need to reform the healthcare sector is envisaged by the World Bank project "Improving health at the service of people", the Memorandum between Ukraine and the International Monetary Fund on economic and financial policies concluded in connection with the signing of a four-year extended agreement within the framework of The International Monetary Fund's Advanced Funding (EFF) mechanism (February-March 2015), the National Strategy for the Construction of a New Health Care System in Ukraine for the period 2015-2020, other normative legal acts and policy documents on health care reform in Ukraine. Recently the draft of the law "On State Financial Guarantees for the Provision of Medical Services and Medicines" was approved by Ukrainian Parliament [5]. One of the main objectives of the law is the introduction of a modern quality management system for healthcare, which provides for the further development of standardization of medical technologies.

The purpose of the study was to assess the experience of implementing local protocols for the standardization of interventional medical technologies at the regional clinical hospital.

**Material and methods.** The study was performed on the basis of the Odessa Regional Clinical Hospital. The clinical outgrowths have been analyzed before and after the introduction of local (intra-hospital) clinical protocols for the provision of medical care to patients with cardiovascular pathology. The term of the retrospective analysis covered 2010-2015.

As units of observation, the standard forms of 003o, 066o were used. There were considered the number of differences between diagnoses during hospitalization and clinical diagnoses, the total number of clinical and instrumental and clinical and laboratory studies, the length of stay in the hospital, the structure of the results of treatment (p.14 pp. 066o). The statistical analysis was performed using frequency and dispersion analysis using Statistica software (Dell StatSoft, USA).

### **Research results**

During the period chosen for the comparative analysis, local clinical protocols were approved for the treatment of patients with coronary heart disease, hypertension, symptomatic

arterial hypertension, including using interventional interventions (radiofrequency catheter, desimpation of the renal arteries), heart failure, including local (intra-hospital) clinical protocol for the provision of medical care to patients with heart failure using left ventricular endocardial cardiostimulation; arrhythmias, emergency treatment for acute coronary syndrome, and the like.

The standard local protocol contains references to the ICD-10 disease code, regulatory requirements with reference to the orders of the Ministry of Health and Medical Sciences of Ukraine No. 102/18 of 19.02.2009 and No. 798/75 of November 3, 2009, Ministry of Health of Ukraine Order No. 597 of September 16, 2011, No.622 dated 03.11.2008 and No.436 dated 03.07.2006; indications for hospitalization, a detailed description of the clinical route at the stages of the regional consultative polyclinic and hospital, if necessary - preoperative and postoperative term of stay; algorithm of diagnostics with indication of the desired volume of sufficient examination, obligatory and additional diagnostic methods. The recommended terms of primary diagnosis, requirements for the formulation of a clinical diagnosis, treatment algorithms, volume of medical interventions in a hospital, including conservative and surgical treatment are given. Particular attention is paid to indicators of the quality of medical care and the desired results for each specific nosoform. Detailed description of the algorithm of an extract from the hospital, recommendations for discharge, indicates the term of further treatment and diagnostic control, provides a brief rehabilitation algorithm and the term of the clinic, including the need and timing of the dispensary supervision. Further analysis showed that the implementation of local clinical protocols allowed to reduce the number of differences between diagnoses during hospitalization and clinical diagnoses, the total number of clinical and instrumental and clinical-laboratory studies, the length of stay in a hospital, and optimize the structure of the results of treatment (Table 1).

Table 1

The effectiveness of the implementation of local clinical protocols

Indices	$\Delta$ , %
Differences in diagnoses (primary and clinical)	-4,2
General number of clinical-instrumental and lab tests	-7,9
Duration of stay in hospital	-4,4
Lethality	-11,3
Improvement	+15,4
Recovery	+9,3
Without changes	-3,8

After the implementation of the clinical protocol for the provision of medical care to patients with heart failure using left ventricular endocardial cardiostimulation, 20 patients with ventricular asynchrony were examined, which was installed by an artificial rhythm driver Biotronik Talos DR (USA). Among the surveyed patients, males dominated - 65%. The age of the patients varied from 48 to 75 years, reaching an average of  $57.5 \pm 2.2$  years. Conducting resynchronization of myocardial contraction by means of biventricular cardiac stimulation significantly improved parameters such as ultimate diastolic pressure in LV, area of mitral regurgitation, functional class on NYHA.

#### Conclusions:

1. The implementation of local clinical protocols can reduce the number of diagnoses for hospitalization and clinical diagnoses, the total number of clinical and instrumental and clinical-laboratory studies, duration of in-hospital stay

2. The resynchronization of myocardial contraction by means of biventricular cardiostimulation, regulated by the clinical protocol, allows to achieve a significant clinical effect on parameters such as ultimate diastolic pressure in the LV, the area of mitral regurgitation, the functional class on NYHA

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