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## Ways of development of processes of standardization and informatization of the field of healthcare

**Viktor D. Gogunskii<sup>1)</sup>**ORCID: <https://orcid.org/0000-0002-9115-2346>; [vgog@i.ua](mailto:vgog@i.ua). Scopus Author ID: 57194244349**Olga O. Mezentseva<sup>2)</sup>**ORCID: <https://orcid.org/0000-0002-8430-4022>; [olga.mezentseva.fit@gmail.com](mailto:olga.mezentseva.fit@gmail.com). Scopus Author ID: 57210290327**Anna S. Kolomiets<sup>2)</sup>**ORCID: <https://orcid.org/0000-0003-4252-5975>; [kolomietsa@fit.knu.ua](mailto:kolomietsa@fit.knu.ua). Scopus Author ID: 57200182743**Kateryna V. Kolesnikova<sup>2)</sup>**ORCID: <http://orcid.org/0000-0002-9160-59823>; [amberk4@gmail.com](mailto:amberk4@gmail.com). Scopus Author ID: 57188623059**Viktor V. Morozov<sup>2)</sup>**ORCID: <https://orcid.org/0000-0001-7946-0832>; [knumvv@gmail.com](mailto:knumvv@gmail.com). Scopus Author ID: 57200186044<sup>1)</sup> Odessa National Polytechnic University, 1, Shevchenko Ave, Odessa, 65044, Ukraine<sup>2)</sup> Taras Shevchenko National University of Kyiv, 60, Volodymyrska Str, Kyiv, 01033, Ukraine

### ABSTRACT

This article is devoted to the analysis of standardization of informatization of medical care projects. In particular, the task of improving the quality and accessibility of medical services on the basis of a scientifically based methodology of portfolio-oriented management is set. To solve this problem, subtasks have been identified, such as the development of methods for estimating the cost of projects in the field of medical services; the creation of a model for financing healthcare based on the introduction of a system of compulsory state medical insurance; the development of a quality management system for healthcare projects, which includes models and methods for planning, ensuring and controlling the quality of medical services; the development of the foundations of state programs for standardization and informatization of healthcare as the basis of a quality management system. Improving the quality of healthcare is recognized as the main goal of reforming the industry at the present stage. The quality of healthcare is defined as the totality of the results of prevention, diagnosis and treatment of diseases determined by the established requirements based on the achievements of medical science and practice. In the work, based on the analysis of the best world experience, it is shown that the use of the principles of standardization in healthcare provides a high level of medical care, regardless of the patient's place of residence, the level of knowledge of a particular doctor or recommendations of a particular scientific school. The paper proposes the main approaches, methods and components of the standardization system. Using the practical experience of private medical centers an algorithm for creating an electronic medical record, its main functions and possible areas of use are proposed. It is shown that the main difficulty in implementing the standardization of medical care is that this work at the level of public and private clinics is controlled not only by the principle of general standardization and modification, but also by a specific project goal for each medical industry, which should be achieved in a comprehensive and balanced manner.

**Keywords:** Health care; informatization of health care; standardization of health care; health care project; electronic medical record

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### INTRODUCTION

Projects and programs in the field of health care are among the most difficult type of project activity due to their social orientation, as well as due to the specificity of goals aimed at achieving a positive effect in the health of patients not only through qualified medical care but also through the introduction of modern mechanisms of project-oriented management. In recent years, the problem of protecting the health of Ukrainian citizens has already turned into a problem of threats to the country's national security [1].

The basis of the project approach is to accurately and clearly define the objectives of the project. In accordance with the results of the analysis of the state of health care in Ukraine [2, 3], [4, 5], the strategic goal of the development of the industry should

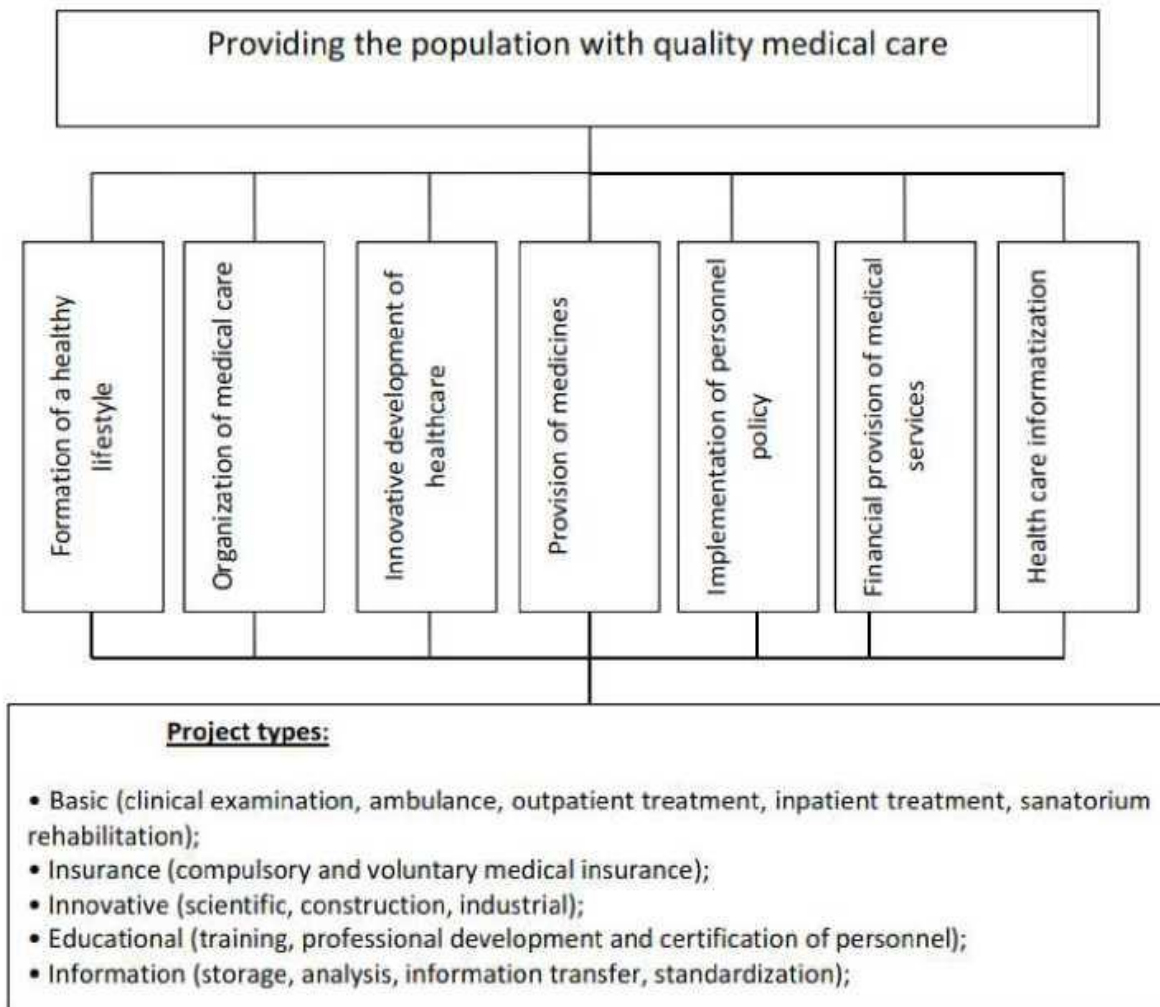
be considered the creation of legal, financial, organizational and technological conditions for the guaranteed provision of the population with quality medical care. In Fig. 1 presents a set of seven tasks, the joint solution of which will solve the problem of providing medical services.

The solution to each of these tasks requires the complex implementation of a number of projects of various types:

- basic (clinical examination, ambulance, outpatient treatment, inpatient treatment, spa rehabilitation);
- insurance (compulsory and voluntary medical insurance);
- innovative (scientific, construction, industrial);
- educational (training, professional development and certification of personnel);
- informational (storage, analysis, the transmission of information, standardization).

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**Fig. 1. Mission, objectives and types of projects in healthcare**

*Source: compiled by the authors*

It should be noted that the overall result of reforming the industry will be determined not so much by the successful implementation of individual projects as by the effect obtained from the implementation of the entire set of projects – a portfolio, in connection with which the relevance of the application of the portfolio-oriented management methodology is significantly increasing [6, 7].

The lack of a comprehensive system of standardization and certification in healthcare currently impedes the introduction of medical insurance into practice, limits the possibilities for strategic planning of the industry, regulation, and control of costs for medical and preventive activities [8, 9].

The creation of a unified system of standardization in health care is aimed at improving the management of the industry, ensuring its integrity through unified approaches to planning, rationing, licensing and certification, improving the quality of medical care, rational use of human and material resources, optimization of the treatment and diagnostic process, integration of domestic health care

into world medical practice.

The purpose of standardization in health care is to improve the quality of preventive and therapeutic and diagnostic measures, to solve the problems of maintaining and improving the health of the population [10, 11], [12].

The main tasks in the field of standardization in healthcare are:

– regulatory support for the implementation of laws in the field of public health protection and the Concept for the development of healthcare and medical science in Ukraine;

– creating a unified system for assessing quality indicators and economic characteristics of medical services, establishing scientifically grounded requirements for their nomenclature, volume and quality, ensuring interaction between entities involved in the provision of medical care;

– establishing requirements for the conditions for the provision of medical care, efficiency, safety, compatibility and interchangeability of processes, equipment, tools, materials, medicines and other

components used in health care;

- regulatory support of metrological control;
- establishment of uniform requirements for licensing and accreditation of medical institutions, training, certification and certification of specialists
- regulatory support for certification and quality assessment of medical services;
- creation and provision of supervision and control over compliance with the requirements of regulatory documents in the prescribed manner;
- basic principles of standardization in healthcare;
- a unified procedure for the development, approval, adoption and implementation of regulatory documents, supervision and control over compliance with the requirements of regulatory documents on standardization (the principle of uniformity);
- social, scientific and economic feasibility of the development and application of normative documents in practice (the principle of significance);
- compliance with the requirements of the legislation of Ukraine, international regulatory documents and modern scientific achievements (the principle of relevance);
- coordination of requirements for standardization objects among themselves (principle of complexity);
- ensuring the possibility of controlling the requirements specified in regulatory documents by objective methods (the principle of verifiability);
- mutual desire of all subjects to reach agreement in the development and implementation of regulatory documents of the standardization system (the principle of the consent). The organization of the standardization system in health care presupposes the solution of both organizational and technical problems and the problems of regulatory support.

### THE PURPOSE OF THE ARTICLE

The aim of this work is to develop an algorithm for creating an electronic medical record, its main functions and possible applications, which would minimize losses in informatization of medical services without compromising the quality with an increase in the number of patients.

### MAIN PART

Health care projects involve four cycles of improvement and management (Fig. 2). Any project is implemented in the coordinates of the system of goals, as well as external and internal constraints. In general, as the target function of the project, a certain generalized performance indicator  $h$  can be adopted this depends on the project management strategy and determines its value:

$$h = \langle S, T, R, A, TE, G, I \rangle, \quad (1)$$

where:

$S \in \{s_1, s_2, \dots, s_t\}$  – set of system states;

$T \in \{t_1, t_2, \dots, t_k; m_1, m_2, \dots, m_v; o_1, o_2, \dots, o_p\}$  – multiple technologies  $\{t_1, t_2, \dots, t_k\}$ , methods  $\{m_1, m_2, \dots, m_v\}$  and operations  $\{o_1, o_2, \dots, o_p\}$ ;

$R$  – multiple reactions of the system to external perturbations;

$A = U \cup F$  – multiple project value creation conditions;

$U$  – multiple input external constraints;

$F$  – multiple process implementations;

$TE$  – project management structure;

$G: \begin{cases} S \rightarrow T \\ S \times A \rightarrow T \end{cases}$  – operational project management model;

$I: \begin{cases} S \rightarrow h \\ S \times A \rightarrow h \end{cases}$  – Project Management Information model.

The project lesson base contains information obtained from experimental research. This base is formed on the basis of already implemented projects and is the basis for improving the legislative and technological base.

Information about the results of already implemented projects using the model forms the knowledge base of the projects.

In the general case the independent variables  $S, T, R, A, TE, G$  and  $I$ . The central place is given to the application of the model of changes in the states of the medical service system.

Planning should be based on predictive estimates of expected results. And the assessment of real results will allow for the improvement of future projects. Each process of developing and executing a project is implemented in the form of a classic cycle in project management theory, known as the PDCA (Plan – Do – Check – Action) – “plan, implement, check, action” [13].

It is rational to predict the efficiency of the developed ones using probabilistic models that reflect the specifics of random processes. Nowadays, model representations take into account many characteristics of patients and characteristics of medical services. Medical statistics do not always fully reflect the specifics of the development of the state of the provision of medical services. The random nature of the action of the environment on the demand for medical services is obvious, which makes it possible

to represent the activities of medical institutions through probabilistic characteristics.

A conceptual model (Fig. 2), which takes into account changes in the states of the system of consumers of services and contains methods of organizational project management and allows you to form cycles of management, monitoring and selflearning in order to effectively implement projects for the provision of medical services and further standardization in the field of health protection.

The main areas of standardization that ensure the development of health care and medical science are (Fig. 3):

- standardization of medical services;
- standardization of drug provision;
- regulation of requirements for the conditions for the provision of medical care;
- standardization of professional activity;
- standardization of information support.
- improving the organizational system, which allows ensuring the formation of a healthy lifestyle

and the provision of high-quality medical care to all citizens (within the framework of state guarantees);

- development of infrastructure and resource provision of health care, including financial, material, technical and technological equipment of medical institutions based on innovative approaches and the principle of standardization.

By now the world practice has accumulated significant experience in the use of information and communication technologies in healthcare. In the USA, Canada, the European Union, and many other countries, national health informatization programs have been implemented for decades [16, 17], [18].

The current global trends are the pursuit of efficient use of resources in the health sector. The health workforce is on the decline as the demand for better quality services is increasing and accountability for results is increasing. Population mobility and urbanization are factors that put forward new requirements for the availability of healthcare anywhere in the city, country, or world.

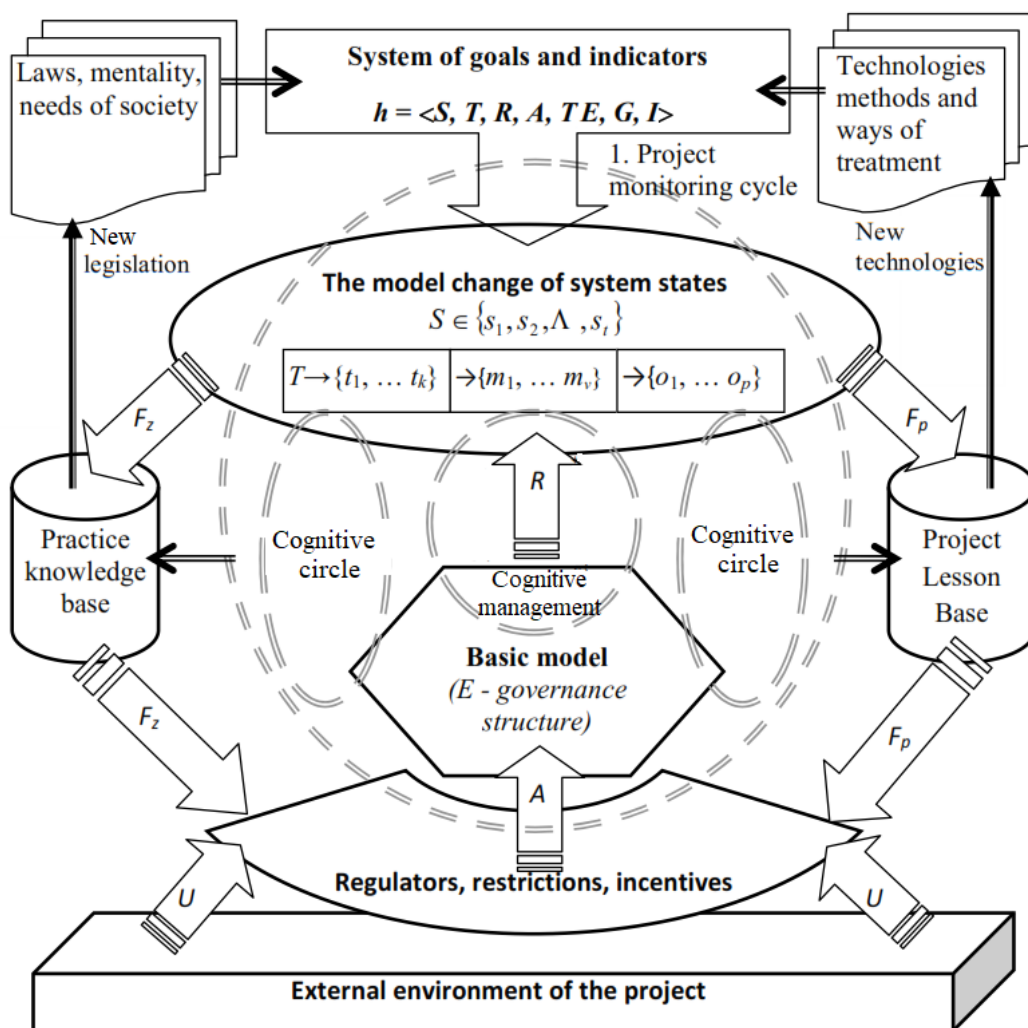


Fig. 2. Conceptual model for health care project management

Source: compiled by the authors

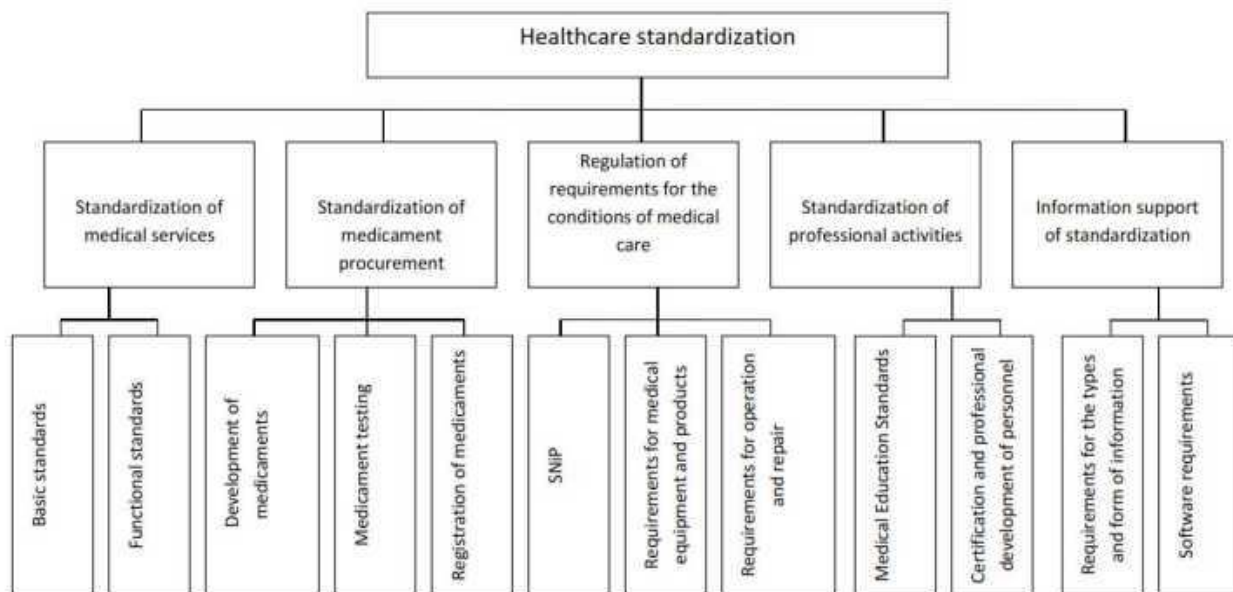


Fig. 3. Components of the health care standardization system

Source: compiled by the authors

The rapid development of information and communication technologies, in particular in the field of big data, artificial intelligence, is considered by most countries as the main response to these challenges. In developed countries, digital transformation has already changed a number of industries and organizations, bringing significant benefits to both public health and personal health care. Digitalization is changing the way health services are delivered and the way health systems are managed at all levels [1].

Medical images used as a result of medical records have a high dimension; in particular, the medical image of a chronic disease is transformed by a publicly available modeling environment into at least 416 parameters. This is far from being the maximum, and if necessary, the dimension of the analyzed medical parameters can be increased. Usually there is a lot of data, but most of them are of low quality (low information content) for the final result in the form of a standard advice or a hint for the attending physician.

There are “bad” parameters with low information content and “good” parameters with high information content. Fig. 4 shows the distributions of the “bad” parameter –  $p(v_1)$  and the “good” parameter –  $p(v_2)$  against the background of the data distribution, all “Strangers” and “good” parameter –  $p(\xi)$  against the background of the data distribution, all “Strangers” –  $p(\zeta)$

In the case of using a “fuzzy extractor” to distribute each the parameter is set to the right and left limits of the allowed values. At the first approximation, we can assume that the distributions of medical

data values are normal. It follows that the limits of acceptable values can be determined by the rule of three standard deviations from the mathematical expectation.

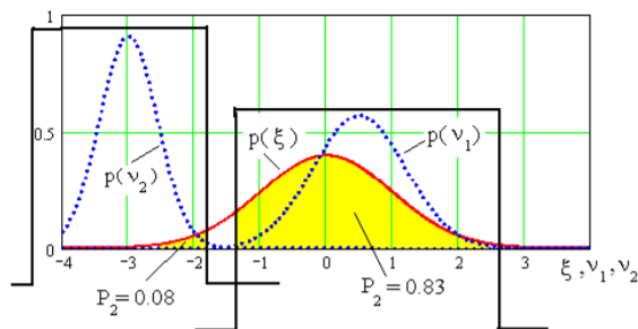


Fig. 4. Examples of distributions of the “bad” parameter -  $p(v_1)$

Source: compiled by the authors

That is, the thresholds of the upper-right border and the lower-left border should be set as follows:

$$\begin{cases} k_R = E(v) + 3 * \sigma(v) \\ k_L = E(v) - 3 * \sigma(v), \end{cases} \quad (2)$$

where:  $E(v)$  is the mathematical expectation of the medical parameter;  $\sigma(v)$  is the standard deviation of the medical parameter.

In this case, the probability of an error of the first kind (failure “To your own”) it turns out that  $P1(v) \approx 0$  is practically zero. The probability of an error of the second kind (false omission of “Alien”) is calculated as the area of the distribution –  $p(\zeta)$  that falls within the range of acceptable values of the parameter

$$P_2(\nu) = \frac{1}{\sigma(\xi)\sqrt{2\pi}} \int_{k_L}^{k_R} \exp\left\{-\frac{(E(\xi)-u)^2}{2\sigma^2(\xi)}\right\} du. \quad (3)$$

This means that the informativeness of the medical parameter can be calculated using the following formula:

$$I(\nu) = -\log_2(P_2(\nu)). \quad (4)$$

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In Fig. 5, the areas proportional to  $p_2$  are marked with a fill. Fig. 5 shows that the first medical parameter is less informative  $p(\nu1) I = 0.27$  bits (the fill area is large), much more informative is the second medical parameter  $p(\nu2) I = 3.6$  bits.

Usually, the variation in the information content of medical parameters is significant. If you focus on the use of the most informative medical parameters, then it will be possible to apply the classic decision rules. However, there is not really much good data with a lot of information content. As a consequence, classical decision rules do not provide high-quality solutions.

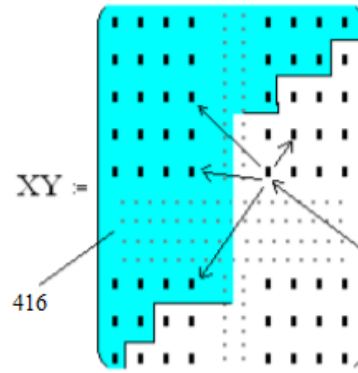


Fig. 5. Matrix of two-dimensional Fourier coefficients used as medical parameters

Source: compiled by the authors

It is possible to significantly improve the quality of decisions made if you create decision-making algorithms that can work with large amounts of bad (low-informative) data. The perfect algorithm data processing should accumulate the information obtained for each medical parameter

## RESULTS

The actual amount of information extracted by the existing decision rules is always less than its limit value. Neural network converters with a single layer of neurons must provide at least one bit of output information for each neuron. This means that the number of inputs for a neuron must be selected more than the total information content of the input data it converts.

Most private medical centers already offer citizens a whole range of medical services: insurance ambulance or comprehensive life insurance programs for patients, a home doctor, inpatient and outpatient treatment, diagnostics and counseling, sanatorium and preventive services.

A single information space is used, which allows:

- increase the number of patients served (higher registration speed, reduced visit time);
- reduce costs by lessing the cost of storing paper documents;
- improve the quality of treatment, since the accuracy of the diagnosis is increased by 50 % if the doctor knows the patient's history; doctors spend more time with the patient and less time searching for information about the patient;
- increase the efficiency of the management system, in particular, better allocation of resources (specialists, equipment).

The electronic medical record (EMR) content is shown in Fig. 6. The EMR architecture includes ac-

counting organization, data organization, data types and formats and information transfer. The requirements for the various components that must be fulfilled in the development of the EMR are summarized in Table [23, 24].

One of the main functions of a neuron is enrichment relatively poor input data. This function is performed by the adder. In this context, it is clear that to get “good” data; you need to use a lot of “bad” data. The worse the data, the more it needs to be enriched and the more inputs the neuron must have. Naturally, to estimate the number of inputs, information content alone is not enough; you also need to take into account the correlation of the input data. This, in turn, sets us the task of changing the approach to standardizing the input data of medical records.

The experience of the medical center “INTO-SANA” (Odessa) in the work on informatization showed that the most important and difficult task is the creation of an EMR.

A number of definitions of EMR can be found in the literature [19, 20]:

– an electronic sequential collection of personal health information, usually associated with an individual, entered or accepted by health care providers, which may be distributed across multiple locations or aggregated at a specific source;

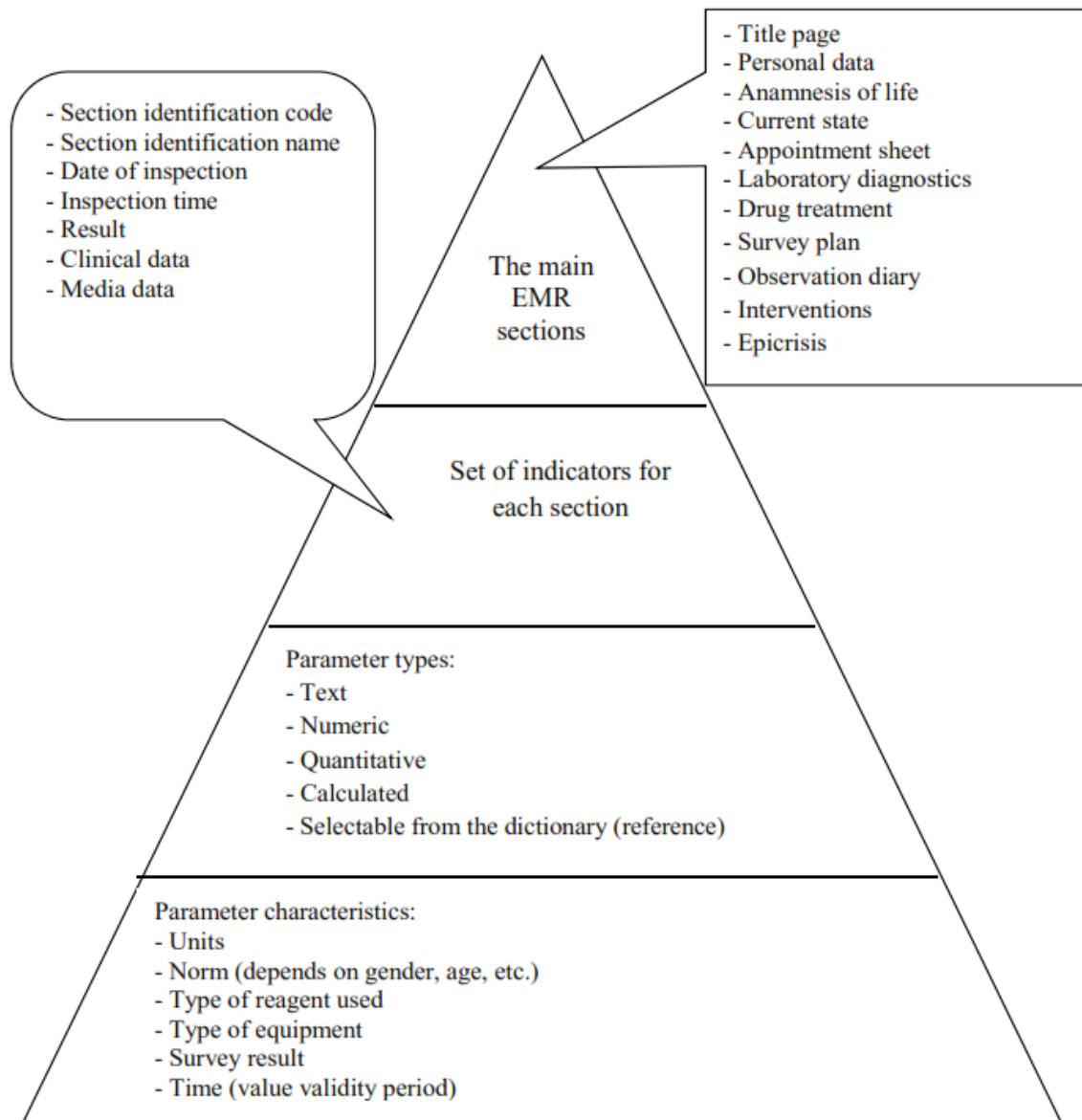
– a sequential collection of personal health information of an individual entered or accepted by health care providers and stored electronically;

– a set of data and information collected or generated to register medical services provided to an individual;

*Table. Electronic medical record architecture requirements*

|                            |                                |   |
|----------------------------|--------------------------------|---|
| Organization of accounting | Sections                       | Structuring the information contained in the EMR for various sections to provide users with the ability to search for data and view sections in accordance with their requests  |
|                            | Format                         | The EMR format as seen by a doctor or user must comply with a set of specifications established by standards organizations  |
|                            | Portability                    | EMR support, which can be transferred between its users and combined with information from other EMR regardless of hardware, software, databases, networks  |
|                            | Secondary applications         | Providing the possibility of organizing and extracting information from the EMR in a way that facilitates its secondary use   |
|                            | Archiving                      | Providing support for data archiving  |
| Data organization          | Structured data                | Providing the ability to store data in the form of lists, tables, structures, simple pairs. Providing the ability to store many values of any parameter obtained when conducting multiple separate measurements in one or in different places   |
|                            | Unstructured data              | Ensuring the inclusion of free text. Support for searching unstructured data and ensuring that structured text is included. Including comments in saved data. Providing the means to link the highlighted elements  |
|                            | Clinical data                  | Providing registration, storage and search of comprehensive information about the patient's treatment, the ability to register, store and search for all the necessary data on the whole range of issues  |
|                            | Administrative data            | Data registration and classification support. Support of information standards that allow to unambiguously identifying the subject of treatment, doctors, place, date, time and duration of treatment. Support for the management of healthcare processes and treatment episodes. Support for the registration of financial and other commercial information  |
| Data format and type       | Data types                     | Support the definition of the logical structure of numeric and quantitative data Provide the ability to quantify percentages. Maintain approximate, partial, and fuzzy dates and times. Maintain a log of future planned events or activities   |
|                            | Support for various data types | Provide integration with various types of data defined in other systems, such as DICOM, MIME, ECG   |
|                            | Reference data                 | Maintain reference data registration  |
|                            | Contextual data                | Maintain the registration of context sensitive data related to: date, time, subject, place  |
|                            | Connections                    | Maintain links with “external reference data” that cannot be stored within the EMR  |
| Transfer of information    | Messaging and recording        | The ability to exchange EMR data in whole or in part. Maintain data ordering for interaction purposes. Determine the semantics of the data to be merged from the selection in the receiving system. Provide audit trail of exchange processes, including authentication for data fusion. The possibility of the rules for the exchange of a sample, consisting of a part of the current indicators or all data from the EMR be the same as the rules for the exchange of EMR as a whole |

*Source: compiled by the authors*



**Fig. 6. Contents of the electronic medical record**

*Source: compiled by the authors*

– a comprehensive structured set of clinical, demographic, environmental, social and financial data and information in electronic form documenting the health services provided to an individual;

– medical record in machine-readable format;

– an electronic map of patient data stored in a system designed to support users by ensuring the availability of complete and accurate data, recommendations and warnings of the attending physician, clinical decision support systems, links to medical knowledge bases and other useful information.

– a virtual compilation of basic data about a person's health throughout his life, including facts, observations, interpretations, plans, actions and results.

The main purpose of EMR is to provide a documented record of medical treatment that supports current and future treatment by the same or other

physicians. This information provides an opportunity for communication between physicians involved in the patient's treatment. The main persons who benefit from such accounting are the patient (consumer) and the doctor (doctors).

Any other purpose for which EMR is used is considered secondary, like any other person who benefits from it.

Secondary uses of EMR are:

– forensic medicine - confirmation of the treatment performed, signs of compliance with legislation, a reflection of the competence of doctors;

– quality management - a study of continuous quality improvement, review of use, monitoring of performance (peer review, clinical audit, analysis of results), the performance of evaluation trials, accreditation;



- education - training of medical students, patients / consumers and doctors;
- research - development and evaluation of new diagnostic methods, measures and means of preventing diseases, epidemiological studies, analysis of public health;
- health of society and population;
- policy making - analysis of health statistics, trends, clinical cases;
- health service management - resource allocation and management, cost management, risk management, reports and publications, marketing strategies;
- payments, finance, compensation - consumers of EMR are insurers, government agencies, funding bodies [21, 22].

### CONCLUSIONS

The health care system in Ukraine is in critical condition, as evidenced by the decline in life expectancy in the last decade and lagging behind other European countries in almost all indicators characterizing the level of population health.

The main reason for the current situation lies in the imperfect system of health care management, insufficient funding and irrational distribution of funds allocated by the state to the industry. The analysis of world experience has proved the need to introduce a health insurance system, despite the variety of forms and features of the organization of medical care in various states.

The strategic goals of health development should be to improve the quality and accessibility of

medical services based on the evidence-based methodology of portfolio-oriented management. Achieving these goals requires a comprehensive solution to the following tasks:

- development of methods for assessing the value of projects in the field of medical services;
- creation of a health financing model based on the introduction of a compulsory state health insurance system;
- development of a quality management system for healthcare projects, which includes models and methods of planning, ensuring and controlling the quality of healthcare services;
- development of the foundations of state programs for standardization and informatization of health care as the basis for a quality management system.

Based on the analysis of the best world experience, it is shown that the use of the principles of standardization in health care provides a high level of medical care, regardless of the patient's place of residence, the level of knowledge of a particular doctor or the recommendations of a particular scientific school. The manuscript proposes the main approaches, methods and components of the standardization system.

Using the practical experience of private medical centers, an algorithm for creating an electronic medical record, its main functions and possible areas of use is proposed.

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## Шляхи розвитку процесів стандартизації та інформатизації галузі охорони здоров’я

**Віктор Дмитрович Гогунський<sup>1)</sup>**

ORCID: <https://orcid.org/0000-0002-9115-2346>; [vgog@i.ua](mailto:vgog@i.ua). Scopus ID: 57194244349

**Ольга Олексіївна Мезенцева<sup>2)</sup>**

ORCID: <https://orcid.org/0000-0002-8430-4022>; [olga.mezentseva.fit@gmail.com](mailto:olga.mezentseva.fit@gmail.com). Scopus ID: 57210290327

**Анна Степанівна Коломієць<sup>2)</sup>**

ORCID: <https://orcid.org/0000-0003-4252-5975>; [kolomietsa@fit.knu.ua](mailto:kolomietsa@fit.knu.ua). Scopus ID: 57200182743

**Катерина Вікторівна Колеснікова<sup>2)</sup>**

ORCID: <http://orcid.org/0000-0002-9160-59823>; [amberk4@gmail.com](mailto:amberk4@gmail.com). Scopus ID: 57188623059

**Віктор Володимирович Морозов<sup>2)</sup>**ORCID: <https://orcid.org/0000-0001-7946-0832>; knumvv@gmail.com. Scopus ID: 57200186044<sup>1)</sup> Одеський національний політехнічний університет», пр-т Шевченка, 1. Одеса, 65044, Україна<sup>2)</sup> Київський національний університет імені Тараса Шевченка, Володимирська, 60. Київ, 01033, Україна**АНОТАЦІЯ**

Стаття присвячена аналізу процесів стандартизації проектів інформатизації медичної сфери. Зокрема, поставлено завдання підвищення якості та доступності медичних послуг на основі науково обґрунтованої методології портфельно-орієнтованого управління. Для вирішення цієї проблеми були визначені підзадачі, такі як розробка методів оцінки вартості проектів у сфері медичних послуг; створення моделі фінансування охорони здоров'я на основі впровадження системи обов'язкового державного медичного страхування; розробка системи менеджменту якості проектів охорони здоров'я, яка включає моделі та методи планування, забезпечення та контролю якості медичних послуг; розробка основ державних програм стандартизації та інформатизації охорони здоров'я як основи системи менеджменту якості. Підвищення якості охорони здоров'я визнано головною метою реформування галузі на сучасному етапі. Якість охорони здоров'я визначається як сукупність результатів профілактики, діагностики та лікування захворювань, що визначаються встановленими вимогами, заснованими на досягненнях медичної науки і практики. У роботі, заснованій на аналізі кращого світового досвіду, показано, що використання принципів стандартизації в охороні здоров'я забезпечує високий рівень медичної допомоги, незалежно від місця проживання пацієнта, рівня знань конкретного лікаря або його рекомендацій. У статті пропонуються основні підходи, методи та компоненти системи стандартизації у галузі охорони здоров'я. Використовуючи практичний досвід приватних медичних центрів запропоновано алгоритм створення електронної медичної карти, її основні функції та можливі області застосування. Показано, що основна складність під час стандартизації у медичній сфері полягає в тому, що ця робота на рівні державних і приватних клінік контролюється не тільки принципом загальної стандартизації і модифікації, але і конкретною метою окремого медичного проекту, яка повинна бути досягнута комплексним та збалансованим чином.

**Ключові слова:** охорона здоров'я; інформатизація охорони здоров'я; стандартизація охорони здоров'я; проект у галузі охорони здоров'я; електронна медична карта

**ABOUT THE AUTHORS**

**Viktor D. Gogunskii** – D.Sc. (Eng), Professor, Head of the Department of Life Safety Systems Management. Odessa National Polytechnic University, 1, Shevchenko Ave. Odessa, 65044, Ukraine

ORCID: <https://orcid.org/0000-0002-9115-2346>; vgog@i.ua. Scopus Author ID: 57194244349**Research field:** Project management; computer science; modeling of complex objects and systems

**Віктор Дмитрович Гогунський** – доктор технічних наук, професор, завідувач кафедри Управління системами безпеки життєдіяльності. Одеський національний політехнічний університет, пр-т Шевченка, 1. Одеса, 65044, Україна



**Olga O. Mezentseva** – Candidate of Economic Sciences, Associate Professor of the Department of Management Technology. Taras Shevchenko National University of Kyiv, 60, Volodymyrska Str. Kyiv, 01033, Ukraine

ORCID: <https://orcid.org/0000-0002-8430-4022>; olga.mezentseva.fit@gmail.com. Scopus Author ID: 57210290327**Research field:** Data analytics; data mining; neural networks

**Ольга Олександрівна Мезенцева** – кандидат економічних наук, доцент кафедри Технології управління. Київський національний університет імені Тараса Шевченка, вул. Володимирська, 60. Київ, 01033, Україна



**Anna S. Kolomiets** – Candidate of Economic Sciences, Associate Professor of the Department of Management Technology. Taras Shevchenko National University of Kyiv, 60, Volodymyrska Str. Kyiv, 01033, Ukraine

ORCID: <https://orcid.org/0000-0003-4252-5975>; kolomietsa@fit.knu.ua. Scopus Author ID: 57188623059**Research field:** Project management; innovation project management; project team management

**Анна Степанівна Коломієць** – кандидат економічних наук, доцент кафедри Технології управління. Київський національний університет імені Тараса Шевченка, Володимирська, 60. Київ, 01033, Україна



**Kateryna V. Kolesnikova** – D.Sc. (Eng), Professor of the Department of Management Technology.

Taras Shevchenko National University of Kyiv, 60, Volodymyrska Str. Kyiv, 01033, Ukraine

ORCID: <http://orcid.org/0000-0002-9160-59823>; amberk4@gmail.com. Scopus Author ID: 57188623059**Research field:** Project management; knowledge management; computer science; modeling of complex objects and systems

**Катерина Вікторівна Колеснікова** – доктор технічних наук, професор кафедри Технології управління. Київський національний університет імені Тараса Шевченка, вул. Володимирська, 60. Київ, 01033, Україна



**Victor V. Morozov** – Candidate of Engineering Sciences, Professor of the Department of Management Technology.

Taras Shevchenko National University of Kyiv, 60, Volodymyrska Str. Kyiv, 01033, Ukraine

ORCID: <https://orcid.org/0000-0001-7946-0832>; knumvv@gmail.com. Scopus Author ID: 57200186044**Research field:** Use of artificial intelligence tools for the development of project management systems; information technologies; management automation; development and implementation of corporate project management systems (csr); management decision – making; computer modeling and visualization of training

**Віктор Володимирович Морозов** – кандидат технічних наук, професор кафедри Технології управління. Київський національний університет імені Тараса Шевченка, вул. Володимирська, 60. Київ, 01033, Україна