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METHODOLOGY FOR THE DEVELOPMENT AND APPLICATION OF CLINICAL DECISIONS SUPPORT INFORMATION TECHNOLOGIES WITH CONSIDERATION OF CIVIL-LEGAL GROUNDS

Currently, there are no clinical decision support information technologies (CDSIT) that would consider civil-legal grounds when forming a decision for clinicians. Therefore, the design, development, and implementation of CDSIT, which considers civil-legal grounds when forming decisions, are actual problems. Methodology for the development and application of knowledge-driven, rule-based, clinical decisions support information technologies with consideration of civil-legal grounds has been developed, which provides a theoretical basis for developing clinical decisions support information technology with consideration of civil-legal grounds and partial CDSITs regarding the possibility of providing medical services of a certain type. In addition to the conclusion about the possibility or impossibility of providing certain medical services, the developed methodology ensures the presence of all essential terms (from the viewpoint of civil law regulation) in the contract for the certain medical service's provision and/or the data on potential patients for the provision of such a service, as well as minimization of the influence of the human factor when making clinical decisions. It is advisable to evaluate the CDSITs with consideration of civil-legal grounds, developed according to the proposed methodology, from the viewpoint of the correctness of the decisions generated by them, as well as from the viewpoint of their usefulness for clinics. In this paper, experiments with the methodology-based CDSIT regarding the possibility of performing a surrogate motherhood procedure with consideration of civil-legal grounds were conducted. Such experiments showed the correctness of the generated decisions at the level of 97 %. Experiments also demonstrated the usefulness of such IT for clinics from the viewpoint of eliminating adverse legal consequences, as they might arise due to violation or disregard of legal, and moral and ethical norms.

Keywords: *methodology; information technology (IT); clinical decision support; clinical decision support information technologies (CDSIT); civil-legal grounds.*

1. Introduction

1.1. Motivation

Every year, information technologies (ITs) in medicine find more and more applications. The need to use large and constantly growing amounts of information when solving diagnostic, therapeutic, statistical, managerial, and other tasks is the reason for the intensification of the use of information technologies in medical institutions today [1, 2].

Modern information technologies in medicine are a set of methods and means for processing medical data for the creation, use, storage, transmission, and protection of an information product [3, 4].

Information technologies can improve the work of the healthcare system thanks to organizational changes, make it accessible to the population, and increase the transparency of the activities of medical institutions. Additionally, ITs are able to increase the efficiency and quality of the provision of medical services, reduce financial costs for their provision, shorten the period of examination and treatment of patients, organize and save the working time of clinicians, and provide consultation support for clinicians. ITs will intensify the integration of the healthcare system of individual countries into the global medical information space, which allows clinicians to effectively and quickly communicate with each other, have access to medical archives and libraries, and interact with different medical equipment [5, 6].

The modern development of medicine provides the clinician with a huge number of various diagnostic and treatment methods, medicines, etc. When using them, the clinician must consider a wide variety of factors – from the indications/contraindications of the method/tool depending on the characteristics and health status of the patient to the compatibility and strengthening/weakening of the effect of certain methods/tools when used together. When prescribing examination and treatment, the clinicians must consider all these features and draw on their own experience and knowledge, as well as multi-volume clinical guidelines. Considering the rapid growth of the amount of knowledge in medicine and the impossibility of increasing the time for making an appropriate decision, it becomes difficult for the clinicians to make accurate and timely decisions. As a result, there is an increase in medical errors [7-9].

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1.2. State-of-the-Art

One of the most promising and effective methods of preventing such medical errors is the implementation of clinical decisions support information technologies. These are the medical information technologies designed to help clinicians and other medical specialists work with tasks related to clinical decision-making through the joint analysis of the results of clinical studies with the data of a specific patient. Such ITs can help the clinician make an accurate and timely decision based on the analysis of available information, improve the quality of the provided medical care, and reduce the number of medical errors. The clinician must interact with the used clinical decision support information technology (CDSIT), using both their own knowledge and experience and information provided by the information technology [10, 11].

For example, the developed in [12] ontology-based clinical decision support system (CDSS) for diabetes improves the medical services' efficiency and quality, the efficiency of diagnosis and treatment, enhances automation and helps generate the correct treatment recommendations.

CDSS for predicting coronary artery stenosis in patients with suspected coronary heart disease, developed in [13], is a noninvasive, accurate, and cost-effective alternative for evaluating the state of patients, suspected coronary heart disease by distinguishing the coronary artery stenosis.

CDSS for hypertension medication based on a knowledge graph, developed in [14], helps in the implementation of the convenient and intuitive hypertension medication and knowledge management by applying knowledge from the knowledge graph.

Surgical decision support systems, reviewed in [15], consider surgical literature and use for facilitating the surgical care delivery. AI-based patient-specific CDSS for osteoarthritis patients concerning surgical knee and hip replacement necessary, developed in [16], enhances the involvement of the patient in decisions, clinical decision support, and their cost-effectiveness.

Ontology-based CDSS OntoPharma, proposed in [17], implements in a hospital setting and reduces prescribing medication errors through the representation of the medication knowledge in a more intuitive and maintainable form.

Machine learning-based CDSS in orthodontic treatment planning, proposed in [18], ensures reduced error, good accuracy, and inter–intra clinician variability.

CDSS for the identification of chronic obstructive pulmonary disease, proposed in [19], is an effective and convenient solution, which helps identify patients with chronic obstructive pulmonary disease in primary health institutions.

CDSS for diagnosis of meniscal injury using magnetic resonance images, developed in [20], detects meniscal injury, provides high specificity and sensitivity, facilitates the diagnosis of meniscal injuries, provides the structured report of meniscus rupture, and saves time for magnetic resonance images reading by clinicians.

CDSS for breathlessness, reviewed in [21], improve diagnosis, help follow the guideline recommendations, improve clinical outcomes, and promote non-pharmacological interventions.

CDSS for dengue, developed in [22], is based on fuzzy cognitive maps, evaluates the clinical and laboratory data about the dengue signs and symptoms, and classifies or predicts the severity of dengue.

CDSS for evaluating suspected monkeypox infection, proposed in [23], helps in the diagnostic of monkeypox infection and in the triage of the potential monkeypox patients.

Evaluation of CDSS for detection of patients from the risk group after kidney transplantation, developed in [24], helps detect more patients at risk for graft failure by detecting the partially different patients at risk compared to clinicians.

Knowledge-driven CDSS RAPID for reducing the time on appropriate antimicrobial therapy in patients with bloodstream infections, described in [25], detects whether there is an antimicrobial agent-pathogen mismatch when positive blood culture result and is an effective tool.

As the review of the known CDSS and CDSIT showed, there are currently a large number of modern solutions in various fields of medicine that have considerable potential and many benefits for clinical practice. When making clinical decisions, the clinician often must consider not only medical aspects but also civil law grounds that allow or do not allow them to perform this or that medical procedure depending on the existing circumstances [26-30]. Failure to consider or violation of civil law norms by the clinic when providing medical services leads to adverse legal consequences – up to lawsuits regarding the illegality of this or that medical procedure. Sometimes medical clinics hire lawyers to advise on the legal basis for making certain clinical decisions, but usually patients borne the lawyer's services due to the increase in the cost of certain clinical services.

As the review of known CDSS and CDSIT showed, currently, there are no clinical decision support information technologies that would consider civil-legal grounds when forming a decision for some clinicians. Therefore, the design, development, and implementation of CDSIT, which considers civil-legal grounds when forming decisions, is an *actual problem.*

1.3. Objective and approach

There are 2 types of CDSIT [31]: knowledge-driven (based on scientific knowledge; consisting of an information base of rules of the "if-then" type, a mechanism of logical conclusion, and a mechanism of communication) and non-knowledge-driven (based on the results of processing the collected statistical data using mathematical methods, for example, machine learning [32]). Considering the presence of clear civil-legal grounds that regulate the possibility of making this or that medical decision, on the basis of which it is possible and expedient to build exactly the rules of the "if-then" type, *the purpose of our research* is the development and application of knowledge-driven, rule-based, clinical decisions support information technologies with consideration civil-legal grounds.

The following tasks should be solved to achieve the set purpose:

1) to develop a decision-making criterion regarding the provision/non-provision of certain medical services;

2) to develop a methodological basis for the semantic analysis of data on potential patients and/or a contract for the provision of certain medical services;

3) to develop a methodological basis for supporting the clinical decision-making considering civil-legal grounds;

4) to design a methodology for the development and application of clinical decisions support information technologies with consideration civil-legal grounds.

So, *the rest of the paper* is structured as follows. Section 2 is a description of the proposed modeling principles and criterion for clinical decision-making with consideration civil-legal grounds. Section 3 is devoted to the development of the method of semantic analysis of data about potential patients and/or a contract for the provision of certain medical services. Section 4 is devoted to the development of the clinical decisions support method with consideration of civil-legal grounds. Section 5 presents the designed methodology for the development and application of clinical decisions supporting information technologies with consideration of civil-legal grounds. Section 6 provides the results of the proposed methodology implementation and discussion about the proposed methodology and the information technology developed by it, and Section 7 provides the conclusions.

2. Modeling principles and criterion of the clinical decision-making with consideration of civil-legal grounds

The main source of information for the process of supporting clinical decision-making with consideration of civil-legal grounds is data on potential patients and/or a contract for the provision of certain medical services.

Let AET be the set of absent essential terms in the data on potential patients and/or the contract for the provision of certain medical services.

Let's develop a decision-making criterion based on the factors and principles on which the decision is based. Considering the interests of all interested parties when choosing the decision-making criteria, the obligation to guarantee the safety of the medical service for the health and life of potential patients, the obligation to guarantee the legal safety of the medical service for clinicians make the presence of all essential terms is mandatory. Therefore, *the criterion for clinical decision-making with consideration of civil-legal grounds* looks like this:

– if AET = $\varnothing$, then the provision of a certain medical service is possible;

– if AET $\neq \varnothing$, then the provision of a certain medical service is impossible.

Given the presented criterion of the clinical decision-making with consideration of civil-legal grounds, for further modeling, we will need a *set-theoretic model of data on potential patients and/or a contract for the provision of certain medical services*. Such a model is based on mandatory essential terms and is represented in the form of the set NET. The set NET is the set of necessary essential terms in the data on potential patients and/or the contract for the provision of certain medical services.

Considering the developed criterion of clinical decision-making with consideration of civil-legal grounds and the set-theoretical model of data on potential patients and/or the contract for the provision of certain medical services, let's perform *modeling of the process of clinical decisions support with consideration civil-legal grounds*.

If PET is a set of essential terms present in the data on potential patients and/or the contract for the provision of certain medical services, then:

$$\mathrm{AET} = \mathrm{NET} \setminus (\mathrm{NET} \cap \mathrm{PET}). \qquad (1)$$

The general rule for deciding about the possibility of providing certain medical services is as follows:

$$\begin{gathered}\text{If} \quad \mathrm{AET} = \varnothing \\ \text{then "medical service is possible",} \\ \text{else "medical service is impossible"}\end{gathered} \qquad (2)$$

Based on the proposed model of the process of clinical decisions support with consideration of civil-legal grounds, detailed models of the processes of supporting various clinical decisions with consideration of civil-legal grounds can be developed.

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Additionally, the proposed model is a theoretical basis for developing a generalized method of semantic analysis of data about potential patients and/or contracts for the provision of certain medical services and a generalized clinical decisions support method with consideration of civil-legal grounds, which, in turn, are the basis for detailed methods of semantic analysis of data about potential patients and/or a contract for the provision of certain medical services, as well as detailed rules and methods of supporting the adoption of various clinical decisions with consideration civil-legal grounds.

3. Method of semantic analysis of data about potential patients and/or contracts for the provision of a certain medical service

The generalized method of semantic analysis of data about potential patients and/or contracts for the provision of certain medical services will be presented in the form of the following scheme – Fig. 1.

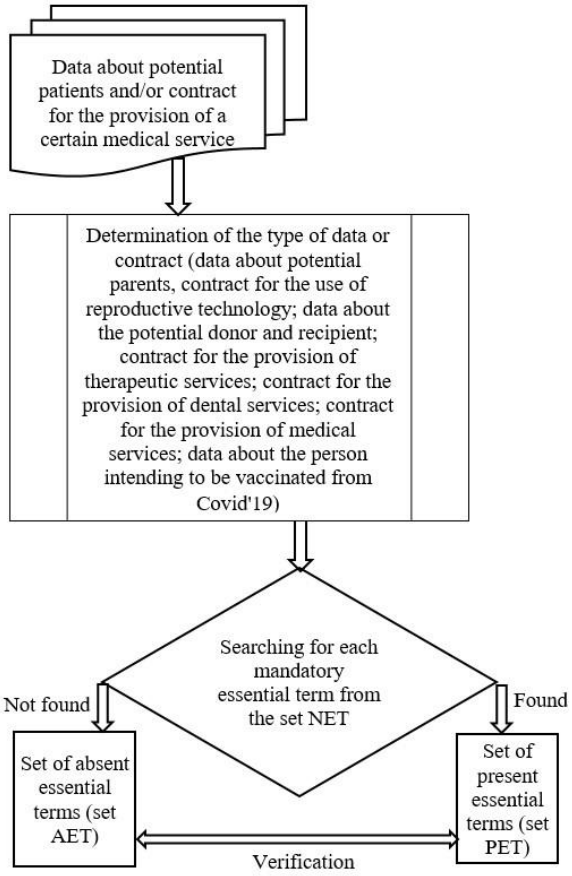

Fig. 1. Scheme of a generalized method of semantic analysis of data about potential patients and/or contracts for the provision of certain medical services

The proposed method consists in determining the type of data or contract, after which a search is done for each mandatory essential term for the data and/or contracts of the determined type in the available data and/or contract. On the basis of such an analysis, the formation of a set of absent and present essential terms, which are subject to verification, occurs.

During verification, the accuracy of the classification of absent essential terms (the share of correctly classified absent essential terms among all essential terms assigned to this class) is calculated using the formula:

$$\text{Precision} = \frac{\text{TP}}{\text{TP}+\text{FP}}, \quad (3)$$

where TP – correctly classified essential terms (correctly assigned to the set of absent essential terms), and FP – incorrectly classified essential terms (wrongly assigned to the set of absent essential terms).

On the basis on the proposed generalized method of semantic analysis of natural-language data about potential patients and/or contracts for the provision of certain medical services, detailed methods of semantic analysis of various natural-language data about potential patients and/or a contract for the provision of certain medical services can be developed.

Additionally, the proposed method forms input data for a clinical decisions support method with consideration of civil-legal grounds.

4. Clinical decisions support method with consideration of civil-legal grounds

The generalized clinical decisions support method with consideration of civil-legal grounds consists of the following general steps:

1) determination of the problem (the possibility of providing a certain medical service from the viewpoint of civil law regulation);

2) determination of decision-making criteria (the criterion of the clinical decision-making with consideration of civil-legal grounds, presented in Section 2);

3) generation of a decision based on the developed criterion and the general rule for deciding about the possibility of providing certain medical services ("the provision of a certain medical service is possible" or "the provision of a certain medical service is impossible");

4) implementation of the generated decision (in the case of the decision "the provision of a certain medical service is possible" – the provision of this medical service; in the case of the decision "the provision of a certain medical service is impossible" - finalization (if possible) of data on potential patients and/or the contract for the provision of medical services (for example, adding absent essential terms to the contract or fulfillment of unsatisfied conditions by potential patients);

5) evaluation of the adopted decisions – this stage is applied only in the presence of the set of adopted decisions; to evaluate the adopted decisions, let's calculate the correctness of the generated decisions about the impossibility of certain medical services (the share of correctly adopted decisions about the impossibility of a medical service among all decisions assigned to this class) using the formula:

$$\text{Precision} = \frac{\text{TPD}}{\text{TPD} + \text{FPD}}, \quad (4)$$

where TPD – correctly generated (correctly assigned to the set of decisions about the impossibility of medical service), FPD – incorrectly generated (incorrectly assigned to the set of decisions about the impossibility of medical service).

Let's present a generalized clinical decisions support method with consideration of civil-legal grounds in the form of a scheme – Fig. 2.

On the basis of the proposed generalized method, detailed methods of supporting various clinical decisions considering civil-legal grounds can be developed.

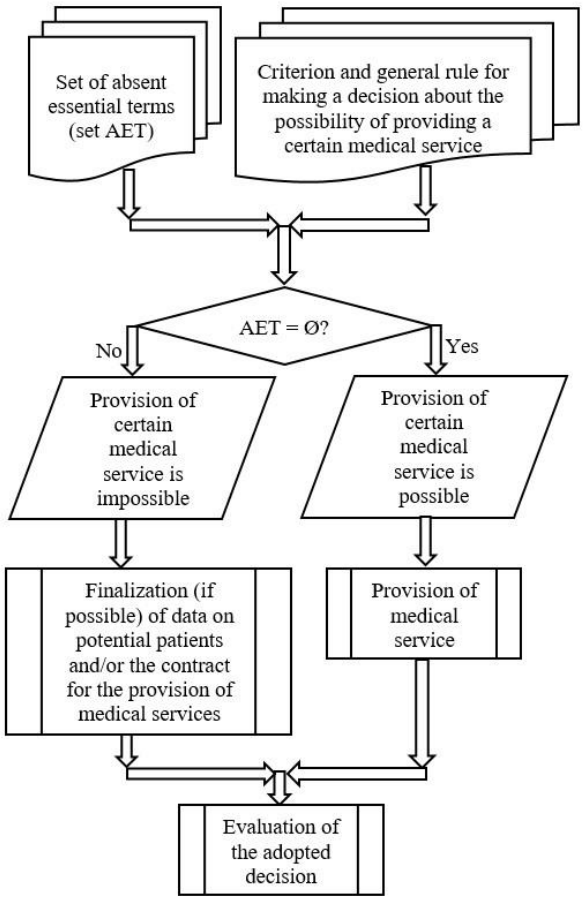

Fig. 2. Scheme of the generalized clinical decisions support method with consideration of civil-legal grounds

5. Methodology for the development and application of clinical decisions support information technologies with consideration of civil-legal grounds

On the basis of the developed model of the process and method of clinical decisions support with consideration of civil-legal grounds, the method of semantic analysis of data about potential patients and/or contracts for the provision of certain medical services, let's develop a methodology for the development and application of knowledge-driven, rule-based clinical decisions support information technologies with consideration civil-legal grounds with the aim of forming the theoretical foundations of such information technologies. The generalized scheme of such a methodology is presented in Fig. 3.

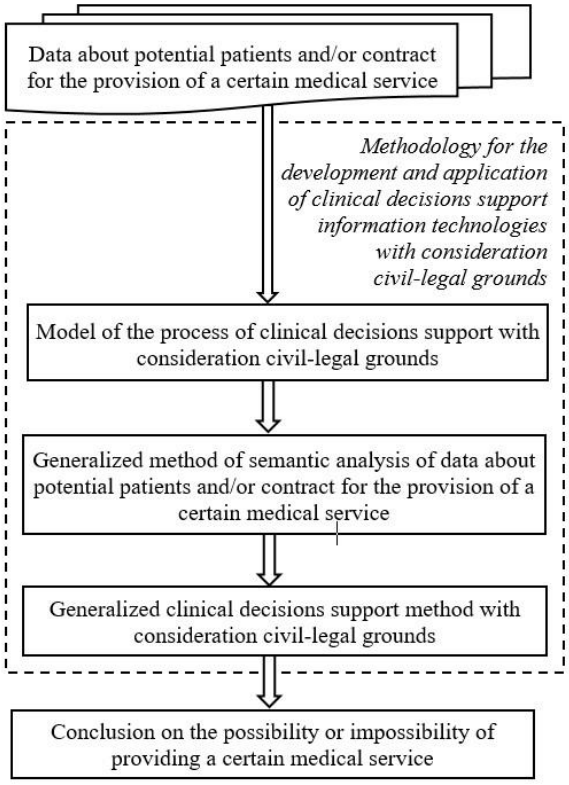

Fig. 3. Generalized scheme of the methodology for the development and application of clinical decisions support information technologies with consideration of civil-legal grounds

Considering the fact that we are interested in conclusions about the possibility or impossibility of providing such medical services from the point of view of civil law regulation: the use of appropriate reproductive technology (if impossible, the reason for the impossibility); donations (if possible, a conclusion on the type of donation); transplantation (if possible, a conclusion on the type of transplantation); the possibility or impossibility of providing therapeutic, dental or general medical ser-

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vices (in the case of impossibility – the reason for impossibility); about the necessity or optionality and the possibility or contraindications for vaccination against Covid'19, let's develop a detailed scheme of the methodology for the development and application of knowledge-driven, rule-based clinical decisions support information technologies with consideration of civil-legal grounds – Fig. 4.

The developed methodology provides the theoretical basis for the development of clinical decisions supporting information technology with consideration of civil-legal grounds and partial clinical decisions supporting information technologies regarding the possibility of providing medical services of a certain type (for example, regarding the use of reproductive technologies, performing donation and/or transplantation, etc.). Integrating the developed models and methods in the methodology for the development and application of knowledge-driven, rule-based clinical decisions support information technologies with consideration of civil-legal grounds, in addition to the conclusion about the possibility or impossibility of providing certain medical services, also ensures the presence of all essential terms (from the viewpoint of civil law regulation) in the data on potential patients and/or the contract for the certain medical service's provision for the provision of such a service, as well as minimization of the influence of the human factor when making clinical decisions.

6. Case study, results and discussion

Let's consider an example of the development and application of knowledge-driven, rule-based clinical decisions supporting information technology regarding the possibility of performing surrogate motherhood with consideration of civil-legal grounds. The authors presented the scheme of such information technology in this paper [27]. Such information technology receives data about potential parents (surrogate mother and biological parents) and the surrogacy contract. According to the method of semantic analysis presented in this paper, it processes natural-language data, looking for all necessary essential terms. On the basis of such an analysis, a set of absent essential terms is formed, which the input data is for the clinical decisions support method with consideration the civil-legal grounds presented in this paper. If the set of absent essential terms is empty, IT generates a decision about the possibility of providing medical services. If the set of absent essential terms is not empty, IT generates a decision about the impossibility of providing medical services, also provides the reasons for the impossibility (missing essential terms), and offers users to finalize the data about potential parents and the surrogacy contract, if it's possible.

Therefore, on the input of such CDSIT, we submit the data about potential parents (surrogate mother and biological parents) and the surrogacy contract prepared by one of the reproductive clinics of Khmelnytskyi (Ukraine). In the case under consideration, a 25-year-old able-bodied woman, who has her own healthy child and has no contraindications to pregnancy and childbirth, and is not an egg donor, wants to become a surrogate mother. The potential parents are a same-sex couple (two able-bodied Swedish women aged 30), and a woman is an egg donor. The reproductive clinic provided all the necessary, complete, and reliable information about the surrogacy service, about the conclusion of the contract, which includes all possible consequences of unplanned events during the provision of the service, and the guarantee of the involvement of highly qualified medical personnel in the procedure.

The method of semantic analysis processes the provided data, looking for every mandatory essential term from the viewpoint of civil law regulation defined by the authors in [27]. On the basis of such an analysis, a set of absent essential terms AET_{SM} = {"different gender of spouses of potential parents", "potential parents are citizens of a country where surrogacy is allowed"} is formed. All of the remaining 34 essential terms were found in the provided input data, so they were listed in the set of present essential terms.

Let's calculate the accuracy of the classification of absent essential terms:

$$\text{Precision} = \frac{\text{TP}}{\text{TP}+\text{FP}} = \frac{2}{2+0} = 1.$$

Therefore, for this case, the method of semantic analysis worked with 100 % accuracy, correctly classifying the essential terms contained in the provided input data.

The clinical decisions support the method with consideration of civil-legal grounds to analyze the set of absent essential terms. Since the set of absent essential terms $AET_{SM} \neq \emptyset$, CDSIT generates the decision "provision of medical service is impossible". Since the reason for the impossibility of providing surrogacy has been being problems with potential parents that cannot be corrected (same-sex couple and citizenship of a country where surrogacy is prohibited), then finalization, in this case, is impossible; therefore, a final decision is made about the impossibility of performing the surrogacy procedure in such a case.

In the further application of such IT, 14 more cases of the same reproductive clinic were considered. In 9 cases, a decision was generated about the impossibility of performing the surrogacy procedure for various reasons, and in 5 cases, a decision was generated about the possibility of performing the surrogacy procedure.

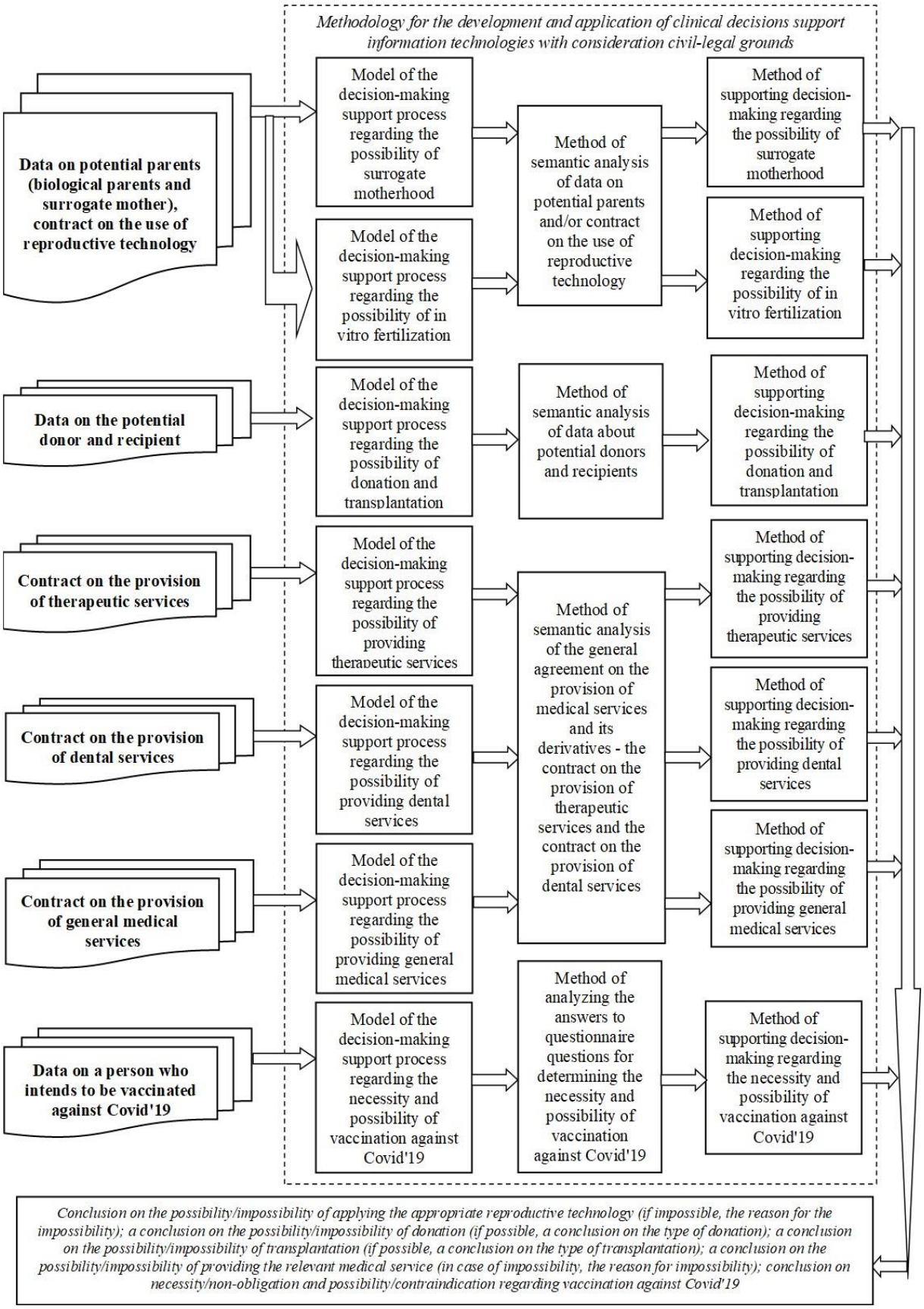

Fig. 4. Detailed scheme of the methodology for the development and application of knowledge-driven, rule-based clinical decisions support information technologies with consideration of civil-legal grounds

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After that, the decisions made were assessed by calculating the correctness of the generated decisions:

$$\text{Precision}_1 = \frac{\text{TPD}}{\text{TPD}+\text{FPD}} = \frac{9}{9+1} = 0.9 .$$

Therefore, when processing 15 cases provided by one reproductive clinic, the decision support method worked with 90 % accuracy, incorrectly generating one decision about the impossibility of performing the surrogacy procedure.

In the further application of the proposed CDSIT, another 176 cases provided by other reproductive clinics in Khmelnytskyi and Lviv were considered. In 90 cases, a decision was generated on the impossibility of performing the surrogacy procedure for various reasons, and in 86 cases, a decision was generated on the possibility of performing the surrogacy procedure. After that, the adopted decisions were evaluated again by calculating the correctness of the generated solutions:

$$\text{Precision}_2 = \frac{\text{TPD}}{\text{TPD}+\text{FPD}} = \frac{99}{99+3} = 0.97 .$$

Therefore, when processing 191 cases provided by various reproductive clinics, the decision support method worked with 97 % accuracy, incorrectly generating three decisions about the impossibility of performing the surrogacy procedure.

To be convinced of the practical value of the proposed CDSIT, it is necessary to confirm the fact of improvement of the clinical workflow or results due to its use. The CDSIT evaluation criteria depend on the purpose of such technology – it is advisable to evaluate the CDSITs with consideration of civil-legal grounds, developed according to the proposed methodology, from the point of view of the correctness of the decisions generated by them, as well as from the viewpoint of their usefulness for clinics.

As it was determined above, the correctness of the decisions made by the proposed CDSIT regarding the possibility of performing the procedure of surrogate motherhood, with consideration of civil-legal grounds, is currently 97 % after processing 197 different cases.

To determine the usefulness of CDSIT regarding the possibility of performing the procedure of surrogate motherhood with consideration of civil-legal grounds for reproductive medicine clinics, let's consider the cases analyzed by IT. From 191 analyzed cases, only 91 cases generated a decision on the possibility of the surrogate motherhood procedure; therefore, only 91 procedures were allowed from the viewpoint of civil law regulation, and the remaining 100 cases (more than half of all considered cases) had omissions or violations of certain civil law norms (Fig. 5).

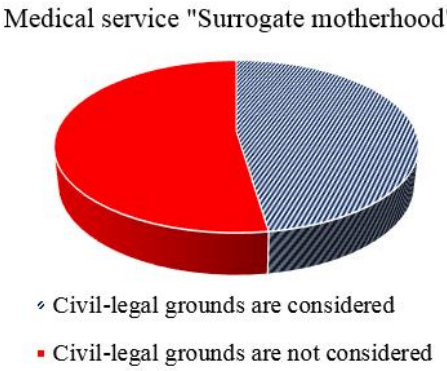

Fig. 5. Demonstration of the usefulness for clinics of CDSIT regarding the possibility of surrogate motherhood with consideration civil-legal grounds

Therefore, 100 considered applications for the surrogacy procedure either had problems in terms of nonfulfillment of essential legal conditions by potential biological parents and/or surrogate mothers, i.e., were not even subject to finalization or required revision in terms of adding the essential terms to the surrogacy contract. Therefore, without the application of the proposed CDSIT regarding the possibility of surrogate motherhood with consideration of civil-legal grounds, only 91 surrogacy procedures (47.6 %) would be correct from the viewpoint of civil legislation. Provision of surrogacy services in the other 100 cases (52.4 %) would certainly lead to adverse legal consequences, lawsuits, and, given the essence of the surrogacy procedure, a violation of moral and ethical standards.

7. Conclusions

Currently, there are no clinical decision support information technologies (CDSIT) that would consider civil-legal grounds when forming a decision for clinicians. Therefore, the design, development, and implementation of CDSIT, which considers civil-legal grounds when forming decisions, is an actual problem.

Considering the presence of clear civil-legal grounds that regulate the possibility of making this or that medical decision, on the basis of which it is possible and expedient to build exactly the rules of the "if-then" type, *the purpose of our research* is the development and application of knowledge-driven, rule-based, clinical decisions support information technologies with consideration civil-legal grounds.

The model of the process of clinical decisions support with consideration of civil-legal grounds is proposed, on the basis of which the detailed models of the processes of supporting various clinical decisions with consideration of civil-legal grounds can be developed and that is a theoretical basis for developing a generalized

method of semantic analysis of data about potential patients and/or contract for the provision of certain medical services and a generalized clinical decisions support method with consideration civil-legal grounds.

The generalized method of semantic analysis of natural-language data about potential patients and/or contracts for the provision of certain medical services is proposed, on the basis of which detailed methods of semantic analysis of various natural-language data about potential patients and/or a contract for the provision of certain medical services can be developed and that forms input data for a clinical decisions support method with consideration civil-legal grounds.

The generalized clinical decisions support method with consideration of civil-legal grounds is proposed, on the basis of which the detailed methods of supporting various clinical decisions considering civil-legal grounds can be developed.

On the basis of the developed model and methods, the methodology for the development and application of knowledge-driven, rule-based, clinical decisions support information technologies with consideration of civil-legal grounds has been developed, which provides a theoretical basis for developing clinical decisions supporting information technology with consideration civil-legal grounds and partial CDSITs regarding the possibility of providing medical services of a certain type.

In addition to the conclusion about the possibility or impossibility of providing certain medical services, the developed methodology ensures the presence of all essential terms (from the viewpoint of civil law regulation) in the data on potential patients and/or the contract for the certain medical service's provision for the provision of such a service, as well as minimization of the influence of the human factor when making clinical decisions.

It is advisable to evaluate the CDSITs with consideration of civil-legal grounds, developed according to the proposed methodology, from the viewpoint of the correctness of the decisions generated by them, as well as from the viewpoint of their usefulness for clinics.

The performed assessments of the CDSIT's regarding the possibility of performing a surrogate motherhood procedure with consideration of civil-legal grounds, developed on the basis of the proposed methodology, showed the correctness of the generated decisions at the level of 97 % and the usefulness of such IT for clinics from the viewpoint of eliminating adverse legal consequences, as they might arise due to violation or disregard of legal and moral and ethical norms.

Future research. The authors' future research will be aimed at the realization and implementation of general knowledge-driven, rule-based clinical decisions support information technologies with consideration civil-legal grounds. Additionally, the authors will deal with the realization and implementation of the partial clinical decisions support information technologies regarding the possibility of providing medical services of a certain type (in particular, regarding the surrogate motherhood possibility; the in-vitro fertilization possibility; the donation and transplantation possibility; regarding the possibility or impossibility of providing therapeutic, dental or general medical services; regarding the necessity or optionality of vaccination against Covid'19 and the possibility or contraindications for vaccination against Covid'19).

Contributions of authors: conceptualization – **Tetiana Hovorushchenko**; methodology – **Yelyzaveta Hnatchuk, Tetiana Hovorushchenko**; formulation of tasks – **Yelyzaveta Hnatchuk. T. Hovorushchenko**; analysis – **Olga Pavlova, Yelyzaveta Hnatchuk**; development of model – **Yelyzaveta Hnatchuk**; development of methods – **Yelyzaveta Hnatchuk, Olga Pavlova, Tetiana Hovorushchenko**; development of methodology – **Yelyzaveta Hnatchuk**; verification – **Yelyzaveta Hnatchuk, Tetiana Hovorushchenko**; analysis of results – **Tetiana Hovorushchenko, Yelyzaveta Hnatchuk, Olga Pavlova**; writing-original draft preparation – **Tetiana Hovorushchenko, Yelyzaveta Hnatchuk**; writing-review and editing – **Tetiana Hovorushchenko, Yelyzaveta Hnatchuk**.

All authors have read and agreed to the published version of the manuscript.

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МЕТОДОЛОГІЯ РОЗРОБЛЕННЯ ТА ЗАСТОСУВАННЯ ІНФОРМАЦІЙНИХ ТЕХНОЛОГІЙ ПІДТРИМКИ ПРИЙНЯТТЯ КЛІНІЧНИХ РІШЕНЬ З ВРАХУВАННЯМ ЦИВІЛЬНО-ПРАВОВИХ ПІДСТАВ

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Наразі відсутні інформаційні технології підтримки прийняття клінічних рішень (ІТППКР), які б враховували цивільно-правові підстави при формуванні того чи іншого рішення для клініциста. Відтак проектування, розроблення та імплементація ІТППКР, які враховують цивільно-правові підстави при формуванні рішень, є актуальною проблемою. Розроблено методологію розроблення та застосування знаннєвих, базованих на правилах, інформаційних технологій підтримки прийняття клінічних рішень з врахуванням цивільно-правових підстав, яка дає теоретичні засади для побудови загальної інформаційної технології підтримки прийняття клінічних рішень з врахуванням цивільно-правових підстав та часткових інформаційних технологій підтримки прийняття рішень щодо можливості надання медичних послуг певного типу. Крім висновку про можливість або неможливість надання певної медичної послуги, розроблена методологія забезпечує також гарантування наявності всіх істотних умов (з точки зору цивільно-правового регулювання) у даних про потенційних пацієнтів та/або договорі з надання певної медичної послуги для надання такої послуги, а також мінімізацію впливу людського фактору при прийнятті медичних рішень. Розроблені за даною методологією інформаційні технології підтримки прийняття клінічних рішень з врахуванням цивільно-правових підстав доцільно оцінювати з точки зору, власне, коректності генерованих ними рішень, а також з точки зору їх корисності для клінік. Проведені оцінки ІТППКР щодо можливості виконання процедури сурогатного материнства з врахуванням цивільно-правових підстав, розробленої на основі запропонованої методології, показали коректність

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генерованих рішень на рівні 97 % та корисність такої ІТ для клінік з точки зору усунення несприятливих юридичних наслідків, як б могли виникнути через порушення або неврахування юридичних та морально-етичних норм.

Ключові слова: методологія; інформаційна технологія (ІТ); підтримка прийняття клінічних рішень; інформаційна технологія підтримки прийняття клінічних рішень (ІТППКР); цивільно-праві основи.

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