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На основі аналізу нормативних документів та функціонуючих інформаційних систем служби крові запропоновано модель інформаційного супроводу бізнес-процесів виробничої трансфузіології. Модель, з урахуванням декомпозиції, формалізує інформаційний супровід, визначаючи склад вимог для збору та обробки даних у визначених контрольних точках процесів. В моделі передбачено врахування важливості даних та ступеню автоматизації їх отримання

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Ключові слова: процеси виробничої трансфузіології, спеціалізована медична інформаційна система, модель інформаційного супровіду

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На основе анализа нормативных документов и функционирующих информационных систем службы крови предложена модель информационного сопровождения бизнес-процессов производственной трансфузиологии. Модель, с учетом декомпозиции, формализует информационное сопровождение, определяя состав требований для сбора и обработки данных в установленных контрольных точках процессов. В модели предусмотрен учет важности данных и степени автоматизации их получения

Ключевые слова: процессы производственной трансфузиологии, специализированная медицинская информационная система, модель информационного сопровождения

1. Introduction

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Using of blood components is an integral part of modern healthcare in hospitals. Production of blood components in blood services (BS) requires continuous management and improvement of the quality system. The quality and effectiveness of BS is estimated by such indicators [1] as a state of donation, a production state of blood products, a state of infectious, immunological safety and quality of blood components, a state of clinical using of blood products, a provision state of blood products supplies, and an economic efficiency of institution. Compliance with the quality and safety of blood and its components are the prime activities of BS (production transfusion), that provides maximum guarantee to prevent transmission of infectious diseases through donations, processing and transfusion, and efficient use of blood components. In the production transfusion processes, obtaining high-quality blood products is primarily ensured by strict control over the implementation of the legal framework and international standards of quality and safety of blood components [2, 3].

Timely monitoring and control of information flows of production transfusion processes becomes a tool for improving the efficiency of BS activity through effects on indicators such as the percentage of rejected blood products in total production; the percentage of blood products that are written off by the expiry date; the incidence of transfusion reactions and complications.

Information support of production transfusion processes should provide specialized medical information system (SMIS), which is a separate class of medical automated information systems [4]. A characteristic feature for this class of systems is the functional focus on tracking relevant information on the technology of the production process –

UDC 004.051

DOI: 10.15587/1729-4061.2016.71673

INFORMATION SUPPORT MODEL OF PRODUCTION TRUNSFUSION PROCESSES

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information receiving, processing and control in real time for the phased implementation of actions in compliance with all requirements of the regulations of the production process. Information support of production transfusion processes using BS SMIS allows to ensure maximum effect of BS activity by minimizing the cost of development, implementation and operation of the system [5].

Implementation of information support in manual or partially automated mode leads to a high probability of potential errors caused by the human factor and untimely tracking of quality parameters of blood products. As a result, we have the increase in the percentage of rejected blood products or increase of the risk of transfusion reactions and complications.

Improving BS SMIS (increase in functionality, integration of additional modules into SMIS, etc.) is possible on the results of identifying the narrow places in information support of production transfusion processes. This, in turn, can be achieved by evaluation or validation of BS SMIS for regulatory compliance on transfusion production. Modeling the information support of transfusion production processes becomes relevant for such assessment. The relevance of the work in this direction also confirmed the necessity of research and evaluation of the current state of SMIS that operate in BS.

2. Analysis of published data and problem definition

The current need for reform of BS to achieve a high level of compliance quality programs [6], improving information support of processes in BS, implementation of effective information systems that provide tracking of business processes to achieve the objectives referred to the transfusion field in the governing documents and decisions of leading world organizations [7], is the reason for directing research to choose a rational decision based on modeling actions of information system, which will perform the function of accurate records, monitoring and evaluation in accordance with the requirements of ISO 9001 quality management system.

In modern scientific literature, much attention is given to the question of process modeling and modeling of their information support, because the model is the basis for evaluation in solving problems of effective management of institutions and rational organization of business processes in them [8, 9].

Modeling of processes in the transfusion field primarily aims at building a reference sequence of actions to monitor indicators of quality of blood products as required by law, and improving the quality management system [10].

The information component can be determined through business process analysis for designing information system (for example, in the production transfusion for SMIS), providing information support of processes. Attempts were made in the modeling of individual parts of information support of transfusion processes. In particular, [11] is devoted to modeling the information support of processes of clinical using of blood products to patients – namely, controlling of transfusions.

To solve the problem of modeling the information support of production transfusion processes, further study of scientific and technical sources [12–15] is needed, which are devoted to the description of existing BS information systems for the purpose of summarizing the experience of their construction. The analysis of the functional definition of the structure and trends of development should be considered as a basis for modeling. BS SMIS were considered, which are used in Ukraine, Kazakhstan, Russia, Sweden, Denmark, the USA, Pakistan and other countries [16–19]. Based on the analysis the trends are defined based on modern approaches to information support of production transfusion processes using BS SMIS [20, 21]. These trends include the following:

 – automatic identification technologies of the donor, donation and each single dose of blood and blood components, test tubes with material for research in each business process;

 use of touch screens for questioning donors, receiving information consent to donation, research, and mobile devices for mobile units;

SMS sending to attract donor and donation management;

 integration of BS SMIS with healthcare hardware, laboratory equipment and automatic data import from devices;

 electronic reporting on the activities of BS and obtaining supporting documentation at each stage of the business process;

- compliance with GMP, GAMP, ISBT-128, the legal and regulatory framework governing the activities of production transfusion concerning the quality of blood products;

 interaction with external systems based on international standards.

Tendencies and features of BS SMIS should be considered in modeling information support for the processes under research.

Thus, creating a model of information support is highly important nowadays with full coverage of production transfusion processes, taking into account the current trends of information support for these processes.

3. The aims and objectives of researching

The purpose of the research is formalized presentation of information support of production transfusion processes as a model for further evaluation of the level of compliance of SMIS that functions in the BS establishment, to the reference level.

To achieve the goal, the following tasks should be resolved:

 – content analysis of information support of production transfusion processes with regard to regulatory compliance;

 – analysis of the functional structure of BS SMIS, trends of automation of production transfusion processes, definition of the properties and functional characteristics of SMIS, requirements for SMIS;

– definition of quantitative and qualitative indicators to data of information support of production transfusion processes taking into account the degree of automation.

4. Analysis of production transfusion processes and functional characteristics of blood services specialized medical information systems

The analysis of BS activities was done, and the content of information support of research processes was found with the purpose to construct a model of information support of production transfusion processes. The symbols in use were introduced in [22] to formalize the contents. The analysis of processes involves decomposition of related production transfusion processes performed sequentially or in parallel on the elements. Operations performed automated or partially automated by staff during the production process are parts of elements. Thus, for each business process from the set $P = \{p_i\}$, for each of its elements from the set $L_i = \{l_{ij}\}$ the set of actions $D_{ij} = \{d_{ijk}\}$ is made. These indexes i, j, k define serial numbers of processes, elements and actions, respectively, and vary according to the ranges $i = 1, \overline{I}, j = \overline{I, J_i}, k = \overline{I, K_{ii}}$.

The basis for the organization of production transfusion processes is the compliance with regulations concerning the quality of blood products. The set of regulatory requirements for production transfusion processes can be formally represented as a set of requirements for each of the following actions d_{iik} :

$$Rqp = \bigcup_{i} \bigcup_{j} \bigcup_{k} Rqp_{ijk}, \qquad (1)$$

where Rqp is the set of all regulatory requirements governing the performance of all production transfusion processes; Rqp_{jk} is the set of requirements for regulatory action d_{ijk} with an element l_{ij} and a process p_i .

The set of requirements that govern the action d_{ijk} , can be represented as follows:

$$\operatorname{Rqp}_{ijk} = \left\{ \operatorname{rqp}_{ijkg} \right\}, \tag{2}$$

where rqp_{ijkg} is a requirement g to an action d_{ijk} with element l_{ij} and process p_i ; g is the index of serial number of requirement to action d_{ijk} with element l_{ij} and process p_i , $g = 1, G_{ijk}$.

Analysis is given of each requirement for each rqp_{ijkg}, correlated to a specific action or several actions to determine the content of the information support of processes as input, output, design parameters that provide information support processes, which should be fixed and treated as appropriate data during performing actions.

Such data can be formally represented as a set, as follows:

$$DS_{ijk} = \left\{ ds_{ijkh} \right\}, \tag{3}$$

where DS_{ijk} is the set, containing data correlated with each action d_{ijk} with element l_{ij} and process p_i ; ds_{ijkh} is the data h obtained when performing action d_{ijk} with element l_{ij} and process p_i ; h is the index of serial number of data for the action d_{ijk} with element l_{ij} and process p_i , h = 1, H_{ijk} .

The complex of all data obtained in the information support of production transfusion processes can be formally represented as a union of sets DS_{ijk} for all actions, all elements and all processes:

$$DS = \bigcup_{i} \bigcup_{j} \bigcup_{k} DS_{ijk}, \qquad (4)$$

where **DS** is the set of all data obtained in information support of production transfusion processes.

SMIS performs data receiving and providing information support of transfusion processes, which consists of subsystems. By denoting BS SMIS as "is" and "sis" for subsystems which results from the system decomposition, and the number of subsystems can be equal to O, then the following formalization takes place:

$$is = \{sis_o\},$$
 (5)

where o is the index of serial number of a subsystem sis from the system is, o = 1, O; O is a possible number of subsystems in a system.

Traditionally, it is decided to allocate the following subsystems: "Registry", "Laboratory before donation examination", "Therapist", "Donation", "Mobile teams", "Department of Transfusion/Branch", "Production components", "Quarantine", "Biochemical laboratory", "Immunological laboratory", "Bacteriological laboratory", "Laboratory screening on bloodborne infections", "Quality control", "Testing and certification", "Expedition", "Analytical unit" [23–25].

Each subsystem provides information support for one or more processes, as shown in the diagram in Fig. 1.

SMIS subsystems are oriented on realization of district functions. Set Fis can be used for BS SMIS functions as a whole:

$$Fis = \bigcup_{o} Fsis_{o},$$
(6)

where Fis is the set of all functions of system is; $Fsis_o$ is the set of functions of subsystem sis_o in system is.

In turn, the set of functions for each subsystem sis_o can be represented as follows:

$$Fsis_{o} = \{f_{om}\},\tag{7}$$

where f_{om} is a function m of subsystem sis_o, $m = \overline{1, M_o}$; m – the index of serial number of a function from subsystem sis_o in system is; M_o – number of functions in subsystem sis_o.

Each function provides data acquisition during the information support of the action or several actions using the BS SMIS.

The study of international experience automating BS [26–30], analysis of current trends of information support of production transfusion processes using BS SMIS, synthesis approaches to construction of BS SMIS made it possible to identify properties and functional features that are character-

istic to BS SMIS. Analysis of existing BS SMIS on certain properties and functional characteristics is given in Table 1.

Table 1

Comparison of BS SMISs based on selected properties and functional features

BS SMIS Proper- ties and functional features	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18
Automatic identi- fication of donor, donation, blood products in each business process	+	+	_	+	+	+	+	+	+	+	/	+	+	+	+	/	/	†
Automated label- ing of blood	+	+	_	+	+	+	+	+	+	+	+	+	+	+	+	+	+	_
Labeling blood products by ISBT-128	_	_	_	+	_	_	/	/	+		/	+	+	+	+	+	/	-
System integration with machine equipment	+	+	_	/	+	/	/	/	+	_	/	+	+	+	+	/	/	+
Entering data through touch screens	_	_	_	+	_	_	_	_	_	_	_	-	+	+	+	/	/	_
Monitoring the distribution of blood products	Ť	_	_	+	+	/	/	/	+	†	+	+	+	+	/	+	+	_
Tracking data from donor to recipient	+	_	_	+	+	/	/	+	†	+	+	/	/	/	/	+	/	t
Interaction with other systems	+	_	_	/	/	/	/	+	+	+	/	_	_	+	+	/	+	_
Support of international standards for data exchange	_		_	+	_	/	/	/	+		+	/	/	+	+	/	+	-
SMS-informing of a donor	-	/	/	/	/	/	/	/	_	_	/	/	/	/	+	+	/	_
Web-base Interface	_	_	_	_	_	-	_	+	+	-	+	_	-	+	+	+	+	-
Completeness of coverage of all processes	+	†	Ť	t	†	Ť	+	+	†	+	+	Ť	+	+	+	/	/	Ť
Control deviations from norms	+	†	†	+	†	†	†	†	/	†	†	+	+	+	+	+	+	†
Separation of roles and user access rights	+	†	†	†	†	+	+	+	/	+	+	+	+	+	+	+	+	+
Formation reporting	+	+	_	+	+	+	+	+	+	+	+	+	+	+	+	+	+	†
Digital signatures	-	-	-	-	-	-	-	-	-	-	-	-	-	+	+	-	-	-

Note: + – availability of property or functional feature in BS SMIS; – – absence of property or functional feature in BS SMIS; † – partial availability of properties or functional features in BS SMIS; / – lack of information; 1 – Smart: Sluzhba krovi, Ukraine; 2 – Crystal, Ukraine; 3 – "BI: Sluzhba krovi" Business-Intellekt, Ukraine; 4 – SoftDonor, ISD, Ukraine; 5 – InfoDonor, Kazakhstan; 6 – Blood, Russia; 7 – qMS SP.ARM, Russia; 8 – "Stantsiia perelivaniia krovi" ICL-KPO VS, Russia; 9 – Pelikan, Russia; 10 – AIST Tsentr krovi FMBA, Russia; 11 – "Transfuziologiia" LLC "Medotreid", Russia; 12 – DoReMe, Sweden; 13 – Prosang, Sweden; 14 – Blood Bank Control System, USA; 15 – eDelphyn hemasoft, Denmark; 16 – ePROGESA, Mac-system international group. USA; 17 – Haemonetics data management system, USA; 18 – HOPe, Pakistan



- processes that are performed in stationary and mobile conditions

Fig. 1. Scheme of information support of production transfusion processes by subsystems of BS SMIS

The analysis of BS SMIS determines the presence or absence of the identified properties or characteristics for these properties, but does not allow to estimate the compliance level and the appropriate level of information support using BS SMIS that corresponds to regulatory requirements, standards, best manufacturing practices to obtain high-quality blood products. Analysis of trends of automation of production transfusion processes, properties and functional characteristics of BS SMIS and regulatory requirements, along with the best practices, can determine the requirements for functionality of BS SMIS and its components. Formal requirements for a functional component of system is can be provided as a collection of sets of requirements for each of subsystem sis_o and the set of requirements for system is in general:

$$Rqis = \left(\bigcup_{o} Rqsis_{o}\right) \cup Rqis',$$
(8)

where Rqis is the set of all requirements for system is; $Rqsis_o - the set of all requirements for subsystem sis_o in a system is; Rqis – the set of requirements for system in general.$

Each set of requirements $Rqsis_{o}$ for subsystem sis_{o} can be represented by a collection of sets of requirements for each function f_{om} in subsystem sis_{o} and the set of requirements for subsystem sis_{o} in general.

$$Rqsis_{o} = (\bigcup_{m} Rqf_{om}) \cup Rqsis_{o}', \qquad (9)$$

where Rqf_{om} – the set of requirements for function f_{om} in subsystem sis_o of the system is; $Rqsis_{o}'$ – the set of requirements for subsystem sis_o in general.

Generally, it is advisable to determine the requirements of each function f_{om} that is a set:

$$Rqf_{om} = \{rqf_{omu}\},\tag{10}$$

where rqf_{omu} – requirement u for function f_{om} of subsystem sis_o from system is; u – the index of serial number of requirement for function f_{om} in a subsystem sis_o of the system is, $u = 1, U_m$.

5. Formation of information support model of production transfusion processes using BS SMIS

Formal designation for components of the content of information support of processes is introduced; BS SMIS functionality with the requirements to components of the process and system can graphically represent the information support of processes using BS SMIS, as shown in Fig. 2.



Fig. 2. Graphical representation of information support of processes using BS SMIS: 1 – decomposition of regulatory requirements governing the performance of all production transfusion processes; 2 – decomposition of production transfusion processes on elements and actions; 3 – decomposition requirements for functionality of BS SMIS;
 4 – decomposition BS SMIS on subsystems and functions; 5 – decomposition the collection of all data obtained during information support of production transfusion processes; 6 – control point at which the data collecting for actions of element l_{ii} process p_i

Connection between the functions of system and actions of production transfusion processes is complex, one function f_{om} may be focused on a single action d_{ijk} or on several actions of the set D_{ij} . Given the complexity of connection between functions and actions expedients input control points, which focus on performance of several functions by system correlated with actions of element l_{ij} in the process p_i .

Formally, control points can be inputted for a full cycle of information support of production transfusion processes by the number of conventionally defined elements of the process:

$$CP = \left\{ cp_{ij} \right\},\tag{11}$$

where CP – the set of control points during performance of production transfusion processes; cp_{ij} – checkpoints which are correlated with the actions of a particular element l_{ij} in a process p_i .

Data obtained in control points have a certain importance in terms of impact on the qualitative and quantitative indicators which can be assessed by the completeness and degree of compliance with the requirements. Inadequate information support can lead to violations of the production transfusion processes, to errors, which in turn affects the performance measures of BS regarding quality. The resulting data in various control points of a process differently affect the overall target compliance with quality indicators. The level of exposure is advisable to determine by an expert, given the demands on production transfusion processes to ensure the quality of blood products. For each control point cp_{ij} experts should determine the level of impact to the entirety, accuracy, relevance of data receiving on the overall task while ensuring the quality of blood products using the coefficient α_{cp_i} .

The set of coefficients of importance of control points is defined as follows:

$$\mathbf{A} = \left\{ \boldsymbol{\alpha}_{\mathrm{cp}_{ij}} \right\},\tag{12}$$

where A – the set of coefficients of importance of control points; α_{cc} – coefficient of importance for control points cp_{ii} .

In turn, some data have characteristic coefficients of importance $\beta_{d_{S_{ijkh}}}$ that are also determined by an expert. In total, coefficients of importance $\beta_{d_{S_{ijkh}}}$ can be presented as a set B:

$$\mathbf{B} = \left\{ \beta_{\mathrm{ds}_{ijkh}} \right\},\tag{13}$$

where B- the set of coefficients of data importance; $\beta_{ds_{ijkh}}$ – coefficient of importance for data ds_{ijkh} .

During the information support of production transfusion processes, data can be obtained with varying degrees of automation and different levels of involvement of modern information technologies. The degree of automation can also be determined by an expert and considered as a factor of the degree of automation of information support $\gamma_{d_{slab}}$.

The set of coefficients for the degree of automation of information support is defined as follows:

$$G = \left\{ \gamma_{ds_{ijkh}} \right\}, \tag{14}$$

where G – the set of coefficients, determining the degree of automation of information support; $\gamma_{ds_{ijkh}}$ – the coefficient degree of automation for receiving data ds_{ijkh} .

Coefficients of the degree of automation of information support can be conditionally designated as shown in Table 2.

Table 2

The degree of automation of information support

The degree of automation	Description of the degree of automation
1	Manual information processing
2	Computerized information processing by standard means of operating system
3	Automated workplace (AWP) with access to the local network using specialized software
4	AWP with access to the local network and exter- nal databases (systems) using specialized software
5	AWP connectivity hardware equipment using specialized software without access to network
6	AWP with access to the local network and exter- nal databases (systems) with hardware equipment connected and the use of specialized software

With the aforementioned in mind, formal model of information support of production transfusion processes using BS SMIS considering the details may be represented as follows:

$$A = \left\langle \begin{cases} p_{i} \}, \{ l_{ij} \}, \{ d_{ijk} \}, \{ rqp_{ijkg} \}, \{ ds_{ijkh} \}, \\ \{ sis_{o} \}, \{ f_{om} \}, \{ rqf_{omu} \}, \\ \{ cp_{ij} \}, \{ \alpha_{cp_{ij}} \}, \{ \beta_{ds_{ijkh}} \}, \{ \gamma_{ds_{ijkh}} \} \end{cases} \right\rangle,$$
(15)

which generally has the form:

$$A = \langle P, L, D, Rqp, DS, is, Fis, Rqis, CP, A, B, G \rangle.$$
(16)

The model can be formed based on the content analysis of information support of production transfusion processes, structural and functional analysis of BS SMIS, with the assistance of expert assessments of the importance of data and its sets obtained by information support based on the quality of processes and blood products, while considering the degree of automation of processes of data acquisition. The model can be considered as a basis for evaluating the information support of production transfusion processes.

6. Discussion of results of using the model of information support

The development of the model is based on previously research on the analysis and formalization of business processes of the subject area that was held in the design of the method of organizational and technical structures formation for blood service IS segments [23].

The model suggested by the results of this work with varying degrees of detail makes it possible to gradually formally represent the information support of production transfusion processes. Different levels of detail allow generally (roughly) or more fully (in details) consider the information system which is evaluated. The model allows to take into account the degree of importance of individual data or their collection received at control points and the degree of automation of data acquisition. This formalization provides a generalized approach for evaluating the information system in BS establishment for compliance with established standards, regulations and best production practice. Coefficients of importance are expected to determine by an expert as part of the model. The current model can be used to calculate the generalized index of the reference level of information support of production transfusion processes in case of compliance with all of the legal and regulatory framework, governing the activities of production transfusion to achieve the quality of blood products and automation of information support for all processes.

Using the proposed model, the generalized indicator can also be calculated for the evaluation of the system under research.

The generalized indicator of the researched system compared to the generalized index of the reference level for information support gives the opportunity to assess and identify the ways to improve the effect of the BS by improving the embedded SMIS, increasing the functionality, automation of priority items of the production transfusion process.

Thus, further researches using the model involve the formation of a generalized indicator or evaluation criteria of BS SMIS. An integral part is determination of the coefficients of importance for certain data obtained in the information support and group of data obtained conventionally defined control points elements of the process. In order to successfully solve the problem, reasonable involvement of experts, the choice of a rational method of peer review, formalization of processing the results of expertises are expedient.

To fill the model to assess compliance of information support of production transfusion processes to standards and regulations by the example of the Kharkov regional blood service center (Ukraine), a study of the element "Introduction, correction, verification of complete information about the donor, the detached person" of the process "Registration" was conducted. To a certain element, the following actions were investigated: "Accounting, correction data of the donor, the detached person", "Registration of current visit". The application of the model showed that the information support of actions of the element corresponds to 95 % of the reference level of information support.

7. Conclusions

1. The structure of requirements for each of the process action was built according to the results of analysis of the content of information support of production transfusion processes with regard to compliance with regulatory requirements. Each requirement to a certain action that is the component of the element of the process should be taken into account in a phased (by gathered data in the control point) and general evaluation (for information support of the production process as a whole), which will be using the built model.

2. Analysis of the functional structure of BS SMIS, trends of automation of production transfusion processes, definition of the properties and functional characteristics of BS SMIS gave rise to the formation of the structure of requirements for components of BS SMIS. This provides for considering the requirements to the whole system and its subsystems, and when considering the subsystems – respectively, provide requirements to subsystems in general and to functions that are implemented to information support of the production transfusion process.

3. The data of information support of production transfusion processes were formalized with definition of quantitative and qualitative indicators to their importance and degree of automation. A list of all process parameters, for which data of information support should be received, is focused on regulations, rules and legal framework for the production transfusion. Coefficients of importance for certain data and data sets that received in control points during performance certain actions are determined by experts. The level of the degree of automation of information support is proposed to determine by the rating scale and take into account when evaluating using the model.

4. Using BS SMIS (15), (16), the model of information support of production transfusion processes was developed according to the research. The proposed model includes formally presented groups of requirements to the process and system, functional components, data of information support, introduced coefficients of importance of indicators, defined control points.

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