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Life-Cycle Contract as an Innovative Business Model for High-Tech Medical Organizations

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Abstract: The active digitalization of the healthcare system has given impetus to the emergence of a new type of enterprise—high-tech medical organizations (HMO). Their main distinguishing feature is the use of innovative high-tech medical equipment. However, the high cost of this equipment has become a factor slowing down the development of such organizations. This paper considers the life-cycle contract (LCC) as a special form of interaction between stakeholders and investments throughout the life cycles of equipment. Moreover, to provide technological support, continuous acquisition and life-cycle support (CALS) technologies, which are based on the same principles of working with the life cycle as LCC, are proposed. This question turned out to be a significant research gap, which was not sufficiently reflected in the available world studies. Thus, the aim of the current study is to describe the features of the use of LCC for HMO using CALS technologies and the impact of the life cycle of high-tech medical equipment on LCC, as well as to present the innovative component of the proposed model. Based on the analysis of the literature and the best world practices, the authors propose a visualization of the interaction of all stakeholders within the LCC for HMO. Such a decision is extremely relevant for developing organizations, public authorities and investors around the world.

Keywords: life-cycle contract; life-cycle contract in health care; high-tech medicine; innovations in health care; CALS in health care; medical equipment

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1. Introduction

The development of medical science and the related branches of science and technology does not stand still. Modern medical care includes the use of complex, unique and complex methods of treatment. Moreover, modern diagnostic methods are becoming more effective, and the range of innovative solutions used is expanding every year. With the advent of the ability to use robotic technology, cell and genetic engineering and other information technologies, a new direction in the development of medicine has emerged, namely high-tech medical organizations (HMO). Such medical organizations become parts of clusters and hubs, develop at the ecosystem level and implement integrated platform solutions [1,2]. This, in turn, forms a whole cluster of special medical equipment.

High-tech medical equipment (HME) is medical equipment specifically designed to provide high-tech medical care. High-tech equipment is one of the key factors for creating value in progressive medical organizations that are open to innovation and consider the ecosystem approach as a way for all stakeholders to interact, ready to implement the latest technologies together [3]. HME is one of the key focuses of the innovative activities of HMOs as it enables the application of new treatment technologies and promotes the industry to a new level of service quality.

Such equipment requires special skills in design, manufacture, maintenance and operation and requires effective approaches to managing its life cycle, including funding models for its development, manufacture, acquisition, use and maintenance. Coordination of all these steps of the equipment life cycle, performed by different actors, seems hardly possible without an open innovative society. Such a society (formal or informal) needs a specific management mechanism for effective management of the HME life cycle. In this regard, it seems completely logical to propose a healthcare-specific model for the life-cycle contract that has already proven itself in other industries. In the context of managing medical equipment for the provision of high-tech care, the task of developing an LCC model seems to be in demand, the results of which we propose to consider in this article.

A life-cycle contract (LCC) is a type of long-term agreement under which the contractor undertakes to purchase goods or to design, build, repair, operate or dispose of (if necessary) the object of the purchase. At the same time, during the entire period of validity of such a transaction, the customer makes payments to the contractor on the terms agreed in the contract. The life-cycle contract model is based on the important principle of unity of control, regardless of the executor of these stages. It should be noted that the same principle is used in another management concept—the CALS (continuous acquisition and life-cycle support) concept.

The CALS concept is based on a systematic approach to life-cycle support. CALS is a concept that combines the principles and technologies of information support for product life cycles at all their stages, based on the use of an integrated information environment. In this paper, the authors propose to consider life-cycle contracts in conjunction with the CALS concept.

Within the framework of the sixth technological wave, which is characterized by neo-Keynesian principles of organizing the real sector, minimizing the risks of the participants in the process of creating and operating an expensive HME is extremely relevant. The more expensive the equipment, the higher the risks and, as a result, the greater the temptation of the parties to save on everything and, ultimately, on quality. How to reduce cost and improve quality while increasing participant motivation? There are precedents and emerging practices for LCC-based approaches. The LCC as a methodology is not included in the regulations. The proposed options for the legislative design of the LCC have little in common with the modern interpretation of the LCC as a scientific and applied phenomenon and does not always ideally reflect the real needs of the participants of the product life cycle in terms of an effective interaction model. In European countries, the term life-cycle costing is stipulated in the legislation [4,5] and refers to considering all the costs that will be incurred during the lifetime of the product, work or service and pay much attention to the environmental objectives [6,7]. In Russian legislation [8], the concept of LCC also refers to a narrow area of public procurement and offers a truncated mechanism compared to the true scope of this concept. As for HME, there is practically nothing for this area: no standards and no laws, but there is an urgent need to develop theoretical foundations. The authors of the paper propose to look at the LCC as an entity with the declared characteristics through the prism of CALS as a scientific direction.

Therefore, it is possible to formulate the purpose of the study, which is to propose models for the application of an LCC to the problem of supplying high-tech medical organizations with high-tech medical equipment.

To achieve this goal, the following research questions were formulated:

RQ1: What is the meaning of using the LCC for HMO?

RQ2: What roles of LCC participants in terms of CALS technology seem to be essential for the analysis?

RQ3: How do the life cycles of HME affect LCC?

RQ4: What are the features of the financial interaction of LCC participants?

RQ5: What is the innovative orientation of the proposed model?

The following sections of the paper address the theoretical basis and methodology of the research, the review of the research literature, the authors' vision on the application of the life-cycle contract for high-tech medical organizations and the topics of future research areas.

2. Materials and Methods

As part of the implementation of the study, the results of which are described in this paper, the authors adhered to a certain work algorithm. This algorithm, expressed as a block diagram, is shown in Figure 1.

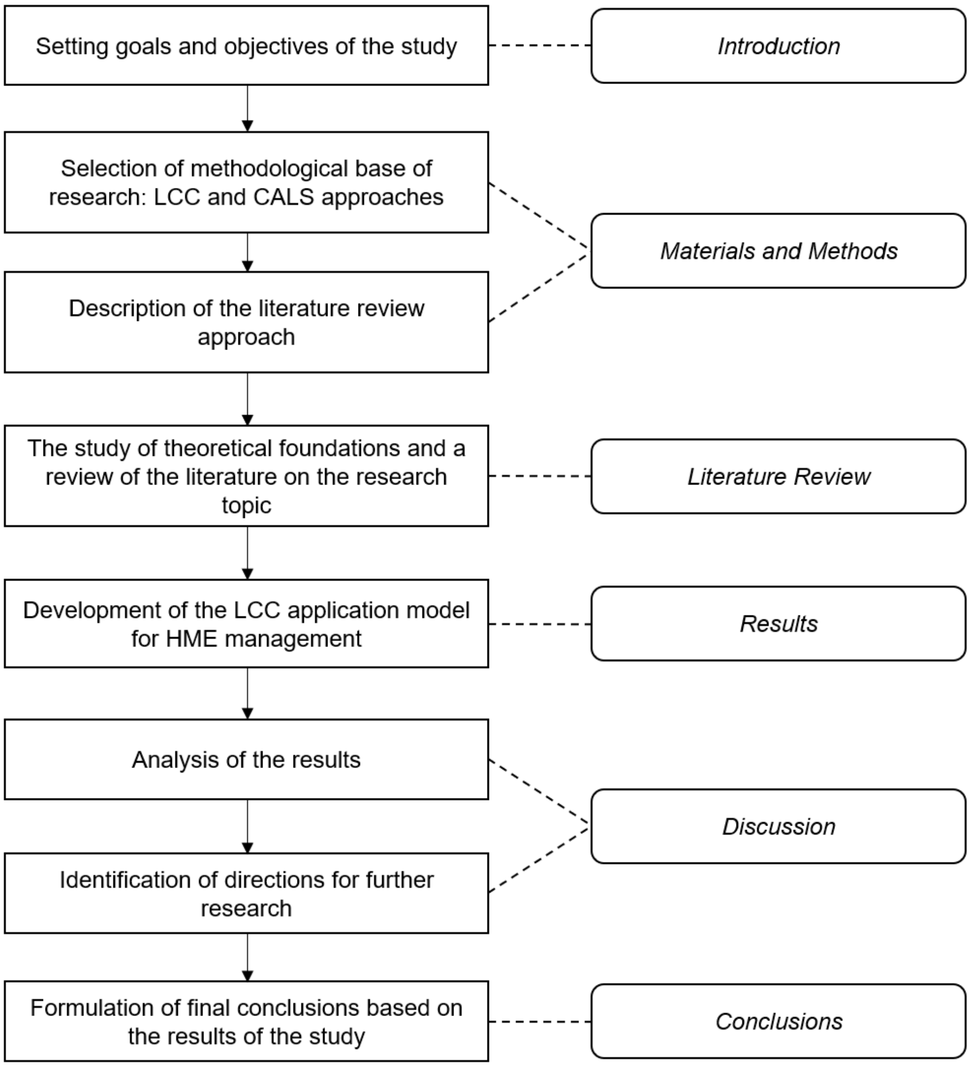


Figure 1. Model of the research algorithm.

As a methodological basis for developing a model for using life-cycle contracts to provide medical organizations with high-tech medical equipment, which is described in the Results section, a product life-cycle management model was chosen, the information aspects of which are visually represented in the CALS model.

The literature review was conducted as defined in Figure 2.

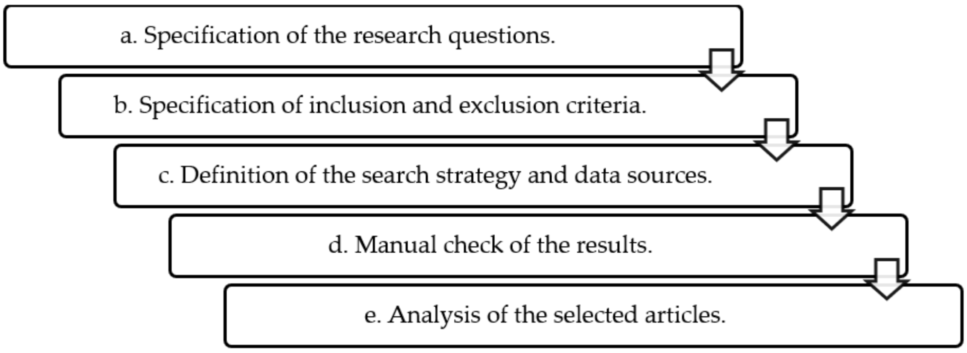


Figure 2. Literature review process.

a. Specification of the research questions.

In the present study, the following research questions were defined:
RQ1: What is the meaning of using the LCC for HMO?
RQ2: What roles of LCC participants in terms of CALS technology seem to be essential for the analysis?
RQ3: How do the life cycles of HME affect the LCC?
RQ4: What are the features of the financial interaction of LCC participants?
RQ5: What is the innovative orientation of the proposed model?

b. Specification of inclusion and exclusion criteria.

Initially, the team of authors understood the narrowness and pin-pointedness of the chosen topic and the research questions posed, so the focus of the search for suitable research papers was the cases of using the LCC as a form of public–private partnership. Moreover, realizing that this form of interaction is not established in all business cultures, it was decided not to limit the results by years and countries.

c. Definition of the search strategy and data sources.

In this study, an electronic search procedure was used to identify a list of papers on the application of LCC in different industries, and a manual search to select studies that could fruitfully influence the results of the studies. Electronic search was used in the Scopus search engine, where the final search query looked like the following:
TITLE-ABS-KEY (life AND cycle AND contract AND public-private AND partnership) AND (LIMIT-TO (OA,"all")).
A total of 10 papers were identified in open access and in English.

d. Manual check of the results.

In the course of the manual search as a result of the analysis of the abstracts of papers, the most relevant ones were selected. The number of papers analyzed was reduced to three. These papers were not enough, so more sources were added, selected in Google Scholar according to identical parameters. This search increased the number of sources to 13. These papers were divided into categories showing the industry of application (Table 1).

Table 1. Matrix of articles collected.

Category	Source Number
Transport	[9–16]
Construction of sports facilities	[17]
Medicine	[18–21]

e. Analysis of the selected papers.

The previously listed advantages of the LCC certainly make life-cycle contracts attractive, and gradually this approach is gaining popularity in the world.

For the first time, a life-cycle contract was concluded in the UK in 1992; however, they became widespread only at the beginning of the 21st century. Today, life-cycle contracts are used mainly in large infrastructure projects. For example, in the UK, the most significant project under a life-cycle contract was a project to create a high-speed connection between London and the Channel Tunnel. Under the terms of the project agreement, the private partner would carry out the design, construction, financing, operation, repair and maintenance of the specific railway line. The UK Department for Transport, in turn, committed to funding the project through the provision of cash grants, as well as of the necessary rights in relation to land. In addition, after the start of the project, a significant part of the funding was secured by a guarantee from the government [9,10].

Life-cycle contracts are actively used in various projects in the Netherlands. For the first time, life cycle contracts were used as part of the implementation of infrastructure projects for the creation of a high-speed railway line in 2001 and the N31 Leeuwarden–Drachten road in 2002. Subsequently, similar contracts were used in the construction of the A12 Lünetten–Weenendal and A15 Maasvlakte–Waanplein motorways. The first LCC for the construction of a building was signed in 2006 for a project to renovate the building of the Ministry of Finance in The Hague [11].

Another example for LCC is the multifunctional sports and entertainment complex, the "Singapore Sports Hub" located in Singapore, which was also created under a public–private partnership agreement. In 2005, a tender was held among three groups of companies, as a result of which a contract was signed with the Singapore Sports Hub Consortium group of companies for 25 years. The signed LCC provided for the obligations of a private partner in the design, construction and management of the complex [17].

Another example of the successful application of the LCC was the innovative management model of the Zona da Mata regional airport in Brazil, where the application of the LCC and public–private partnerships reduced the public management costs by almost 70% [12].

In Russia, the use of life-cycle contracts is currently not as popular as abroad; however, every year there are more and more projects implemented under LCC. For example, the Russian Railways concluded a contract with Siemens Transportation Systems for the purchase and maintenance of Sapsan high-speed electric trains. On the St. Petersburg–Moscow section, these trains began to run at the end of 2009. Under the mentioned contract, the contractor carries out repair and maintenance of electric trains during the entire period of their operation. The duration of the contract is 30 years. The calculation of the remuneration rate for maintenance and repair is based on the agreed cost of repair and maintenance of trains per one million kilometers. The contract contains a requirement that the contractor ensures the level of technical readiness—not lower than 98%—of the trains, and in case of noncompliance with the requirement, the contractor is subject to pre-agreed penalties [13,14].

The LCC format is also being actively implemented by the Moscow government. In the third quarter of 2016, the 17th bus depot, owned by SUE Mosgortrans, switched to work under a life-cycle contract. According to the agreement concluded between the GAZ Group and the 17th bus depot, the manufacturer is engaged in maintaining the buses purchased under an LCC model for 7 years, while the technical readiness factor must be at least 0.95. At the same time, the manufacturer provides a full range of maintenance and repair services, except for washing the rolling stock, passing the state technical inspection and refueling. According to experts, the cost of maintaining buses in working condition according to the LCC model decreased by 20.8% per 1 km of run, from 46.4 rubles/km to 36.8 rubles/km. At present, SUE Mosgortrans also operates bus depots in the Zapadny and Yuzhny branches under a life-cycle contract [15].

The LCC is also used by the State Unitary Enterprise Moscow Metro, which in 2013 signed a life-cycle contract for the maintenance of metro cars with the Metrovagonmash company. According to this contract, the contractor is obliged to maintain, repair and daily deliver high-quality rolling stock to the line for 30 years [16].

The life-cycle contract model is also gradually gaining popularity in various healthcare projects. For example, in 2011, a 12-year contract was signed between the government of Moldova and the national sales company Magnific SRL for the construction, equipment and launch of a new center for radiology and diagnostic imaging at the Timofei Mosneaga Republican Clinical Hospital. Under this contract, Magnific is committed to supplying and operating the equipment and providing clinical services. In turn, the government agency and the hospital pay an annual fixed fee for services provided to government inpatients and outpatients [18].

In 2009, Siemens Healthcare and the Spanish Ministry of Health entered into a contract until 2024 to supply biomedical equipment to two new public hospitals in the Autonomous Community of Murcia in Spain. This contract includes the supply of equipment for the two hospitals, its maintenance, the training of those who will use it during the term of the contract and any need to upgrade or repair the equipment, as well as the provision of necessary materials and replacement. Payments are made subject to quality and availability indicators [19].

The industrial company Sistemas Genómicos (SG) and a private nonprofit partner from Uruguay (AESM) signed a contract in 2016 to develop the first platform for clinical analysis and interpretation of whole genome sequencing data in Uruguay. The contract includes technical assistance from SG to introduce this advanced technology, knowledge transfer for its use (both in Uruguay and Spain), remote technical support throughout the project (seven years), supply of genetic testing kits, joint participation in R&D projects and joint patent filings, if necessary [20].

Since 2019, with the help of life-cycle contracts, Moscow has been acquiring innovative medical equipment for city hospitals and polyclinics. Within the framework of contracts signed last year, approximately 760 units of modern medical equipment were purchased for the amount of RUB 26.7 billion. The world's largest manufacturers were among the winners of the competitions. In just two years, the city signed 122 contracts worth RUB 90 billion for the supply of medical equipment [21].

In summary, the review of the sources showed that at the moment there is only a description of existing cases and projects where the LCC is applied in the literature, and there are no theoretical reference models. The current state of research and the lack of integrated approaches to the problem of supplying HMO with high-tech medical equipment according to the LCC model make this study extremely relevant.

3. Literature Review

An LCC is an agreement in which the contractor assumes obligations for the design, creation, maintenance, operation and, in some cases, disposal of an object during the entire period of its operation, and the customer undertakes to pay for the results of the work of the contractor [22]. The term "life-cycle contract" itself come from Scandinavia; however, in the practice of many other Western countries, there are terms such as DBFM contracts (design, build, finance, maintain) and DBFO contracts (design, build, finance, operate). Despite terminological differences, coverage of the entire period of the "life" of the product within the framework of the mentioned models allows us to consider them as entities of the same class.

As the most common practice, an LCC is considered one of the forms of public–private partnership (PPP), where the customer is a state or municipal body and any legal entity or individual can act as a contractor. Why PPP? Because the negative impact on the effectiveness of activities under the LCC in most cases can be compensated for only by the state, which has leverage on tax benefits, the ability to provide state guarantees if the appropriate mechanism is applicable, the ability to guarantee demand in the form of targeted areas financed by the compulsory medical insurance fund and the ability to provide asset insurance, influence tariffs, etc. The essence of using a life-cycle contract is as follows: the public partner, on a competitive basis, concludes an agreement with a private partner (a contractor) for the design, construction and operation of an object for the entire life cycle of the object. At the same time, within the contract frame, the public partner pays in equal installments after the facility is put into operation, provided that the private partner maintains the facility in accordance with the specified functional requirements. The main value of a life-cycle contract lies in the fact that the state gets the opportunity to use the useful properties of the object without participating in either its production or its subsequent maintenance and disposal [23].

The LCC has the following features [24,25]:

a. The implementation of the various stages of the project is delegated to one private contractor through a comprehensive contract, while the selection of the contractor is carried out, as a rule, on a competitive basis.
b. The private partner in the LCC independently makes all design and technical decisions necessary for the implementation of the project.
c. The contract is concluded for a long time period (15–30 years on average). A long-term perspective is necessary for the contractor to be able to recover its investments in the project at the stages of commissioning and maintenance of the created asset.
d. The private contractor is responsible for financing the project. The private party does not receive payment when the asset is created but receives a monthly fee for the availability of the asset during the term of the contract (availability fee).
e. Project risks are distributed between the customer and the contractor and fall on the party that can best manage them.

The life-cycle contract is an alternative to "traditional" public procurement [26], which is short term (rarely medium term) in nature. Within the framework of such a traditional approach, tenders for the supply of goods/provision of services are most often held annually, which is justified for many areas of activity and allows the state to derive maximum benefit from interactions with the private sector [27]. At the same time, there are areas where long-term interaction is needed, in other words, where projects are of a long-term nature. First of all, this is infrastructure—the construction of highways, sea and river ports, airfields, public infrastructure systems, underground and ground electric transport, etc. In addition, long-term projects can be implemented in the construction and operation of other public sector facilities, such as hospitals, schools, etc. [28].

Implementing a long-term project within the framework of the traditional approach, the state is forced to involve a large number of different private contractors at different stages—design, construction and subsequent operation. On the one hand, with this approach, the state can potentially save on costs by choosing the most preferred contractor at each stage and reducing the conditional duration of the project as a whole—if each stage is considered as an independent project. However, at the same time, the costs of conducting competitive selections increase (for example, holding three tenders instead of one), as well as the risks of opportunistic behavior of various participants who may seek to achieve greater self-interest by reducing the quality of the commodity provided. In this regard, the state is forced to conduct constant monitoring and quality control.

With the transition from traditional procurement to LCC, the role of the state is significantly reduced, which is expressed in a reduction in the levels of interaction with other participants. The customer (state) within the framework of the life cycle formulates the requirements for the object of the contract, conducts a competitive selection among applicants for the implementation of the project and makes payments according to the agreed schedule. All other project activities are delegated to the selected private contractor, which completely eliminates the possibility of opportunistic behavior of an individual private entity in relation to the subsequent project participant.

Thus, compared to traditional public procurement, the life-cycle contract has the following advantages [29–32]:

a. For the state:
   - No dilution of responsibility for the result between different performers and, as a result, minimization of the risks of delaying the deadline (or complete failure) of the project;
   - Simplification of the contract execution control process;
   - No need to conduct competitive procedures at each stage of the project implementation and, as a result, the absence of these costs;
   - Payment under the contract only if the object is maintained in accordance with the functional parameters;
   - "Installment plan" of payment under the contract (payment occurs from the moment the facility is put into operation and is divided into relatively small payments paid in set periods of time, so the state does not need to reserve a significant amount in the budget);
   - No unpredictable future costs for infrastructure support, as the private partner is also engaged in the maintenance of the created object;
   - Increased motivation of the private partner to put the object into operation as soon as possible, since it is after commissioning that the contractor begins to receive cash payments.
b. For a private partner (contractor):
   - Freedom of choice of design technical solutions, project management meth-ods, organization of the production process, service operations, etc.;
   - A higher chance of return on investment compared to an open market player, since the risks of market uncertainties are hedged with state guarantees (subject to the fulfillment of the terms of the contract);
   - Financing of value creation activities outside the credit mechanism of bank financing, since in the case of a consortium of performers, the financial institution provides direct financing for operating activities and creates reserves for success fees, which are possible under a long contract;
   - Innovative nature of activities to create added value: innovation is the key to higher efficiency: design, production and service.

The use of LCC to provide high-tech medical organizations with high-tech equipment is due to the following factors:

a. The long-term nature of the project;
b. The existing potential for delegating several project stages to one contractor;
c. The complexity of the control of each individual stage;
d. Guaranteed availability of demand for equipment for a long period of time;
e. The need for support, repair and modernization of equipment during the entire period of operation;
f. The social significance of such projects and often the need for a high speed of implementation (the main theoretical and empirical literature supports the assumption that LCCs lead to faster implementation of projects [33,34], so it is advisable to use them).

Thus, taking into account and summing up the above, it can be noted that in this paper we will focus on LCCs provided to high-tech medical organizations—this is a form of interaction when all participants in the created product are responsible for their work area throughout the entire life cycle. Moreover, the return on investment and payment by the end user also occurs throughout the life cycle (useful life). In other words, the end user (in this context, the HMO) pays a subscription fee for the use of medical equipment and does not pay a one-time fee for it.

CALS is a concept that combines the principles and technologies of information support of a product life cycle at all its stages, based on the use of an integrated information environment (single information space), providing uniform ways of managing processes and interacting with all participants in this cycle—customers of products (including government agencies and departments), suppliers (manufacturers) of products and operating and maintenance personnel—implemented in accordance with the requirements of the system of international standards governing the rules for this interaction, mainly through electronic data exchange. In other words, CALS technologies represent a modern organization of the processes of development, production, after-sales service and operation of products through information support of their life-cycle processes based on the standardization of data presentation methods at each stage of the life cycle and paperless electronic data exchange. Such technologies give an important basis for the digitalization of modern medical organizations [35].

The CALS concept is based on the idea of creating a single integrated product model. Such a model should reflect all aspects of a product and accompany it throughout its life cycle from conception to disposal. The concept of a "single model" means a model that contains all the information about the specific product required at any stage of the life cycle. The concept of "integrated" means a model in which common tools and methods are used in the construction of each of the fragments to ensure the integrity of the entire model that describes the product.

CALS technologies are actively used, first of all, in the development and production of complex science-intensive products, since the complexity and laboriousness of creating such products always require the involvement of a large number of various stakeholders. The purpose of using CALS technologies as a tool for organizing and providing information supports for all participants in the creation, production and use of a product is to increase the efficiency of their activities by accelerating the processes of research and development of products, giving the product new properties, reducing costs in the production and operation of products and increasing level of service in the processes of its operation and maintenance.

The use of CALS technologies is associated with a number of advantages:

- Improvement in product quality;
- Reduction in material and time costs for the implementation of various stages of the product life cycle;
- Guaranteed security of work results that are due to the implementation of the principle of succession and safety of work results at all stages of the product life cycle;
- Increased flexibility to respond to changes;
- Reduction in calendar terms for bringing new competitive products to the market.

Consequently, the expediency of using CALS technologies in projects based on the LCC model is due to the fact that the CALS concept is based on the same principles of working with the life cycle as the LCC, namely the principle of unity of control, regardless of which of the participants implements these stages. However, it is important to note that in this context, CALS technologies are considered as a method of information support for business processes, and the LCC is precisely the financial model for ensuring the entire product life cycle (RQ2).

4. Results

Practically, the life cycle of managing high-tech medical equipment is as follows in Figure 3.

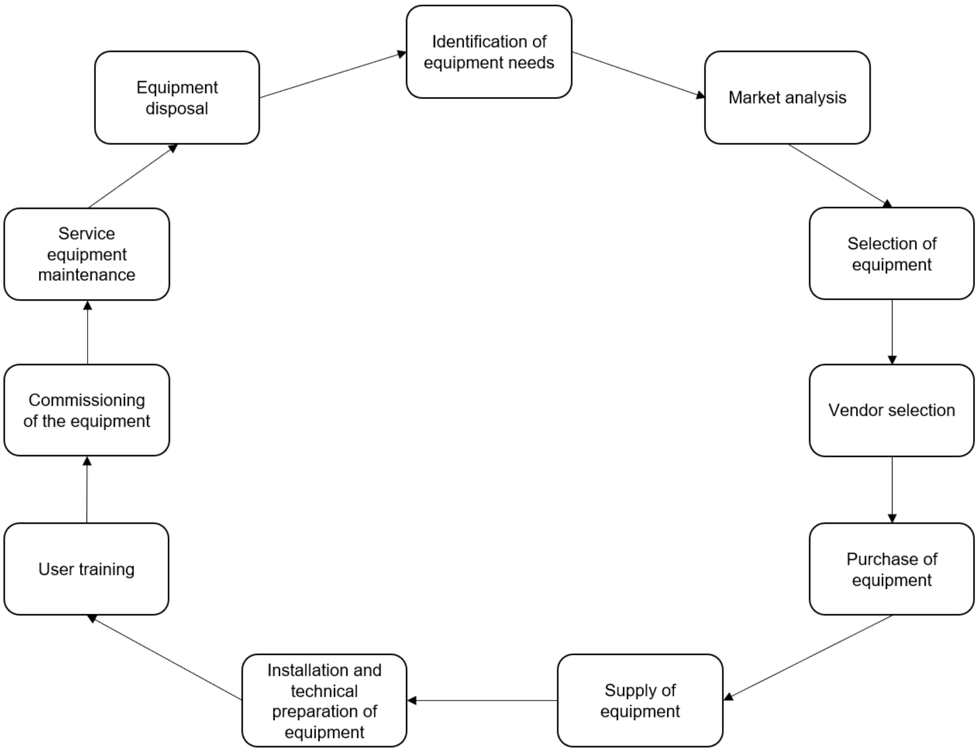


Figure 3. HME management life cycle "as is".

The cycle in Figure 3 can be considered as an "as is" version of the cycle. It is an integrated result of the interviews and observations of the medical organizations of Russia, Uzbekistan and Switzerland during the lasting research work on the healthcare system optimization of Peter the Great St. Petersburg Polytechnic University during the period 2016–2022. This cycle model, derived from practical experience and business logic, includes the following steps:

a. *Identification of the need for equipment*: at this stage, the medical organization determines the equipment needs, and also formulates the requirements for this equipment.
b. *Market analysis:* representatives of the medical organization conduct a market analysis to identify and select suitable equipment options, which meet the requirements mentioned at stage 1.
c. *Equipment selection*: at this stage, a comparative analysis of the previously selected options is carried out and the most suitable option for a particular medical organization is selected, involving, however, several modifications of the equipment.
d. *Vendor selection*: if the selected equipment can be purchased from several different suppliers, a comparative analysis of the terms of cooperation and further ranking and selection of the supplier is carried out. The supply contract with the selected supplier is carried out. Delivery logistics can be the subject of a separate contract.
e. *Purchase of equipment:* payment procedures and documentary support of the purchase contract are carried out.
f. *Supply of equipment*: at this stage, the purchased equipment is delivered in the proper form to the medical organization as part of a delivery contract or as part of a purchase contract.
g. *Installation and technical preparation of equipment:* carrying out activities to prepare equipment for commissioning: preliminary preparation of the premises, installation of equipment, configuration, commissioning, etc.
h. *User training:* training of personnel to work with new equipment.
i. *Commissioning of the equipment*.

j. *Service equipment maintenance*: activities for the maintenance of equipment throughout the entire period of its operation (repair, maintenance, software updates, etc.) [36].
k. *Disposal of equipment*: equipment decommissioning and subsequent disposal.
l. *Modernization of equipment*: an optional step that is applicable to certain types of HME.

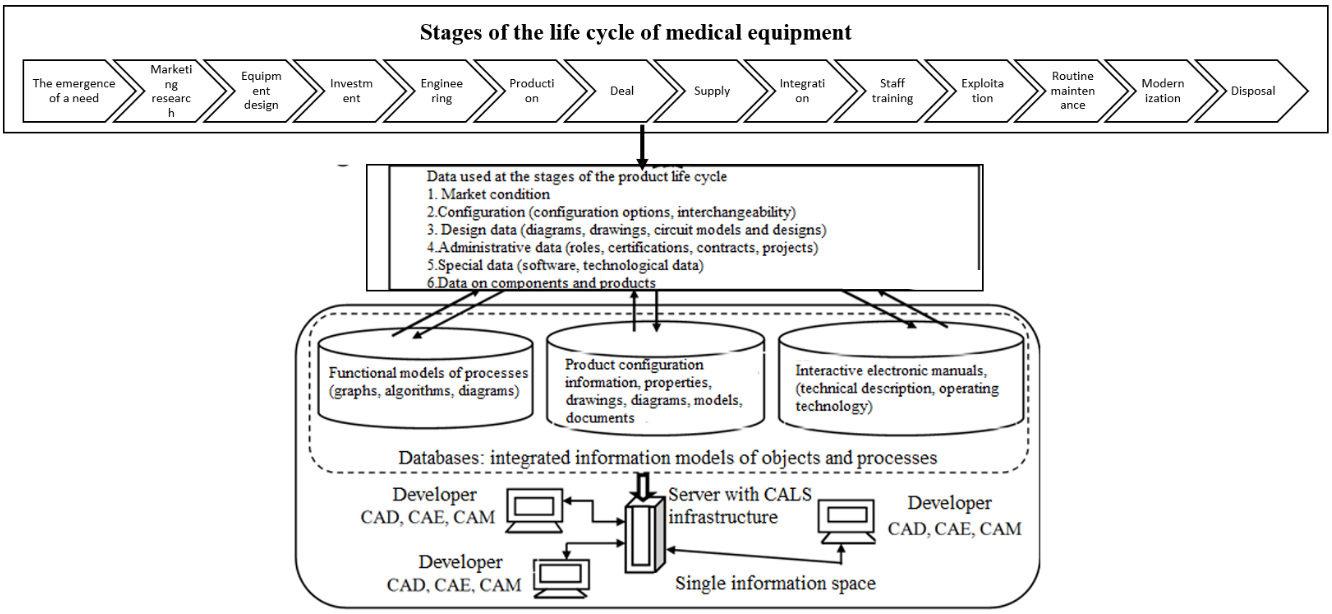
The proposed life cycle of high-tech medical equipment includes the involvement of a significant number of different stakeholders to implement the stages of the cycle:

a. *Medical organization*—acts as a customer who has a need for certain high-tech equipment.
b. *Equipment supplier*—transfers the equipment to the ownership of the medical organization after the customer pays the contractual cost of the equipment.
c. *Transport organization*—delivers equipment to the place of operation.
d. *An organization providing maintenance services for medical equipment*—performs installation and commissioning.
e. *Responsible for personnel training*—organizes training and certification of personnel on the basics and principles of the operation of new equipment and issues of correct functional operation of equipment.
f. *Service organization*—ensuring the smooth operation of equipment as part of a set of maintenance and repair activities.
g. *Recycling company*—disposes of equipment.
h. *Financial organizations*—can be involved in the process to support a financial flow to finance the design, production, service, disposal and, possibly, modernization of equipment. A financial institution can be a bank that provides financial security in the form of a bank loan or the own treasury of participants in the creation of equipment if own funds are used for financing.
i. *State body*—can act as an investor or a guarantor within certain obligations.

The following describes the transition from the existing HME life-cycle model (Figure 3) to the *equipment life-cycle management model* within the framework of the LCC. The functional roles indicated above retain their place in the logic of the process of creation, delivery and operation of HME, since the technology of creation, delivery and operation of HME does not change—this is obvious when analyzing the HME life cycle in terms of the CALS model. Functions are being added to the role of a "state body", whose task is to provide guarantees that compensate for changes in market situations (refinancing rate, tariffs, inflation, taxes, etc.). As part of the proposed changes, new organizational principles for the interaction of roles and principles for managing financial flows are fixed. Such an agreement seems logical, in which the above features are the subject of an agreement between the two parties: the customer, who assumes the role of the operator of the supplied HME, and the contractor, whose responsibility is to ensure the entire list of operations provided for by the design, manufacture, delivery model and service in terms of CALS. The simplest option is one in which the contractor is the only counterparty. However, in fact, most business cases involve the participation of several counterparties on the side of the contractor, in connection with which the contractor is a consortium of counterparties whose task is to perform a full list of functions within the supply chain (according to CALS: design, production, logistics, incoming and outgoing, service and maintenance and recycling), financing cost centers, accepting payments as a profit center and distributing the incoming financial flow as part of the return on investment.

For the formation of process and component architectures that support the implementation of tasks within the HME LCC, we use CALS libraries and formulated financial principles that CALS does not cover. The result of the synthesis of the information system architecture is shown in Figure 4.

It should again be noted that within the framework of the presented model, the participants of the process in most cases are independent counterparties that are part of the consortium of performers (upper part of Figure 4). The task of each counterparty is to perform part of the end-to-end process of creating the added value of HME in accordance with the provisions of the CALS model or support for the implementation of a set of operations (financial and insurance support). Representation of the complex of tasks and operations within the framework of the HME LCC in terms of the CALS model is shown in Figure 5.



* Abbreviations used: CAD – Computer-aided design; CAE – Computer-aided engineering; CAM – Computer-aided manufacturing.

Figure 4. Information support for the life-cycle processes of medical equipment in HMOs based on CALS.

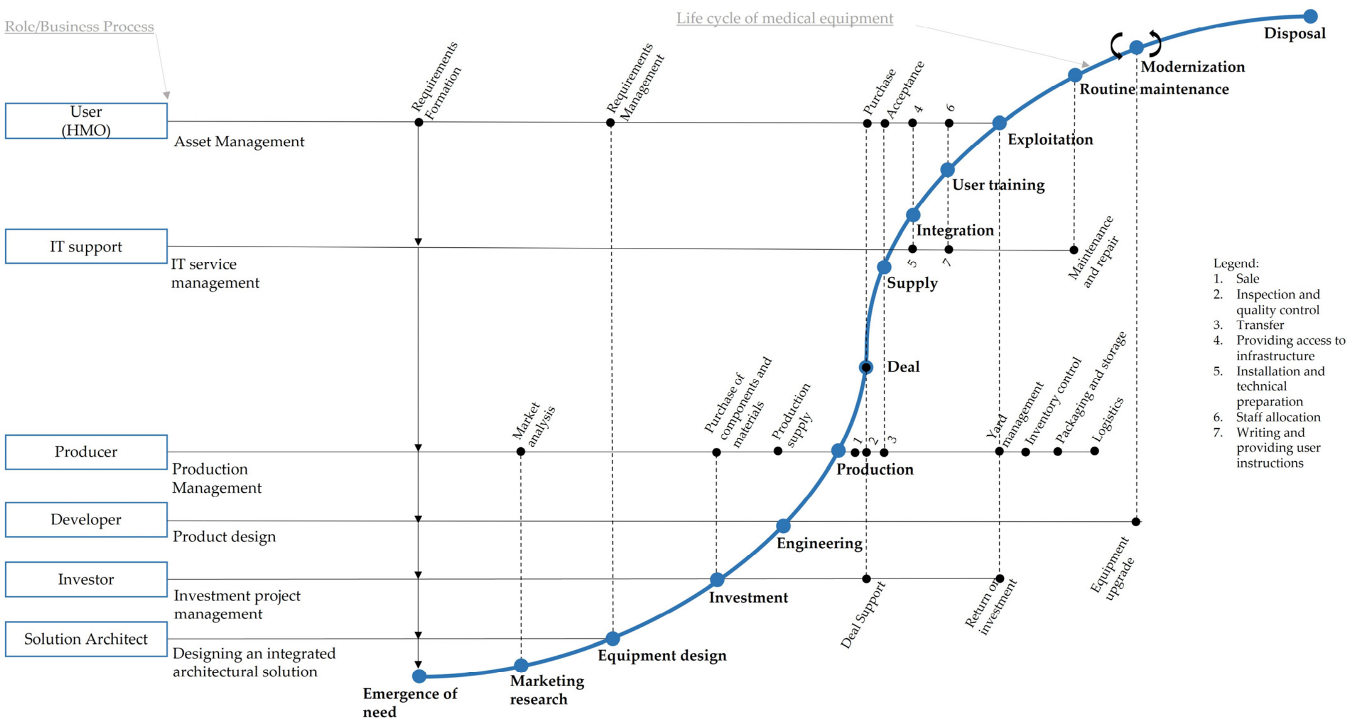


Figure 5. Visualization of the application of an LCC for the management of medical equipment of a medical organization.

The following describes the model in Figure 5 in more detail. On the left, the roles and categories of business processes, the execution of which is in their area of responsibility, are signed. It is important to note that the rectangles do not indicate the stakeholders but the roles that one stakeholder can perform (for example, the developer and manufacturer are one company). The implementation of each stage of the HME life cycle is the responsibility of a specific role, and the integrated scenario for the implementation of process categories within a single process represents the principle of unity of control (RQ3).

For greater clarity and descriptiveness of the proposed scheme, authors consider an abstract example of HME life-cycle management in a fictitious medical organization. The authors assume that this organization has a need for a particular HME. The first step in meeting this need is to create a consortium that unites counterparties according to the list of roles indicated on the left side of the diagram (from the user (operator) to the solution architect). As the operations included in the HME life-cycle model are implemented, an increasing number of stakeholders are included in the integrated HME creation and operation scenario. Each category of HME life-cycle management operations involves financial support provided by an involved financial institution (investment agency, bank, own treasury, venture fund, etc.). For example, the supply of the latest equipment for osteosynthesis involves the designers, manufacturers, technical specialists (with the tasks of launching and commissioning equipment at a new location, integration with existing medical systems and staff training) and a service partner to perform maintenance and repair operations.

Considering various financing schemes, the model of stakeholder interaction in terms of the life cycle is shown in Figure 6.

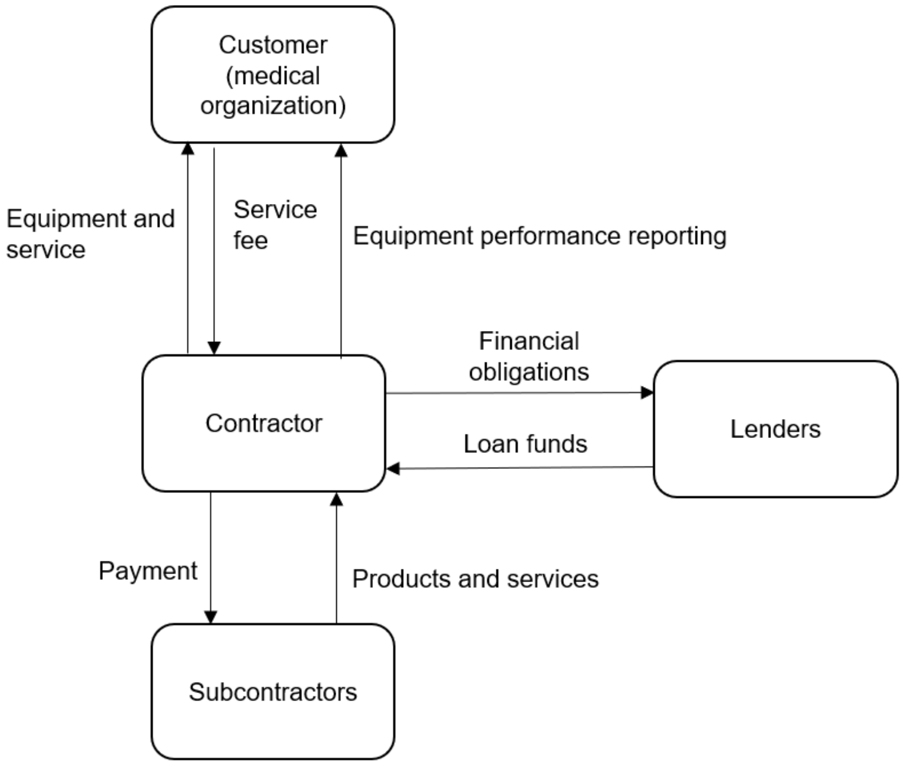


Figure 6. Scheme of the life-cycle contract for high-tech medical equipment.

As can be seen from Figure 6, the following scheme of interaction between participants is assumed. The conclusion of the LCC between the customer and the contractor assumes that there is a single entry point for the customer, which is actually performed by either a single real contractor or a consortium of performers. The contractor undertakes to put the equipment into operation, as well as provide service support for the equipment throughout the entire period of the LCC. To perform a set of operations prior to the commissioning of HME, the financing of operations is carried out according to the estimated principle outside the credit scheme (there is no payment of interest for the use of financial resources). The estimate does not imply compensation for normal profits; it is taken into account in the form of a success fee payable upon fulfillment of the conditions specified in the appendix to the LCC regarding the quality of services and work performed by the counterparty—a member of the consortium. The implementation of the investment mechanism on the indicated principles is possible because of the involvement of a state agent as a guarantor under commercial conditions and the fact that the financial institution is included in the project regulated by the LCC for a long period, which means a lot of money for this counterparty in terms of return on investment.

The customer makes regular payments to the financial institution throughout the term of the LCC, starting from the moment the HME is provided to it for its intended use. At the same time, payments are made only when the equipment is operating correctly, according to a formula whose basic parameter is the equipment availability time with a given technical readiness. In the case of equipment downtime caused by malfunctions, the amount of payments is reduced according to the scheme prescribed in the contract.

Mitigation of and compensation for commercial risks, which are practically inevitable in the long period of the LCC, are partly carried out by the insurance organization, but mainly by the state agent, which has levers of influence on the tariff policy, compensation for inflation losses, uncertainty in the foreign exchange market and in bank loan interest, etc. The range of funds available to the state agent is quite rich and is not subject to consideration within the framework of this paper. The principle of including a state agent in the relationship of the parties within the framework of the LCC is shown in Figure 7.

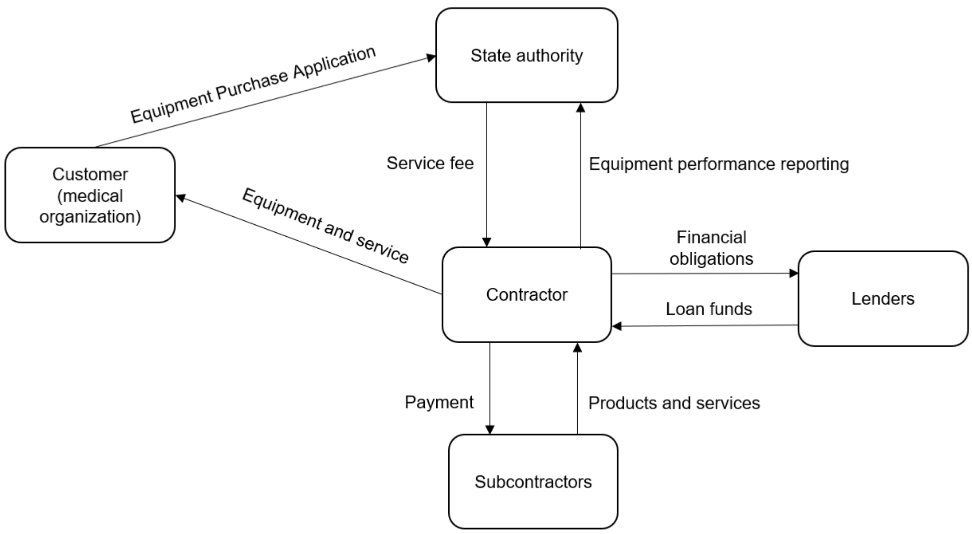


Figure 7. Scheme of a life-cycle contract for high-tech medical equipment with the participation of the state.

The models in Figures 5–7 together with their description are supposed to meet the RQ2 and RQ3.

An important aspect of the fulfillment of tasks within the framework of the LCC is the information transparency of the activities of the participants in the process prescribed by the CALS model and the principles of financing activities. We suggested earlier to consider modern communication technologies as a means of ensuring information transparency, considering IoT as the most obvious tool. The innovativeness of the tools will almost inevitably lead to the implementation of predictive scenarios in terms of HME reliability management and its improvement. In this context, the implementation of continuity of innovation activity is obvious (RQ5).

The legal and financial obligations of the proposed life-cycle interaction of the participants are supposed to be explained as an answer to RQ4. In this paper, we will consider various aspects of using the LCC for HME support, understanding the LCC as an agreement between counterparties involved in the design, production, operation and maintenance of equipment used in HME. The agreement covers the relationship of two or more counterparties: the customer (operator) and the contractor (consortium of contractors), whose task is to design, manufacture, service and, if applicable, upgrade equipment. The agreement of the participants assumes risk insurance—traditional and in the form of guarantees provided, as a rule, by the Ministry of Health. The agreement does not imply withdrawal of the participants from it until the end of the activities provided for by the terms of reference, agreed upon by the participants, for the maintenance and modernization of HME equipment. The responsibility of the contractor (of the consortium of contractors) remains with him until the end of the LCC; the customer (operator) is also responsible for the operation of medical equipment regulated by the agreed conditions. The customer pays for the time the equipment is in use; if the operational parameters of the equipment meet the technical conditions, payment is made in accordance with the agreed schedule: it is not the purchase of the equipment by the customer, but payment for the time of its availability on the basis of a subscription fee. It should be noted that the LCC is not equipment leasing; it is not an implementation of the EaaS (equipment as a service) model but a special way of using the useful properties of equipment for HME within the framework of the LCC.

To compare the life cycle with leasing, let us pay attention to the essential parameters of this option for providing equipment to the operator to compare them in the life-cycle option. Despite the fact that in the case of a financial lease (leasing), as in the case of LCC, there is a payment for the equipment provided by the operator. In the case of leasing, the future lessors are present in the agreement between the counterparties—it is they who buy the finished product from the manufacturer. In fact, there are several agreements, namely agreements between production participants in the HME equipment production chain, an agreement on the sale of equipment to a leasing company and a financial lease agreement.

So, what is the difference between an LCC and leasing? The main differences are:

- In the case of leasing, the technical readiness of the equipment is not taken into account when accruing the operator's debt: if the equipment breaks down, the customer still pays according to the payment schedule. In the case of the life cycle, payment is made for the time the equipment with operational properties is available.
- In the case of leasing, the operator independently decides on maintenance and repair issues. Yes, in this case there are many options for organizing this process, but they have little effect on the financial obligations of the operator to the leasing company. In the LCC option, the operator does not participate in any service agreements as a direct participant.
- In leasing, there are no strict technical transparency requirements for the operator: although he is obliged to comply with technical regulations, in case of disputes, technical expertise is the arbiter in disputes related to compliance with regulations. This exists also in cases of an LCC, but its conclusions are based on objective data obtained using communication tools: IoT, data obtained from an array of control parameters, recorded in a temporary storage and uploaded to the control system through controllers.
- In the case of leasing, the HME is not the property of the customer (operator): he only gets the right to use a share of the rights: the right to use, the right to income and the right to safety. In this sense, the end of the leasing agreement opens up for the HME operator the opportunity to buy the equipment at residual value, which is valuable if the evolution of the types of such equipment is conservative. In the case of the LCC, another bundle of property rights for the customer is relevant: the right to own, the right to use and the right to income (with restrictions). The right to perpetual possession and the right to inheritance arise only in the case of appropriate clauses in the LCC: the agreement may allow the transfer of equipment in favor of the

counterparty providing HME disposal. Comparative analysis of an LCC and leasing is given in Table 2.

Table 2. LCC and leasing comparison.

Parameter	LCC	Leasing
Prepaid expense	From a financial institution/from own funds, and not from the customer	From 10%
Ownership	According to share of rights of LCC	According to the share of rights of leasing. Possibility of redemption (including ahead of schedule)
Contract term	By the duration of the life cycle of equipment (from 5 to 30 years)	Usually up to 8 years
Contracts for equipment service, purchase of spare parts/consumables	Included in one contract, are the responsibility of the contractor	Individual contracts and purchases
Organizations providing maintenance and repair services	Service member of the consortium	At the choice of the operator (possibly subject to the recommendation of the lessor)
Price, tariff, tax, inflationary, currency risks	Compensation by state jurisdictions (guarantees, subsidies, direct compensation, etc.), insurance indemnities in terms of certain risks	Insurance indemnities in terms of risks considered as force majeure (limited)
Maintenance and repair fee	According to a complex formula when confirming a violation of the rules of operation	Fixed under the contract (is agreed with the lessor)

Summing up all the arguments mentioned above, we can conclude that LCC is a more effective form of interaction that allows for saving the budgetary funds of medical organizations, getting better interaction with manufacturers throughout the entire product life cycle (RQ1).

5. Discussion

The study relies on the following assumptions, which act as limitations of the considered situation of interaction between the HME life-cycle participants:

a. For simplicity, we consider that an LCC is concluded between the customer and a single contractor, who undertakes complex obligations to perform the operations stipulated by the CALS model: from the idea, through design to production, service and maintenance of the equipment delivered to the customer.
b. A competitive or noncompetitive nature of the relationship between the parties is not essential for the purpose of this paper.
c. The contractor has a right to make necessary design, technical, production, service, logistic decisions independently or to involve third parties for this purpose.
d. The contract is concluded for the term, which is estimated on the basis of the contractor's need to perform the actions, as stipulated by an LCC: production of the ordered equipment units, modernization and provision of service operations (including post-warranty period). Taking into account the fact that an LCC is expedient in the context of capital-intensive production, the life cycle of which consists of years, the LCC period is also long and extends for a period of 10 or more years.
e. The long-term nature of an LCC entails the peculiarities of exit from the contract: as a rule, an LCC involves the possibility of replacing a partner without changing the essence of the participants' obligations.
f. The actual way of financing an LCC is the attraction of a financial institution within a consortium of participants of the LCC, providing financing of the measures provided by the model of creation and use of added value according to CALS: design, production, service and modernization (if applicable). The financial institution involved

to create a cash flow to ensure the operational activities is not motivated to apply the mechanism of credit financing because by entering into a long-term relationship within the consortium, it provides itself a long financial contract, which provides it with an incoming cash flow, formed by the use for the intended purpose of the created value added. A simpler financing scheme can be applied when the contractor provides the implementation of this function independently (own funds, loans, etc.). The widespread scheme of return on investment is the periodic payment to the contractor (or the financial operator of the consortium) of the amount calculated according to a transparent rule, the key parameter of which is the availability of the equipment transferred to the customer with the agreed indicator of its technical readiness. In this regard, it is relevant to fix the communication aspect of operation, such as the use of IoT technologies to control the modes of operation of the equipment provided to the customer.

g. The risks of an LCC are distributed between the customer and the contractor (contractors, if we are talking about a consortium of participants) and fall on the party that can best manage them. For example, the designer is responsible for design errors, the manufacturer for manufacturing defects, the service agent for maintenance and the customer for operation.

It is worth noting that the proposed model of interaction between stakeholders and equipment, in contrast to traditional models of equipment use (full buyout or leasing), is more innovation oriented: all participants in the HME life cycle operate in a single ecosystem and in a single information environment, as well as in constant interaction, thus in a format of an open innovation-oriented society. Once the developers propose hardware upgrades, manufacturers can rapidly implement these innovations into existing user equipment, making the innovation process a continuous one (RQ5).

The results of the study can themselves be considered as a result of an open innovation process, as they are developed as a fruit of the interaction of participants in the St. Petersburg healthcare ecosystem (including the university, its IT partners and representatives of medical organizations)—an open information environment that promotes information and idea exchange between the participants to provide faster and more effective feedback for the technological challenges arising in the current dynamic market conditions.

It should be noted that today, open innovation is usually associated with fast-growing, knowledge-intensive industries, such as, for example, the information and communication technology sector [37,38]. However, there is growing evidence that this concept and related strategies may also prevail in more traditional and mature industries, especially under certain circumstances. These circumstances include high reliance on other organizations—whether other firms, government research institutes or end-user communities—for the supply, development and/or commercialization of new technologies [39,40]. The approach to open innovation, which involves the integration of the public into the corporate innovation process, is well suited to the field of health care, which is also confirmed in a number of the literature sources [41–50]. The analysis of research data showed that, despite a number of constraints to open innovation (for example, the complex organizations of health care, the need to establish routines for capturing knowledge from patients and clinicians, regulations and healthcare data laws), the practice of open innovation can bring positive results, such as improving the quality of care and reducing costs. Applied to health, innovation has a wide range of meanings. Health innovation includes innovations in health care, as well as innovations to prevent illness and promote health and wellbeing. It might take the form of new products, services, processes, organizations or policies. In fact, it often involves several of these simultaneously. Successfully launching a new technological innovation, for example, might require developing complementary technologies, new business models, new processes, new roles for patients and clinicians or policy changes [51–53]. It should also be noted that the support of information and digital technologies especially contributes to the development of open innovation, since, first of all, it simplifies the process of collecting and exchanging data [54–57]. This is extremely important for the healthcare industry, where huge amounts of meaningful data are generated and used.

However, when considering Figures 6 and 7, it is important to take into account that such schemes are formed on the basis of the regulatory norms of the Russian Federation, where an LCC is described as a special agreement or even a legal act. In addition, despite the fact that in the present study the LCC as a concept of interaction is considered, the formal side of the issue, fixed at the state level, is a limitation of this study.

Nevertheless, the issue of developing life cycles as a concept and supplementing it with technological solutions, to which all participants in the innovation process are ready, is an actual direction of research and is considered by the authors as a potential direction for future publications. As further research, the authors propose to develop the proposed idea of applying the LCC in health care in the following areas:

– Analysis of how the concept of the life cycle can be applied to other health problems (for example, development and production of vaccines and vaccination of the population);
– An important function of the LCC—financial—is not explicitly presented in Figure 5 as it is a subject of separate research. One of the important tasks in this area is the development of a system of mathematical models for financing HME LCC;
– Aspects of the development of the LCC as a concept and supplementing it with innovative IT solutions, for example, ERP 4, is an actual area of research and is considered by the authors as a vector for future publications.

6. Conclusions

Summarizing the results of the study, it is worth concluding that the topic of the application of the LCC for HMOs is neither disclosed not displayed both within the region under study and at the global level, although it is extremely relevant. This relevance is ensured by the transition of medical organizations toward the digitalization of their processes at a higher level of innovation and the fact that support for such a high level is impossible without attracting additional investments and public–private partnerships.

Answering the research questions posed, it is worth emphasizing the following.

The meaning of the LLC for HMOs is to form an effective interaction mechanism that ensures the transparency of processes, supports innovative development and also allows organizations to save budget funds (RQ1).

In turn, to ensure high-quality interaction of all stakeholders of this mechanism, the expediency of using CALS technologies is noted. This method of information support unites all participants in a common information space, supporting the principle of unity of control (RQ2).

Considering the features of the life cycles of HME, their integration into the life cycle of HMO management was described, where an LCC became the basis for the interaction of all partners. The model proposed in Figure 5 is a visual explanation of the processes that is relevant for all stakeholders (RQ3). In addition to this model, the features of the financial interaction of the life-cycle participants are explained (RQ4).

Moreover, the innovative orientation of the proposed scheme of interaction was noted as a tool for maintaining constant innovation by attracting investments and the direct, open communication of all interested parties (RQ5).

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