DOI: https://doi.org/10.17816/DD111146

Как создать современный медицинский центр в текущих условиях?

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АННОТАЦИЯ

Современная многопрофильная клиника представляет не только медицинский, но и инженерно-технический и нередко биотехнический объект. Технологическая сложность объекта зависит от планируемых (био)медицинских профилей и функционала, потребности в масштабируемости и модернизируемости, а также множества других факторов.

При взгляде со стороны, создание современного профильного или многопрофильного медицинского центра от идеи до запуска в эксплуатацию не выглядит запредельно сложным, а его этапы (предпроектные изыскания, медико-техническое задание, эскизный проект, стадии проектирования, строительства, оснащения и выхода на запланированную производственную мощность) видятся понятными и достижимыми. Однако наш собственный опыт непосредственного участия и анализа реализации различных профильных медицинских центров в нашей стране свидетельствует о наличии массы ложных предубеждений, ошибок, устаревших принципов и прочих проблем на практике.

В статье мы анализируем, объясняем и систематизируем типичные заблуждения и пороки при создании онкологического центра, однако те же проблемы возникают при создании любого многопрофильного медицинского центра. Мы полагаем, что наш опыт окажется полезным для ознакомления не только проектировщикам, технологам и архитекторам, но и врачам, организаторам здравоохранения, как, впрочем, и всем специалистам, привлекаемым к созданию медицинских центров современного уровня.

Ключевые слова: проектирование; медико-техническое задание; медицинский центр; онкологический центр.

Как цитировать

Румянцев П.О., Черкасов Д.А. Как создать современный медицинский центр в текущих условиях? // *Digital Diagnostics.* 2022. Т. 3, № 4. С. 404–412. DOI: https://doi.org/10.17816/DD111146

Рукопись получена: 30.09.2022 **Рукопись одобрена:** 13.10.2022 **Опубликована:** 19.12.2022

DOI: https://doi.org/10.17816/DD111146

How to create a modern medical center in the current conditions?

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ABSTRACT

A modern multidisciplinary clinic is not only a medical facility, but also an engineering and often biotechnical facility. The technological complexity of the object depends on the planned (bio) medical profiles and functionality, the need for scalability and upgradability, as well as many other factors.

When viewed from the outside, the creation, from an idea to commissioning, of a modern specialized or multidisciplinary medical center does not look prohibitively complicated, and its stages (pre-project surveys, medical and technical specifications, draft design, design stages, construction, equipping, and entering the planned production power) are seen as understandable and achievable. However, our own experience of direct participation and analysis of the implementation of various specialized medical centers in our country indicates the presence of a lot of false prejudices, mistakes, outdated principles, and other problems in practice.

In the article, we analyze, explain, and systematize typical misconceptions and vices when creating an oncology center, but the same problems arise when creating any multidisciplinary medical center. We believe that our experience will be useful for familiarization not only to designers, technologists and architects, but also to doctors, healthcare organizers, as well as to all specialists involved in the creation of modern medical centers.

Keywords: engineering; medico-technical enquiry; medical center; oncology center.

To cite this article
Rumiantsev PO, Cherkasov DA. How to create a modern medical center in the current conditions? *Digital Diagnostics.* 2022;3(4):404–412.
DOI: https://doi.org/10.17816/DD111146

Received: 30.09.2022 **Accepted:** 13.10.2022 **Published:** 19.12.2022

DOI: https://doi.org/10.17816/DD111146

在当前条件下如何建立现代医疗中心？

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简评

一个现代的、多学科的诊所不仅是一个医疗机构，也是一个工程设施，而且往往是生物技术设施。该设施的技术复杂性取决于计划中的（生物）医疗概况和功能，对可扩展性和可升级性的需求，以及一系列其他因素。

从外面看，建立一个现代的专科或多学科医疗中心看起来并不十分复杂，其阶段（项目前的研究、医疗和技术任务、概念设计、设计、施工、设备和达到计划的生产能力）似乎很清楚，可以实现。然而，我们自己直接参与和分析我国各种专科医疗中心的实施的经验表明，在实践中存在大量错误的先入为主的观念、错误、过时的原则和其他问题。

在这篇文章中，我们分析、解释并系统化了建立肿瘤中心的典型误区和缺陷，但在建立任何多学科医疗中心时都会出现同样的问题。我们相信，我们的经验不仅对规划师、技术专家和建筑师有用，而且对医生、医疗保健组织者，乃至所有参与创建最先进的医疗中心的专业人士也有用。

关键词：设计；医疗和技术任务；医疗中心；肿瘤中心。

To cite this article
Rumiantsev PO, Cherkasov DA. 在当前条件下如何建立现代医疗中心? *Digital Diagnostics.* 2022;3(4):404–412.
DOI: https://doi.org/10.17816/DD111146

收到：30.09.2022 **接受：**13.10.2022 **发布日期：**19.12.2022

INTRODUCTION

A mountain cannot turn, but a road can.
A Chinese proverb

Over the last 10 years, we have seen numerous healthcare facilities and helped establish at least a dozen of them (most often cancer centers). We would like to share our observations and practical experience in this article.

Now is not the time to expect spare parts to arrive overnight or a service engineer to fly to your location at the drop of a hat. Of course, it appeared somewhat utopian even in the best of times. However, the power of persuasion or exaggeration, future contract promises, or other forms of manipulation could make things easier.

In our practice, it felt like going on a long hike or climbing a mountain every time it became clear that equipping a cancer center step by step would be impossible. Thus, requests for facility modernization and phased launch should be considered during the initial investigation and design phase.

At present, the integrated approach to establishing healthcare facilities at all stages, from design to commissioning, is widely recognized and growing in importance.

The long-accepted conventional approach to medical engineering in our country is becoming unrealistic in terms of achieving the desired result. Moreover, to say that this approach is completely impractical is not an exaggeration. This is supported by our observations and the fact that many medical centers in our country are unfinished, were launched late, or failed to meet performance targets. This is true for cancer centers that require the most advanced and complex technologies. In this context, a cancer center can be viewed as an example of any modern medical center. Oncology employs the most advanced technologies available, including structural and functional imaging, surgery, pathology, radiation therapy, nuclear medicine, and genetics.

Of course, a distinctive exterior and interior design will always catch the eye. However, only the most advanced technologies and their expert application can win and maintain a medical center's reputation. A mismatch between form and content, which will become increasingly obvious over time, will inevitably lead to disappointment for both the medical community and patients.

A MODERN CANCER CENTER: WINNING AND MAINTAINING REPUTATION

Things not to do

The chain of mishaps begins with a medical and/or technical design specification, which occurs frequently during the design or even construction phase. Following that, the most common "design" scenario usually includes the following steps:

1. The design specification barely corresponds to the layout of the future hospital, let alone its purpose. A design specification is typically just a copy-and-paste job based on a previous "similar" project. Furthermore, there is no guarantee that the project in question was not created by simply copying data from an even older specification.
2. This is followed by a two-stage design with mostly ambiguous and vague descriptions. Again, this design is frequently inherited from previous "successful" projects to reduce questions and comments from authorities during multiple expert evaluations.
3. The general contractor then gives the finishing touches to this "Frankenstein's monster"; facade and interior designers can also contribute.
4. The resulting structure necessitates numerous modifications; thus, additional holes are drilled, utility lines that were not included in the design are installed, openings are mured up, and so on.
5. Finally, a manufacturer installs the equipment in the brand-new building and departs with the satisfaction of a job well done.
6. Several months later, the hospital's facilities manager requests additional supplies, elimination of several functions, and mandatory personnel briefings and training. However, some doctors in this position are well aware that such requests and complaints can negatively affect their careers.
7. After 10–15 months of costly visits by the manufacturer's service engineers and additional supplies of equipment that are now at least 1.5–2 times more expensive, the work finally begins. The work is frequently interrupted by a failing connector or valve when moisture gets into a device, resulting in its damage. However, this happens more often during the installation and commissioning of utility systems and medical equipment. Even more frequently, especially recently, there has been a need to replace "equivalent" equipment with that from friendly countries. Moreover, replacement is sometimes required because of medical technology updates that occur during the construction phase. In these cases, you must do without this or that piece of equipment, and you are lucky if these restrictions are only temporary and do not apply to basic medical technologies.

Almost all of the processes listed above are unrelated. In practice, they have no continuity or interconnection. Each contractor is in charge of a specific area of work and is not responsible for the functionality, reliability, or performance of a complex medical engineering system. The more multicomponent and multifunctional the healthcare facility, the higher the risks, and today's reality is even harsher.

What is today's reality?

At the time of this writing, six packages of sanctions had been introduced, with more possibly on the way. Some people

continue to believe that this has had and will have no effect on medicine. This is mostly correct in theory. However, in practice, this effect is significant and will most likely become even greater over time. Let us explain why we think this way.

In our practice, we had to work in parallel with several manufacturers (vendors), each of whom had an approach to dealing with the sanctions. Every week, the situation changes dramatically. As a result, here are our main conclusions:

1. Manufacturers are unaware of our country's current regulatory framework and make no effort to learn more about it.
2. The export policy of each country is determined by its commissions and structures.
3. Most manufacturers understand the gravity of the measures and the risk of criminal prosecution.
4. It is a mistake to believe that manufacturers will gladly take risks in exchange for the profits offered by the Russian market. Typically, sales in Russia account for only 5%–15% of the total international revenue. Thus, halting all activity in the region is simpler for some manufacturers.
5. "But they have a manager in Russia, and the representative assured me that everything would be fine." Managers in representative offices rely on a local market and will go to great lengths to support it. Local managers are frequently unaware of the internal political nuances of companies, which is done for the company's security.
6. Some manufacturers simply take a negative stance toward the Russian market. This is entirely their choice and is not governed by any EU or US laws. We can still argue about obligations in international courts; however, we cannot force them to sign a contract.
7. Co-product manufacturers can also take a radical stance. We have already had to deal with this issue in the context of heavy medical equipment. You may be unaware, for example, that some pieces of equipment are made by such "radical" manufacturers. However, they have the authority to compel a large manufacturer not to use its components or spare parts, citing sanctions and other local laws. As a result, manufacturers are at odds with one another; it is as if the left leg wants to walk but the right leg does not.
8. "Chinese manufacturers can make almost anything." It is mostly true… until it is not. "Anything" refers primarily to consumer goods. Industry-specific solutions that are in high demand in healthcare have been developed for many years by small high-tech companies. In many cases, these solutions have no counterparts anywhere in the world. China does not seek to replicate them because of small batch sizes, patents, and technical nuances. Furthermore, achieving a high level of quality, safety, and customer confidence takes many years, if not decades. Service is not even worth mentioning: proper support necessitates a sizable fleet of equipment in the country.
9. Uniqueness and serial numbers. This function was introduced to ensure quality and safety. Each spare part, similarly to equipment, has a unique identification number and, in some cases, a built-in chip. When ordering such parts, the final product's ID (ultimate product) must be specified. Accordingly, the manufacturer can verify that the maintenance was done correctly and on time. It also allows for the prevention of rogue schemes during the order stage (e.g., it is hardly necessary to replace brake pads five times a month).
10. Human factor. A modern product consists of a unique solution and the expertise of a specialist. The latter is a kind of "fifth element": without it, nothing works. This is another impediment, even in terms of logistics. Moreover, a specialist must be willing to travel to the customer's location; it is not just about the customer's importance and respect.

Taking these 10 factors into account (and we believe that these are far from exhaustive), a simple one- or two-move combination will clearly never work. It might be possible in other fields, but not in medical engineering, which is becoming increasingly reliant on multimodality and technology transfer.

Thus, in the current situation, integrity and continuity are critical when establishing a modern medical facility. Moreover, not to be overlooked is the creative collaboration of all those involved: doctors, biologists, chemists, physicists, engineers, process managers, architects, and designers. This is by no means an exhaustive list.

What exactly do we mean by an integrated approach?

A contractor or general contractor must be in charge of all processes, from concept formulation, design, procurement, and construction, to the technology's launch and maintenance for at least 2–3 years.

But first things first. A good concept, or pre-design specification, saves money on medical center construction while lowering operating costs. Ideally, this should be done in accordance with evidence-based architecture principles, with the participation of an expert group and the development of competitive solutions within this expert group.

1. A project based on the building information modeling (BIM) technique can coordinate ideas, budgets, construction, and timelines.
2. Procurement planning. This includes the development of priority criteria for equipment selection, such as upgradability, compatibility, replaceability, adaptability, maintainability, and fault tolerance.
3. A unified, minimally specific, maximally simple, and flexible technology transfer structure, universal units, open architecture, alternatives for consumables, etc.
4. Modern construction includes, among other things, the installation, assembly, and adjustment of biomedical equipment. The days of only needing sockets and well-painted walls to install equipment are long gone.

Construction readiness stages 1, 2, 3, and so on are the stages of facility readiness that correspond to the stages of technology launch. They should be an integral part of the launch process, with unified management and coordination, rather than a circular firing squad.

5. Quality system development and validation should be provided for at all stages, from design to operation.
6. Unified project management and BIM-compliant support. The so-called designer's supervision is obviously insufficient.
7. A unified launch and operation management team. Most processes require 2–3 years of adjustment.
8. Centralized control of information about the facility and its processes is another requirement for high-quality project management.
9. Establishing HR management processes and laying the groundwork for proper communication and growth.

As a result, regardless of the negative external factors, the project can achieve the required level of communication and be launched.

Correcting errors during construction is becoming increasingly difficult. Constructing and launching a modern healthcare facility is reminiscent of an airplane in flight or a group of climbers on an ascent. There is no way to go to the store for a spare part or start over. Engineering consulting, process audits, and scenario planning and preparation (i.e., simulating different scenarios on paper and on screen rather than in concrete) are becoming more important than ever.

What is the doctor's role in creating a new cancer center?

In our opinion, doctors must take the lead and be the most active and engaged participants in the process. After all, the involvement of healthcare professionals determines the innovativeness and creativity of the project. Who, if not a doctor, should be interested in self-fulfillment and skill development within a new medical center? Who else, besides a doctor, will determine the appropriate range of medical technologies and services, as well as the future trends in their advancement?

To be fair, none of us were taught to create new medical centers or their components during our college years. It never occurred to us in college or in our scientific and practical work that it was the responsibility of a doctor. Complaining and criticizing are always easier than improving or creating something new. What good is it to be able to write a medical and then a technical design specification? It is not just that we were not taught to do it; it was never even discussed. It was probably assumed that the job would be done by "specially trained people" or that no special knowledge or training would be required at all. Of course, "what man has done, man can do." However, any job requires skill, and establishing a complex medical engineering facility also requires specialized knowledge, experience, and rapid learning. This is a collaborative effort in which expertise, sharing of best practices and communication skills are essential.

In modern medicine, the level of technology integration (such as medical, engineering, biotechnological, and information) is extremely high and will only increase. Unfortunately, it can only be learned firsthand. Even the most highly qualified doctors and health administrators are frequently unable to comprehend the full scope and complexity of integration. Typically, the doctors involved simply go with general requirements and preferences based on their specialty and its specifics. They sincerely believe that these requirements are as straightforward as they can be and that issues such as standards, building codes, and prohibitions are the responsibility of specially trained people. Consequently, the doctors involved are disappointed at least twice: once when they have to spend time explaining what they want, and again when they accept work that is anything but what they wanted. However, the most difficult aspect is not conveying the idea but making it a reality with the best possible outcome under the given circumstances. Lots of effort, diligence, patience, perseverance, ingenuity, and sociability are needed. Even the most capable doctor may not be appropriate for such a role, where passion and a visionary approach are essential.

In general, engaging a doctor in such a mission is not the best idea if they are content with what they have, are unpretentious and rational, and do not aspire to master modern technologies or compete with the best. Such a mindset is simply unfit for the role of general designer, a visionary of a new generation of medicine, and everyone will be disappointed.

What should we focus on and strive for?

To begin with, because the future center will primarily serve Russian patients, provisions for implementing existing domestic guidelines are required. If the cancer center intends to enter the global medical market (medical tourism and participation in international clinical trials), compliance with international standards (GCP, GMP, JCI, etc.) is also recommended. Finally, providing modernization without incurring capital-intensive costs will be strategically important to increase efficiency and introduce innovations. Replacing heavy medical equipment is extremely expensive; thus, selecting a device that ensures high performance, compatibility with other equipment, upgradability, and fault tolerance is critical. Because up-to-dateness, dependability, and operational stability are highly valued in the medical industry, the redundancy (duplication) of production lines, channels, and bottlenecks should be planned from the start.

Why do Russian patients prefer to be treated abroad when they can be treated for free at home?

Several factors are involved. Let us concentrate on the obvious differences.

DOI: https://doi.org/10.17816/DD111146

First, patients are not kept in the dark in foreign clinics; they receive clear explanations of what tests and procedures will be performed, what they are for, and what the outcome will be. Doctors and support staff are always available and ready to help patients. Doctors are open to differing viewpoints and treat one another with dignity, and the patient's interests and preferences are always prioritized. Second, patients are always at the forefront of Western medicine: they are the primary customers and managers of their health, including diagnosis and treatment. Patients' preferences are respected, but more importantly, doctors listen to them and explain everything without rushing them to make a decision. Following such a positive experience, the patient will strive to repeat it and strongly advise others to do the same.

Third, clinics value their reputation in the foreign competitive practice of evidence-based medicine and are constantly improving in technology and personnel. It is hardly surprising that leading clinics care more about existing patients receiving the best medical care and being satisfied, referring the clinic to others, and leaving "likes" than prospective patients choosing them. They frequently accept difficult clinical cases with enthusiasm, even when other clinics have failed, because such cases allow them to creatively improve their skills and thus their reputation. If the treatment is successful, it will be these patients with difficult-to-treat cases who will publicize the clinic in the media and on social networks, serving as a "golden pool" for the clinic's popularity to grow. Furthermore, clinics are sometimes willing to treat such patients for free.

Our country provides government-funded healthcare through the distribution (quotation) of resources in the healthcare network. This program does not encourage competition among individual healthcare facilities or groups of clinics to improve medical and economic efficiency. According to the logic of the system's supporters, competition is replaced by planned volume distribution and uniform standards and tariffs for healthcare services. However, demanding patients are willing to pay or pay extra not only for health restoration but also for the most effective and high-quality medical and diagnostic care on the market. In many countries, medical care can be co-financed by the patient or another source (charity, employer, etc.). By contrast, in our country, a single-channel system for healthcare financing is strictly enshrined in law. Perhaps this was done to promote social equality. However, in practice, the accessibility, efficiency, and quality of healthcare vary, and such an approach does not contribute to market mechanisms for improving it.

Another important aspect of patient trust in Western medicine is adherence to appropriate quality standards and evidence-based improvements in medical and economic efficiency. Rather than simply distributing and setting aside resources, regulatory authorities seek to encourage multicenter studies and improve diagnostic and treatment approaches. The highly competitive, open-market environment of global medical tourism compels medical centers and groups of clinics to constantly improve the efficiency and quality of healthcare services. They are primarily concerned with improving the efficacy and safety of new algorithms/technologies/drugs, as evidenced by extensive and long-term clinical data. Guidelines are now updated and implemented in clinical practice by leading clinics in weeks (2–3 months at most) rather than years, as was previously the case.

Furthermore, today's efficacy and safety criteria include not only the novelty of the method or algorithm but also the reproducibility of results in other clinics under similar conditions. Forward-thinking clinics are actively involved in multicenter studies and the development of multidisciplinary data banks and clinical and epidemiological registers. Evidence-based medical practice puts everything in its proper place in the end, with state regulators (Food and Drug Administration and European Medicines Agency) and expert medical communities playing an active role.

Patients' trust in leading clinics, earned through purposeful and dedicated work, is perhaps the most important factor in why they choose them for health restoration. Health is the most valuable asset, and its preservation is worth all the money in the world. As a result, modern medicine attracts interest and investment in areas beyond its practical applications, which are only the tip of the iceberg and would have "melted" long ago if extensive fundamental and translational research had not been conducted. Any modern multidisciplinary medical center is a biomedical cluster that combines the following three key factors of continuous development that are inextricably linked:

1) Production (such as medical services, development of medical radioisotopes, radiopharmaceuticals, and genetic tests).

2) Research (such as pathology, transcriptomics, biobanking, collaborative research, data and biomaterial banks, and evidence-based data analysis).

3) Education (such as transfer of knowledge, experience, technologies, innovations, and artificial intelligence development).

How reliant are we on imported equipment, reagents, drugs, and techniques?

Briefly, reliance is extremely high: it has been increasing for decades and will continue to increase in the future. This is a global trend associated with the global market's competitive development. To some extent, our country has established production in medicine and pharmaceutics; however, this list is short and does not cover the need for high-tech medical equipment. There are no worthy domestic alternatives to leading manufacturers' modern solutions in endoscopic equipment, radiotherapy irradiation devices, brachytherapy, single-photon emission computed tomography, positron emission tomography, and so on. The situation with drugs is slightly better; however, the stability of the quality targeted anticancer drugs is a source of concern, as are the efficacies

and toxicity of domestic generic biosimilars in relation to original drugs.

In turn, reliance on imported production equipment and ingredients is one of the most significant barriers to increasing high-quality import substitution in the field of biomedicine, not to mention the existing regulatory framework, which is out of date and frequently contradictory. The regulatory environment must improve to promote, rather than stifle, the development of the industry.

Each segment has numerous problems and contradictions that are organically interconnected, making resolution increasingly difficult. The primary reason is that no one wants to be the change they want to see in the world. There is also a lack of motivation and result-oriented teamwork skills.

Thus, we must change our mindset and learn new skills. Otherwise, dreams will remain just that, dreams.

Do we really need international experience? Can't we get by on our own?

No, we cannot because the goal is not to write another program but to demonstrate success in developing competitive and innovative products for modern biomedicine.

What is the point of reinventing the wheel? It may make sense in other fields, but it is simply impossible in medicine. It will almost certainly be time-consuming and possibly fruitless, and patients do not have the luxury of waiting. This makes even less sense given the willingness of foreign colleagues to share knowledge and experience, at least for the time being. The global scientific, practical medical, and biotechnological communities are open to all physicians and researchers. Our mission is to preserve and extend people's lives through the advancement of life sciences.

One could argue that limited access to technology provides an additional incentive for creativity. This is undeniably correct. However, medicine is very conservative, and new technologies are few and limited to specific countries. Any innovation, such as a new surgical technique necessitates independent evidence-based validation in other medical institutions. In the global medical community, which strictly adheres to the principles of evidence, impartiality, and ethics, such validation occurs much more quickly. Even if all individual innovations are successful, can they compensate for the knowledge, experience, and technology transfer gaps? Certainly not. Furthermore, innovations necessitate advancements in equipment and consumables, service, and modernization, and any country is heavily reliant on the global market in this regard. Progress is not on the horizon, no matter how you look at it.

CONCLUSION

Of course, we need global experience in biomedicine, just as our experience may be valuable to the world. It is no good to learn only from our mistakes and fall further and further behind. However, the worst part is wasting time that could have been put to better use. While the opportunity exists, learning from and obtaining innovative solutions from global industry leaders is critical, first and foremost, for the benefit of our patients and the future of our successors. Creativity and flexibility are essential skills to master, especially in today's force majeure and competitive environment.

Nothing is impossible, and we must be the change we wish to see in the world. These words of wisdom, along with the epigraph to this article, best capture the essence of our thoughts on the topic.

ADDITIONAL INFORMATION

Funding source. This article was not supported by any external sources of funding.

Competing interests. The authors declare that they have no competing interests.

Authors' contribution. All authors made a substantial contribution to the conception of the work, acquisition, analysis, interpretation of data for the work, drafting and revising the work, final approval of the version to be published and agree to be accountable for all aspects of the work. P.O. Rumiantsev — discussion of the concept, design elaboration, writing and edition, preparing of the manuscript for publication; D.A. Cherkasov — idea and writing of the manuscript.

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