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IMPLEMENTATION OF TELEMEDICINE SOLUTIONS IN THE FIELD OF CHRONIC OBSTRUCTIVE PULMONARY DISEASE: RISK MANAGEMENT AND REMEDIAL ACTIONS

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A – study design, **B** – data collection, **C** – statistical analysis, **D** – interpretation of data, **E** – manuscript preparation, **F** – literature review, **G** – sourcing of funding

ABSTRACT

Background: Introducing innovations in the healthcare sector often involves testing groundbreaking solutions, ranging from advanced diagnostic technologies to new therapies and modern patient data management systems. Thorough and systematic risk monitoring not only enhances the chances of project success but also constitutes a crucial element in building trust in innovative healthcare solutions.

Aim of the study: Presenting and discussing risks and risk management strategies in a pilot project implementing telemedical solutions in the field of pulmonology.

Material and methods: The paper analyzed key risks along with remedial actions taken during the implementation of a pilot telemedical project in the field of pulmonology. Systematic analyses covered technological, financial, legal, organizational, external, clinical, and competency areas. The description of a specific project case was used, along with a narrative of personal experiences during its execution in the given year.

Results: The telemedical project for patients with chronic obstructive pulmonary disease (COPD), focusing on clinical assessment and observation of spirometric parameters, aimed to address the challenges related to the care of individuals with COPD. The innovative aspects of the pilot project were emphasized, along with its potential impact on improving pulmonological care. The paper discusses aspects related to risk management and remedial actions, identifying areas where the project could serve as a model for further research and practices in the field.

Conclusions: The coordination of medical teams, primary care physicians, pulmonology specialists, and nurses with strong and multifaceted administrative support constituted a key element of remedial actions. This collaboration enabled effective counteraction against potential negative consequences of testing telemedical solutions in pulmonology by implementing appropriate corrective measures and efficient remedial actions.

KEYWORDS: telemedicine, healthcare, pulmonology, chronic obstructive pulmonary disease, risk management, solutions

Background

The introduction of innovations in the healthcare sector often involves testing novel solutions, ranging from advanced diagnostic technologies to new therapies and modern patient data management systems [1]. These relatively innovative initiatives, while promising, come with significant risks, especially when they are intended to impact the lives and health of patients. In the context of new diagnostic methods, designers of medical systems must consider result precision, error minimization, and the ability to integrate with existing diagnostic methods. In the case of therapies, new approaches require a thorough assessment of effectiveness and safety for patients, posing unique challenges for medical organizations [2].

The complexity of medical technologies, such as artificial intelligence in diagnostics or innovative patient monitoring systems, brings both the potential for significant improvements in healthcare and inherent risks associated with potential malfunctions or misinterpretation of results, impacting patient safety [3]. In terms of risk management, the process of introducing innovations in healthcare becomes a crucial element. This involves not only identifying potential threats but also developing effective strategies to minimize risk and respond rapidly to any complications [4]. Awareness of these issues is of fundamental importance for building trust among the medical community and patients, as well as all of the decision-makers and stakeholders interested in modern healthcare solutions [5].

The introduction of innovation in the healthcare sector often involves testing novel solutions, ranging from advanced diagnostic technologies to new therapies and modern patient data management systems [6]. In the specific context of pulmonology, the implementation of telemedicine solutions emerges as a transformative initiative. Telemedicine facilitates clinical assessment and spirometric parameter observation, aiming to address the challenges associated with caring for individuals with chronic obstructive pulmonary disease (COPD) [7,8]. The innovative aspects of the pilot telemedicine project in pulmonology were underscored, emphasizing the potential impact of this project on enhancing pulmonary care. Risks related to clinical management and remedial actions were analyzed, identifying areas where the project could serve as a benchmark for further research and practices in the field. This strategic integration of telemedicine in pulmonology aligns with the evolving landscape of healthcare and signifies a paradigm shift towards patient-centric, accessible, and technologically supported respiratory care [9,10].

The team responsible for a pilot project, both the Steering Committee (SC) and the Patient Evaluation and Support Team (PEST), as well as the medical and administrative personnel of the project, should be equipped with effective risk indicator tracking tools. These tools enable a prompt response to any anomalies and the adjustment of risk management strategies in real time [11]. Thorough and systematic risk monitoring increases the chances of project success and constitutes a crucial element in building trust in innovative healthcare solutions. This is particularly important from the perspective of funding institutions [12,13].

The risk register is a crucial tool in risk management for telemedicine pilot projects. It serves as a central database where all relevant information about identified risks, their assessment, and the strategies to manage them are collected [14,15]. In the telemedicine sector, where innovations can directly impact patient healthcare, the risk register plays a significant role in identifying potential threats associated with new technologies and medical practices [16]. Current and transparent risk registrations are essential for effectively monitoring and quickly responding to the variable and dynamic conditions of the project while enabling healthcare organizations to maintain patient safety and the effectiveness of healthcare services amid the implementation of telemedical technologies [17].

Remedial and corrective actions are key elements of the risk management process in pilot projects within the healthcare sector [18,19]. When identified risks materialize, or the situation changes during the project, it is necessary to take swift and effective actions to mitigate the negative consequences of events or eliminate objective and measurable obstacles that disrupt the proper project implementation.

Aim of the study

The aim of this article is to present and discuss the risks, risk management strategies, and remedial actions to reduce and eliminate risks during the implementation of the project titled "Implementation and testing of pilot telemedicine solutions in the field of the 'Chronic Diseases' model in Wroclaw and the Lower Silesian Voivodeship in the years 2022-2023."

Material and methods

The paper analyzes key risks along with remedial actions undertaken during the implementation of a pilot telemedicine project in the field of pulmonology. The final analysis is based on the collection and analysis of data regarding the effectiveness of remedial actions and the efficiency of the implemented telemedicine solutions. Systematic analyses and ongoing evaluation covered technical/technological,

financial, legal, managerial/organizational, external, clinical, and competency areas. The research methodology aims to provide a comprehensive view of the implementation process of telemedicine solutions in chronic diseases, considering effective risk management and remedial actions. The entire methodology aims to provide an in-depth understanding of risk management and remedial actions in the context of a telemedicine project in pulmonology and respiratory medicine, contributing significantly to understanding the process of implementing innovations in the care of patients with COPD.

Discussion

The paper discusses and summarizes key risk areas related to caring for the pulmonology population and the implementation of innovative telemedicine and e-health solutions. The critical data analysis also assessed the effectiveness of applied remedial actions in eliminating or reducing identified threats. The innovative aspects of the pilot project and its potential impact on improving care for patients with COPD were emphasized. Aspects related to risk management and remedial actions were addressed, and areas where the project can serve as a model for further research and practices in the field were identified.

Project assumptions

The project encompasses individuals above 18 years of age diagnosed with COPD who have provided informed consent to participate. The target group includes not only patients but also medical personnel, including primary care physicians, nurses, pulmonology specialists, and, to some extent, caregivers. Patients will receive health support and education, medical staff will gain additional knowledge regarding the care of COPD patients, and caregivers will receive information about the functioning of the telemedical platform and health education. The project aims to conduct tests confirming the effectiveness of the solution, with the prospect of broader implementation. It focuses on monitoring the progress of COPD and forecasting disease exacerbations through regular self-administered spirometric tests. It is assumed that the number of patients covered by the project will be 520, evenly distributed between genders. The project does not favor any specific group, allowing the testing of the model as a universal solution without access limitations. Priority in participation is given to individuals from municipalities with lower income per capita, located in areas that are difficult to access for healthcare. This will ensure the achievement of project goals and direct support mainly to residents in areas distant from large cities, where access to healthcare services may be limited [20].

Risk management

During the project implementation, the focus was on ongoing monitoring and reporting of key risks related to progress assessment in various areas by the SC. Analyses covered technical, financial, legal, managerial, external, clinical, and competency aspects. Attention to these diverse risk spheres allowed for the flexible adjustment of strategies, ultimately contributing to minimizing potential threats and effectively achieving the project's intended goals. Below, we discuss exemplary risks and actions to reduce/eliminate them.

Technological risks

Among the identified risks was a lack of necessary skills to navigate and operate on the www platform and the risk associated with creating, implementing, and operating central system components, including the development planning of the patient.gov.pl and gabinet.gov.pl applications. In this case, considerations should include both the issue of acceptance at the central level and the designated potential deadline for execution, as well as access to technology and the digital competence of project participants. Another significant issue is the lack of accessibility to both the Internet and devices capable of connecting to the Internet and running web applications. Another risk is the lack of digital competence in a significant portion of the patients targeted by the project. Some have never used such devices, and others may have difficulty independently operating touch screens.

The following remedial actions were implemented: Regular meetings of the SC were conducted to develop optimal solutions and implement remedial actions to reduce technical/technological risks. Specific information about the demand for tablets or laptops was obtained from partners; adjustments/simplifications of the platform's functionality were made, reducing the number of modules and solutions to efficiently guide the patient through the system and ensure the smooth implementation of the project's objectives; the need to improve the intuitiveness of the platform was reported; work was carried out adapting the platform to the age and technological competence of the patient; redundant functionalities unrelated to the project (billing module, dispensing visits) while retaining the option to schedule video or teleconferences were eliminated; the technological partner was monitored to ensure the effective delivery of the plat-

form; concrete tools were established to influence the technological partner; integration principles were determined with the platform by transferring licenses to IPA → exchanging a paragraph in the tender documentation; difficult communication and delays on the part of the technological partner were counteracted; the application was provided and adapted for patient usability without simplifying functionality and eliminating the risk identified in March ("developer changes requiring time"); a decision was made to start the project with the current technical state of the platform (delaying the indicated changes by the partner → inviting the technological partner to expedite the finalization of the telemedical platform in its ultimate form meeting the project's requirements). The remedial actions resolved issues related to difficulties in pairing spirometers with the telemedical platform.

Addressing technological risks is paramount in any project but is especially important when involving telemedicine innovations. The project identified potential technological challenges, such as difficulties in using and navigating the online platform, risks associated with developing and implementing central system components, and concerns regarding the digital competencies of both project participants and patients. A series of remedial actions were implemented to mitigate these technological risks. These included regular SC meetings to devise optimal solutions, obtaining specific information about the demand for tablets or laptops from partners, streamlining platform functionalities for smoother patient navigation, and addressing the platform's intuitiveness. Additionally, efforts were made to adapt the platform to patients' age and technological competencies and eliminate unnecessary functionalities not directly related to the project. These proactive measures demonstrate the commitment to overcoming technological challenges and ensuring the successful implementation of the telemedicine project, ultimately contributing to the project's overall success and the delivery of quality healthcare services.

Financial risks

Among the identified risks were the public payer's incorrect valuation of the service and financial liquidity issues caused by a large number of users accessing the service simultaneously. It's important to address these risks through proactive financial planning, regular communication with the public payer to ensure accurate valuation, and implementing measures to manage service demand during peak times to maintain financial stability. Additionally, contingency plans should be in place to address potential financial challenges arising from fluctuations in user volume.

The following remedial actions were implemented: regular SC meetings to develop optimal solutions, implementation of remedial actions to reduce financial risk, and preparation of contract templates and payment terms for specific services by the legal team of the Leader. The Leader has a team and legal department with experience in contract execution based on agreements with the National Health Fund (NFZ). The Leader will prepare a contract template specifying and clarifying the obligations of contract performers, defining schedules, responsible individuals, contact details, settlement and reporting formats, responsibility principles, and employment contracts, detailing the project-related duties of the Leader and Partners, which will be prepared before the project; the project team will be trained (management, doctors) on basic financial risks and ways to minimize and counteract them (document signing methods, documentation management). Contact information between economic specialists of the Partners will be provided to quickly respond to emerging financial risk issues related to liquidity, relationships with service providers, suppliers, and among Partners, with provisions in contracts that financially secure Partners, including termination of cooperation in case of project implementation failures. A safeguarding amount needs to be ensured on the Leader's account for project implementation in case of delays and difficulties with payments from the NFZ to ensure the financial liquidity of project implementation. Remedial plan: prepare an accurate calculation of all costs and benefits associated with implementing the model, emphasizing the possibility of shifts between cost categories in case of savings. According to the model tested within this project, in the case of more frequent than expected health issues of a dietary/mobility nature, dieticians and physiotherapists, whose remuneration is lower than that of doctors, especially specialists, will be allowed to perform some services.

Financial risks in a project are a critical aspect that requires careful consideration and strategic planning. These risks encompass various factors, including the potential for misjudging service valuation by public payers, liquidity challenges due to a high volume of simultaneous service users, and uncertainties related to the financial stability of project participants. In response to these challenges, the project has implemented a comprehensive set of remedial actions. These actions involve regular meetings of the SC to develop optimal solutions, the preparation of well-defined contract templates and payment terms, and the establishment of a safeguarding amount on the Leader's account. Additionally, a thorough remedial plan has been devised, focusing on accurate cost-benefit calculations and flexibility in adapting to shifts between cost categories. The proactive approach to addressing financial risks reflects the project's com-

mitment to ensuring fiscal stability and success in the face of dynamic challenges.

Legal risks

Among the identified risks were issues related to the problematic manner and form in which patients express consent for examinations and the provision of healthcare services. This includes challenges in obtaining patient consent for processing personal data, verifying patient identity, and ensuring the confidentiality and security of personal data. Addressing these concerns is crucial for maintaining ethical standards, patient privacy, and data security throughout the healthcare process.

The following remedial actions were implemented: regular meetings of the SC to develop optimal solutions and implement remedial actions to reduce legal risks. The appropriate form and method were established for verifying patient identity, obtaining patient consent to participate in the pilot ("visit 0" → collecting a document of informed consent to participate in the project and a document on the personal data protection of the project participant or legal guardian of the patient, and then initiating a visit incorporating the patient into the project/study), and obtaining consent for survey research and any laboratory blood tests. One person was trained in the managing team at each participating Partner to handle legal aspects of project participation; these individuals were responsible for clarifying any legal doubts that arose. In turn, explanations from medical professionals, supplementing written information, were provided through information technology systems (via phone and video calls).

Legal risks are critical to address in any project, especially in the healthcare sector, where privacy, consent, and data protection are paramount. The implementation of regular SC meetings to develop optimal solutions and remedial actions is a proactive approach. Ensuring proper forms and methods for patient consent, identity verification, and data protection align with legal best practices. Training key personnel across Partners on legal aspects and having a streamlined communication process for addressing legal concerns demonstrates a commitment to navigating complex legal landscapes. This comprehensive strategy mitigates legal risks and fosters a secure and compliant environment for the successful execution of the telemedicine project.

Managerial risks

Among the identified risks were a lack of adequate communication regarding participation and project implementation, a limited reach of information about the model to patients with COPD, technical issues during the project launch phase (such as information gaps, unclear interpretation, and collaboration problems), and threats associated with testing solutions on a pilot basis.

The following remedial actions were implemented: regular meetings of the SC to develop and implement corrective measures to reduce management/organizational risk; creation of a plan for organizing the project's kick-off conference (representatives of senior organizations, primary care partners, and administration, connection with the technological partner and Norwegian partner via teleconference, discussion of similar telemedical projects based on the Norwegian partner's experience, presentation of the platform); involvement of the spokesperson for 4WSK in attracting representatives and media; initiation of collaboration and leveraging the promotional potential of the Wroclaw City Office (displaying information in public transportation); attempting to collaborate with additional partners to support patient recruitment (attempting to negotiate agreements with additional primary care partners); training pulmonologists on the platform's operation; equipping the medical/consultation office with personal protective equipment; securing the working time of 4WSK doctors for project implementation (determining the availability of staff to develop a schedule for primary care visits); obtaining information about the number of potentially eligible patients for recruitment according to the project's assumptions (urgent!); deciding on the impossibility of conducting follow-up visits due to the project's limited implementation time; creating an initial patient database and recruiting a smaller number of patients to ensure "progress" through the entire pathway (a total of 3 visits) according to the project's agreements; and improving communication with the technological partner to ensure project implementation according to the adopted schedule. A support system (help desk) was launched, including chat/email and phone support, which is particularly important for older individuals. The project implementation conditions were adapted due to delays related to signing an agreement with the Ministry of Health and issues with purchasing an adequate number of spirometers for remote monitoring of respiratory parameters in patients with COPD.

Managerial risks encompass potential challenges related to project management and organizational aspects. These risks often involve coordination, communication, and decision-making within the project team. To mitigate these risks, it is crucial to establish effective management practices, such as regular meetings, clear communication channels, and adequate training for key personnel. Additionally, creating contingency plans and adapting project strategies

in response to unexpected developments can enhance resilience in the face of managerial challenges. Addressing these risks is essential for the successful execution of the telemedical project and ensuring that organizational and management aspects align with the project's objectives.

Clinical risks

Among the identified risks were unexpected changes in the health status of potential project participants, threats arising from improper patient treatment due to incorrect information, and uncertainties on the part of the doctor regarding the appropriate course of action with the patient.

The following remedial actions were implemented: regular meetings of the SC aimed at developing optimal solutions and implementing corrective actions to reduce clinical risk; the possibility of telemedical monitoring of spirometric test results and the use of an indicator, based on which the current health status can be assessed; and in the event of a deterioration in health status being registered, the patient will be directed to additional consultation. This proactive approach aims to enhance the overall clinical management of participants, contributing to the effectiveness of the project's healthcare interventions. The systematic incorporation of telemedical tools for continuous monitoring represents a key element in minimizing clinical risks and ensuring timely responses to changes in the patient's health conditions.

The identified clinical risks underscore the importance of implementing a robust strategy to monitor and respond to potential health complications among participants. The proactive approach, involving regular meetings to devise optimal solutions and corrective actions, demonstrates a commitment to minimizing clinical risks. The incorporation of telemedical monitoring for spirometric test results, coupled with a responsive referral system in case of health deterioration, adds an extra layer of clinical vigilance. These measures collectively contribute to the overall clinical risk management, ensuring a proactive stance in addressing health-related challenges throughout the project's duration.

Competency risks

Among the identified risks were insufficient incentives for implementing the model, patients' reluctance to use new technological solutions, patients' mistrust of information obtained over the phone, insufficient competencies for unrestricted access to online resources and the telemedical platform, and a lack of trust in telemedical treatment.

The following remedial actions were implemented: regular meetings of the SC to develop optimal solutions and implement remedial actions to reduce competency-related risks; counteracting the mistrust of potential participants towards telemedical advice/treatment; educating patients about the benefits of regular and free telemedical consultations with a GP and a pulmonology specialist; presenting the benefits in the form of increased access to medical services, a current and remote path for monitoring the patient's health, and providing health education; developing and disseminating informational brochures outlining the benefits of participating in the project, as well as educating patients about pulmonary diseases; and conducting detailed instructions for patients on how to use the platform during telemedical consultations.

Competency risks refer to the challenges associated with the knowledge, skills, and abilities required by various stakeholders to effectively participate in and benefit from the telemedicine project. These risks include potential difficulties in understanding and using the telemedical platform, addressing patients' limited digital literacy, and ensuring that healthcare professionals possess the necessary expertise to deliver telemedical services. Remedial actions, such as education initiatives and instructional support, are crucial to mitigate these competency risks and enhance the overall effectiveness of the telemedicine project.

Conclusions

Thanks to the well-organized cooperation of the SC, including the evaluation specialist, and the arrangements of the PAST, it was possible to effectively monitor, report, and classify all risks. The coordinated work of medical teams, primary care physicians, geriatrics specialists, as well as nurses and physiotherapists, with strong and multifaceted administrative support, is a key element of corrective actions. This collaboration enables effective counteraction to potential negative consequences by implementing appropriate corrective measures and efficient remedial actions.

In summary, the pilot project focusing on telemedical solutions in pulmonology aimed to revolutionize healthcare for individuals diagnosed with COPD in Wroclaw and the Lower Silesian Voivodeship. The incorporation of advanced technologies, such as artificial intelligence for diagnostics and innovative patient monitoring systems, holds significant potential for enhancing healthcare quality. However, the introduction of these technologies

poses inherent risks related to potential malfunctions or misinterpretation of results, impacting patient safety. Effective risk management was identified as a crucial element in the project's success, encompassing the identification of potential threats, development of efficient risk mitigation strategies, and swift responses to complications. Awareness of these issues is fundamental to fostering trust among the medical community, patients, decision-makers, and all stakeholders involved in modern healthcare solutions. The article also delves into specific risk categories, including technological, financial, legal, managerial, clinical, and competency risks, emphasizing the importance of proactive measures in each domain. Additionally, it sheds light on the implementation of risk registers and the significance of addressing and mitigating risks throughout the project's lifecycle. The ultimate goal was to present a comprehensive perspective on risk management, remedial actions, and the overall process of implementing telemedical innovations in the field of pulmonology and respiratory medicine, contributing significantly to understanding the innovation deployment process in the care of patients with COPD.

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