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ScienceDirect

Procedia Computer Science 219 (2023) 1388–1395

Procedia Computer Science

www.elsevier.com/locate/procedia

CENTERIS - International Conference on ENTERprise Information Systems / ProjMAN - International Conference on Project MANagement / HCist - International Conference on Health and Social Care Information Systems and Technologies 2022

Procurement of artificial intelligence for radiology practice

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Abstract

The development of artificial intelligence (AI) technology for radiology has accelerated in the past decade, but its deployment in radiology practices has been slow. We take a sociotechnical approach and suggest that the limited use of AI in radiology practices can be attributed to a recurring tension between planned and emergent change. The paper contributes with a conceptualization and understanding of the tension during the procurement of AI for radiology. To balance this tension, we suggest that health organizations need to redefine the concept and scope of traditional procurement projects, with well-defined goals and project time. Instead, we propose that health organizations need to conceptualize their procurement and implementation projects of AI technology as evolving change processes. The study is based on an interpretive research approach and informed by the Information Infrastructure framework. Empirically, we study the procurement of AI solutions for radiology at a large health trust in Norway.

Keywords: Artificial intelligence; Procurement; Planning; Information infrastructures

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10.1016/j.procs.2023.01.427

1. Introduction

The promises of artificial intelligence (AI) technology for medical diagnostics have accelerated rapidly in the past decade [1]. The promises, followed by the increasing development of AI for medical diagnostics is a response to the worldwide situation in which the volume of diagnostic imaging examinations has risen sharply, but available radiology expertise for interpreting the images is limited [2]. Despite the vast range of AI software available for radiology, its implementation in clinical practice has been slow [3][4][5]. Existing studies have largely blamed this on the technology [6][7], while organizational aspects have been overlooked [4].

In this paper, we take a sociotechnical position and suggest that the limited use of AI in radiology practices can be attributed to a recurring tension between planned and emergent change. Public hospital trusts planning to procure new technology need to adhere to strict procurement procedures in accordance with public tender regulations [8]. This is typically combined with a business plan, a benefits realization plan, and milestones over a well-defined short-term period. In this regard, the solution is developed as part of a plannable future within the timeframe of the project [9].

For AI solutions in their infancy, this is problematic for implementation. AI technology is characterized by a lot of uncertainty in terms of functionality, behavior, and organizational consequences. For example, the AI tools for clinical imaging are tested on datasets based on a specific population, which will most likely be different from the population affected by the AI tool in its clinical use [2]. The consequence is that it is difficult to predict how learning mechanisms in a specific algorithm will unfold. AI technologies are also supposed to be integrated seamlessly into complex radiology practices with a considerable amount of existing high-tech equipment. This calls for a more experimental and open long-term approach for evolving AI solutions towards an emergent changing future.

Based on this, we ask the following research question: What characterizes the tension between *planned* and *emergent* changes in large-scale AI projects for radiology in public hospitals? And how can a socio-technical approach be used to understand this tension?

The paper contributes with a conceptualization and understanding of dealing with the tension of planned and emergent changes during the procurement of AI for radiology. Empirically, we use an interpretive research approach to study the procurement of an AI solution for radiology practice at a large health trust in Norway. This procurement serves as a national pilot for procurements and implementation of AI solutions for clinical practice in general. Conceptually, we draw on the information infrastructure literature to account for the size and scope of the sociotechnical system [10][11][12][13].

2. Theory

There are many definitions of AI, and these are also evolving, perhaps conforming to what is technologically possible. We follow the EU's expert group's definition: "Artificially intelligent systems perform actions, physically or digitally, based on interpretation and processing structured or unstructured data, for the purpose of achieving a given goal. As part of an AI system, specialized algorithms operate on specific datasets, i.e., an algorithm takes the dataset as input and produces some output, specifically, a classification" [14]. The algorithms may also have machine learning (ML) abilities that enable them to learn from previous actions [15], which means that they can change behavior.

In healthcare, there are great expectations for using AI, particularly in radiology. In high-tech radiology practices, AI can be used to plan examinations, such as the correct position of body parts to be examined; to prioritize tasks, such as sequencing images according to severity; or to perform time-consuming and repetitive tasks, such as processing images [5]. AI can support radiologists by suggesting diagnoses and increasing the likelihood of earlier detection of problems. Aligned with these expectations, there are huge investments being made nationally and internationally [15][16][17].

Being classified as a medical device, an AI solution must be CE-marked before it is allowed on the European market [3]. This means that it meets the essential requirements of the relevant directives and that it may legally be placed on the market freely throughout European member states [18]. Currently, there are over 100 commercially available CE-marked AI products from 54 different vendors [3]. Radiology departments that consider acquiring algorithms for image interpretation need to ensure that the algorithms work for their patient population. The supplier has usually tested and trained the algorithm on a dataset based on a different patient population from the target patient population. If the algorithm has ML capabilities, it may also learn to work better for certain patient groups than others. Thus, neither the performance of a CE-marked algorithm nor how well it evolves over time can be fully predicted in advance. In addition, the number of approved CE-marked devices does not say anything about the extent to which they can be implemented into clinical practice [19].

Despite the many studies that tout the benefits of AI in radiology, there are very few products that have made their way into actual use [3][5]. To understand why this is the case and what it takes to get to the starting point of implementing these systems in clinical settings, we examine two different perspectives during the procurement of technology in complex healthcare organisations: planned and emergent change. Large investments in technology in public healthcare generally involve a thoroughly planned change process. This implies adhering to rigorous procurement procedures, requirement specifications, and well-defined business cases. The requirements typically also contain specifications about how the new technology needs to be interoperable with existing equipment. For radiology, this includes radiology information systems (RISs), Picture Archiving and Communication systems (PACS), and the equipment used for examinations e.g., Magnetic Resonance Imaging (MRI) Computed Tomography (CT) scans and conventional radiography and other modalities. The acquisition process also occurs within a delimited time frame. After the AI solution is put into regular use, the organization is expected to get immediate benefit from it in accordance with its benefits realization plan.

AI and ML are associated with an uncertainty that requires engagement from users to ensure that the algorithms adapt in a useful direction and conform seamlessly to the sociotechnical configuration in radiology departments. Grønsund and Aanestad use the term “human-in-the-loop pattern” to account for how humans and algorithms are configured and reconfigured in multiple ways over time in an implementation process. This suggests that vendors need to be a lot more involved than in traditional technology acquisition due to uncertainty about how the AI portfolio and algorithms may unfold in the long term. This points to a more evolving and emergent perspective on the change process [20].

To conceptualize the tension between the planned and emergent views on AI implementation in radiology, we turn to the concept of information infrastructure. This concept has been frequently used for analyzing the implementation and use of large-scale socio-technical information systems [10][11][12][13]. Systems in an information infrastructure are never seen as standalone entities; rather, they are integrated with other information systems and deeply embedded in conventions and practices [10]. In healthcare, this means that an information infrastructure consists of a range of systems, health professionals, institutions, and established practices, i.e., the installed base that evolves gradually over time, and possibly in many directions [21]. In this regard, there is a tension between the users’/customers’ need to have a useful product within the framework of the project (planned change) and an open-ended evolving information infrastructure [12]. This also reflects two different perspectives on time, conceptualized by Karasti et al. as project *time* and *infrastructure time* [9].

3. Method

We focus on the Use of AI in Radiology (AIRad) project in Norway, whose aim is to acquire an AI solution for radiology practice at a large health trust (Health Trust A). Health Trust A is one of the largest trusts in Norway, with about 9,800 employees and the responsibility of providing specialist health services for about 500,000 people. The imaging department is organised as one department that has branches across four hospitals. In 2019, the department performed approximately 50,000 CT examinations, 17,500 MRI examinations, and 155,000 X-ray examinations.

This study applies an interpretive approach to case study research to provide insight about the key mechanisms at play in the formative stages of procuring an AI solution for radiology [22][23]. In interpretive research approaches, the understanding of social processes is obtained by getting involved inside the world of those generating them, rather than by hypothesis-driven deductions or predefined variables. To that end, we aim to see the AI procurement in question from the viewpoint of different stakeholders while also considering the broader context [22].

Data collection in interpretive research is generally based on interviews, participant observations, document analyses, and informal discussions [22]. Between December 2020 to June 2021, the authors conducted 19 semi-structured interviews, each interview lasting about one-hour interviews, with 5 radiologists, 7 hospital managers, and 7 managers in collaborating organizations. We participated as observers in 15 dialogue meetings between the AIRad project and five different vendors, in where technical, clinical, and financial issues were discussed, constituting a total of 45 hours. We also participated in several formal coordination meetings with the AIRad project to discuss and clarify issues during the process, in addition to a number of informal discussions with project members. All interviews and observations in meetings were conducted on Microsoft Teams. The interviews were recorded and transcribed verbatim. The authors also conducted document analyses of minutes from project meetings, tender documents, and relevant policy documents at the national level.

The interpretive research approach calls for detailed case descriptions, which in this study covers the procurement process, followed by data analysis for potential analytical themes. The data collection and analysis are guided by a hermeneutic approach and the principle of the hermeneutic circle. This means that we understand a complex whole from preconceptions about the meanings of its parts and their interrelationships [22, p.71]. First, to improve our understanding of the project as a whole, we shifted our focus back and forth in an iterative way between the viewpoints of the different stakeholders, our observations, as well as national ambitions related to AI. When analysing the first interviews, we looked for recurrent themes and patterns, which we explored further in the interviews that followed. Second, we discussed the empirical data thoroughly within our research project group. To get a balanced picture of the AIRad process, we presented our findings to the stakeholders. Third, theoretical tools are essential for orienting and executing analysis [24]. The themes that emerged from our data (presented in section 5 Results), were informed by the information infrastructure framework and its concern for challenges and opportunities related to the procurement of large-scale socio-technical information systems. Accordingly, while the theme of emergence, open characteristics, and the installed base arising from the empirical data, our theoretical constructs illuminated and validated them [24].

4. Background

In Norway, there are several research initiatives related to the development of algorithms for diagnostic imaging, but almost no commercialised "off-the-shelf" AI solutions have been implemented in clinical practice. This paradox is of national concern and based on exploration by the Norwegian Directorate of E-health, it was decided to try acquiring and implementing a commercially available AI solution for the healthcare sector [15].

In connection with the national initiative, Health Trust A's AIRad project gradually emerged as a national pilot for procuring and implementing commercial ready-to-use AI solutions for clinical practice. The motivation for Health Trust A's ambitions is a steady increase in labor-intensive imaging examinations, estimated at 5–10% per year. There is no correlation between the growth in demand and the increase in production capacity, meaning that radiologists have an ever-increasing workload. In addition, the current educational capacity is insufficient to keep up with increased demands. Therefore, the trust wanted to use AI technology to 1) process the screening of images more effectively, 2) finding those with the most severe pathology quickly and prioritising them, and 3) tagging those with algorithm-detected pathology that needed quick follow-up. Generally, there was a positive attitude towards procuring an AI solution that could alleviate challenges in radiology practices. The AIRad project was given a budget of 1.7 MNK by the regional health authority and was expected to use internal human resources as well. Given its role as a national pilot, the AIRad project aims to explore challenges and assess potential benefits more broadly related to the procurement and implementation of AI solutions. Due to the complexity of the procurement, it conforms to the principle of competitive dialogue. This means that AIRad has developed a requirement specification, but in accordance with a dialogue-based tender process, it is an object for adjustments and (re)specification in collaboration with involved vendors.

5. Results

5.1 The bid for tender

According to the tender documents, AIRad was expected to procure AI solutions already in use in radiology practices in Europe and/or the US. The anticipation was that several large reputable vendors had commercial AI solutions available, that is, off-the-shelf products that could be implemented in the health trust's radiology practice. These companies included several of the major RIS/PACS providers in Europe, as well as providers of specific AI solutions with special-purposed algorithms.

In early 2020, AIRad started the first phase of the project, which involved clarifying and assessing mercantile dependencies, technological feasibilities, protection of patient privacy, and information security. The project had to prepare the procurement, landing on I) CT thorax for lung nodules, pulmonary embolism, and lung metastases, II) MR caput for multiple sclerosis (MS) follow-up, and III) Conventional X-ray for skeletal X-ray and chest X-ray. In addition, the AIRad project had three broad requirements: First, they wanted to procure commercially developed CE-marked solutions tested in European clinical practices to limit the need for validating the algorithms at the local hospital. Second, they were going to acquire static CE-marked solutions and by that, limit the need for training the algorithm on local data. Third, the AI solution should not operate autonomously but act as an assistant for the radiologists when evaluating images, indicating pathology, and improving the prioritisation of patients in need of medical follow-up and treatment. Accordingly, the AI solutions should have predictable behaviours and not make autonomous decisions. The radiologists need to approve the assessment made by the algorithm, in this way ensuring that radiologists have the final say in evaluating the images. Based on these requirements, the AIRad project invited vendors to the tender process.

5.2 Algorithms and platforms

In August 2021, AIRad started the dialogue-based procurement process with five international vendors. One vendor offered single algorithms and the four others offered platform solutions with algorithms from different third-party vendors. Formal physical visits to hospitals using the vendors' AI solutions were not possible due to the pandemic. All the dialogue-based procurement meetings took place using Microsoft Teams. The vendors provided AIRad with contact information about where their solutions were in clinical use.

The single-algorithm vendor argued that they could provide a close relationship with their customers and that single-algorithms were better customised and cheaper to deploy. The platform vendors argued that they could offer in-house developed and/or third-party vendors' algorithms for different clinical uses and that it was easier to change algorithms within a platform. All the vendors underlined that as of today, a limited number of AI solutions are implemented in clinical practice. These AI solutions are tailored to specific use cases and generate values in specific clinical practices. However, AI in radiology is in its early stages and by choosing a platform, these vendors argued that AIRad would get access to a number of algorithms through a single point of integration. The platform vendors will take care of all legal, ethical, and practical collaboration with third-party vendors. The platform vendors also pointed out that the variety of solutions makes it difficult for healthcare providers to know which solutions to choose and which will fit a particular clinical use case in a specific organisational context. They underlined that choosing algorithms from different vendors for each of the three modalities (described in 5.1) would involve more complex technical integration and business processes for a healthcare trust, compared to a platform solution with one point of integration only and one vendor to address. If AIRad chooses a platform vendor, they get the opportunity to select among the algorithms from the platform vendors' menu. With a single-algorithm vendor, a new tender process will be necessary for changing an algorithm if it does not fit the use case.

It is challenging to know what requirements to specify when you don't quite know what you are buying. (Radiologist-15)

The starting point for the AIRad project was to improve clinical practice. From this perspective, a platform solution would make it possible to test different algorithms to identify which ones that have the potential to optimize clinical practice. However, the platform vendors were all clear about the fact that a platform is a starting point for broad-scale adoption. At this point of the procurement process, the platform solutions were implemented only in single hospitals that had a research collaboration with the vendors. The platform vendors underlined the need for close collaboration with AIRad during the implementation and further scaling of AI in clinical practice. At this stage of the procurement process, AIRad was inclined towards a platform approach due to the difficulties of knowing which AI solution to procure before having the possibility to test it in real clinical use and the benefits of only one point of integration, as described above.

5.3 How to trust the algorithms

There were pros and cons when comparing platform solutions versus single-algorithm vendors. All five vendors offered CE-marked algorithms tested or in use in European hospitals. Even if these CE-marked algorithms had been implemented in other hospitals abroad, AIRad's clinical stakeholders emphasised that it was difficult to trust algorithms that had not been validated on data from their own patient population. The CE-marking was not enough to convince clinicians to trust that the solutions would work in their clinical context. A common concern from the radiologists was that the available studies about the algorithms were based on small datasets, and to trust AI solutions, they needed larger studies. In addition, they questioned whether an AI solution developed in and tested on a patient population from a foreign country would be safe to use for interpreting pathology in a Norwegian population.

It is problematic that the algorithms are trained on other datasets compared to where they will be used, for example when it comes to different genetics or images from other types of machines. (Radiology-16)

The training of algorithms is a very demanding and time-consuming process, and so far, CE-marked AI solutions cannot learn by themselves because it is contrary to the principles of the CE approval itself. The radiologists underlined the importance of testing and gaining experience with using AI solutions in their clinical practices, as well as conducting retrospective analysis based on datasets from Health Trust A.

Consequently, for AIRad, it was difficult during the procurement process to evaluate which solutions were optimal for their use. AIRad analysed the documentation of design (training and validation datasets) and peer-reviewed papers on algorithms' functionalities, but even if the algorithms were CE-marked, the documentation of their structure and function were to a large extent incomplete. AIRad discussed the possibility of setting up a study to compare the images flagged by the AI solutions with the results outlined by the radiologists, at different time intervals to find out how the algorithms worked. It was discussed that the study should be supplemented with interviews with radiologists, focusing on their perceptions of safety, trustworthiness, and usefulness when using the solutions.

5.4 Integration with existing infrastructure and organizational practice

The motivation for implementing AI solutions in radiology for Health Trust A and health trusts, in general, is to improve the throughput in interpreting images. As underlined by the vendors, an improved throughput does not depend on AI only, but also on the reorganization of existing workflow and specific organisational benefits defined in each clinical use case, e.g., which step in a patient pathway the algorithm is meant to support (emergency department or follow-up examination of chronic conditions), the need for collaboration with other medical specialties based on the results of the examination, impact on the overall workflow in the organisation, and how the results of the algorithm require integration with both PACS and RIS. The vendors were explicit about the importance of evaluating efficacy considering the specific use case, which presupposed mapping existing workflow as a starting point for understanding how AI can improve practices. Several of the stakeholders in the project highlighted that implementing AI is an organisational change.

In AIRad, the AI solutions are expected to work as underlying systems for RIS/PACS, in terms of delivering reports of findings, flagging and prioritising in RIS, and linking the messages to relevant images in PACS. In this regard, the clinical stakeholders expressed that the AI solutions had to be part of the work processes in RIS and PACS.

When it comes to computer systems, it is really necessary that the AI solutions work seamlessly with RIS/PACS; that is important to us. (Radiologist-14)

The vendors pointed out that their solutions conformed to vendor-neutral standards like DICOM, HL7, and HL7 FHIR. However, even if vendor-neutral standards provide the basis for integration between RIS/PACS systems and platforms distributing AI solutions, the vendors stated that if RIS/PACS and the platform were from different suppliers, there would be a need for integration and development of user interfaces within the existing RIS/PACS systems. These integrations must be performed by the suppliers of the RIS/PACS solutions.

5.5 Changing the focus

The procurement process can be summarised from two viewpoints. On one hand, changing the focus from single CE-marked AI applications to a platform solution opens the possibilities for testing and failing, which AIRad perceived as necessary in an ever-changing AI market. On the other hand, as the platform vendors pointed out, an AI platform requires a long-term view when it comes to realizing the potential and benefits. The realization of profits depends on how well an algorithm is tested, validated, and tailored to its specific use case before implementation in clinical practice. AIRad as a project has a limited operating time and has estimated the need for one year to test and validate the AI solutions they choose.

6. Discussion

The information infrastructure literature reflects an interesting paradox. On the one hand, several studies indicate how important it is to offer users (a small piece of) functionality that can be put into immediate use [11], for instance, through strategies such as “boot-strapping” [10] and building on the installed base [21]. On the other hand, a key characteristic of information infrastructure is that it is open and evolves over long-term, sometimes in unforeseen ways [10], [11]. These two dimensions of information infrastructure represent a tension between planned and emergent changes. This tension also reflects the activities in the AIRad project, where the project has a well-defined goal framed in a public bid for tender acquisition (project time), while AI technology represents an unknown field that needs to be explored (infrastructure time) [9]. Informed by the information infrastructure literature, we will discuss what characterizes the tension between *planned* and *emergent* change in large-scale AI projects for radiology in public hospitals.

Even if AIRad is operating in a new field of technology acquisitions, the project reflects a traditional procurement process in public healthcare. The goal is to acquire an AI solution for Health Trust A within a certain timeframe. When the procurement process ends, the implementation of the AI solutions in clinical practice starts. Then, the organization is expected to benefit from a more efficient throughput of the interpretation of images in its radiology practices. Initially, the strategy was to procure a few CE-marked algorithms, where the CE marking conveys the perception of market readiness. The static nature of the CE mark enforces this perception because any change to an algorithm will require a new formal CE certification. Accordingly, there are many factors in play that push the AIRad project towards a planned change perspective [12]: the public tender, the focus on just a few algorithms, the static CE marking, and the expectations of implementing the AI technology within one year. In accordance with the information infrastructure perspective [11], this strategy may offer radiologists something useful in the foreseeable future. However, during the procurement process, the project’s stakeholders and, in specific the radiologists, questioned the perception of CE-marking as approval for being an off-the-shelf solution due to the need for local testing and validation, as well as adaption to local work practices. Apparently, the CE-marked AI technology meets the need for planned changes, but during the procurement, it is clear that AI solutions address the necessity for a more open long-term approach including test, validation, and tailoring to different clinical contexts towards emergent changes. Moreover, based on experiences from previous implementation processes, the AI Vendors point out that to reach the overall goals of acquiring AI solutions, it is important to map the existing pre-implementation workflow to be able to address the need for changes in clinical work processes during implementation. For example, the benefit of an algorithm for pulmonary embolism is early detection, where the examination needs to be flagged in a worklist as a priority. Early diagnosis and treatment can reduce the risks of complications and death, but it also points to the need for a team of clinicians, from several medical specialties, who take immediate action and responsibility for following up with the patient. This emphasizes that the implementation of AI in radiology has much wider implications, where humans and algorithms will be co-constructed in multiple ways over time during the scaling of the information infrastructure [20].

The tension between planned and emergent change is also evident in the choice between standalone algorithms and AI platforms. Choosing a standalone algorithm from one vendor might ensure that a working solution can be achieved quickly, managed more easily, and integrated more effectively with the existing installed base in the hospital. In some ways, this argument is valid for the exploratory perspective as well. However, a platform “promises” a more open alternative where different algorithms can be added, i.e., a change alternative pointing to an emerging long-term future, [9], [10], [11], [13]. This is not an easy choice, as both planned and emergent change strategies have their benefits and drawbacks.

7. Conclusion

As this study shows, AI technology in radiology represents a new field with limited real-world experiences with hospital trusts procuring of the technology. AI solutions in their early stages are characterized by a lot of uncertainty in terms of functionality, behavior, and organizational consequences, which addresses a tension between the planned and emergent changes for hospitals during procurement and implementation. To balance this tension, we suggest that hospital trusts need to redefine the concept and scope of traditional procurement and implementation projects with a well-defined goal framed in a public bid for tender acquisition and benefit plans. We propose that health organizations need to conceptualize their procurement and implementation projects of AI technology as evolving change processes, that account for the immediate usefulness of the technology, as well as scaling the socio-technical usefulness over time. This means that the evolving information infrastructure must be planned during the project (project time) and handed over as a continuation to the organization by the end of the project (infrastructure time).

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