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Review

Agile Software Development in Healthcare: A Synthetic Scoping Review

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Abstract: Even though software can be found everywhere, software development has encountered many problems, resulting in the emergence of new alternative development paradigms. Among them, agile approaches are the most popular. While much research has been published about agile software development (ASD) in general, there is a lack of documented knowledge about its use in healthcare. Consequently, it is not clear how ASD is used in healthcare, how it performs, and what the reasons are for not using it. To fill this gap, we performed a quantitative and qualitative knowledge synthesis of the research literature harvested from Scopus and Web of Science databases, employing the triangulation of bibliometrics and thematic analysis to answer the research question *What is state of the art in using ASD in the healthcare sector?* Results show that the research literature production trend is positive. The most productive countries are leading software development countries: the United States, China, the United Kingdom, Canada, and Germany. The research is mainly published in health informatics source titles. It is focused on improving the software process, quality of healthcare software, reduction of development resources, and general improvement of healthcare delivery. More research has to be done on scaling agile approaches to large-scale healthcare software development projects. Despite barriers, ASD can improve software development in healthcare settings and strengthen cooperation between healthcare and software development professionals. This could result in more successful digital health transformation and consequently more equitable access to expert-level healthcare, even on a global level.

Keywords: software development; agile approaches; healthcare; bibliometrics; thematic analysis

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1. Introduction and Rationale

The introduction of the agile approach into software engineering has changed how software is developed. The agile approach is an umbrella of methodologies based on shared beliefs, values, and practices. Agile software development (ASD) emphasises active end-user involvement, embracing change, and evolutionary/iterative delivery of products [1]. It is claimed that agile methods per se are more focused on delivering value to the customer than quality to the actual end-users and that values of the user-centred design are not the same as the ASD values [2]. Consequently, much recent research has been devoted to integrating user experience into ASD [3]. Nevertheless, recent surveys show that in 2018, 97% of respondents' organisations practiced an agile approach, compared to 84% in 2007. The main challenges in 2007 were problems with up-front planning and predictability, lack of documentation, and consequently loss of management control, compared to problems with scaling to large projects and organisations, and inadequate management support. Interestingly, even in 2018, 84% of organisations reported that they were still maturing their agile practices [4]. While the agile approach has been successfully used in smaller projects, only a few comprehensive overviews of ASD adoption to large-scale software development have been performed [5–7]. Additional research gaps exist in agile approach employment in safety-critical systems [8] and global software development [9]. Furthermore, there is a gap/lag between research and practice [10,11].

The aims of using ASD in the healthcare sector follow the same trends as ASD use in general; however, it has some more specific goals, like improving clinical outcomes, quality of healthcare delivery, healthcare management, and patient safety [12,13]. Even though ASD is starting to be used in developing safety-critical software in regulated environments [14], like the aerospace industry [15,16], or the automotive system industry [17], there is little evidence of the successful use of ASD in developing safety-critical IT-supported healthcare solutions [18]. Additionally, it is not clear in general how ASD is used in healthcare, how it performs and what the reasons for not using it are. Consequently, we performed a customised scoping review of the literature to answer the following general research question: *What is state of the art in using ASD in the healthcare sector?*

Recently, scoping reviews have become increasingly popular as a knowledge and research synthesis [19]. They proved very useful and efficient in synthesising research evidence and categorising and grouping existing literature in a given field [20]. Arksey and O'Malley's seminal scoping review methodology [21] has evolved and was recently adopted or customised for specific research synthesis applications [22–25]. Despite the lack of evidence, there is still some coverage of using ASD in the digitalisation of healthcare in the scientific literature.

We customised the scoping process to be more effective in using resources, enabling digitalisation and visualisation of tasks performed in stages 4 and 5 of Arksey and O'Malley's framework. We triangulated bibliometric analysis and mapping with thematic analysis [26] and integrated this triangulated method into the scoping framework [27]. This framework was used to synthesise the research literature on the use of agile software in healthcare retrieved from Scopus and Web of Science bibliographic databases to identify the content, trends, and more prolific agile approaches, methodologies, and tools used. In this way our study will generate new synthesised knowledge that can inform healthcare and software development professionals about the broader aspects of ASD use in healthcare and enable them to develop a perspective on more specific research aspects, like the most popular research themes, trends, methods, tools, and benefits of using agile approaches in a healthcare environment. From a more practical view the study outcomes can serve as a basis for future research to improve the quality and timely delivery of healthcare software and possibly reduce the use of software development resources.

2. Background

Software design problems have led to alternative design approaches such as extreme programming, scrum, crystal clear, pragmatic programming, and feature driven development. The developers of these ideas met in February 2001 and signed the Manifesto for Agile Software Development document, which stated four fundamental values and 12 principles. It recognises that software development organisations are complex adaptive systems where decentralised and independent individuals interact to create innovative and emergent results [1]. As the name suggests, agility, or the ability to rapidly adapt to volatile requirements, is at the foundation of ASD. Whenever during a software development process a decision has to be made, four fundamental value statements should be taken into account [28]:

- Individuals and interactions value more than processes and tools
- Working software values more than comprehensive documentation
- Customer collaboration values more than contract negotiation
- Responding to change values more than following a plan

ASD caused a paradigm shift in software development. Contrary to plan-driven models like waterfall, where the software development process is carried out in sequential and ordered phases, ASD entails collaborative development in incremental iterations. Thus, ASD enables managing frequently changed user requirements, focuses on delivering more value to customers and stakeholders, and considers the social and technological changes in the IT industry and in general [29]. Other distinguishing features of ASD include enhanced focus on soft aspects of software engineering, increased collaboration between business customers, increased velocity and flexibility of software teams, and a strong emphasis on frequent delivery of business value [30,31].

In 2008 Dyba and Dingsoyr reviewed 36 empirical studies. They found that ASD had a profound impact on the software industry in that it may improve job satisfaction, productivity and customer satisfaction; however, it might not be very successful in larger projects [32]. Ten years later, Hoda et al. [30] found that significant progress has been made regarding usability, conforming to capability maturity models, improved focus on management-oriented approaches, and translating the use of the agile approach to embedded systems development. More recently, ASD has also been used successfully in global software system development [9]. It has been shown that ASD positively affects the quality of communications and reduces budget and functionality in distributed systems development [33]. Additionally, ASD use can reduce work exhaustion [34] and introduce many benefits over conventional methodologies [35].

ASD was synonymous with poor quality and lack of documentation in healthcare settings. However, ASD has recently been shown to deliver quality healthcare software faster than traditional software development methodologies and life cycles, even when considering medical domain regulatory frameworks [36,37]. Recently, an ASD based approach has been used to develop health Internet of Things reactive applications that can be used for elderly care in smart city homes, in the manner to overcome traditional software development life cycle weaknesses. To address the changing needs and expectations of various multiple users, ASD has been employed in the development of an agile digital population health platform [38]. ASD become even more frequently employed during the recent digital healthcare transformation [39] in the health telemedicine applications development during COVID-19 [40], like developing software for COVID-19 crisis management [41], multiple stakeholder requirement analysis in medical software development [42], digital transformation in pharmacies [43], and improving healthcare software user interfaces [44]. The adoption of agile software development in the healthcare domain encountered barriers, like lack of documentation and front-up planning, regulatory compliance, maintenance traceability [45], and managing non-functional requirements [46]. However, most of those barriers could be overcome [47].

One of the "fathers" of bibliometrics, Pritchard, explained bibliometrics as "the application of mathematical and statistical methods to books and other media of communication" [48]. Hawkins extended the above explanation by defining bibliometrics as "the quantitative analysis of the bibliographic features of a body of literature" [49]. The main units of bibliometric analysis are journal publications, books, reports, theses, and similar. They are analysed using quantitative methods to identify bibliometric characteristics of literature production, such as the most prolific authors, institutions, countries, journals within a field, citation and sponsorship patterns, communication and collaboration between research entities, history of knowledge development, and similar. In addition, bibliometric mapping can be used for content and context analysis of the specific research areas of interest, for example, to identify popular research themes, research direction and gaps, get a view of the size and structure of the field and relevant subfields, and to identify how they relate to each other. A recent review has shown that bibliometrics can be successfully employed in healthcare [50].

3. Methodology

Scoping was performed using the customised Arksey–O'Malley framework [21,25,51] augmented with triangulation of bibliometric mapping and thematic analysis [27]. The customised framework is presented below:

1. ***Identifying the research question***: the following research question was identified: What is state of the art in using ASD in the healthcare sector? As a sub-question, we also analysed the following question: How did ASD adapt to safety critical nature of healthcare software development?

2. ***Identifying relevant studies:*** the corpus was harvested from the Scopus database using the search *string TITLE-ABS((agile* OR scrum* OR {Adaptive software development} OR crystal OR DSDM OR {extreme program*} OR {test driven development} or Kanban OR {Lean development} OR {Feature?driven}) and (software and development)) and PUBYEAR AFT 2000 AND (LIMIT-TO (SUBJAREA,"MEDI") OR LIMIT-TO (SUBJAREA,"HEAL") OR LIMIT-TO (SUBJAREA,"NURS"))* in titles and abstracts. The search was performed on 1st August 2022. All publications not concerned with ASD use in healthcare were removed from the corpus. No further inclusion/conclusion criteria were employed.
3. ***Study Selection:*** remaining publication's titles, abstracts and keywords were screened using the following protocol: all publications should be explicitly concerned with agile software development. Publications dealing with agile management of health systems, in general, should be excluded. Two research colleagues performed the screening process.
4. ***Charting the data using descriptive and performance bibliometrics and bibliometric mapping:*** the publications metadata was analysed first to determine the most prolific countries, institutions, source titles, and literature production dynamics. For the bibliometric mapping, we used the VOSviewer Version 1.6.17 software (Leiden University, Leiden, The Netherlands) [52]. Using a customised thesaurus file, we excluded common terms like study, significance, reproducibility, article, and experiment. We eliminated geographical names and time stamps and combined synonyms into one term, for example, various terms for medical records, mobile phones, and plurals into singulars and similar. VOSViewer uses quantitative methods to visualise the corpus of scientific publications from a specific research field in the form of different bibliometric landscapes. Landscapes can represent the structure of the research field, research themes, and how they relate to each other, the timeline of knowledge development, cooperation, etc. VOSviewer uses text mining to identify relevant noun terms (terms in titles and abstracts, keywords, country names, institutions, etc.) and uses a unified approach to both mapping and clustering. This approach computes a normalised term co-occurrence matrix and a similarity measure which analyses association strength between phrases [52]. Based on identified associations, software merges closely associated terms into clusters denoted by the same cluster colour on the induced landscape. The proximity of terms can be interpreted as an indication of their similarity; terms closer together are semantically more similar than distant phrases. VOSviewer also enables the creation of timeline landscapes in which terms are coloured according to the average year of their emergence in the scientific literature and various networks (i.e., co-citation, bibliometric coupling, co-authors, and similar networks). Another measure shown on the landscape is the term node size, which represents the term popularity: larger nodes represent more popular terms.
5. ***Collating, summarising and reporting the results using bibliometric mapping triangulated with thematic analysis:*** in the inductive part of the thematic analysis the author keywords from the VOSviewer-induced cluster landscape were used as codes. Each cluster was denoted with an appropriate theme, using terms as codes and analysing similarities and associations between codes. In the deductive thematic analysis, the following codes were used: *ASD Methodology* and *Healthcare domain*. The timeline landscape was used to analyse the historical aspects of agile software development in healthcare and the institutional co-authorship network to analyse collaboration aspects.

Hot topics were identified by an approach devised by Kokol et al. [53]. The author's keyword landscape for the period 2017–2018 (Period 1) was compared to the landscape for the period 2019–2022 (Period 2), searching for author keywords emerging in Period 2, but not in Period 1, in both periods, but in the scope of different clusters in Period 2, or author keywords with increased popularity in Period 2. All such author keywords were identified as hot topics.

4. Results and Synthesis

The search in Scopus resulted in 282 publications. Among them 58 publications were removed because they were not concerned with agile software development. Thus, 224 papers remained in the corpus for further analysis. Among them were 131 articles, 82 conference papers, seven reviews, three book chapters and one short survey. The first indexed paper was published in 2006 and presented the agile management of the development of information technology health projects [54].

The dynamics of the overall literature production (Figure 1) show that the trend in the number of publications in the first ten years was slightly positive. After 2015 the steeper positive trend began, reaching its peak in 2021 with 33 publications.

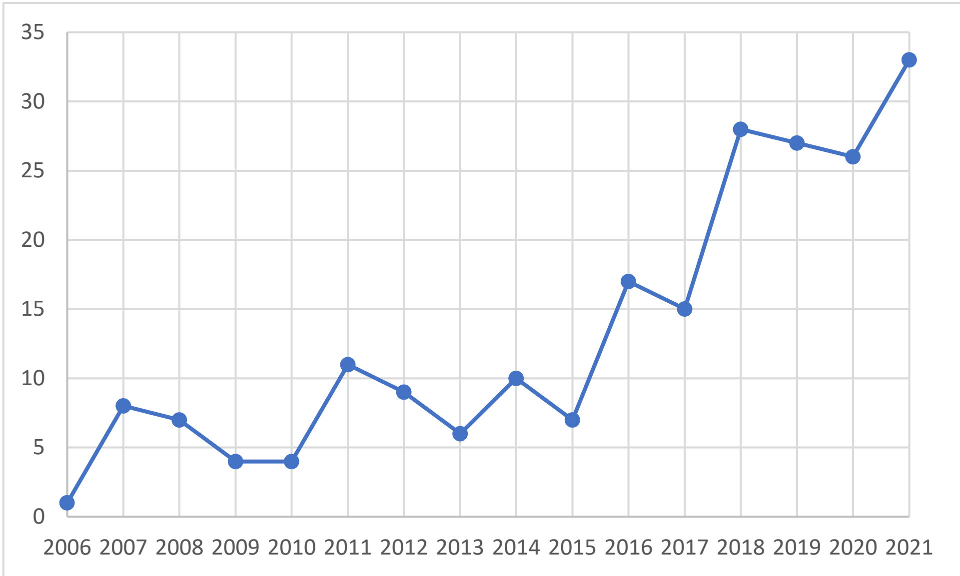

Figure 1. The dynamics of research literature production in agile software development in healthcare.

Since 2006, the research community has also become more extensive and global. From 2006 to 2015 there were 128 institutions from 23 countries involved in the research, while in the period from 2016 to 2021, the number of institutions increased to 197 from 81 countries.

4.1. Descriptive Bibliometrics

The papers were published in 102 different source titles. Most were in the *Journal of Medical Internet Research* (n = 8), followed by *Studies in Health Technology and Informatics* (n = 7), *JMIR mHealth and UHealth* (n = 6), *Jmir Research Protocols* (n = 5) and the *International Journal of Medical Informatics* (n = 4). The SNIP impact factor of the above source titles ranged from 0.33 to 2318, and the CiteScore from 1.4 to 8.2. Among 59 countries the most productive countries were the United States (n = 49), China (n = 22), the United Kingdom (n = 21), Canada (n = 15), Germany (n = 14) and India (n = 13). The United States (USA) is the country producing the most software globally [55]. The USA employs the largest number of programmers (ca. four million) globally, and Germany has the largest number of programmers in Europe (ca. 850,000) [56]. India is among the best countries for outscoring software development [57]. Among 103 funding agencies sponsoring the published research., most publications were funded by the National Institutes of Health, USA (n = 17), the National Cancer Institute, USA (n = 6), the Horizon 2020 Framework Programme, Europe (n = 5), and the U.S Department of Health and Human Services (n = 5).

The corpus publications were cited in total 1898 times, reaching the h-index of 22. The number of citations increased exponentially from 13 in 2008 to 394 in 2022. The 10 most cited papers were cited between 159 and 38 times. They were concerned with the agile development of mobile health applications [58], an image-guided surgery toolkit [59], and an extensible software framework for understanding and improving healthcare costs and outcomes [60].

4.2. Thematic Analysis

As explained in the Methodology section, terms and authors' keywords emerging in landscapes presented in Figure 2 were used as the codes for the thematic analysis. Those codes are shown in the last column in Table 1. The thematic analysis resulted in four research themes, named in the first column in Table 1.

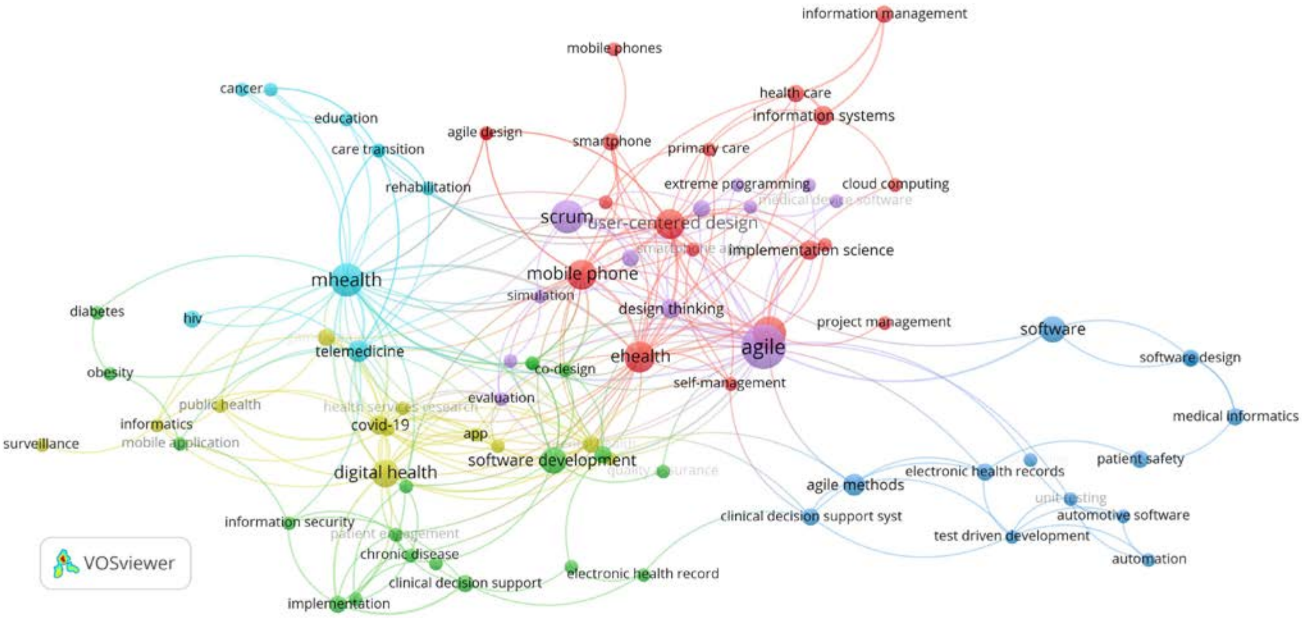

Figure 2. The author keyword cluster landscape of the agile software development in healthcare. A total of 84 (from 845) keywords appearing in more than one publication are shown.

Table 1. Themes in agile software development in healthcare.

Theme	Colour	Representative Author Keywords Used as Codes in the Thematic Analysis
Patient management and engagement in chronic disease with mobile applications	Green	Software development, Diabetes, Obesity, Mobile application, Patient management, Patient engagement, Chronic diseases, Information security, Quality assurance, Co-design
Agile user-centred design of smart eHealth application	Red	eHealth, User centred design, Agile software development. Mobile phone. Information System, Information management, Self management
Agile development of medical device software and virtual reality applications Digital public health during COVID-19	Viollet	Agile, Scrum, Medical device software, Design thinking, Virtual reality, Kanban, Extreme programming
	Yellow	Digital health, Public health, COVID-19. Health service research, Mental Health. Gamification, Informatics
Implementing safe telemedicine with mHealth	Light blue	Telemedicine, mHealth, Care transition, HIV, Cancer, rehabilitation
Test driven development of safe clinical decision support systems	Blue	Clinical decision support systems. Test driven development, Electronic health records, Software design, Patient safety, Medical informatics

Patient management and engagement of chronic diseases with quality and usable mobile apps: quality and usability are two main factors to engage patients to use healthcare software [61,62], especially in case of mobile applications [63]. To improve the quality and usability, ASD was used in healthcare software development [60,64] primarily to better understand the healthcare customers/users' requirements [65,66], by employing user stories [67] and iterative user-centred development life cycle [68–70] thus providing continuous delivery of software [71]. In such a manner, usability, acceptability, functionality, comprehensibility, and end-user experiences of patients and health professionals were improved [72–74]. Additionally, studies report that the use of ASD in developing healthcare software has improved inter-professional communications [75], maintainability [76] and functionality [77]. ASD was used in the development of mobile health application to support management of breast cancer care [78], psychiatric care [79], medication adherence [80], HIV care [81], and health in general [82].

Agile user-centred design of smart eHealth application: the importance of user-centred design in developing medical software and eHealth solutions was recognised about 15 years ago [83]. In general, the research claims that user-centred design should also be used in ASD in healthcare. Not using it will result in a significant waste of human and economic resources [84], software lacking content and functionality [85], or challenging-to-use user interfaces [86]. On the other hand, recent studies show that user-centred design can considerably improve user experience with medical software [87,88]. However, unlike the traditional user-centred approaches, ASD puts the user in the centre of the software development process by employing user stories and intense involvement of users in, for example, scrum ceremonies. Some studies showed that user stories enhance the quality of medical software requirements' elicitation processes and requirements themselves [89,90]. This is especially important when developing eHealth solutions for users with unique needs and individuals who are elderly or who have cognitive impairments. This problem was solved, for example, with agile co-design [91,92]. The interactions with clinicians were improved using agile principles and a user participation approach [81]. An agile based user-centred approach is also very important in developing collaborative self-management eHealth services [93].

Agile development of medical device software and virtual reality applications: after some skepticism [94] that due to strict regulatory requirements in medical device software (MDS), development enforced by safety critical nature of the domain the use of ASD is very limited, new research shows that agile practices can be incorporated with MDS requirements [95]. Scaled agile and software craftmanship actually helped Philips HealthTech to improve the code quality of its medical devices, reduce release cycle time and field defects, and increase the number of delivered features. Adapted ASD has been successfully used also in other MSDs development [96]. Similar to MDS, therapeutic virtual reality systems (VRS) also need regulatory clearance for clinical and home use. It has been shown that, with proper risk assessment, VRS development can also benefit from agile practices [97]. Agile development has been successfully used in various educational VRS tools and environments [98,99].

Agile digital public health during COVID-19: ASD has become a vital part of digital health transformation [39]. The COVID-19 pandemic has presented software developers with a brand-new problem: how to develop software in an environment where it is necessary to develop completely new mission critical software solutions (for example vaccine distribution or emergency software) in a few days with fluidly changing requirements. ASD proved to be viable also in such hyper-agile environments [100,101]. ASD also worked well in developing self-monitoring systems [40] and gamification systems for the spread of information regarding COVID-19 [102].

Implementing safe telemedicine with mHealth: one of the goals of care transition is to make healthcare safer [103]. To make telemedicine and mHealth services safer and better, ASD was employed in developing mobile applications for dementia support [91], medication adherence [80], self-management of health [104], and HIV care [105].

Test driven development of safe clinical decision support systems: defects in clinical decision support which are based on electronic health records are quite common. By using agile test-driven development (TDD) those defects can be effectively reduced [106]. TDD has also been used to asses smart healthcare ontologies, a technology which deals with healthcare information and IoT devices [107].

Regarding the adaptability of ASD to healthcare software development, our study showed that ASD is employed comparably to other fields with a focus on user experience, mobile applications, and continuous delivery of software. Scrum is the most frequently used agile approach. Regarding the use of ASD in safety-critical healthcare software development, very few publications were concerned with this matter [94], mainly dealing with developing embedded software in medical devices [108]. Thus, in this regard, ASD in healthcare has yet to follow this global SD development trend.

4.3. Country and Institutional Cooperation

Country cooperation was analysed using the inter-country cooperation based on co-authorships shown in Figure 3. A partnership based on authorships was established between 22 countries which produced three or more publications. The most cooperative counties were the USA and Switzerland with eight cooperation links, followed by Germany and Indonesia with five links. The most cited publications were published by authors from the USA, Australia, and Norway. The cooperation pattern thus follows the global trend, namely that research cooperation on an international and national level is critically important, especially in multidisciplinary research fields such as software development in healthcare, where international collaboration enables better sharing of expertise and knowledge and more optimal allocation of resources [109].

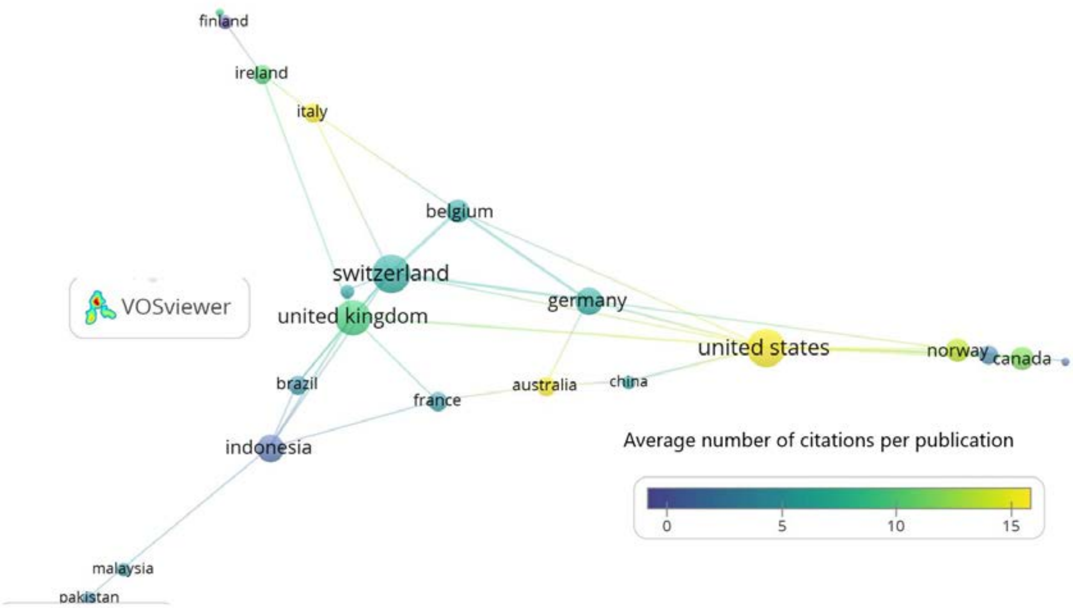

Figure 3. The landscape of institutional cooperation based on co-authorship.

4.4. Hot Topics and Gap Analysis

We identified hot research topics, which we believe will also shape future research endeavours in using agile approaches in healthcare software development. Those topics are agile development in mHealth [110], supporting agile healthcare software development with machine learning [111], and increasing adherence and patient safety [112,113].

Comparing the research content on agile software development in healthcare to the research on agile software development in general, the central research gap seems to be the employment of the agile approach in the development of large healthcare software systems, requiring the scaling of agile approaches [114] to multiple agile teams and global software development.

4.5. Strengths and Limitations of the Study

This study's aims were to contribute to the recent literature on employing agile approaches in healthcare software development. However, this study has certain limitations. First, we used only two bibliographic databases, namely Scopus and Web of Science. The reason was that Scopus and Web of Science are the largest databases containing peer-reviewed publications published in recognised scientific journals, books, and conference proceedings. Second, to maintain the broadness required for scoping, we created a comprehensive database of existing literature; hence, the literature volume was too large to chart the publications in more depth. Consequently, we opted to produce the research field's bibliometric maps (visual and tabulated). Finally, thematic analysis is a qualitative approach, thus susceptible to bias. While the author performed the study as objectively as possible, other authors might yield different results.

On the other hand, our study is the first comprehensive bibliometric study focusing solely on using agile approach employment in healthcare software development. Additionally, the study was performed with a novel triangulating approach, combining bibliometric mapping and thematic analysis.

5. Conclusions

The synthetic scoping review presents a holistic analysis of the research literature concerning the use of agile approaches in healthcare software development performed by descriptive and content-based bibliometric analysis. The increasing number of studies and the growth of the research community reveal that the popularity of ASD use in healthcare is growing, indicating that the healthcare community recognises that ASD can be used in creating high-quality software solutions that deliver more value to a high volume of stakeholders and end users, but still meet security and regulatory requirements. Following those requirements, risk management and a significant share of healthcare software operating in real-time environments seem to be the most significant barriers to ASD adoption in healthcare settings. In this respect, healthcare could investigate other critical industries like aviation or smart car production, where agile has already been successfully adopted. Additionally, the International Medical Informatics Association Technology Assessment & Quality Development in Health Informatics Working Group and the European Federation of Medical Informatics Working Group on Digital Health could be urged to add ASD adoption to their priorities.

The thematic analysis revealed that the research on ASD use in healthcare is tackling similar themes to ASD research in general, focusing on improved user experience, more value for end users, increased quality of software, and optimisation of software development resources. Technologically, the research focuses on mobile platforms, telemedicine, and ubiquitous healthcare, and the most popular agile approach used is scrum. International cooperation exists but should be intensified to enable sharing of knowledge, resources, and best practices, especially between developed and less developed countries.

The results of our study can inform healthcare and software development professionals about the broader aspects of ASD use in healthcare and enable them to develop a perspective on more specific research aspects like most popular research themes, trends, methods, tools, and benefits of using agile approaches in a healthcare environment.

Despite barriers, ASD can improve software development in healthcare settings and strengthen cooperation between healthcare and software development professionals. This could result in more successful digital health transformation and consequently more equitable access to expert-level healthcare even on a global level, and reduced global health and quality of life gaps.

In future work analysis could be extended to other databases like PubMed, Research Dimension, and Google Scholar. The analysis could be also extended with sentiment analysis to reduce bias.

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