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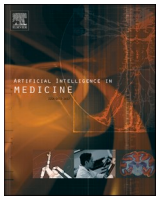

Research paper

The AI ethics of digital COVID-19 diagnosis and their legal, medical, technological, and operational managerial implications

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ABSTRACT

The COVID-19 pandemic has given rise to a broad range of research from fields alongside and beyond the core concerns of infectiology, epidemiology, and immunology. One significant subset of this work centers on machine learning-based approaches to supporting medical decision-making around COVID-19 diagnosis. To date, various challenges, including IT issues, have meant that, notwithstanding this strand of research on digital diagnosis of COVID-19, the actual use of these methods in medical facilities remains incipient at best, despite their potential to relieve pressure on scarce medical resources, prevent instances of infection, and help manage the difficulties and unpredictabilities surrounding the emergence of new mutations. The reasons behind this research-application gap are manifold and may imply an interdisciplinary dimension. We argue that the discipline of AI ethics can provide a framework for interdisciplinary discussion and create a roadmap for the application of digital COVID-19 diagnosis, taking into account all disciplinary stakeholders involved. This article proposes such an ethical framework for the practical use of digital COVID-19 diagnosis, considering legal, medical, operational managerial, and technological aspects of the issue in accordance with our diverse research backgrounds and noting the potential of the approach we set out here to guide future research.

1. Introduction

The COVID-19 pandemic has given rise to a broad range of research from fields alongside and beyond the core concerns of infectiology, epidemiology, and immunology. The World Health Organization (WHO) global COVID-19 database lists more than 750,000 published papers on COVID-19 to the end of 2022, covering a highly diverse thematic spectrum [1]. One key strand of research literature in this context centers on machine learning-based approaches to support medical decision-making around COVID-19 (see, for example, the review by [2], and [3]), in relation to aspects of the disease including prevention, diagnosis, treatment, prognosis, and outcome prediction. For the purpose of this article, we narrow our focus to one of these aspects: diagnosis. Thus, this article primarily explores the use of data from electronic health records, including, laboratory parameters, vital signs, and medical imaging, in digitally diagnosing COVID-19.

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In addition to machine learning-driven digital COVID-19 diagnosis, essential non-digital, i.e., conventional biochemical, tools encompass nucleic acid amplification tests (NAT) and Point-of-care (POC) antigen testing. NAT, such as the polymerase chain reaction (PCR) testing currently regarded as the gold standard in COVID-19 diagnosis, are costly and tie up staff and laboratory resources. The time required to obtain the test result (some hours) is a further drawback of the method. POC antigen testing is a speedier alternative, but has disadvantages in terms of performance, particularly as regards sensitivity [4–6] and new challenges posed by the virus. Further, antigen testing is currently unable to analyze variants of concern. Digital COVID-19 diagnosis may therefore prove of great utility in healthcare institutions, providing a balance between performance, specifically sensitivity, and turnaround time, at a considerably lower cost compared to antigen and PCR testing. As an illustration, based on an estimation using data of the University Hospital of Augsburg, the cost of digital COVID-19 diagnosis is estimated to be up to 5.8 times lower than that of POC antigen or PCR testing.

Most existing research on digital COVID-19 diagnosis applies standard machine learning classifiers, such as support vector machines and neural networks, to single-center data (see, for example, [7]). Recent State-of-the-Art (SOTA) works in AI-based COVID-19 diagnosis have primarily centered around features derived from medical imaging. Noteworthy examples include the paper by Shome et al. [8] and the review conducted by Subramanian et al. [9]. Occasionally, these approaches incorporate textual features, as exemplified by works such as Yu et al. [10] and Zhang et al. [11]. The findings thus generated are yet to be validated by clinical assessment or external data, but the number of authors proposing a digital application for actual use in healthcare institutions is small (see, for instance, [12]); the algorithms' performance in correctly diagnosing COVID-19, that is, their sensitivity, nevertheless appears promising on the pandemic situation researched on. To date, various challenges have meant that researchers' focal interest in digital diagnosis of COVID-19 does not match the actual use of these methods in hospitals, which remains incipient at best, despite such systems' potential to relieve pressure on scarce medical resources, prevent instances of in-house infection, and help manage the difficulties and unpredictabilities surrounding the emergence of new mutations. In the subsequent discussion, we delve into the challenges and concerns associated with digital AI-based tools in healthcare in a broader context. We then articulate the rationale behind our interdisciplinary approach, specifically designed to address these challenges and concerns within the realm of digital diagnosis of COVID-19.

In their study, Khan et al. [13] delineate six pivotal concerns pertaining to the application of AI-based tools in healthcare: “data collection concern,” “algorithms development concerns,” “ethical concerns,” “social concerns,” “clinical implementation concerns,” and “biased and discriminatory algorithms.” They underscore the absence of guidelines for AI application in healthcare as a significant drawback. In a parallel investigation, Maslej et al. [14] identify psychiatrists' preference for “human-derived clinical decision support” while asserting that medical expertise or prior knowledge in AI does not impact the results. On a related note, Keller et al. [15] contend that skepticism surrounding AI-based tools in healthcare is linked to the lack of transparency in models, the proliferation of new applications, and the absence of result transferability across different hospitals. Esmaeilzadeh [16] sheds light on the “perceived risks of using AI applications in healthcare”, emphasizing “technological, ethical (trust factors), and regulatory concerns” as significant contributors. Meanwhile, Lee and Yoon's [17] literature review highlights the manifold advantages of AI-based tools in healthcare but acknowledges major challenges, including the “accountability of system use”, the “AI divide”, “cybersecurity for privacy and security”, “loss of managerial control”, “job loss”, “training/education needs and the pain of transformation”.

Hence, the reasons behind the paradoxical gap between research and application of AI-based tools in the safety-critical area of healthcare, especially in the domain of digital COVID-19 diagnosis, are manifold and imply an interdisciplinary dimension that goes beyond the technological context. We argue that the discipline of AI ethics may be able to provide a framework for interdisciplinary discussion and create a roadmap for the application of digital COVID-19 diagnosis in healthcare institutions, taking into account all disciplinary expertise involved. This article therefore proposes such an ethical framework for the practice of digital COVID-19 diagnosis, on the basis of existing policy papers and considering legal, medical, operational managerial, and technological aspects of the issue in accordance with our diverse research backgrounds; our ultimate aim in this context is to improve the quality of care and efficiency in the clinical setting.

Recent years have doubtless seen highly significant contributions to the academic discourse on the ethics of AI-based algorithmic decisions (see, for instance, [18–23,60]) and of digital health in particular (examples are [24–28]). The focus of this work is often on the question of whether to apply a digital tool in general rather than on how to responsibly apply a digital tool in a special use case that brings on board the viewpoints of all relevant disciplinary stakeholders during development and implementation. Our article responds to this lacuna by proposing an interdisciplinary consideration of the use case of digital COVID-19 diagnosis. Specifically, distinct from prior research, our focus revolves around addressing the responsible application of a digital COVID-19 tool within healthcare institutions. The team of authors that has worked on this article comprises a member of the German Ethics Council; the head of the Research Centre for *E*-Health Law at the University of Augsburg, Germany; a medical doctor with substantial experience in the care of patients with COVID-19; and researchers in healthcare operations / data science. Our approach expands on the multidisciplinary perspective taken by Amann et al. [24], who limit their detailed considerations to the aspect of explainability, while omitting an operational/managerial view.

Summarizing, the fundamental objectives and rationales of the study can be outlined as follows:

- We present an ethical framework designed for the application of AI-based clinical decision support systems addressing the research-application gap in the field.
- We systematically align the ethical framework with the development process and involve various stakeholders in the discipline of AI-based clinical decision support systems, exemplified through the use case of digital COVID-19 diagnostic tools.
- We present the prototype of an application for digital COVID-19 diagnosis.

The article will proceed as follows: In Section 2, we set out the problem of digital COVID-19 diagnosis in detail and list the relevant disciplinary stakeholders during development and implementation. In Section 3, we justify our thesis why AI ethics can be a useful basis for thinking about an ethical framework for interdisciplinary collaboration. Section 4 outlines this ethical framework, which we propose based on existing policy papers and reflections on AI ethics. Section 5 elaborates on the implications of this ethical framework for the individual disciplines and how the ethical requirements can be implemented in interdisciplinary collaboration. In Section 6, we discuss the limitations of our approach in detail. Section 7 concludes the article and looks ahead to future research in this area. It develops an integral view of ethics in this field.

2. The issue and the disciplinary stakeholders involved

2.1. Status quo of COVID-19 diagnosis

As noted in the introduction to this article, healthcare institutions have thus far generally used nucleic acid amplification testing (NAT), such as polymerase chain reaction (PCR) tests, or point-of-care (POC)

antigen tests for identifying cases of COVID-19. The latter has benefits as regards turnaround time (approx. 20 min; according to data of the University Hospital of Augsburg), but drawbacks in terms of sensitivity (approx. 50–60 %; see [4]). A major advantage of PCR testing is its superior sensitivity (approx. 97–99 %; according to information issued by manufacturers). The progress of the pandemic has occasioned increasing variation in turnaround times and in test availability due to both infection rates and new testing approaches. In general, we assume that a PCR test takes about 300 min (according to data of the University Hospital of Augsburg) on average.

2.2. Digital COVID-19 diagnosis

It is in this context that digital COVID-19 diagnosis may have the potential to become a staple method of identifying COVID-19 in healthcare institutions. For the purpose of this article, we will use as an example the machine learning classifier COVIDAL, proposed by Bartenschlager et al. [29]. COVIDAL is based on relevant standard laboratory parameters such as C-reactive protein and hemoglobin, which are available within a reasonable period of time after sample collection (approx. 60 min, according to data of the University Hospital of Augsburg). One use case of the classifier is its application in emergency departments for classification of symptomatic incoming patients. Physicians and medical professionals would be provided with a clinical decision support system called COVIDAL-APP, which would consolidate the laboratory parameters in terms of the probability that they indicate a current infection. The COVIDAL-APP currently exists in prototype form; Fig. 1 shows a mock-up of the final COVIDAL-APP. Using an interface to the hospital information system, the application would provide healthcare workers and physicians with the risk that the patient in question is infected and, drawing on this, a classification of the patient as infected or not infected with SARS-CoV-2. Staff will be able to view the laboratory parameters used for the classification, which may allay concerns relating to the explainability and trustworthiness of AI in this context. Please be aware that the mock-up of the COVIDAL-APP provides the reader with an initial concept of the app, devoid of a formal prototyping process that considers UI/UX standards. The comprehensive discussion of the prototyping process is elaborated further below in the context of the ethical framework.

The digital COVID-19 classifier has a clear advantage over point-of-care (POC) antigen testing in terms of sensitivity (approx. 70–90 %; according to [29]) and over PCR testing in relation to turnaround time (see Fig. 2). The cost of diagnosis – encompassing staff cost for healthcare workers and the cost of materials provided by Augsburg University Hospital, where our research took place - is significantly lower for the COVIDAL-APP (approx. 2.60 Euro per case; according to data of the University Hospital of Augsburg) than for PCR or POC antigen testing (approx. 15.00 Euro per case; according to data of the University Hospital of Augsburg). As the COVIDAL classification is a by-product of routine blood testing, the COVIDAL-APP is the only classifier for COVID-19 that does not use any dedicated resources (beyond the app itself). Fig. 2 compares the various diagnostic procedures in the context of emergency department use as referenced above. It becomes evident that the COVIDAL classifier adeptly balances performance, specifically sensitivity, and turnaround time, at a considerably lower cost of diagnosis compared to POC antigen and PCR testing.

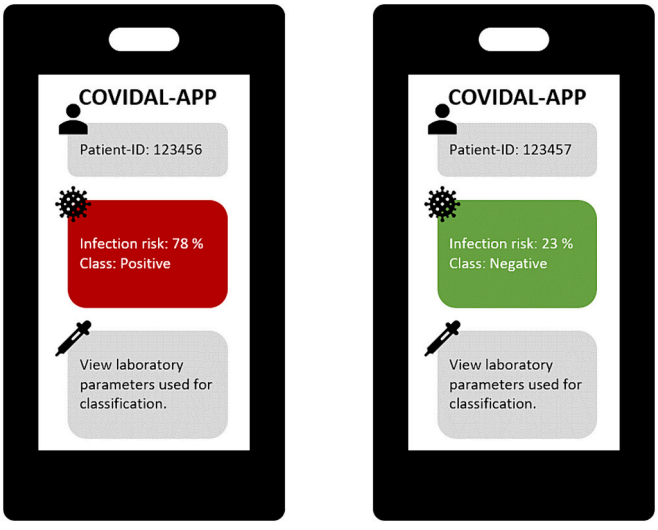

Fig. 1. Mock-up of the COVIDAL-APP showing patients classified as positive (left) and negative (right) for SARS-CoV-2.

2.3. Disciplinary stakeholders of digital COVID-19 diagnosis in practice

Operationalizing the proposed COVIDAL-APP as an additional method of COVID-19 diagnosis in healthcare contexts would require the technological, legal, medical, and operational managerial expertise of various stakeholders during development and implementation, alongside AI ethical input as a foundation to guidelines for the system's practical use in the healthcare setting. Data science and health IT specialists would train the COVIDAL algorithm and implement the app. Legal experts would consider data protection issues and matters of medical law. The input of physicians would be crucial to configuring the algorithm in terms of feature selection, validation, and practical insights. A managerial/operational perspective, finally, would oversee coordination among stakeholders and the tool's integration into existing processes (see Fig. 3). In the following sections, the ethical framework for the practical application of COVID-19 digital diagnosis is elaborated in order to highlight the implications of this framework for the required interdisciplinary contribution of all stakeholders in the fifth section.

3. AI ethics as the basis for ethical frameworks for interdisciplinary cooperation

"AI ethics" contains two buzzwords and must be concretized at this point. In the context of AI and ethics, some speak of a "moral AI", i.e., of programming machines in such a way that they act morally (for us; [30]). Others - and so do we - speak of AI ethics as a science of reflection on a specific technical field [31]. Possible misunderstandings arise from an unreflective use of the terms morality and ethics as well as from implausible expectations of the functionality of technical processes such as AI systems [32].

The term AI should also be seen as a collective term that is based on at least one field of computer science, a large number of technologies and applications are more or less based on them.

Thus, AI ethics is used to refer to different things. In our paper, we use the term AI ethics to describe the consideration or demand that ethical considerations should be incorporated into the development and implementation process of such systems or into their use. To ensure that ethical reflection and judgement are incorporated into the process of designing, developing, and using AI systems, interdisciplinary cooperation should be pursued.

Technology - and thus also AI - is not a neutral tool but implies at least implicit social, cultural, or idiosyncratic values and norms in the process of its creation [33]. These values and norms should be subjected to ethical evaluation. The special feature of AI systems is that the various components are relatively independent. There is the underlying learning algorithm, the model trained by data and the actual application involving different actors at different times. This fact can make it more difficult to trace the values involved in the creation process.

In order to make these involved values transparent and accessible for interdisciplinary collaboration, we will formulate an ethical framework in the following, based on policy papers and AI ethical considerations.

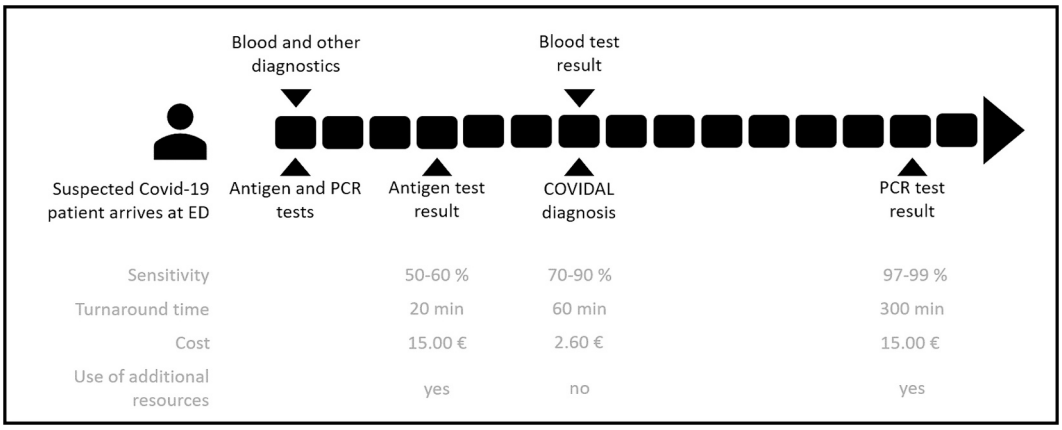

Fig. 2. Process of testing suspected COVID-19 patients after arrival at the hospital (ED: Emergency Department). The data presented is based on Bartenschlager et al. [29], and data of the University Hospital of Augsburg.

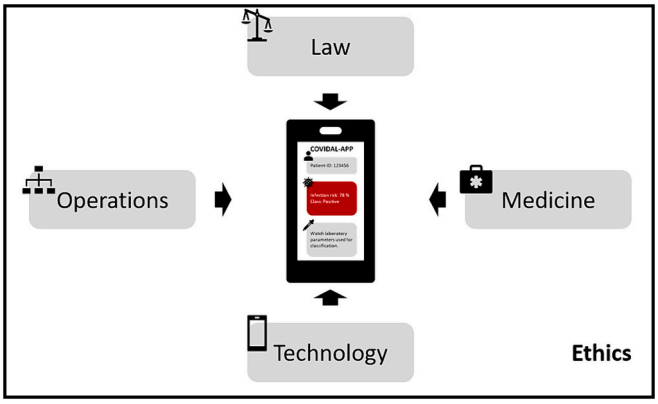

Fig. 3. Stakeholders in digital COVID-19 diagnosis as applied in healthcare institutions.

4. An ethical framework for the practical use of digital COVID-19 diagnosis in the healthcare setting

The ethical framework we propose here draws inspiration from the global view set out by Jobin et al. [19] on AI ethical guideline and is based on a detailed review of various recent sources, including policy papers and existing ethical requirements closely related to digital health, at international and European levels. We also took specific account of prominent contributions to the literature from Germany. It represents the state of the art in the field of policy papers. This state of the art is examined in particular for its commonalities with regard to the AI ethical values mentioned, which are subsequently related to COVIDAL. This provides the basis for formulating concrete ethical requirements for COVIDAL that are suitable for interdisciplinary cooperation and practical use in the health care system.

4.1. WHO guidance (2021)

The recently issued WHO guidance on 'Ethics and governance of artificial intelligence for health' [34] references the COVID-19 pandemic in its considerations on AI: "*Although the [COVID-19] pandemic is not a focus of this report, it has illustrated the opportunities and challenges associated with AI for health […] Several applications have raised ethical concerns in relation to surveillance, infringement on the rights of privacy and autonomy, health and social inequity and the conditions necessary for trust and legitimate uses of data-intensive applications.*" ([34], p. Xii). The guidance also engages with the ethics and governance of AI for health, giving a prominent place to accountability and responsibility. In particular, the guidelines set out "[k]ey ethical principles" for the use of AI in health as follows: "Protect autonomy"; "Promote human well-being, human safety, and the public interest"; "Ensure transparency, explainability and intelligibility"; "Foster responsibility and accountability"; "Ensure inclusiveness and equity"; and "Promote [AI] that is responsive and sustainable".

4.2. Ethical guidelines for trustworthy AI (2019)

The guidelines issued by the European Commission's High-Level Expert Group on AI in 2019 define "trustworthy AI" as consisting of "lawful," "ethical," and "robust" systems meeting seven requirements: "Human agency and oversight", "Technical robustness and safety", "Privacy and data governance", "Transparency", "Diversity, non-discrimination and fairness", "Societal and environmental wellbeing", and "Accountability".

4.3. Ethics and AI in Germany (2019 and 2021)

The citizen-centered Platform for Artificial Intelligence,[1] a network of experts on issues relating to AI, seeks to provide an overview of the various challenges that may arise with the emergence of AI applications. In view of the major objectives of ethical guidelines in AI - prevention of harm, compliance with legal norms, and technical robustness - the contribution of Heesen et al. [35] to the group's work outlines three fundamental ethical values and, issuing from these, requirements for the development and application of AI systems: self-determination, justice, and the protection of privacy. With regard to the last of these, the authors call for data collection and processing to be kept to a minimum, transparency, and privacy by design of the algorithm and the application. From justice flows a duty of disclosure during the development and application of AI systems and accountability for their actions and decisions. Explainability, comprehensibility, a system openness, and interoperability realize self-determination as a core value of ethical AI.

Further significant guidance in this regard is the statement on clinical decision support systems (CDSS) issued in August 2021 by the Central Ethics Committee of the German Medical Association (*Zentrale Ethikkommission bei der Bundesärztekammer*), of which several aspects have central relevance to digital diagnosis of COVID-19. The statement stipulates that the general aim of all CDSS must be the improvement of patient care, that patients should be able to trust healthcare professionals to consistently center them as individuals, their wellbeing,

[1] The Platform for Artificial Intelligence outlines its work and objectives here: https://www.plattform-lernende-systeme.de/home-en.html

and their autonomy, and that they should never be left with the impression of having been reduced to the status of a data set ([36], A 4). In exploring the matter of responsibility[2] at various levels, the document discusses the need for individual healthcare professionals to acquire the appropriate skills for use of the systems, for adequate training in this area, and for societal actors to create ethically founded conditions that enable those involved in producing and implementing these technologies to meet their responsibilities. As in many other fields of ethics, autonomy is a weighty issue in relation to CDSS, encompassing both the autonomy of patients and that of medical staff, which should necessarily be increased and not decreased.

4.4. The case for COVIDAL as CDSS

One of the risks of CDSS mentioned in this policy paper is that of automation bias, that is, unquestioning acceptance of information delivered by the CDSS. Another problem may be alert fatigue, that is, a habituation to repeated alerts over time which may lead to an eventual failure of the user to respond to them. Alert fatigue origins in the fact that there is a certain probability for false positive and false negative results for COVIDAL. Further, although most CDSS are trained to produce false positive rather than false negative results, a risk remains, in terms of possible overtreatment of false positive cases. Another danger here is of a loss of experiential knowledge held by medical practitioners due to an over-reliance on the system. These are all challenges for COVIDAL.

These guidelines and principles give rise to multiple considerations around keeping CDSS to an auxiliary role rather than allowing them to take the lead in diagnosis, ensuring that physicians using CDSS do not lose sight of a holistic view of those they treat, and understanding the expectations held by society at large toward CDSS and their use.

4.5. Ethical requirements for COVIDAL

We have analyzed the state of the art elaborated in this chapter for their commonalities in terms of ethical values. In the process, a fundamental consensus emerges on an AI ethics for the practical use of digital COVID-19 diagnosis, encompassing overarching ethical requirements as follows: (1) accountability, (2) autonomy, (3) diversity, (4) human wellbeing, (5) protection of privacy, (6) sustainability, (7) safety, (8) system openness, and (9) transparency.

Table 1 describes the nine ethical requirements that define our ethical framework and their origins from the literature discussed above.

Table 1
Synopsis of ethical requirements for digital COVID-19 diagnosis.

Requirement	WHO [34]	European Commission's High Level Expert Group on AI [37]	Heesen et al. [35]	Central Ethics Committee of the German Medical Association [36]
Accountability	✓	✓	✓	✓
Autonomy	✓	✓	✓	✓
Diversity	✓	✓		
Human wellbeing	✓	✓		✓
Protection of privacy		✓	✓	
Safety		✓		
Sustainability	✓	✓		
System openness			✓	
Transparency	✓	✓	✓	

We believe that ethical principles and values, as delineated in our framework, are urgently needed. However, we acknowledge their inherently high-level nature, and as Anderson and Fort [38] aptly point out, mere endorsement of principles does not inexorably translate into tangible actions. In agreement with this perspective, we posit that elaborating further on the abstract concept of ethical values, such as autonomy, in a general sense, may not yield substantial practical insights. Consequently, we contend that these principles must be expounded upon with a minimum degree of specificity, preferably within the pertinent context, and ideally tailored to the specific actors involved. This nuanced contextualization is precisely the focal point of our forthcoming exploration in Chapter 5.

As an illustration of the context-specific but non-actor-specific application of the framework, we can delineate two specific cross-actor challenges that hold significance for COVIDAL. These challenges emanate from the ethical imperative of *autonomy*.

(1) We recommend the recognition of two specific challenges related to the ethical value of autonomy and the technological application of COVIDAL - automation bias and alert fatigue - and appropriate measures to address them. Automation Bias, the automatic acceptance by medical staff of information provided by the CDSS, should be eliminated by appropriate means. Unquestioned acceptance and adoption of the diagnosis or recommended course of action leads to a loss of autonomy - of doctors and patients - at least in the medium term.
(2) The use of CDSS should take place in consistent awareness that, while the systems are part of the decision-making process, authority in decision-making remains with human actors. It is vital to encourage a relationship of shared decision-making between patients and medical professionals at a general level, and, more specifically, to formulate a three-way shared decision-making process encompassing the patient, medical staff, and the CDSS, with appropriate preponderance given to the human participants.

These two challenges to the value of autonomy are by no means exhaustive; there remain, for instance, the risk of computer paternalism and that of the loss of experiential medical knowledge through the use of CDSS.

5. Interdisciplinary discussion

Each group of disciplinary stakeholders will find some of these predefined ethical requirements and guidelines of particular relevance to their task; there is a close association between the extent of this relevance in each instance and the various stages of work on creating a digital COVID-19 classifier. The major purpose of this section is therefore to map the ethical framework and the nine requirements onto the development process. In this way, we aim to facilitate interdisciplinary work with the help of AI ethical considerations and bridge the gap between research and application. Our overarching goal is to streamline interdisciplinary collaboration by incorporating considerations of AI ethics, thereby bridging the gap between research and practical application. Therefore, it is imperative to underscore that, within this narrative, the chapter serves a dual purpose. It not only functions as a comprehensive mapping of the ethical framework onto the developmental process but also serves as an illustrative exemplar, showcasing the practical application of the aforementioned ethical principles. As explicated earlier, the implementation of the ethical framework necessitates a granular explication tailored to the unique dynamics of specific cases and actors.

Vayena et al. [39] define three general stages of the development of a machine learning-based device for the medical field: (1) data sourcing,

[2] At this point, we would like to point out that responsibility is a very important but very complex issue in connection with the use of AI in the medical field. For further reading, we recommend, for example, Heidbrink et al. [59].

(2) product development, and (3) clinical use. We have adapted this roadmap for our COVID-19 use case to include four stages: (1) data collection and preparation, (2) training and evaluation of the algorithm, (3) development and validation of the application, and (4) introduction and use of COVIDAL in daily clinical routines. In view of our ethical framework, the interdisciplinary perspective of our work, and our key question, we have split stage (2) in Vayena et al. [39] into two stages, (2) and (3).

Our discussion of the implications of the ethical framework at each stage of development examines their relevance to the four key disciplinary stakeholder groups outlined in Section 2 above. Fig. 4 gives an overview of our recommendations as to which stakeholder should bear which principles particularly in mind at each stage of development. Please be aware that Fig. 4 presents a simplified representation. It is essential to acknowledge that there could be interdependencies extending beyond the depicted stages of development. We derive the shared responsibilities from our disciplinary experience and will explain our recommendations listed in Fig. 4 in more detail for each discipline, i.e., technology, law, medicine and operational management, in the next sections directly in relation to COVIDAL. The transition from discourse concerning explicit requirements to the exploration of shared responsibilities is not imperative but closely intertwined. By introducing the concept of shared responsibilities, we aim to catalyze further discourse on the interwoven nature of these considerations.

5.1. The impact of the ethical framework for technology

The technological implications of this ethical framework ensue from almost all of its aspects and are influential in COVIDAL-APP's development, as the development process of the COVIDAL-APP mock-up demonstrated. The meeting of requirements on autonomy and transparency would necessitate, among other things, training of COVIDAL as an explainable AI technique and disclosure of the underlying concepts to patients and physicians [40]; thus, these actions may additionally help avoid alert fatigue and automation bias. Additionally, proposing a confidence score for the algorithm output, which is a common topic in explainable AI (see, e.g., [41]) would contribute to address the major challenges mentioned. Regarding data collection, selection, preparation, output and storage, it would be imperative to devote special attention to non-discrimination, i.e., diversity, alongside data protection issues and reduction of data collection to a minimum to the end of protecting privacy. Data selection criteria necessitate discussion and collaboration with both medical and legal experts. Consequently, these criteria might be derived from a combination of data-driven statistical methodologies and expert-crafted selection processes. Federated machine learning, a rather new machine learning technology that secures data governance by the healthcare institution, might be another promising approach for AI-based decision-making around COVID-19 (see, for example, [42]). The protection of human wellbeing and safety would call for detailed evaluation of the algorithm, including advanced techniques such as cross-validation, and an adequate amount of training, testing and validation data (see criticism by [43], on the small amount of data in AI-related COVID-19 contributions). Technical interoperability of the COVIDAL-APP would support the requirement for a system openness and sustainability. In the third step of the development process, which involves app development and evaluation, the prototyping design process necessitates collaboration between medical and technological domains. This collaboration is particularly crucial to fulfill transparency and sustainability requirements. Moving to the fourth step of the development process, where the digital classifier is integrated into routine use, the technology discipline, in conjunction with operational managerial experts, holds responsibility for devising system integration and maintenance strategies. These strategies are imperative to ensure the safety and continued effectiveness of the tool.

5.2. The impact of the ethical framework for law

A focal concern of legal provisions for the AI-based diagnosis of COVID-19, in light of the ethical framework we set out here, would be data protection requirements, with specific reference to privacy and autonomy. One central issue in this regard is the question of whether the training data for the software tool can be classified as anonymized, particularly in the continued absence of an authoritative decision of the European Court of Justice on this matter.

Further issues of data protection law arise in connection with the application's use, one example being the core question of the legality of consent. In this respect, it will be particularly important to examine whether COVIDAL could use the model patient consent wording

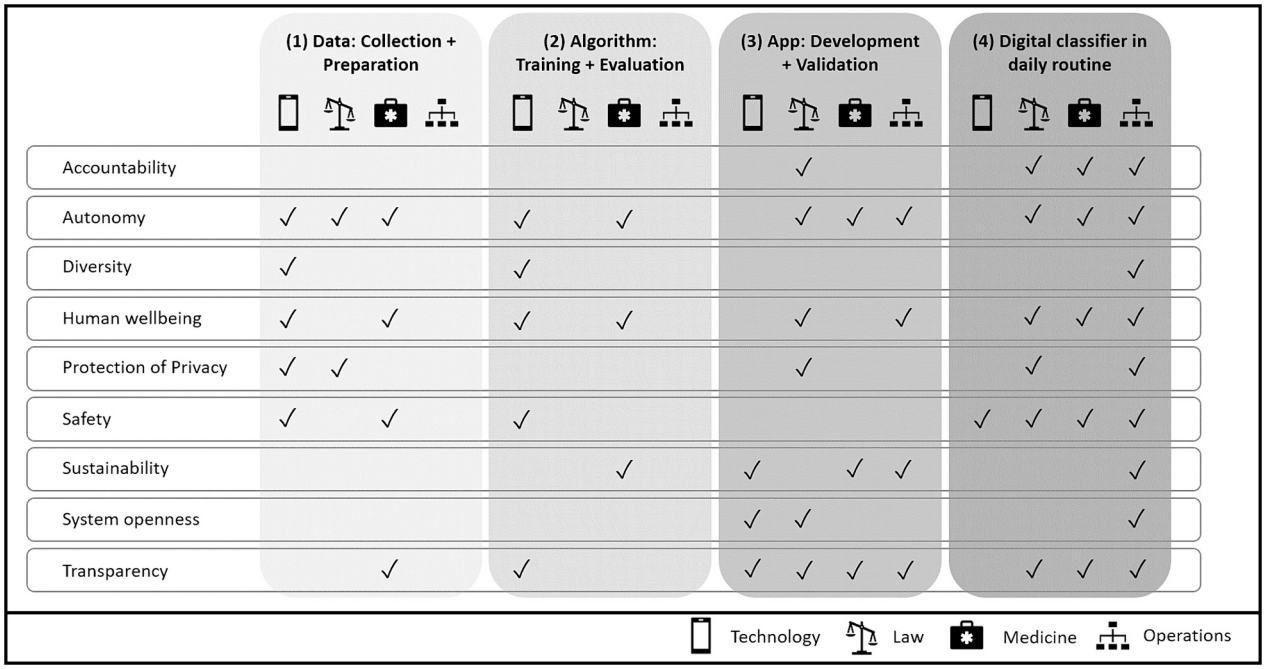

Fig. 4. Ethical requirements during the development of a tool for digital COVID-19 diagnosis: interdisciplinary implications and shared responsibilities.

developed as part of Germany's Medical Informatics Initiative[3] data networking project. The aim of explainable AI pursued here calls for compliance, at a minimum, with European special requirements that are in place *de lege lata*. At the very least, it will be necessary to develop a tool-specific minimum standard as a practical extension to meta-legal ethical requirements. In this context, discussion will be required as to which duties of disclosure are incumbent on the physician using the AI-based software, with regard to her accountability, and indeed as to whether COVIDAL in fact qualifies as software as the EU Medical Devices Regulation defines it. Possible follow-up questions include the extent to which purely in-house use without certification would be possible and the general standards of regulation. Additional issues, specifically around medical device legislation and liability, would arise were the intent to incorporate the tool into a hospital information system. [44–46].

Finally, with a view to future legal implications, we note that in April 2021, the European Commission submitted a proposal for an AI Act [47], the first ever attempt to enact legislation around AI, with the purpose of promoting AI and innovation while protecting health, safety, human rights, and ethical standards. The proposal entails a classification for AI systems, with requirements and obligations assigned according to a risk-based approach. In the proposed framework, AI-based medical devices such as COVIDAL will be classified as high-risk AI systems. However, the proposal does not fully explicate the interplay between the requirements it contains and the regulatory obligations deriving from the EU's Medical Devices Regulation. It remains to be seen whether the legislative process will produce sufficiently specific outcomes in this regard.

At an earlier date, in 2019, the Data Ethics Commission of the German Federal Government had proposed a system criticality framework involving a scheme of levels defining specific regulatory requirements for an algorithmic system [48]. The five levels are set in accordance with the potential of the system to cause harm, which derives from both the probability of harm occurring and the severity of that harm should it occur (see Fig. 5). The sensitivity of COVIDAL is of relevance in this context. The system's true-positive rate is about 70–90 %, and its specificity (true-negative) is reasonable. The probability of harm in terms of misclassification of a SARS-CoV-2-positive patient is therefore approximately 10–30 %. The potential harm here is a failure to isolate a positive patient or take specific protective measures. Consequently, vulnerable patient groups and personnel important for medical care get infected with severe implications for patients' life and medical services. However, COVIDAL is a CDSS; that is, while it provides automated processing of laboratory parameters, the intent is that the results it generates be reviewed in context. For example, vital signs or medical imaging scans can complete the picture for final assessment by healthcare professionals. In terms, then, of the system criticality scheme defined by the Data Ethics Commission, the algorithm would fall within levels 2–4, which means it represents an application with a certain potential to cause harm and therefore triggers obligations for regulatory transparency and communication. The recently published white paper by Heesen et al. [49] discusses a very similar criticality concept. In contrast to the levels defined in the aforementioned contribution, Heesen et al. [49] only differentiate between higher and lower criticality and also include the individual's handling capabilities in their considerations.

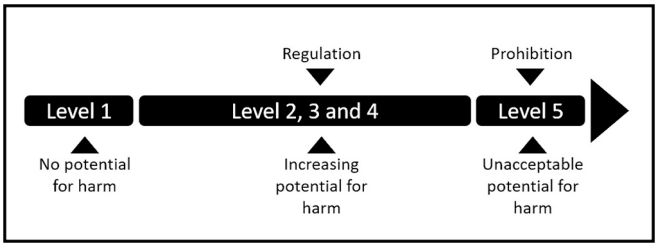

Fig. 5. Levels of system criticality (based on [48], p. 177).

5.3. The impact of the ethical framework for medicine

The implications of this proposed framework for medical staff, and for the discipline of medicine in general, issue primarily from the requirements defined above and their concern with autonomy, human wellbeing, transparency, accountability, and safety. Medical experts should be part of the COVIDAL development process throughout, starting from data collection (see [50]). Interdisciplinary collaboration with computer scientists during development will support the system's trustworthiness, transparency, and explainability, the safety of its outcomes, and, in the end, consecutive long-term accessibility of the solution. COVIDAL is intended to be a solution that reduces physicians' day-to-day workloads without requiring additional effort from them and automates patient classification on the basis of data that are available in medical information systems via open interfaces. The implication here is that information systems which to date have been purely data-managing systems will experience a change of role. We assume a basic level of interest in the system's technological and legal aspects, such as those pertaining to disclosure and accountability, among those physicians who will use it. They will need to engage in relevant training that includes discussion of autonomy and biases, specifically automation bias and alert fatigue, alongside information on the potential benefits and challenges of COVIDAL as a CDSS.

5.4. The impact of the ethical framework for operational management

Previous research has demonstrated the importance of operational managerial methods in process manipulation in emergency departments [51] and operating rooms [52], in optimized training plans for physicians [53], and in the implementation of digital solutions in hospital visitor management [54]. A recent consideration of operational managerial research is sustainability and resilience (see, for example, [55,56], and [57]). From a managerial/operational perspective, the ethical framework proposed here requires the implementation of COVIDAL as a CDSS in clinical routines, to incorporate plans for adequate training of medical staff and the inclusion of all levels of management, stakeholders, and quality management in the process. Hence, the operational management team plays a pivotal role in orchestrating collaboration across diverse disciplines and seamlessly integrating the new technology into established workflows. The use of COVIDAL may, for example, influence existing processes of triage in emergency departments. It may be appropriate to make use of operational management methods such as simulation and mathematical modeling techniques to support decision-making prior to the introduction of the COVIDAL-APP and during its use. Concerning staff training, there's not only the inquiry of when and how frequently to provide training optimally but also the collaborative decision-making process involving various stakeholders to determine the training contents. The process-related view of operational experts will also engage with sustainability and resilience. For example, the process for the generation of automated readouts from the laboratory system will need to maintain the principle of COVIDAL's status as a by-product of existing processes; any departure from this would have a corresponding impact on additional resources (see Fig. 2). The integration of operational management experts is of special importance in the latter stages of the development process, particularly concerning interdisciplinary solutions related to system integration, devising maintenance strategies, and determining optimal data storage solutions.

[3] The Medical Informatics Initiative outlines its work and objectives here: https://www.medizininformatik-initiative.de/en/start

6. Limitations

Our study possesses several noteworthy limitations, which we delineate as follows. First, it is important to recognize that our study adopts a framework-based approach, resulting in preliminary findings. This necessitates further empirical validation and iterative refinement of the framework in real-world clinical settings. A key limitation arises from the absence of practical and operational framework implementation. Second, we do not specifically address the potential future integration of Generative Pre-Trained Transformers (GPT) as a baseline, which could raise questions about the framework's scalability to Large Language Models (LLMs).

Third, our evaluation of the cost-effectiveness of the application, when compared to POC antigen testing and PCR testing, relies on data exclusively from the University Hospital of Augsburg, where our research was conducted. While we anticipate that the data from the University Hospital of Augsburg is likely representative of a broad spectrum of European hospitals, it is crucial to acknowledge that costs during the pandemic were subject to significant volatility. This volatility may have implications for our conclusions regarding the cost-effectiveness of the application. In addition, broadening the app's scope to include multiple algorithmic classifiers for various tasks would enhance its cost-efficiency. As we address the research-application gap and acknowledge the existence of numerous algorithms and initial applications for digital COVID-19 diagnosis in research (see introduction), our cost-effectiveness considerations omit development costs for the application. We focus solely on costs of diagnosing, similar to our approach for POC antigen and PCR testing. However, considering the Robert Koch Institute's [58] report of approximately 1,000,000 tests conducted on average per week in Germany during the pandemic, the development costs per diagnosis for the app are expected to be insignificant, if the app is broadly applied.

Fourth, it is important to acknowledge the potential limitations of our approach in mitigating automation bias. Despite our concentrated efforts to reduce automation bias, such as involving physicians in the entire development process and implementing regular training sessions by operational experts, it is essential to recognize that automation bias can still inadvertently creep into daily routines. With respect to addressing automation bias comprehensively, our framework, initially designed to encompass the process from data handling to the implementation of the app into clinical routines, may benefit from expansion to cover the entire lifecycle of the application.

7. Conclusion; a look ahead

In this article, it was shown that AI ethics serves as a basis to formulate ethical frameworks for interdisciplinary collaboration. In addressing the implementation gap, our paper specifically aimed to reconcile the disconnect between advanced research outcomes and their practical utilization, which was hindered by numerous ethical challenges associated with the deployment of AI products. The identified challenges posed impediments to the effective application of research findings in real-world scenarios. However, our proposed ethical framework was designed to simplify the implementation process.

The crux of our contribution lies in the elucidation of an AI ethics framework for the digital diagnosis of COVID-19 in Germany, including an overview of the implications of this framework for interdisciplinary collaboration in the realization of such a system. Having identified nine fundamental AI ethical requirements of a clinical decision support system for this purpose, including the prevention of two major challenges - alert fatigue and automation bias -, we progressed to a detailed analysis of relevant guidelines and policy papers, covering international, European, and German points of view. Our work additionally explores the interdisciplinary implications for the stages of such a proposed system's development, from data collection to use in clinical routines. The process of mapping these implications onto the development process reveals that the technological perspective on the process engages almost all the AI ethical requirements identified during the early stages of development, and that the same is true for the managerial-operational perspective at later stages. Legal and medical expertise is of particular importance at the beginning and likewise at the end of the development process. While legal specialists will take an acute interest in the ethical requirements of human autonomy, accountability and the protection of privacy, medical considerations centering patients' and physicians' autonomy will also seek to prevent alert fatigue and automation bias and to promote the comprehensibility of the underlying algorithms. Alert fatigue and automation bias represent changes in user behavior driven by the AI system, rather than by the autonomous actions and decisions of the professional using it, and therefore represent phenomena that impact on autonomy.

The consistent consideration of interdisciplinary implications on the basis of an AI ethical framework will be essential to the practice of digital COVID-19 diagnosis in hospitals. Were such a framework in place, it might help stakeholders to overcome existing skepticism around AI in general and clinical decision support systems in particular. Our framework fills a need for an actionable, interdisciplinary ethics approach tailored to a specific AI application, i.e. COVID-19 diagnosis. Our framework also has the potential to guide decision-makers as they seek to meet the challenges of a pandemic situation with the associated significant demands on resources in medical facilities.

Future research in this area could usefully attempt to validate our literature-based framework via empirical approaches and draw up a detailed evaluation of current barriers to the use of digital COVID-19 diagnosis specifically and to AI-assisted healthcare decision-making in general. The framework might also guide future operational managerial literature on the integration of AI methods into healthcare processes. The understanding of the interdisciplinary character of digital health, and specifically digital diagnosis of COVID-19, which has emerged in this study should, in our view, constitute a further key impetus for research going forward, with AI ethics supplying the overarching framework for the discussion. We believe that the process set out in this article, structured around the ethical and interdisciplinary scaffolding we have outlined, may help pave the way toward optimization of medical treatment alongside a reduction in strain on scarce healthcare resources. Specifically, our research has the potential to provide valuable insights for guiding future endeavors in related domains, such as AI-driven medical analysis in areas like cancer detection or mental disorders analysis.

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CRediT authorship contribution statement

Christina C. Bartenschlager: Writing – review & editing, Writing – original draft, Visualization, Project administration, Methodology, Investigation, Formal analysis, Conceptualization. **Ulrich M. Gassner:** Writing – review & editing, Writing – original draft, Investigation, Formal analysis. **Christoph Römmele:** Writing – original draft, Investigation, Formal analysis. **Jens O. Brunner:** Writing – review & editing, Supervision, Methodology. **Kerstin Schlögl-Flierl:** Writing – review & editing, Writing – original draft, Methodology, Investigation, Formal analysis, Conceptualization. **Paula Ziethmann:** Writing – review & editing, Writing – original draft, Visualization, Methodology, Formal analysis.

Declaration of generative AI and AI-assisted technologies in the writing process

During the preparation of this work the author(s) used ChatGPT in order to improve language and readability. After using this tool/service,

the author(s) reviewed and edited the content as needed and take(s) full responsibility for the content of the publication.

Declaration of competing interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

Data availability

Not applicable.

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