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Model for ASsessing the value of AI in medical imaging (MAS-AI)

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Abstract

Introduction: Artificial intelligence (AI) is seen as a major disrupting force in the future healthcare system. However, the assessment of the value of AI technologies is still unclear. Therefore, a multidisciplinary group of experts and patients developed a Model for ASsessing the value of AI (MAS-AI) in medical imaging. Medical imaging is chosen due to the maturity of AI in this area, ensuring a robust evidence-based model.

Methods: MAS-AI was developed in three phases. First, a literature review of existing guides, evaluations, and assessments of the value of AI in the field of medical imaging. Next, we interviewed leading researchers in AI in Denmark. The third phase consisted of two workshops where decision-makers, patient organizations, and researchers discussed crucial topics for evaluating AI. The multidisciplinary team revised the model between workshops according to comments.

Results: The MAS-AI guideline consists of two steps covering nine domains and five process factors supporting the assessment. Step one contains a description of patients, how the AI model was developed, and initial ethical and legal considerations. In step two, a multidisciplinary assessment of outcomes of the AI application is done for the five remaining domains: safety, clinical aspects, economics, organizational aspects, and patient aspects.

Conclusions: We have developed an HTA-based framework to support the introduction of AI technologies into healthcare in medical imaging. It is essential to ensure informed and valid decisions regarding the adoption of AI with a structured process and tool. MAS-AI can help support decision-making and provide greater transparency for all parties.

Keywords

Value assessment, HTA, evaluation, artificial intelligence, medical imaging

1 Declarations

1.1 Ethics approval and consent to participate

Not applicable

1.2 Consent for publication

Not relevant

1.3 Availability of data and materials

The interviews and workshop material used during the current study are available from the corresponding author on reasonable request.

1.4 Conflict of interest statement

The authors declare that they have no conflicting interests.

1.5 Funding

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1.6 Authors' contributions

IF, BSR, and KK conceived and designed the study. IF, BSR, TK, KK and MNB contributed to data collection, while all authors contributed to data analyses. All authors discussed the results and contributed to the final manuscript. All authors read and approved the final manuscript.

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2 Introduction

Artificial Intelligence (AI) includes various technologies based on advanced algorithms and learning systems. Different terms are used in connection with AI, such as machine learning, deep learning, and conventional neural networks [1]. Furthermore, there is no universally agreed-upon definition of AI, but the definition *a system capable of interpreting and learning from data to produce a specific goal* is suggested [2].

Medical specialties working with medical imaging have encountered a dramatic increase in the number of images produced over the past decade without an equivalent increase in the workforce [3]. The excessive workload and burnout among physicians contribute to more mistakes and a prolonged answering time [3]. Especially within pattern recognition, promising results have been accomplished and published across different artificial intelligence (AI) technologies and healthcare areas [4], which could significantly help medical staff and patients. However, it is important to recognize the low quality of the evidence and potential pitfalls behind the AI technology, especially in a clinical setting [5]. In addition, implementing advanced technology such as AI in a complex healthcare system could be difficult. A recent review of the scientific literature found a broad range of essential domains when assessing the impact of AI technologies; legal and ethical aspects were highlighted as important [6].

Although several reporting guidelines, frameworks, and checklists [7-12] have been presented, an evidence-based and holistic assessment tool for valuing AI technology is still needed. The abovementioned guidelines are either not evidence-based [8, 11] or rather narrow, e.g. focussing on reporting of clinical outcomes [7, 9], clinical performance metrics, validation, or robustness of the model [10, 12]. Health technology assessment (HTA) provides a broad framework for evaluating healthcare technologies, with several examples being tailored for specific areas and digital healthcare services [13, 14]. HTA is a multidisciplinary process which summarizes information that has been collected in a systematic, transparent, unbiased, and robust manner [15]. One example is the HTA based MAST (Model of ASsessment of Telemedicine), which has been accepted and used widely [16]. MAST has been used, adapted and adjusted for assessment of telemedicine projects in rural areas in Germany [17]. Also, a review of the use of MAST in European telemedicine projects was described by Ekeland and Grøttland [18], and MAST has been used as a framework for assessment of telemedicine in several European telemedicine projects, including more than 29,000 patients [19]. Recently the MAST was chosen as a tool/assessment framework within the area of AI [20] despite not being adapted for this area - underlining the need for an assessment tool for AI which includes assessment of safety, clinical outcomes, economic consequences and organizational impact.

This study presents the development of a specialized HTA model for evaluating AI technologies within medical imaging

– The model of assessment of artificial intelligence (MAS-AI). Medical imaging is chosen due to the maturity of AI in this area, ensuring a robust evidence-based model. The purpose of the framework is to support decision-makers when deciding whether or not to invest in AI technologies in medical imaging.

3 Methods

MAS-AI was developed by a multidisciplinary group of experts and patient representatives from Denmark, i.e., HTA experts including health economists, clinicians, technical, legal, and ethical experts, and patients. A mixed method approach was used combining data from different sources and the MAS-AI guideline development was structured into three phases. First, we reviewed the existing guides, evaluations, and assessments of the value of AI in the field of medical imaging. In total, 5890 studies were assessed, while 86 studies were included in the scoping review. Eleven essential domains were identified: 1) health problem and current use of technology, 2) technology aspects, 3) safety assessment, 4) clinical effectiveness, 5) economics, 6) ethical analysis, 7) organizational aspects, 8) patients and social aspects, 9) legal aspects, 10) development of AI algorithm, performance metrics and validation, and 11) other aspects. The frequency of mentioning a domain varied from 20 percent to 78 percent within the included papers. See the published study for more details [6]. Next, we conducted interviews with six leading researchers in AI in Denmark, lasting from 45 min to 90 minutes. Interviews added new subtopics for some of the eleven domains identified through the review, but no new domains were identified. The third phase consisted of two full-day workshops with decision-makers, patient representatives and researchers in Denmark. The multidisciplinary team revised the model between the workshops according to comments from the workshop participants.

3.1 Details about the workshops and model development

On the 20th of September 2021, we held the first MAS-AI workshop with 18 participants in Odense, Denmark. Participants were divided into groups for the group work. Participants included five decision-makers from hospitals or the regional healthcare sector, one patient representative and twelve experts within various AI domains, i.e. researchers and clinicians. Experts were radiology and nuclear medicine clinicians, three professors in data science, ethical and health aspects of AI, a researcher in anthropology, and HTA experts. There were three facilitated group sessions. During the first two sessions, participants discussed crucial domains and topics when evaluating AI based on results from the review and the interviews. In the last session, overall advice for the model work was discussed. The multidisciplinary team revised the model between workshops according to comments from workshop participants. For instance, at the first workshop, eleven domains were presented and discussed, and participants voiced a need for simplifications and a step-wise approach. Thus, at the second workshop, a model with nine domains and two steps was presented and discussed.

On the 22nd of November, the second MAS-AI workshop was held in Odense, Denmark with a total of 19 participants who were divided into groups for the group work. Participants included four decision-makers from hospitals or the regional healthcare sector level, two patient representatives and 13 experts within various AI domains, i.e. researchers and clinicians. Experts were radiology and nuclear medicine clinicians, a professor in ethical aspects of AI, two representatives from The Danish Medicines Agency, a legal expert, and HTA experts. One facilitated group session was held with several plenum discussions about the revised model. Again, the multidisciplinary team revised the model according to comments from workshop participants. Also, the model development was supported by answers from a Delphi questionnaire indicating which topics and subtopics were considered most important by the participants. Lastly, a final model was circulated via email to participants of the workshops for their final comments. The following paragraph presents the MAS-AI model.

4 Results

The MAS-AI model has three parts and Figure 1 provides an overview of the content of these parts. There are two steps covering nine domains and process factors for an MAS-AI assessment. Note that the order of domains has no particular significance. Step one contains a description of patients, how the AI model was developed, and initial ethical and legal considerations. Finishing the four domains in step one is a prerequisite for moving to step two. In step two, a multidisciplinary assessment of outcomes of the AI application is done for the five remaining domains: safety, clinical aspects, economics, organizational aspects, and patient aspects. The last part consists of five process factors to facilitate a good evaluation process.

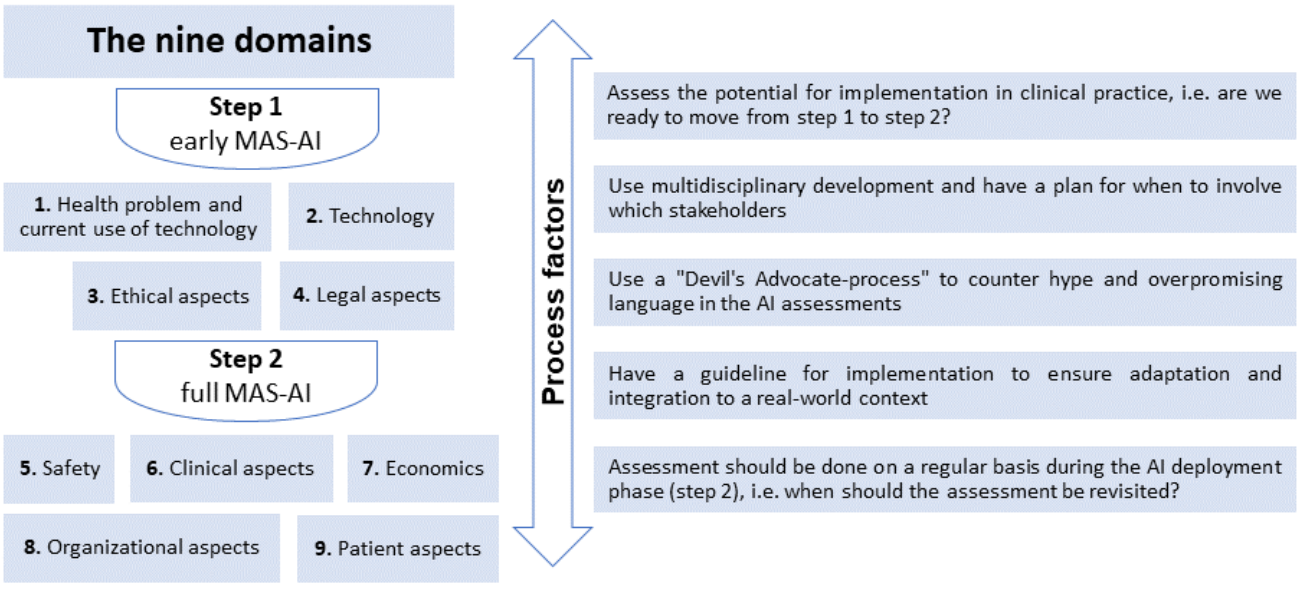

Figure 1 Overview of MAS-AI

Finishing both steps is a complete MAS-AI assessment. Finishing only the first step is considered an "early MAS-AI", i.e. an initial assessment in the stage when only limited data are available in a few domains. Hence, step one can be seen as a pre-screening, and if step one turns out positive, the second step can proceed.

4.1 Resume of all nine domains

Table 1 shows a brief description of the content of all nine domains. It is important to mention that MAS-AI utilize an existing checklist, e.g., "Checklist for Artificial Intelligence in Medical Imaging (CLAIM)", see Mongan et al. (2020). The CLAIM guideline has 42 items which are all incorporated into MAS-AI. The full description of all domains, including specific outcomes can be found in the online Supplementary S1, which contains the complete MAS-AI guideline.

Domain	**Brief description of the content**
1) Health problem and description of the application	• Health problem of the patients (e.g. burden of disease, current treatment of patients) • Description of the application (e.g. what does the AI intervention include) • Study objectives (hypotheses), the study design of the model evaluation, and the aim/goal of the study
2) Technology	• Development, performance and validation of the AI model (the CLAIM guideline) • Maturity (history of prior use and vendor credibility) • Compatibility & Adaptability (application fit with operator's context) • Manageability (level of control provided to the operator of the application) • Security (aspects of integrity and availability, cyberattacks) • Usability (human-computer-interaction perspectives)
3) Ethical aspects	• Is the AI application integrating Ethics by Design? • Beneficence and patient integrity (e.g., risk of over-diagnosis, risk of misdiagnosis/patient harm) • Privacy (e.g., patient confidentiality) • Equity (e.g., equitable use and access to AI applications) • Trust, transparency, accountability, and responsibility (risk of lack of confidence in the AI) • Autonomy (e.g., ensure human oversight and control of AI applications)
4) Legal aspects	• With relevant legal counselling, map the legal landscape for the entire lifecycle of the AI application • Are the legal requirements (the legal landscape) transformed into functionalities in the AI application? • Is the AI application CE-marked following the MDR regulation?
5) Safety	• Clinical safety (e.g. impact on the safety of patients and staff, adverse events) • Technical safety (e.g. technical reliability of IT systems or platforms) • Continues monitoring of safety and new practice (e.g. establish quality assurance (QA) program) • Upcoming challenges regarding safety assurance
6) Clinical aspects	• Sensitivity, specificity, and receiver operating characteristic curve (ROC) • Effects on morbidity (effects on incidence or prevalence of a disease or condition) • Effects on mortality (e.g. effects on the number of cancer-related deaths) • Time to event, e.g., time to treat or decision • Effects on quality of life (e.g. effects on QALYs)

Domain	Brief description of the content
7) Economic aspects	• Societal economic evaluation (e.g. cost-effectiveness analysis) • Business case (e.g. expenditures and revenue in total for a hospital during the first years) • Use of health service (e.g. effects on the number of medical imaging examinations)
8) Organizational aspects	• Consequences for the workflow (e.g. task shifting, change in time spent on specific tasks) • Consequences for the user (e.g. patient and clinician acceptability, trust, and convenience) • Implementation requirements and culture (management anchoring, cultural mindset or norms among staff, extent of "no-use" of AI among clinicians) • Consequences for roles (e.g. does the AI application change clinical decision making)
9) Patient aspects	• Patients' willingness and satisfaction (e.g. effects on subscales for patient satisfaction) • Technical improvement during imaging process (e.g. shortening scanning time) • Clinical-based patient benefits (e.g. ensuring earlier diagnosis, continuous monitoring) • Overall patient and social benefits

Note: See the list of abbreviations.

Table 1 Description of the content of all domains in MAS-AI

The information and data needed for assessment of the nine domains will come from different sources. Information for the domains in the first step will often be available from the company that produces the AI solution, while the legal issues typically will require legal counselling from hospital staff. Data for the remaining domains in step 2 will primarily be supplied by the healthcare organization that is going to deploy the AI solution and / or HTA experts. The online Supplementary S2 provides cases as examples of how to use MAS-AI. A MAS-AI assessment will typically be around 5-10 pages, including a one-page executive summary.

4.2 Process factors for a MAS-AI assessment

The following five factors should be considered during the process of assessing an AI technology:

1. Assess the maturity: Judge the potential for clinical practise implementation through classification in development phases, i.e., are we ready to move from step 1 (project phase) to step 2 (operation phase)?
2. Use multidisciplinary development with active participation across all stakeholders – make a plan for when to involve which stakeholders.
3. Use a "Devil's Advocate-process" to counter hype and overpromising language in the assessments of AI, e.g., by having people in the assessment team who are sceptical towards the AI application.
4. The organization should have a guideline for implementation to ensure adaptation and integration to real-world existing workflows and context.
5. Assessment should be done on a regular basis during the AI deployment phase, so when should the assessment be revisited?

5 Discussion

To our knowledge, no evidence-based and holistic framework has yet been presented to assess AI in medical imaging. We present the MAS-AI as a structured approach for assessment of AI technology in three parts. Two steps cover nine domains, and subsequently there are process factors relevant for the MAS-AI assessment. Step one is a description of patients, the AI model developed, and initial ethical and legal considerations. Finishing the four domains in step one is a prerequisite for moving to step two. In step two, a multidisciplinary assessment of outcomes of the AI application is done for the five remaining domains: safety, clinical aspects, economics, organizational aspects, and patient aspects. Lastly, the model includes five process factors to facilitate the evaluation process.

As stated in a recent review by our group [6], a multifaceted, structured process and tool are needed to facilitate AI's implementation in the healthcare system and provide greater transparency. The MAS-AI was developed based on HTA, a robust and well-known assessment tool for decision-makers with specific reference to the EUnetHTA framework [21]. Also, the Checklist for Artificial Intelligence in Medical Imaging (CLAIM), a similar method well-proven, was an important inspiration [10]. Further, in contrast to other guidelines or frameworks [12, 22], the MAS-AI assessment model is built not only on concepts or viewpoints (e.g., experts' opinions, consensus statements) but on peer-reviewed evidence, interviews, and workshops. This approach ensures a high level of evidence combined the relevant knowledge and expertise from stakeholders, decision-makers, patients, and other experts. In addition, the workshop and interview participants were selected to reflect end-users and support the interdisciplinary collaboration AI evaluations call for.

In developing the model, we observed topic overlap (especially between ethical, legal, and patient domains). Although significant efforts were invested in separating the domains, some overlap remains – a more structured approach could have reduced the problem, e.g. formal content mapping of the workshop outputs. Further, HR-Quality of life is considered a clinical effect/outcome in HTA Core Model from EUnetHTA. However this outcome could also be in the patient domain as in the Canadian "decision determinants" framework [23]. Medical imaging is a broad term which could be viewed as a limitation. However, in the field of telemedicine, which like AI covers a broad range of different technologies and approaches, it was possible to develop a common framework for valuing different types of telemedicine technologies (i.e. the MAST model: Model for Assessment of Telemedicine). The MAS-AI aims to be a broad framework, e.g. covering both supervised and unsupervised techniques. However, we acknowledged that local adaption to the model could be necessary and developed further in specific areas. The model is currently undergoing a local validation and an external validation in Canada.

One of the major strengths of MAS-AI is the team behind the model. It consisted of an interdisciplinary group reflecting the complexity of AI [22], thus covering all the identified domains in the model with specific experts within each field. Also, patients were an active part of the development of MAS-AI and one is a co-author of this article. To our knowledge the MAS-AI is the first model that aims to cover all types of AI, thus covering both supervised and unsupervised techniques.

5.1 Transferability and perspectives

Medical imaging was chosen as an area of interest mainly due to the maturity of AI in medical imaging, ensuring a robust evidence-based model. Furthermore, most of the evidence was retrospective with scarce clinical prospective studies, thus limiting the model's clinical effectiveness, organizational and economic aspects. This could restrict the use of MAS-AI to medical imaging, although we believe that most domains have a high level of transferability to other AI healthcare areas. The domains with least transferability are the once including the elements from the Checklist for Artificial Intelligence in Medical Imaging (CLAIM) which are specific to medical imaging, i.e. domains 1 and 2.

Further, decisions about which AI technology to use and implement in health care can be structured differently and based on different decision levels between countries. This condition affects the transferability of MAS-AI. MAS-AI is primarily an assessment model whose main target group are decision-makers in health care, e.g. medical directors, head of departments at hospitals, local or national treatment councils, procurement organizations, etc. However, developers, researchers, and clinicians could also use the MAS-AI to guide the development, data collection, or research process. Further, the regulatory side, e.g. policymakers from the government and HTA organizations or other regional and national authorities, may also find parts of MAS-AI helpful. Thus, MAS-AI may provide input to an evaluation in the entire lifespan of an AI technology. However, it is important to underline that MAS-AI is not intended as a "one-size-fits-all"-evaluation model. If the AI application is not very patient-critical, less rigorous evaluation might be appropriate.

The next phase includes empirical tests of MAS-AI usability. A validation workshop has been conducted in Toronto with Canadian health care decision-makers and policymakers, AI researchers, clinicians, and patient organizations. Preliminary results (unpublished) from this workshop indicate that MAS-AI is relevant in a Canadian context based on a Delphi questionnaire regarding the perceived importance of the different types of information included in an MAS-AI assessment. Further research is planned to validate the framework in the Canadian context and explore the context specificities reflected in certain domains of framework and its implementation challenges in the Canadian setting. Thus, the transferability of MAS-AI between Denmark and Canada will be thoroughly investigated. Also, we believe MAS-AI

is sufficiently generic to be relevant for assessing other types of AI technologies in healthcare. However, this claim needs to be validated.

6 Conclusions

We present a holistic model for assessing artificial intelligence in medical imaging applications. This framework could provide a strong foundation for evaluation and help decision-makers and other stakeholders make informed decisions when deliberating about or choosing to implement AI technologies. Secondly, we hope that MAS-AI will guide researchers and policymakers to conduct and evaluate AI research and ensure that only technologies that produce value for money are implemented in the health care systems globally.

7 List of abbreviations

AI = Artificial Intelligence

CE = Conformité Européene

CLAIM = Checklist for Artificial Intelligence in Medical Imaging

HTA = Health Technology Assessment

MDR = Medical Device Regulation

QA = Quality Assurance

QALY = quality-adjusted life year

ROC = receiver operating characteristic curve

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