

Introduction

This is a the third round questionnaire to establish a Delphi consensus among experts on an Ethical use of Medical-AI.

Questions are based on a Likert scale. State if you agree or disagree with each statement. Use the Statement space provided for any additional feedback.

Thank you for your time!

The questionnaire is divided into 6 blocks:

- Bioethical problems of using medical-AI.
- Ethical values.
- New bioethical principles.
- Guidelines for a bioethical use of medical-AI.
- Checklist for clinicians.
- Institutional Ethical Assurance

Before starting the survey, here are a few points and definitions we would like to make clear:

When answering the survey think about AI in the healthcare setting, not AI in general.

What we mean by Artificial Intelligence: there is no consensus on what is AI. Russell and Norvig, in their AIMA texts (1995, 2002, 2009), identify AI in relation to its goals. They identify 4 categories to define AI as a system that:

1. Thinks like humans.
2. Acts like humans.
3. Thinks rationally.
4. Acts rationally.

More recently, Stanford's AI100 defined AI as "getting a machine to carry out behaviors that we think of as requiring intelligence"

We hope this clarifies some ideas about AI. When answering the survey please take into account current healthcare AI technologies, as well as foreseeable, likely, future developments and uses of AI in Healthcare.

By autonomous AI we mean a system that is capable of carrying out its tasks without requiring direct human instruction or real-time supervision.

Lastly, Control is the set of techniques, constraints, and oversight systems used to guide, limit, or regulate an AI system's behavior so that it acts within desired boundaries and achieves intended outcomes without causing unintended or harmful consequences.

General Background Information

Gender

- Male
- Female
- Prefer not to say

Geographical location

- Africa
- Asia
- Europe
- North America
- Oceania
- South America

In what of the following fields is your main background

- Healthcare
- Business
- Policy maker
- Researcher / Academic
- Law specialist
- IT / AI specialist
- Pharmaceutical company representative
- Patient representative / Advocate

Other

Other:

SOCIAL RESPONSIBILITY MARKERS

Block: Institutional Use of Medical-AI

We also aim at establishing markers for risk management and adverse event reporting by institutions (such as hospitals) that use Medical-AI.

When answering this section, think of a hospital (or other institution that uses Medical-AI) and state if you agree or disagree with each statement being used to evaluate or even audit their risk management and adverse event reporting, and in general helps to report that they are doing an ethical use of Medical-AI

In a sense, this could act as an institutional assurance checklist.

Please state if you agree or disagree with each item being used to guarantee an ethical use of AI by medical institutions. If you would like to comment feel free to do so in the Statements box provided below.

Note: by discrepancies we mean differences in proposed paths of action.

	Strongly disagree	Somewhat disagree	Neither agree nor disagree	Somewhat agree	Strong agree
Were the medical devices that use AI sufficiently validated to be used safely? If yes, explain how and what validation standards were followed. If not, explain why this technology is being used regardless of validation and what protocols are being implemented to ensure the technology is safe and accurate for use	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Are the Healthcare Professionals in charge of using medical devices that incorporate AI informed and knowledgeable of the risks of using these AI devices? Explain what steps were taken to assure this. If not, explain why.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
How much money has been spent on topics related to Medical-AI (such as acquisition and maintenance costs)? Explain why spending money on this technology is better option than other (also necessary) non-AI resources, and if any money has been saved due to this.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Are the Healthcare Professionals in charge of using medical devices that incorporate AI trained and knowledgeable on how to interpret the output provided by these AI devices? Explain what steps were taken to assure this. If not, explain why.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

Is there a way of knowing when a medical device that uses AI is behaving in an unexpected or dangerous way? If yes, explain which one. If not, explain why it is been used regardless.

Have there been any complains or notifications regarding possible biases of medical systems that use AI? If yes, how many? What measures have been taken to address future issues like this one? Explain these measures.

When were the medical devices that incorporate AI last maintained, supervised and updated? How regularly is this process done?

Have there been any complains or notifications regarding lack of trust on medical systems that use AI? If yes, how many? What measures have been taken to address future issues like this one? Explain these measures.

Has there been any breaches in informed consent where an AI system was involved? If yes, how many? What measures have been taken to address future issues like this one? Explain these measures.

Have there been any complains or notifications regarding discrepancies between medical systems that use AI and Healthcare Professionals? If yes, how many? What measures have been taken to address future issues like this one? Explain these measures.

Have there been any complains or notifications regarding unclear accountability and responsibility related to medical systems that use AI and Healthcare Professionals? If yes, how many? What measures have been taken to address future issues like this one? Explain these measures.

Has there been any violation of human rights where an AI system was involved? If yes, how many? Have any measures been taken to address these issues in the future? Explain these measures.

Did the medical devices that use AI address ethical issues during the development process? If yes, explain how and what possible issues could have been left out. If not, explain why this technology has been used regardless of not addressing ethical issues during development.

Have there been any complains or notifications regarding lack of control over medical systems that use AI? If yes, how many? What measures have been taken to address future issues like this one? Explain these measures.

Statement:

CHECKLISTS FOR CLINICIANS

Block: Checklist for Clinicians

Based on a previous review of the literature regarding the bioethical issues and solution proposals for a bioethical use of Medical-AI, we developed a checklist clinicians could use in their medical practice. This checklist aims to aid clinicians during moral deliberations regarding the use of Medical-AI, as well as help them identify bioethical problems they must avoid. Please

state if you agree or disagree with this checklist. If you would like to add new points, remove some points or give any additional feedback, feel free to do so in the Statements box provided below.

	Dislike a great deal	Dislike somewhat	Neither like nor dislike	Like somewhat	Like a great deal
What would my clinical judgement be, if I did not use this AI?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Is there anyone I can contact in case I need help regarding the use of this AI?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Am I properly trained to use this AI?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Do I know who to contact to report a complaint or adverse event with the AI tool?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Can I trust this AI?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Do I have sufficient control over this technology?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Does this decision taken with AI impact Human Rights?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Do I Know if ethical issues were addressed during the development process?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

Statement:

GUIDELINES FOR A BIOETHICAL USE OF MEDICAL-AI

Block: Guidelines For a Bioethical Use of Medical-AI

Here you will find a list of proposals to deal with the bioethical issues of Medical-AI. These proposals intend to guarantee an ethical use of Medical-AI. Please state if you agree or disagree with the following proposals to guarantee a Bioethical Medical-AI. If you would like to propose any other solutions, amendments to these proposals or any other further reasoning, feel free to do so in the Statements boxes provided below.

Solutions should be specific

	Strongly disagree	Somewhat disagree	Neither agree nor disagree	Somewhat agree	Strongly agree
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Other than the general solutions proposed, solutions for use of AI in medicine should be assessed on a case-by-case basis as there are many variables to consider. But always taking into consideration this guidelines.

Guidelines - Responsibility

Responsibility

	Strongly disagree	Somewhat disagree	Neither agree nor disagree	Somewhat agree	Strongly agree
Humans are always responsible for AI actions	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Healthcare workers, specifically, are to be held accountable for the actions involving AI in healthcare.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Responsibility should also be shared with regulatory bodies that approve medical AI	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Responsibility should also be shared with patients themselves	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Responsibility should also be shared with the Health Institution or corporation that bought the AI	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
There must be shared responsibility between all stakeholders mentioned	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Responsibility should also be shared with the individual person using the Medical-AI	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Responsibility should be decided based on the specific circumstances and the particulars of each situation	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
The degree of responsibility of each stakeholder should depend on the specific circumstances and the particulars of each situation	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

Statement:

Guidelines - Explicability

Explicability

	Strongly disagree	Somewhat disagree	Neither agree nor disagree	Somewhat agree	Strongly agree
Individuals are currently not able to properly challenge the results provided by algorithms, so individuals must have the right to an explanation of how and why AI took a decision.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
It is important for healthcare professionals working with AI to be prudent, as explicability might not be possible.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Explicability should not be absolute, as healthcare professionals and patients do not have to understand and have an explanation for EVERYTHING the AI does, but rather just enough to take informed decisions.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

Statement:

Guidelines – Informed Consent

Informed Consent (IC)

Here we want to establish when would Informed Consent be required in cases were a Medical-AI is involved.

There are many cases of new medical technologies were IC is not generally required. For example, electronic medical records, were IC is not required . With previous medical technology IC is generally not required, but based on specific circumstances it might be required.

Here we want to know if AI should follow the trend of previous medical technologies, were IC not required generally but it is required in some specific circumstances, or if, on the other hand, IC should generally always be required, and not required in some specific circumstances.

Strongly Agree	Somewhat Agree	Neither Agree nor Disagree	Somewhat Agree	Strongly Disagree
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IC should generally NOT be required, even though there might be specific situations or circumstances were an IC IS required regarding the use of Medical AI.

<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
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IC should generally BE required, even though there might be specific situations or circumstances where IC is NOT required regarding the use of Medical AI.

IC should ALWAYS be required.

The implementation of IC in relation to Medical-AI should depend on the specific Medical-AI and the specific situation where it is being used.

Statement

Guidelines - Embedded Ethics

Embedding Ethics into AI Design

Strongly disagree Somewhat disagree Neither agree nor disagree Somewhat agree Strongly agree

A value sensitive design could mitigate some ethical concerns regarding AI. This is, to introduce values directly into the AI during development.

Ethics must be integrated into the AI (Embedded ethics), to make the AI an ethical agent.

Patients must have the opportunity be involved in the development process of Medical-AI.

Embedded ethics is not enough, by it self, to guarantee an ethical AI, therefore other measures, such as human oversight should be used.

For an AI to perform "ethically", we cannot expect to "implement ethics in the system" (we cannot use embedded ethics), rather, we must design the AI to be functional in context, including contexts of oversight and review.

Statement:

Guidelines - Constant Learning

Constant Learning

Strongly disagree Somewhat disagree Neither agree nor disagree Somewhat agree Strongly agree

Regardless of Human oversight, Medical-AI should be self-improved, constantly receiving new data to improve its performance an avoid unnecessary harm.

Statement:

Guidelines - Control

Control

Strongly disagree Somewhat disagree Neither agree nor disagree Somewhat agree Strongly agree

Medical-AI must only be used to aid in healthcare professional's decision making (use AI only as a tool). (Note: not necessarily physicians only)

Medical-AI should only be used by physicians or under physician orders.

Medical-AI must always be controlled by healthcare workers. Autonomous AI must be avoided.

Statement:

Guidelines - Continuity of Care

Continuity of Care

Strongly Disagree Somewhat Disagree Neither Agree nor Disagree Somewhat Agree Strongly Agree

Patients must be granted appropriate, quality care and continuity of care, with alternative and adequate means or methods, in the case they voluntarily reject the use of Medical-AI on their health.

Statement

Guidelines - Data Management

Data Management

Strongly disagree Somewhat disagree Neither agree nor disagree Somewhat agree Strongly agree

Dynamic informed consent models should be used. Dynamic consent models aim at embedding evolving data subject preferences into an open communication process between participants and researchers. When data is used and reused for different research projects, they are only used according to the indicated preferences of participants, who are notified of such use.

There should be dynamic informed consent models where participants can withdraw their personal data at any given time for any reason.

Informed Consent might not always be necessary for the use of AI on patient health.

Statement:

Guidelines - Validating AI

Validating AI

Strongly disagree Somewhat disagree Neither agree nor disagree Somewhat agree Strongly agree

An impact assessment should be carried out prior to the implementation of each Medical-AI to make sure benefits outweigh the negative effects of using medical-AI

Medical-AI should only be used in the general population after appropriate medical clinical trials are carried out.

It should be openly stated what population what used to train a certain medical-AI.

Statement:

Guidelines - Training

Training

	Strongly disagree	Somewhat disagree	Neither agree nor disagree	Somewhat agree	Strongly agree
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Accreditation must be needed to use Medical-AI, provided prior training, when using Medical-AI.

Accreditation might NOT always be needed to use Medical-AI, provided prior training, when using Medical-AI.

Statement:



ETHICAL VALUES

Block: Ethical Values

To address the bioethical issues of Medical-AI, we must consider important ethical values. Please state which values we should consider when addressing an ethical use of Medical-AI.

Take into account we are talking about values, more generally, not specific principles.

These are NOT values AI should reflect or represent, but rather, values healthcare professionals should integrate into their practice to make an ethical use of Medical-AI.

	Strongly disagree	Somewhat disagree	Neither agree nor disagree	Somewhat agree	Strongly agree
Governance	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Rule of Law	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Lawfulness	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Democracy	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

Human Rights	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Teamwork and Cooperation	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Solidarity	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Inclusivity	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Diversity/Pluralism	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Accessibility	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Sharing of benefits	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Human Dignity	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Body and Mental Integrity	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Application of Human Values	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Empathy and Compassion	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Vulnerability	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Awareness of Misuse	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Caution	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Relevance	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Utility	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Interpretability	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Trustworthiness	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Explicability	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Contestability	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Sustainability	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Penalty for non-compliance	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Respect for religious, ethnic, and cultural identity	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Primacy of individual human life value	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

Statement:

NEW ETHICAL PRINCIPLES

Block: New Bioethical Principles

To address the bioethical issues of Medical-AI, several new ethical principles have been proposed. By “new bioethical principles” we mean principles other than the main four bioethical principles proposed by Beauchamp and Childress: Autonomy, Non-Maleficence, Beneficence and Justice.

Here we are talking about principles, not values. We can have many values, for example: human dignity or respect for human life, governance..., but few principles.

It is important to know that our goal is to establish which of the following principles has enough intrinsic value in it self, not instrumental value.

To clarify, this part of the survey is about new ethical PRINCIPLES

other than autonomy, non-maleficence, beneficence and justice; NOT about values or virtues necessary for a bioethical use of Medical-AI. Take into account the 4 main bioethical principles and think which of the following has enough intrinsic value, if any, to be considered independent ethical principles.

New Bioethics Principles

	Strongly Disagree	Somewhat Disagree	Neither Agree nor Disagree	Somewhat Agree	Strongly Agree
Accountability and responsibility has enough intrinsic value to be considered an independent new bioethical principle.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Explicability, has enough intrinsic value to be considered an independent new bioethical principle.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Transparency, has enough intrinsic value to be considered an independent new bioethical principle.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Trustworthiness, has enough intrinsic value to be considered an independent new bioethical principle.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

Statement

BIOETHICAL ISSUES OF THE USE OF MEDICAL-AI

BLOCK: Bioethical problems of using medical-AI.

On a previous review, we classified Bioethical issues derived from the use of medical-AI into the following categories.

State if you agree or disagree with each of these categories being a bioethical issue of relevance:

	Strongly disagree	Somewhat disagree	Neither agree nor disagree	Somewhat agree	Strongly agree
Effect of AI on clinical relationships	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Self-regulation (by this we mean business could develop their own internal standards of ethical use of AI with no external coercion to enforce them)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

Technological imperialism: AI developers having a monopoly over AI and gaining excessive power over healthcare.

Drug development: AI could be used to cut safety regulations that help make drugs safe.

Health Law

Human rights: AI could violate Human Rights

Employment (such as AI increasing unemployment and taking over jobs).

Beneficence

Maleficence: AI could harm patients

Statement:

Bioethical issues

Strongly Disagree Somewhat disagree Neither agree nor disagree Somewhat agree Strongly agree

Bioethical issues should be analyzed specifically and depend on the particular factors of each situation.



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