

REVIEW ARTICLE

The Ethical Challenges of Artificial Intelligence (AI) Algorithms in Health Care

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Abstract

Generative artificial intelligence (AI), a groundbreaking health care technology in the United States, could create ethical challenges without proper safeguards. Of particular concern are AI clinical algorithms, which critics claim could magnify harmful biases and exacerbate health disparities. Since initiation of three class action lawsuits in 2023, alleging AI insurance coverage algorithms denied medically necessary care via an almost fully automated claims decision process, largely devoid of human oversight, such has become a public concern. Our case illustration details major flaws in application of such a coverage algorithm, as an elderly Medicare Advantage Plan beneficiary is left without access to essential medical care. Although advocates at the state and national level are seeking remediation, such practices will likely persist, as insurers know only a small percentage will appeal these denials. It is apparent these algorithms are not a “crystal ball for care,” as human input is needed at critical junctures in the process. The design, development and deployment of these AI tools must be done in the utmost ethically responsible way, similar to what some health entities have already accomplished. Such perhaps can be best accomplished by adhering to the ethical principles established by the World Health Organization. By doing so, key stakeholders can help assure that these generative AI clinical support tools are utilized as support tools, and do not replace the clinical team while preserving human oversight.

1. Background

Artificial Intelligence (AI) in the health care field in the United States (US) is rapidly becoming a groundbreaking technology with the potential to benefit public health in numerous ways. However, the latest version of AI, which is called generative AI, comes with a set of trade-offs that could create ethical dilemmas without proper safeguards, as opposed to the earlier version of AI, which is often called traditional AI or narrow AI. An understanding of the difference between the earlier and latest versions is essential to discerning the potential pitfalls of the latest version. Whereas traditional AI focused on performing a specific task, generative AI, which is the next generation of AI, can create something new from pieces of information supplied to it. In essence,

generative AI models can be trained on a set of data and then learn the underlying patterns to generate new data which can mirror the training set.¹

AI clinical decision support algorithms are a form of generative AI, which are increasingly utilized in the field of health care worldwide; however, their usage could potentially be magnifying harmful biases and exacerbating health disparities.² Addressing these potential biases goes beyond ensuring fair and just opportunities for optimal health outcomes, as a key aspect of it will also promote universal safeguards for patient safety.³ AI coverage algorithms are now widely utilized by health insurers to make payment decisions, which can impact millions of individuals in the US, especially the elderly in post-acute and long-term care settings.

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The potential misuse of these AI coverage algorithms by health care insurers is now becoming a matter of public concern. On July 24, 2023, a federal class action lawsuit was filed in California's eastern district against Cigna Healthcare, alleging that it violated California law by using such an algorithm to "deny payments in batches of hundreds or thousands at a time," in conjunction with an almost fully automated claims decision process.⁴ In spite of the seriousness of these allegations and the scope of its impact, the initial news report of the California class action lawsuit generated little attention by the bulk of the US news media.

Another class action lawsuit, however, is garnering more attention, as it involves Medicare Advantage insurance plans, which insure the elderly and the disabled. On November 14, 2023, a proposed class action lawsuit was filed in US District Court of Minnesota, alleging that UnitedHealth Group Inc, the nation's largest private health insurer, uses an AI coverage algorithm that systematically denies elderly patients' claims for extended care such as nursing facility stays.⁵ According to the report, the lawsuit focuses on an AI coverage algorithm, which is known as nH Predict, developed by NaviHealth Inc, a company UnitedHealth acquired in 2020, which it contends that UnitedHealth utilizes to evaluate and systematically deny claims for post-acute care, which includes stays in skilled nursing facilities, and also for in-home care. The complaint notes that about 90% of these coverage denials are reversed when appealed to federal administrative law judges, which demonstrates the "blatant inaccuracy" of the algorithm. The lawsuit alleges that the use of this AI algorithm violates patients' contracts and the insurance laws of many states by deciding claims without properly evaluating them.

Yet another class-action lawsuit was filed on December 12, 2023 against health insurer Humana, alleging that it has been using an AI coverage algorithm that systematically denies seniors rehabilitation care recommended by their doctors, making it the second major health insurer to be accused of using an AI tool to restrict medically necessary care for Medicare Advantage plan (MAP) patients.⁶

By mid-2024, at least 40 states have introduced or passed legislation in regard to AI regulations, with the central focus on oversight of insurers who use AI tools to help expedite coverage decision.⁷ The Bloomberg news report notes that insurer groups argue that these state measures go too far, due to the limited authority of these states, which could

complicate the establishment of common standards on these issues. It also raises the point that although consumer protection and insurance laws have mainly been a state function, AI is clearly different in that it is being promulgated at the national level, and for that reason, it should not be regulated by states.

At the national level, a bipartisan group of lawmakers, in a letter sent on June 25, 2024, called upon the Centers for Medicare and Medicaid Services to toughen oversight of AI and algorithmic tools that discriminate against the elderly and infirmed.⁸ However, in spite of allegations by critics which claim that these insurers utilize flawed technologies, such practices may well continue, as only a small percentage of policyholders appeal these claim denials. In addition, the financial incentive will remain for these insurers to continue to fight these class action law suits in the court system, which may drag on for years, knowing that it will cost them relatively little in comparison to the huge amounts of expenditures that they will save as a result these denied claims.

2. Mounting Public Frustration with Health Insurers

These class action lawsuits may perhaps be the tip of the iceberg of an emerging public health care concern, as critics claim that these non-transparent AI coverage algorithms selectively overlook factors favorable to a patient's insurance claim while relying almost exclusively on other factors which favor claim denial, and which, in turn, remove or rubber stamp the human element from the overall decisional process to the detriment of the patients, resulting in potential harm to those who have been denied necessary medical services.

As a result of the fallout from these lawsuits and widespread public dissatisfaction with the health insurance industry, a landmark California law (SB 1120), also known as the "Physicians Make Decisions Act," went into effect on January 1, 2025, which requires that health insurers in the state must have a licensed physician or qualified health care provider directly involved by reviewing and deciding the merits of any denial, delay, or modification of care which is based on medical necessity.⁹ The intent of this legislation is to prevent insurers from denying medical necessity claims based solely upon AI coverage algorithms. In view of the scope of this problem which was at the core of these class action law suits, it seems likely that other states will consider similar legislation.

Perhaps the public reaction to the coldblooded, execution-style murder of Brian Thompson, CEO of UnitedHealthcare, the nation's largest health care insurer, on December 4, 2024, is most revealing of the low regard that many Americans presently hold for health insurers.¹⁰ Rather than expressing remorse for the senseless killing of this 50-year-old father of two, the initial news coverage revealed just the opposite public reaction, as many instead expressed feeling of exasperation, helplessness, anger and resentment toward health insurers, recanting personal stories of how their loved ones were denied medically necessary coverage and suffered greatly at the hands of these corporate giants. Based upon the public sentiment thus far expressed toward these health insurers, several of which were named in these class action law suits, it, indeed, leads one to ponder what measures need to be taken to restore trust and accountability to the claims review process.

3. Case Illustrating Potential Harm from Misuse of AI Coverage Algorithms

This composite illustration is drawn from similar case scenarios, which involve denials of continued care by MAP insurers, based upon AI coverage algorithms. Andrew Jones, an 87-year-old male, was recovering from triple vessels coronary bypass and an aortic valve replacement at a Pennsylvania nursing home in December 2023 when he received a notice from his MAP that it would no longer cover his care because he appeared well enough to go home. It stated that after receiving 9 days of restorative rehabilitation that he was now able to walk 50 feet with a rolling walker with supervision, and that further rehabilitation therapy could be provided in an outpatient setting.

The denial letter, however, did not mention that he could not yet climb stairs due to a partial right femoral neuropathy, a complication from the intra-aortic balloon pump used during the surgery, and that he still suffered from congestive heart failure which was slowing improving with the combination of Furosemide and Metolazone, but that it significantly limited his endurance and stamina. Mr. Jones, a widower, was living alone in a split-level house prior to the surgery. In order to access his home, he would have to climb 4 steps to get to his front door. Once inside, he had to climb an additional flight of stairs to get to his bedroom.

Mr. Jones was extremely upset when he received the denial notice, and he immediately contacted Dr. James, his attending physician at the nursing home

and also his family physician for many years, in order to assist him in appealing the denial of services. Dr. James, in turn, summoned the members of the care team, along with the MDS coordinator (an RN who handles claim denials for the nursing home), and he notified Dr. Johnson, the medical director of the nursing home.

The MDS coordinator subsequently contacted the case manager from the MAP, who informed her that the plan utilized the latest coverage algorithm to assist in the decision-making, and that their medical director, not mentioned by name in the denial notice, was the one who authorized the denial.

The MDS coordinator questioned the MAP case manager further about the algorithm utilized, but the case manager was unable to provide her with pertinent details such as to its name, how it functioned, and whether it took into consideration Mr. Jones' femoral neuropathy, which impaired his right hip flexion, hindering his gait and preventing him at the time from climbing stairs, as well as his lingering congestive heart failure which still significantly limited his endurance. When asked about the medical specialty of the MAP medical director, the case manager did not know. When questioned about the possibility of a peer-to-peer discussion, the case manager stated that the MAP did not offer this option. Finally, the MAP case manager informed her that if Mr. Jones wished to appeal the denial, the appeal process was detailed in the denial notice.

4. Discussion

4.1 Rationale for Human oversight of AI in Health Care

At present, AI does not possess the ability to fully grasp the complexity of human experiences and the unique factors which shape a person's health care needs. According to Ann Skeet, the Director of Leadership Ethics at Santa Clara University's Markkula Center for Applied Ethics, moral reasoning and human level judgement are two major components to human cognition which AI systems cannot meaningfully cultivate.¹¹ Moral reasoning, a byproduct of consciousness and sentience, requires the ability to experience feelings and sensations, which machines simply cannot. Although some may argue that machines could potentially later develop moral reasoning based upon other factors, devoid of subjective experiences, that day has not yet come. At the present time, technological uses and outcomes remain under the control of people.

There are, however, many what if scenarios to ponder. For instance, what if AI continues to develop at such a furious pace in the coming decades that it exceeds all aspects of human abilities, like in some futuristic science fiction movie script, then what components of our humanity will we wish to preserve? In essence, do we wish to create such a paradigm in which humans become completely subservient to AI processes which they can no longer control? Such a scenario, however, can only occur if human oversight of AI is ever relinquished. What now seems undeniable is that all this talk of AI processes gaining control over humans has spurred a great deal of interest among business executives in the field of ethics, which was far from the case a decade ago.

Thankfully, at the present time, a critical element of any well-designed AI system is human oversight which ensures that such systems function in a manner which is transparent, accountable, and aligned with human values.¹² As illustrated in our case study, the AI coverage algorithm that was utilized did not provide human oversight, which directly led to its failure to address the essential health care needs of the subject.

4.2 A Lesson Learn for Socrates

When the question was asked of Socrates, whether there was anyone wiser than him, after searching long and hard, Socrates discovered that he, indeed, was the wisest, in large part due to his self-awareness of the limits of his knowledge.¹³ In other words, Socrates did not truly think that he knew more than he did, and he did not profess to others that he did. Let us contrast Socrates with a large language model such as ChatGPT4, which has no built-in awareness of what it does not know. For such large language models are not based upon empirical evidence or logic, as they make statistical guesses, which, in many cases, may be wrong. These models, however, don't inform users that they are making statistical guesses, leading users to think that they are presenting facts, as they do so with such confidence that most users do not question otherwise.

The great folly is how often the public is fooled by this exhibition which they readily accept as the truth. However, in regard to AI health coverage algorithms, unlike large language models, the public is becoming increasingly aware of their shortcomings, as outcome adversely impact them like the subject in our case study, leading many to now question their continued usage.

4.3 A Computer Program Is Not a Crystal Ball for Care

As illustrated in this case study, the general public

must become vigilant of the increasing reliance of all categories of health care insurers on AI coverage algorithms as a major means to make payment decision for patient treatment, as this could precipitate serious disputes, pitting clinical teams and the patients/families that they represent against these insurers, which could delay or prevent medically necessary and beneficial treatment for those in need. For a computer program, no matter how well designed, "is not a crystal ball for care," as there are many similar real-life stories in which such AI coverage algorithms can go awry for patients.¹⁴ Like in our case illustration, such AI coverage algorithms may not fully consider a patient's actual needs and may not enable human input at critical junctures in the process. Accordingly, key stakeholders must be cognizant of the potential of such AI coverage algorithms to conflict with coverage plan rules and guidelines, such as those that apply to original Medicare, as well as MAP, which are intended to safeguard access to essential health care services for all those enrolled in these plans.

4.4 AI Must Be Used to Support Clinical Ethical Decision-Making

A systemic review¹⁵ concluded there are enormous potential benefits of using AI in clinical ethical decision-making however, in terms of development and use, the ethical pitfalls must be avoided. Among these ethical pitfalls related to clinical decision support systems, which are of key importance in the debate on AI for clinical ethics, it cautions that those concerns tied to justice and explicability or human-machine interaction thus far have not been adequately addressed. Our case illustration with its elderly, debilitated subject, in desperate need of continued essential medical services while at the mercy of his insurer, touches upon some of these ethical concerns.

From a governmental perspective, as AI tools are intended to help improve the health and wellbeing of the American people, the role of those in high-ranking governmental positions and their key advisors must be to maintain public trust by ensuring that all solutions are ethical, effective, and secure.¹⁶ Perspectives from key stakeholders are essential to accomplish this, as trustworthy AI cannot be best understood by listing its design features, but rather in terms of how it relates to the ethical values which matter most to its end-users.¹⁷ Thus, the process utilized in the development and deployment of these AI clinical tools is key, as it must be transparent, ethical and inclusive of all stakeholders, with human oversight built-in at critical junctures as a safeguard in order to be deemed trustworthy.

After careful analysis, all of the aforementioned lawsuits appear to be attributable to process failures in the development and deployment of these AI coverage algorithms, rather than as a result of technological shortcomings. Moreover, like in our case illustration, these failures, as critics claim, can be traced to a lack of human involvement and oversight in the loop, which may be motivated by cost savings and increased profit.

To a large degree, the discipline necessary to roll out AI based solutions for clinical use requires the same rigor as that applied to any other new medication or medical device. Hence, there should not be any shortcuts, as vendors and health systems need to ensure rigorous testing and validation. Thus, the process utilized is the key, which must be based upon transparency, explainability, presence of human oversight in the loop, a mechanism for bias detection and mitigation, along with safeguards for security and privacy. It must be sustainable and rely upon continuous monitoring and updates, governance, a fallback mechanism, and must include redundancies, interdisciplinary collaboration and user training and education. In addition, it must be in keeping with established ethical guidelines, which critics claim were lacking by the users of these AI coverage algorithms in these aforementioned lawsuits.

A key lesson learned is that all of the key stakeholders must work together and proactively to help assure that the design, development and deployment of generative AI tools for health care are done so in the utmost ethically responsible way. This perhaps can be best accomplished by adhering to the six key ethical principles established by the World Health Organization,¹⁸ which are: (1) protect autonomy; (2) promote human well-being, human safety, and the public interest; (3) ensure transparency, explainability, and intelligibility; (4) foster responsibility and accountability; (5) ensure inclusiveness and equity; and (6) promote AI that is responsive and sustainable.

4.5 Should Health Care Coverage AI Algorithms Be Regulated?

Perhaps, as some critics of the health insurance industry recommend, we should look at this problem from a different perspective, in terms of whether the United States Food and Drug Administration (FDA) should regulate AI algorithms that are being utilized by health insurance companies for the processing of claims and the determination of coverage decisions?

In a forthcoming article, Jennifer D. Oliva, professor of law at Indiana University Maurer School of

Law, points out that these coverage algorithms are unregulated and not evaluated for safety and effectiveness by the FDA before they go to market, as opposed to clinical algorithms used by healthcare institutions and providers to diagnose and treat patients. She notes that coverage algorithm manufacturers are often the very health insurance companies that use them to make coverage decisions, which take the view that their products are “proprietary” and not subject to public disclosure. Thus, she contends that these coverage algorithms are immunized from any external mechanism for safety and effectiveness by peer review. In effect, Oliver suggests that these health plans which rely on profit driven coverage algorithms to deny and delay treatment disparately impacts the health of those who have medically complex needs such as Medicare beneficiaries and must utilize high-cost health care resources at high rates.¹⁹

When we weigh the far reaching impact that these unregulated and often non-transparent coverage algorithm could have upon medical treatment decisions, which may be based largely upon cost considerations and to a lesser degree upon what is medically necessary for the patient, as illustrated in our case study, some may be swayed to the opinion that these coverage algorithms should be regulated by the FDA, much like clinical algorithms used by health care institutions for patient treatment before they go to market. Others, however, may not be swayed in this direction and may be of the opinion that such action would be tantamount to overkill, by adding a further level of bureaucracy to a complex problem while overburdening a federal agency with a new task that it is ill-equipped to handle at the present time.

4.6 How AI Clinical Support Tools Can Be Developed and Deployed Properly

There is, indeed, cause for optimism on the horizon, as some health care entities have already developed and deployed generative AI tools properly. For example, in an August 14, 2024 press release, Kaiser Permanente announced the availability of a new clinical documentation AI tool at 40 hospitals and more than 600 medical offices in eight states and the District of Columbia, powered by ambient listening technology, which will support its clinical teams by securely capturing clinical notes during patient visits, so that clinicians can remain focused on the patients rather than on documentation or administrative tasks.²⁰ Kaiser highlighted that it worked closely with the developer of this AI technology for the past year

on this assisted clinical documentation tool, which securely summarizes relevant medical information from spoken, natural conversations. It detailed how it responsibly implemented this AI tool after undergoing rigorous testing, which included conducting quality checks, safe-guarding patient privacy and mindful of their preferences. This tool requires both patient consent and that clinicians must review clinical notes before entering them into a patient's medical record. The press release noted that this AI technology was well received by both their patients and their clinicians.

It is noteworthy that the process utilized by Kaiser Permanente was transparent, highly collaborative, inclusive, with perspectives from key stakeholders and its end-users incorporated, and it underwent rigorous testing and quality checks before being deployed. The AI tool was explainable, with human oversight built-in at critical junctures to ensure safe application, in accordance with the Trustworthy AI Playbook¹⁶ and the ethical principles established by the World Health Organization in 2021.¹⁸ If the same rigorous process utilized by Kaiser Permanente is employed by other health insurers before they roll out their AI coverage algorithms, it is likely that the ethical concerns raised in these aforementioned class action lawsuits can be averted.

5. Conclusions

Like other major technological innovations, AI clinical algorithms have the potential to significantly improve patient care if designed and utilized properly, contributing to better patient outcomes, more efficient health systems operations and improved patient safety. It, however, is crucial that perspectives from

key stakeholders are actively sought to accomplish this. Above all, it is essential to address ethical challenges posed by such innovations, some of which may be difficult to discern without making the design and implementation process transparent to all users. A key focus should be how it relates to the ethical values which matter most to its end-users.¹⁷ As we proceed along this journey which will transform our health care system, we must be mindful of the need to maintain a safe balance between AI and human oversight in order to reap the full potential of these transformative technologies. We must also learn from those health care entities which have exercised due diligence in their processes for the development and deployment of generative AI tools, which can serve as models for how to do so in the utmost ethically responsible way.

To accomplish this in a safe and effective way, we perhaps may be best served by adhering to the 6 key ethical principles which were developed by the World Health Organization.¹⁸ Figure 1 depicts how such was not done, when applied to our case study. By doing so, the AI and bioethics communities, along with all the other key stakeholders can help assure that these AI coverage algorithms, along with clinical algorithms used by health care institutions and providers to diagnose and treat patients, are all utilized as support tools and do not eliminate human oversight. For such AI coverage algorithms, in many cases, presently do not consider all relevant factors on a case-by-case basis, some of which may be subtle as illustrated in our case study, but nevertheless important in a clinical setting, which require the human element to discern and interpret, and which are essential to delivery of high-quality person-centered care.

Figure 1. WHO Ethical Principles Applied to Clinical Decision Support Algorithm in Case Study

WHO 6 Ethical Principles	Adheres to 6 Principles	Explanation
Protect autonomy	No	No human oversight evident on health decision — appear to be entirely by machine—doctors do not appear able to override decisions.
Promote human safety	No	Developers do not continuously monitor these AI tools to be certain they function properly and are not causing harm.
Ensure transparency	No	Developers failed to provide information about design of AI tools, or indication they can be fully audited/ understood by users and regulators.
Foster accountability	No	When something goes wrong, resulting in harm, no mechanism evident to determine who is responsible (like manufacturers and clinical users).
Ensure equity	No	No evidence AI tools were tested on diverse sets of data and that biases do not exist, which can discriminate against a group, such as the elderly.
Promote AI that is sustainable	No	No indication that AI tools are regularly updated — that there are means to adjust a tool if it seems ineffective — or that tools can be repaired.

Disclaimer

The opinions expressed by the authors are entirely their own and should not be construed to be reflective of any organization or entity with which they are associated.

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