American Society of Clinical Oncology (ASCO)

Principles for the Responsible Use of Artificial Intelligence in Oncology

May 2025

Introduction

The speed with which artificial intelligence (AI) is being developed and integrated, particularly in clinical oncology and scientific research is remarkable. Clinicians are challenged to navigate the heterogeneity of cancer care, interpret large data sets from various sources, keep pace with new evidence and drug approvals, understand the numerous fields of molecular biology, and the spectrum of disease states and responses while also considering individual needs and circumstances of patients, all of which interact in complex ways. AI promises to help address these challenges.

AI is predicted to have a profound impact on the contours of health care and research with the potential to either increase or reduce efficiency, accuracy, quality, and the accessibility of cancer care. As its use and sophistication accelerate, there is a growing sense of urgency among clinicians, patients, and policymakers to understand both its potential benefits and its risks.

Oncologists and other cancer care stakeholders have significant concerns about a variety of legal, ethical, and operational issues. These include the potential for authoritative presentations of fake information, bias in algorithms, erosion of patient trust and autonomy, blurring or even substituting the roles of clinicians, other health care workforce shifts, and broad issues around the oversight of AI as it inevitably evolves. Conversely, AI could be used to improve medical literacy among patients, create better clinician decision support tools, or help practices operate more efficiently. That is the reason so

many organizations are already turning their attention to the promise and potential perils of AI and developing resources and guidance.[1-4]

As the national organization representing nearly 50,000 physicians and other health care professionals specializing in cancer treatment, diagnosis, prevention, and research, ASCO has a duty to help our community develop and understand the principles for responsible use of AI in cancer care. By fostering a multidisciplinary dialogue, promoting ethical and legal guidelines, and investing in research and education, we can harness the power of AI while safeguarding against misuse or unintended consequences. In addressing AI's inherent risks, we can enable a more efficient, accessible, and affordable health care system that prioritizes the health and well-being of all patients with cancer.

To achieve these aims the ASCO Board of Directors has appointed a task force that will explore the application of AI in cancer care and research and to make recommendations on ASCO's role in the evolving uses of AI. ASCO will continue to investigate the impact of AI in oncology with ongoing research and deeper analysis of its role in cancer care. In the coming years, we expect to learn a great deal about how AI will change our health care system in both negative and positive ways. ASCO will continue to follow these developments closely and analyze how new lessons learned can be applied to future policy development.

Thus far, ASCO has developed the following six principles that will guide our consideration of all aspects of AI:

1. Transparency – AI tools and applications should be transparent throughout their lifecycle.
2. Informed Stakeholders – Patients and clinicians should be aware when AI is used in clinical decision-making and patient care.

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[1] The American Medical Association. Press Releases. AMA adopts policy calling for more oversight of AI in prior authorization. https://www.ama-assn.org/press-center/press-releases/ama-adopts-policy-calling-more-oversight-ai-prior-authorization
[2] American Medical Association. Future of Health: The Emerging Landscape of Augmented Intelligence in Health Care. https://www.ama-assn.org/system/files/future-health-augmented-intelligence-health-care.pdf
[3] American Nurses Association. Position Statement: The Ethical Use of Artificial Intelligence in Nursing Practice. https://www.nursingworld.org/~48f653/globalassets/practiceandpolicy/nursing-excellence/ana-position-statements/the-ethical-use-of-artificial-intelligence-in-nursing-practice_bod-approved-12_20_22.pdf
[4] American Hospital Association. Artificial Intelligence (AI). https://www.aha.org/topics/artificial-intelligence-ai

3. Fairness – Developers and users of AI should protect against bias in AI model design and use and ensure access to AI tools in application.
4. Accountability – AI systems must comply with legal, regulatory, and ethical requirements that govern the use of data. AI developers should assume responsibility for their AI systems, its decisions, and their adherence to legal, regulatory, and ethical standards.
5. Oversight and Privacy – Decision-makers should establish institutional compliance policies that govern the use of AI, including protections that guard clinician and patient autonomy in clinical decision-making and privacy of personal health information.
6. Human-Centered Application – Human interaction is a fundamental element of health care delivery; AI does not eliminate the need for human interaction and should not be used as a substitute for sensitive interactions that require it.

Background

AI is a dynamic field of research representing several subfields that, either individually or in combination, leverage computer science and robust data sets to simulate human intelligence.[5] AI is an umbrella term for a diverse set of concepts, including machine learning, deep learning, natural language processing, and neural networks, among others. While these concepts do not encompass the entirety of current AI applications, it is important to note that AI research and breakthroughs will continue to expand its conceptual subcategories, use concepts, avenues for research—and even the terminology used to discuss it.

The Current and Near-Term Uses of AI in Oncology

Although AI tools are at varying stages of maturity and adoption, their use and potential are already apparent in the daily lives of clinicians, showing potential in enhancing diagnosis and treatment, improving patient outcomes, and streamlining administrative processes. It is also enabling advanced clinical decision support systems that combine genomics, digital pathology, radiotherapy, and precision oncology. Clinical AI tools are being used in oncology to recommend treatments, aid in diagnosis through computer-assisted image analysis and virtual biopsies, predict health outcomes, project risk of treatment

[5] IBM. What is artificial intelligence (AI)? https://www.ibm.com/topics/artificial-intelligence

complications and hospitalizations, guide surgical care, monitor patients, and support population health management.[6-10]

Precision Oncology

Applying machine learning and its subset, deep learning, in histopathology and genomic profiling has the potential to enable a new kind of workflow in oncology and cancer research, enhancing personalized treatments and advancing precision oncology.[11-12] New data inputs, such as genome sequencing and circulating cell-free DNA (cfDNA), combined with medical imaging and AI models could provide clinically actionable outputs from complex data and provide opportunities for improved risk stratification and increased accuracy and efficiency in early disease detection strategies. Machine learning's increased role in improving next generation sequencing for disease identification and treatment may also significantly impact decision-making.[13-14] AI algorithms used to analyze cfDNA and

[6] Farina E, Nabhen JJ, Dacoregio MI, Batalini F, Moraes FY. An overview of artificial intelligence in oncology. Future Sci OA. 2022 Feb 10;8(4):FSO787. doi: 10.2144/fsoa-2021-0074. PMID: 35369274; PMCID: PMC8965797.

[7] Jacob T. Shreve et al., Artificial Intelligence in Oncology: Current Capabilities, Future Opportunities, and Ethical Considerations. Am Soc Clin Oncol Educ Book 42, 842-851(2022). DOI:10.1200/EDBK_350652. https://ascopubs.org/doi/10.1200/EDBK_350652?url_ver=Z39.88-2003&rfr_id=ori:rid:crossref.org&rfr_dat=cr_pub%20%200pubmed

[8] Mansur A, Saleem Z, Elhakim T, Daye D. Role of artificial intelligence in risk prediction, prognostication, and therapy response assessment in colorectal cancer: current state and future directions. Front Oncol. 2023 Jan 25;13:1065402. doi: 10.3389/fonc.2023.1065402. PMID: 36761957; PMCID: PMC9905815.

[9] Kirthika Senthil Kumar et al., Artificial Intelligence in Clinical Oncology: From Data to Digital Pathology and Treatment. Am Soc Clin Oncol Educ Book 43, e390084(2023). DOI:10.1200/EDBK_390084

[10] Hindocha S, Zucker K, Jena R, Banfill K, Mackay K, Price G, Pudney D, Wang J, Taylor A. Artificial Intelligence for Radiotherapy Auto-Contouring: Current Use, Perceptions of and Barriers to Implementation. Clin Oncol (R Coll Radiol). 2023 Apr;35(4):219-226. doi: 10.1016/j.clon.2023.01.014. Epub 2023 Jan 23. PMID: 36725406.

[11] Unger M, Kather JN. Deep learning in cancer genomics and histopathology. Genome Med. 2024 Mar 27;16(1):44. doi: 10.1186/s13073-024-01315-6. PMID: 38539231; PMCID: PMC10976780.

[12] Gianfrancesco MA, Tamang S, Yazdany J, Schmajuk G. Potential biases in machine learning algorithms using electronic health record data. JAMA Intern Med. 2018;178(11):1544-1547. doi:10.1001/jamainternmed.2018.3763

[13] Choon YW, Choon YF, Nasarudin NA, et al. Artificial intelligence and database for NGS-based diagnosis in rare disease. Front Genet. 2024;14:1258083. Published 2024 Jan 25. doi:10.3389/fgene.2023.1258083

[14] Dlamini Z, Francies FZ, Hull R, Marima R. Artificial intelligence (AI) and big data in cancer and precision oncology. Comput Struct Biotechnol J. 2020;18:2300-2311. Published 2020 Aug 28. doi:10.1016/j.csbj.2020.08.019

investigate the development of pancreatic cancer can achieve high predictive accuracy.[15-16] AI models can predict an individual's risk of lung cancer from chest x-rays alone which could be used to guide personalized screening intervals.[17] Skin and breast cancer detection also have benefited from automated diagnosis with AI technology. An AI algorithm trained on 129,450 biopsy-proven photographic images was tested against 21 board-certified dermatologists, achieving performance on par with all tested experts and demonstrating that AI is capable of classifying skin cancer comparable to a dermatologists' assessment.[18] These types of algorithms can also classify skin lesions from readily available mobile images with equal performance to specialist and novice physicians.[19-20]

Computer-aided detection (CAD) algorithms built on deep learning frameworks can identify suspicious regions of interest on imaging scans for radiologists to review, matching the performance of human radiologists when acting as a second reader.[21] Although they have potential to reduce physician workload, CAD algorithms have also shown mixed performance in mammographic interpretation.[22]

AI and Health Care Administration

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[15] Adams SJ, Topol EJ. Rebooting cancer screening with artificial intelligence. Lancet. 2023 Aug 5;402(10400):440. doi: 10.1016/S0140-6736(23)01576-3. PMID: 37544321.

[16] Bahado-Singh RO, Turkoglu O, Aydas B, Vishweswaraiah S. Precision oncology: Artificial intelligence, circulating cell-free DNA, and the minimally invasive detection of pancreatic cancer-A pilot study. Cancer Med. 2023;12(19):19644-19655. doi:10.1002/cam4.6604.

[17] Walia A, et al. Clinical validation of a deep-learning–based model to predict lung cancer risk from chest X-rays.. JCO 40, 10507-10507(2022). https://ascopubs.org/doi/abs/10.1200/JCO.2022.40.16_suppl.10507.

[18] Esteva, A., Kuprel, B., Novoa, R. et al. Dermatologist-level classification of skin cancer with deep neural networks. Nature 542, 115–118 (2017). https://doi.org/10.1038/nature21056.

[19] Kolla L, Parikh RB. Uses and limitations of artificial intelligence for oncology. Cancer. 2024 Mar 30. doi: 10.1002/cncr.35307. Epub ahead of print. PMID: 38554271.

[20] Menzies SW, Sinz C, Menzies M, et al. Comparison of humans versus mobile phone-powered artificial intelligence for the diagnosis and management of pigmented skin cancer in secondary care: a multicentre, prospective, diagnostic, clinical trial. Lancet Digit Health. 2023; 5(10): e679-e691. doi:10.1016/S2589-7500(23)00130-9.

[21] Hindocha S, Zucker K, Jena R, Banfill K, Mackay K, Price G, Pudney D, Wang J, Taylor A. Artificial Intelligence for Radiotherapy Auto-Contouring: Current Use, Perceptions of and Barriers to Implementation. Clin Oncol (R Coll Radiol). 2023 Apr;35(4):219-226. doi: 10.1016/j.clon.2023.01.014. Epub 2023 Jan 23. PMID: 36725406.

[22] Retson TA, Eghtedari M. Expanding Horizons: The Realities of CAD, the Promise of Artificial Intelligence, and Machine Learning's Role in Breast Imaging beyond Screening Mammography. Diagnostics (Basel). 2023;13(13):2133. Published 2023 Jun 21. doi:10.3390/diagnostics13132133.

Administrative AI tools have been used to reduce provider burden and increase efficiency by recording digital notes, optimizing operational processes, and automating laborious tasks.[23] The Dana-Farber Cancer Institute recently deployed a large language model for use in all business areas (but not in direct clinical care), including IRB-approved research and operational exploration.[24] AI could accelerate execution and participation in clinical trials by generating streamlined study protocols for IRB review, producing patient friendly consent forms, and enhancing efficiency of clinical trial matching.[25-26] Recent reports also have revealed insurers are beginning to use proprietary AI systems that automate claim denials with little to no clinician involvement.[27-29] In one case, an insurance company denied more than 300,000 claims over a two-month period as part of a review process that used AI; the company's doctors spent an average of 1.2 seconds on each case.[28]

In one report, researchers estimated that broad adoption of AI into the health care system could lead to savings up to $360 billion.[30] However, one of the major challenges in effectively deploying AI in health care is managing implementation and maintenance costs. There is limited economic analysis of

[23] U.S. Government Accountability Office. Artificial Intelligence in Health Care: Benefits and Challenges of Technologies to Augment Patient Care. https://www.gao.gov/products/gao-21-7sp.
[24] Umeton, Renato & Kwok, Anne & Maurya, Rahul & Leco, Domenic & Lenane, Naomi & Willcox, Jennifer & Abel, Gregory & Tolikas, Mary & Johnson, Jason. (2024). GPT-4 in a Cancer Center — Institute-Wide Deployment Challenges and Lessons Learned. NEJM AI. 1. 10.1056/AIcs2300191.
[25] Ismail A, Al-Zoubi T, El Naqa I, Saeed H. The role of artificial intelligence in hastening time to recruitment in clinical trials. BJR Open. 2023 May 16;5(1):20220023. doi: 10.1259/bjro.20220023. PMID: 37953865; PMCID: PMC10636341.
[26] Wang L, Song Y, Wang H, Zhang X, Wang M, He J, Li S, Zhang L, Li K, Cao L. Advances of Artificial Intelligence in Anti-Cancer Drug Design: A Review of the Past Decade. Pharmaceuticals (Basel). 2023 Feb 7;16(2):253. doi: 10.3390/ph16020253. PMID: 37259400; PMCID: PMC9963982.
[27] The American Medical Association. Principles for Augmented Intelligence Development, Deployment, and Use. https://www.ama-assn.org/system/files/ama-ai-principles.pdf.
[28] ProPublica. How Cigna Saves Millions by Having Its Doctors Reject Claims Without Reading Them. https://www.propublica.org/article/cigna-pxdx-medical-health-insurance-rejection-claims.
[29] Stat. Denied by AI: How Medicare Advantage plans use algorithms to cut off care for seniors in need. https://www.statnews.com/2023/03/13/medicare-advantage-plans-denial-artificial-intelligence/.
[30] Sahni, Nikhil and Stein, George and Zemmel, Rodney and Cutler, David M., The Potential Impact of Artificial Intelligence on Healthcare Spending (January 2023). NBER Working Paper No. w30857, Available at SSRN: https://ssrn.com/abstract=4334926.

AI's financial impact on organizations.[31] Existing modelling methods and reporting standards may be insufficient to assess cost-effectiveness or facilitate easy modeling of downstream costs, but there are rising concerns that AI implementation, maintenance, staffing, and training has the potential to be cost prohibitive.[31-32]

Algorithmic Bias and Misuse

In contrast to the perceived benefits of AI in oncology care, there is growing literature on the potential for this technology to amplify existing problems of disparate outcomes and experiences in oncology care, as previously highlighted by ASCO.[33] The impact and role of AI on health access and quality in oncology remains underexplored.[34] AI has already demonstrated the potential for algorithmic bias and misuse in other areas of research. There is growing evidence of AI's potential to erode quality and access to care among disparate populations due to data limitations within their electronic health record – data used by machine learning algorithms in clinical decision support.[12] In a landmark study on racial bias, researchers found a widely used algorithm assigned Black patients the same level of risk as White patients despite being sicker, deprioritizing them for access to care.[35] In cases where AI tools were used to schedule medical appointments, algorithms predicted which patients would be "no shows" for clinic appointments, booking them into less desirable time slots that lead to longer wait times than other

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[31] Adler-Milstein J, Aggarwal N, Ahmed M, Castner J, Evans BJ, Gonzalez AA, James CA, Lin S, Mandl KD, Matheny ME, Sendak MP, Shachar C, Williams A. Meeting the Moment: Addressing Barriers and Facilitating Clinical Adoption of Artificial Intelligence in Medical Diagnosis. NAM Perspect. 2022 Sep 29;2022:10.31478/202209c. doi: 10.31478/202209c. PMID: 36713769; PMCID: PMC9875857.

[32] Vithlani J, Hawksworth C, Elvidge J, Ayiku L, Dawoud D. Economic evaluations of artificial intelligence-based healthcare interventions: a systematic literature review of best practices in their conduct and reporting. Front Pharmacol. 2023 Aug 8;14:1220950. doi: 10.3389/fphar.2023.1220950. PMID: 37693892; PMCID: PMC10486896.

[33] Patel MI, Lopez AM, Blackstock W, Reeder-Hayes K, Moushey EA, Phillips J, Tap W. Cancer disparities and health equity: a policy statement from the American society of clinical oncology. J Clin Oncol. 2020 Oct 10;38(29):3439–48.

[34] Istasy P, Lee WS, Iansavichene A, et al. The Impact of Artificial Intelligence on Health Equity in Oncology: Scoping Review. J Med Internet Res. 2022;24(11):e39748. Published 2022 Nov 1. doi:10.2196/39748.

[35] Obermeyer Z, et al. Dissecting racial bias in an algorithm used to manage the health of populations. Science366,447-453(2019).DOI:10.1126/science.aax2342.

patients and, in some cases, making it unlikely to see their provider at all.[36] The impact was felt disproportionately by underserved groups.[37] A lack of understanding and oversight of AI opens the opportunity for misuse and can harm patient access to care.

Evaluation and Validation Challenges

AI is not immune from persistent barriers that have blocked full realization of a longstanding vision for rapid learning systems in health care. Adoption of electronic health records has improved collection of clinical information but gaps in structured health data continue to challenge its use in gaining clinical insights absent substantial human intervention/curation. There also are issues of siloed data, lack of interoperability across health systems, and concerns about the "black box" nature of some AI tools.[38] To enable trust, clinicians must have sufficient information about AI tools and how they arrive at information.[39-40] Understanding how complex AI algorithms arrive at their decision output is particularly challenging and it is unrealistic to assume that clinicians will scrutinize every output. Clinicians should receive assurance by a responsible authority within their respective organization that the algorithm has undergone rigorous validation.

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[36] Shanklin R, Samorani M, Harris S, Santoro MA. Ethical Redress of Racial Inequities in AI: Lessons from Decoupling Machine Learning from Optimization in Medical Appointment Scheduling. Philos Technol. 2022;35(4):96. doi: 10.1007/s13347-022-00590-8. Epub 2022 Oct 20. PMID: 36284736; PMCID: PMC9584259.

[37] Samorani M, Harris SL, Blount LG, Lu H, Santoro MA. Overbooked and overlooked: machine learning and racial bias in medical appointment scheduling. https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3467047.

[38] U.S. Department of Health and Human Services. Trustworthy AI (TAI) Playbook. https://www.hhs.gov/sites/default/files/hhs-trustworthy-ai-playbook.pdf.

[39] Dolezal JM, Srisuwananukorn A, Karpeyev D, Ramesh S, Kochanny S, Cody B, Mansfield AS, Rakshit S, Bansal R, Bois MC, Bungum AO, Schulte JJ, Vokes EE, Garassino MC, Husain AN, Pearson AT. Uncertainty-informed deep learning models enable high-confidence predictions for digital histopathology. Nat Commun. 2022 Nov 2;13(1):6572. doi: 10.1038/s41467-022-34025-x. PMID: 36323656; PMCID: PMC9630455.

[40] Howard FM, Dolezal J, Kochanny S, Schulte J, Chen H, Heij L, Huo D, Nanda R, Olopade OI, Kather JN, Cipriani N, Grossman RL, Pearson AT. The impact of site-specific digital histology signatures on deep learning model accuracy and bias. Nat Commun. 2021 Jul 20;12(1):4423. doi: 10.1038/s41467-021-24698-1. PMID: 34285218; PMCID: PMC8292530.

Researchers are actively exploring techniques to enhance interpretability and explainability of machine learning and deep learning algorithms.[41] While new methods have the potential to help understand AI algorithms to some extent, complete transparency will continue to be a challenge in an ever-evolving technology. Because the interpretability of AI algorithms can vary, the level of their interpretability is dependent on the application and the context in which it is used.

Many efforts are underway to develop model evaluation and validation of safe and effective AI, including the use of federated evaluation and the deployment of assurance labs with the purpose of enabling transparent and localized testing of AI models.[42-43] In one of the largest federated learning studies to date, to generate an automatic tumor boundary detector for the rare disease of glioblastoma, researchers reported a 33% delineation improvement for the surgically targetable tumor, and 23% for the complete tumor extent, over a publicly trained model.[44]

Liability Concerns

Liability risk associated with AI may also slow adoption by providers. For example, a study from Johns Hopkins Carey Business School showed that physicians were less likely to use predictive AI when they thought it would deviate from their assessment in higher-complexity cases due to concerns about medical liability.[45] Moreover, the researchers said that as AI gets more precise, physicians may be even less likely to consult AI at all, out of fear of malpractice liability.[45] The researchers suggest that we may

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[41] Frasca, M., La Torre, D. Pravettoni, G. et al. Explainable and interpretable artificial intelligence in medicine: a systematic bibliometric review. Discov Artif Intell 4, 15 (2024). https://doi.org/10.1007/s44163-024-00114-7.
[42] Karargyris, A., Umeton, R., Sheller, M.J. et al. Federated benchmarking of medical artificial intelligence with MedPerf. Nat Mach Intell 5, 799–810 (2023). https://doi.org/10.1038/s42256-023-00652-2.
[43] Shah NH, Halamka JD, Saria S, et al. A Nationwide Network of Health AI Assurance Laboratories. JAMA. 2024;331(3):245–249. doi:10.1001/jama.2023.26930.
[44] Pati S, Baid U, Edwards B, et al. Federated learning enables big data for rare cancer boundary detection [published correction appears in Nat Commun. 2023 Jan 26;14(1):436]. Nat Commun. 2022;13(1):7346. Published 2022 Dec 5. doi:10.1038/s41467-022-33407-5.
[45] Dai, Tinglong and Singh, Shubhranshu, Artificial Intelligence on Call: The Physician's Decision of Whether to Use AI in Clinical Practice (October 15, 2023). Johns Hopkins Carey Business School Research Paper No. 22-02, Available at SSRN: https://ssrn.com/abstract=3987454 or http://dx.doi.org/10.2139/ssrn.3987454.

eventually have to change the legal "standard of care."[46] Research also has shown that when AI provides incorrect results, radiologists are more likely to change diagnosis than they would have without AI.[47] The fundamental responsibility borne by clinicians for treatment decisions remains--and will need to be understood by all users of this technology.

Evaluation of Clinical Research

There has been growing recognition that interventions involving AI need to undergo rigorous, prospective evaluation to demonstrate impact on health outcomes.[48] In 2023, The New England Journal of Medicine (NEJM) launched a new journal, NEJM AI.[49] In its first editorial, the editors discuss the crucial need for AI in medicine to undergo the same level of scrutiny as any clinical intervention.[50] Following its launch, NEJM AI made the editorial decision that any trial in which human data are gathered prospectively to determine the utility of an intervention requires trial registration even if the local institutional review board or ethics committee determines that exercise is for quality improvement and that individual patient consent is not needed.[50] In its editorial, they acknowledge the uncertainty within the medical AI community about what constitutes a clinical trial that requires registration versus a quality improvement endeavor.

The editors at NEJM AI recommend that researchers follow agreed-upon standards, such as SPIRIT-AI and CONSORT-AI. CONSORT-AI was developed as a reporting guideline for clinical trials

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[46] Johns Hopkins Carey Business School. Malpractice concerns impact physician decisions to consult AI. https://carey.jhu.edu/articles/research/malpractice-concerns-physician-consult-ai.

[47] Bernstein MH, Atalay MK, Dibble EH, Maxwell AWP, Karam AR, Agarwal S, Ward RC, Healey TT, Baird GL. Can incorrect artificial intelligence (AI) results impact radiologists, and if so, what can we do about it? A multi-reader pilot study of lung cancer detection with chest radiography. Eur Radiol. 2023 Nov;33(11):8263-8269. doi: 10.1007/s00330-023-09747-1. Epub 2023 Jun 2. PMID: 37266657; PMCID: PMC10235827.

[48] Liu X, Cruz Rivera S, Moher D, Calvert MJ, Denniston AK; SPIRIT-AI and CONSORT-AI Working Group. Reporting guidelines for clinical trial reports for interventions involving artificial intelligence: the CONSORT-AI extension. Nat Med. 2020 Sep;26(9):1364-1374. doi: 10.1038/s41591-020-1034-x. Epub 2020 Sep 9. PMID: 32908283; PMCID: PMC7598943.

[49] Kohane IS. Injecting Artificial Intelligence into Medicine. NEJM AI. https://ai.nejm.org/doi/full/10.1056/AIe2300197.

[50] Drazen JM, Haug CJ. Trials of AI Interventions Must Be Preregistered. NEJM AI. https://ai.nejm.org/doi/full/10.1056/AIe2400146#core-collateral-fulltext-options.

evaluation to demonstrate impact on health outcomes and developed in parallel with SPIRIT-AI, a companion guideline for clinical trial protocols.[51] These guidelines provide the first international standards for clinical trials of AI systems and illustrate promising examples of evaluative methods to ensure rigorous research that could build trust and transparency.[51]

Monitoring AI Implementation

Currently, there is not an organized approach to monitoring, documenting, and reporting of AI incidents, including their impact on data collection and reporting inconsistency.[52] The US has not developed the infrastructure or framework to identify and report AI incidents. To ensure an AI ecosystem that adheres to ASCO's principles, a system to examine and assess reported AI incidents will be necessary. A 2023 Executive Order on artificial intelligence outlines its federal response to AI oversight, directing federal agencies to establish new standards and regulations.[53] Specifically, it directs the Department of Health and Human Services to establish a safety program to receive reports of, and act to remedy, harms or unsafe health care practices involving AI.[53]

The development of a reporting framework starts with defining an AI incident and related concepts. The Organisation of Economic Cooperation and Development (OECD) has begun working on a reporting framework including definitions and, separately, a complementary project to develop a global AI Incidents Monitor (AIM).[54] The OECD AIM documents AI incidents to help policymakers, AI practitioners, and all stakeholders to gain valuable insights into the incidents and hazards from reported

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[51] Ibrahim H, Liu X, Rivera SC, Moher D, Chan AW, Sydes MR, Calvert MJ, Denniston AK. Reporting guidelines for clinical trials of artificial intelligence interventions: the SPIRIT-AI and CONSORT-AI guidelines. Trials. 2021 Jan 6;22(1):11. doi: 10.1186/s13063-020-04951-6. PMID: 33407780; PMCID: PMC7788716.

[52] Ren Bin Lee Dixon and Heather Frase, "An Argument for Hybrid AI Incident Reporting" (Center for Security and Emerging Technology, March 2024). https://doi.org/10.51593/20230046.

[53] The White House. Executive Order on the Safe, Secure, and Trustworthy Development and Use of Artificial Intelligence. https://www.whitehouse.gov/briefing-room/presidential-actions/2023/10/30/executive-order-on-the-safe-secure-and-trustworthy-development-and-use-of-artificial-intelligence.

[54] OECD.AI. OECD Working Party and Network of Experts on AI. https://oecd.ai/en/network-of-experts/working-group/10836.

AI incidents.[55] The OECD defines an AI incident as an event where the development or use of an AI system results in actual harm, while an event where the development or use of an AI system is potentially harmful is termed an AI hazard.[55] As AI continues to be adopted, an exponential increase in AI incidents can be expected. Current media and publication may only represent a small subset of incidents. Gaining insight into a diverse range of possible incidents may uncover novel perspectives of mishap that have been previously unreported.

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ASCO Principles for the Responsible Use of Artificial Intelligence in Oncology

1. ***TRANSPARENCY. AI tools and applications should be transparent throughout their lifecycle.***

The ability to evaluate, scrutinize, validate, and optimize AI throughout its lifecycle will depend on researchers and clinicians having access to data that can be easily understood and explained. A recent survey in the Journal of American Medical Association reported that 84.8% of US oncologists reported that AI needs to be explainable by oncologists and 81.4% agreed that patients should consent to AI use for cancer treatment decisions.[56] AI applications should be reproducible, and developers should provide the opportunity for other stakeholders to test, recreate, and/or verify their research through model and data transparency.

Although there may be proprietary challenges associated with this approach, AI developers—at a minimum—should be explicit about how the AI model was created, its inputs, and its process for

[55] OCED.AI. OECD AI Incidents Monitor (AIM). https://oecd.ai/en/incidents?search_terms=%5B%5D&and_condition=false&from_date=2014-01-01&to_date=2024-04-14&properties_config=%7B%22principles%22:%5B%5D,%22industries%22:%5B%5D,%22harm_types%22:%5B%5D,%22harm_levels%22:%5B%5D,%22harmed_entities%22:%5B%5D%7D&only_threats=false&order_by=date&num_results=20.

[56] Hantel A, Walsh TP, Marron JM, et al. Perspectives of Oncologists on the Ethical Implications of Using Artificial Intelligence for Cancer Care. JAMA Netw Open. 2024;7(3):e244077. doi:10.1001/jamanetworkopen.2024.4077.

procurement, curation, and use. AI developers should also offer tools and resources that allow users to evaluate how the AI model was created, how it uses personal health information, and include mechanisms that allow clinicians to assess performance validation metrics in a way that is easily understood and does not increase administrative burden.

2. INFORMED STAKEHOLDERS. Patients and clinicians should be aware when AI is used in clinical decision-making and patient care.

Before adopting an AI system into clinical practice, clinicians should be well informed and educated on how it should be used. As AI systems continue to be developed, tested, and deployed into the health care system, there is a greater need to understand how the data are being used to make decisions. Currently, few relevant educational materials exist for clinicians.[57] A lack of knowledge and awareness of AI could lead to providers being held liable for unintended consequences such as misuse of clinical AI tools or failure to recognize inaccurate outputs.

Hospitals, clinics, clinical associations, and oncology practices should develop robust training programs and AI use guidelines to prevent unintended consequences, misuse, or errors while limiting risks and mitigating bias.[58-59] As part of the informed consent process, clinicians and their health systems should disclose to patients when and how AI is used in their clinical decision making. Moreover, patients should be aware when AI is involved in non-clinical circumstances such as AI responding to patient inquiries by phone. This information should be tailored appropriately to populations served. Education, together with transparency, is essential for establishing clinician and patient trust –and adoption—of AI.

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[57] United States Senate Committee on Finance. Artificial Intelligence and Health Care: Promises and Pitfalls. Testimony. https://www.finance.senate.gov/imo/media/doc/02082024_mello_testimony.pdf.

[58] Harvey HB, Gowda V. Clinical applications of AI in MSK imaging: A liability perspective Skeletal Radiol 2021. [Epub ahead of print].

[59] Scherer, Matthew U., Regulating Artificial Intelligence Systems: Risks, Challenges, Competencies, and Strategies (May 30, 2015). Harvard Journal of Law & Technology, Vol. 29, No. 2, Spring 2016, Available at SSRN: https://ssrn.com/abstract=2609777 or http://dx.doi.org/10.2139/ssrn.2609777.

3. FAIRNESS. ***Developers and users of AI should protect against bias in AI model design and use and ensure access to AI tools in application.***

Lacking government and regulatory oversight, AI systems can potentially be trained with biased, limited, and/or poor data sets. Data that is inherently biased can result in research conclusions that produce negative health outcomes for individuals or perpetuate poor health for populations.[60] The development of guidance on the most appropriate methods, tools, and training should be provided to clinicians to identify, assess, and mitigate bias.[61-62] AI developers should identify metrics to measure fairness , and make deliberate efforts to promote the ability of AI to help all patients thrive.

Adoption of modern technology can vary widely depending on awareness, resources, and level of trust. Developers should invite a variety of perspectives and stakeholders to achieve more robust data sets, ones that are more likely to avoid algorithmic bias. Understanding and accommodating differences among individual patients and practice settings within the health care system may also improve adoption and use of this emerging technology. Patients often are overlooked in stakeholder conversations on AI, but their involvement is critical. As with clinicians, patient involvement should include perspectives from individuals across practice settings, geography, and range of experiences. Patients and clinicians must also be made aware when use of automated systems results in worse outcomes and denial of care without professional—human—participation and expertise. Finally, institutions should consider developing ethical guidelines on the use of AI in their systems, including guidance on specific use cases and how they assess and mitigate bias so that patients can share in the benefits.

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[60] Assistant Secretary of Planning and Evaluation. Office of Health Policy. Report: Trustworthy Artificial Intelligence (TAI) for Patient-Centered Outcomes Research (PCOR) https://aspe.hhs.gov/sites/default/files/documents/1348a9a067fd4d225981a822dfe25ea5/trustworthy-ai.pdf.

[61] Jain A, Brooks JR, Alford CC, et al. Awareness of Racial and Ethnic Bias and Potential Solutions to Address Bias With Use of Health Care Algorithms. JAMA Health Forum. 2023;4(6):e231197. doi:10.1001/jamahealthforum.2023.1197.

[62] Venkatesh, V. "Adoption and Use of AI Tools: A Research Agenda Grounded in UTAUT," Annals of Operations Research, forthcoming. https://doi.org/10.1007/s10479-020-03918-9.

4. ACCOUNTABILITY. ***AI systems must comply with legal, regulatory, and ethical requirements that govern use of data. AI developers should assume responsibility for their AI systems, its decisions, and their adherence to legal, regulatory, and ethical standards.***

Determining the appropriateness of AI use cases is a collective responsibility involving AI developers and users. When an AI system is adopted by a clinician, practice, or health care system, it is the responsibility of the institution and its clinicians to recognize its limitations and specific utility.[58] Given the uncertainty of AI's use in clinical decision-making, cancer patients may be particularly vulnerable and be subject to dangerous consequences due to over-, under- and mistreatment. However, it is the responsibility of developers to perform rigorous validation to ensure trust, confidence, and safety prior to an AI system's deployment. Clinicians should not be expected to further erode time with patients in order to conduct independent validation of detailed processes that drive AI tools. However, they should have access to data and processes if requested. Health systems should be responsible for limiting use to AI products and platforms that demonstrate adherence to appropriate standards for development and validation that are established by an objective and transparent oversight body.

The Government Accountability Office (GAO) has developed an AI accountability framework which addresses governance, data, performance, and monitoring.[63] In its framework, the GAO recommends that entities document methods to assess performance and, in the event of performance deficiencies, correct them in a timely manner while documenting how often corrective actions were needed and how they affected performance. Similarly, the OECD, of which the United States is a member, acknowledges that when data used in an AI system are well documented and traceable, it enables effective analysis of its outcomes and ensures they are consistent and appropriate to the context

[63] U.S. Government Accountability Office. Artificial Intelligence: An Accountability Framework for Federal Agencies and Other Entities. https://www.gao.gov/products/gao-21-519sp.

for its use.[64] The Office of the National Coordinator for Heath Information Technology already certifies electronic medical records and other associated health information products and can establish a similar framework for AI.[65] The National Institute of Standards and Technology have also designed guidance to address user concerns and promote trustworthiness in AI.[66] These emerging rules of the road for AI are promising, and ASCO will continue to monitor and learn from their implementation.

5. OVERSIGHT AND PRIVACY. Decision-makers should establish institutional compliance policies that govern the use of AI, including protections that guard clinician and patient autonomy in clinical decision-making and privacy of personal health information.

The increasing availability of big data has led to the potential for more sophisticated attacks on privacy that can re-identify previously anonymized health data. An essential part of health data analytics using AI involves the aggregation and/or generation of an enormous volume of patient data. The role of big data in advancing health care AI models has major implications on patient privacy. Concerns remain about the paucity of large-scale diverse data sets, a lack of publicly available multi-centric and diverse data sets along with confidentiality and privacy concerns with sharing medical data. Further, a lack of big data leads to generalizability problems when data are trained in one site and can't generalize well onto different sites, leading to poor performance of an AI model.

Researchers have begun to explore the use of privacy enhancing technologies (PETs) which can help preserve privacy while leveraging big data in training AI models, allowing researchers and clinicians to train AI models across data from several institutions without explicitly sharing patient data. PETs such as differential privacy have enabled researchers to use deep learning models to predict breast cancer

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[64] Organisation of Economic Co-operation and Development (OECD). OECD Council Recommendation on Artificial Intelligence. https://www.oecd.org/digital/artificial-intelligence/.
[65] U.S. Department of Health and Human Services. HHS Finalizes Rule to Advance Health IT Interoperability and Algorithm Transparency. https://www.healthit.gov/topic/laws-regulation-and-policy/health-data-technology-and-interoperability-certification-program.
[66] National Institute of Standards and Technology. AI Risk Management Framework (RMF). https://airc.nist.gov/AI_RMF_Knowledge_Base/AI_RMF.

status and cancer type, and drug sensitivity prediction in raw genomic data sets that would typically not be shared with researchers.[67] Another PET, federated learning, has demonstrated high quality comparable results to centralized data.[68] Federated learning used in conjunction with differential privacy in analyzing decentralized medical data such as histopathology images, achieving comparable results compared to conventional centralized training.[69]

More research will be necessary to harness the potential of PETs; striking a balance between insights gained from big data and respecting individual privacy. Current peer-reviewed evidence on PETs express concerns with inconsistency, opacity, or outright absence of clear discussions about the usefulness of PETs for health data use.[70] The White House Office of Science and Technology Policy (OSTP) and National Institute of Standards and Technology (NIST) have previously sought public input on how to responsibly advance adoption of PETs, including federated learning and differential privacy.[71-72]

6. HUMAN-CENTERED APPLICATION OF AI. Human interaction is a fundamental element of health care delivery; AI does not eliminate the need for human interaction and should not be used as a substitute for sensitive interactions that require it.

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[67] Islam MM, Mohammed N, Wang Y, Hu P. Differential Private Deep Learning Models for Analyzing Breast Cancer Omics Data. Front Oncol. 2022;12:879607. Published 2022 Jun 23. doi:10.3389/fonc.2022.879607.

[68] Sheller, M.J., Edwards, B., Reina, G.A. et al. Federated learning in medicine: facilitating multi-institutional collaborations without sharing patient data. Sci Rep 10, 12598 (2020). https://doi.org/10.1038/s41598-020-69250-1.

[69] Adnan M, Kalra S, Cresswell JC, Taylor GW, Tizhoosh HR. Federated learning and differential privacy for medical image analysis. Sci Rep. 2022;12(1):1953. Published 2022 Feb 4. doi:10.1038/s41598-022-05539-7.

[70] Jordan S, Fontaine C, Hendricks-Sturrup R. Selecting Privacy-Enhancing Technologies for Managing Health Data Use. Front Public Health. 2022 Mar 16;10:814163. doi: 10.3389/fpubh.2022.814163. PMID: 35372185; PMCID: PMC8967420.

[71] The White House. Advancing a Vision for Privacy-Enhancing Technologies. https://www.whitehouse.gov/ostp/news-updates/2022/06/28/advancing-a-vision-for-privacy-enhancing-technologies/.

[72] National Institute of Standards and Technology. U.S. Department of Commerce. NIST Special Publication. Guidelines for Evaluating Differential Privacy Guarantees. https://nvlpubs.nist.gov/nistpubs/SpecialPublications/NIST.SP.800-226.ipd.pdf.

AI systems should promote continuous interaction between algorithmic models and clinicians. This concept of "human-in-the-loop" should apply throughout all stages of the AI lifecycle.[73] Human-in-the-loop interaction must incorporate meaningful human interaction and should only be integrated to serve human needs, respect personal identity, value human agency and clinician autonomy, and should include regular auditing.[74] AI systems that pose a threat of serious injury or death calls for urgent priority, heightened safety considerations, and a thorough risk management processes.[75]

Implementation should include early-phase training and testing stages in order to improve a model's behavior. Verification, supervision, acknowledgement, and approval should involve clinician consent and final review prior to any decisions made. The human-centered approach can play a critical role in achieving AI accuracy, efficiency, transparency, oversight, and confidence that the ultimate design is provider- and patient-focused. The American Medical Association (AMA) uses the term *augmented AI* as a concept of AI's *assistive* role, emphasizing that it enhances human intelligence rather than replaces it.[76] AI can perform complex tasks that include reasoning, decision making, and problem solving. This is an important boundary to draw as AI can enhance, augment, prompt, and supplement clinician decisions but should not seek to replace them.

Conclusion

The rapid development and deployment of AI is disrupting all sectors of society, including cancer care delivery and clinical research. Reducing barriers to AI adoption in health care will require funding for clinicians, their health care systems and, ultimately, for patients. Mechanisms that support patient

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[73] Mosqueira-Rey, E., Hernández-Pereira, E., Alonso-Ríos, D. et al. Human-in-the-loop machine learning: a state of the art. Artif Intell Rev 56, 3005–3054 (2023). https://doi.org/10.1007/s10462-022-10246-w.
[74] Jotterand, F., Bosco, C. Keeping the "Human in the Loop" in the Age of Artificial Intelligence. Sci Eng Ethics 26, 2455–2460 (2020). https://link.springer.com/article/10.1007/s11948-020-00241-1.
[75] National Institute of Standards and Technology. AI Risk Management Framework. https://nvlpubs.nist.gov/nistpubs/ai/nist.ai.100-1.pdf.
[76] American Medical Association. Augmented intelligence in medicine. https://www.ama-assn.org/practice-management/digital/augmented-intelligence-medicine.

affordability and access while balancing innovation, promoting competition, regulation, and oversight are paramount. Policies will need to address fundamental questions about legal, regulatory, and ethical issues regarding data stewardship, data sharing, and security while safeguarding patient privacy, autonomy and rights. Regulatory approval standards, and clarity about who is legally responsible when reliance on AI is found to have caused harm will be necessary. Any solution to AI accountability should involve legal experts, policymakers, researchers, health care organizations, clinicians, malpractice insurance providers, and patients.[77]

With this manuscript, ASCO joins colleagues across medicine in offering principles that should be applied in development and implementation of AI. These principles in part echo others that have been shared and are offered as a framework to help us safely use AI to the benefit of patients and the clinicians who care for them. By collectively embracing the above principles, ASCO hopes to enable a future where AI serves as a driver of innovation and clinician empowerment, enhancing the practice of medicine.

As we enter a new era of discovery in cancer care and research fueled and supported by AI, ASCO understands the potential for this new technology to provide global benefits, but is also aware of the need for thoughtful deployment and monitoring. We appreciate the work already underway in Congress, the Administration, and across the medical community to support AI's potential and protecting against its risks. ASCO will be an active participant in shaping policy and law in this important area. ASCO will continue to be a thought leader for cancer care professionals and their patients in the face of AI's rapid pace of encroachment into our health and well-being.

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[77] Choudhury A, Urena E. Artificial Intelligence in NICU and PICU: A Need for Ecological Validity, Accountability, and Human Factors. Healthcare (Basel). 2022 May 21;10(5):952. doi: 10.3390/healthcare10050952. PMID: 35628089; PMCID: PMC9140402. (V,A).