EHRA
HIMSS ELECTRONIC HEALTH RECORD ASSOCIATION

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September 6, 2024

Brian Anderson, MD
Chief Executive Officer
Coalition for Health AI (CHAI)
Boston, MA

Dear Dr. Anderson,

On behalf of the 29 member companies of the HIMSS Electronic Health Record (EHR) Association, we appreciate the opportunity to provide feedback to the Coalition for Health AI (CHAI) regarding the draft framework for responsible health AI, including the Assurance Standards Guide and Assurance Reporting Checklist (ARC).

As the national trade association of EHR developers, our member companies serve the vast majority of hospital, post-acute, specialty-specific, and ambulatory healthcare providers using EHRs and other health IT across the United States. Together, we work to improve the quality and efficiency of care through the adoption and use of innovative, interoperable, and secure health information technology.

The EHR Association appreciates the potential for effective collaboration with stakeholders across the industry and is committed to the ongoing discussion on how to ensure safe and high-quality AI-driven software tools in healthcare. The Association's leadership can be reached by contacting Kasey Nicholoff at knicholoff@ehra.org. Our specific comments follow.

Sincerely,

Stephanie Jamison
Chair, EHR Association
Greenway Health

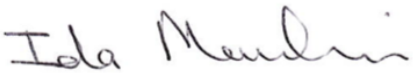
HIMSS EHR Association Executive Committee

David J. Bucciferro
Foothold Technology

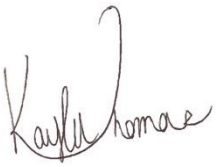
Leigh Burchell
Altera Digital Health

Danielle Friend
Epic

Cherie Holmes-Henry
NextGen Healthcare



Ida Mantashi
Modernizing Medicine



Kayla Thomas
Oracle Health

Established in 2004, the Electronic Health Record (EHR) Association is comprised of 29 companies that supply the vast majority of EHRs to physicians' practices and hospitals across the United States. The EHR Association operates on the premise that the rapid, widespread adoption of EHRs will help improve the quality of patient care as well as the productivity and sustainability of the healthcare system as a key enabler of healthcare transformation. The EHR Association and its members are committed to supporting safe healthcare delivery, fostering continued innovation, and operating with high integrity in the market for our users and their patients and families. The EHR Association is a partner of HIMSS. For more information, visit www.ehra.org.

CR78, LS1.S.C5.EC3

Is there a transparent process in place to inform patients about the use of AI in their care and request informed consent when applicable, ensuring coverage in case of adverse events or legal challenges?

The EHR Association acknowledges the importance of transparency in the use of AI in patient care, particularly when it comes to informed consent and managing potential risks. However, we believe this criteria is only relevant for developers who build patient-facing software. Vendors who create electronic health records and health technology that is used by a physician/clinician for patient care do not interact or have a relationship with patients; therefore, the obligation to decide whether to inform patients that AI is used in decision-making regarding their care should be placed on the clinician. We recommend that this criterion be refined to specifically address patient-facing solutions, ensuring that clinicians retain the appropriate authority and responsibility to communicate with their patients about AI's role in their care.

AC1.CR162, LS4.T.C12, LS4.T.C1.EC2

Is there a method in place to measure the understanding of key actions by end users and key stakeholders based on the AI model's outputs, ensuring consistency with defined limitations, and intended use of the AI solution?

The EHR Association agrees that it is crucial to measure whether end users and stakeholders understand key actions based on AI model outputs. However, the responsibility for ensuring consistent use of AI with its defined limitations and intended purposes cannot reasonably be placed on the developer or vendor. Instead, clinicians are best positioned to determine whether an AI tool is appropriate for their specific patient population, regardless of the tool's intended scope, similar to off-label uses of prescription medications. We recommend revising this criterion to "'Is there a method in place to measure the understanding of key actions by end users and key stakeholders based on the AI model's outputs?"

AC3.CR33, LS6.T.C2.EC2

If the end user is a clinician, is the clinician given adequate guidance on how to explain model output to patients?

The responsibility for communicating AI model outputs to patients should lie with the clinician, not the vendor. Vendors should focus on providing comprehensive documentation, information, and training that equips clinicians to fully understand the AI tool, including details on its development, testing, and intended use. This would enable clinicians to make informed decisions about how and when it is merited to communicate this information with their patients, including whether to explain model outputs or seek informed consent. The EHR Association recommends revising the criteria to: "Has the vendor provided clinicians with adequate information to evaluate the model for use with and explain the model to a particular patient?"

AC3.CR41, LS6.F.C1.EC2; LS6.T.C2.EC1

Is there a defined level of patient awareness regarding the AI solutions' use in their care, with reasons identified for informing or not informing patients, considering potential risks and benefits?

Determining the appropriate level of patient awareness regarding the use of AI in their care should be the responsibility of the clinician, not the vendor. The Association is clear that vendors should focus on providing clinicians with thorough documentation, information, and training to ensure they fully understand the AI tool, including its development, testing, and transparency about its use, and enable clinicians to make informed decisions about whether and how to communicate AI use to patients. The EHR Association recommends revising the criteria to: "Has the vendor provided clinicians with adequate information to evaluate the model for use with a particular patient?"

AC3.CR42, LS6.F.C11.EC3

Have human factors or behavioral science experts been consulted to determine the optimal approach for presenting information about the AI solution to patients, aiming to build trust and empower patients?

The EHR Association recognizes the importance of building trust and empowering patients when introducing AI solutions in their care process. However, we believe that the responsibility for determining how best to present this information to patients lies with the clinician, not the vendor. Clinicians, who have direct patient interactions and understand the unique context associated with each patient, are best suited to decide how to communicate AI-related information. Conversely, vendors should be responsible for providing clinicians with comprehensive documentation, training, and transparency about the AI tool's development, testing, and intended use. We recommend revising the criteria to: "Has the vendor provided clinicians with adequate information to evaluate the model for use with a particular patient?"

AC3.CR30, LS6.S.C6.EC1; LS6.S.C6.EC2

Is there a mechanism for reporting unintended uses of the AI solution, including periodic audits to evaluate alignment with its intended purpose and identify "off-label" use?

Medical malpractice case law consistently holds clinicians accountable for making judgments about what is appropriate for their patients. While vendors can and should provide clear information about the intended purpose of their tools, they definitively are not responsible for auditing or policing how these tools are used in clinical practice. The EHR Association is clear that the responsibility for determining appropriate use, including any "off-label" applications, should rest with the clinician, not the developer or vendor.

Initial Planning Checkpoint 1: Purpose

These criteria are overly prescriptive and repetitive of steps that are likely already part of a company's software development lifecycle. For example, in the Planning Checkpoint, Stage 1, companies that already employ a robust software development lifecycle framework ask and answer these questions when proposing new development.

It would be more beneficial for the CHAI framework to focus on novel questions related to fairness and potential bias that may not yet be integrated into existing frameworks. A mature software company that

is already building and deploying commercial software at scale would not likely use this checklist verbatim; instead, it would likely appreciate the opportunity to incorporate novel elements into its existing framework. While the checklist may be useful for new entrants to the market, it will necessarily be blended with existing processes for those who already have established procedures for determining appropriate functionality.

AC2.CR31 (LS5.T.C3.EC3)

Have all unforeseen, unintended negative outcomes been sufficiently assessed and documented during the pilot stage, ensuring comprehensive understanding and strategies for mitigation?

The EHR Association appreciates the importance of addressing negative outcomes during the pilot stage of AI solutions, but the current phrasing of the criteria is unclear. While it is impossible to anticipate all unforeseen and unintended consequences during a pilot, we believe the intent is to ensure that any negative outcomes identified during the pilot phase are thoroughly assessed and documented, with appropriate mitigation strategies developed before the solution is used in production. In order to more accurately reflect the practical realities of piloting AI solutions and ensure known issues are addressed before broader deployment, we recommend rewording the criteria to: "Have all negative outcomes identified during the pilot stage been sufficiently assessed and documented with mitigation strategies in place?"

Multiple Sections

Human in the loop, human override requirements and recommendations

Throughout the framework, the language varies in terms of whether human-in-the-loop or human override capabilities are recommended or required. For example:

- AC3.CR32 appears to require human override capabilities, stating: "Is a plan established to manage user disagreements with the AI output, including a mechanism by which users can override algorithmic decisions based on clear guidelines?"
- In contrast, the CHAI Assurance Standards Guide, General Section 3.0, states that it is "preferable, and for many applications a requirement, to keep a human involved in the decision-making process with support from an AI solution" in high-stakes areas like healthcare.
- Section 4 - AI Lifecycle, Stage 2, suggests: "When possible, design the AI system to keep a human in the loop to contest or override AI output, ensuring that a human-machine teaming model specifies how the user interfaces with outputs. As indicated by the consideration above, it is important to clearly assess whether there is a human in the loop who can oversee, override, or contest the AI solution's output. If not, the team should determine what would be required to add a human to the workflow, or else implement additional quality control processes to assess AI system accuracy and safety."
- However, the language in Stage 6 is stronger: "Finally, when possible, ensure that the AI solution is designed to keep a human in the loop to contest or override its output. When this is not possible, quality control processes can be implemented to assess accuracy and safety."

The EHR Association requests that the documents be updated to provide consistent guidance/requirements.

CHAI Assurance Standards Guide, General Section 3.3

Definition of Business Owner

A Business Owner is identified as an end user—such as a healthcare professional, healthcare administration staff member, or clinical administration staff member. However, in the ambulatory space, someone who has purchased technology for their healthcare organization is unlikely to have specific expertise in AI, data science, informatics, or even an IT background. They are most likely an office administrator, physician, or other staff member, and it is important to recognize that not all ambulatory practice implementers will have the ability to define the impact measures needed to determine the AI's effectiveness. Instead, they will expect those measures to be provided by the vendor and will rely on us to monitor and ensure that the AI operates within the appropriate guardrails.

The EHR Association suggests that end-user, "deployer," or "implementer" obligations should consider the different care settings and their capabilities (e.g., acute care hospitals vs. small ambulatory family practices). It is important to understand end-user capabilities and align responsibilities accordingly.

CHAI Assurance Standards Guide

Section 4 - AI Lifecycle, Stage 5 – Pilot

> *Prior to the general deployment of an AI system, careful review and consideration must be made by the health system to decide whether and how to proceed.*

Section 4 - AI Lifecycle, Stage 5 - Pilot Criteria assumes that implementers have the capability to deploy to a test or development environment before implementing in production. However, many ambulatory practices may not have an alternative environment available for such testing and regularly deploy updates directly into production. In this scenario, the Stage 4 Assessment would likely need to be handled by the vendor, potentially with one client serving as a beta or pilot site for all customers. Many customers using web-based technology may deploy updates directly into a production environment as part of a standard release cycle, accompanied by the necessary documentation and training. The EHR Association, however, recommends that the criteria allow for alternative testing scenarios. We believe that regulations impacting end users (providers and practices) should consider the varying levels of internal IT support available to practices of different sizes, as well as the options available to them for testing new functionality. We encourage the development of regulations that are manageable for both large health systems and small independent clinics, ensuring equitable use of AI tools regardless of organization size.

CHAI Assurance Standards Guide, Transparency, Intelligibility, and Accountability: Stage 4, Section titled: Consider risk, change, and competitive analysis

Finally, determine whether a competitive analysis has been performed and if risk mitigation success can be compared against competitors.

The EHR Association agrees that risk mitigation is a critical consideration. However, requiring vendors to perform a competitive analysis and compare their risk mitigation success against competitors is impractical and inherently problematic. Vendors do not have access to the performance metrics of their competitors, as this information is typically private and confidential. Consequently, such comparisons would be impossible to conduct accurately, and we therefore recommend removing this criterion based

on the infeasibility of completion. Instead, the focus should more practically remain on the effectiveness of each vendor's own risk mitigation strategies.