



S.M.A.R.T. and S.A.F.E.

A Novel Framework for Clinical Artificial Intelligence Evaluation by the Analytics Oversight Committee at UC Davis Health

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Healthcare systems are facing significant challenges in supporting responsible adoption of Artificial Intelligence (AI). The rapid rise in new technologies and data assets are major factors systems are facing. Health care systems are eager to implement solutions that improve both operations and patient outcomes. However, without careful evaluation of AI-based technologies, health care systems are at risk of losing more than time and money. Poor AI model implementations can cause adverse patient outcomes, perpetuate or magnify health inequities, worsen provider dissatisfaction, and cause reputational harm.

At UC Davis Health, the oversight of all advanced analytics models, including AI, intended for clinical decision-making and clinical research is delegated to the Analytics Oversight Committee (AOC). Co-chaired by the Chief Nursing Informatics Officer and the Chief Research Informatics Officer, AOC membership includes broad organizational representation and the technical expertise required to evaluate the safety, efficacy, and appropriateness of proposed AI models. Members include practicing clinicians from multiple disciplines, biostatisticians, informaticists, epidemiologists, and members representing operations, Information Technology, diversity/equity/inclusion, and compliance.

In addition to its decision making and consultative functions, the AOC was also charged by UC Davis Health's Vice Chancellor/CEO to establish best practices and standard operating procedures for the evaluation of proposed AI models. In response to this charge, the AOC has created a novel framework for examining proposed models: The S.M.A.R.T. and S.A.F.E. framework.

The **S.M.A.R.T. criteria** ensure that AI models are evaluated for strategic alignment, organizational fit, and feasibility. The committee evaluates proposed models based on the questions below:

Category	Specifications
Specific	<ul style="list-style-type: none"> • Has the proposed use of AI been defined in relation to specific business objectives (clinical, research, strategic, financial, etc.)? • Has the proposed implementation plan been defined?
Measurable	<ul style="list-style-type: none"> • How and when will the impact of the proposed solution be measured? • Will both benefit and potential consequences (direct and/or indirect) be measured? • Is there a way to differentiate if the post-implementation outcomes are attributable to the AI solution, other associated changes in business workflows, or unrelated secular trends?
Aligned	<ul style="list-style-type: none"> • Is the proposed use of AI aligned with a defined, organizational strategic objective (e.g. – enterprise clinical strategic plan, Institute for Healthcare Improvements Quintuple Aim, etc.)? • Who else may be affected by the proposed AI implementation?

	<ul style="list-style-type: none"> • Has the proposed AI solution received conditional support from organizational stakeholders required for successful implementation?
Realistic	<ul style="list-style-type: none"> • What are the chances that the proposed AI solution will work as promised? • Will clinical/operational practices change if the proposed AI solution is implemented?
Transformative	<ul style="list-style-type: none"> • Will the proposed use of AI have an incremental or transformative effect on how we deliver care, conduct research, or manage the organization? • Will the proposed use of AI transform the way others outside UCDH deliver care, conduct research, or manage the organization?

Table 1: UC Davis Health S.M.A.R.T. framework

Without clear strategic alignment including buy-in of all impacted stakeholders, projects involving AI technologies need to be re-evaluated by the sponsor before moving forward. If a proposed model and its implementation satisfy the S.M.A.R.T. criteria prerequisites, the request moves into the next phase of evaluation: S.A.F.E.

The **S.A.F.E. criteria** ensure that AI models are **s**afe, **a**ccurate, **f**air/unbiased, and **e**vidence-based before being applied to patient care. The committee reviews every proposed model based on the questions below:

Category	Criteria
Safety/Risk	<ul style="list-style-type: none"> • What is the IMDRF¹ safety category of the proposed implementation? • Is the model to be used on- or off-label? • Have potential harms been identified and mitigated? • Will the model’s use maintain or improve the current standard of care? • Is the model acceptably safe to implement?
Accuracy	<ul style="list-style-type: none"> • Was the model trained and tested in patients similar enough to the deployment population? • Were the right metrics used to assess model accuracy? • Was model calibration assessed and if so, was model calibration acceptable? • Does the model perform equivalent to or better than existing methods? • Is the model acceptably accurate relative to the degree of risk?
Fairness/Bias	<ul style="list-style-type: none"> • Is model performance fair and unbiased when evaluated in vulnerable subgroups? • Was fairness and bias assessed for both model accuracy and calibration? • If unfair performance is discovered, can it be reasonably mitigated?
Evidence	<ul style="list-style-type: none"> • Has model performance been evaluated in peer-reviewed studies and if so, what is the level of evidence? • Has the model been cleared by the FDA and if so, through what mechanism (eg, De Novo, 510(k))? • If available, do post-marketing real-world studies substantiate or refute initial claims to the FDA? • Does the overall assessment of the evidence support the use of the model at our institution?

Table 2: AOC S.A.F.E. criteria for assessing AI models intended for clinical use within UC Davis Health.

¹ <https://www.imdrf.org/documents/software-medical-device-possible-framework-risk-categorization-and-corresponding-considerations>

Since the committee's inception in March 2021, the AOC has evaluated 20 AI models, originating from various sources (Epic-sourced, home-grown, or commercial/third-party vendors) intended for use in multiple health system departments including Population Health, both Ambulatory and Inpatient environments, the Emergency Department, Intensive Care, Inpatient Radiology, Ophthalmology, Surgery, and Hospital Capacity Management. To date, the committee has approved 14 models for deployment (including those contingent upon successful pilot testing). Of those, 11 models were referred for additional evaluation utilizing data science and biostatistics expertise from our enterprise IT Health Analytics Core (HAC) to further examine the model features, performance, and any areas of concern. Additionally, the AOC has declined to further evaluate one model implementation due to a lack of stakeholder alignment and has decommissioned one model due to questions regarding the fairness/bias of its features.

Assessment

After the AOC consultation with [REDACTED] and reviewing the additional model evidence and local performance metrics, the AOC triage team does not have any concerns with the use of the two (2) [REDACTED] modules, [REDACTED] and [REDACTED], based on the AOC S.A.F.E. criteria. The following information was provided by the vendor:

Safety/Risk – No changes to the existing standard of care which is deficient. Implementation workflow had no identified safety concerns. Committee felt that program substantially increased patient safety.

Accuracy – Proposed solution was felt to be sufficiently accurate and implementation plans appears to be used “on label”. Local analysis to date supports vendor claims of accuracy when generalized to UCDH .

Fairness/Bias – No significant fairness and bias concerns were identified.

Evidence – Quality of evidence provided by the vendor was felt to be fair but similar to many AI products on the market. Local analysis of performance helped to strengthen the quality of evidence supporting safety and accuracy.

Figure 1: Example of a S.A.F.E. assessment that was part of an AOC decision.

Through the evaluation process, the AOC also oversees the allocation of Health Analytics Core resources for specialized biostatistics and data science support to aid in the creation, evaluation, validation, and implementation (or decommissioning) of AI models including assistance with study design. The AOC has created a safe, responsible, transparent, and educational process to articulate the potential risks and benefits of AI at UC Davis Health, helping to drive innovation and improve patient outcomes.

The advent of generative AI and other rapidly emerging AI-enabled technologies has highlighted the urgent need for multifaceted health AI governance. Without robust oversight, health care organizations, patients, and their providers may be exposed to

substantial risks when implementing AI. The Analytics Oversight Committee's S.M.A.R.T and S.A.F.E governance framework represents an efficient, transformative methodology to enable responsible, ethical, and effective advancements in health AI on behalf of the patients and communities we serve.