

Summit Communique

A multi-stakeholder initiative to advance non-regulatory approaches to CDS quality

December, 2020

Healthcare leaders call for high-quality CDS to improve health outcomes through Summit Communique on CDS Quality

Healthcare leaders representing physicians, provider networks, hospitals and life sciences and technology innovators are calling for a greater focus on high-quality decision support to navigate the increasing complexity of clinical decision making.

The need for high-quality clinical decision support

In many fields of medicine, knowledge is expanding faster than healthcare providers can assimilate. This results in care disparities, missed opportunities to improve outcomes, and an epidemic of avoidable medical errors. A recent study concluded that “about 5% of adult outpatients in the United States experience a diagnostic error annually... Diagnostic mishaps contribute to about 1 out of 10 patient deaths, cause as much as 17% of hospital adverse effects, and affect approximately 12 million adult outpatients a year, which translates into 1 out of 20 Americans.”¹

Clinical decision support (CDS) systems are an important tool for addressing this complexity. CDS systems are software tools that leverage data and analytics to provide healthcare professionals (HCPs) and patients with timely knowledge to inform diagnosis and treatment decisions. By providing person-specific information, intelligently filtered or presented at appropriate times, CDS becomes “the user-facing representation of evidence-based clinical insight.”²

“CDS is essential. We cannot have effective medicine going forward without robust, high-quality CDS.”

A principles-based approach to CDS quality

At a recent virtual CDS Quality Summit, a group of senior healthcare leaders called for CDS to adhere to a set of Quality Principles developed to set clear expectations for this rapidly-evolving field. The principles-based approach to quality is intended to complement the work of regulators, creating guardrails for a range of unregulated applications. Highlighting the importance of this work, a Summit participant commented, “CDS is essential. We cannot have effective medicine going forward without robust, high-quality CDS.”

The development of CDS is driven by increasing access to electronic healthcare data and advancing analytical capabilities, including artificial intelligence and machine learning (AI/ML). Measures to ensure the quality of CDS systems, and that high-quality CDS can be shared across users, have not kept pace. This has led some corners of the market for CDS to be characterized by uneven quality, a situation participants likened to “the Wild West”.

Done right, CDS systems can improve patient outcomes and population health, reduce provider cognitive burden, and improve healthcare resource utilization.² However, poor-quality CDS has the potential to cause patient harm, unduly restrict care decisions, and perpetuate bias in healthcare delivery.³

The CDS Quality Principles – detailed below – center on three key themes:



Patient centricity

CDS must put the interest of the patient first, serving as an accurate source of medically beneficial options for joint patient-HCP consideration



CDS validity

CDS should utilize the most relevant and accurate data available and accurately translate that data into unbiased insight



Proper implementation

CDS must integrate effectively with clinical workflows to fit the way medicine is practiced, and be readily shared across care settings

"Given the uneven quality of CDS, it's the Wild West out there"

Next steps in advancing CDS quality

While endorsing the Quality Principles, Summit participants agreed that they are but the first step to realizing the promise of a CDS-enabled healthcare ecosystem

Next steps in this work will focus on two general themes:



Ensuring that healthcare decision-makers – including HCPs and patients – have reason to trust that CDS will do what it says it will do, in their specific care setting



Ensuring that high-quality CDS developed in one care setting can be readily used in another care setting

Summit participants discussed a variety of approaches to advancing these goals, concluding that *"we need a collection of motivated organizations to band together."*

"There has been no successful migration of CDS from one institution to another"

Preamble – The Promise and Necessity of CDS



Harness data and analytics to deliver effective individualized patient care

The rapid expansion of medical knowledge and the complexity of healthcare considerations is straining the bounds of human decision-making. By applying analytics to patient-specific data, CDS systems can place applicable medical insight within reach of healthcare professionals (HCPs)

By integrating relevant data and insight for consideration by HCPs, CDS can provide a comprehensive view of the patient and recommend personalized care based on a patient's unique characteristics and preferences



Broaden access to high-quality evidence-based practice while supporting efficient use of healthcare resources

CDS can support population health through the broad diffusion of best practice, increasing consistency of clinical decisions across a fragmented healthcare landscape while bringing expert knowledge into community care

CDS can advance dual healthcare objectives of improving quality and promoting value by recommending the interventions that are most likely to benefit the patient and reducing inappropriate healthcare expenditures



Enhance the doctor-patient relationship

CDS can reduce the cognitive load and administrative burden on healthcare providers, freeing time for more meaningful patient interactions and improved patient experience

Principles of CDS Quality

There is a significant need for CDS, but the benefit it can deliver depends on the quality of the technology solution and the context for its implementation. Health system stakeholders believe that adherence to the following Principles is necessary to ensure that CDS delivers on its promise:

Patient Centricity



Prioritize achieving the best outcome for the patient

CDS should aim to provide the healthcare provider with a holistic view of the patient by gathering all relevant and available information across the care continuum and over time

CDS recommendations should reflect the most medically beneficial diagnostic and treatment options for the patient in their care environment

Where possible, CDS should communicate efficacy, safety, cost and quality of life differences among its treatment recommendations



Present evidence-based interventions for joint provider-patient consideration

CDS should be a tool to allow shared decision-making between a patient and their healthcare provider, respecting a patient's individual preferences. Engaging patients in their own care has been shown to result in better health outcomes⁵

CDS Validity



Utilize the most relevant and accurate data available, including patient-specific data

CDS recommendations should be based on the best data available at the time of decision⁶. Efforts to enhance data quality serve to improve CDS performance

Where a rapidly-evolving clinical environment requires decision-making based on limited information, CDS systems should clearly disclose the limitations of the evidence base

CDS systems should be maintained using good lifecycle knowledge management practices. This includes regular reviews and updates to ensure that their recommendations continue to reflect the best options for a given clinical situation



Accurately translate data into valid and meaningful insight while seeking to minimize bias

All models, no matter how sophisticated, have limitations. CDS systems should be confirmed through best methodological practice to accurately, reliably and precisely generate the intended clinical insight from the input data.^{7,8}

CDS tools should be developed and applied with the goal to minimize health inequities based on race, ethnicity, gender, socio-economic status or other determinant. To minimize bias, the CDS algorithms should be broadly representative of the patient population to be treated, including but not limited to sub-population, race, socio-economic and care setting components



State the data inputs and analytical approach used to generate a recommendation

CDS systems should provide information about the data, analytical methodology, and clinical decision rules they apply, and the appropriate conditions for using them. This enables clinicians and patients to understand and trust the recommendations generated

Proper Implementation



Provide actionable recommendations at the appropriate time and integrate effectively with clinical workflows

CDS should be tailored to ease the cognitive burden on healthcare providers and eliminate unnecessary and untimely interventions that lead to alert fatigue. Doing so yields safer and more efficient care

CDS should be designed to integrate effectively into clinical workflows, with usability confirmed by the end user



CDS should support, not replace, HCP decision making

Experienced healthcare professionals can pick up on nuances of patient well-being that are not fully captured by digital health tools. The context for using CDS must support the ability of healthcare providers to exercise independent judgment in the best interest of their patient

