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The Technology Landscape of Patient-Centered Clinical Decision Support – Where Are We and What Is Needed?

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Abstract

Patient Centered Outcomes Research (PCOR) and health care delivery system transformation require investments in development of tools and techniques for rapid dissemination of clinical and operational best practices. This paper explores the current technology landscape for patient-centered clinical decision support (PC CDS) and what is needed to make it more shareable, standards-based, and publicly available with the goal of improving patient care and clinical outcomes. The landscape assessment used three sources of information: (1) a 22-member technical expert panel; (2) a literature review of peer-reviewed and grey literature; and (3) key informant interviews with PC CDS stakeholders. We identified ten salient technical considerations that span all phases of PC CDS development; our findings suggest there has been significant progress in the development and implementation of PC CDS but challenges remain.

Keywords:

Decision Support Systems, Decision Making, Patient Reported Outcome Measures

Introduction

As part of the transition toward value-based, patient-centered care, the 21st Century Cures Act created new expectations for data interoperability across the health system, and for patient participation in data generation, access, and use. This transition depends, in part, upon the translation of patient-provided data into evidence, and the accessibility of that evidence in the form of clinical guidelines that support patients and clinicians in their health care decision-making.

Clinical decision support (CDS) tools have traditionally disseminated clinical guidelines at the point of care, and are typically presented to the clinician rather than to a patient.[1] Patient-centered CDS (PC CDS) is "CDS that supports individual patients and their approved caregivers and/or care teams in health-related decisions and actions by leveraging information from patient-centered outcomes research (PCOR) findings and/or patient-specific information."[2] Patient centered care and patient engagement have become increasingly important over the past decade. This shift is reflected in the modalities

through which PC CDS is now delivered (i.e., digital apps, websites, patient portals, short message system (SMS)/text, and electronic health records (EHRs)).

This paper explores the current technology landscape for PC CDS and what is needed to make PC CDS more shareable, standards-based, and publicly available, with the goal of improving patient care and clinical outcomes.

Methods

The goals of the study were to: (1) assess the current state of standards for PC CDS; (2) identify gaps and challenges within PC CDS standards; and (3) identify future directions for PC CDS. We investigated three sources of information to inform our study: (1) a 22-member technical expert panel (TEP); (2) a review of peer-reviewed and grey literature; and (3) key informant interviews (KIIs) with PC CDS stakeholders.

TEP. The TEP consisted of a range of PC CDS stakeholders: federal agencies (n = 4); academic medical centers (n = 3); health IT app vendors (n = 4); patient advocacy organizations (n = 2); researchers/research organizations (n = 4); health systems clinical staff and providers (n=2); health plans and value-based purchasers (n=2); and quality standards and measures developers (n = 1). These individuals had knowledge and expertise in PC CDS design, implementation, knowledge representation, standards, and measurement.

Literature review. We conducted a search via PubMed for peer-reviewed literature, Google for the grey literature, and targeted searches such as presentations from the American Medical Informatics Association (AMIA) "HL7 FHIR® Showcase."[3] Our search terms encompassed key areas of standards for CDS, including: IT standards, Fast Healthcare Interoperability Resources (FHIR), interoperability, decision support, and patient-centered. We screened titles and abstracts using inclusion/exclusion criteria, and reviewed the full-text of the literature that remained, ultimately including 22 resources.

Key Informant Discussions. We interviewed a convenience sample of 18 individuals with subject matter expertise in a diverse range of disciplines related to PC CDS: health IT vendors/consultants (n=5), health care clinical staff and providers (n=4), clinical content vendors (n=3), researchers/research organizations (n=3), patient representatives/patient advocacy organizations (n=1), federal agencies (n=1), and payers (n=1). During each 60-minute interview, we used a semi-structured interview guide to gather perspectives on the facilitators, challenges, and areas for future PC CDS research.

Results

Based on the data sources, we developed a model of the PC CDS technical landscape aligned with five phases of PC CDS development: Prioritizing, Authoring, Implementing, Measuring, and External factors to encompass the policy, legal, governance, and marketplace issues that impact design, development, and implementation of PC CDS.[4] Below, we discuss **ten salient technical considerations** that span each phase of the PC CDS lifecycle, and propose suggestions to advance the field of PC CDS.

Prioritizing. Identifying and prioritizing evidence-based findings for translation and dissemination via PC CDS is a critical aspect of ensuring that providers and patients have the resources needed to make informed care decisions.

Consideration 1: Standards and Guidelines for Increasing Patient Trust and Safety. Putting patients at the center of PC CDS requires increasing the utility of PC CDS for patients. This arrangement can lead to better patient outcomes and also reinforce patient trust in the decision support tools (EHR-based, patient-facing app, etc.).[5] Providers can also benefit from understanding the evidence used in PC CDS to inform their discussions with patients. Both patients and providers need to have confidence in the validity of health apps and other PC CDS tools; thus, key informants felt the prioritization of evidence-based findings for PC CDS and the underlying research from which the findings are derived should be explicit to enable patients trust.

Several suggestions for improving trust and safety are related to federal engagement with the standards development community and health system stakeholders. To address the potential risks posed by unvetted or unreliable PC CDS, the federal government could take an active role in convening stakeholders to discuss the most effective way to prioritize and develop guidance on best practices for health app developers (e.g., an ethical and safety framework), and/or a rating system for the health app industry to certify they have met certain safety and quality criteria, particularly when the apps involve decision-making support. In addition, app developers should have to demonstrate that they follow good software engineering practices including: performing hazard analyses of their products; designing for safety; documenting these designs; and verifying that their systems work as designed.

Authoring. From a technologic vantage point, translating PCOR into PC CDS requires (1) standards for representing recommendations and logic in a format that is computable so that evidence can be used in PC CDS interventions; and (2) standards for structuring clinical content, such as patient data, so that CDS artifacts can be shared.

Consideration 2: Standards for representing clinical recommendations. A central challenge to knowledge translation is the variability created when multiple clinical practice guidelines are developed for the same clinical condition. This challenge is exacerbated when EHR vendors and health care organizations develop site- or product-specific CDS interventions, meaning that the CDS guidance may differ by stakeholder, depending on which guideline was selected, how the guideline was interpreted and then translated into computable knowledge. This kind of variation can create heterogeneity to guideline adherence among clinicians. In response to the problem, the Centers for Disease Control and Prevention (CDC) initiated a program called "Adapting Clinical Guidelines for the Digital Age," to develop a standardized process and improve the timeliness, accuracy, and consistency with which guidelines are translated and implemented.[6] The field would benefit from additional coordination and rapid-cycle translation of real-world evidence into clinical guidelines into structured logic for use in EHRs. Another issue is the lack of a generally accepted standards for knowledge translation. While the Clinical Quality Language (CQL) has been proposed as a standard for knowledge representation, to date the standard has not been broadly adopted.

Consideration 3: Patient Generated Health Data (PGHD) Standards. PGHD standards are integral to the future of PC CDS. These data can be manually entered by patients or collected from mHealth devices, such as activity trackers or blood pressure cuffs that automatically transmit data. However, the diversity of data types and devices used to collect PGDH presents a challenge when managing data across multiple platforms.[7] Standardized data elements are lacking for PGHD, hindering the seamless incorporation of PGHD into care, the aggregation of data from diverse participants and datasets, and the ability to analyze and interpret PGHD.[8]

Implementing. The implementation phase applies standardized methods and architectures to operationalize PC CDS interventions into clinical workflows to deliver the "CDS Five Rights": (1) the right information; (2) to the right user; (3) through the right channels; (4) in the right intervention formats; and (5) at the right time.[4]

Consideration 4: Integration of PGHD into EHRs. PGHD encompasses a wide range of data that flows directly from patients—via assessments, apps, remote monitoring devices, or wearables—and thus provides clinical information that is not routinely captured in a provider office. While health care providers report a preference for integrating PGHD into existing clinical workflows,[9] clinical integration of PGHD into EHRs has lagged behind other types of data for reasons that include: poor interoperability to support linkage and scaling of PGHD across health care systems, inconsistent provider engagement in use of PGHD, lack of interfaces for health care providers to receive, store, and display PGHD, and lack of incorporation of PGHD into workflows at the point of care.[9]

A major challenge for using PGHD in the health setting and specifically within the EHR is that the standards needed to effectively integrate these data are lacking, or because the standards are immature and not widely available for implementation.[10] As CDS moves outside the clinic and into more patient-facing modalities such as apps and devices, the risk increases that PGHD will remain inaccessible to the clinician. Mature data exchange standards are needed to allow integration into the EHR and/or data linkages that give providers access to valuable data on patients' medical history, devices, etc.

Consideration 5: Managing PGHD Volume. When PC CDS involves data from wearables, patient-reported outcomes (PROs), and other PGHD, the large volume of asynchronous or continuous streams of data can be difficult to manage, process, and review without intelligent filtering and summarization. Currently, there is no standardized approach to using human or machine processing power to make sense of these large amounts of data, and different approaches can yield different answers.[8] Thus, providers are concerned about lack of oversight of PGHD and often skeptical of the value of PGHD. However, intuitive data visualizations that focus on important clinical information can help overcome these concerns.[9] Providers indicate a desire to sort or summarize PGHD in a descriptive manner, to manipulate or graph it in different ways, to see patterns more quickly in the data patients generate, and to extrapolate meaningful conclusions from these data.[11]

Consideration 6: Managing Data Provenance. Data provenance solutions can help address lack of an accepted gold standard or single validated approach for assessing whether PGHD are of adequate quality.[10] The consistent use of Unique Device Identifiers (UDI) to convey device provenance could provide linkages between PGHD and data sources, as well as the source-specific processes for cleaning, normalizing, and standardizing data that need to be defined in order to present information in a meaningful way to health care providers.[10] However, additional methods for expedient verification of PGHD through trusted sources such as health care providers or through linkages to complementary information the EHR may be needed.[8]

Consideration 7: FHIR Standards for Information Exchange. While FHIR standards have greatly improved access to data for use in CDS, several issues remain—including variable implementation, inconsistent availability across vendors, and limited functionality. Even within the same health system, interpretation and implementation of FHIR profiles can differ.[12] The definitions of the US Core FHIR profiles need to be more specific to support interoperability—so that there is a use of standard terminology rather than something vendor- or institution-specific.[13] FHIR-based questionnaires need to be developed to facilitate data collection from patients in a standardized format that can be shared across systems.[14]

Consideration 8: CDS-focused APIs. Key informants noted a lack of FHIR APIs to access data in the EHR for use in PC CDS and the lack of CDS Hooks triggers to invoke CDS. The APIs to access many types of data within EHRs remain proprietary.[15] Further, even when EHRs have APIs for FHIR resources, they largely are limited to reading the data and do not support writing data from apps to the EHR.[13] To promote interoperability, vendors should use FHIR APIs that allow data to be passed from an external application to the EHR (i.e., write APIs), such as those required for real-time interactions during order entry and documentation.[16]

There is also a need to standardize CDS insertion points into the clinical workflow.[17] While CDS Hooks have been developed to trigger CDS in the workflow,[18] there is wide variation amongst across EHR vendors on where specifically to place CDS trigger points (e.g., provide dose checking as soon as each order is entered, or wait until a full session of multiple orders is ready to be signed).[19] Additionally, most EHRs severely limit these integration points, only enabling a "hook" in response to a patient's chart being opened.[13]

Measuring. Standardized measurement is critical to ensure that PC CDS interventions measurably improve clinician and patient decision-making, care processes, and outcomes.

Consideration 9: Standardization of patient-centered outcomes. We found that the published literature has focused predominantly on measuring aspects of PC CDS related to implementation processes, such as the acceptability/usability and feasibility of interventions. Some progress has been made in measuring the "success" of PC CDS with studies that measure knowledge acquisition, patient activation, patient satisfaction, and quality of life. These patient-focused measures illustrate promising movement in the field toward measuring patient engagement and shared decision-making outcomes more frequently and more robustly. The International Consortium for Health Outcomes Measurement promotes the standardization of patient outcome measures by publishing consensus-based measure sets for many common conditions, placing a priority on those measures that are important to patients themselves.[20]

External Factors. Ensuring privacy and security is fundamental to patient and provider trust.

Consideration 10: Privacy and Security Standards. Standards that address privacy and security of data used in PC CDS are needed.[21] Data security mechanisms need further refinement to be more nuanced—so that, giving an app access to specific patient's data does not result in other sensitive data being inadvertently shared.[13] Furthermore, there is a need for standards, policies, and guidelines regarding the use and ownership of PGHD.[22] Clarity around data ownership and related legal issues remains a barrier to greater use of PGHD in some circumstances.[22] To ensure patient privacy, there are policies, procedures, and mechanisms that need to be developed that give patients control over how their PGHD is utilized. Mobile app companies need to be transparent about their data use and ownership policies so that patients, in conjunction with their providers, can make informed choices about when and how to create and transmit PGHD. Such transparency will make possible the discussions about patient expectations and provider concerns needed for both parties to benefit from use of PGHD.[22]

Discussion

PC CDS is challenging because the patient-centered focus accentuates the complex, adaptive, sociotechnical systems involved. These challenges increase exponentially when you combine the complexity of the health care delivery system with the systems required to design, develop, implement, and deliver high-quality, evidence-based PC CDS that meets patients' and providers' needs and expectations, and fits into their respective lifestyles and workflows.

Technical limitations of PC CDS included lack of 'true' integration of PGHD into EHRs; and limitations of exchange standards for representing and sharing this knowledge, particularly around device/wearable data and patient preferences. At present, the lack of industry-wide standards for PGHD collection, transfer, and tracking using different technologies, and for interoperability across devices, limits its clinical utility. Additional research needs to focus on developing and piloting standards for PGHD, curating and controlling its flow so it is clinically meaningful and actionable, and creating a quality framework for PGHD data types.[23]

Solutions are needed to improve individual-level data sharing from diverse sources (including PGHD) to make data useful and interoperable regardless of whether they are captured in community settings, in office-based provider settings, or by bulk data sharing among health systems to facilitate population level analysis. Health care stakeholders and technology vendors must work together on standards and interoperability to increase security and reduce the burden of data sharing.

Beyond these technical concerns, there remains work to be done to address concerns about patient and clinician trust in PC CDS. A robust technical infrastructure will ensure that PC CDS is easily deployed for patients and incorporated in the clinical workflow, as well as support the collection and integration of PGHD. However, these advancements will be moot if there is not sufficient trust for PC CDS tools to be meaningfully used.

Conclusions

Early work has identified the technical infrastructure needed to collect PGHD, to combine it with data from the EHR, and to develop robust evidence-based clinical guidelines that deliver patient-centered information to patients via web-based or smartphone-based apps.

Our findings from the literature and KIIs confirm that the domain of PC CDS has made significant progress in development and implementation; however, several technical issues remain and must be addressed for the field to move forward. Future PC CDS efforts should focus on real world implementation and ensuring that the PC CDS does in fact improve patient outcomes.

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