New Standards for Clinical Decision Support: A Survey of The State of Implementation

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Summary

Objectives: To review the current state of research on designing and implementing clinical decision support (CDS) tools using four current interoperability standards: Fast Healthcare Interoperability Resources (FHIR); Substitutable Medical Applications and Reusable Technologies (SMART); Clinical Quality Language (CQL); and CDS Hooks.

Methods: We conducted a review of original studies describing development of specific CDS tools or infrastructures using one of the four targeted standards, regardless of implementation stage. Citations published any time before the literature search was executed on October 21, 2020 were retrieved from PubMed. Two reviewers independently screened articles and abstracted data according to a protocol designed by team consensus.

Results: Of 290 articles identified via PubMed search, 44 were included in this study. More than three quarters were published since 2018. Forty-three (98%) used FHIR, 22 (50%) used SMART, two (5%) used CQL, and eight (18%) used CDS Hooks. Twenty-four (55%) were in the design stage, 15 (34%) in the piloting stage, and five (11%) were deployed in a real-world setting. Only 12 (27%) of the articles reported an evaluation of the technology under development. Three of the four articles describing a deployed technology reported an evaluation. Only two evaluations with randomized study components were identified.

Conclusion: The diversity of topics and approaches identified in the literature highlights the utility of these standards. The infrequency of reported evaluations, as well as the high number of studies in the design or piloting stage, indicate that these technologies are still early in their life cycles. Informaticists will require a stronger evidence base to understand the implications of using these standards in CDS design and implementation.

Keywords
Health information interoperability, clinical decision support, FHIR, SMART, CQL, CDS Hooks

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1 Introduction

The management of information in clinical settings has long been recognized by designers of clinical decision support (CDS) tools to be a highly complex problem [1, 2]. For roughly the last decade, the HITECH Act has led to rapid adoption of electronic health record (EHR) systems [3]. While the HITECH Act envisioned interoperability of data across EHR systems, there have continued to be challenges with the interoperable exchange of clinical data extracted from the proprietary data models of different EHR systems. Efforts by standards organizations such as Health Level Seven International (HL7) have sought to address this issue by offering EHR-agnostic services, data models and languages to improve interoperability across EHRs and organizations [4-6].

In this literature survey, we examine the state of research on the implementations of four current HL7 standards for healthcare information in the context of CDS: Fast Healthcare Interoperability Resources (FHIR); Substitutable Medical Applications and Reusable Technologies (SMART); Clinical Quality Language (CQL); and CDS Hooks. We chose SMART and FHIR because both are now federally regulated standards in the United States. Additionally, CQL is now the standard used by the U.S. Centers for Medicare & Medicaid Services (CMS) for specifying electronic clinical quality measures. We further added CDS Hooks so that our review could examine a full suite of integrated standards that allow CDS sharing at multiple levels (e.g., logic, apps, services). Previous CDS standards were developed in isolation and were not always interoperable among themselves. Beyond these core issues, we opted to examine HL7’s standards because it is the largest international health information technology standards development organization worldwide and has potential relevance anywhere EHRs are being implemented. Before describing our review process, we briefly summarize each of these four standards. Further detailed background on these HL7 standards can be found in Strasberg et al. [7].

1.1 Fast Healthcare Interoperability Resources

Fast Healthcare Interoperability Resources (FHIR) is a standard that allows different systems to exchange healthcare data in a standard format. The core of the standard consists of “resources”, which define commonly used healthcare concepts and relationships. FHIR is distinguished from previous HL7 standards by its use of a Representation State Transfer (REST) application programming interface (API), and the ability to share resources in Extensible Markup Language (XML), JavaScript Object Notation (JSON) or Resource Description Framework (RDF). To avoid over-specification of the standard, resources desired by 80% or more of developers are intended to be included as a part of the core specification, whereas those less commonly used are expected to require additional specification, for example in what are known as FHIR profiles. The first draft of FHIR was published in 2014. The most recent version as of December 2020, Version 4.0.1, was published in October 2019 [5, 6, 8, 9].
1.2 Substitutable Medical Applications and Reusable Technologies

Substitutable Medical Applications and Reusable Technologies (SMART) is a standard designed to enable the integration of EHR-agnostic medical applications within EHR systems using existing Web standards. Since its development starting in 2010, SMART has often been used in conjunction with FHIR in a configuration known as “SMART on FHIR” [9, 10]. SMART enables EHR users to launch add-on apps within the EHR through a single sign-on mechanism, while FHIR enables these apps to exchange patient data with the EHR in a standard data format.

1.3 Clinical Quality Language

Clinical Quality Language (CQL) is a human-readable expression language first published as a draft HL7 standard in 2015 that is intended for the representation of CDS logic and quality measures. The language is organized in terms of artifacts that include three components: metadata, clinical quality information and expression logic. CQL provides a standard approach to representing the “if” component of “if-then” decision rules. CQL also can be used to specify a data model and the specific patient data needed [11, 13]. While not required, CQL implementations often use FHIR as the data model.

1.4 Clinical Decision Support Hooks

Clinical Decision Support (CDS) Hooks is a specification first balloted in HL7 in 2018 for provisioning CDS within the EHR via Web services. “Hooks” are events that are automatically triggered upon certain user actions within the EHR, such as opening a patient’s chart or ordering a medication. A CDS Hooks request embeds information about the context of clinical workflow, a set of data requested by the CDS service (“prefetch” mechanism), and access to the EHR’s FHIR server for additional data requests as needed. CDS services return “cards” to the EHR that may include relevant information (e.g., a patient assessment), actionable suggestions (e.g., a medication order), or links to SMART on FHIR apps relevant to the current clinical process. CDS Hooks uses FHIR to meet its data needs [14, 15].

2 Objectives

To inform ongoing efforts to implement interoperable CDS within clinical environments by surveying the current state of research on designing and implementing CDS using the HL7 FHIR, SMART, CQL and CDS Hooks standards, including types of CDS used, domains of application and stage of development of current interventions.

3 Methods

3.1 Inclusion Criteria

The review included research on the use of FHIR, SMART, CQL, or CDS Hooks for CDS. We followed Osheroff et al. [1] in defining CDS as “a process for enhancing health-related decisions and actions with pertinent, organized clinical knowledge and patient information to improve health and healthcare delivery”. The review included studies both on infrastructure development (e.g., work intended to support a wide range of different CDS interventions), and on the development of problem-specific CDS tools regardless of development stage. Healthcare professional- and patient-facing tools were both included. Any professionals such as physicians, advanced practice clinicians, pharmacists or nurses were considered healthcare professionals for the purposes of this study.

3.2 Exclusion Criteria

We excluded viewpoint articles; reviews; research-focused applications without a significant focus on CDS; public health applications without a significant focus on CDS; non-English language articles; and articles that lacked sufficient detail to populate the majority of our data extraction fields. Finally, we excluded: i) articles reporting on application or data clearinghouses that did not emphasize CDS applications; ii) general standards development or interoperability efforts not explicitly focused on CDS; and iii) tools focused solely on patient data collection without a clear CDS component.

3.3 Literature Search

Medical Subject Heading (MeSH) synonyms for CDS yielded poor results in terms of their relevance and failed to capture articles related to CDS Hooks and CQL. For these reasons, we opted to use the names of the standards instead of MeSH terms. The PubMed database was searched in October 2020 using the following search strategy with no date limits:

(“Substitutable Medical Applications” or “Substitutable Medical Apps” or “Clinical Quality Language” or “CQL” or “FHIR” or “Fast Healthcare Interoperability Resources” or “CDS Hooks” or “Clinical Decision Support Hooks”)

Articles that were not returned via PubMed search but which were known to the authors to be relevant were also included in the review.

3.4 Literature Screening

Citation titles and abstracts were screened by two reviewers working independently (PT and CR). Next, the full text of included articles was reviewed to confirm eligibility. Conflicts were resolved via discussion to achieve consensus between the reviewers. Where uncertainty remained after discussion, articles were brought to the full team for resolution. The software Rayyan was used to manage the process (QCRI, Doha).

3.5 Data Extraction

Extraction fields were defined in a study protocol through discussion and consensus with the full research team. Definitions of data extraction fields can be found in the online supplement. Ten articles (23%) were randomly selected and reviewed by the two...
reviewers simultaneously to establish consistency in the data extraction process. Data in the remaining articles were then abstracted individually by the same two reviewers. To describe these CDS evaluations, we used the “problem-intervention-comparison-outcome” (PICO) framework. Study design was categorized using a simplified version of the typology designed by Parab and Bhalerao [16]. To categorize the development of CDS technologies, we distinguished between three stages: design (architecture design and very early prototype development); piloting (creation of a functional prototype and potential evaluation); and deployment (use of the technology in its intended healthcare setting). To assess the types of CDS implemented in the selected studies, we used a simplified version of the typology offered by Wright et al. [17]. Results were summarized in a tabular format.

## 4 Results

The PubMed search yielded 290 articles. Two highly similar articles reporting on the same study were identified and the article containing less information was removed. One relevant article known to the authors but not returned via the PubMed search was added to the set. Of 290 articles screened using the title and abstract, 83 were selected for full-text review, and 44 articles met criteria for inclusion. Across both screening phases, 173 articles were excluded for not reporting on CDS-specific technologies. Of those, 45 were focused primarily or exclusively on research applications. Another 38 were excluded because they were found to be on unrelated topics; 19 viewpoints were excluded; six articles were excluded because they reported on public health applications; and four reviews were excluded. Five non-English articles were also excluded [18-22]. The overall screening process is described in Figure 1.

Among the 44 included articles, FHIR was the most frequently investigated standard (n=43), followed by SMART (n=22), CQL (n=2), and CDS Hooks (n=8). Over half (n=23) of the studies reported designing, building or deploying technologies in the U.S. The remaining 21 studies included efforts in nine countries, including three in Russia, two each in Germany and Austria, and one each from Switzerland, Spain, Norway, Korea, Japan and Argentina. Location was not specified for six studies. Five Cerner® EHR, 11 reported using Epic®, and one reported using a “home-grown” EHR. No EHR was specified for 30 studies. The settings reported in the studies ranged from 18% focused solely on inpatient settings, 36% on outpatient, and 5% on both. Setting was not specified for 41% of articles. While 75% of the articles focused on healthcare professional-facing tools, 5% focused on patient-facing tools, and 16% focused on tools with components for both providers and patients. Intended users were not specified for 5% of articles. Common clinical domains included primary care (n=9; 20%); oncology (n=5; 11%); emergency care (n=3; 7%) and intensive care units (n=3; 7%). We found 55% of studies described CDS tools that were in the design stage, 34% in piloting stage, and 11% that have been deployed in clinical settings. Table 1 summarizes characteristics of the included articles by development stage.

An examination of temporal trends in the use of the standards of interest for CDS indicates significant growth beginning in 2018, when the number of total citations more than doubled. FHIR has been the most...
| Authors and Year Published | Development Stage | Decision/Workflow Supported | Country where Technology Designed or Implemented | Clinical Setting | Clinical Domain | EHR(s) Targeted | Healthcare Professional- or Patient-Facing | Standard(s) Used | CDS Type |
|---------------------------|-------------------|-----------------------------|--------------------------------------------------|-----------------|----------------|----------------|------------------------------------------|----------------|---------|
| Abedin et al., 2020 [26] | Design            | Atrial fibrillation treatment | United States Outpatient | Cardiology     | --             | Professional | FHIR, SMART                           | 1              |
| Alterovitz et al., 2020 [29] | Design            | Genomic data and pharmacogenomic guidelines | -- | -- | -- | -- | Professional | FHIR, SMART | 1 |
| Bergquist et al., 2018 [30] | Design            | Improve heart failure patient compliance; Improve care management; Decrease 30-day readmissions for heart failure patients | United States Outpatient | Cardiology | Epic | Both | FHIR, SMART | 1,2 |
| Bosl et al., 2013 [31] | Design            | Monitoring medication adherence | -- | -- | -- | -- | Professional | SMART | 1,2 |
| Crump et al., 2018 [32] | Design            | Point-of-care reporting of genetic results | United States | -- | -- | -- | Professional | FHIR | 3 |
| De Bruin et al., 2020 [33] | Design            | Supporting CDS Hooks in Arden Syntax can be generalizable to CDS tools incorporating references to knowledge databases | Austria | -- | -- | -- | -- | FHIR, CDS Hooks | N/A |
| El-Sappagh et al., 2019 [34] | Design            | Type 1 diabetes outpatient monitoring | -- | Outpatient | Endocrinology | -- | Professional | FHIR | 1 |
| Gaebel et al., 2016 [35] | Design            | Oncology care/surgery | Germany | Outpatient | Oncology | Cerner | Professional | FHIR | 1 |
| Glachs et al., 2020 [36] | Design            | Supporting diabetes self-management goals; monitoring vitals and glucose | Netherlands, Spain | Outpatient | Self-management | -- | Patient | FHIR | 1 |
| Authors and Year Published | Development Stage | Decision/Workflow Supported | Country where Technology Designed or Implemented | Clinical Setting | Clinical Domain | EHR(s) Targeted | Healthcare Professional- or Patient-Facing | Standard(s) Used | CDS Type |
|----------------------------|-------------------|-----------------------------|-----------------------------------------------|-----------------|----------------|--------------|------------------------------------------|----------------|---------|
| Gordon et al., 2017 [37]   | Design            | Identify patients who develop Platelet Transfusion Refractoriness and require human leukocyte antigen-matched platelets | United States | -- | Oncology | -- | Professional | FHIR, SMART | 1 |
| Henry et al., 2018 [24]    | Design            | Real-time sepsis risk scores for intensive care unit patients | United States | Inpatient | Intensive care unit | -- | Professional | FHIR, SMART | 1,2 |
| Kamel and Nagy, 2018 [38]  | Design            | Radiology image interpretation | United States | -- | Radiology | -- | Professional | FHIR | 1 |
| Karhade et al., 2020 [39]  | Design            | Spine surgery risk assessment | -- | Inpatient | Surgery | -- | Professional | FHIR, SMART | N/A |
| Khalilia et al., 2015 [40] | Design            | General risk assessment for arbitrary conditions | United States | Outpatient | -- | -- | Professional | FHIR, SMART | 1 |
| Kimura and Ishihara, 2015 [41] | Design | CDS interoperability | Japan | -- | -- | -- | -- | FHIR | N/A |
| Kogan et al., 2018 [42]    | Design            | Treatment of patients with multi-morbidities | -- | -- | Primary care | -- | Professional | FHIR | 1,2 |
| Nguyen et al., 2019 [12]   | Design            | Drug-drug interaction detection | -- | Both | -- | -- | Professional | FHIR, CQL, CDS Hooks | 1,2,3,4 |
| Schweitzer et al., 2018 [43] | Design           | Vital sign monitoring for patients in rural areas | -- | Outpatient | -- | -- | Both | FHIR | 1,2 |
| Séroussi et al., 2018 [44] | Design            | Clinical recommendations for patients with breast cancer | -- | -- | Oncology | -- | Professional | FHIR | 1,3 |
| Sinha et al., 2017 [45]    | Design            | Opioid prescribing based on clinical guidelines | United States | -- | -- | Epic, Cerner, Allscripts | Professional | FHIR, SMART | 1,2,3,4 |
| Authors and Year Published | Development Stage | Decision/Workflow Supported | Country where Technology Designed or Implemented | Clinical Setting | Clinical Domain | EHR(s) Targeted | Healthcare Professional or Patient-Facing | Standard(s) Used | CDS Type |
|---------------------------|-------------------|-----------------------------|-----------------------------------------------|-----------------|----------------|--------------|-------------------------------------------|----------------|----------|
| Spineth et al., 2018 [15] | Design            | CDS interoperability        | Austria                                       | Outpatient      | Primary care   | ----         | Professional                             | FHIR, CDS Hooks | 1        |
| Tippenhauer et al., 2020 [46] | Design            | Assess gene-drug combinations | Switzerland                                   | ---             | Oncology       | ----         | Professional                             | FHIR, SMART    | 1,2,3    |
| Warner et al., 2018 [47]  | Design            | Identify actionable genetic information for oncologists | United States                                 | ---             | Oncology       | Epic, Cerner | Professional                             | FHIR, SMART    | 1,3      |
| Watkins and Eilbeck 2020 [48] | Design            | Incorporating genetic risk factors for medication into clinical decision support; | United States                                 | ---             | ---            | ---          | Professional                             | FHIR, SMART, CDS Hooks | 1,2      |
| Alterovitz et al., 2015 [49] | Piloting          | Genomic information visualization dashboard | United States                                 | ---             | ---            | ---          | Professional                             | FHIR, SMART    | 1,3      |
| Amrollahi et al., 2020 [23] | Piloting          | Sepsis risk prediction      | United States                                 | Inpatient       | Intensive care unit | ---       | Professional                             | FHIR           | 1        |
| Curran et al., 2020 [27]   | Piloting          | Disease management for COPD, hypertension, diabetes | United States                                 | Outpatient      | Primary care   | Epic        | Professional                             | FHIR, SMART    | 1,2,4    |
| Del Fiol et al., 2020 [25] | Piloting          | Cancer risk evaluation      | United States                                 | Outpatient      | Primary care   | Epic        | Both                                      | FHIR, CDS Hooks | 1,3,4    |
| Dolin et al., 2018 [14]    | Piloting          | Provide drug-gene interaction information at point of care | United States                                 | ---             | ---            | ---          | Professional                             | FHIR, CDS Hooks | 1,2      |
| Gesell et al., 2018 [50]   | Piloting          | Identify emergency department patients with acute chest pain who may be candidates for early discharge; reduce harmful hospitalizations | United States                                 | ---             | Emergency care | Epic, Cerner | Professional                             | FHIR, SMART    | 1,2,4    |
| Giordanengo et al., 2019 [51] | Piloting          | Diabetes treatment         | Norway                                        | Outpatient      | Primary care   | ----         | Both                                      | FHIR           | 1,3,4    |
Table 1 continued | Characteristics of included studies by development stage and first author (n = 44). Dashes indicate the study did not provide sufficient information on a particular attribute.

| Authors and Year Published | Development Stage | Decision/Workflow Supported | Country where Technology Designed or Implemented | Clinical Setting | Clinical Domain | EHR(s) Targeted | Healthcare Professional-or Patient-Facing | Standard(s) Used | CDS Type |
|---------------------------|-------------------|----------------------------|-----------------------------------------------|------------------|----------------|----------------|----------------------------------------|-----------------|---------|
| Gruendner et al., 2019 [52] | Piloting          | General platform for developing statistical models, machine learning and CDS in the EHR | Germany | ---- | ---- | ---- | Professional | FHIR, SMART | 1       |
| Kukhareva et al., 2019 [53] | Piloting          | Hyperbilirubinemia screening and treatment | United States | Both | Neonatal care | Epic | Professional | FHIR, SMART | 1,2     |
| Michel et al., 2019 [54]  | Piloting          | Clostridium difficile treatment | United States | Inpatient | Acute care | Epic | Professional | FHIR, CQL | 2,3     |
| Rubin et al., 2019 [55]   | Piloting          | HIV screening               | Argentina | Outpatient | Primary care | Custom | Professional | FHIR, CDS Hooks | 2,3,4    |
| Schleyer et al., 2019 [56] | Piloting          | Care management for patients with chest pain chief complaint | United States | Inpatient | Emergency care | Cerner | Professional | FHIR, SMART | 1       |
| Semenov and Kopanitsa, 2018 [57] | Piloting          | Interpreting laboratory results | Russia | Outpatient | Laboratory | ---- | Both | FHIR | 1,2,3,4 |
| Warner et al., 2016 [58]  | Piloting          | Genetic test reporting, Professional-facing | United States | Outpatient | Primary care | ---- | Professional | FHIR, SMART | 1,3     |
| Williams et al., 2018 [59] | Piloting          | Genetic test interpretation for patients | United States | Outpatient | Primary care/patient decision-making | Epic | Both | FHIR, SMART | 1,3,6   |
| Bloomfield et al., 2017 [60] | Deployed          | Patient-centered pediatric growth chart | United States | Inpatient | Pediatrics | Epic | Both | FHIR, SMART | 1,3     |
| Hur et al., 2020 [61]     | Deployed          | Acute coronary syndrome treatment | Korea | Inpatient | Emergency care | ---- | Professional | FHIR | 1,2,5   |
| Kawamoto et al., 2019 [28] | Deployed          | Hyperbilirubinemia screening and treatment | United States | Inpatient | Neonatal care | Epic | Professional | FHIR, SMART | 1,3     |
| Authors and Year Published | Development Stage | Decision/Workflow Supported | Country where Technology Designed or Implemented | Clinical Setting | Clinical Domain | EHR(s) Targeted | Healthcare Professional- or Patient-Facing | Standard(s) Used | CDS Type |
|---------------------------|-------------------|-----------------------------|-----------------------------------------------|------------------|----------------|----------------|-------------------------------------------|----------------|---------|
| Semenov et al., 2018 [62] | Deployed          | Patient interpretation of lab results | Russia                                        | Outpatient       | Primary care   | ----           | Patient                                   | FHIR           | 1       |
| Semenov et al., 2019 [63] | Deployed          | CDS rule design, modeling     | Russia                                        | ----             | ----           | ----           | Professional                              | FHIR, CDS Hooks | N/A     |

Key for CDS Type: 1=Relevant information display; 2=Alerts/notifications; 3=Reference information/guidance; 4=Order facilitators; 5=Workflow/protocol pathway support; 6=Document forms/templates; N/A=Not applicable (CDS described was highly general or not developed enough to evaluate type).
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frequently studied standard by year in all years since its inception, except in 2016, when a single SMART on FHIR study was published. Frequencies of studies investigating each standard by year since 2013 are provided in Figure 2.

Many studies involved more than one CDS type (e.g., both relevant information display and an alert). When using FHIR, SMART or CDS Hooks, relevant information display was the most common CDS type reported. Among these three standards, 33–50% also reported implementation of alerts/notifications or reference information guidance and 18-38% reported implementation of order facilitators. Workflow support and document forms or templates were rarely emphasized across any of the standards. A summary of CDS type frequencies by standard can be viewed in Table 2.

To assess the topical foci of CDS interventions, we took a “bottom up” approach and classified topic summaries abstracted from articles into seven major groupings. “Condition management and treatment” was the most common focus of CDS using current standards and tended to focus on specific diseases (n=15). “CDS infrastructure” was used to designate the development of generalizable technologies to assist in building and implementing a range of more specific CDS tools (n=7). A significant proportion of included studies focused on the development of CDS for genomics lab result interpretation (n=7). Similarly, the analysis of risk factors was an important focus of work (n=6), including work on sepsis risk [23, 24], familial cancers [25], drug-gene interactions [14], and CHA2DS2-VASc scores [26]. Tools intended to assist clinicians or patients by monitoring particular health metrics, whether for inpatient or outpatient care, constituted a fifth category (n=5). Finally, three tools for non-genomics lab result interpretation were identified, as well as one tool related to HIV screening. Table 3 summarizes the standards used by the included studies in relation to the seven topics identified, as well as the number of studies within each topic that include an evaluation.

Only 12 (27%) studies reported performing any form of evaluation of their proposed technology. The most common study design was observational (n=8; 67%), with three studies (25%) reporting CDS needs evaluations. We identified only two studies with randomized components reporting on the use of any of the standards of interest (Curran et al. [27] and Kawamoto et al. [28]). Two (17%) articles reporting evaluations were in the design stage, seven (58%) were in the piloting stage, and a further three (25%) were deployed in real clinical settings. Table 4 summarizes the characteristics of studies that reported an evaluation.

| Topic | # Studies Reporting Evaluations |
|---|---|
| Condition Management and Treatment (n=15) | 4 (27) |
| CDS Infrastructure (n=7) | 1 (14) |
| Lab Result Interpretation -- Genomics (n=7) | 1 (14) |
| Risk Factor Analysis (n=6) | 1 (17) |
| Health Metric Monitoring (n=5) | 2 (40) |
| Lab Result Interpretation -- Other (n=3) | 2 (67) |
| HIV Screening (n=1) | 1 (100) |

Table 2 Frequency of CDS type reported by standard.

| CDS Type | FHIR (n=43) | SMART (n=22) | CQL (n=2) | CDS Hooks (n=8) |
|---|---|---|---|---|
| Relevant Information Display | n (%) | n (%) | n (%) | n (%) |
| Alerts/Notifications | 16 (37) | 9 (41) | 2 (100) | 4 (50) |
| Reference Information/Guidance | 16 (37) | 7 (32) | 2 (100) | 3 (38) |
| Order facilitators | 8 (19) | 3 (14) | 1 (50) | 3 (38) |
| Workflow/Protocol Pathway Support | 1 (2) | 0 (0) | 0 (0) | 0 (0) |
| Documentation Forms/Templates | 1 (2) | 1 (5) | 0 (0) | 0 (0) |

Table 3 Summary of topics addressed by standards used and evaluation performed.
| Authors                | Stage       | Standards               | Study Design        | Problem                                                                 | Intervention                                                                 | Comparison                                                                 | Outcomes                                                                 |
|-----------------------|-------------|-------------------------|---------------------|--------------------------------------------------------------------------|------------------------------------------------------------------------------|---------------------------------------------------------------------------|--------------------------------------------------------------------------|
| Abedin et al, 2020    | Design      | FHIR, SMART             | Observational       | Automated calculation of CHA2DS2-VASc score                               | MDCalc on FHIR-enabled app                                                   | With application vs. without                                            | 61% of scores for 111 patients differed; adjusted classification difference was 4%; application captured condition not documented by clinician in 57 cases |
| Khalilia et al, 2015  | Design      | FHIR, SMART             | Observational       | Checking feasibility of implementation in terms of system runtime        | Iterative processing of patient health information                          | Estimating average system speed over multiple runs                       | 16ms for 200 pts; under 2.5 seconds for 1000 pts                          |
| Curran et al, 2020    | Piloting    | FHIR, SMART             | Randomized          | Usability and effectiveness evaluation of Disease Manager app             | Dashboard use for chronic disease management                               | 2 different disease scenarios; with dashboard vs without dashboard      | 33% more tasks completed; 2 more tasks/min; improved workload measures   |
| Giordanengo et al, 2019 | Piloting    | FHIR                   | Observational - needs evaluation | Assessing usability of dashboard for collecting patient generated data for diabetes management | Dashboard                                                                  | N/A                                                                      | 100% of participants expected system to be useful; 81.8% of suggestions related to adding functionalities; 18.2% related to removing functionalities; 64% considered existing functionalities relevant; 77.8% of GPs were satisfied with system, 60% of other professionals wanted some kind of change; GPs do not need the same data as dieticians and nurses |
| Kukhareva et al, 2019 | Piloting    | FHIR, SMART             | Observational - needs evaluation | Assessing usability of bilirubin application                              | Dashboard                                                                  | N/A                                                                      | Qualitative feedback on application usability; identification of omittable features; bilirubin results and phototherapy results deemed most important to display |
| Rubin et al, 2019     | Piloting    | FHIR, CDS Hooks         | Pre-Post            | Effectiveness of HIV screening notification in increasing screening rate | EHR alert                                                                  | Pre/post implementation (for overall orders)                             | 36% more tests ordered post-intervention; 67% acceptance rate of screening recommendation; 2.6x increase in orders from gynecology |
| Schleyer et al, 2019  | Piloting    | FHIR, SMART             | Cohort              | Improving health information exchange use for chest pain management      | Chest pain dashboard                                                        | Accessing health information exchange data with and without dashboard   | Intervention ED had greater INPC usage (10.5 vs 3.2 % of encounters); 2.5% increase in INPC use in intervention ED; difference-in-difference estimate indicates increased health information exchange use by intervention ED; qualitative outcomes indicated usefulness, but study identified issues with response time, and information quality |
### Table 4 continued: Summary of studies reporting an evaluation by design stage and author (n = 12).

| Authors                          | Stage         | Standards | Study Design | Problem                                                                 | Intervention                                                                 | PICO                                                                 | Comparison                                                                 | Outcomes                                                                 |
|----------------------------------|---------------|-----------|--------------|--------------------------------------------------------------------------|------------------------------------------------------------------------------|----------------------------------------------------------------------|---------------------------------------------------------------------------|---------------------------------------------------------------------------|
| Semenov and Kopanitsa, 2018 [55] | Piloting      | FHIR      | Observational| Evaluate the correctness of generated laboratory reports and recommendations | A sample of 256 randomly selected reports was performed and two independent experts reviewed the reports independently. The results of the experts' views were used to calculate precision, recall, and F-measure. | CDS-generated laboratory reports with recommendations, information for additional tests, and prediction of health problems. | The CDS tool is accurate compared to the expert results. The CDS tool made mistakes 0.7% of the time. Precision 0.99; Recall 0.99, F-measure 0.99; Cohen's kappa 0.99 |                                                                            |
| Warner et al, 2016 [56]         | Piloting      | FHIR, SMART | Observational – needs evaluation | Assessing usability and usefulness of genetic test reporting app          | Reporting application                                                        | N/A                                                                   | Qualitative feedback on desired features; feedback on desired content    |                                                                            |
| Hur et al, 2020 [59]            | Deployed      | FHIR      | Observational | Improving response time for suspected acute coronary syndrome          | FHIR-based alert triggered by ECG                                            | Cardiac vs. non-cardiac symptoms                                      | 6% of alerts delayed; 2.7 minutes transmission time with cardiac related chief complaint, 3.0 minutes without cardiac chief complaint; 21.9 min from arrival to ECG capture for cardiac CC; 78.5 min for non-cardiac CC |                                                                            |
| Kawamoto et al, 2019 [60]       | Deployed      | FHIR, SMART | Randomized/Observational/Pre-Post | Assesses clinical impact and usability of a dashboard for managing bilirubin levels in newborns | Dashboard                                                                     | Treatment course with and without application                         | Roughly 10% increase in phototherapy ordering for patients with hyperbilirubinemia and 26% increase in ordering for patients with projected hyperbilirubinemia. Time savings of 66 seconds per use. Mean SUS score of 83.9 |                                                                            |
| Semenov et al, 2018 [61]        | Deployed      | FHIR      | Observational | Interpretation of patient-facing lab reports and treatment plan recommendations | Application of CDS to lab report generation                                  | Retrospective evaluation of report recommendation accuracy vs. human recommendation | 1000 reports analyzed; 7% mistakes; 99 precision; 99 recall; 99 F-measure |                                                                            |
5 Discussion

The large proportion of studies in the design or pilot stages (55% and 34%, respectively) highlights the newness of the technology and ongoing efforts to implement the key CDS standards. Similarly, the low proportion of studies reporting any form of evaluation (27%), and the fact that only two studies with randomized evaluation components exist, highlight the continued need for building a strong evidence base around the performance of these standards in practice.

While work with these standards is clearly still in its early stages, there are reasons to be optimistic about their development. Since 2018, we found the use of new healthcare interoperability standards in CDS to be a highly active area of research. Predictably, tools for condition management and treatment are the most common uses for the standards we examined. However, the development of new infrastructures to support a wide range of platform-agnostic CDS development, as well as support for the highly technical domain of genomics lab interpretation, show the promise of these new standards. The high proportion of studies making some use of FHIR in and outside the United States suggests general buy-in to the standard. The low number of studies focused on CDS Hooks and CQL suggests that it is still too early in their life cycles to evaluate their uptake, though we note that CQLs adoption by CMS may encourage widespread implementation in the future.

This survey had some limitations. Although our article screening was modeled on, and generally complies with, scope review methodology, the search strategy, data extraction, and data analysis were more informal. For example, we searched only one database, our search strategy was not one database, our search strategy was not standardizing scoping review methods. As another limitation, the study was conducted over a short period in which we observed rapid development of the literature; the most recent article captured in the search was published in August, 2020 [27]. It is highly likely that new studies have been published that were not captured in our October 21, 2020 literature search at the time of writing. Nevertheless, we believe that this review provides a useful representation of the current state-of-the-art related to the implementation of new CDS standards, and a point of reference for future assessments of the field.

6 Conclusion

The diversity of topics and approaches identified as well as rapid growth in the recent literature highlights the potential utility of and increased interest in the adoption of this emerging set of standards for CDS. The infrequency of reported evaluations, as well as the high number of studies in the design or piloting stage, indicate that use of these technologies for CDS is still nascent and requires further study. Informaticists will require a stronger evidence base regarding the use of these standards in CDS design and implementation to make design decisions going forward.

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