

Designing, Conducting, and Reporting Clinical Decision Support Studies: Recommendations and Call to Action

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By enabling more efficient and effective medical decision making, computer-based clinical decision support (CDS) could unlock widespread benefits from the significant investment in electronic health record (EHR) systems in the United States. Evidence from high-quality CDS studies is needed to enable and support this vision of CDS-facilitated care optimization, but limited guidance is available in the literature for designing and reporting CDS studies. To address this research gap, this article provides recommendations for designing, conducting, and reporting CDS studies to: 1) ensure that EHR data to inform the CDS are available; 2) choose decision rules that are consistent with local care processes; 3) target the right users and workflows; 4) make the CDS easy to access and use; 5) minimize the burden placed

on users; 6) incorporate CDS success factors identified in the literature, in particular the automatic provision of CDS as a part of clinician workflow; 7) ensure that the CDS rules are adequately tested; 8) select meaningful evaluation measures; 9) use as rigorous a study design as is feasible; 10) think about how to deploy the CDS beyond the original host organization; 11) report the study in context; 12) help the audience understand why the intervention succeeded or failed; and 13) consider the financial implications. If adopted, these recommendations should help advance the vision of more efficient, effective care facilitated by useful and widely available CDS.

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Clinical decision support (CDS) systems analyze electronic patient data against a computerized knowledge base to deliver patient-specific assessments and guidance as alerts or reminders (1). Other types of CDS include order sets and documentation templates (2) that guide by channeling users via the limited options offered, as well as emerging CDS involving artificial intelligence (3).

Research on the effect of CDS on clinical care has a long history. In 1976, one of us (C.J.M.) published the first 2 randomized controlled trials (RCTs) of clinical computer systems (4, 5). Both studies doubled provider compliance with care process rules to greater than 50%. More than 150 RCTs of CDS interventions have followed (6). These studies showed that CDS systems could improve the application of preventive care (6), ordering of diagnostic studies (6, 7), and prescribing of medicines (6, 8, 9). They also reduced adverse events (10, 11), morbidity (6), and possibly mortality (9, 10).

Government incentives (12) have led to widespread adoption of electronic health record (EHR) systems in the United States (13, 14). Many assumed that the adoption of CDS systems would parallel the adoption of EHRs and that care providers would comply with their recommendations happily. However, clinicians have ignored up to 93% of alerts (15), and they complain about excessive rates of false-positive reminders (16–18). Nearly one third of CDS systems have had no effect, and those with effects have generally influenced care processes, not outcomes (8, 10, 19–25).

High-quality CDS studies are needed to learn the best ways to apply CDS systems to achieve important improvements in health and care quality. Whereas the CONSORT (Consolidated Standards of Reporting Tri-

als) (26) and SQUIRE (Standards for QUality Improvement Reporting Excellence) 2.0 checklists (27) provide guidance on how to design and report RCTs and quality improvement studies, respectively, only limited guidance is available for the design and reporting of CDS studies (28, 29). This article seeks to fill this gap.

For illustrative purposes, we will reference a 2-year RCT in which 27 primary care practice teams were randomly assigned to receive or not receive reminder messages generated by 1490 rules on physician behavior (30). The CDS system improved compliance with care recommendations among resident physicians from 29% to 49% ($P < 0.001$) and staff physicians from 29% to 44% ($P < 0.01$) (30).

KEY ISSUES ENCOUNTERED IN PREVIOUS CDS STUDIES

Structured Data Required for Accurate CDS May Not Be Available in the EHR

In our view, a mismatch between the information needed for decision rules and the availability of that information in the EHR is the major cause of failed CDS intervention studies. For example, to be accurate, decision rules about cervical cancer screening require information about the patient's age, gender, Pap smears, human papillomavirus test results, and hysterectomy history. Such relevant patient data are often distributed across an archipelago of outside clinics, pharmacies, insurers, and other data sources to which a given EHR does not have access. Other important information may be present in the EHR but not accessible to the CDS system because it is recorded as free-text narrative. In

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the example CDS case study, chart audits revealed that Pap smears were often done, but were documented only in a narrative note (30).

Reminders based on inadequate information will often be false-positive (31), leading to alert fatigue (32) and provider noncompliance. On the other hand, when complete and accurate information is available, provider compliance can be exceptional. In one study, Kho and colleagues (33) provided inpatient isolation guidance using a multidrug-resistant organism database that was meticulously maintained by a full-time infection control expert. This CDS system achieved 90% compliance with isolation guidelines for multidrug-resistant organisms and reduced the median time to isolation from 16 hours to minutes.

Decision Rules Lack a Strong Evidence Base or Collide With Local Medical Beliefs

Providers are unlikely to comply with reminders about new practices they have not internalized, regardless of the published evidence. In the example study (30), care providers ignored suggestions about using β -blockers for myocardial infarction despite strong published evidence in its favor. It took several years and reinforcement from cardiology consultants to acculturate them to this practice.

Users and Workflows Targeted for CDS Are Not the Optimal Ones

Compliance with reminders can be boosted by workflow-appropriate targeting of the right recipients, including the broader care team and patients themselves (34). Reminders that can be institutionally defined as standing nursing orders and delivered to nursing can be quite effective. For example, reminders for influenza vaccination suggested to nurses at discharge were more effective than the same reminders delivered to physicians (35).

The CDS Takes Too Much Effort to Access or Use

Use of EHRs already takes too much time from providers (36, 37). Ideally, CDS systems should provide feedback within physicians' workflow as part of their routine interactions with the EHR, such as when they enter a problem or an order (34, 38–40). For example, the computer could remind about needed preventive care when the physician first accesses a given patient's record and about needed drug monitoring when the applicable drug is ordered.

Too Many Reminders and Too Little Clinician Time

Provider time with patients is already quite limited: Fifteen minutes or less may be all that is allotted to a return visit. Too many reminders may feel like the rush of snowflakes in a blizzard, to be brushed aside to stay on schedule.

Inadequate Attention to Potential CDS Success Factors

Because of a consistent finding that CDS interventions often fail to improve care (8, 10, 19–25), substantial research exists on why some CDS interventions suc-

ceed and others fail. We emphasized some of the most important reasons above. Prior literature in this area includes meta-regression analyses of trials identifying CDS features statistically associated with improved care (38–43), systematic reviews of trials directly comparing the effect of CDS with and without a given feature (34, 38), systematic reviews of potential CDS success factors suggested in the literature (38, 44–49), and the opinions of CDS experts (50–52).

RECOMMENDATIONS FOR RESEARCH AND REPORTING OF CDS STUDIES

To address the key issues identified here, as well as others that often arise in CDS studies, this section provides recommendations on how to design, conduct, and report CDS studies. The Table summarizes these recommendations.

1. Ensure That EHR Data to Inform the CDS Are Available

Verify that your EHR includes the data needed by your candidate study rules, via chart audits or pilot use. When EHR data are inadequate, consider using surrogates. For example, diabetes can be inferred from an insulin prescription and sexual activity from a contraceptive prescription (53).

Also, if the needed data are absent, consider collecting them via staff or patients. For example, an outpatient pediatric CDS system asked the parents and nursing staff to answer a set of questions at visit check-in to inform its care recommendations to providers (54).

Natural-language processing (55) can be used to unlock the content of free-text notes, including for CDS (56, 57). Although the use of natural-language processing in CDS is still uncommon, it should be on CDS developers' watch list.

Finally, consider accessing external data sources. Some organizations already have access to health information exchanges (58) or routinely import prescription information from central resources (59). External data will be difficult to use for decision rules unless the data sources follow guidance from the U.S. Office of the National Coordinator for Health Information Technology (ONC) (60) and use standard coding systems, including LOINC, for laboratory tests and other measurements (61).

The Fast Healthcare Interoperability Resources (FHIR) from Health Level Seven (HL7) (62) standard is an elegant health data interoperability standard built on modern technologies. Recently, it has attracted strong support from major industry players, including EHR vendors; technology giants, such as Apple, Google, Microsoft, and Amazon (63); and a consortium of health insurance companies (64). The FHIR standard has also attracted large numbers of supporting open-source software packages (65). Even more important to its adoption are the Notices of Proposed Rulemaking from the Centers for Medicare & Medicaid Services (66) and the ONC (67). The ONC's proposed rules require certified health care information systems to support FHIR and associated data coding standards (67). A provision

in the proposed Centers for Medicare & Medicaid Services' rule requires insurance payers to give patients and their providers access to all the claims and clinical data they carry, which could help provide a more comprehensive data set for CDS (66). Also out for comment from ONC is TEFCA (Trusted Exchange Framework and Common Agreement), a proposal to interconnect networks of health care systems (68).

When reporting CDS studies, describe the EHR data elements used, including details on relevant stan-

dard codes used (for example, International Classification of Diseases codes for problem list entries). This will help readers understand the degree to which the data used were probably available in the EHR. Also describe any approaches used to improve or validate CDS accuracy, and consider quantifying the accuracy. In the example CDS case study (30), for each of the 5 most frequently suggested clinical actions, 100 chart audits were conducted to identify the proportion of charts missing important data.

Table. Recommendations for the Design, Conduct, and Reporting of CDS Studies

| Issue | Recommendations: Design and Conduct | Recommendations: Reporting |
|---|---|--|
| Ensure that EHR data to inform the CDS are available | Assess potential effects of missing data on the accuracy of CDS (such as via chart audits and pilot use) Consider options for addressing data gaps: use of surrogate data points, addition of data collection steps to workflow (e.g., by staff or patients), use of natural-language processing, use of external data | Describe the EHR data elements used by the decision logic Describe any approaches used to improve or validate CDS accuracy Consider quantifying CDS accuracy |
| Choose decision rules that are consistent with local care processes | Choose decision rules that support care practices with which target care providers agree If providers disagree with evidence-based recommendations, incorporate educational measures | Where relevant, describe potential for clinician disagreement with underlying care guidelines and approaches taken to educate end users |
| Target the right users and workflows | Target the right recipients at the right point in the workflow Consider targeting the broader care team or patients in addition to, or instead of, physicians | Unless patently obvious, justify the choice of targeted user and workflow |
| Make the CDS easy to access and use | Incorporate CDS into routine clinical workflows Save providers time and be succinct Make it easy to implement suggested actions | Describe approaches taken to make the CDS easy to access and use |
| Minimize the burden on users | Reduce volume of reminders by increasing specificity or eliminating less important ones Deliver reminders less frequently Prioritize reminders and deliver only the most important ones | Describe any steps taken to reduce CDS burden on end users |
| Incorporate CDS success factors identified in the literature | Consider incorporating CDS success factors previously identified in the literature, and in particular the automatic provision of CDS as a part of clinician workflow | Describe how the CDS intervention incorporates CDS success factors or best practices previously reported in the literature |
| Ensure that the CDS rules are adequately tested | Before initiating full study, test CDS rules by examining CDS results against patient data and/or conducting formative evaluations Correct any errors | Describe testing and formative evaluation process |
| Select meaningful evaluation measures | Seek to ensure sufficient statistical power for detecting changes in meaningful process measures, and ideally intermediate or health outcome measures | Report impact on meaningful process measures, and where possible, outcome measures |
| Use as rigorous a study design as is feasible | If doing an RCT, use a cluster randomized study design If not doing an RCT, use an interrupted time series study design or otherwise address the potential for confounding secular trends | If using a cluster-randomized study design, follow CONSORT reporting guidelines and use statistical methods that consider intraclass correlation and take advantage of all available study data If not doing an RCT, address the potential for confounding secular trends |
| Think about how to deploy the study CDS beyond the original host organization | Consider implementing the CDS using relevant interoperability standards, including HL7 FHIR, HL7 Clinical Quality Language, HL7 CDS Hooks, and HL7 SMART | Consider describing a path toward wide dissemination, including through use of relevant HL7 standards Provide a detailed description of the CDS intervention and its implementation context, including screenshots |
| Report the study in context | Design a study that builds on prior CDS research | Include a review of the literature Specify what the article adds to the current body of research |
| Help the audience understand why the intervention succeeded or failed | Follow known CDS best practices outlined above, so that CDS studies do not fail because of predictable problems | Postulate on why the intervention succeeded or failed Contextualize findings in terms of factors previously identified as influencing CDS success or failure |
| Consider the financial implications | If the CDS is expected to have a large effect on the host organization's finances, evaluate the financial impact | Where relevant and feasible, report on financial impact and return on investment |

CDS = clinical decision support; CONSORT = Consolidated Standards of Reporting Trials; EHR = electronic health record; FHIR = Fast Healthcare Interoperability Resources; HL7 = Health Level Seven; RCT = randomized controlled trial; SMART = Substitutable Medical Applications and Reusable Technologies.

2. Choose Decision Rules That Are Consistent With Local Care Processes

When multiple competing clinical guidelines exist for a care topic, consider allowing providers or practices to choose among the guidelines. Otherwise, pick the most conservative and widely accepted guideline. Also consider providing education on the evidence underlying care recommendations.

3. Target the Right Users and Workflows

Deliver reminders to users who can easily act on the CDS at appropriate steps in their workflows. In the example study, reminders were attached to patient charts so that they were readily available to physicians when making care decisions (30). Also consider providing CDS to patients and care team members beyond physicians. When reporting CDS studies, the choice of targeted user and workflow should be justified where appropriate.

4. Make the CDS Easy to Access and Use

Minimize the provider effort needed to receive and react to the CDS (69). Make it easy to implement the suggested actions, such as by enabling providers to order them with one or a few clicks. Physicians did not use computers directly in the example study (30). However, they could “order” suggested actions by simply circling them on the printed form. Also, avoid excessively wordy recommendations and justifications. Just say what is suggested and why (69, 70). Users could access further information through a link.

5. Minimize the Burden on Users

Consider throttling back reminders, by tightening the specificity of the reminder rule and dropping less important reminders altogether (16). When nonspecific reminders cannot be avoided, take steps to deliver them less frequently to any given provider—for example, once per 6 months or longer. Interruptive reminders take the most time, so be stingy with their use (71), although there are tradeoffs. Many CDS interventions have been effective without interruptions (72). Reminders can be prioritized from most to least important, and the system could generate only the 3 or 4 most important ones at each visit (30). In the example study, non-interruptive reminders were used, and even with 1490 decision rules, each patient only had an average of 6 different clinical actions recommended during the course of the 2-year study (30). When reporting, describe any steps taken to reduce CDS burden on end users.

6. Incorporate CDS Success Factors Identified in the Literature

Examine the literature on factors that underpin successful CDS interventions, including the literature described earlier (34, 38–52). Consider incorporating these success factors into your intervention. In particular, consider providing the CDS automatically as a part of clinician workflow, because this practice has been repeatedly identified as a strong predictor of CDS success (34, 38–40). In the CDS case study (30), reminders were printed and placed at the top of the chart to en-

able availability within the workflow. Also describe in CDS reports how you incorporated such success factors or best practices into the intervention.

7. Ensure That the CDS Rules Are Adequately Tested

Before initiating the study, run the study rules on a large set of patients and examine the CDS results against each patient's EHR data. Also consider formative evaluations that include pilot testing. If the results are not sensible, tune the rules before initiating the study (73). For example, when Regenstrief developers moved CDS rules from its outpatient EHR system to its inpatient system, prestudy testing immediately found inappropriate reminders due to missing exclusions, such as those that recommended mammography in patients with do-not-resuscitate orders or who were on a ventilator. Describe the testing and formative evaluation process, whether in the main study report or in a separate paper.

8. Select Meaningful Evaluation Measures

Studies of CDS interventions tend to use a variety of evaluation measures to estimate the CDS benefits. These include measures of compliance with standards of care, time (such as patient length of stay or order completion time), cost (for example, per patient, per disorder, or per admission), and intermediate outcomes (such as hemoglobin A_{1c} values or blood pressure).

Funding for CDS studies tends to be meager compared with that for large drug and device trials. Consequently, sample sizes of these studies tend to be small and durations short, with inadequate power to detect effects on long-term health outcomes and sometimes not enough power to detect effects on intermediate outcomes. For instance, the example 2-year study (30) did not find any effects on survival, costs, vital signs, or laboratory measures, although it had large effects on process measures. In fairness, one should not expect that CDS studies focused on prevention will be sufficiently powered to demonstrate measurable effects on major outcomes. For example, the Health Insurance Plan breast cancer screening study that demonstrated the benefits of screening mammography on breast cancer mortality included approximately 60 000 patients who were randomly assigned at the patient level and followed for over 5 years (74).

Studies of CDS often use measures, such as guideline compliance rates, CDS override rates, and cost savings, instead of long-term health outcomes. Measures of usability, changes in user knowledge, and user opinions of the system provide helpful supplementary information but are not adequate substitutes for stronger measures, such as intermediate outcomes and compliance rates.

9. Use as Rigorous a Study Design as Feasible

Studies of CDS face complex design and analysis problems because they are almost always cluster cohort studies (75). Many such studies often include multiple levels of clustering—for example, providers clus-

tered by clinic, patients clustered by provider, and encounters and reminders clustered by patient. Complicating things further, the intervention is usually applied to the provider, but its effect is measured through responses to reminders at the patient level or through direct measures of patient outcomes.

Given these complexities, what should the unit of randomization be? Patient-level randomization may sometimes be inappropriate, owing to the potential for a training effect on the clinician. Some say it should always be at the level of the provider group, owing to the potential for contamination across providers. However, the answer may not always be that simple, because the degree of actual contamination may depend on site-specific personnel arrangements as well as the nature of the CDS intervention. The number of groups is usually much smaller than the number of providers, so choosing to randomize according to provider group tends to decimate the study's statistical power. Statistical methods exist that consider intracluster correlations and can take advantage of all the available study data. Such methods include generalized linear models (76), empirical Bayes estimators (77), and other methods (78). Incidentally, there was little evidence of contamination (or intracluster correlation) in the example study (30).

Different analysis methods will be needed according to the goals of the study. And more than one method might be necessary to identify the intervention's effect on the provider's behavior and its effect on patient outcomes. Such multifaceted analysis was conducted in the example case study (30), which found a large effect on provider behavior and no effect on patient outcomes.

Depending on the strength of the interactions within the clusters and the adjustments applied during the analyses, the patient, provider, or provider group could serve as the primary unit of analyses (79). A strong biostatistical collaborator with cluster design expertise can help with those choices and will be important to the success of the project. Studies of CDS systems almost always involve clusters, and the reporting of CDS RCTs should follow the CONSORT 2010 statement for cluster randomized trials (80).

In many cases, hospital policy, technical constraints, or provider concerns may prevent the implementation of a true RCT with parallel controls. Pre-post studies, especially at points of introduction of new computer capabilities, face fewer such obstacles. When the institution plans to introduce new software capabilities throughout the institution, it can be possible to persuade stakeholders to stage the installation at different time points across pairs of similar wards or organizational units to provide better controls. Pre-post studies at the institutional scale face the risk for confounding changes, such as in organizational policy, regulation, and reimbursement rules. The interrupted time series analysis is one defense against such confounding because it is able to control somewhat for secular trends (81). Many other issues in general study design are dis-

cussed elsewhere; see the *Users' Guides to the Medical Literature* from the American Medical Association (82).

10. Think About How to Deploy the Study CDS Beyond the Original Host Organization

Implementers of CDS systems should think about how to deploy the CDS beyond the original host. As described earlier, the HL7 FHIR is a promising data exchange standard for obtaining the data required for CDS. In addition, other FHIR-related HL7 standards are increasingly being adopted by the health care community to enable CDS at scale; these include the HL7 Clinical Quality Language for expressing CDS and electronic clinical quality measurement logic using a standard language (83), as well as the HL7 CDS Hooks standard for integrating external CDS prompts into an EHR (84) and the HL7 Substitutable Medical Applications and Reusable Technologies (SMART) standard for integrating external CDS apps into the EHR user interface (85). Consider using these standards-based implementation approaches to facilitate broad dissemination and impact of the CDS.

Clinical decision support interventions are often complex and multifactorial, and even small details (such as behavioral nudges [47]) can make the difference in their success or failure (38). Describe the CDS implementation in sufficient detail to permit replication by others, using online appendices where needed. Details would ideally include descriptions of the workflow event that triggers the CDS (for example, opening a patient chart, placing an order, or adding a problem). Also specify the users targeted (for example, physicians in primary care clinics), the decision logic (for example, include women aged 50–74 years with no mammogram in the past 2 years and no history of bilateral mastectomy), the reminder message (for example, get mammography), and screenshots. The Notices of Proposed Rulemaking (67) includes wording that should reduce barriers to including EHR screenshots in academic publications.

11. Report the Study in Context

When reporting on a CDS study, include a review of the literature to contextualize the work. Also specify what the article adds to the current body of research—for example, evaluating a novel intervention, verifying the results of a previous study, or extending an established CDS approach to a new clinical problem.

12. Help the Audience Understand Why the Intervention Succeeded or Failed

Provide potential explanations for why the intervention succeeded or failed. Such postmortems are important to continuous improvement of CDS. Also try to attribute the success or failure to CDS issues listed in the Table or identified as a potential CDS success factor in the literature (34, 38–52). Follow known CDS best practices as discussed earlier, so that the CDS study does not fail because of a predictable problem.

13. Consider the Financial Implications

Whereas financial impact is typically a secondary or nonexistent consideration in CDS studies, in opera-

tional clinical contexts they are often a significant consideration. Clinical decision support can have many positive effects on finances, including by reducing care costs, adverse events, and resource utilization in the inpatient setting (86). In contrast, CDS that discourages unneeded testing (87) can have negative financial effects in fee-for-service payment contexts and positive effects in capitated payment contexts. Also remember that the use of CDS is not limited to clinical quality improvement. A large portion of CDS rules implemented in a health care system may be driven by administrative needs, such as the need to ensure compliance with in-patient admission rules to avoid penalties. These kinds of uses should also be studied and reported. Clinical decision support may also facilitate participant recruitment in clinical studies (88). Such nonclinical CDS can have financial effects, such as by averting penalties and reducing clinical trial recruitment costs.

When CDS studies have large effects (up or down) on the host organization's finances, call out those financial impacts. If benefits substantially outweigh the costs of CDS implementation, a study can help motivate other organizations to invest in similar CDS given the expected financial return on investment.

In conclusion, research is needed to enhance CDS specificity, for example by integrating data from health information exchanges, collecting data directly from patients through questionnaires, and extracting meaning from free text through natural-language processing. Other promising areas of research include leveraging artificial intelligence, optimizing human factors, focusing on cost and other economic issues, and using standards to expand the reach and effects of the CDS. To enable more rapid progress in CDS-enabled care optimization, funding agencies should continue to support research in these areas. Furthermore, journals should encourage authors to use the Table as a CDS publication checklist and to include enough detail about the CDS system and study design to enable replication of the work.

With the near-universal adoption of EHRs in the United States, CDS holds great potential for improving patient care. However, more research is needed on how best to design and implement CDS for optimal impact. If adopted, the recommended practices for designing, conducting, and reporting CDS studies could help accelerate progress toward the vision of CDS-enabled care optimization.

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SUPPLEMENT

Recommendations for Clinical Decision Support Studies

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