# CDS Standards and Regulatory Frameworks Workgroup: Approaches to Standardizing Override Reasons for Patient-Centered Clinical Decision Support

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#### **PURPOSE**

The Clinical Decision Support Innovation Collaborative (CDSiC) aims to advance the design, development, dissemination, implementation, use, measurement, and evaluation of evidence-based, shareable, interoperable, and publicly available patient-centered clinical decision support (PC CDS) to improve health outcomes of all patients by creating a proving ground of innovation. The Standards and Regulatory Frameworks Workgroup is charged with identifying, monitoring, and promoting standards for the development of PC CDS and examining the current state of the regulatory environment. The workgroup comprises 12 experts and stakeholders representing a range of perspectives within the CDS community. This report is intended to be used by the broader CDS community to advance the use of standards for PC CDS. The CDSiC will also use the report to inform product development under its Stakeholder and Community Outreach Center Workgroups and for projects developed through its Innovation Center. All qualitative research activities conducted by the CDSiC are reviewed by NORC at the University of Chicago Institutional Review Board (FWA00000142).

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#### **Executive Summary**

#### Introduction

Patient-centered clinical decision support (PC CDS) provides timely, evidence-based, and patient-specific recommendations to clinicians, patients, or caregivers to support decision making. Recipients of PC CDS may choose to decline a recommendation if it is not applicable or feasible. When declining, they are often prompted by the PC CDS to provide a reason, which is known as an "override reason."

The Clinical Decision Support Innovation Collaborative (CDSiC) Standards and Regulatory Frameworks Workgroup developed a taxonomy to standardize and analyze the reasons clinicians, patients, and caregivers override PC CDS recommendations. The taxonomy includes six domains and 28 subdomains that capture a wide range of motivations for override across clinician- and patient-facing PC CDS tools. The taxonomy serves as a framework for improving PC CDS by enabling consistent categorization of overrides.

The taxonomy was originally developed for analytical purposes and consists of high-level concepts not well-suited for implementation into PC CDS applications, where override reasons typically need to be concise and specific. To support effective implementation of the override taxonomy in PC CDS applications, this report presents options for user-override reasons and strategies for implementing the override taxonomy into PC CDS applications.

#### Methods

The team conducted concurrent workstreams to 1) develop example user override reasons based on the override taxonomy and 2) identify standards and strategies for implementing the taxonomy into PC CDS clinical workflows and patient lifeflows (i.e., their daily activities).

**Develop Example User Override Reasons.** The team developed an initial set of example user override reasons with the goal of developing override reasons that are succinct, easy to understand, specific to PC CDS, and unambiguous. The team interviewed four key informants (including two standards developers, an informatician, and a clinician) to assess whether the override reasons fit these criteria. The team refined the override reasons based on key informant feedback and presented them to the CDSiC Standards and Regulatory Frameworks Workgroup members for further review and refinement.

Identify Standards and Strategies for Implementation. To identify strategies for implementing the taxonomy, the team developed a sample Health Level Seven (HL7) CDS Hooks card incorporating some of the example user override reasons. CDS Hooks, managed by the HL7 CDS Workgroup, is a standard for integrating external CDS services into electronic health records (EHRs) and other applications and can include a list of user override reasons to present to the user. The team conducted key informant interviews with three members of the HL7 CDS Workgroup to get feedback on the CDS

Hooks card and to explore other implementation approaches, including modeling approaches, terminology standards, and workflow integrations.

#### Results

The results include the example user override reasons that can be incorporated into PC CDS override interfaces and options for standards and strategies to implement the taxonomy in PC CDS.

**Example User Override Reasons.** The report presents example user override reasons for the 28 subdomains of the override taxonomy. Some of the override reasons include fill-in-the-blank options to allow for context-specific customization by PC CDS developers (e.g., Contraindication: \_\_\_\_ [reason, e.g., drug, procedure, allergy]). The example user override reasons can support consistency in override implementation, though developers may choose other terms or modify these examples as needed.

**Standards and Strategies for Implementation.** Integrating the taxonomy into standards-based PC CDS systems involves two main steps: 1) identifying a standardized code system to incorporate the concepts from the taxonomy, and 2) integrating the override codes into PC CDS applications using standards-based approaches (e.g., HL7 CDS Hooks) to allow for their use within EHR workflows.

Standardizing the Override Taxonomy Subdomains. The team explored options to add the override taxonomy subdomains to an existing terminology—Logical Observation Identifiers Names and Codes (LOINC) or Systematized Nomenclature of Medicine - Clinical Terms (SNOMED CT)—or to register it as a new terminology—via HL7 Terminology (terminology.hl7.org, or THO) or a Fast Healthcare Interoperability Resources® (FHIR) Implementation Guide. The taxonomy should only be added to one terminology to avoid duplication. Key informants who were also members of the HL7 CDS Workgroup advised that LOINC may not be a suitable option due to its "question/answer" structure and expressed that SNOMED CT would be a better fit. SNOMED CT has an established process for requesting new terms, though this requires multiple steps and stakeholder involvement. Key informants noted that HL7 THO and an FHIR Implementation Guide would also be appropriate options but highlighted that this approach would limit its implementation (to HL7 standards only if it is added to HL7 THO or only to applications using the specific FHIR Implementation Guide).

Integration Into Standards-Based PC CDS Approaches. Once the taxonomy subdomains are incorporated into a code system, they can be integrated into various standards-based PC CDS tools at the point of care and between clinical visits. Based on discussions with the same key informants, the team explored how the codes could be implemented within four standards: HL7 CDS Hooks, Adren Syntax (a knowledge representation standard for event-condition-action type rules), and two FHIR resources, CarePlan (which is used to document a patient's care plan) and PlanDefinition (which defines clinical actions to be taken). Key informants expressed that all four approaches could feasibly incorporate the taxonomy. CDS Hooks would be a good option because it already provides the schema for including user override reasons; the override taxonomy could be used to implement this part of the standard. One key informant noted that there are opportunities to add the override subdomains to medical logic modules written in Arden Syntax, thus allowing them to be used in clinical workflows.

Finally, FHIR CarePlan and FHIR PlanDefinition could both benefit from inclusion of user override reasons to record reasons for deviating from these plans.

However, there are limitations in two of these standards. Specifically, the CDS Hooks standard would potentially need to be modified to allow for modeling the user override reasons as a CodeableConcept, and FHIR Plan Definition would need to be extended to allow for inclusion of user override reasons.

#### Discussion and Future Directions for Research and Use

This report highlights the need for a standardized approach to override terminology in PC CDS to enhance analysis of PC CDS and reduce burden on PC CDS users. To support standardized implementation of the taxonomy, the report suggests the following:

- New codes, either added to an existing terminology or as a new code system, will need to represent
  the taxonomy concepts. To facilitate testing in real-world settings, registering the codes with HL7
  THO would be a prudent first step. Once tested and refined, the codes could be proposed for
  inclusion in SNOMED CT.
- CDS Hooks, Arden Syntax, FHIR CarePlan, and FHIR PlanDefinition standards could incorporate the override taxonomy to support various PC CDS use cases, after addressing the identified limitations.
- More research is needed to develop innovative modeling approaches that allow for override reasons to capture clinical specificity in a standardized way.

Future efforts to facilitate implementation of the override taxonomy include these:

- Conducting additional qualitative research with clinicians, patients, and health information technology (IT) experts regarding example user override reasons to optimize their usability and contextual relevance.
- Deploying the taxonomy concepts via Connectathons to identify gaps and spread awareness of the taxonomy within the standards community.
- Pilot testing the implementation of the override taxonomy with multiple health systems to evaluate and improve the proposed implementation strategies.
- Integrating the example user override reasons into United States Core Data for Interoperability Plus (USCDI+)—for example, the Quality Domain—once they are sufficiently refined to support broader adoption.

#### Conclusions

Establishing a consistent, standards-aligned approach to implementing the taxonomy of override reasons for PC CDS recommendations can enhance both the presentation of override reasons to PC CDS recipients and the structured capture of override data for PC CDS analysis. Ongoing stakeholder engagement, pilot testing, and iterative refinement will be critical to ensuring the override taxonomy's relevance and usability for PC CDS applications.

#### 1. Introduction

Patient-centered clinical decision support (PC CDS) provides timely, evidence-based, and patient-specific recommendations to clinicians, patients, or caregivers to aid decision making. PC CDS recommendations can support higher-quality care and improve safety. Recipients of PC CDS may choose to decline or ignore a recommendation if it is not relevant or feasible, if they disagree with the recommendation, or for other reasons. Often, recipients are prompted to provide a reason—selecting from a predefined list or writing in a reason2—for why they declined the recommendation. These reasons are known as "override reasons."

Collection and analysis of override reasons can support PC CDS improvement. Feedback from override reasons can be an important part of knowledge maintenance in a PC CDS system, which helps to keep such systems up to date.<sup>4</sup> By analyzing override reasons, developers can identify potential issues with PC CDS logic or data inputs and subsequently fix these issues to improve the relevance of recommendations.<sup>3, 5, 6</sup> Health systems can uncover systemic challenges faced by clinicians, such

### Patient-Centered Clinical Decision Support (PC CDS)

PC CDS encompasses a spectrum of decision-making tools that significantly incorporate patient-centered factors related to knowledge, data, delivery, and use. Knowledge refers to the use of comparative effectiveness research (CER) or patient-centered outcomes research (PCOR) findings. Data focus on the incorporation of patient-generated health data, patient preferences, social determinants of health, and other patient-specific information. Delivery refers to directly engaging patients and/or caregivers across different settings. Finally, use focuses on facilitating bidirectional information exchange in support of patient-centered care, including shared decision-making.1

as limited time to address certain types of recommendations (e.g., nutrition counseling). Understanding patients' and caregivers' reasons for overrides can also point to nonclinical barriers to care (e.g., cost, transportation, does not align with patient goals, or patient does not understand the recommendation), which healthcare providers and systems can work to address.

The Clinical Decision Support Innovation Collaborative (CDSiC) Standards and Regulatory Frameworks Workgroup previously developed a taxonomy of reasons for overriding PC CDS recommendations to provide a standard framework for analyzing override reasons for research and improvement purposes. The taxonomy includes six domains and associated subdomains that represent broad reasons why clinicians, patients, and caregivers may override PC CDS. Health systems and other implementers can map override reasons collected from PC CDS tools to the taxonomy domains/subdomains to analyze, compare, and draw lessons learned across PC CDS applications.

While the taxonomy provides a standard approach to secondary analysis, real-world override reasons presented to users in PC CDS applications vary widely. This variation exists in both the types of reasons offered, which differ by context and user, and the terminology used, which can differ when referring to the same concept. For example, the reason a patient may decline a recommendation to get a preventive screening test (such as cost concerns or limited time availability) would differ from the

reason a clinician might opt to override a drug allergy alert (such as low-risk or an incorrect allergy in the patient's file). Additionally, applications and health systems may use different terms to convey the same override reason, such as "Inaccurate allergy" and "Allergy is erroneous."

Removing unnecessary variation in how similar override concepts are worded and presented could reduce cognitive burden for recipients (i.e., clinicians, patients, and/or caregivers) as they use PC CDS.<sup>8</sup> A more standard approach to user override reasons also supports consistent data collection and analysis across PC CDS tools, enabling developers, health systems, and researchers to identify patterns and make informed improvements. For example, if "Benefits outweigh risks" is commonly selected as an override reason for clinicians prescribing high-dose opioids to postsurgical patients, the health system may adjust the alert threshold for short-term surgical pain and provide additional guidance to clinicians. If different user override reasons are used to represent a similar concept, it may be harder to recognize such insights. Additionally, user-friendly (i.e., concise and understandable) override reasons for patient-facing PC CDS tools could facilitate meaningful feedback loops between patients and clinicians. For example, if a patient selects "Don't know how" in response to a recommendation in a patient-facing PC CDS tool, their clinician may follow up to provide patient education.

Based on the taxonomy of override reasons for PC CDS recommendations, this report explores opportunities to introduce more consistency in the user override reasons used in PC CDS applications. It first presents efforts to translate the taxonomy subdomains into more user-friendly PC CDS override reasons with examples. Then, it presents possible strategies for standardizing the taxonomy using recognized terminologies and integrating the taxonomy into standards-based approaches to PC CDS.

#### 1.1. Overview of the Override Taxonomy

The override taxonomy was developed based on a review of the literature on CDS overrides, collection of real-world override reasons from CDS and PC CDS applications, and key informant feedback from clinicians, patients and patient advocates, informaticians, and health services researchers. More information on the initial taxonomy's development is available in this report. The final validated taxonomy is provided in Appendix A. The taxonomy was designed to apply to a wide range of PC CDS use cases and recipient types. Specifically, it applies to clinician-facing and patient-facing PC CDS, includes clinical and nonclinical override reasons, applies to PC CDS that recommends an action (e.g., a screening test) and PC CDS that challenges a recipient's intended action (e.g., flagging an allergy), and captures a range of override reasons, allowing for analysis of different PC CDS applications. For patients, the taxonomy encompasses reasons where a patient—or a caregiver serving as a patient's proxy—declines a PC CDS recommendation either directly through a patient-facing tool or by communicating their reason to a clinician, who then records the reason in a clinician-facing tool.

The final taxonomy contains six domains (and associated subdomains) of override reasons: 1) PC CDS does not apply to patient, 2) PC CDS delivered in suboptimal context, 3) recipient disagrees with recommendation because of issues with the evidence, 4) recipient has concerns regarding potential

<sup>&</sup>lt;sup>1</sup> These are override reasons from real-world PC CDS applications in two U.S. health systems.

health outcomes, 5) recommendation does not align with patient preferences or values, and 6) recommendation is not convenient or feasible. Domains 1–4 are primarily associated with clinician-facing PC CDS; however, some subdomains may also be relevant to patient-facing PC CDS, depending on the context. While the taxonomy was designed to incorporate the patient perspective across all domains, Domain 5 and specific subdomains within Domain 6 were developed specifically to capture override reasons relevant to patient-facing PC CDS.

The taxonomy was originally developed for analytical purposes and, as such, consists of high-level, abstract concepts (e.g., "Patient has contraindication to recommended action"). In contrast, user override reasons used in CDS applications are often more specific (e.g., "Patient has GI bleeding"). Due to the vast number of potential override reasons for specific use cases, it is not feasible to incorporate all possible override reasons in the taxonomy. Furthermore, the existing domain and subdomain labels are lengthy, abstract, and broadly worded, making them unsuitable for use in patient-or clinician-facing user interfaces where concise and intuitive language is essential to clinical workflows and patient lifeflows (i.e., daily activities).

#### 1.2. Roadmap of the Report

To support effective implementation of the override taxonomy in PC CDS applications, this report first presents options for translating the taxonomy subdomains into user-friendly override reasons and then describes possible approaches for integrating the taxonomy into PC CDS applications. The remainder of this report is organized as follows:

- Section 2 describes the methods used to develop user override reasons based on the taxonomy and to identify and assess potential implementation strategies.
- Section 3 presents the proposed user override reasons and describes the feasibility of several different implementation strategies for the taxonomy.
- Section 4 discusses the implications of this work, including future directions and limitations.
- Section 5 provides a brief conclusion.

#### 2. Methods

Concurrent workstreams were conducted to 1) develop user override reasons based on the override taxonomy and 2) identify standards and strategies for implementing the taxonomy into PC CDS clinical workflows and patient life flows.

#### 2.1. Development of User Override Reasons

For each subdomain in the taxonomy, the team developed user-facing terminology through an iterative process involving three rounds of drafting and revision. The goal was to create user override reasons that are succinct, easy to understand for the user, specific to the PC CDS, and unambiguous. While the

user override reasons are intended to be specific enough to support individual PC CDS interventions, they are also designed to reduce unnecessary variation across systems by using patterns and templates.

The domains and subdomains of the override taxonomy were informed by prior literature as well as override data from three health systems and were iteratively refined by the team in response to key informant feedback. To translate the taxonomy subdomains into user override reasons, the team first mapped the subdomains to the QICore Negation Reason Codes value set. This value set includes Systematized Nomenclature of Medicine - Clinical Terms (SNOMED CT) codes and term strings and is maintained by the Health Level Seven (HL7) Clinical Quality Information (CQI) Work Group. The QICore Negation Reason Codes value set is designed to capture reasons why clinical actions were not taken for measuring and reporting quality of care. As such, the team anticipated that the value set and the override taxonomy might comprise terms describing similar concepts. However, the mapping revealed limited overlap between the value set and the override taxonomy. Still, the team used the SNOMED CT display terms from the value set to generate additional ideas for user interface terminology. The team then generated at least one example user override reason per taxonomy subdomain by trying to simplify the subdomain language, using the goal outlined above as a guiding principle. For some subdomains, multiple examples were developed to offer flexibility across clinical contexts and to accommodate variations in user needs.

After developing an initial set of draft user override reasons, key informants were interviewed to gather feedback on the terms. Key informants were selected based on their background and expertise in consultation with the Standards and Regulatory Frameworks Workgroup, whose membership includes clinicians, standards developers, electronic health record (EHR) system developers, informaticians, CDS developers, researchers, and a patient advocate. The team interviewed four key informants—two informaticians, one clinician, and one EHR developer—using a semistructured discussion guide to elicit feedback on the user override reasons, including whether they were understandable, succinct, specific, and unambiguous. A background document on PC CDS and override reasons was provided to key informants prior to their interviews, along with the final taxonomy of override reasons for PC CDS recommendations (Appendix B).

Key informant interviews were conducted via Zoom and began with a background on the taxonomy of override reasons before transitioning to a discussion of the user override reasons and broader implementation strategies. Each interview lasted approximately 60 minutes. With informants' approval, all interviews were recorded. A team member took transcript-style notes, which the team thematically analyzed to identify patterns within and across interviews.

The user override reasons were then revised based on informants' feedback and with input from the Standards and Regulatory Frameworks Workgroup members, with a focus on the accessibility and completeness of the override reasons. After discussion and refinement, the team confirmed the final set of user override reasons.

#### 2.2. Identification of Implementation Standards and Strategies

Several Standards and Regulatory Frameworks Workgroup members, who were also cochairs of the HL7 CDS Workgroup, recommended CDS Hooks as a possible vehicle for integrating the override taxonomy into PC CDS applications deployed in health systems. CDS Hooks is a standard for integrating external CDS services into EHRs and other applications. The standard comprises an application programming interface (API) that is triggered by a specific action (e.g., ordering a diagnostic test, opening a patient record) within a workflow (called a "hook") and displays CDS information or recommendations relevant to the recipient's action in a "card." A CDS Hooks card can include a list of override reasons to present to the user.

To explore the possibility of incorporating the taxonomy in CDS Hooks, the team developed a sample HL7 CDS Hooks card representing a specific CDS recommendation (e.g., "order Apixaban") and incorporating several user override reasons (e.g., "contraindication", "medication is expensive") related to the recommendation (see Appendix C for the sample card). The sample comprised a visual mockup of the card and the data for the card that would be sent from the CDS service to the EHR. As a visual aid, it depicted the need for short and simple user override reasons to be practical (i.e., to fit on the card or interface) and to minimize cognitive load (i.e., to limit the cognitive burden on the user).

The taxonomy and sample CDS Hooks card were presented to the HL7 CDS Workgroup at one of its meetings. Members weighed in on the card and suggested additional implementation strategies. Additionally, the team conducted three key informant interviews—with a health informatician, an EHR developer, and a physician informaticist—to gather feedback on the card and identify considerations and limitations of possible implementation strategies, including modeling approaches, terminology standards, and workflow integrations. The key informant interviews were facilitated using a second semistructured interview guide, lasted 60 minutes, and were conducted via Zoom. As detailed above, these sessions were recorded with informant approval, and a team member took transcript-style notes. The team shared high-level takeaways from the interviews with the Standards and Regulatory Frameworks Workgroup members for discussion and additional suggestions.

#### 3. Results

This section presents the example user override reasons (section 3.1) and potential strategies for implementing the taxonomy in PC CDS systems (section 3.2).

#### 3.1. Example User Override Reasons

This section includes example user override reasons that can be used by health systems implementing the override taxonomy. We provide these override reasons as examples to support consistency where possible. PC CDS developers should configure the user interface to incorporate these terms dynamically and should customize them for the specific PC CDS contexts (e.g., different clinical specialties or workflows). For example, we include general user override reasons such as

"Contraindication" with an option to provide additional insight into the specific clinical context using a fill-in-the blank format (e.g., "Contraindication: \_") When designing a PC CDS tool for which contraindication is a relevant override option, PC CDS developers should list common potential contraindications in the blanks.

As described in section 2.1, the team developed an initial set of example user override reasons to support the implementation of the override taxonomy (Appendix D). Key informants reviewed these draft override reasons against the guiding principle for representing user override terms and offered insights and feedback, resulting in the following recommendations and supporting rationale for each criterion.

- Specificity to PC CDS context: The user override reasons should be specific to the PC CDS in
  which they are presented, meaning that they should not be generic or vague. Additionally, the
  override reasons should allow for flexibility to support customization for various clinical and sitespecific contexts. In this regard, informants appreciated draft override reasons that included fill-inthe-blank components for their potential to increase relevance and specificity.
- **Succinctness:** Given that clinicians and patients are often under time pressure, key informants stressed that user override reasons should be succinct. Long, verbose terms can slow down the workflow or lead to cognitive overload.
- User-appropriate language: Given that the override taxonomy can apply to patient- and clinicianfacing PC CDS, key informants shared that the user interface language should be appropriate for
  the intended user. For example, for patient-facing override reasons, key informants underscored the
  importance of ensuring the override reasons were understandable and without medical jargon. Also,
  given the movement toward greater patient access to health data and clinical notes (e.g., through
  OpenNotes), 12 developers should recognize that patients may view override reasons intended for
  clinicians. As such, user override reasons, whether for patient-facing or clinician-facing applications,
  should be carefully reviewed to ensure they are respectful, nonjudgmental, and free from potentially
  insulting phrasing regarding the patient or their preferences. While the wording of the override
  reason in the standard can differ, as long as it is correctly mapped to the user override reason,
  careful wording of the user override reasons is important to help maintain trust, support shared
  decision making, and ensure that the override reasons are appropriate for all potential end users.
- **Unambiguous:** Several draft user override reasons were flagged as having multiple potential interpretations. Key informants stressed the importance of clear, single-meaning language to reduce confusion or misinterpretation.

**Exhibit 1** provides the final example user override reasons mapped to the taxonomy subdomains. Some override reasons include fill-in-the-blank options to allow for context-specific customization (e.g., subdomain 1.1). These blanks are intended to be populated by the PC CDS developer before deployment, not by the PC CDS recipient. Some override reasons have multiple examples (e.g., subdomain 1.6) to accommodate different use cases.

Exhibit 1. Final example user override reasons

Domain	Taxonomy Subdomain	Final Example User Override Reasons
Domain 1: PC CDS Does Not Apply to Patient	1.1 Patient does not meet eligibility for recommended action	Not indicated     Not indicated: (reason, e.g., procedure, treatment, drug, age, condition)
	1.2 Patient has indication/order for intended action	Indicated: (reason, e.g., travel, diagnosis)
	1.3 Recommended action was already completed	Already performed
	1.4 Recommended action was previously unsuccessful	Previously unsuccessful
	1.5 Intended action was performed previously without adverse effect	Previously tolerated
	1.6 Recommended action is not relevant or a priority in current state of health	<ul><li>Not relevant currently</li><li>Not a priority currently</li><li>Not a priority in this visit</li></ul>
Domain 2: PC CDS Delivered in	2.1 Could not address recommended action due to limited time	<ul><li>Not enough time</li><li>Will address in (future/next) visit</li></ul>
Suboptimal Context	2.2 PC CDS delivered at wrong time in workflow or patient lifeflow	<ul> <li>Remind me in (time interval, e.g., 2 days)</li> <li>Inconvenient currently</li> <li>I am busy (patient reason)</li> </ul>
	2.3 PC CDS delivered to inappropriate recipient/role	<ul> <li>Not my role</li> <li>PCP responsibility</li> <li> responsibility (specialty, e.g., cardiologist)</li> </ul>
	2.4 Could not address recommended action due to need for more information/pending results/pending consult	Awaiting (e.g., consult, lab results, more information)
Domain 3: Recipient	3.1 Recommended action does not align with the latest evidence	Outdated evidence
Disagrees With Recommendation Because of Issues With the	on recommended action	Specialist recommendation     recommendation (specialist type, e.g., cardiologist)
Evidence	3.3 Institutional policy/guideline contradicts the recommended action	<ul><li>Payer policy</li><li>Institutional policy</li></ul>
	3.4 Recipient does not agree with or trust the recommended action	<ul><li>Disagree with recommendation</li><li>Disagree</li></ul>

Domain	Taxonomy Subdomain	Final Example User Override Reasons
Domain 4: Recipient Has Concerns Regarding Potential Health Outcomes	4.1 Recipient assessment of risk/benefit ratio	Risks outweigh benefits     Benefits outweigh risks
	4.2 Action taken to mitigate risk of negative outcome	<ul> <li>Ordered (risk reducing intervention, e.g., Ser K lab)</li> <li>Followup scheduled</li> </ul>
	4.3 Recommended action likely to have negative health outcomes	Risk of (potential negative outcome, e.g., liver toxicity)
	4.4 Patient has contraindication to recommended action	Contraindication     Contraindication: (reason, e.g., drug, procedure, allergy)
Recommendation Does Not Align With Patient Preferences or Values  recommended action  • Pa  (e.  • W  tas  • Di		<ul> <li>Patient anticipates discomfort</li> <li>Patient concerned about (e.g., pain, bad taste, side effects)</li> <li>Worried about (e.g., pain, bad taste, side effects)</li> <li>Discomfort with (e.g., pain, bad taste, side effects)</li> </ul>
	5.2 Patient does not want to change behavior or believes the change is unnecessary	<ul><li>Patient opted out</li><li>Patient prefers current plan</li><li>Patient decided no change</li></ul>
	5.3 Patient has a cultural or religious reason for not following the recommended action	<ul><li>Patient's beliefs</li><li>Religious beliefs</li><li>Cultural reasons</li></ul>
	5.4 Patient prefers an alternative approach or treatment	Patient prefers alternative     Patient prefers (alternative, e.g., surgery, medication)
Domain 6: Recommendation	6.1 Patient has inadequate caregiver/social support	No (missing support, e.g., caregiver support, transportation)
Is Not Convenient or Feasible	6.2 Treatment or service is not practically available	<ul><li>Unavailable at facility</li><li>Unavailable locally</li></ul>
	6.3 Recommended action cannot be implemented due to technology challenges	<ul><li>Technology challenges</li><li>Technology problems</li></ul>
	6.4 Recommended action is too costly or not covered by insurance	<ul><li>Not covered by insurance</li><li>Too expensive for patient</li><li>High out-of-pocket cost</li><li>Medication is expensive</li></ul>
	6.5 Recipient does not understand the recommended action or know how to perform the recommended action	<ul><li>Don't understand recommendation</li><li>Don't know how</li><li>Unclear recommendation</li></ul>
	6.6 Patient has comorbidity or disability that hinders them from completing recommended action	<ul> <li>Patient has (condition or barrier, e.g., disability)</li> <li>Patient unable to (recommendation, e.g., exercise)</li> </ul>

## 3.2. Potential Strategies for Implementing the Override Taxonomy in PC CDS Systems

The team explored several approaches to standardize the taxonomy and integrate it into PC CDS workflows, seeking a general and standardized approach. A standardized approach can support wider and more efficient adoption of the taxonomy across different PC CDS tools and health systems.<sup>13,14</sup>

Integrating the concepts from the override taxonomy into standards-based PC CDS systems will involve two main steps. The first step is to identify a standardized code system to incorporate the concepts from the taxonomy, thereby facilitating a unique and permanent code for each type of override reason (concept). Based on discussions with key informants, it was determined that the most feasible approach would be to codify the concepts from the taxonomy subdomains rather than attempt to define unique codes for the user override reasons. The user override reasons presented in Section 3.1 are examples meant to be used by PC CDS developers, but they are not exhaustive. In some cases, developers may need to tailor the example user override reasons by adding "fill-in-the-blank" options. Additionally, as PC CDS becomes more prevalent, they may need to create new user override reasons to fit specific applications. As a result, it would be impractical to maintain a code system of these user override reasons since there would likely be a continually growing list of terms that would vary by site to reflect the needs of different health systems implementing PC CDS applications. In contrast, the 28 subdomains in the override taxonomy have been validated, are mutually exclusive, and provide a comprehensive collection of general override reasons. Additionally, while it is expected the subdomains may evolve over time as new PC CDS use cases emerge, these changes would be comparatively infrequent and manageable since the subdomains are broader than individual user override reasons.

The taxonomy subdomains could be added as codes to an existing code system, such as Logical Observation Identifiers Names and Codes (LOINC) or SNOMED CT. These code systems have established processes to request new codes. Alternatively, a new code system could be created to represent the subdomains.

The second step is to integrate the override codes into PC CDS applications using standards-based approaches. This would allow the override codes to be used in practice. The codes could be implemented through multiple PC CDS approaches to expand their reach, especially since different EHR systems and PC CDS applications have different functional requirements and data models.

The following sections describe the considerations and limitations of different options for 1) adding the taxonomy subdomains into a code system and 2) integrating the codes into standards-based approaches to PC CDS.

#### 3.2.1. Standardizing the Override Taxonomy Subdomains

The first step in standardizing the override taxonomy is to incorporate the taxonomy subdomains into a code system so that they can be electronically represented in a standard way. The team considered the feasibility of integrating the subdomains into two existing code systems: LOINC and SNOMED CT. We

also explored developing a new code system to make the subdomains accessible within HL7 CDS standards, including two specific options: 1) creating a code system in HL7 Terminology (terminology.hl7.org, or THO) and 2) adding the override subdomains as a new code system to a Fast Healthcare Interoperability Resources® (FHIR) Implementation Guide. These options are described below, including considerations around their appropriateness for this use case and any limitations.

The LOINC coding system and the SNOMED CT terminology are both recognized standards and allow for interoperable exchange of health data. Therefore, they are potentially good options for integrating the taxonomy subdomains as codes. However, there are differences in their scope. LOINC provides a standardized set of names and codes for identifying measurements, observations, and documents. LOINC codes represent a "question," such as "What is the result of a laboratory test?"; other code systems (e.g., SNOMED CT) may be used to provide the "answer" to that question. SNOMED CT is a clinical terminology that supports consistent electronic representation of healthcare information and is comprised of clinical concepts, relationships (between two concepts), and human-readable descriptions of the concepts.

Key informants advised that LOINC may not be a suitable option to code the override taxonomy subdomains due to the "question/answer" format, noting that the subdomains are more akin to "answers" than a LOINC "question." Instead, key informants expressed that SNOMED CT would be a better fit for adding the subdomains to an existing standard code system. As discussed in Section 2.1, the team conducted a mapping between the QICore Negation Reason value set, which is comprised of SNOMED CT codes, and the override taxonomy subdomains. Based on the results of our mapping, we determined that some existing SNOMED CT codes could possibly be leveraged when adding the taxonomy subdomains in SNOMED CT, though these are limited and may not exactly align with the subdomains. Specifically, we found there was limited overlap between the value set and the taxonomy. In some cases, the taxonomy concept was broader. For example, the value set had a code "Procedure contraindicated," which we mapped to the broader subdomain of the taxonomy, "Patient has a contraindication to recommended action." In fewer cases, the taxonomy was narrower. For example, the value set had a code "Drug declined by patient - patient beliefs," which we mapped to the more specific taxonomy subdomain, "Patient has a cultural or religious reason for not following the recommended action." For most of the subdomains, there was no equivalent concept in the value set. However, SNOMED CT has a process in place to request the addition of new concepts. 17

Another option for encoding the taxonomy subdomains is to establish a new code system. HL7 terminology, or THO, is a central repository for accessing code systems and value sets cited in HL7 artifacts. <sup>18</sup> If the subdomain terminology is registered as a code system in THO, it would be accessible across HL7 standards, including, for example, FHIR-based standards (e.g., CDS Hooks) and version 3 standards (e.g., Clinical Document Architecture [CDA]). However, use of the taxonomy outside of HL7 (e.g., retrospective coding and analysis of user-reported free text reasons for CDS overrides that are currently collected in EHR systems, not through CDS Hooks or reported through other methods) would be limited.

Finally, the subdomains could be included in an HL7 FHIR Implementation Guide, a resource that describes how FHIR can be used to support a specific data exchange (e.g., of override reasons). 19 A

benefit of including the subdomains in an FHIR Implementation Guide is that the process could be managed by an HL7 Workgroup, such as the CDS Workgroup, and the codes maintained by the Workgroup over time. A drawback of integrating the subdomains into a FHIR Implementation Guide is that they would only be accessible to applications that use that specific FHIR Implementation Guide. Therefore, the FHIR Implementation Guide would need to be widely adopted by health systems to have broad impact.

**Exhibit 2** summarizes the considerations and limitations of the four options considered for coding the subdomains. In all cases, the codes would have to be maintained over time as the override taxonomy evolves to accommodate changes in PC CDS scenarios and related override reasons.

**Exhibit 2.** Considerations and limitations of potential terminology standards

Terminology Standard	Considerations	Limitations
LOINC	Externally maintained     Established process for requesting new codes	<ul> <li>Not appropriate structure—subdomains do not adhere to LOINC's "question/answer" structure</li> <li>Process for requesting new codes involves multiple steps and stakeholder involvement</li> </ul>
SNOMED CT	<ul> <li>Some of the subdomains may already be represented, as grouped in the QICore Negation Reason value set</li> <li>Externally maintained</li> <li>Established process for requesting new codes</li> </ul>	Process for requesting new codes involves multiple steps and stakeholder involvement
HL7 Terminology Code System	Would result in a new code system that could be used by other HL7 standards	Use would be limited to HL7 standards only; will not easily support retrospective analysis of overrides as currently collected (outside of HL7-based data exchange)
FHIR Implementation Guide	Could be maintained by an HL7 Workgroup Group	Use would be limited to specific implementation guides only; will not easily support retrospective analysis of overrides as currently collected (outside of FHIR-based applications)

## 3.2.2. Standardized Approaches for Integrating the Override Taxonomy Into PC CDS Workflows

This section first discusses how the taxonomy can be modeled in PC CDS applications. Then, it explores options for standards-based PC CDS approaches in which the taxonomy could be used.

#### Modeling Approaches

A challenge in standardizing override reasons is the need to balance consistency with specificity. Across PC CDS use cases, the specific override reasons may need to vary to capture clinically

significant information. For example, the general override reason "Contraindication" could be applied across different PC CDS tools, but on its own does not provide insight into the types of contraindications specific to patients. Reporting a patient's specific contraindication may be more helpful, such as "Contraindication: Gastrointestinal bleeding." However, it is impractical to capture every conceivable contraindication—or specific override reason, more broadly—within a taxonomy that is both manageable from an implementation standpoint and analytically meaningful. Therefore, when exploring how to model the taxonomy subdomains and example user override reasons in PC CDS applications, the team looked for approaches that would allow for some flexibility in capturing the specific reason, where needed, while still supporting a consistent overall structure (i.e., the standardized taxonomy).

There are different datatypes in FHIR for using terminology codes and terms. These include Coding and CodeableConcept. A Coding data type represents a single code from a code system (e.g., SNOMED CT code "74474003" for gastrointestinal hemorrhage). A CodeableConcept is a more flexible approach. It can include a list of one or more Coding items. These items can be from different code systems (e.g., SNOMED CT, LOINC) but must represent the same semantic concept (e.g., gastrointestinal bleeding). A CodeableConcept can also include an associated "text" element for a human-friendly plain text description of the concept that may be different from the wording used in the Coding items.<sup>20</sup>

Key informants familiar with FHIR and standardized terminologies advised that the taxonomy subdomains should ideally be modeled as a CodeableConcept within PC CDS standards such as CDS Hooks. The advantage of a CodeableConcept over Coding is that it can convey additional contextual information in the text element. This could address the issue of providing specificity to the PC CDS recipient (e.g., displaying a specific contraindication) without having a code for each potential contraindication in the taxonomy. Specifically, the Coding element could represent a code for a specific subdomain concept (e.g., "Patient has contraindication to recommended action"), and the text element could represent the user override reason, which is what would be displayed to the user on the CDS Hooks card or other interface (e.g., "Contraindication: Gastrointestinal bleeding").

While the text element could provide specificity to the PC CDS recipient (e.g., clinician, patient, caregiver), using a CodeableConcept would not capture this specificity for back-end, post hoc analysis. Therefore, the specific clinical context would be unavailable to analysts trying to improve the PC CDS; only the subdomain code would be available. An alternative approach would be to develop a "reference" structure in FHIR that would allow the override to reference another data point in the EHR, such as the patient's specific contraindication. However, developing this structure would add considerable complexity to EHR developers' workload and would also require additional effort from the CDS user to select the appropriate reference data point.

#### Integration Into Standards-Based PC CDS Approaches

Once taxonomy subdomains are incorporated into a code system, they can be integrated within different standards-based tools for PC CDS. Based on discussions with key informants, we considered

whether and how the taxonomy could be included in HL7 CDS Hooks, Arden Syntax, and two HL7 FHIR Resources: CarePlan and PlanDefinition.

HL7 CDS Hooks (described in Section 2.2) is a standard to integrate recommendations from external CDS services into workflows. CDS Hooks already provides the schema for including override reason codes in cards. It does not, however, specify or suggest a set of codes to use for override reasons. The taxonomy subdomains thus address a gap in the implementation of the standard. One concern with the CDS Hooks standard is that it currently uses the Coding datatype for an override reason. As discussed previously, the CodeableConcept datatype allows more flexibility in the override reasons displayed to users, and key informants recommended using it for the taxonomy and user override reasons. This is a limitation that can potentially be addressed in future versions of the CDS Hooks standard.

HL7 International Arden Syntax for Medical Logic Modules (Arden Syntax) is a knowledge representation standard for event-condition-action type rules. Arden Syntax encodes clinical knowledge, which can be used by EHR systems and other applications to present PC CDS recommendations to recipients (e.g., clinicians) through a rules-based approach.<sup>21</sup> One key informant noted that there are opportunities to add the standardized override subdomains to medical logic modules (MLMs) written in Arden Syntax, thus allowing them to be used in clinical workflows. Moreover, Arden Syntax incorporates FHIR as its standard data model, thereby allowing it to leverage any standard representation of override reasons that uses the FHIR standard.

Finally, the team considered two FHIR Resources for which the PC CDS override reasons may be relevant: CarePlan and PlanDefinition. FHIR CarePlan is a resource that is used to document the intended care plan for a patient or community. The information may be specific to a single condition or activity (e.g., immunization schedule) or may be more comprehensive, covering multiple conditions and providers/organizations.<sup>22</sup> FHIR PlanDefinition is a resource that defines the types of actions to be taken in a clinical context and can be used in CDS.<sup>23</sup>

Incorporating override reasons in the CarePlan or PlanDefinition resources would allow users to document reasons for deviation from the care plan or the planned actions for a patient. In CarePlan, the "reason" attribute can record the reason for why an action was not or should not be performed. In PlanDefinition, the "reason" attribute is intended only to record reasons why an action should not be performed. This limitation would need to be addressed to use override reasons with PlanDefinition.

**Exhibit 3** summarizes the considerations and concerns/limitations of these different implementation approaches.

Exhibit 3. Considerations and limitations of potential implementation approaches

Implementation Approaches	Considerations	Limitations
CDS Hooks	Already provides the schema for including override reason codes in cards	Uses the Coding datatype, not CodeableConcept; the standard would need to be modified to allow this

Implementation Approaches	Considerations	Limitations
Arden Syntax	<ul> <li>Provides a mature and existing knowledge representation standard for CDS</li> <li>Override reasons with CDS recommendations could be included in event-condition-action rules encoded as MLMs</li> <li>Incorporates FHIR as a standard data model, leveraging FHIR-based representation of override reasons</li> </ul>	None identified
FHIR CarePlan	"Reason" attribute allows for recording why an action was not performed	None identified
FHIR PlanDefinition	FHIR-based representation for various types of knowledge artifacts, such as event-condition-action rules and order sets	"Reason" attribute currently only records a reason why an action should not be performed, not an override reason; this would need to be addressed to integrate override reasons

#### 4. Discussion

A consistent approach to override terminology could improve analysis of PC CDS functionality and relevance and reduce burden on PC CDS users (e.g., clinicians, patients, caregivers). This report provides a basis for introducing consistency in user override reasons by providing examples based on the taxonomy of override reasons for PC CDS recommendations. These reasons cover both clinician- and patient-facing PC CDS and can apply to a wide range of PC CDS use cases. It also considers options to 1) standardize the override taxonomy by integrating the taxonomy subdomains into a new or existing code system and 2) integrate the taxonomy into standards-based approaches to PC CDS.

There are considerable gaps in the standard terminologies for representing the override reason concepts; hence, new codes would need to be added to an existing terminology, or a new code system would be needed. The team explored several options for including the override reasons in a code system, including adding the override taxonomy subdomains to existing code systems like LOINC or SNOMED CT or creating a new code system within the HL7 standard. Based on key informant discussions, we determined that SNOMED CT, an FHIR Implementation Guide, or HL7 THO are the most appropriate options. Since the taxonomy subdomains have not been piloted in real-world settings, a prudent strategy may be to integrate them into THO as a first step. Adding a new code system in THO requires less time and effort than registering new codes in SNOMED CT. Therefore, THO may offer an ideal balance between the effort and speed needed to develop the code system and the benefit of being able to use the subdomains in PC CDS in the near future. The subdomains and associated user override reasons could then be tested in PC CDS in health systems, with the goal of gathering feedback to improve them. These improved subdomains and user override reasons could, in the future, be submitted to SNOMED CT to make them more broadly accessible beyond HL7.

Several standards could incorporate the override taxonomy, benefiting various PC CDS use cases. The team identified four potential specifications that can adopt the standardized taxonomy: CDS Hooks, Arden Syntax, and two FHIR Resources (CarePlan and PlanDefinition). Key informants agreed that the taxonomy could feasibly be integrated into any of these, though, as noted above, there are limitations that will need to be addressed in CDS Hooks and FHIR PlanDefinition. These limitations would be worth addressing to increase uptake of the taxonomy. Additionally, there may be other tools and approaches beyond those explored in this report where the taxonomy could be useful.

Innovative modeling approaches may be needed to ensure override reasons can capture clinical specificity as needed. When selecting the modeling approach to use when integrating the taxonomy into implementation approaches like CDS Hooks, it is important to consider how much detail the override reasons should capture. For example, is "Patient contraindication" sufficient, or is the specific contraindication (e.g., "Gastrointestinal bleeding") important for the health system or PC CDS developer to know? The answer depends on how the override data are to be used. The approach suggested in this report—using the CodeableConcept datatype in FHIR-based PC CDS applications—would allow the PC CDS recipient to view the specific contraindication in the PC CDS override interface (if it is entered as a text element). However, this information would not be captured for analytic purposes. This is a potential drawback if the goal is to analyze specific patient/clinical context for a given PC CDS tool. There is no easy solution to this issue, but it is important and warrants further discussion to determine the most useful and feasible approach.

Finally, when deciding whether to require override reasons in a PC CDS application, developers and health systems should carefully weigh the value of collecting override reasons against the burden this collection places on PC CDS recipients. A few key informants speculated that PC CDS recipients may be more likely to thoughtfully select an override reason if they feel the data will be meaningfully reviewed and acted on (e.g., used to improve the patient care experience). In contrast, if recipients believe the data will go into a "black box" or not be reviewed by the health system or PC CDS implementer, they may be more likely to select override reasons perfunctorily or default to the first option. Therefore, PC CDS developers and health systems should carefully consider the value of including override reasons in each PC CDS tool—potentially omitting collection of overrides when there is not a compelling value proposition—and communicate this to PC CDS recipients. This may increase the quality of override data provided by recipients. This type of consideration points to potential improvements beyond the standardization of override language, extending to changes in workflows and analytic processes, that could be implemented to improve the quality of PC CDS and the patient experience and reduce the burden on patients and clinicians.

Regardless of the technical approach, ongoing communication and collaboration among stakeholders will be essential to support consensus in the application of the taxonomy, particularly when implemented using FHIR-based standards. Additionally, as PC CDS tools become increasingly patient-facing, <sup>24</sup> patients may gain visibility into override reasons, bringing new expectations for transparency and use of patient-provided override reasons in shared decision making. This shift will necessitate thoughtful design that balances clinical integrity with patient understanding and engagement.

#### 4.1. Future Directions for Research and Use

Future efforts to ensure the implementation of the override taxonomy are described below.

Additional qualitative research to optimize usability and contextual relevance. The example user override reasons included in this report offer an initial foundation for this work. Continued discussions regarding the level of specificity required for overrides and the best modeling approach will allow for adequate post hoc analysis of override reasons. Qualitative research with clinicians, patients, and health IT experts will help define the optimal level of granularity, balancing usefulness for data analysis with usability in clinical workflows and patient lifeflows. This analysis could also support additional exploration of how different levels of specificity may impact alert fatigue. This work could also inform the development of guidance or frameworks to support implementation and allow for context-sensitive adjustments based on clinical setting or alert type.

**Connectathons.** Testing these concepts via Connectathons (e.g., HL7 Connectathons) could help identify gaps and spread awareness of the user override reasons within the standards community. These venues offer the opportunity to identify implementation gaps and gather real-time feedback. Insights gained could further development, inform recommendations, and build consensus around best practices. Connectathons are high-impact venues that are well-positioned to surface implementation barriers; insight could guide recommendations and build consensus and awareness within the standards community.

Pilot testing and refinement. To evaluate and improve the proposed user override reasons and implementation strategies, future work could include conducting pilot implementations of the override taxonomy in one or multiple health systems. These pilots will allow for real-world testing, enabling feedback and data collection to refine implementation strategies and document lessons learned. Pilot studies should be carried out in diverse clinical settings—including rural, safety net, and specialty care environments—as well as with patient-facing applications to capture variations in context. Analysis of override behavior before and after implementation can be conducted to assess impact. Feedback gathered during these pilots can be used to enhance the usability and relevance of the user override reasons.

**Integration into USCDI+.** Integration of the taxonomy subdomain terminology into the United States Core Data for Interoperability Plus (USCDI+), for example, in the Quality Domain, <sup>25</sup> could be pursued to support broader adoption. Mapping the finalized override reasons to existing USCDI+ data elements would promote standardization, enabling greater consistency across EHR systems and healthcare organizations. Inclusion would also enhance interoperability and facilitate more uniform data capture and analysis.

Harmonization with clinical quality measure override concepts. Previous efforts have highlighted the value of aligning CDS and electronic clinical quality measurement (eCQM), particularly as CDS (and PC CDS) can be used to support eQCM measurement and reporting. <sup>26</sup> As noted previously in this report, we found limited overlap in override reasons and the QICore Negation Reason Codes value set. To support better alignment of PC CDS and quality measurement initiatives, future efforts could seek to

harmonize, where appropriate, the taxonomy subdomains and override reasons used for eCQMs, and associated implementation approaches.

#### 4.2. Limitations

Feedback on user override reasons was gathered from a limited number of key informants, which may not represent the range of perspectives across different clinical roles and informatics approaches. While the feedback provided valuable insights regarding the example user override reasons and implementation strategies, the limited sample size may have introduced bias or limited capture of important contextual nuances.

Furthermore, changes in policy or interoperability standards could affect the proposed approaches; therefore, new potential strategies for implementation may emerge over time. As such, the implementation approach must remain adaptable. Ongoing discussions, engagement with standards development organizations and health systems, and participation in forums like Connectathons can aid in aligning implementation strategies accordingly.

#### 5. Conclusions

Establishing consistent approaches to implement the concepts from the taxonomy of override reasons for PC CDS recommendations has the potential to allow for consistent presentation of override reasons to PC CDS recipients and capture of override reasons for analysis. By encoding the taxonomy subdomains in a standard terminology and integrating them into recognized standards such as HL7 CDS Hooks, Arden Syntax, and FHIR Resources, the field can move toward greater interoperability and more meaningful data capture. While several viable pathways exist for implementation, there are limitations that need to be addressed to move forward. Ongoing stakeholder engagement, pilot testing, iterative refinement, and harmonization with clinical quality measure override concepts will be critical to ensuring the override taxonomy's relevance and usability in PC CDS applications. Ultimately, a standards-aligned approach to implementing the override taxonomy can facilitate robust analysis of PC CDS effectiveness, thus improving usability.

#### Appendix A. Taxonomy of Override Reasons for PC CDS Recommendations

PC CDS does not apply to patient	PC CDS delivered in suboptimal context	Recipient disagrees with recommendation because of issues with the evidence	Recipient has concerns regarding potential health outcomes	Recommendation does not align with patient preferences or values	Recommendation is not convenient or feasible
Patient does not meet eligibility for recommended action	Could not address  recommended action due to limited time	Recommended action  does not align with the latest evidence	Recipient assessment of risk/benefit ratio	Patient fears discomfort from complying with recommended action	Patient has inadequate caregiver/social support
Patient has  — indication/order for intended action	PC CDS delivered at wrong time in workflow or patient lifeflow	Advice from expert  - contradicts the recommended action	Action taken to  mitigate risk of negative outcome	Patient does not want to change behavior or believes the change is unnecessary	Treatment or  service is not practically available
Recommended — action was already completed	PC CDS delivered to inappropriate recipient/role	Institutional policy/guideline contradicts the recommended action	Recommended action  likely to have negative health outcomes	Patient has a cultural or religious reason for not following recommended action	Recommended action cannot be — implemented due to technology challenges
Recommended action was previously unsuccessful	Could not address recommended action due to need for more information/pending results/pending consult	Recipient does not agree with or trust the recommended action	Patient has contraindication to recommended action	Patient prefers an  alternative approach or treatment	Recommended action is too costly or not covered by insurance
performed previously without adverse effect	Consult			Patient refuses/declines	Recipient does not understand the recommended action
Recommended action is not relevant or a priority				(no context given)*	or know how to perform the recommended action
in current state of health					Patient has co- morbidity or disability — that hinders them from completing recommended action

Notes: "Recipient" means the individual who received the PC CDS, which could be a clinician for clinician-facing PC CDS, or a patient or caregiver for patient-facing PC CDS. "Recommended action" refers to the action suggested by the PC CDS. "Intended action" refers to the course of action that the PC CDS recipient (clinician, patient, or caregiver) meant to take, and which triggered the PC CDS. "The category "Patient refuses/declines (no context given)" is included to acknowledge that override reasons that document patient refusal without providing more information are common in current CDS tools. However, this category is separated from the main taxonomy to indicate that it is not a preferred option; in the future, it would be ideal if PC CDS tools provided more specific patient override reasons.

#### Appendix B. Background Document for Key Informant Interviews

## Background for Interview on Override Reasons for Patient-Centered Clinical Decision Support (PC CDS) Recommendations

#### Background:

Clinical decision support involves digital tools that inform patient care decisions across platforms including electronic health records (EHRs), patient portals, and mobile apps. Patient-centered clinical decision support (PC CDS) specifically incorporates patient-centered factors related to knowledge (e.g., evidence), data, delivery, and use).

Recipients of PC CDS (e.g., clinicians, patients, or caregivers) may choose to dismiss a PC CDS recommendation. When doing so, they may be asked by the system to provide a reason for why they dismissed the recommendation, called an "override reason." This could be free text, or the recipient may be asked to select from a list of override options.

The Clinical Decision Support Innovation Collaborative (CDSiC) Standards and Regulatory Frameworks Workgroup developed a taxonomy to help standardize how override reasons are analyzed for research and improvement purposes. The taxonomy offers a standard set of override domains that developers and researchers can use to analyze why users (e.g., clinicians or patients) reject PC CDS recommendations. See <u>Appendix A</u> for the taxonomy.

Currently, our team is leveraging the taxonomy to develop standardized terms and templates that can be offered as override reasons in real-world PC CDS applications. Use of standard terms and templates can reduce unnecessary variation in override reasons across different PC CDS applications. Standardizing override reasons in this way may reduce cognitive burden on clinicians, who review many PC CDS recommendations daily. It may also support standardized analysis of override reasons, which can lead to improvements in PC CDS to make it more relevant to patients.

#### Purpose of the Interview:

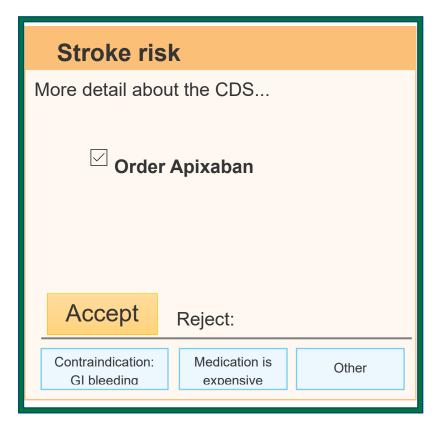
During the interview, we will present the standard terms and templates that we have developed (*Appendix B*). We would like to hear your feedback on whether the terms are clear and understandable to a potential recipient (e.g., clinician, patient, caregiver) and how we might improve them. We would also like to get your feedback on the examples we provide.

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https://cdsic.ahrq.gov/cdsic/patient-centered-clinical-cds-infographic

#### Appendix C. Example CDS Hooks Card

```
"cards": [
   "summary": "Stroke risk",
   "detail": "More detail abouthe CDS...",
   "indicator": "info",
   "overrideReasons": [
       "code": "contraindication-to-recommendation",
       "system": "http://hl7.org/fhir/CodeSystem/override-
       "display": "Contraindication: GI bleeding"
       "code": "recommendation-cost",
       "system": "http://hl7.org/fhir/CodeSystem/override-
       "display": "Medication is expensive"
        "display": "Other"
   "suggestions": [...],
```



# Appendix D. Initial Example User Override Terms Presented to Key Informants for Feedback

Taxonomy Subdomain	Initial Example User Override Terms
1.1 Patient does not meet eligibility for recommended action	Not indicated: (e.g., procedure, treatment, drug, age, condition)
1.2 Patient has indication/order for intended action	Patient indicated for intended action: (e.g., travel, condition, symptom, pre-surgery)
1.3 Recommended action was already completed	Already performed
1.4 Recommended action was previously unsuccessful	Previously unsuccessful
1.5 Intended action was performed previously without adverse effect	Side effect not seen in prior treatment
1.6 Recommended action is not relevant or a priority in current state of health	Not relevant/priority currently
2.1 Could not address recommended action due to limited time	Insufficient time to address
2.2 PC CDS delivered at wrong time in workflow or patient lifeflow	Not right time to address
2.3 PC CDS delivered to inappropriate recipient/role	Wrong recipient
2.4 Could not address recommended action due to need for more information/pending results/pending consult	Awaiting (e.g., consult, lab results, more information
3.1 Recommended action does not align with the latest evidence	Outdated evidence
3.2 Advice from expert contradicts the recommended action	Consulted with (e.g., expert, specialist)
3.3 Institutional policy/guideline contradicts the recommended action	Does not align with policy
3.4 Recipient does not agree with or trust the recommended action	Disagree with recommendation
4.1 Recipient assessment of risk/benefit ratio	<ul><li>Risks outweigh benefits</li><li>Benefits outweigh risks</li></ul>
4.2 Action taken to mitigate risk of negative outcome	Ordered     Followup scheduled
4.3 Recommended action likely to have negative health outcomes	• Risk:
4.4 Patient has contraindication to recommended action	Contraindication: (e.g., drug, procedure, allergy)
5.1 Patient fears discomfort complying with recommended action	Patient fears discomfort
5.2 Patient does not want to change behavior or believes the change is unnecessary	Patient feels it is unnecessary

Taxonomy Subdomain	Initial Example User Override Terms
5.3 Patient has a cultural or religious reason for not following the recommended action	Patient's beliefs
5.4 Patient prefers an alternative approach or treatment	Patient prefers alternative
6.1 Patient has inadequate caregiver/social support	Patient lacks support (e.g., caregiver, social, transportation)
6.2 Treatment or service is not practically available	Unavailable <at facility="" locally=""></at>
6.3 Recommended action cannot be implemented due to technology challenges	Technological challenges
6.4 Recommended action is too costly or not covered by insurance	<ul><li>Not covered by insurance</li><li>Too expensive for patient</li><li>High out-of-pocket cost</li></ul>
6.5 Recipient does not understand the recommended action or know how to perform the recommended action	<ul><li>Do not understand recommendation</li><li>Do not know how to perform recommendation</li></ul>
6.6 Patient has co-morbidity or disability that hinders them from completing recommended action	Patient has (condition or health-related barrier)

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