CDS Standards and Regulatory Frameworks Workgroup:
An Initial Taxonomy of Override Reasons for PC CDS Recommendations

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Clinical Decision Support Innovation Collaborative

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 is comprised of 19 experts and stakeholders representing a diversity 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 the NORC at the University of Chicago Institutional Review Board (FWA00000142).

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Executive Summary

Introduction

Clinical decision support (CDS) provides clinical alerts, recommendations, or other guidance to support evidence-based care and reduce patient harm. Patient-centered clinical decision support (PC CDS) is distinct from traditional CDS in that it can be patient- or clinician-facing and aims to deliver evidence-based guidance that significantly incorporates patient-centered factors related to knowledge, data, delivery, and use. Increasingly, PC CDS is being put directly in the hands of patients to help manage conditions such as COVID-19 and hypertension during pregnancy. There is also a growing emphasis on shared decision making between clinicians and patients. This creates an impetus to monitor and analyze how recipients (i.e., patients, caregivers, and clinicians) interact with PC CDS, including whether and why recommendations are overridden.

The analysis of recipient-provided override reasons can help researchers and PC CDS developers to understand if/why alerts are relevant or acceptable to different users and can inform improvements in PC CDS logic and deployment. This analysis would benefit from a shared taxonomy to characterize and group the many different override reasons; however, there is no standard or widely adopted taxonomy of override reasons for PC CDS.

The lack of a taxonomy of override reasons hinders research in PC CDS and the optimization of PC CDS recommendations. Currently, analysis of overrides is inefficient, and lessons learned from studies of CDS performance cannot be easily generalized from one study to another or one institution or setting to another. A common taxonomy of override reasons for PC CDS can support a better understanding of the barriers and challenges to its use, and what can be done to improve PC CDS, thereby promoting adoption and broader use.

This report presents a taxonomy of override reasons for PC CDS, composed of reasons that may be selected by patients, caregivers, clinicians, or other recipients of PC CDS. The taxonomy serves as a foundation for analysis, providing a shared set of domains and subdomains that capture a broad range of potential override reasons. It is meant to be used by PC CDS developers and researchers when analyzing why users do not accept PC CDS guidance.

Methods

The taxonomy was created through a three-stage process: 1) draft taxonomy development, 2) refinement, and 3) validation. During the development process, override reasons used in real-world CDS and PC CDS implementations were identified through a literature review and soliciting reasons from CDS and PC CDS developers and health systems. The search included CDS in addition to PC CDS given the nascency of PC CDS, which means there is less literature and fewer real-world

implementations on which to draw. Many CDS override reasons could apply to PC CDS as well, however, making them appropriate to consider in the taxonomy development.

Override reasons were identified in 30 articles. The team also conducted a supplemental search for literature on barriers to patient adherence with clinical recommendations, given the limited literature on patient override reasons. These barriers pointed to potential reasons for override (e.g., related to access, caregiver/social support). Additionally, six organizations—three health systems, two CDS tool developers/vendors, and one electronic health record (EHR) vendor—provided lists of override reasons from their CDS implementations; this yielded 150 override reasons. A draft taxonomy was developed by employing inductive and deductive approaches to categorize the identified override reasons into thematic domains. During this process, the team also drew on the patient barriers literature to develop domains and subdomains of patient and caregiver reasons for override that did not appear in the literature or CDS examples, but that are particularly relevant to PC CDS. The goal was to identify a manageable number of distinct but comprehensive categories for analysis.

The taxonomy was then refined through feedback from interviews with key informants and a card sorting exercise in which override reasons from CDS systems were mapped to concepts in the draft taxonomy. Finally, to validate the taxonomy the team conducted a second round of virtual interviews and used the feedback to finalize the taxonomy.

Results

Taxonomy Design Features. There are several noteworthy features of the taxonomy.

- The taxonomy domains are recipient agnostic. While some categories may be more relevant to patient-recipients and others to clinician-recipients, the taxonomy does not a priori limit who would choose any given type of reason.
- Additionally, the taxonomy is meant to be applicable to a broad range of PC CDS covering different use cases and recipients. As such, not all domains or subdomains in the taxonomy may be applicable to every PC CDS.
- Finally, the taxonomy is forward looking and includes some override categories that were not offered in the real-world override reasons reviewed while creating the taxonomy. The taxonomy includes additional (and more descriptive) categories of reasons why patients/caregivers may decline PC CDS, based on literature examining patient barriers to adhering to care recommendations and insights from key informants.

PC CDS Recipients

In the taxonomy, a recipient is defined as anyone who receives PC CDS (e.g., a patient, clinician, or caregiver). Some taxonomy domains and subdomains may be more relevant to patients/caregivers and others to clinicians, but the taxonomy does not limit who can choose a given reason. For example, a patient or a clinician may choose to decline a recommendation because of issues with the evidence or because of concerns regarding health outcomes.

Taxonomy Use. The taxonomy is meant to be used by PC CDS developers and researchers for analysis of why recipients do not accept PC CDS. The taxonomy can be implemented by health

systems to assess in detail why a given PC CDS alert is being frequently overridden, and point to ways in which the PC CDS can be improved. It can also be used by researchers when investigating override reasons. It is particularly suited to facilitating comparison of overrides of PC CDS across different institutions to share lessons learned.

The terms included in the taxonomy domains and subdomains may not represent the terms a recipient (e.g., a patient or clinician) may see when they override PC CDS in an EHR system or patient-facing application. Rather, users of the taxonomy should map these recipient-provided override reasons to the taxonomy domains/subdomains and report their results using the taxonomy terminology.

Taxonomy Structure. The Taxonomy of Override Reasons for PC CDS Recommendations contains six domains, each with several subdomains (Exhibit E1). The taxonomy encompasses override reasons related to 1) the applicability of the PC CDS to the patient, 2) the context in which the PC CDS is delivered, 3) the evidence underlying the PC CDS, 4) potential health outcomes, 5) patient preferences and values, and 6) logistical and other barriers to completion of the actions recommended by the PC CDS.

Exhibit E1. Initial Taxonomy of Override Reasons for PC CDS Recommendations

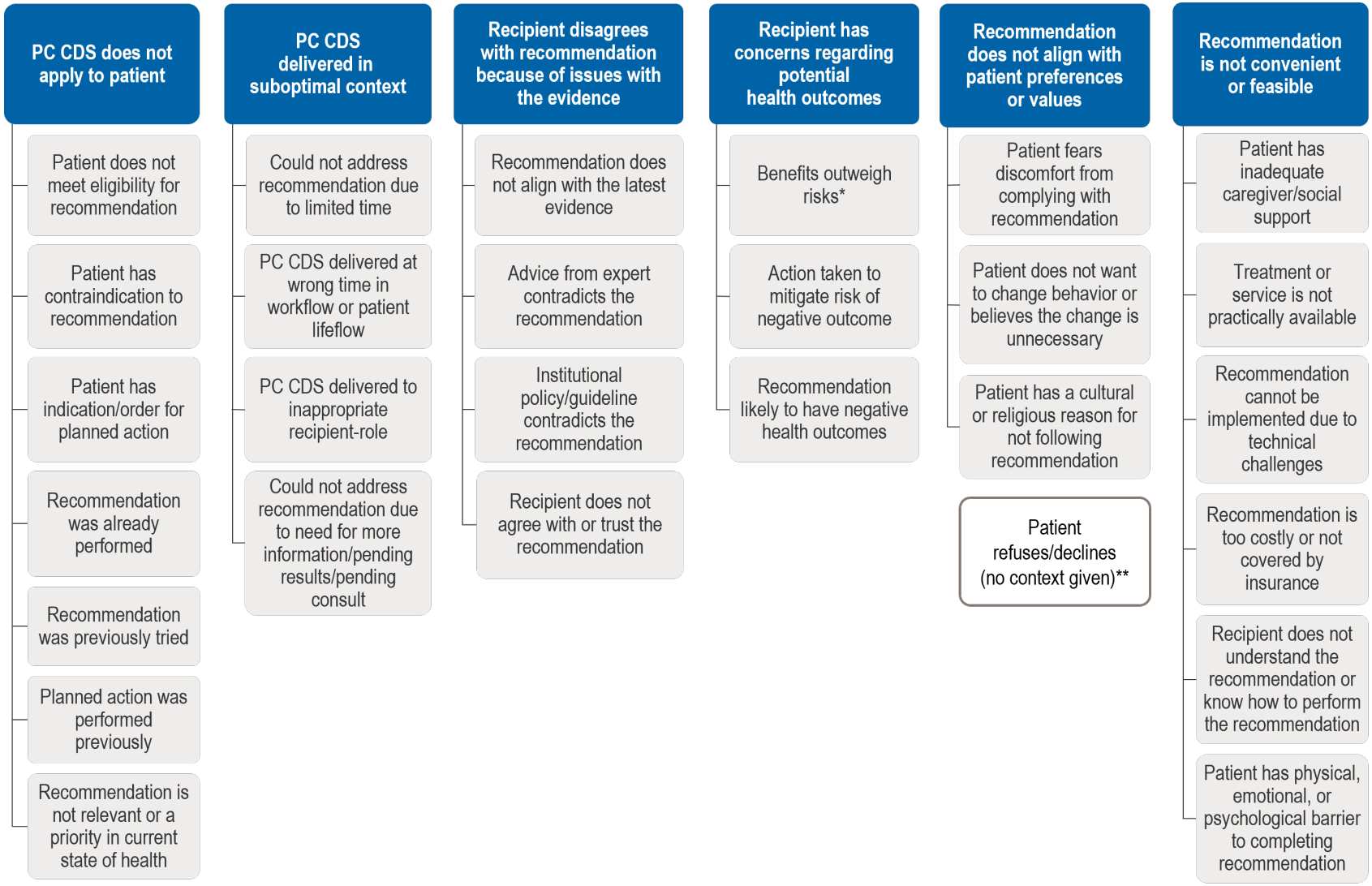

Exhibit notes: The taxonomy domains are recipient agnostic. While some categories may be more relevant to patient-recipients and others to clinician-recipients, the taxonomy does not a priori limit who would choose any given type of reason. *This subdomain encompasses two scenarios: 1) a recipient may find it more beneficial to override the PC CDS than to implement it, or 2) the recipient may choose to perform an action contrary to the PC CDS if the benefit of such action outweighs the risk raised by 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.

Discussion and Future Directions for Research and Use

While override reasons for traditional CDS have been discussed in the peer-reviewed literature (including taxonomies for specific CDS use cases, such as drug–drug interactions), this product provides a unique contribution by providing a taxonomy specifically focused on PC CDS. The taxonomy was developed based on a review of hundreds of override reasons identified in the literature and crowdsourced from several delivery systems and CDS systems. This taxonomy is not limited to a specific set of use cases such as medications but, rather, applies to varied PC CDS scenarios. Additionally, unlike prior work that looked at traditional CDS in which clinicians are the recipients, this taxonomy encompasses PC CDS of which the recipients may be clinicians, patients, or caregivers.

While the taxonomy was designed with a broad range of use cases in mind, it is not meant to be static. Over time, the types of domains offered may evolve, especially as PC CDS itself evolves to apply to new situations and use cases, necessitating updates to the taxonomy. Additionally, future efforts can further validate and standardize the taxonomy.

Refinement of the taxonomy based on experience and testing. The taxonomy serves as an initial framework that can potentially be refined and expanded through additional research and testing. While the taxonomy was developed through a data-driven approach and was iteratively refined with input from experts, it would benefit from additional piloting in real-world settings. In particular, validating the taxonomy against additional patient-facing PC CDS tools and with additional patients/caregivers would help ensure that it captures the breadth of reasons why a patient may choose not to (or be unable to) adhere to an alert/recommendation.

Development of approaches to standardize user-presentation. The descriptions of the domains and subdomains in the current version of the taxonomy are higher level and not suitable for use as override reasons displayed to a PC CDS recipient. Creating a recipient-friendly terminology associated with the taxonomy domains and subdomains will allow the taxonomy to be used directly within PC CDS and possibly incorporated in PC CDS interoperability standards such as Health Level Seven International (HL7) CDS Hooks. In turn, this will allow consistent presentation of override reasons to PC CDS recipients and capture of override reasons directly into the taxonomy concepts.

Use of the taxonomy to conduct analyses of PC CDS override reasons. The taxonomy can be used in its current version to analyze PC CDS override reasons in different scenarios. This would demonstrate the value of the taxonomy and how it can be used, and may also point to further directions for refinement.

Several limitations affect the scope and depth of the final taxonomy. The taxonomy may not encompass the universe of override reasons, particularly patient overrides, since it was based on a nonrepresentative sample of overrides from the literature and health systems/CDS developer. Additionally, the analysis of override reasons that underpinned the taxonomy development was hindered by lack of context in some cases, making override reasons difficult to interpret. Finally, the taxonomy validation was limited and primarily qualitative.

Conclusions

The taxonomy provides a framework for analyzing PC CDS overrides and can be used by PC CDS developers, PC CDS researchers, health systems, EHR developers, and patient groups as they investigate why users of PC CDS tools dismiss PC CDS recommendations and alerts. Standardized analysis facilitated by the taxonomy can support the translation of results across clinical settings and PC CDS types. Ultimately, the use of this taxonomy can support improvements in PC CDS to ensure that it is delivered at the right time, for the right patients and clinicians, and that it conveys clinically valuable and actionable information to inform shared decision making.

1. Introduction

Digital health technologies, such as electronic health record (EHR) systems, patient-facing applications, and wearable devices, often incorporate clinical decision support (CDS) that provides clinical alerts, recommendations, or other guidance to support evidence-based care and reduce patient harm.[2] For example, a CDS alert may notify a clinician of a potential drug–drug interaction, a patient allergy, or laboratory results relevant to their proposed course of action.[3] Patient-centered CDS (PC CDS) significantly incorporates patient-centered factors related to knowledge, data, delivery, and use.[1]

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 focuses 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 bi-directional information exchange in support of patient-centered care, including shared decision-making.[1]

While PC CDS aims to deliver evidence-based guidance and insights, recipients—such as patients or clinicians—may choose to not follow that guidance.[4 5] Literature on PC CDS is limited, especially when patients or caregivers are the recipients; most research has focused on clinician-facing CDS. This research has identified reasons why CDS guidance is not followed, such as the recommendation not applying to the patient, the benefit of the proposed action outweighing the risk raised by the CDS, or the evidence underlying the CDS being outdated.[6 7 8] Additionally, the CDS may be presented at the wrong time in the workflow or may not be a priority for a given patient.[9]

Some (though not all) CDS systems request that recipients identify a reason when they choose not to follow the guidance, called an "override reason." Systems may offer a coded list of predefined override reasons specific to the CDS, allow the recipient to input a reason as free-text, or both.[10] While rates of override vary depending on the CDS and context, they have been shown to be as high as 90 percent in some cases.[5 6] Often, these overrides are clinically justified,[5] suggesting potential issues with the CDS design or implementation. High rates of incorrect, irrelevant, uninformative, or nonspecific CDS alerts and recommendations contribute to alert fatigue and clinician burnout, which may in turn lead to recipients inadvertently dismissing or ignoring alerts that are clinically beneficial.[2 3 11 12] These types of concerns may be relevant in PC CDS implementations as well.

PC CDS is increasingly being put directly in the hands of patients to help manage conditions such as COVID-19 and hypertension during pregnancy.[13 14] There is also a growing emphasis on shared decision making between clinicians and patients.[15] This creates an impetus to monitor and analyze how recipients interact with PC CDS, including whether and why recommendations are overridden. By analyzing recipient-provided override reasons, researchers and PC CDS developers can understand if

and why alerts are relevant or acceptable to different users, which can inform improvements in PC CDS logic and deployment.[9 12] For example, analysis may reveal that the guidance is being delivered at the wrong time in the workflow or not considering relevant patient data, which developers could then address to make it more useful and acceptable to recipients.[16]

Currently, however, there is no standard or widely adopted taxonomy for analyzing override reasons, for CDS or PC CDS. Each system seems to use its own set of terms, and, while there is some overlap in concepts, specific wording and reasons vary. A taxonomy of override reasons was previously developed for drug–drug interaction alerts[6] and a separate taxonomy categorized reasons for CDS alert malfunctions,[7] but no taxonomy covers broad use cases or extends to PC CDS.

This lack of a taxonomy of override reasons hinders research in PC CDS and the optimization of PC CDS recommendations. Currently, analysis of overrides is inefficient, and lessons learned from studies of CDS performance cannot be easily generalized from one study to another or one institution or setting to another.[4] A common taxonomy of override reasons can support analysis of PC CDS and scaling the science of PC CDS optimization.

This report presents a taxonomy of override reasons for PC CDS tools, composed of reasons that may be selected by patients, caregivers, clinicians, or other recipients of PC CDS. The taxonomy serves as a foundation for analysis, providing a shared set of domains and subdomains that capture a broad range of potential override reasons. It is meant to be used by PC CDS developers and researchers when analyzing why users do not accept PC CDS guidance.

1.1 Roadmap of the Report

This report is organized in the following sections:

- Section 2 describes the methods used to develop the taxonomy.
- Section 3 presents the results, starting with a summary of the types of override reasons identified that informed the taxonomy development, followed by a description of the taxonomy.
- Section 4 discusses the taxonomy and explores future directions for research and use.
- Section 5 provides a brief conclusion.

2. Methods

The taxonomy was created through a three-stage process: development, refinement, and validation (Exhibit 1). These stages included a rapid literature review, solicitation of override reasons from CDS developers and health systems (referred to throughout the report as “crowdsourcing”), refinement through key informant feedback and a card sorting exercise, and validation through a second round of key informant interviews and a mapping exercise for quality assurance. Additional information about these methods is provided below.

Exhibit 1. Taxonomy Development Process

2.1 Identification of Override Reasons and Draft Taxonomy Development

To guide the construction of the taxonomy, the team first compiled a list of override reasons used in real-world CDS and PC CDS implementations. To start, the team conducted a rapid literature review to identify current override reasons. The search included CDS in addition to PC CDS given the nascency of PC CDS, which means there is less literature and fewer real-world implementations on which to draw. Many CDS override reasons could apply to PC CDS as well, however, making them appropriate to consider in the taxonomy development. A PubMed search yielded 76 articles, and, after screening titles and abstracts, 40 articles underwent full-text review. Through snowballing, an additional 15 articles were included. Override reasons were identified in 30 articles (see Appendix A).

Additionally, the team conducted a supplemental search for literature on barriers to patient adherence to clinical recommendations and reviewed an additional seven articles (see Appendix B). Given the limited literature on patient reasons for overriding CDS, this search provided information on why patients might choose not to follow clinical advice, allowing the team to identify parallels to clinician override reasons.

Concurrently with the literature review, the team also identified override reasons through crowdsourcing requests. CDS override reasons were received from six organizations: three health systems, two CDS tool developers/vendors, and one EHR vendor. The inputs were received as either complete system lists of override reasons from the organization's EHR system or product's system, a subset of reasons specific to a given CDS application, or a list of the most commonly selected overrides. In total, the crowdsourcing yielded 150 unique override reasons.

Next, the team developed the draft taxonomy by employing both inductive and deductive approaches to categorize override reasons. Deductively, the team developed initial high-level domains based on the PC CDS life cycle framework [17] and grouped the identified override reasons within these categories. The team revised this initial categorization inductively by iteratively grouping override reasons thematically, modifying the initial groupings and domains as needed. The team also drew on the patient barriers literature to develop domains and subdomains of patient and caregiver reasons for override that did not appear in the literature or CDS examples, but that are particularly relevant to PC CDS. The team then divided high-level domains into associated subdomains.

2.2 Refinement of the Taxonomy

To refine the taxonomy, the team conducted virtual interviews with four key informants—three informaticians with PC CDS expertise and one health services researcher who studies patient-centered

care delivery—to solicit feedback on the draft taxonomy. Interviewers used semistructured discussion guides to garner feedback on the comprehensiveness, clarity, and structure of the taxonomy, as well as how it could be disseminated and used in practice. Given that few patient-specific override reasons were identified in the literature and crowdsourcing, insights from the interviews were also used to expand on potential patient/caregiver override reasons. Informants were provided with a working draft of the taxonomy in advance of the interviews.

The interviews were conducted via Zoom and lasted approximately 30–60 minutes. With informants' approval, all sessions were recorded. A team member took transcript-style notes, which the team thematically analyzed to identify patterns within and across interviews.

In tandem with the interviews, eight members of the team conducted a card sorting exercise in which the override reasons identified through the literature and crowdsourcing were grouped under the draft taxonomy domains. This exercise aimed to assess the alignment between the draft taxonomy domains and real-world override reasons.[6] Based on findings from the card sorting exercise and interviews, the team iteratively revised the taxonomy by either adding or removing domains and subdomains, restructuring the grouping of concepts, and revising the language.

2.3 Validation of the Taxonomy

To validate the taxonomy, the team conducted a second round of virtual interviews with six informants representing clinicians, informaticians, patient representatives, and researchers to solicit feedback on the refined taxonomy. The team also received two additional lists of override reasons from two health systems.

After receiving feedback, the team implemented final adjustments to the taxonomy, followed by a final mapping exercise for quality assurance. In this exercise, the team acquired new override reasons from a recent study of free-text override responses to CDS alerts [18] and mapped them to the taxonomy domains, comparing and discussing discordant use of the codes and refining the wording or instructional guidance for certain codes. This process allowed the team to confirm that the taxonomy domains adequately captured the variety of override reasons encountered in clinical practice.

3. Results

This section presents the results of the sourcing of override reasons, followed by a description of the taxonomy and considerations for the use of the taxonomy.

3.1 Summary of Identified Override Reasons

All the CDS-specific articles identified in the literature reviewed clinician-facing CDS tools; no articles reviewed patient-facing CDS tools. Moreover, the overwhelming majority of concepts identified in the literature review could be considered clinician focused. These covered a variety of clinical topic areas, including drug–drug interaction,[5 6 8 10 19 20 21 22 23 24 25 26 27 28] drug allergies/patient

allergies,[5 8 12 16 26 27 28 29 30 31 32] formulary substitutions,[8 27] duplicate drugs,[8 26 27] drug dosage,[27] renal recommendations (e.g., related to renal function),[8 27 33 34] preventive care,[35] age-based CDS/geriatrics,[8 27] and pharmacogenetics,[36] among others. Drug–drug interactions, drug-allergy/allergy, and other drug-related use cases were the most frequently studied.

Two high-level themes emerged across the identified override reasons and CDS tools. First, while most CDS tools used context-specific override reasons, several generic reasons appeared across multiple tools. For example, reasons capturing concepts such as "no reasonable alternative," "benefit outweighs the risk," and "alert does not apply to this patient" were offered as override options in a range of CDS tools/contexts (though the specific wording may have varied).

Second, while most of the clinician-facing CDS tools (e.g., embedded in EHR systems) documented override reasons from the clinician perspective, some captured the patient perspective, albeit in a rudimentary manner. For example, in some systems clinicians could enter reasons such as "Patient declined" or "Patient refuses." The override reasons from one of the CDS tools obtained through the crowdsourcing, which focused on colorectal cancer screening, provided a few additional patient override reasons such as "Cost concerns" and "Cultural concerns." The vast majority of identified reasons captured the clinician/health system perspective, however.

3.2 Taxonomy of Override Reasons for PC CDS Recommendations: Design Features, Use, and Structure

The sections below describe some of the key design features of the taxonomy, how it should be used, and its structure.

3.2.1 Taxonomy Design Features

There are several noteworthy features of the taxonomy. First, the taxonomy applies to both clinician- and patient-facing PC CDS, and the domains are recipient agnostic. While some categories may be more relevant to patient-recipients and others to clinician-recipients, the taxonomy does not a priori limit who would choose any given type of reason. For example, a patient could select to override a recommendation delivered in a patient-facing application because it does not align with their preferences. Alternatively, they might tell a physician during a clinical encounter that a given recommendation does not align with their preferences, in response to which the physician would enter the reason in the EHR system when prompted for an override explanation.

PC CDS Recipients

In the taxonomy, a recipient is defined as anyone who receives PC CDS (e.g., a patient, clinician, or caregiver). Some taxonomy domains and subdomains may be more relevant to patients/caregivers and others to clinicians, but the taxonomy does not limit who can choose a given reason. For example, a patient or a clinician may choose to decline a recommendation because of issues with the evidence or because of concerns regarding health outcomes.

Second, not all domains or subdomains in the taxonomy may be applicable to every PC CDS tool. Developers of PC CDS may choose to offer override reasons that align with some or all of these categories in any given tool. The taxonomy is meant to capture a broad range of possible override categories. It is also meant to apply to PC CDS that is recommending an action (e.g., recommending a screening test) as well as to PC CDS alerts that are critiquing/flagging a recipient's planned course of action (e.g., alerting that a patient has an allergy to a drug that is being prescribed).

Third, the taxonomy is intended to provide overarching thematic concepts under which specific override reasons can be grouped. Many of the override reasons observed in the literature and crowdsourcing applied to specific clinical scenarios. Including such numerous, specific concepts would make the taxonomy unwieldy to use and impractical to maintain. The taxonomy instead provides higher-level concepts. For example, override reasons from the crowdsourcing included "Contraindication to modality," "Contraindication: Brain injury/edema," and "Contraindication: Hyperkalemia"; the taxonomy captures these under the subdomain "Patient has contraindication to recommendation."

Finally, the taxonomy is forward looking and as such includes some override categories that were not offered in the real-world override reasons reviewed while creating the taxonomy. In particular, very few real-world override reasons captured the patient/caregiver perspective.

In reviewing override reasons from the literature and crowdsourcing, the team found that reasons for patients declining were limited and generally did not describe *why* the patient chose to decline. For example, identified reasons included "Patient preference,"[37] "Patient refused,"[37] "Patient/guardian declines,"[37] "Patient/caregiver declines,"[37] and "Pt counseled, prefers discontinuation."[37] These reasons do not specify the patient's motivation for refusing/declining, whether it be personal preference, concerns regarding negative side effects, logistical challenges associated with completing the recommendation such as cost barriers, or something else. This taxonomy extends what is currently available to include additional (and more descriptive) reasons why patients/caregivers may decline PC CDS, drawing upon literature on patient barriers to adhering to care recommendations and insights from key informants. While these types of override reasons may not currently be offered in PC CDS, in the future, PC CDS developers should consider including override options that provide deeper insight into decision context and motivation.

A Note on the Current and Future State of Patient Reasons for Override

The taxonomy domains provide options for why a patient may override a PC CDS alert or recommendation. The category "Patient refuses/declines (no context given)" is also included in the taxonomy to acknowledge that override reasons indicating that a patient declines/refuses without providing more information are common in current CDS tools. However, this category is visually separated from the main taxonomy (see Exhibit 2) to indicate that it is not a preferred option.

3.2.2 How To Use the Taxonomy

The taxonomy is meant to be used by PC CDS developers and researchers for analysis of reasons expressed by PC CDS recipients for not accepting PC CDS guidance. The taxonomy can be implemented by health systems to gauge with more specificity why a given PC CDS alert is being frequently overridden, and point to ways in which the PC CDS can be improved. It can also be used by researchers to investigate override reasons. It is particularly suited to facilitating comparison of overrides of PC CDS across different institutions to share lessons learned.

The terms included in the taxonomy domains and subdomains may not represent the terms a recipient (e.g., a patient or clinician) may see when they override PC CDS in an EHR system or patient-facing application. Rather, users of the taxonomy should map these recipient-provided override reasons to the taxonomy domains/subdomains and report their results using the taxonomy terminology.

Additionally, it is important to note that the scope of this taxonomy is to investigate recipient-provided reasons for overriding PC CDS. This taxonomy is not meant for analysis of the underlying issues with a PC CDS algorithm or its data inputs. For example, a user may indicate they did not follow the PC CDS recommendation due to a patient contraindication, a reason that is reflected in the taxonomy. Further investigation may reveal that the contraindication was not detected because the patient data are incomplete in the patient's EHR. This secondary analysis is beyond the scope of the taxonomy.

3.2.3 Taxonomy Domains

Exhibit 2 presents the Taxonomy of Override Reasons for PC CDS Recommendations. The taxonomy contains six domains, each with several subdomains. The taxonomy encompasses override reasons related to 1) the applicability of the PC CDS to the patient, 2) the context in which the PC CDS is delivered, 3) the evidence underlying the PC CDS, 4) potential health outcomes, 5) patient preferences and values, and 6) logistical and other barriers to completion of the actions recommended by the PC CDS.

Exhibit 2. Initial Taxonomy of Override Reasons for PC CDS Recommendations

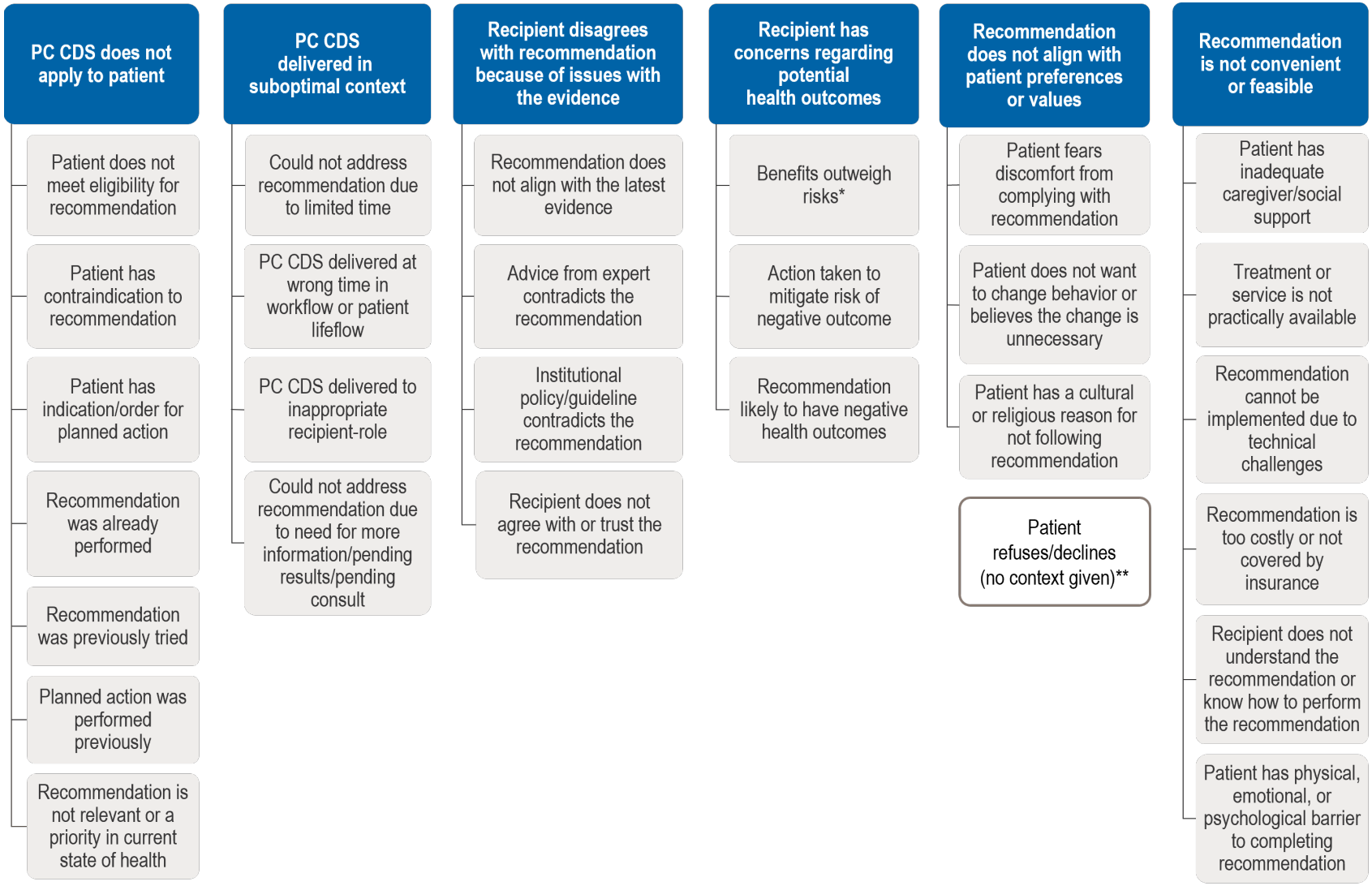

Exhibit notes: The taxonomy domains are recipient agnostic. While some categories may be more relevant to patient-recipients and others to clinician-recipients, the taxonomy does not a priori limit who would choose any given type of reason. *This subdomain encompasses two scenarios: 1) a recipient may find it more beneficial to override the PC CDS than to implement it, or 2) the recipient may choose to perform an action contrary to the PC CDS if the benefit of such action outweighs the risk raised by 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.

In the following sections, each of the taxonomy domains and associated subdomains is described in more detail with examples of overrides from real-world implementations.

3.2.3.1 PC CDS Does Not Apply to Patient

A PC CDS alert or recommendation may not apply to the patient. This may occur when the patient's data are missing or not up to date in the EHR. From the perspective of a PC CDS recipient, the alert/recommendation may not be applicable for several reasons, which the taxonomy captures in seven subdomains.

1. **Subdomain: Patient does not meet eligibility for recommendation.** An alert or recommendation may appear for a patient who is not eligible for it. For example, a patient may not fall within the age requirements for a given alert/recommendation or a patient may no longer be taking a drug that is the subject of a drug–drug interaction alert. Examples of override reasons from the source reasons related to this subdomain include "Patient not eligible,"[37] "Clinical info/calculation incorrect,"[37] "Does not apply to patient,"[22] and "Patient is not pregnant."[27]
2. **Subdomain: Patient has contraindication to recommendation.** A patient may have a contraindication that causes the recipient not to accept the PC CDS recommendation. For example, the patient may have an allergy to a recommended drug, may not tolerate a recommended mode of treatment delivery, or may have some other condition that makes the recommendation clinically inappropriate. Examples of override reasons from the source reasons related to this subdomain include "Contraindicated,"[37] "Medical contraindication,"[37] and "Contraindication: Brain injury/edema."[37]
3. **Subdomain: Patient has indication/order for planned action.** A patient may have an indication or a planned course of action that renders the alert/recommendation not applicable. For example, a clinician may receive an alert if they try to reorder a CT within a certain period from the last test; however, they may determine that the repeat imaging is necessary due to the onset of new clinical symptoms or worsening of existing symptoms.[38] Examples of override reasons from the source reasons related to this subdomain include "Patient on clinical trial requiring study"[37] and "Indicated for impending international travel."[37]
4. **Subdomain: Recommendation was already performed.** It is possible that the action recommended by the PC CDS, such as administration of a screening test, was already performed but is not reflected in the data that inform the PC CDS. For example, a PC CDS may recommend a patient receive a colonoscopy based on their age and reported date since last exam in the EHR, but the patient might report to their clinician that they recently received a colonoscopy at a separate institution, causing the clinician to override the recommendation. Examples of override reasons from the source reasons related to this subdomain include "Received at outside facility,"[37] "Already under specialist care,"[37] "Has pending consult already,"[37] and "Patient already had therapy."[37]
5. **Subdomain: Recommendation was previously tried.** A PC CDS recommendation/alert may flag or recommend a course of action for a patient, but it has already been tried for that patient and

proven unsuccessful, and thus an alternative is being pursued. An override example from the source reasons related to this subdomain is “History of minimum three failed trials of monotherapy.”[37]

6. **Subdomain: Planned action was performed previously.** In this case, the PC CDS may issue an alert flagging a concern about a planned course of clinical action, but the recipient overrides the alert because it was previously performed without an adverse result. For example, a patient with a drug allergy may have previously tolerated a combination drug, so a clinician may represcribe it. An override example from the source reasons related to this subdomain is “Patient tolerated before.”[27]
7. **Subdomain: Recommendation is not relevant or a priority in current state of health.** A patient may meet the eligibility criteria for a recommendation offered by PC CDS, but it may not be a priority or relevant given their current health state or based on their goals. For example, preventing diabetes is likely not a priority for a patient with a terminal illness. Examples of override reasons from the source reasons related to this subdomain are “Palliative care,”[37] “Comfort care,”[39] “Defer 6 months due to acute comorbidity,”[37] and “Screening not applicable due to chronic comorbidity.”[37]

3.2.3.2 PC CDS Delivered in Suboptimal Context

In contrast to the reasons above that relate to the appropriateness of alert to a particular patient for various reasons, a PC CDS alert/recommendation may be dismissed by a recipient because it was not delivered in the right context. Context includes factors such as timing and the role of the (nonpatient) recipient in the delivery of care to the patient. The taxonomy includes four subdomains that cover these contextual reasons for override.

1. **Subdomain: Could not address recommendation due to limited time.** PC CDS may be relevant to a patient, but a recipient may choose to decline to address it because they do not have enough time to address it. For example, in the context of a clinical visit, a PC CDS may raise a valid recommendation, such as suggesting a flu vaccination for a patient, but there may not be enough time within the 15–20-minute encounter to discuss vaccination with the patient due to more pressing healthcare needs. In this case, the recommendation may be overridden and possibly deferred until a later date. Examples of override reasons from the source reasons related to this subdomain include “Defer”[37] and “Snooze,”[37] both of which offer options to postpone for specific periods of time (e.g., one week, one month, one year), and “Show me next time.”[37]
2. **Subdomain: PC CDS delivered at wrong time in workflow or patient lifeflow.** PC CDS may be delivered at the wrong time in the clinical workflow or, in the case of patient-facing PC CDS, in the patient’s lifeflow. For example, an alert may appear upon opening a patient’s chart in the EHR system, before a clinician has had time to assess the patient, causing them to dismiss the alert; ideally, it would have been delivered after the clinician completed their assessment. Examples of override reasons from the source reasons related to this subdomain include “Patient has not yet arrived,”[37] “I have not yet seen the patient,”[37] and “I need to review the chart.”[37]
3. **Subdomain: PC CDS delivered to inappropriate recipient-role.** PC CDS may be overridden if it was not delivered to the appropriate recipient. For example, an alert/recommendation may be

delivered to a specialist when it is raising an issue that should be addressed by the patient's primary care provider. Alternatively, the alert may appear when a registered nurse opens the patient's chart, but the alert is intended for the physician. Examples of override reasons from the source reasons related to this subdomain include "I am not the attending physician,"[37] "Not a member of the patient's care team,"[37] "Not appropriate provider,"[37] and "Not a member of the Primary Admitting Service."[37]

4. **Subdomain: Could not address recommendation due to need for more information/pending results/pending consult.** A recipient may override a PC CDS recommendation/alert if they do not have the needed data—such as information from an outstanding laboratory result or advice from a specialist—to act on it. A clinician may, for example, choose to order additional diagnostic tests before they decide on the course of action suggested by the PC CDS. Examples of override reasons from the source reasons related to this subdomain include "Defer until further information can be gathered,"[37] "Need to defer for additional assessments,"[37] and "Patient requires additional procedures/consultations prior to [...] ICU admission."[37]

3.2.3.3 Recipient Disagrees With Recommendation Because of Issues With the Evidence

A PC CDS recipient may dismiss an alert/recommendation because the evidence used in building the PC CDS logic does not align with the most recent evidence or the recipient may be following a different set of evidence. For example, there may be newer evidence that renders the PC CDS alert or recommendation outdated. Alternatively, it may be a complex or unique clinical situation in which the recipient is relying on advice from an expert for their specific situation. The taxonomy includes four subdomains of override reasons related to issues with the clinical evidence.

1. **Subdomain: Recommendation does not align with the latest evidence.** Clinical evidence is constantly changing, and, in some cases, updates to PC CDS tools may not keep pace with the latest clinical guidelines. As a result, an alert/recommendation may appear that does not align with the latest clinical best practices. Examples of override reasons from the source reasons related to this subdomain include "New evidence supports therapy of this type"[8] and "Published guidelines suggest follow-up."[38]
2. **Subdomain: Advice from expert contradicts the recommendation.** Recipients of PC CDS may override an alert/recommendation because they have received different advice or guidance from someone else (e.g., a specialist, another patient). For example, antibiotic selection for presumptive treatment of a condition may be based on advice from an infectious disease consultation, leading the clinician to override a CDS alert about the choice of antibiotic that is based on the patient's symptoms. Examples of override reasons from the source reasons related to this subdomain include "Surgeon requested early redose [of anesthesia],"[37] "Consulted with Radiology,"[37] "Contacted provider & confirmed med,"[37] and "Specific attending request."[37]
3. **Subdomain: Institutional policy/guideline contradicts the recommendation.** In some cases, an institution's policy/guidelines may not align with the content of the alert/recommendation raised by

the PC CDS. An example override reason from the source reasons related to this subdomain is "per protocol."[22]

4. **Subdomain: Recipient does not agree with or trust the recommendation.** A recipient may override a PC CDS alert/recommendation if they do not agree with or trust the recommendation. For example, it has been documented that trust in the COVID-19 vaccination, including perceptions of the vaccine's safety and efficacy, played a role in acceptance of the vaccine.[40] Examples of override reasons from the source reasons related to this subdomain include "Disagree with appropriateness score"[37] and "Physician objection to guidelines."[37]

3.2.3.4 Recipient Has Concerns Regarding Potential Health Outcomes

A PC CDS recipient may dismiss an alert/recommendation because they have concerns regarding the potential clinical outcomes resulting from implementing the recommendation. In this case, the recommendation/alert is applicable but could cause negative health outcomes to the patient if implemented, or the benefits of the clinician's/patient's proposed course of action outweigh the risk to the patient raised by the PC CDS. The taxonomy includes three subdomains of override reasons related to concerns regarding potential clinical outcomes.

1. **Subdomain: Benefits outweigh risks.** PC CDS may deliver an alert/recommendation for an action by the recipient in which it may be more beneficial to the patient to override than to implement. The recipient may also choose to perform an action despite the PC CDS alert or recommendation if they perceive the benefit of such action outweighs the risk suggested by the PC CDS. In the literature, "benefit outweighs risk" was identified as a common override reason for studies reporting drug–drug interaction and prescription override reasons.[19] For example, a clinician may prescribe a medication even though the patient has mild intolerance to the medication. Examples of override reasons from the source reasons related to this subdomain include "Benefit outweighs risk,"[6 41 42] "Low risk,"[43] and "No reasonable alternatives."[27]
2. **Subdomain: Action taken to mitigate risk of negative outcome.** Recipients of PC CDS may override an alert/recommendation because they have already taken, or plan to take, an action that would mitigate the risk of the negative outcome suggested by the PC CDS. For example, an alert may flag a potential drug interaction and the clinician may override the alert, acknowledging the potential interaction but noting that they will monitor the patient closely for symptoms of concern. Examples of override reasons from the source reasons related to this subdomain include "Will monitor,"[37] "Follow-up action(s) taken,"[37] and "Known diagnosis managed by me."[37]
3. **Subdomain: Recommendation likely to have negative health outcomes.** PC CDS may deliver an alert/recommendation that the recipient deems would have a negative health outcome for the patient if implemented. An example of this could be that a pregnant patient is experiencing extreme nausea and the CDS prescribes an increased dose of antiemetic. The physician may decide not to give the patient this dose because of concerns for the fetus. An example of an override reason from the source reasons related to this subdomain is "Potential side effects."[37]

3.2.3.5 Recommendation Does Not Align With Patient Preferences or Values

For PC CDS to be patient-centered, it should consider the preferences and values of patients. When a PC CDS recommendation/alert does not align with patient preferences or values, a recipient may override it. For example, some patients have religious or cultural reasons for not wanting to accept certain services or treatments (e.g., some religious beliefs preclude blood transfusions[44]). The taxonomy includes three subdomains related to patient preferences and values.

1. **Subdomain: Patient fears discomfort complying with recommendation.** A patient may not feel comfortable complying with a PC CDS recommendation, because they believe it may cause them discomfort. For example, a PC CDS tool may recommend a vaccine or medication that the patient anticipates will be uncomfortable for them (e.g., the administration of the vaccine/medication itself or its side effects). Examples of override reasons from the source reasons related to this subdomain include "Anxiety/fear,"[37] "Views test with distaste/disgust,"[37] and "Fear of discomfort or results."[35]
2. **Subdomain: Patient does not want to change behavior or believes the change is unnecessary.** PC CDS may deliver an alert/recommendation for the patient to change a behavior such as their diet or exercise regimen. Recipients of PC CDS may override these if the patient does not want to change their behavior or believes the change is unnecessary. For example, some elderly patients may not want to implement dietary or other changes given their age.[45] Additionally, there may be situations in which a patient is monitoring their health very closely and may have observational insights that contradict recommendations from a PC CDS. Examples of override reasons from the source reasons related to this subdomain include "Feels benefits are not worth the effort,"[37] "Not convinced of screening importance,"[37] and "Believe test not necessary."[35]
3. **Subdomain: Patient has a cultural or religious reason for not following the recommendation.** A recipient may override a PC CDS alert/recommendation because it does not align with the patient's culture or religious beliefs. For example, some patients may not agree to have a blood transfusion due to religious beliefs. Examples of override reasons from the source reasons related to this subdomain include "Cultural concerns"[37] and "Patient DOES NOT ACCEPT transfusions."[37]

3.2.3.6 Recommendation Is Not Convenient or Feasible

While ideally PC CDS would incorporate a patient's health-related social needs (such as barriers to care information) when possible, at times a PC CDS alert/recommendation may not be convenient or feasible for the patient and/or provider.[46] For example, a PC CDS alert/recommendation may recommend a patient receive a screening MRI that would be too costly to the patient; the patient may elect to receive an X-ray instead or forgo a screening altogether. From a provider perspective, PC CDS may deliver a recommendation/alert that is not practically available at their facility or a nearby facility. The taxonomy includes six subdomains of override reasons related to convenience and feasibility of the recommendation.

1. **Subdomain: Patient has inadequate caregiver/social support.** A recipient may override a PC CDS recommendation or alert if the patient does not have adequate social support to implement

it. For example, an elderly patient may be discharged to a nursing home or skilled nursing facility if they do not have a caregiver at home; thus, PC CDS recommendations that involve at-home support from caregivers may be overridden. An example override reason from the source reasons related to this subdomain is "Ride not available (specify family or ambulance)."[37]

2. **Subdomain: Treatment or service is not practically available.** PC CDS may deliver a recommendation/alert for a treatment or service that is not available at the current care facility or one nearby, making it inconvenient for the recommendation to be implemented due to distance or logistical challenges (e.g., driving distance, inability to take time off work). Examples from the source reasons related to this subdomain include "Logistical concerns,"[37] "Patient access issues,"[37] and "Equipment or supplies not available at [facility]."[37]
3. **Subdomain: Recommendation cannot be implemented due to technical challenges.** A recipient may not be able to implement a PC CDS recommendation/alert due to technical challenges. For example, the recipient may not have the technology available to store a given drug at the appropriate temperature.[47] This subdomain was developed based on the literature on patient barriers to adherence to care recommendations and on feedback from key informants. No real-world CDS overrides examples relevant to this subdomain were identified in the literature or crowdsourcing. However, the patient barriers literature points to a relevant scenario: a patient who is asked to regularly monitor their blood glucose may be unable to do so because their glucometer is defective.[48]
4. **Subdomain: Recommendation is too costly or not covered by insurance.** In some cases, patients may decline a recommendation/alert that is too costly for them or not covered by their insurance. For example, a patient that needs anticoagulation for atrial fibrillation may decide that they cannot take one of the novel anticoagulant drugs due to the cost of the medicine and would opt to take Coumadin instead. Examples of override reasons from the source reasons related to this subdomain are "Cost concerns"[37] and "Financial Limitations."[37]
5. **Subdomain: Recipient does not understand the recommendation or know how to perform the recommendation.** In some cases, the recipient may dismiss a recommendation/alert if they do not understand what the recommendation/alert is saying or if they do not know how to perform the recommended action. This may include reasons related to health or digital literacy and patient education. It could also be due to the recommendation/alert being unclear or not providing sufficient context. A key informant shared the example of patients not fully understanding how much of a medication to take based on the dose recommended. As another example, a patient may be recommended to monitor and report their daily fasting blood glucose but may not know how to do so. An example of an override reason from the source reasons related to this subdomain is "No education performed."[37]
6. **Subdomain: Patient has physical, emotional, or psychological barrier to completing recommendation.** The patient may have a physical, emotional, or psychological barrier that prevents them from completing the PC CDS recommendation. This subdomain was developed in conversation with key informants and based on the literature on patient barriers to adherence to care recommendations. While no real-world PC CDS override reasons were identified related to this

subdomain, a key informant shared this could include not being able to follow a recommended exercise regimen, for example, due to disability or injury. The literature also identifies age-related physical constraints as another potential reason for not complying with a recommended exercise regimen.[45]

4. Discussion

This taxonomy includes high-level domains and corresponding subdomains of reasons why recipients of PC CDS—including clinicians, patients, and caregivers—might choose not to follow the guidance. It provides a framework for grouping override reasons in a way that can support standardized override analysis across PC CDS tools and implementations.

While override reasons for traditional CDS have been discussed in the peer-reviewed literature (including taxonomies for specific CDS use cases, such as drug–drug interactions), this product provides a unique contribution by providing a taxonomy focused on PC CDS specifically. The taxonomy was developed based on a review of hundreds of override reasons identified in the literature and crowdsourced from several delivery and CDS systems. This taxonomy is not limited to a specific set of use cases such as medications but, rather, applies to varied PC CDS scenarios. Additionally, unlike prior work that looked at traditional CDS in which clinicians are the recipients, this taxonomy encompasses PC CDS of which the recipients may be clinicians, patients, or caregivers.

While the taxonomy was designed with a broad range of use cases in mind, it is not meant to be static. The taxonomy was built based on the override reasons offered by contemporary CDS tools. Over time, the types of reasons offered may evolve—especially as CDS itself evolves to apply to new situations and use cases, and as PC CDS becomes more prevalent—necessitating updates to the taxonomy. Certain types of overrides may also be phased out. For example, the taxonomy includes the broad category “Patient refuses/declines (no context given)” since this is commonly offered in today’s CDS systems. While this reason is not ideal (in that it provides little insight into the “why” behind the override), it is still important to capture and can alert researchers to investigate more; for example, local researchers could investigate patient refusals to get more information on why they refused. Over time, additional, specific patient reasons may be added to PC CDS tools, which could then be incorporated into the taxonomy, while the less prevalent reasons could be removed.

4.1 Future Directions for Research and Use

Future efforts can further validate and standardize the taxonomy, as described below.

Refinement of the taxonomy based on experience and testing. The taxonomy serves as an initial framework that can potentially be refined and expanded through additional research and testing. While the taxonomy was developed through a data-driven approach, and was iteratively refined with input from experts, it would benefit from additional piloting in real-world settings. In particular, validating the taxonomy against additional patient-facing PC CDS tools and with additional patients/caregivers would

help ensure that it captures the breadth of reasons why a patient may choose not to (or be unable to) adhere to an alert/recommendation.

Development of approaches to standardize user-presentation. The descriptions of the domains and subdomains in the current version of the taxonomy are higher level and not suitable for use as override reasons displayed to a PC CDS recipient, either a patient, a clinician, or any other role type. Creating a recipient-friendly terminology associated with the taxonomy domains and subdomains will allow the taxonomy to be used directly within PC CDS and possibly incorporated in PC CDS interoperability standards such as Health Level Seven International (HL7) CDS Hooks.[49] In turn, this will allow consistent presentation of override reasons to PC CDS recipients and capture of override reasons directly into the taxonomy concepts. The considerations associated with creating such terms include 1) creating separate sets of terms for clinicians and for nonhealthcare professionals, such as patients and caregivers, and 2) allowing creation of terms that are very specific to the PC CDS. The latter consideration could lead to an explosion of terms based on clinical criteria. This can be managed through the creation of term templates. For example, a template could be "<diagnostic test> is elevated," and the PC CDS would replace the placeholder with a specific value (e.g., "diagnostic test" with "Serum potassium" or "K").

Use of the taxonomy to conduct analyses of PC CDS override reasons. The taxonomy can be used in its current version to analyze PC CDS override reasons in different scenarios. This would demonstrate the value of the taxonomy and how it can be used, and may also point to further directions for refinement.

4.2 Limitations

There are limitations that affect the scope and depth of the final taxonomy. First, although the team aimed to construct a broad taxonomy that would apply to most PC CDS scenarios, it may not encompass the universe of override reasons. The taxonomy evolved from a review of the literature as well as lists of overrides obtained from real-world CDS implementations. Despite this, there may be unique override reasons and scenarios that are not adequately captured in our taxonomy due to limitations of the data sources. Furthermore, the team primarily looked at structured override reasons, not free-text responses.

In the same vein, certain patient-specific override reasons may not be adequately captured. The review of existing literature revealed a lack of research on patient reasons for PC CDS override. Factors such as patient preferences, unique clinical circumstances, or variations in healthcare settings may contribute to override scenarios, the breadth of which may not be fully represented in this taxonomy.

Additionally, in some cases, analysis of override reasons was impeded by insufficient clinical context in which the PC CDS alert or recommendation was delivered. This made it difficult to interpret the override reason. The team attempted to mitigate this by looking at multiple sources of override reasons, but there may be some influence on the taxonomy's comprehensiveness.

Finally, the validation of the taxonomy was limited and primarily qualitative, through insights from interviews with key informants and a mapping exercise. The taxonomy did not undergo a formal validation process.

5. Conclusion

The Taxonomy of Override Reasons for PC CDS Recommendations provides a first-of-its-kind framework for analyzing PC CDS overrides. The taxonomy can be taken up by PC CDS developers, PC CDS researchers, health systems, EHR developers, and patient groups as they investigate why users of PC CDS tools dismiss PC CDS. Future efforts can validate the taxonomy to ensure that it fully captures the breadth and depth of override reasons—particularly for patients. Additionally, future work can standardize the taxonomy to maximize its utility for research and other applications. Over time, the taxonomy can be updated to reflect the current state of PC CDS overrides.

Standardized analysis facilitated by the taxonomy can support translation of results across clinical settings and PC CDS types. Ultimately, the use of this taxonomy can support improvements in PC CDS to ensure that it is delivered at the right time, for the right patients and clinicians, and that it conveys clinically valuable and actionable information to inform shared decision making.

Appendix A. Literature That Identified Override Reasons

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Appendix B. Supplemental Articles on Patient Reasons for Declining Health or Healthcare Advice or Recommendations

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