A General Model to Evaluate Clinical Decision Support (CDS) Interventions

Measure CDS Impact with Open-Source Quality Improvement (QI) Tools

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A General Model to Evaluate Clinical Decision Support (CDS) Interventions: Measure CDS Impact with Open-Source Quality Improvement (QI) Tools

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Publication date September 2017

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Chapter 1. Introduction

Clinical decision support (CDS) interventions are common applications in contemporary health information technology (HIT) systems. As a front-runner in the use of HIT, the U.S. Department of Veterans Affairs (VA) has employed CDS interventions for decades. CDS interventions have the potential to significantly improve patient care and healthcare processes if they are properly designed, implemented, and used. Therefore, **the purpose of this document is to describe a *General Model to Evaluate CDS Interventions* (referred to as *theGeneral Model* or *the model*) to identify measures to evaluate the impact of CDS interventions in the VA.**

Continuous quality improvement (CQI) efforts in the U.S., in informatics, and at VA do not yet use a model-based approach to evaluate CDS interventions; likewise, a clear, step-by-step approach for CDS evaluations is not available. This document offers both. Evaluators will be able to use the General Model to guide thinking about CDS evaluations, potentially leading to richer results in the short term, improved CDS interventions and better care outcomes in the long term.

1.1. Assumptions

Several assumptions were made about the material in this document and its readers. The material primarily addresses the evaluation of fielded CDS interventions. The General Model could be used to guide impact measurement early in the life cycle of a CDS intervention, but the view in this document is post-implementation after the CDS intervention is in actual use in the field. This view will be helpful as the VA moves toward a vendor-based strategy for their HIT. The document is also targeted for use by CQI teams and clinical users versus informatics experts. Readers are expected to have at least basic knowledge about the CQI process and the use of CDS interventions in the VA. Readers are not expected to be experts in research or informatics, although the document can be useful to these readers as well.

Evaluations must certainly consider both the cost and quality impact of CDS interventions. However, the processes outlined in the General Model to Evaluate CDS Interventions, Practical Guide for Clinical Decision Support (CDS) Evaluation, and Assessment Protocol: Applying Usability Assessment Methods to Evaluate Clinical Decision Support (CDS) Interventions concentrate primarily on quality measures versus costs.

1.2. Prevalence and Importance of CDS Interventions

Two central goals of health information technology (HIT) are to improve patient care and to make its processes more efficient. One aspect of improving patient care is supporting clinical staff in their decision making to prevent errors, increase efficiency, and provide knowledge at the point of care (Kawamoto & Del Fiol, 2018). Specific HIT tools to support decision making are called CDS interventions. Widely employed in the VA and elsewhere, CDS interventions can range from simple alerts and reminders to more complex protocols, order sets, and best practice guidelines.

A main premise of CDS interventions is that knowledge at the point of care can help prevent healthcare errors. Meta-analyses and systematic reviews indicate CDS interventions can change clinicians' decisions and actions, decrease medication errors, increase preventive screenings, and increase the use of evidence-based recommendations for prescriptions (Osheroff, et al., 2012, p. 19). Current evidence is available in addition to the sources listed in Osheroff et al (2012). A 2017 review of systematic reviews examined the available, and sometimes conflicting, evidence about the impact of CDS interventions on overall medication safety and concluded, despite the variability in study quality, that CDS improved the processes and outcomes for medication safety (Jia, Zhang, Chen, Zhao, & Zhang, 2016). Another systematic review indicated that CDS interventions improved the appropriateness of antimicrobial prescriptions (Baysari, et al., 2016; Borab, Lanni, Tecce, Pannucci, & Fischer, 2017), and yet another described how CDS interventions increased the use of

appropriate prophylactic measures to prevent thromboembolism in surgical patients, with corresponding decreases in these adverse events (Borab, Lanni, Tecce, Pannucci, & Fischer, 2017).

An important aspect of CDS interventions concerns knowledge sharing and the vast increase in healthcare knowledge each year. Healthcare knowledge is evolving so rapidly that if those graduating from medical school in 2005 were to read two articles per day, by the end of their first year, estimates indicate that students would already be behind by 1,225 years (Stead, Kelly, & Kolodner, 2005). These rapid advancements in knowledge can be routed to the front lines of care delivery when CDS interventions help facilitate knowledge transfer and knowledge-based decisions and actions from the evidence presented in CDS interventions.

Despite clear results on CDS impact for some areas such as medication safety, many authors indicated mixed results on CDS impact and they advise further research (Berner, 2016; Bright, et al., 2012; Byrne, et al., 2010; Zhang, Johnson, Patel, Paige, & Kubose, 2003; Miller, et al., 2015). This creates an opportunity for the VA to evaluate CDS interventions using a systematic approach. Therefore, this document describes a General Model to identify the impact and sample measures for evaluating CDS interventions. Use of the General Model will allow future VA evaluators to have a common measurement framework across the VA and within their specific sites.

1.3. Definitions

1.3.1. CDS Interventions

A *CDS intervention* is the delivery of information to enhance decisions and actions related to health and healthcare (Osheroff, et al., 2012, p. 14). Modern definitions of CDS have expanded beyond the notion of simple alerts and reminders to a set of tools providing person-specific information to inform decision making (Kawamoto & Del Fiol, 2018). More formally, CDS includes “a variety of HIT tools that provide clinicians, staff, patients, or other individuals with knowledge and person-specific information, intelligently filtered or presented at appropriate times to enhance health and healthcare” (Osheroff, et al., 2007).

Put more simply, CDS is any tool or technique that enhances decision making by clinicians, patients, or their surrogates in the delivery or management of healthcare (NQF, 2010). Examples of CDS interventions are (Kawamoto & Del Fiol, 2018):

- A reminder for immunizations or other preventive care;
- An alert about a potential drug interaction or patient allergy;
- Pre-constructed order sets for patients with specific conditions;
- Seamless access to information in the literature about patients with similar conditions including treatments and outcomes; or
- The use of data analytics to estimate risk for a specific patient to have a fall, for hospital readmission, or other untoward event.

1.3.2. CDS Impact

CDS impact is the measurable change(s) in the quality (i.e., *effectiveness*, *safety*, *efficiency*, and *satisfaction*) of health care generated by the introduction of CDS interventions.

Change can be measured anywhere in the healthcare process. Commonly, impact is measured as a patient outcome (effectiveness, safety). However, impact can be measured much earlier in the healthcare process. For example, it is important to understand the impact of CDS on clinician workflow, clinicians’ decision making, and adoption and use of the CDS tool early in the process or early post-implementation. Once the early impact is understood, especially related to unintended negative impact, subsequent improvements can be made to avoid adverse outcomes and realize the full potential of the CDS intervention.

1.3.3. Assessment Versus Evaluation

In this document, we use the term *assessment* to mean a specific technique or an interim measure, such as a formative assessment or assessing a patient outcome 2 months post-implementation. The term *evaluation* is used to mean a collection of assessment techniques or the overall process of determining the value, outcomes, or impact of a CDS intervention.

1.4. Reasons to Measure CDS Impact

There are significant reasons to measure the impact of CDS interventions. Osheroff (2012) lists these reasons to evaluate CDS interventions:

- Assuring CDS helps improve care;
- Determining whether CDS interventions are working as expected;
- Learning continually from end user experience and feedback;
- Determining whether CDS interventions are cost-effective;
- Justifying CDS interventions;
- Communicating CDS impact and effectiveness; and
- Creating new knowledge about best implementation practices.

Moreover, the goal of any CDS intervention is to improve patient care and healthcare processes. That goal is congruent with the goal of evidence-based practice (EBP), which is to improve care using healthcare practices that are based upon science (Stevens, Horn, Kean, & Deshmukh, 2018). Providing evidenced-based knowledge at the point of care is a crucial function of CDS interventions. Basic evaluation questions about the impact of CDS interventions can address whether this available knowledge is used by clinicians or patients and whether knowledge-based CDS interventions actually improve care in specific settings and across the enterprise.

Measuring CDS impact can help evaluators and others understand where, when, and how CDS interventions can be applied for maximum benefit and, on the other hand, where CQI efforts need to be employed to improve CDS use or outcomes (Osheroff, et al., 2012). Measuring CDS impact can identify errors, gaps, and omissions in CDS-supported care processes. Through evaluations and assessments, evaluators can understand the effects CDS interventions have on health processes, clinicians' work, and patient outcomes—a purpose that is congruent with CQI efforts everywhere.

1.5. Introduction to CQI and CDS Evaluations

1.5.1. CQI and CDS Interventions

CDS interventions and CQI are inextricably linked. The principal goal of both is to improve healthcare processes and outcomes. CDS interventions are one type of CQI tool, and as such, they can be evaluated as part of any organization's CQI process. Likewise, CDS interventions should include quality improvement processes in their development and use in order to be effective in healthcare delivery. For example, assessments and monitoring should occur throughout the CDS intervention life cycle versus waiting until a CDS intervention is deployed and in use.

CDS interventions are tightly linked to information flow and workflow processes (Osheroff, et al., 2012, pp. 87-89). In fact, CDS intervention success depends upon evaluators and designers recognizing this fact. Without integration into workflow, CDS interventions can cause interruptions, potential errors, or omissions.

Without integration into workflow, CDS interventions might not even be used. Therefore, one aspect of impact assessment will be for evaluators to understand how CDS interventions are used in the field and how they are integrated into workflow and clinical activities. These important components are addressed in the General Model.

Before evaluators consider specific measures of impact, they will want to understand overall CDS goals and the CDS evaluation process.

1.5.1.1. CQI and CDS Organizational Drivers

The CDS evaluation process and use of the General Model begins by first understanding an organization's CQI goals related to a CDS intervention. Organizations will have high-level CQI goals amenable to CDS interventions based upon their own drivers to improve care and/or contain costs.

Organizational CDS goals may be based upon federal directives or internally-derived goals. Sample drivers and potential CDS interventions are in Table 1.1, "Sample Drivers and Related CDS Opportunities (Osheroff, et al., 2012)". Evaluators can use the examples in Table 1.1, "Sample Drivers and Related CDS Opportunities (Osheroff, et al., 2012)", even though they were created for Meaningful Use requirements. Evaluators can see how they were constructed and translate them into the most current needs, for example the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA).

Table 1.1. Sample Drivers and Related CDS Opportunities (Osheroff, et al., 2012)

Driver Type	Driver Example	Sample CDS Opportunity
Promote performance measurement and transparency through incentives for reporting care process and outcomes measures	• Centers for Medicare and Medicaid Services (CMS) / Joint Commission care measures reported via CMS Hospital Compare and Physician Compare websites • Includes process (e.g., rates of appropriate test and medication use); outcome (e.g., mortality and readmission rates); and patient satisfaction measures (e.g., Hospital Consumer Assessment of Healthcare Clinicians and Systems [HCAHPS] scores) • The U.S. National Quality Strategy points toward a measurement trajectory	• Support gathering data needed for measurement at the point of care • Improve performance on publicly reported measures
Provide incentives for those who deploy specific CDS interventions or capabilities	Meaningful Use, MACRA, or other regulations	Leverage good CDS practices to ensure that the selected intervention delivers optimal value
Avoid complications caused by care delivery	Avoidable medication errors, infections, and other healthcare-associated conditions (HACs) that are not reimbursed	Monitor care delivery via CDS rules and notify when precursors suggest increased risk for HACs
Define increasing threshold for better patient-focused outcomes	Stage 3 Meaningful Use, MACRA, or other regulations	Improve outcomes by helping ensure that best clinical practices are reliably used
Promote more cost-effective care	Financial incentives to decrease hospital readmissions	Support more cost-effective decisions by stakeholders within care delivery processes
Coordinate care across delivery settings	Incentives for forming Accountable Care Organizations	Promote context-specific data access and outcome-improving information delivery across the care continuum
Local improvement needs and imperatives	Improvement imperatives identified by internal quality assurance efforts or externally generated performance analytics	Ensure that CDS efforts simultaneously address priority improvement opportunities evident from local care processes

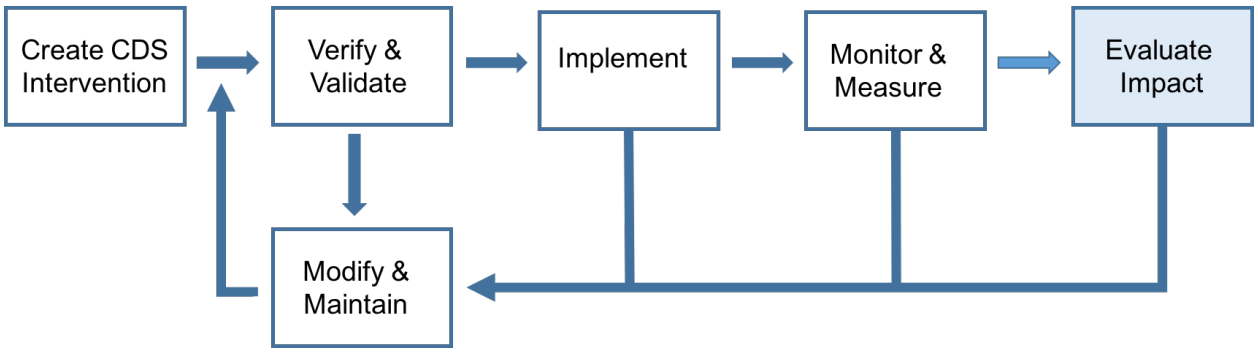
Understanding these organizational goals provides the rationale (the "why") for the CDS intervention and gives evaluators a notion about whether the CDS is being designed and deployed for the right reason. Organizational goals can also assist in helping determine overall project goal(s) later on (e.g., did the CDS intervention actually promote more cost-effective care or improve care delivery coordination across settings?).

As evaluators move to create CDS assessment goals (keeping in mind the CQI and CDS goals), one way to create CDS assessment goals is to use models or categories to help define the impact and associated measures (Osheroff, et al., 2012). The important point is that employing a model or framework can assist evaluators in determining evaluation goals and measures.

1.5.2. The CDS Evaluation Model

A model adapted from Osheroff et al. (2012) provides an overview of the CDS evaluation process.

Figure 1.1. Adapted CDS Evaluation Model (Osheroff, et al., 2012, p. 92)



This document focuses on post-implementation of CDS interventions; therefore, the steps about creating and implementing CDS interventions for quality improvement (the first and second steps in the model) are generally beyond its scope. However, the General Model and evaluation processes may be used during the Verify & Validate as well as the Modify & Maintain steps in the CDS Evaluation model. Other resources on this process are also available. Readers are referred to:

- Foundational considerations for effective CDS interventions (Osheroff, et al., 2012, pp. 153-182), Selecting Interventions to Deliver Targeted Improvements (Osheroff, et al., 2012, pp. 183–212), Configuring the Interventions (Osheroff, et al., 2012, pp. 213–238), and Putting Interventions into Action (Osheroff, et al., 2012, pp. 239–268).
- Tip sheet for CDS [https://www.cms.gov/Regulations-and-Guidance/Legislation/EHRIncentivePrograms/Downloads/ClinicalDecisionSupport_Tipsheet-.pdf]—This document gives an overview of CDS interventions, definitions, and requirements for Meaningful Use 2 but it can be used by evaluators to see how to construct and use newer material (HealthIT, 2017b). Readers can review these for relevant information on design even though Meaningful Use is being replaced with MACRA.
- Essential eCQI worksheet [https://www.healthit.gov/playbook/pdf/health-it-enabled-ecqi-ambulatory.pdf]—This worksheet is helpful for planning and implementing a CDS intervention as it steps readers through current workflows to identify opportunities for improvements using CDS interventions. (HealthIT, 2017b)

To conduct CDS evaluations, the evaluators need measures to assess performance and outcomes against the original CDS goal(s). The need for measures is discussed in recent standards: efforts by ONC, refinements of the Clinical Quality Framework (CQF) by the CMS, and CDS standards from the Health Level Seven (HL7) committees (Rhodes, Walonoki, & Hadley, 2016).

Evaluation categories can be helpful in determining potential CDS evaluation measures. Osheroff et al. (2012) provides these categories:

- **System response times** (e.g., timing specific tasks with defined start and stop events);

- **Structure, process, and/or outcome** (e.g., structure = the number and nature of interruptive alerts deployed, the number of order sets deployed; process = intervention use [who is using, what the CDS adoption curve looks like, etc.], effects on workflow, users' time, and satisfaction; outcomes = adverse drug events, effects from a new order set [length of stay, errors], and costs);
- **Safety** (e.g., medication errors, adverse events, missed health maintenance tests, and laboratory monitoring);
- **Quality** (e.g., mortality and morbidity); and
- **Financial** (e.g., cost savings for laboratory and radiologic tests).

Likewise, another partial list of evaluation categories and measures is available from the ONC (Table 1.2, "Examples of CDS Impact (ONC, 2016)") on HealthIT.gov.

Table 1.2. Examples of CDS Impact (ONC, 2016)

Impact	Examples (Most Are Comparisons Before and After CDS Implementation)
Patient Outcomes	Disease management related to adoption of guidelines (e.g., blood pressure control, lipid levels, H1ac levels), hospital lengths of stay, re-hospitalization
Patient safety	Error reports, adverse events, transfers to ICU, death, medication prescribing errors
CDS use by clinicians	Alert use, rate of alerts firing, alert overrides, feedback from clinicians, clinical objectives addressed with CDS
Care processes, adherence to guidelines	Adherence to clinical guidelines; time to complete orders of important medications
CDS satisfaction, usage, usability	Usability assessments from end users, end user feedback, use of CDS from logs
Workflow impact, efficiency	Time to complete work tasks before and after CDS (e.g., direct order entry, medication turn-around time)
Healthcare services utilization and efficiencies	Reductions in unnecessary or inappropriate laboratory test orders
Costs	Resource management, clinician medication (number, type, class), and laboratory test costs
Unintended consequences (includes all measure types above)	Alert fatigue, overrides of serious alerts, adverse events due to CDS

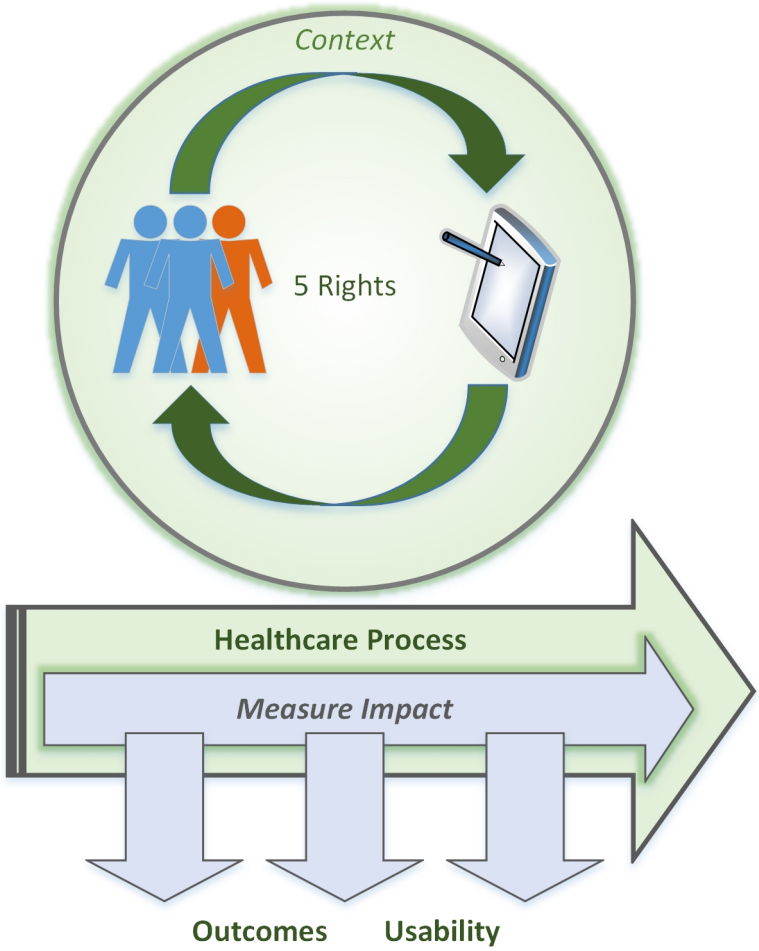
The Osheroff and ONC categories and sample measures provide a beginning understanding of the process for evaluating CDS interventions. However, some of the categories and measures overlap, and no complete list of measures is yet available. Measures are not consolidated in Osheroff, so readers must extract them as they are woven throughout the text (Osheroff, et al., 2012, pp. 268-283). The measures in the ONC list are consolidated but not as robust as those in Osheroff. Therefore, a new model and set of consolidated measures is needed.

Instead of these partial lists, the General Model assists evaluators in determining more comprehensive CDS evaluation goals, potential impacts, and salient measures. The categories and measures in the cells in the General Model can guide evaluators in thinking beyond Osheroff's basic categories or other disparate lists of CDS evaluation measures.

General Model concepts of interest are outlined in Figure 1.2, "CDS Impact Framework" in a framework that illustrates the relationship of these concepts. At the center of the figure, people (clinicians, patients, and/or team members) interact with CDS interventions. The interactions are designed with the five rights in mind (right

information, right person, right workflow, right channel, and right format.) These interactions occur as part of the healthcare process over time. People and CDS interventions are embedded in a context (environment) with the CDS intervention being used in and (optimally) tailored to the context at hand. As Figure 1.2, “CDS Impact Framework” shows, impact can be measured at various times in the healthcare process. Impact measures are across outcome and usability categories (effectiveness, safety, efficiency, and satisfaction).

Figure 1.2. CDS Impact Framework



The General Model shows a more granular view of the concepts in Figure 1.2, “CDS Impact Framework” and can help evaluators identify relevant impact and measures for CDS intervention evaluations. It also allows flexibility for evaluators as they determine and tailor CDS measures to their specific goals and define new measures befitting their specific settings and situations.

1.6. Categories for CDS Impact

The General Model is composed of three categories: (1) Osheroff’s five rights; (2) usability; and (3) outcomes. These categories were chosen deliberately because they are highly relevant for evaluating CDS interventions, and they are consistent with the Institute of Medicine (IOM) domains of safe, effective, efficient, timely, and patient-centered. Osheroff’s five rights are considered imperatives for CDS intervention success (Osheroff, et al., 2012, p. 15). Likewise, usability is an essential and often under-appreciated component of HIT adoption and success (Osheroff, et al., 2012, p. 27, 86). Usability is less often employed in CDS intervention evaluations and may not be part of the current tool set for CQI evaluators. Including usability addresses aspects such as integration with workflow which are known to be essential for CDS adoption (Kawamoto & Del Fiol, 2018; Osheroff, et al., 2012). Expanding upon this notion allows for more robust impact evaluation of CDS interventions across effectiveness, safety, efficiency, and satisfaction. Usability categories (effectiveness, safety,

efficiency, and satisfaction) can also be used and interpreted more broadly to include aspects across the five rights and outcomes. Last, outcomes are important and constitute CQI measures of at two levels: patients/populations and process/organizational categories.

1.6.1. The Five Rights of CDS

Osheroff's *Five Rights Framework* provides five essential categories in the General Model. Consideration to all of these can assist in CDS intervention success when creating CDS evaluation goals and measures (Osheroff, et al., 2012, p. 15). The framework includes these specific categories:

- The right information (what) is delivered to…
- The right person (who) at the…
- The right time (when) through…
- The right channels (where) and in…
- The right formats (how).

The *Five Rights Framework* can be useful for examining CDS interventions in any phase of the CDS intervention life cycle. As evaluators concentrate on post-deployment, thoughts about the *Five Rights Framework* should be kept in mind. However, the five rights do not directly address certain critical aspects of CDS. The user interface, for example, is implied across the five rights (e.g., in the right information category), but no specific category focuses on the various dimensions of the user interface. Therefore, we add specific categories about usability in Section 1.6.2, "Usability and Related IOM Concepts". Evaluators may want to explicitly examine the user interface as part of their goals, in the "format" categories, for example. Evaluators would then want to employ usability methods (outlined in more detail in the Assessment Protocol) and make one of their CDS goals specifically about examining the user interface in depth.

1.6.2. Usability and Related IOM Concepts

Poor HIT usability is a global concern for electronic health record (EHR) users (Smith, 2013; Harrington, 2015; Kushniruk, Bates, Bainbridge, Househ, & Borycki, 2013; Roman, Ancker, Johnson, & Senathirajah, 2017; Topaz, et al., 2017). While usability problems are not new to HIT, the increased deployment of EHRs has exacerbated these issues. In the U.S., the American Medical Association (AMA) spoke to the impact of usability on physicians' productivity and revenue (AMA, 2014). A recent international survey of nurse informaticists in 45 countries found low EHR satisfaction (Topaz, et al., 2017). More than one-half of respondents indicated systemic usability issues (e.g., missing functionality, poor system usability and lack of interoperability). Examples of HIT usability issues are widely available in the published literature (Alexander & Staggers, 2009; Harrington, 2015; Koppel, et al., 2005; Kushniruk, Bates, Bainbridge, Househ, & Borycki, 2013; Patterson, Cook, & Render, 2002; Staggers, Clark, Blaz, & Kapsandoy, 2011; Staggers, Elias, Hunt, Makar, & Alexander, 2015; Weir & Nebeker, 2007). Therefore, usability is a critical component to evaluate for CDS interventions.

Usability is a subset of the larger concept of user experience. User experience (UX) concerns perceptions about and responses from the use or anticipated use of a product, system, or service (ISO 9241-11, 1998). UX is a common term in industry and often connotes activities around product design or broad perceptions about a service or system. Usability, on the other hand, is defined as "the extent to which a product can be used by specified users to achieve specified goals with effectiveness, efficiency, and satisfaction in a specified context of use" (ISO 9241-11, 1998). We concentrate on the usability of CDS interventions in the General Model to Evaluate CDS Interventions, Practical Guide for Clinical Decision Support (CDS) Evaluation, and Assessment Protocol: Applying Usability Assessment Methods to Evaluate Clinical Decision Support (CDS) Interventions and outline these categories: effectiveness, safety, efficiency, and satisfaction.

Effectiveness is the accuracy and completeness with which specified users achieve specified goals in particular environments (ISO/IEC 9126-1:2001). The concept of effectiveness is congruent with one of the six aims to improve healthcare in "Crossing the Quality Chasm: A New Health System for the 21st Century" (IOM, 2001).

In its report, the IOM indicated that healthcare should be effective. It should be “providing services based on scientific knowledge to all who could benefit and refraining from providing services to those not likely to benefit (avoiding underuse and misuse, respectively).”

Safety is often subsumed into the effectiveness category during usability evaluations. In healthcare, obviously, safety is of utmost concern so it is made more prominent in the general model.

In usability, efficiency addresses the resources expended in relation to the accuracy and completeness of the achieved goals. This category is congruent with another IOM aim, that healthcare should be efficient, defined as “avoiding waste, including waste of equipment, supplies, ideas, and energy” (IOM, 2001).

Satisfaction concerns the users’ comfort and acceptability of the tool (HIMSS Usability Taskforce, 2011). When well designed and implemented, CDS interventions should lead to improved satisfaction among users. To summarize, components in the General Model are then: effectiveness, safety, efficiency, and satisfaction.

1.6.3. Outcomes

Outcomes are an important category for any evaluation of CDS interventions (Osheroff, et al., 2012) and one of the main categories that come to mind for most clinicians. For clarity, the General Model is divided into two levels or types of outcomes: patient/population and process/organizational. These are described in more detail in Section 2.3, “Categories and Measures in the General Model”.

Chapter 2. General Model to Evaluate CDS Interventions

2.1. Description of the General Model

The General Model is shown in Table 2.1, “The General Model”. The categories discussed in Section 1.6, “Categories for CDS Impact” frame the model and are listed as headings and subheadings: (1) the five rights; (2) usability and IOM components of effectiveness, safety, efficiency, and satisfaction; and (3) outcomes (patient/population and process/organization). The effectiveness and safety categories in the model are highly interrelated. When thinking of usability, safety is usually subsumed within the effectiveness category. However, safety is explicitly listed in the model because of its paramount importance in CDS interventions (i.e., a CDS intervention cannot be effective without being safe). This inextricable link between effectiveness and safety is represented by a dashed line in the model. The cells provide sample measures evaluators might consider when designing their evaluations.

Table 2.1. The General Model

Measure	Effectiveness: CDS intervention is based on scientific knowledge & performs its designed task effectively	Safety: CDS intervention avoids harm to patients & performs its designed task safely	Efficiency: CDS intervention avoids waste & performs its designed task efficiently	Satisfaction: CDS intervention improves end user satisfaction
Right Information Presented to End User	**Clinical Information**: Correct information available for decision or action, supports situational awareness, supports task completion	**Information Safety**: Decision accuracy, misunderstood or omitted information, error tolerance during interactions, cognitive overload, alert fatigue	**Clinical Information Efficiency**: Time on task, number of clicks to compete tasks, information overload	**CDS Satisfaction Score** (e.g., perceptions about ease of use, complexity, learnability, value, cognitive fit, readability, quick completion of work, functional adequacy)
Right Person to Receive Intervention	**Recipient Accuracy**: Correct end user or team to act on the intervention	**Recipient Accuracy**: Wrong recipient receives intervention or intended recipient never receives it	**Recipient Efficiency**: Avoids wasted effort, notification and response time, target audience accuracy	
Right Time in the Workflow	**Workflow Effectiveness**: Interruptions in workflow, matches cognitive and behavioral workflow	**Workflow Safety**: Errors in sequence or timing, interruptions in workflow, team (mis)communication	**Workflow Efficiency**: Time to complete decision/action sequence, time to complete overall workflow, interruptions in workflow, unexpected workflow (new or unexpected tasks), workflow traps	
Right Channel (Device) for Delivery	**Delivery Channel Effectiveness**: Device supports task completion, multiple channel distribution	**Delivery Channel Safety**: Accuracy rates, device supports adequate situational awareness & decisions, interoperability, information gathering & consistency across channels	**Delivery Channel Efficiency**: Optimal task sequence for device, task initiation on one device and completion on another, information gathering across channels	
Right Intervention Format (Interaction)	**Intervention Type & Format**: Compliance with screen design standards, heuristics, appropriate intervention type	**Intervention Format Safety**: Error tolerance during interactions, decision accuracy, alert fatigue	**Intervention Format Efficiency**: Time on task, learnability, usability	
Patient (Individual or Population) Outcomes	**Efficacy**: Correct treatment with positive outcome, panel/population measures (e.g., preventive care rates), compliance rates for guidelines & standards	**Patient Safety Accuracy**: Correct patient, correct treatment, correct time, QI measures for individual patients or populations (medication errors, adverse events)	**Patient-Level Efficiency**: Optimal patient communication, scheduling & service delivery (e.g., scheduling multiple appointments in the same day or with minimal locations), timely treatments	
Process or Organizational Outcomes (Avoided or Incurred)	**Process/Organizational Effectiveness**: QI measures across patients & clinicians (e.g., checklist use, prophylaxis use), CDS adoption/ usage rates, number of overrides (e.g., for alerts) **Cost:** ROI benefit of intervention use greater than cost of not using the intervention	**Process/Organizational Safety**: QI measures across patients & clinicians (e.g., medication errors, readmission rates, pressure ulcers, falls, post-op infection rates, compliance rates for guidelines & standards for risk reduction) **Cost:** Legal costs, readmissions, extended hospital stays	**Process/Organizational Efficiency**: Clinician productivity (clinic visits for CDS-related conditions, ordering times across clinicians), operational efficiency (e.g., supply delivery, cases in OR, patient through-put) **Cost:** Intervention development/acquisition, training, and maintenance and support costs	

2.1.1. The Intersection of Impact Categories

The three categories (Section 1.6, “Categories for CDS Impact”) intersect in the General Model to form cells that outline potential measures. Evaluators may use the sample measures as listed, knowing that the measures are not exhaustive. They may need additional measures depending upon the goals of the evaluation and the context.

Evaluators can also keep these thoughts in mind as they consider categories and measures:

1. Measures can have both positive and negative aspects, for example, safety may be risk avoidance (positive) as well as errors. Organizational outcomes may be positive (decreased costs for adverse events, increased productivity) or negative (increased adverse events, decreased productivity)

2. Information in the cells may be broader than listed and cross additional cells. For example, team communication measures may be applicable across effectiveness, safety, efficiency, and satisfaction categories.

2.2. Uses of the Model

The General Model can be used as a reference and guide for thinking about and determining the impact and measure for CDS evaluations. Evaluators may find the impact categories helpful as they think about possible and practical ways to measure impact. Evaluators may find that the model in general is a catalyst for creating measures tailored to their own sites and CDS interventions. The sample measures in the cells may be used outright, or they may spark insights into new measures. The components and examples may, in fact, serve as an impetus to define new measures tailored to a particular site and the CDS intervention being assessed. Evaluators may select the most appropriate measures to evaluate the CDS intervention at hand, knowing that not every cell or measure needs to be included in a particular assessment or evaluation. Last, as evaluators think about CDS evaluations or assessments and their related primary assessment goals, they may cycle across goals and measures before finalizing the purpose of the evaluation. Thus, the model may help evaluators expand and refine their thinking about CDS evaluation goals and measures.

2.2.1. In Phases of the CDS Evaluation Model

The General Model may be used to determine impact in any phase of CDS development and deployment. Evaluators will want to think through the appropriateness of measures for each phase, however, some measures are more appropriate post-deployment (e.g., adoption rates, organizational impact measures after use). Other measures may be emphasized during development (fit to workflow, accuracy of information, avoiding critical errors and patient safety issues) to avoid errors as much as possible post-implementation. Some are amenable to either phase (fit to workflow, avoiding errors).

2.2.2. In Assessing Impact Post-Implementation

As mentioned in Section 1.1, “Assumptions”, the General Model is targeted to CDS intervention evaluations post-implementation. The model may be used in at least three situations: (1) to determine measures for problem-solving known CDS intervention issues (e.g., lack of use, large volume of overrides, increases in adverse events that the CDS intervention was designed to solve); (2) to select measures as part of routine post-implementation monitoring; or (3) to determine whether the CDS intervention met its pre-implementation goal (the reason it was originally designed and deployed).

2.2.3. Considerations for Selecting Measures in the General Model

Evaluators will likely deliberate about the appropriateness of various measures as they begin the initial phases of setting primary assessment goals (discussed in more detail in the practical guide) and planning their project. Evaluators can use the following main considerations or rules of thumb as they choose measures to evaluate:

- Link the measures to the CDS goals and the CDS primary assessment goals, considering the type of CDS being evaluated. Some goals and measures can be unique for different types of CDS interventions.
- Prioritize measures according to the organization's need for evaluation (e.g., patient safety issues and federal directives may be a priority). What precisely is important to know for this particular CDS intervention?
- Consider the availability of the data to be measured (e.g., medication error rates and alert override rates may be available locally, but more granular data linking these to clinician specialties may not be. Other data, such as workflow processes, may need to be gathered anew).
- Consider the effort needed to determine the validity of the data (e.g., efforts to "clean" the data, assess for missing data, determine the sources of the data and their veracity, completeness of the data and/or the time to develop and conduct usability testing.
- Think about the availability of the participants and the chosen measures. Clinician time may be a significant constraint. For example, scheduling 2 hours for summative usability testing may be impossible for most physicians.
- Think about the total level of effort of the project against the available resources (e.g., personnel hours, costs, etc.)
- Consider the level of expertise needed in the evaluation team. Is training needed?
- Think about how long the CDS intervention has been deployed. Is the intervention still being affected by initial implementation issues?
- For CDS lack of adoption issues, consider and identify how the CDS intervention was implemented to tease out potential implementation issues (e.g., lack of executive support, less than optimal change management issues, lack of a clinical champion).
- Choose a combination of assessment methods. A suite of methods and measures can result in more comprehensive findings and be a source of validity of the findings (i.e., salient findings may surface across methods, and different methods may also surface unique usability findings [Georgsson & Staggers, 2016]).

2.3. Categories and Measures in the General Model

Each major category of the General Model is explained in this section. The model incorporates Osheroff's five rights as described in Section 1.6.1, "The Five Rights of CDS". Now, the usability and outcomes categories are explained.

2.3.1. Effectiveness

Building on the discussion in Section 1.6, "Categories for CDS Impact", the effectiveness category in the General Model identifies whether the CDS intervention is based upon scientific knowledge and whether it is targeted towards populations or individuals that could benefit from the intervention.

Questions to ask about effectiveness include:

- Is the information content complete and based upon current knowledge?
- Does it appear at the right time in a clinician's workflow?
- Does the information content, format, and/or channel support solid decision making?

- Does the CDS intervention support accurate decision making?

2.3.2. Safety

Safety is a separate category in the model as mentioned earlier. It is correlated to effectiveness but emphasized in CDS interventions. Safety is important beyond usability considerations and to include all manner of risk, risk avoidance, harm, errors, and error mitigation, and safe task performance. Questions evaluators might ask about safety can include:

- Are the results or impact congruent with current safety guidelines?
- What positive safety effects or adverse events are a result of the CDS intervention?
- Does the CDS intervention create any unintended consequences?

2.3.3. Efficiency

From a CDS intervention perspective, efficiency speaks to minimizing the waste of resources, including time, personnel, and costs. Questions evaluators might ask related to CDS interventions include:

- What productivity impact occurs due to the CDS intervention?
- Is the process for the CDS intervention efficient or does it create additional workload or confusion for team members?
- What logistic impact is there from the CDS intervention (e.g., need for supplies, equipment, scheduling, etc.)?
- How long does a clinician interact with the CDS intervention (time on task)?

2.3.4. Satisfaction

Subjective satisfaction concerns perceptions about ease of use, CDS complexity, learnability, value, etc. For example, evaluators may wish to understand how a new CDS intervention compares to others already in the organization. (This implies that there are baseline measures for other CDS interventions or measures will be taken.) Or evaluators may administer a satisfaction tool to screen for potential issues with fielded CDS interventions, that is, those with low satisfaction ratings.

Questions to ask about subjective satisfaction might include:

- Is the subjective satisfaction rating at least at an acceptable level post-implementation for this CDS intervention?
- Which CDS intervention of the critical ones employed has the lowest and highest satisfaction rating?
- Does the satisfaction rating change over time for the CDS intervention? Is the satisfaction greater than at baseline?
- Is the CDS intervention perceived value greater than at baseline?

The categories and measures in the rows of the model are explained in more detail in the next section.

2.3.5. Right Information Presented to the End User

Evaluators may consider several measures related to presenting the right information to the end user. The right information might mean assessing the requisite data sources for the CDS intervention. This component could

include measures on whether data is accurately integrated from other HIT modules or applications. One measure might be to assess that data are accurate, complete, and congruent with best practices or accepted clinical guidelines. Evaluators might include measures dealing with systems integration (e.g., Are data from glucometers integrated with the EHR? Are the data accurate?). Another aspect might be an assessment of the user interface to determine whether the screen layout supports the way clinicians think about the process and its language (i.e., medical specialty terms).

Considering efficiency, evaluators might measure the time it takes an individual to interact with the CDS, find needed information in other sources, and integrate it or the time it takes to complete the CDS intervention process across team members. Evaluators might use the safety and/or effectiveness components to measure functionality gaps, information omissions, missing data from module integrations, interaction errors, decision errors, and the like. A main point is whether the available data support sound decision making and appropriate actions or whether decision or action errors are induced. Regarding efficiency measures, evaluators may want to capture measures about improved or wasted efforts and impact on productivity. For example, a CDS alert may be sent to a team of people. Each recipient has to consider the order and determine its appropriateness: Is this the right order for me? Do I need to process it or send it along or just ignore it (e.g., a medication alert sent inappropriately to an aide)? Likewise, if the CDS alert is sent to only the appropriate people, clinician productivity may be improved.

This category implies that evaluators need to have the requisite knowledge about clinical practices (or include someone on the team with that knowledge). Then, evaluators might decide to compare current information displays with practice guidelines, expert guidelines, or federal regulations. Other aspects might include whether clinicians trust the information source, whether the knowledge is based upon evidence, and whether it is current (i.e., a review date is available).

Some important questions about the right information might include:

- Did the CDS intervention create new errors or other unintended consequences?
- Is the underlying evidence or knowledge explicit?
- Are the sources of data clear (e.g., evidence from systematic reviews or clinical trials) and logically unambiguous?
- Are standard terminologies being used? If so, are the terms consistent across data locations? Do these make sense to clinicians?
- Are current or best practice guidelines available for this clinical problem? Are they reflected in the current CDS intervention?
- Is the CDS intervention display congruent with the way clinicians think and work (e.g., is correct medical terminology used for the specialty at hand?)
- Is the CDS screen display information accurate and complete for the task at hand?
- Does the CDS intervention support its intended decisions and actions?

2.3.6. Right Person to Receive the CDS Intervention

A key aspect of CDS interventions is to assess whether the right person received the CDS intervention. The right person may be one person or a team. Evaluators can examine each of the categories of effectiveness, efficiency, and safety to define or select appropriate measures related to this category. For effectiveness, evaluators might assure that the right people received the CDS intervention. For instance, if the CDS intervention is targeted to a healthcare team, then evaluators could measure whether each team member appropriately received the CDS intervention when they should have received it within the care process. Evaluators can also examine the time it took for the right people to receive the right information (efficiency), whether errors in the process occurred

(effectiveness and/or safety depending upon the error), or whether critical people were omitted from the process (safety).

By definition, this category requires evaluators to understand the full set of target people for a specific CDS intervention. Defining the set of people can be done as part of the assessment process or before the assessment begins.

Important questions to ask about the right person category might include:

- Who are the right people to receive this CDS intervention?
- Did they, in fact, receive it?
- Did they receive the CDS intervention at the right time (e.g., every 30 days for medication reconciliation)?

2.3.7. Right Time in the Workflow

As Osheroff et al. (2012) noted, a key to CDS is that the intervention occurs at the right time in the clinicians' workflow. This simple statement belies the complexity of understanding workflow—potentially knowing what the workflow was before CDS implementation, whether the process was redesigned before the CDS intervention was deployed, what the workflow is now, and when the CDS intervention should optimally occur in the care process. Therefore, this category is rich with possibilities for evaluation.

In thinking across available categories, evaluators may decide to measure the effectiveness of CDS impact on workflow. Several measures are possible. Evaluators may decide to compare pre- and post-implementation workflows to determine if the changes meet with projected CDS goals. Evaluators may decide to assess the timing of the CDS intervention within the post-implementation workflow to minimize iatrogenic disruptions in thinking or gaps in care (effectiveness and/or safety). As for efficiency, evaluators might compare the number of steps in the workflow process pre- and post-CDS and/or time the workflow process. Evaluators might trace the workflow and identify errors in the CDS intervention and/or the care process against best practices. Tracing workflow may help evaluators understand why a CDS intervention has a low adoption rate, for instance.

Questions leading to the selection of measures related to workflow might be:

- Does the CDS intervention cause interruptions in clinicians' workflow? Do these interruptions result in errors or gaps in care?
- Does the CDS intervention create new, less efficient workflows, especially across team members?
- Does the CDS intervention follow best workflow practices (e.g., safe practices for medication administration)?
- Does the CDS intervention occur in a logical place within the user's (team's) workflow?

Measures might include:

- Total time for the entire workflow;
- Total time for each team member to complete their tasks within the workflow;
- Total time for patients to complete the entire clinical process or to complete their own interactions with the CDS (if needed);
- Changes in number of steps or subtasks (e.g., patient sees the provider, then the patient then stands in line at the lab window, then receives a phone call from the provider); and
- Changes in resource needs or sources of necessary information.

2.3.8. Right Channel (Device) for Delivery

CDS interventions may be available through various channels or devices. Evaluators can assess whether the channel or device is the best fit given the setting, task, and clinician. A sample list includes:

- EHR modules or means (e.g., alerts, reminders, and orders sets that incorporate best practice guidelines);
- Smartphones (e.g., reminders, alerts);
- Paper (reminders, guidelines, or flowsheets);
- Personal health record (PHR) (alerts, reminders); and
- Email (reminders, alerts, new guidelines).

Evaluators will want to understand the current channel for delivery (this may include multiple channels) and choose to evaluate the outcomes, effectiveness, efficiency, safety, and/or satisfaction of the chosen channel. For example, evaluators may want to determine the effectiveness of a new CDS intervention delivered via an alert against the suite of existing alerts throughout a clinician's day (effectiveness, safety, and/or satisfaction). An example is assessing a CDS intervention designed for a mobile device, but its use is impossible when nurses need to use it in an isolation room (due to possible contamination).

The right channel can be related to the right person category. For example, an alert is send to a patient about scheduling a colonoscopy. The right channel may be a paper postcard reminder, message via a PHR, or text message to a smartphone. Most importantly, evaluators will want to assess CDS interventions for team interactions. For example, an alert might go to multiple team members, but who acted upon it? Who was responsible for acting upon the alert?

Questions leading to the selection of measures related to the channel might be:

- Is the device appropriate given the CDS goal, the setting, the required tasks, and the person receiving the CDS intervention?
- What are the response rates for the CDS intervention sent via a particular channel or device?
- What are clinicians' satisfaction rates with the chosen channel?

To begin discriminating among the intervention channels, formats (Section 2.3.9, "Right Intervention Format (Interaction)"), and appropriate measures, evaluators may want to understand the suite of CDS tools already available in their institutions. An online tool, the CDS Knowledge Asset Inventory, is available from the ONC for this kind of initial assessment (Table 2.2, "CDS Knowledge Asset Inventory Example (ONC, 2017a)").

Table 2.2. CDS Knowledge Asset Inventory Example (ONC, 2017a)

Asset Name	Source/Entity Responsible for Review (Version)	Delivery System	Go-Live Date (Action)	Date of Last Review	Date of Next Review / Review Frequency	Target Population, Role, Location	Purpose of Intervention	Intervention Effects (Process/ Outcomes)	Actions/ Comments
Drug allergy alert trigger rules	CPOE alerts committee (v1)	CPOE	4/25/12	5/12/17	5/12/18 annual	Prescriber entering orders for pediatric population in the wards	Eliminate preventable allergic reactions to drugs	Early feedback that triggering frequency is acceptable to end users; override rate 30%; outcome data pending	Continue close monitoring
Drug-drug interaction (DDI) database	Commercial vendor	CPOE, Pharmacy system	2/20/12	5/18/17	6/18/17 After each database update	Prescriber, pharmacist	Eliminate serious DDIs	Early feedback that triggering frequency is somewhat excessive; override rate 70%	Task force to monitor and consider options for further refinement

2.3.9. Right Intervention Format (Interaction)

While the channel is a device or major delivery method, the CDS intervention format is a subcomponent of the channel category to include the layout, display, or the like within a device. For example, an EHR is a channel, but the format may be an alert. Intervention format can be considered a CDS intervention type.

This category includes clinician interactions with the CDS intervention and its measures of impact. For example, evaluators may consider task success, error tolerance, task times, etc. Evaluators will want to keep in mind that CDS interactions can be a dyad (clinician and CDS intervention); a team and its interactions with a CDS intervention and other team members; patient interactions and/or provider-patient interactions with a CDS intervention.

Various formats are available to deliver CDS interventions. Examples may include:

- Infobuttons;
- Alerts;
- Reminders;
- Order sets;
- Protocols;
- Patient monitoring system functions (e.g., parameters and guardrails for settings, alerts);
- Documentation templates; and
- Screen displays, especially across various devices (e.g., comparing the displays for large and small screens and their adequacy).

This category includes measures and outcomes for patient/clinician interactions with CDS formats. For example:

- Correct type of CDS intervention (an alert versus an order or a suite of CDS interventions, such as a practice guideline with associated order set);
- Decision and actions accuracy based upon the type of format (screen design) used;
- Error tolerance, meaning formats that help avoid errors, prevent them, reduce the number and kinds of errors, and allow easy error detection and recovery; or
- Comparison data for baseline and CDS intervention measures (efficiency, safety, satisfaction).

Depending upon the problem being solved, evaluators will want to think about these kinds of questions as they select appropriate measures:

- Is the knowledge in the CDS intervention most appropriately delivered via this format?
- Is the presentation format optimal for the context of use (e.g., the information, the person, the task, the decision, or the action)?
- How often do clinicians and/or patients respond to the intervention in this format (e.g., response rates)?
- Are clinicians or patients satisfied with the information delivered via this format?
- Is the presentation format optimal for the context of use (e.g., the information based upon the context, the person, the task, and the decision and actions at hand?)

2.3.10. Patient (Individual or Population) Outcomes

Patient outcomes are important and usual CQI measures for CDS. These measures include safety considerations, such as the correct treatment for the correct patient at the correct time. Examples of patient outcomes might be (Osheroff, et al., 2012, pp. 23-24):

- Mortality;
- Mortality and resistant rates for patients on antimicrobial therapies;
- Length of stay;
- Quality of life;
- Adverse events;
- Adverse events related to known conditions (e.g., prescribing diphenhydramine to patients >65 and delirium rates);
- Results over the last 6 months on AIC tests for the population of patients with diabetes; and
- Impact on patient knowledge (for patient CDS interventions).

Evaluators can review material in Osheroff, et al. (2012) as they consider selecting various patient and population measures. To date, little evidence is available that CDS interventions statistically affect mortality, length of stay, and quality of life. Of course, evaluators may still want to choose these measures to see if their own CDS interventions affected these outcomes, and they may see particular issues to monitor in their own organizations. As indicated in Section 1.2, “Prevalence and Importance of CDS Interventions”, other areas have evidence that CDS affects outcomes (e.g., medication safety, deep vein thrombosis, preventive care).

Evaluators can consider these kinds of questions as they select appropriate clinical outcome measures:

- What clinical outcomes are most pertinent to the initial CDS goal?
- What clinical outcomes are most appropriate for my organization at this point in time?
- Given my (or the organization’s) most prevalent patient diagnoses, what negative changes have occurred in clinical performance measures (related to CDS interventions) over the last quarter or the last year?

2.3.11. Process or Organizational Outcomes (Avoided or Incurred)

Process measures indicate how CDS interventions affect care processes and how well users accept and value the specific CDS interventions (Osheroff, et al., 2012). These measures range from more typical CQI measures to formal cost analyses and include outcomes that were avoided and actual occurrences. Process measures might be:

- Recommended treatments ordered or prescribed (Osheroff, et al., 2012, p. 21);
- Recommended preventive care service(s) ordered or prescribed (Osheroff, et al., 2012, p. 21);
- Measures for specific condition for patients (e.g., A1C testing rates, annual eye exams for patients with diabetes);
- Adoption or usage rates (e.g., checklist use);
- Number of overrides for alerts;

- Percent of patients being treated with recommended medications for specific conditions (Osheroff, et al., 2012);
- Percent of patients requiring a specific therapy (e.g., VTE prophylaxis) that actually received it (Osheroff, et al., 2012);
- Percent of patients receiving appropriate antimicrobial prescriptions; and
- Impact on clinician knowledge.

Organizational measures can be aggregated across patients and/or providers and also include measures such as costs. These may include CDS intervention adoption rates across the organization or clinician productivity after the introduction of a CDS intervention (e.g., number of clinic visits, number of cases in the operating room, patient through-put). Satisfaction measures can address perceptions about format use or aspects about the interaction with the CDS intervention. Other examples are:

- Hospital readmission rates;
- Specific measures on conditions or events such as pressure ulcers, falls, or infection rates;
- Compliance rates for guideline and standards use and/or risk reduction (or errors);
- Clinician productivity (clinic visits, time spent interacting with a CDS intervention across clinicians); and
- Operational efficiency (supply delivery to match conditions in the CDS intervention, changes in patient through-put).

Cost is an important consideration for a CDS intervention as the cost may be prohibitive although a CDS intervention is efficient. Cost can be complex to evaluate and often requires sophisticated methods. If this factor is selected, clinical and CQI teams will want to enlist the help of the business and/or IT departments as well as an economist if available.

Evaluators will want to consider cost impact in relation to published findings. This outcome has fewer published findings on CDS interventions overall. The findings on cost and cost-effectiveness of CDS interventions to date are decidedly mixed. Lobach's review (Lobach, et al., 2012) showed modest evidence for cost savings (a trend toward lower treatment costs, total costs, and greater cost-savings than control groups.) CDS resulted in substantial cost avoidance for reducing potential malpractice claims and $40M of indemnity (Zuccotti, et al., 2014). However, other recent examples show no cost savings for CDS interventions on cardiovascular disease (Jacob, et al., 2017) or on pharmacist order review in conjunction with the use of CDSs (Gallagher, et al., 2016). Evaluators may first want to analyze which costs are likely to be affected by a specific CDS intervention or assess new areas to determine impact on cost.

Sample questions to consider on cost can include:

- Does the CDS intervention bring value to the organization (error reduction, cost avoidance via litigation compared to the cost to develop and maintain it)?
- Does the CDS intervention result in lower treatment costs?
- Does the CDS intervention result in improved practices, fewer hospital readmissions, and lower morbidity costs?

Chapter 3. Use Case Example

3.1. Context

As an example of how the General Model can be applied to a CDS intervention, consider a clinical reminder for medication reconciliation.

Clinical Reminder for Medication Reconciliation Use Case

In this use case, a clinical reminder is triggered every 30 days at the beginning of a non-urgent patient visit to prompt the clinician to ask the patient for their current medications while the list stored in the EHR is displayed for comparison.

Evaluators can apply the guidelines from the General Model to develop measures for their evaluation. For example, the evaluators would know that medication reconciliation is part of ongoing performance monitoring. They could access patient, population, and process measures related to medication reconciliation and compare to current rates for the chosen measures. Then, applying the principles of the General Model results in a table like that shown in Table 3.1, “General Model Sample: Medication Reconciliation”. Please note that not all cells are filled in. Evaluators would select only the measures most relevant to their interests. Seldom would evaluators use all possible categories and measures in each cell.

Table 3.1. General Model Sample: Medication Reconciliation

Measure	Effectiveness CDS intervention is based on scientific knowledge & performs its designed task effectively	Safety CDS intervention avoids harm to patients & performs its designed task safely	Efficiency CDS intervention avoids waste & performs its designed task efficiently	Satisfaction CDS intervention improves end user satisfaction
Right Information Presented to End User	**Clinical Information**: Imported data is correct and information is complete (date med began or discontinued, who ordered the med, etc.). Clinician can see the "big picture" or situation awareness of the med list.	**Information Safety**: Critical meds included. Medication interactions identified for new medications.	**Clinical Information Efficiency**: Time on task, number of clicks to compete med reconciliation at each step	**CDS Satisfaction Score** Score on PSSUQ and brief responses to open-ended questions about satisfaction
Right Person to Receive Intervention	**Recipient Accuracy**: Nurse or clinic med-tech receives the alert first	**Recipient Accuracy**	**Recipient Efficiency**: Completed med list goes to physician versus the alert	
Right Time in the Workflow	**Workflow Effectiveness**: Alert occurs for the med-tech after patient check-in. Med list appears in physician's workflow at the start of the encounter.	**Workflow Safety**: Med-tech has a mechanism to communicate to the clinician about any questions in context of the med list (not email or verbal)	**Workflow Efficiency**: Number of steps clinician must complete in the process	
Right Channel (Device) for Delivery	**Delivery Channel Effectiveness**	**Delivery Channel Safety**	**Delivery Channel Efficiency**	
Right Intervention Format (Interaction)	**Intervention Type & Format**: Heuristic evaluation: Format is easy to read and discern information (columns, ability to filter current versus discontinued meds)	**Intervention Format Safety**: Interaction errors during observed use	**Intervention Format Efficiency**: Time on task (to find new medications for example) during observed use	
Patient (Individual or Population) Outcomes	**Efficacy**: Rate of completion for this patient over time; Rate of completion for all patients over time	**Patient Safety Accuracy**: Adverse events for this patient, for the patient population with this condition related to medication reconciliation	**Patient-Level Efficiency**: Optimal patient communication, scheduling & service delivery (e.g., scheduling multiple appointments in the same day or with minimal locations), timely treatments	
Process or Organizational Outcomes (Avoided or Incurred)	**Process/Organizational Effectiveness**: Rate of completion across clinicians, rate of completion for this clinician over the last 6 months	**Process/Organizational Safety**: Rate of adverse events organization-wide due to absence of medication reconciliation	**Process/Organizational Efficiency**: Baseline comparison on number of clinic visits pre- and post-deployment of the CDS intervention	

3.2. Discussion

The medication reconciliation use case shows how the General Model can direct and inform thoughtful consideration of specific impact measures. Evaluators consider each of the three categories (the five rights, usability, and outcomes) and its importance to this CDS intervention at hand. For example, under effectiveness as it relates to the right information, evaluators might select a measure for completeness to ensure that the medications listed under the reconciliation reminder were the same as those stored in the system and what the patient says are current. Under the outcomes category, evaluators might want to know the overall medication reconciliation rate in the last 6 months across all ambulatory clinics and rates by specific clinician. From a safety standpoint, a measure might be to verify that critical medication interactions were highlighted and none were omitted from the list. This use case includes a robust number of sample measures for illustration, but evaluators may find a parsimonious set of measures more typical of CDS evaluations.

Chapter 4. Summary

This document proposes a General Model for CDS intervention evaluations in the VA. The model integrates important categories: the five rights, usability, and outcomes. The strengths of the model are several. The model provides a more comprehensive view into the selection of measures than is currently available. It includes new concepts on usability that can provide CQI teams with new ideas and provides a structure for thinking about potential measures across a robust set of categories. Evaluators can use the model to direct and inform the creation of tailored measures for their own sites and specific CDS evaluations. No similar model is yet available in the literature or the VA.

Weaknesses and limitations of the model are twofold. The model is, as yet, untested. It would require validation to be considered publishable as a formal, theoretical work. The measures are applicable across CDS intervention types, but the General Model does not include an exhaustive list of possible measures, such as those for new types of CDS interventions not yet developed. Therefore, measures can evolve over time and as CQI teams and clinicians provide input.

The requirements for the model include that evaluators/readers have basic knowledge about healthcare and CQI processes. They do not need extensive knowledge about either informatics or research, although knowledge about research will be helpful. Those with advanced knowledge in informatics and research can also use the model easily. Thus, the General Model is a useful tool for a large population of readers for designing evaluations of CDS interventions.

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