Practical Guide for Clinical Decision Support (CDS) Evaluation

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

Department of Veterans Affairs (VA)
Office of Informatics and Information Governance (OIIG)
Health Informatics (HI)
Office of Knowledge Based Systems (KBS)

Practical Guide for Clinical Decision Support (CDS) Evaluation: Measure CDS Impact with Open-Source Quality Improvement (QI) Tools

by , Department of Veterans Affairs (VA), Office of Informatics and Information Governance (OIIG), Health Informatics (HI), and Office of Knowledge Based Systems (KBS)

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Chapter 1. Introduction

The *Practical Guide for Clinical Decision Support (CDS) Evaluation* is a companion document to the *General Model to Evaluate CDS Interventions* and *Assessment Protocol: Applying Usability Assessment Methods to Evaluate Clinical Decision Support (CDS) Interventions*. **The purpose of the Practical Guide is to provide a step-by-step process for the U.S. Department of Veterans Affairs' (VA) Veterans Health Administration (VHA) to evaluate CDS interventions after a particular intervention is identified for assessment. It applies the General Model (DVA, 2017b), outlines an evaluation process and integrates material from Osheroff et al. (2012).**

Readers are referred to an adapted CDS evaluation model from the General Model Figure 1.1 (DVA, 2017b). Because evaluators already know they want to assess a particular CDS intervention post-implementation, they and the Practical Guide will focus on the *evaluate impact* phase of that model.

1.1. Target Audience and Assumptions

The document is targeted for use by continuous quality improvement (CQI) teams and clinicians rather than informatics experts. Readers are expected to have at least basic knowledge about the CQI process and the use of CDS interventions in the VA, but they are not expected to be experts in research or informatics, although the document can be useful to these populations as well.

This Practical Guide integrates a collection of open-source documents throughout. Some of the documents may have been created in earlier steps of the model in General Model Figure 1.1 (DVA, 2017b). The full set of documents is available within the Healthcare Information and Management Systems Society (HIMSS) CDS Guidebook on the Health Information Technology Evaluation and Quality Center (HITEQ) website [http://hiteqcenter.org/Portals/0/pdf/HITEQ-HIT-QI-Guide-Worksheets-HIMSS-CDS-Guidebook.pdf]. Several documents in the HIMSS CDS Guidebook are related to CDS intervention design and implementation (e.g., worksheets numbered in the 6–8 series) and are available on the website. The Practical Guide includes open-source documents for post-implementation CDS intervention evaluations only.

1.2. How to Use This Guide

This Practical Guide applies the General Model by walking readers through how to choose and apply measures of impact using a combination of assessment approaches. Approaches include patient-related, process, and effectiveness measures (e.g., 30-day readmissions, number of adverse drug events [ADEs], etc.) using open-source tools and the General Model. The document introduces less typical assessment methods related to usability and their measures (e.g., interruptions in workflow, CDS interaction times, situational awareness, etc.). The Assessment Protocol provides in-depth information on these assessment methods. The Practical Guide helps readers consider the specific CDS type; the CDS users; the clinical problem the CDS goal is to solve; and other elements, such as patient demographics and supported decisions and actions.

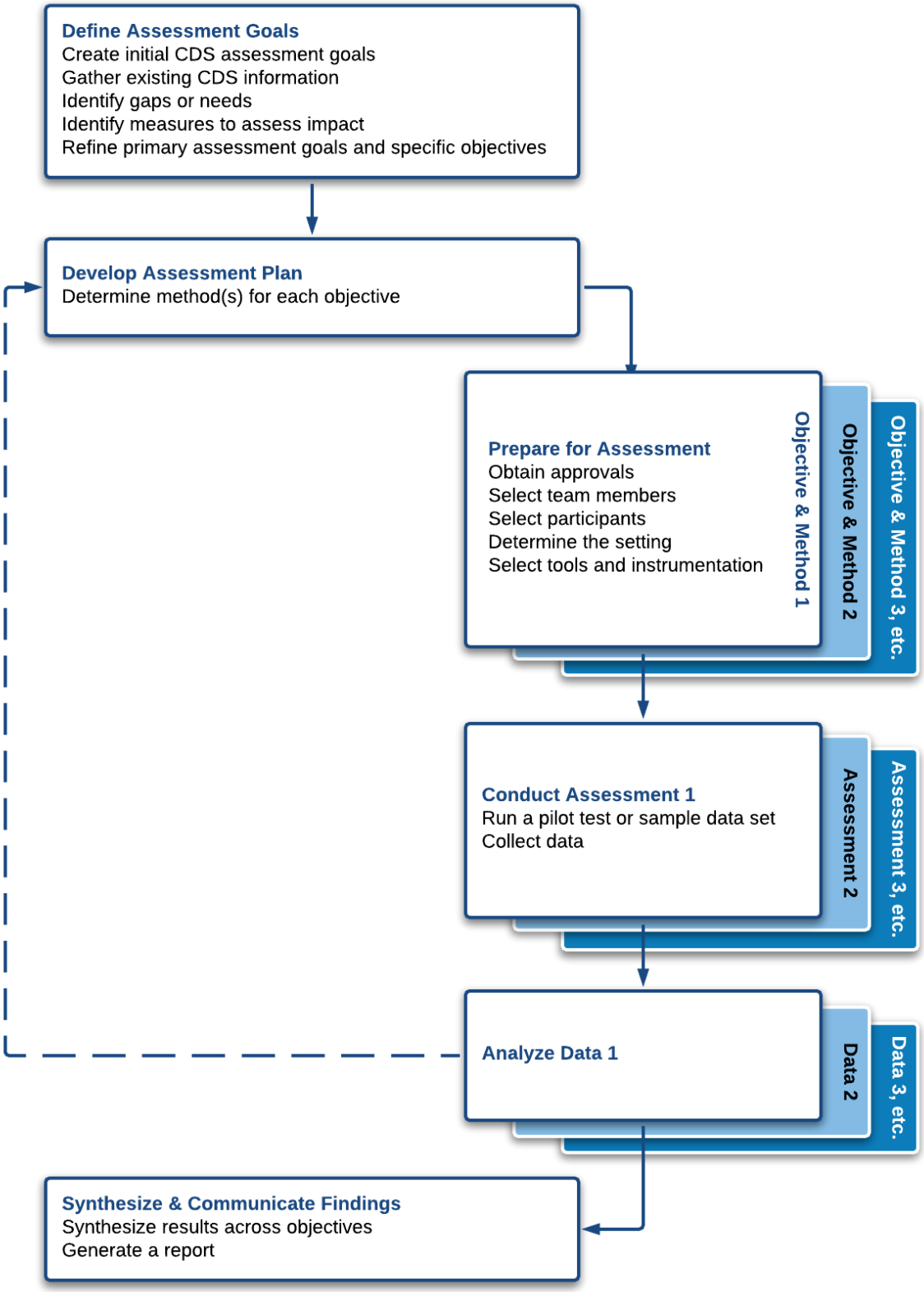
Chapter 2. Introduction to the CDS Impact Evaluation Framework

Evaluators will want to use a structured process to complete CDS intervention evaluations like the one described in this document. Use of a structured process has several benefits. It will allow evaluators to consider a robust number of factors in their assessments, carefully plan the process to avoid most unexpected events, allow for reproducible findings, and provide some assurance that the findings have validity. (DVA, 2017a)

2.1. Basic Impact Evaluation Process

The Practical Guide, like its companion document the Assessment Protocol (DVA, 2017a), will follow a step-by-step framework consisting of high-level actions such as defining an assessment goal, planning the assessment, preparing for the assessment, conducting the assessment, analyzing the data, and synthesizing the findings and creating a report. This process is illustrated in Figure 2.1, “CDS Impact Evaluation Framework (DVA, 2017a)”.

Figure 2.1. CDS Impact Evaluation Framework (DVA, 2017a)



2.2. Use Case as an Application of the Process

For the purposes of illustration, this document outlines a use case on the evaluation of the CDS intervention, Separation from Active Duty SMARTForm. At appropriate points, the General Model and open-source materials will be applied to the evaluation of this SMARTForm to illustrate how the process can be used in everyday CQI evaluation efforts. The following sections describe each of the assessment steps in detail and apply each step to the evaluation of the SMARTForm.

Chapter 3. Define Assessment Goals

If unfamiliar with the introductory CDS evaluation material, readers are referred to General Model section 1.5, Introduction to CQI and CDS Evaluations.

A critical first step to any evaluation is defining the primary goals of the assessment project (i.e., the goals for evaluating the CDS intervention). The goal-setting process is iterative and several drafts are usually necessary to refine the assessment goals.

To understand goals of the project, it is critical first to understand the goals of the CDS intervention itself. CDS intervention goals are measurable statements that specify the desired effects, which result from the deployment of the intervention. CDS goals must describe both the intended external effect, such as reducing the time it takes for a patient to get an appointment, and the impact on the staff who will interact with the intervention, such as prompting a patient for additional information. However, it is not sufficient to consider only external or internal effects. CDS interventions can fail by being overly cumbersome to use or by requiring more resources to implement than are available. Conversely, an easy-to-use intervention that does not improve patient outcomes or increase efficiency is also a failure.

The genesis of CDS goal statements may arise from:

- Federal directives;
- CQI organizational goals (such as reducing adverse drug events, patient incidences, legal requirements such as requirements for a Burn Pit registry and system iatrogenic errors); specific goals defined during the CDS development process;
- Professional experience;
- User comments;
- Health information technology (hit) “pain points”;
- Published literature;
- Performance gaps; or
- Policy directives.

For example, the overall goal may be to address a known problem with a CDS intervention (e.g., The CDS intervention is being used by only 20% of clinicians), or it may be to track impact after implementation (e.g., Did the medication alert for diphenhydramine HCL in patients greater than 65 result in fewer cases of delirium in intensive care units?). For many sources, goal statements will need to include a comparison to a baseline value to be measurable. Investigations about why clinicians are not using a CDS intervention may not need this comparison; instead, the assessment could include detailed examination of the workflow process. In either case, the specific CDS goal needs to be articulated. This makes it critically important to adapt unbounded problem statements, such as “It takes too long to get an appointment,” into specific measurable statements that reference a baseline, such as “Reduce the time required to obtain an appointment from 3 weeks to 1 week within 6 months of the CDS intervention implementation.”

3.1. Create Initial CDS Assessment Goals

Evaluators may have initial goals in mind for the evaluation of a CDS intervention. These may be more general in nature (e.g., “Identify patient outcomes for the new CDS intervention”). As evaluators progress through each step within the Define Assessment Goal, the goals will be edited and refined as more information becomes available.

Evaluators will find it helpful to write out the initial assessment goal(s) and rationale (e.g., “to comply with The Joint Commission’s (TJC) guidelines,” or “to comply with Federal regulations,” or “to assess progress toward

2019 organizational CQI goals." This will help the team stay focused on exact assessment purposes, provide specifics for communication to others, and also help the team adhere to project boundaries.

The creation of primary assessment goals must be balanced with the resources required to measure them. For example, using a survey to collect assessment data from early adopters may be problematic if it requires an extra hour per week to complete and submit. Capturing click stream data within an application (i.e., information about mouse tracking, buttons pressed, time consumed on a form) may require significant storage and a specialized resource to analyze the results. Goals must also be realistically achievable. Consider the goal: "Complete a ward surveillance report by midnight each day." This statement is precise and measurable, but if the report is derived from data in a reporting system that over 24 hours in the past, it will be impossible to achieve. Once initial goals are drafted, evaluators will gather any existing information about the CDS intervention.

3.2. Gather Existing CDS Intervention Information

Evaluators may be assigned a specific CDS intervention to evaluate. Even if an assignment is made, evaluators will want to consider its appropriateness versus the original, stated goal of the evaluation. This is important because several intervention types may address the same clinical problem (e.g., reduce medication errors.) The team may cycle between the assigned CDS intervention type and determining primary assessment goals before refining the exact CDS intervention type to be evaluated or choose a collection of interventions for evaluation.

Many organizations will have information about the selected CDS intervention, including its design and development. At a minimum, evaluators will want to gather or create the material in Table 3.1, "Existing CDS Intervention Information".

Table 3.1. Existing CDS Intervention Information

Element	Content
Describe the CDS Intervention	The purpose, intent, and stated goals of the CDS intervention in addition to all related components of the CDS intervention, as it may be a suite of tools (e.g., practice guidelines with associated alerts and an order set[s])
Identify Intended Stakeholders	The intended end users, as well as the organizational sponsors and key proponents in the organizations (e.g., IT; quality, safety, value)
Describe Implementation	The intended scope (versus actual deployment), start date, its current implementation status (number of users, settings, etc.), implementation tactics (responsible parties, training, whether CDS use is mandatory, etc.)
Locate Baseline Information and Metrics	Any historical information about fit to workflow processes, workflow redesign efforts, proposed evaluation metrics, current available performance data

Two areas in Table 3.1, "Existing CDS Intervention Information" are important to discuss further: Describe the CDS intervention and identify intended stakeholders. Documents are typically created to describe the CDS intervention development during early steps in General Model Figure 1.1 (DVA, 2017b). Similar information is reflected in open-source worksheets from the Office of the National Coordinator for Health Information Technology (ONC) (see Appendix B, *ONC Open-Source Worksheets*) and can be resources for evaluators as they write the goal(s) for the CDS intervention assessment: (a) Section B.1, "Worksheet 2-2—Checklist for CDS Goal Charter"; (b) Section B.4, "Worksheet 5-1—Selecting and Prioritizing CDS Goals "; (c) Section B.5, "Worksheet 5-2—Objectives to Achieve Goals "; and (d) Section B.6, "Worksheet 6-1—Determining the Best CDS Type for Your Objective".

These documents are from earlier phases of the systems life cycle (in Steps 1 and 2 of the adapted Osheroff CDS Evaluation model shown in General Model Figure 1.1) and, if available, will have excellent historical information of use to evaluators, such as the clinical objectives and intent of the CDS intervention (DVA, 2017b). For instance, Worksheet 2-2 (Table B.1, "Sample Checklist for CDS Goal Charter (ONC, 2017)")

captures crucial information, such as the purpose and goals of the CDS intervention as well as critical success factors and risks. Evaluators may want to modify the worksheet by creating a separate column for risks as this is consistent with the safety category in the General Model. Worksheet 5-1 (Table B.5, "Goal Selection and Prioritization Worksheet (HITEQ, 2017)") outlines various opportunities for CDS interventions and their prioritization. The prioritization is of less interest, but the other information in the forms will be very helpful as it gives evaluators additional insight into the rationale for a particular CDS intervention. Worksheet 6-1 (Table B.9, "Blank Determine the Best CDS Type for **[Objective]** Worksheet (HITEQ, 2017)") lists likely CDS types based upon an evaluator's objective (e.g., Is there a new event that could create a hazardous situation for a patient or an entire service? Is help required to create orders for particular situations, such as screening for Zika if the patient traveled to countries with the condition?).

Evaluators may want to categorize the type of CDS intervention (Table 3.2, "Type of CDS Intervention and Examples") as part of the information gathering process, to assure all components of the CDS intervention are identified and also to understand how a particular CDS intervention fits into the organization's population of CDS interventions. Section B.2, "Worksheet 3-1—Clinical Information System (CIS) Inventory" in Appendix B, *ONC Open-Source Worksheets* lists available CDS interventions and related tools linked to an organizational goal, such as reducing medication errors. Worksheet 3-1 (Table B.3, "Sample CIS Inventory (HITEQ, 2017)") could help evaluators understand whether the current CDS intervention overlaps with other tools or if a gap in support exists. If a CIS inventory is not available, it may be worthwhile to create one, at least to understand related CDS intervention tools. Also, such an inventory will be helpful if evaluators are conducting HIT CDS impact evaluations over the long term.

Table 3.2. Type of CDS Intervention and Examples

Type of CDS Intervention	Examples
CDS during data entry tasks	• SMART documentation forms • Order sets, care plans, and protocols • Parameter guidance • Critiques and warnings (e.g., "immediate alerts")
CDS during data review tasks	• Relevant data summaries (single patient) • Multi-patient monitors • Predictive and retrospective analytics
CDS during assessment and understanding tasks	• Filtered reference information and knowledge resources • Expert workup and management advisors
CDS not triggered by user tasks	• Event-driven alerts (data-driven) • Reminders (time-driven)

3.2.1. Identify Stakeholders

Identifying key stakeholders is necessary to create a solid foundation for the evaluation as well as to communicate a shared vision for the assessment project. The stakeholders may not even be participants or part of the team, but can be influencers of assessment success. The stakeholders will potentially be important advocates for the assessment as well. Evaluators can take time to identify and assemble these individuals and communicate the overarching goals or context for the effort to stakeholders. Evaluators may find historical information on stakeholders if Worksheet 2-2 (Table B.1, "Sample Checklist for CDS Goal Charter (ONC, 2017)") was created during early steps in the CDS intervention process. Then, current stakeholders can be added.

A useful tool for determining current stakeholders is a publicly available document from Robert Wood Johnson on stakeholder engagement (Preskill & Jones, 2009). In the document, Steps 2 and 3 in Preskill and Jones stakeholder model outline considerations for identifying and prioritizing a list of stakeholders. Considerations include:

- Having deep expertise in the subject (i.e., the CDS intervention being evaluated);
- Possessing a position of influence (e.g., clinical champion or chief clinical informatics officer);
- Being important for buy-in and support of the project;
- Having diverse perspectives and experiences;
- Being intensely interested in the issue; and
- Being responsible for the CDS intervention (however, for CDS evaluations, this criterion should be carefully considered to rule out issues with stakeholder objectivity or conflicts of interest).

Evaluators can create a potential list of stakeholders and then categorize them as: (a) vital, (b) important, or (c) nice to have (Preskill & Jones, 2009). The authors include tips on the process (e.g., keeping the list confidential during planning, being careful about communication as to who is categorized as "vital," and deciding how many diverse stakeholders are needed).

Once historical information about the CDS intervention is gathered, the next step is to identify gaps or needs for the CDS assessment.

3.3. Identify Gaps or Needs

Evaluators can analyze the gathered information to determine any gaps, issues, or needed information. These may point evaluators toward more specific goals and objectives. For example, baseline data about fit to workflow might not exist, but the evaluators may have informal reports about its mismatch with workflow and the underutilization of the CDS intervention. Thus, one primary goal for that particular assessment might be to assess the current CDS intervention fit to workflow. Another example is that by comparing information in Worksheet 6-1 (Table B.9, "Blank Determine the Best CDS Type for **[Objective]** Worksheet (HITEQ, 2017)"), evaluators could help identify any mismatches between intervention type and the clinical problem being addressed or confusion in the purpose of the CDS intervention.

The use case provides an example on gathering information about the SMARTForm CDS intervention.

SMARTForm Use Case: Gather CDS Intervention Information

This use case is based upon the setting in which the Separation from Active Duty Assessment SMARTForm would be completed by the actors who participate in its use. Many situations exist in which subjects interact with VA clinicians to complete an assessment during or after separation from active duty for possible cause(s) of current or future disabilities.

CDS Intervention Description: The organization's CDS goal is to create a smooth transition for the Veteran from active duty to VA care (i.e., to prevent errors, gaps, and omissions in the Veteran's health care). A secondary goal is to facilitate clinician input in completing complete and accurate information for the health record at hand.

Stakeholders: The primary stakeholders in this use case include the patient; the evaluator; and the director of the quality, safety, and value (Q, S & V) department:

- **Patient:**The patient in the context of this use case is a Veteran who is the subject of an evaluation for potential short or long-term disability due to active duty exposure. The patient will typically be asked a series of questions in a particular way and in a particular order in order to assess whether there are sequelae related to active duty.
- **Clinician:**The clinician is a physician with privileges to treat patients for the VA. His or her purpose is to be the evaluator of potential sequelae from active duty exposure using the system being designed. The evaluator will typically complete the SMARTForm by asking the subject a series of questions in a particular way and order. They will then make an assessment based on the answers the subject provided.
- **Director Q, S & V:** This is the primarily person responsible for assessing the outcomes of this SMARTForm.

Implementation: The implementation started 1 year ago across all ambulatory clinics in the setting. All clinicians received standard training on the form, a 10-minute informal session during routine staff meetings.

Baseline Information: Few data are available for pre-implementation comparisons on workflow and workflow redesign. The target completion rate for the SMARTForm post-implementation is 95%.

The next step in defining assessment goals is to identify potential measures to assessment CDS intervention impact.

3.4. Identify Measures to Assess Impact

The selection of measures is critical to refining primary assessment goals. Examples of CDS categories and measures of impact are in the General Model (DVA, 2017b; U.S. Department of Veterans Affairs, Veterans Health Administration, 2009). Evaluators can use the model to consider the initial CDS primary assessment goals, to select potential measures of interest, and then refine the goals. For more details about the General Model and its structure, readers are referred to the General Model section 2, General Model to Evaluate CDS Interventions.

Other tools can help during this phase of the process (e.g., Worksheet 9-1 and Worksheet 9-2). Table B.10, "Metrics Selection & Use, CDS Objective: Prevent Prescription of Medication to Allergic Patients Intervention Name: Prescription Allergy Alert Window (HITEQ, 2017)" (in Appendix B, *ONC Open-Source Worksheets*) includes examples of typical assessment measures (metrics) for CDS intervention assessments (e.g., mortality rates, errors, outcomes using National Coordinating Council for Medication Error Reporting and Prevention [NCC MERP] criteria, etc.)

As a reminder from material in the General Model document, a mixture of more usual and less typical measures might be:

- Interaction effectiveness (task success; impact on workflow, such as interruptions; and CDS appearing in the correct place in workflow);
- Safety (patient safety errors related to interactions with the CDS);
- Interaction efficiency (time on task, interaction errors, impact on clinician productivity); and
- Satisfaction (at an acceptable level according to ratings on a validated instrument).

Thus, Section B.8, “Worksheet 9-2—Use and Usability Issue Log” in Appendix B, *ONC Open-Source Worksheets* offers other thoughts about the use and usability monitoring of a CDS intervention. This worksheet could be used as an evaluation tool or to brainstorm additional assessments based upon initial findings recorded in the usability log.

Readers can see these ideas applied to the SMARTForm use case. Here the General Model is used to identify measures related to the primary assessment goals in Table 3.3, “Example General Model for the SMARTForm Use Case”.

SMARTForm Use Case: Determine Measures

Table 3.3. Example General Model for the SMARTForm Use Case

Measure	Effectiveness	Safety	Efficiency	Satisfaction
Right Information Presented to End User	• Pre-populated and calculated data are correct • Information is complete for the task	Critical information is captured related to safety	Form content is consolidated and easily readable by users	N/A
Right Person to Receive Intervention	N/A	N/A	N/A	N/A
Right Time in the Workflow	N/A	N/A	N/A	N/A
Right Channel (Device) for Delivery	N/A	N/A	N/A	N/A
Right Intervention Format	• Organization of the SMARTForm (Does it makes sense to the clinician?) • Form provides situation awareness of the patient's condition (e.g., the clinician see the "big picture" of patient problems, needed actions)	• Format is not misleading, accurate • Format promotes safety (minimal scrolling, critical information not out of view)	Completion time matches pre-set benchmark time	N/A
Patient or Population Outcomes	Form identifies pertinent conditions for follow-up in the VA	• Adverse errors related to missed conditions over the last 6 months of form use • Gaps in care continuity	N/A	N/A
Process or Organizational Outcomes	• Adoption rates across clinicians • Completeness of fields	Rates of SMARTForm completion over the last 6 months	Average time clinicians take to complete the form across all clinicians	N/A

3.5. Refine Primary Assessment Goals and Create Objectives

The last step in defining assessment goals is to refine them and create specific objectives. Evaluators should keep in mind at least two sets of guidelines as they refine materials: General and CDS intervention value considerations.

3.5.1. General Considerations in Refining Assessment Goals and Creating Objectives

- **Primary goals that address the suite of associated CDS interventions—**Each aspect of the CDS intervention may need to be evaluated as well as how they interact together.
- **The burden to participants—**The more selected factors and measures that involve participants the more time they will need to commit to the evaluation.
- **The number of required resources—**The evaluators will want to consider the extent of required resources across personnel, systems, data, etc. This may limit the number or kinds of possible CDS evaluation goals.
- **The skill and knowledge of the evaluator(s)—**Does the evaluator and the team have the necessary knowledge to complete the study? Will they need external help? Are people with required technical skills (e.g., for data analytics) available?
- **The impact of implementation factors on CDS intervention outcome—**Implementation strategy and subsequent CDS use are intertwined, especially after initial fielding versus later in the CDS life cycle. As evaluators think about goals, they may want to understand the "dose" (strength) of implementation factors received. That is, did the organizational strategy for implementation make clear the reason for the CDS, provide adequate organizational support, and other aspects such as training so that the combined effect helps meet the intent of the CDS intervention design? If implementation effort is weak, the effect of the CDS intervention may not be as intended or adoption may be low (e.g., the organizational support is not evident or the training was insufficient and did not outline the fit of the CDS intervention into typical workflow).
- **Available resources—**For example, using a survey to collect assessment data from early adopters may be problematic if it requires an extra 30 minutes per day to complete and submit. Capturing click stream data within an application (i.e., information about mouse tracking, buttons pressed, time spent on a form) may require significant storage and a specialized resource to analyze the results.
- **Realistic goals—**Goals must also be realistically achievable. Consider the goal: "Complete a ward surveillance report by midnight each day." This statement is precise and measurable, but if the report is derived from data in a reporting system that is a minimum of 1 day behind live data, it will be impossible to achieve.

3.5.2. CDS Intervention Value

- The information in Table 3.4, "Factors to Consider to Determine CDS Intervention Value Adapted from Osheroff et al. (2012)" can be used to weigh the measures and associated goals. Because resources are limited, evaluators will want to select CDS intervention measures and factors with high impact.

Table 3.4. Factors to Consider to Determine CDS Intervention Value Adapted from Osheroff et al. (2012)

Identifier	Definition
P	Patient impact (individual/population) (e.g., safety, quality, cost-effective care; morbidity and mortality; patient satisfaction; of interest to Veterans)
O	Organizational impact (e.g., audit, accreditation, or regulatory compliance; appropriate resource use; reduced liability)
C	Clinician impact (e.g., impact on workflow, local standards, feasibility, of interest to health care team members)
N	Number of patients affected
G	Gap(s) between ideal or target behavior and actual behavior related to the intervention
D	Difficulty associated with obtaining data and information to answer the goal

Identifier	Definition
C	Cost of addressing the goal

Next, the selected measures and guidelines are used to refine primary goals. Table 3.5, "Sample Refined Primary Goals Based Upon the General Model Categories" offers sample refined primary assessment goals.

Table 3.5. Sample Refined Primary Goals Based Upon the General Model Categories

General Model Category	Sample Refined Primary Goals
Effectiveness	• Determine the acceptance rate for a medication alert across clinicians • Determine the completion rate for a SMARTForm across all clinicians • Determine whether the screening rate increased for blood pressures and abnormal cholesterol levels for patients with diabetes • Determine the follow-up rate for critical lab and radiology tests • Determine why only 20% of clinicians are using the suicide risk CDS intervention • Determine whether the CDS intervention changed clinician behavior • Determine whether the costs for lab tests on magnesium levels were lower after CDS implementation
Safety	• Determine whether adverse drug interactions decreased with the new weight-based dosing CDS intervention • Determine whether the new weight-based dosing intervention decreases (or increases) medication errors • Determine whether a new CDS intervention reduced hospital readmissions
Efficiency	• Determine whether the new weight-based dosing CDS intervention is seamless or if it decreases productivity • Determine whether the CDS intervention meets its predetermined benchmark for data entry times • Determine the workflow among physicians, nurse practitioners, and staff nurses for a CDS alert pre- and post-implementation
Satisfaction	• Determine if the CDS intervention on screening for blood pressures and abnormal cholesterol meets the threshold for acceptable usability (e.g., 60 on a scale of 100)
Patient or Population Outcomes	• Determine medication error rates pre- and post-implementation • Determine rates of compliance for preventive care reminders (e.g., immunizations) • Determine whether the CDS intervention generated any new types of medication errors • Determine the population outcomes pre- and post-implementation for adverse events related to the CDS intervention
Process or Organizational Outcomes	• Determine the CDS impact on clinician productivity (changes in appointment length, time to address the new CDS intervention) • Determine A1C rates for patients with Type 2 diabetes pre- and post-implementation

3.5.3. Create Specific Assessment Objectives

Specific assessment objectives are created using the example of how the primary goal about medication alert acceptance rates might be translated into specific objectives. Importantly, evaluation projects usually have a number of specific objectives. For example, Table 3.6, “Samples of Specific Objectives for CDS Intervention Assessments” shows specific objectives for an evaluation of the acceptance rate for a medication alert (the first primary goal in Table 3.3, “Example General Model for the SMARTForm Use Case”).

Table 3.6. Samples of Specific Objectives for CDS Intervention Assessments

General Model Category	Primary Assessment Goals	Specific Assessment Objectives
Effectiveness	Determine CDS medication alert acceptance rates (i.e., whether a CDS medication alert changes clinician behavior)	• If acceptance rates are lower than anticipated (i.e., clinician behavior is unchanged), evaluate why (e.g., determine whether any fields are confusing to end users) • Determine changes in medication errors for the specific medication • Identify usability problems with the CDS application (if clinician behavior is unchanged) • Measure the number of times the alert is accepted • Measure the times the alert is overridden and the reason for the override • Observe the number of alerts by role (physician, nurse practitioner, staff nurse) and whether the CDS configuration considers that it should not fire in designated cases (by role, setting, etc.)
Safety	Determine whether a CDS medication alert results in fewer medication errors	Compare specific medication error rates for this medication, this setting, and this patient population pre- and post-implementation
Efficiency	• Determine whether clinician workflow is interrupted with the new alert • Determine the average time clinicians take to address this alert	• Observe the number and kinds of interruptive alerts for the CDS by role in a naturalistic setting • Observe and record the time 15 users take as they interact with the new CDS intervention during a representative task
Satisfaction	No goal selected for this category in this particular project	N/A
Patient or Population Outcomes	Determine any patient outcomes related to the medication alerts (adverse events or unintended effects)	• Identify any ADEs related to this alert • Identify any medication errors related to the alert, especially for alert overrides • Identify any new errors (unintended) related to the new alert
Process or Organizational Outcomes	Determine CDS intervention adoption	• Determine the rate of use across the organization, by clinic, and by type of provider

Now, the guidelines on refining primary assessment goals are applied and specific objectives are written for the Separation from Active Duty SMARTForm use case.

SMARTForm Use Case: Refine Primary Assessment Goals and Create Specific Objectives

Goals: The SMARTForm has been implemented for 1 month. The evaluators want to complete an assessment to: (a) determine its initial adoption (use) rate, and (b) determine any usage issues (e.g., with usability or productivity).

Objective on Effectiveness: (a) Determine the use rate of the SMARTForm by all clinicians (percent), (b) determine the completeness of all fields to date, (c) determine if critical items were identified for follow-up, and (d) identify usability problems that may interfere with either efficiency or effectiveness.

Objective on Efficiency: Determine if the SMARTForm takes less time to complete than the clinician-set benchmark of 3 minutes.

Objective on Patient Outcomes: Determine whether patient incident reports related to missed follow-up are related to items addressed in the SMARTForm and categorize their severity.

Chapter 4. Develop Assessment Plan

Once the specific assessment objectives are defined, the next step is to develop a plan for the evaluation of the CDS intervention. The first step in the planning process is to select an appropriate method or methods. (DVA, 2017a)

4.1. Determine Method(s) for Each Objective

Two points are important regarding methods. The first is that different methods may be appropriate for different goals (e.g., data analytics to search for trends in CDS medication alert usage and then user observations to determine how the alert is being used/not in clinical settings). Second, evaluators may want to conduct assessments using more than one method as multi-method evaluations can identify different and complementary usability problems (Georgsson & Staggers, 2016a). Multi-method evaluations are highly recommended to evaluate CDS interventions.

The suite of CDS assessment methods and study designs are robust. Examples of basic assessment methods and potential resources are:

- Completing electronic health record (EHR) chart reviews to monitor routine performance measures (e.g., length of stay, medication errors, mortality) and/or to calculate healthcare quality measurements (e.g., length of stay, mortality) (Horton, 2012);
- Employing natural language processing techniques during chart reviews to gather needed data;
- Using data analytics, including data mining techniques, to calculate organizational measures or impact selected from the General Model;
- Observing end users as they interact with CDS interventions to identify CDS intervention effect on workflow;
- Interviewing end users about their use/non-use of CDS interventions;
- Using The Joint Commission tracer methodology to outline clinical processes (TJC, 2017);
- Using established research methods (qualitative, quantitative, or mixed methods) to examine metrics before and after implementation (e.g., organizational changes, changes in clinician behavior, changes in routine performance measures, environmental variations) (Osheroff, et al., 2012, pp. 274-282); and
- Using economic techniques to complete financial impact assessments of CDS interventions (Osheroff, et al., 2012, pp. 282-283).

Qualitative methods include completing interviews, focus groups, and observations. Quantitative methods use experimental and quasi-experimental designs (Shadish, Cook, & Campbell, 2002). For example, evaluators might compare pre- and post-implementation measures (pre-experimental) or sample three points pre- and three points post-implementation (quasi-experimental time series).

Chapter 5. Prepare for the Assessment

This section includes typical elements evaluators will need for the plan for quality and usability methods. A checklist is in Table 5.1, “Checklist for Elements in an Assessment Plan” and the elements are described after that.

Table 5.1. Checklist for Elements in an Assessment Plan

Element	Quality Methods	Usability Methods	Person Responsible	Due Date	Notes
Obtain approvals	X	X			
Managerial Support	X	X			
Develop consent forms		X			
Select team members	X	X			
Select participants		X			
Determine and prepare the setting (including software and hardware)	X	X			
Select tools and instrumentation	X	X			
Write scenarios		X			
Create tasks		X			
Develop data collection plan	X	X			
Prepare briefing instructions		X			
Develop training materials		X			
Develop test materials					
Write a script		X			
Prepare data collection forms (e.g., chart reviews, demographic form, formal tools, blank forms prn)	X	X			
Compile participant packets		X			
Develop a communication plan	X	X			
Run a pilot test	X	X			

5.1. Obtain Approvals

Evaluators will want to consider whether managerial support is needed for assessments and obtain them as needed. Supervisors may need to approve work on specific assessments (e.g., for resource allocations) and stakeholders may need to be informed about the assessments. For routine CQI measures, typically no approval is needed.

Routine CQI evaluations are usually exempt from the Institutional Review Board (IRB) approval process (e.g., monitoring routine performance measures, compiling data for standard external reporting). If the evaluators are conducting a more formal study, they usually need IRB approach and may need to provide informed consent forms for participants to sign. Evaluators can keep in mind that VA does allow evaluators to conduct pilot studies for a few hours without the need for formal approvals, but if, for example, evaluators plan to collect data from patients as they interact with a new CDS intervention on a consolidated medication list, they are likely to

need IRB approval. See VHA Handbook 1004.01 [https://www.va.gov/vhapublications/viewpublication.asp?pub_ID=2055] (VHA, 2009) for guidance. The lines between CQI and formal research can be blurry. If in doubt, evaluators can contact the local IRB to determine the assessment project's status. (DVA, 2017a)

5.2. Select Team Members

Evaluators should develop and use criteria to select team members. Readers are referred to the Assessment Protocol for criteria specific to three usability methods, Select Team Members sections 6.2.2., 7.2.2, and 8.2.2. Team member expertise requirements are linked to the CDS project goal and method (DVA, 2017a). Sample considerations might be:

- Experience with the CDS intervention;
- Familiarity with the CDS intervention from an IT perspective (e.g., rules and logic);
- Familiarity with the process being supported by a CDS intervention (a plus) or at least basic knowledge about healthcare operations and clinical processes;
- Experience with the chosen method(s) (e.g., qualitative methods can be time-consuming and more than one person should code data, so team members should be selected accordingly); and
- The number of selected measures (the more measures, potentially, the more team members needed).

If the evaluators are conducting observations, they may need only a small team of evaluators. If a relatively small number of participants are to be observed, then even one team member can be sufficient. At least 2–3 team members are required if qualitative data are being analyzed (for validity), such as comments or interviews about a CDS intervention.

However, if the project is a summative usability test (i.e., a formal interaction test with participants after implementation using objective measures), evaluators may find that two team members ease the logistics and data collection efforts. Per NIST 7804, one team member's role could be to interact with the participant while the second team member collects the needed data.

Part of this process will also include making sure there is appropriate support at a managerial level to facilitate the analysis and remove any barriers preventing the analysis. Successful identification of the team, the stakeholders, and managerial support, completed earlier in the planning process, will all be important for constituent buy-in when carrying out the CDS intervention evaluation effort.

5.3. Select Participants

5.3.1. Participant Inclusion and Exclusion Criteria for User Studies

The evaluators will want to think through inclusion and exculsion criteria for each assessment objective (e.g., which clinicians would use a SMARTForm). They may need to work with a data analyst for this portion of the plan.

As part of the plan for the usability objectives, evaluators will want to develop a set of inclusion and exclusion criteria for participants. Readers are referred to the Select Participant sections 7.2.3 and 8.2.3 in the Assessment Protocol (DVA, 2017a) if employing usability methods.

Sample inclusion criteria might be:

- Representative users of the application—The interdisciplinary nature of many applications should be taken into consideration; think across physicians, nurses, pharmacists, aids or technicians, unit clerks, and administrators;

- A range of novice versus expert users of technology in general and for this application specifically;
- A range of users new to the organization versus long-term employees; and
- A representative age range (broad versus narrow is typically better) or other pertinent demographics.

Exclusion criteria might be:

- Participants who are less than 3 months out of their basic educational programs;
- Participants who have visual acuity issues; or
- Participants who have little or no experience with EHRs or computerized clinical care.

5.3.2. Numbers of Participants

A common question evaluators have concerns the number of participants needed for a CDS evaluation. This depends upon the type of assessment being conducted and the method being used. Table 5.2, "Participant Criteria by Assessment Method" outlines examples and numbers of participants required.

Table 5.2. Participant Criteria by Assessment Method

Type of CDS Intervention Assessment or Method	Number of Participants
Effectiveness and safety measures (e.g., ADEs, mortality, CDS usage, etc.)	The identified population during a specified time period
Data analytics (including data mining techniques)	Can be hundreds, thousands, or more depending upon the measure and the data sources (Cummins, Luangkesorn, & Staggers, 2018)
Exploratory, descriptive (e.g., interviews)	At least 3–5 representative end users (Nielsen & Mack, 1994); qualitative researchers recommend sampling until saturation occurs (Patton, 2002)
Heuristic evaluation	3–5 single-domain experts; 2–3 dual domain experts (Nielsen, 1992)
Observations (e.g., identify workflow, workflow interruptions, usability problems)	At least 3–5 representative users (Nielsen & Mack, 1994).
Summative usability testing (e.g., time on task, interaction errors, task success)	At least 15; 15 –20 if possible (Faulkner, 2003)

Evaluators will want to consider at least the following as they determine the number and types of participants:

- The depth and breadth of data needed (more depth may mean including fewer participants);
- The participant burden;
- Participant availability;
- Any method requirements; and
- Participant and/or time constraints.

5.3.3. Plan to Recruit Participants

Evaluators will need to include a section about how participants will be recruited within VHA regulations. Readers are referred to Assessment Protocol section 8.2.3.1. Plan to Recruit Participants (DVA, 2017a).

The use case shows sample information for the steps in the planning process discussed to this point.

SMARTForm Use Case: Approvals, Study Design, Team Members, Stakeholders & Participants

Approvals: The IRB indicated this assessment is a CQI effort. No IRB approval or formal consent by participants is required.

Design: The assessment is descriptive, exploratory.

Team Members: Two team members were selected. One is a CQI team member who is familiar with the CDS intervention. The other team member has expertise in usability assessments. The team will work with a member of the IT department for the analytics.

Participants: Participants are needed to evaluate the efficiency and effectiveness and to identify existing usability problems. Using the inclusion and exclusion criteria in Section 5.3.1, “Participant Inclusion and Exclusion Criteria for User Studies” , the team will select a maximum of five participants.

Recruitment Plan: Evaluators will work with clinic managers to identify potential participants (because the number of participants is small) and evaluators will contact them via email.

5.4. Determine the Setting

Like other aspects of the plan, the setting will be determined based on the purpose and method of the CDS intervention assessment. Setting considerations are important to many methods. Readers are referred to the Assessment Protocol sections 6.2.4, 7.2.4, and 8.2.4 on Determine the Setting for details (DVA, 2017a).
For many types of CDS intervention assessments, evaluators will need to carefully plan for hardware and software support as part of determining the setting. For example, for data analytic techniques, evaluators need to understand and evaluate the five V’s of big data: volume, variety (data sources), velocity (the speed that data are generated and change over time), veracity (data accuracy, completeness), and value (available data to fulfill the purpose) (Cummins, Luangkesorn, & Staggers, 2018). Evaluators will need to work with IT professionals, such as data analysts, who are specialists in the local, regional, or national data warehouse or methods, such as natural language processing.

CDS assessments using performance measures (e.g., ADEs, mortality, morbidity) have established methods like EHR data extractions (chart reviews) and data delivered via routine reports from the IT department. The setting could be less relevant to these kinds of assessments as it may be in the evaluator’s office or the IT department.

Another option is to design and develop a CDS assessment method on a laptop. Evaluators can include assessment materials as well as data collection software, such as MoraeTM. MoraeTM has capabilities to capture participant video, audio, and interactions, such as keystrokes. It allows for analysis afterward. If evaluators want to use this method, they will likely need to collaborate with a usability expert.

5.5. Select Tools and Instrumentation

5.5.1. Write Scenario(s)

Some methods commonly use scenarios (e.g., usability methods). Readers are referred to the Assessment Protocol section 8.2.5.1, Write Scenarios (DVA, 2017a). The SMARTForm use case shows an example of a scenario.

SMARTForm Use Case: Sample Scenario for SMARTForm Assessment (DVA, 2017a)

Mr. Jones presents for pulmonary consultation at the request of his primary care physician (PCP) regarding exertional dyspnea. He is 38 years old and was discharged from the Army in 2016. He smoked cigarettes for 6 years in his 20s, but he has since quit. Mr. Jones has always been athletic, and he played on multiple sports teams while in high school without any respiratory limitation. After high school, he joined the Army and served for 3 years. He was deployed to Iraq for 8 months in 2014 and again for 9 months to Afghanistan in 2015.

Mr. Jones notes that while he still exercises, he is just "not the same" as he used to be. Prior to his deployment to Iraq in 2014 he recalls feeling great, with no previously noted respiratory symptoms. He could complete his required 2-mile run in 13 minutes and 45 seconds. While he has always been able to complete his required 2-mile runs, his times have gradually gotten worse; he now finishes in 17 minutes and 30 seconds. He goes to a gym 4 days per week, but he usually focuses on strength training because he feels so short of breath while running or biking. He does not report cough or chest pain. He reports having chest tightness and an inability to completely fill his lungs with air.

He has a pet dog, but he has never had any symptoms related to being around the dog. There is a family history of hypertension in both parents, but it is otherwise unremarkable. He has never required use of oxygen, has no history of any cardiac problems, and has had no treatment to date or any hospitalizations.

- Physical exam reveals mild wheezing at the bases of both lungs.
- Pulmonary function testing: Pre-bronchodilator FVC is 98% predicted, FEV-1 is 75% predicted, FEV-1/FVC is 88% predicted, and DLCO is 99% predicted. Post-bronchodilator FVC is 98% predicted, FEV-1 is 98% predicted, and FEV-1/FVC is 98% predicted. FEV-1 is the test considered to most accurately reflect the claimant's level of disability.
- Chest X-ray is clear.

You have asked the patient his name and social security number, located the patient's record, and launched the Separation from Active Duty SMARTForm.

In the next step, evaluators create tasks for CDS evaluations that can be used with or without the scenario depending upon the evaluators' backgrounds and the technique chosen.

5.5.2. Create Tasks

For observations and usability testing methods, evaluators will need to create tasks as they are commonly used tools. Readers are referred to the Assessment Protocol sections 6.2.5.1, 7.2.5.2, and 8.2.5.2 on Create Tasks (DVA, 2017a).

5.5.3. Develop the Data Collection Plan

Evaluators will want to create a data collection plan (or access one commonly used in CQI efforts) as part of every project. The data collection plan is tailored to the method. For usability methods, readers are referred to the Assessment Protocol sections 7.2.5.3 and 8.2.5.3 on Develop a Data Collection Plan (DVA, 2017a). The data collection plan includes the kind of data being collected and the source. For instance, if the project includes chart reviews or data analytics, the source and quality of data become a critical aspect to evaluate to assure data validity (Cummins, Luangkesorn, & Staggers, 2018). Some assessments might include the use of established reports about ongoing performance measures or it might include logging the use rates of a number of CDS interventions with suggestions for improvement. ONC Worksheet 9-2—Use and Usability Issue Log can assist in the latter effort across CDS types (see Appendix B). The data collection plan could include a blank form (or an expanded one) similar to worksheet 9-2.

The use case provides examples of information for this portion of the planning process.

SMARTForm Use Case: Setting, Tools & Measures

Setting: The Portland, Oregon VA Medical Center (VAMC) is the pilot site for the SMARTForm. The setting for the objectives on efficiency and usability problems will be a quiet conference room in the clinician's work area. The team will use a laptop to deliver/access the assessment materials, time the interactions, count appropriate elements, and score the System Usability Scale (SUS).

Measures for Effectiveness and Safety:*Effectiveness regarding usage and completeness*—The team will work with the IT department to determine the usage of the form across all clinicians in its first month post-implementation, determine the breakdown of usage by specialty and department, and create a percent of use (over total possible uses). The report will indicate blank forms and missing fields. *Patient and process outcomes* for *patient incident reports and severity of impact*. Last, the IT team will search incident reports for missed follow-up issues. The evaluators will work with the IT team to find data related to outcomes of missed follow-up items as it may be difficult to obtain these data. The team has defined low, moderate, and severe patient impact to categorize incident reports.

Effectiveness on clinician interactions—The team will count the number of abnormal values and follow-up items the participants identify during interactions. They will note whether critical items are identified (the evaluators will need to identify these ahead of time).

Effectiveness regarding usability problems—The team will ask clinicians to step through the form a second time and ask the participants questions like:

- Does this section of the form make sense to you?
- What do you like about this section of the form?
- What do you not like about this section of the form? Is anything confusing to you?
- Are there any questions you want to ask but do not see on the form?
- What else might you expect to see here?
- What might you expect to do here?
- Do you envision any challenges in filling out this section of the form?
- Are the features you've used with other forms or Separation Risk Assessment protocols that you'd want to use here?
- Do you have any suggestions for making this part of the form simpler or easier to use?

Efficiency—The participants will be timed as they interact with the SMARTForm.

Patient and process outcomes—The team will analyze the initial incident reports to assure they are applicable to the purpose (linked to the SMARTForm). They will develop a categorization scheme on patient impact, such as low, moderate, severe.

Scenario and Tasks: Participants will use the defined scenario to: (a) Access the SMARTForm; (b) Enter the provided data; (c) Find abnormal values (the team will create 3 abnormal values, 1 is critical); and (d) Create items for follow-up (the team identified 2 items, 1 is critical).

The total time for participant involvement is about 45 minutes.

5.5.4. Develop Briefing Instructions

For assessments that include participants, evaluators will want to write briefing instructions. Readers are referred to the Assessment Protocol sections 6.2.5.2, 7.2.5.4, and 8.2.5.4 on Prepare Briefing Instructions (DVA, 2017a). The use case shows sample briefing instructions.

SMARTForm Use Case: Briefing Instructions

Thank you for participating in this assessment. Our session today will last about 45 minutes. During that time, you will take a look at the SMARTForm on Separation from Active Duty.

I will ask you to complete tasks using the SMARTForm and answer some questions. We are interested in how easy or how difficult this CDS intervention is to use, what actions are useful to you, and how we could improve it. You will be asked to complete these tasks on your own trying to do them as quickly as possible with the fewest possible errors. Please save your detailed comments until the end of a task or the end of the session as a whole when we can discuss freely. Please be honest with your feedback.

We will have you go through the SMARTForm a second time and ask you questions.

We will observe you as you work with the SMARTForm, and we will ask you questions after you complete the form. All of the information that you provide will be kept confidential, and your name will not be associated with your comments at any time.

Do you have any questions or concerns?

5.5.5. Develop Training Materials

Training may not be required depending upon the purpose of the study and the method selected. However, a need for training is common for either evaluators or participants who may need training on the CDS intervention or the assessment method. The evaluators will need to decide who needs to be trained on the application and the depth of training required. The goal is for the team and participants to have sufficient baseline knowledge about the CDS intervention content and navigation. Readers are referred to details on Develop Training Materials in the Assessment Protocol sections 6.2.5.3 and 8.2.5.5 (DVA, 2017a).

5.5.6. Develop Test Materials

For many assessments, evaluators will need to gather and/or develop needed testing materials (e.g., demographic forms, data collection forms, and any existing tools needed to measure concepts of interest). These can be sequenced to display electronically or compiled into a packet (or some mixture of methods.) Readers are referred to various sections in the Assessment Protocol about how to develop the test materials packet in sections 6.2.5.4, 7.2.5.5, and 8.2.5.6 (DVA, 2017a). The use case shows these elements in more detail.

SMARTForm Use Case: Training, Demographics, Participant Materials & Script

Training: No participant training is needed on this SMARTForm as it has been deployed in the setting. Evaluators will need training. They will work with the VA trainers and get access to the standard online training for the SMARTForm.

Demographics: The team created an interactive demographics form in Word. Demographics include: education, age, experience in healthcare, experience with the SMARTForm, time at the VA, and computer experience.

Procedure Script:

> You will complete several tasks with the Separate from Active Duty SMARTForm. The first task is to access the form and enter the data we have provided. Complete the task quickly and independently. Please let me know when you are ready to begin and when you are finished with the task. The next task is to find abnormal values. The third task is to find items for follow-up. (Similar phrasing would be completed for any subsequent tasks.)
>
> Next, we will ask you to step through the SMARTForm and talk aloud. We will ask you questions—such as "Is any information missing?"—and we would like you to talk about the form as you interact with it.

5.5.7. Develop a Communication Plan

Evaluators will want to consider developing a communication plan no matter the type of CDS assessment (except for very small evaluations with few team members). Even if the communication plan is not formal or written, evaluators will find it helpful to consider communication needs before, during, and after the assessment. Pre-study communication can involve communication to selected stakeholders to: (a) obtain approval for the assessment; (b) obtain support for conducting the assessment; (c) assure needed resources are available including appropriate participants or data; and (d) obtain other crucial information, such as scheduling requirements. Communication during the study can include contacting managers and participants about the final dates for the assessment and recruiting participants or other resources as needed. Evaluators can also plan for post-assessment communications to stakeholders, leaders, and/or participants. More formal communication can be via reports or publications. If the team plans to create publications, it is worthwhile early on to sketch out potential article(s) with draft titles and author order.

Chapter 6. Conduct Assessment

In this step, evaluators carry out the assessment using the assessment plan. Details on conducting an assessment are outlined in the Assessment Protocol sections on Conduct the Assessment (or Observations) sections 6.3., 7.3., and 8.3.(DVA, 2017a). Readers are referred to sample open-source documents such as Section B.3, “Worksheet 3-2—Workflow Process Mapping Elements” (Appendix B, *ONC Open-Source Worksheets*), which outlines methods for identifying workflow processes. Readers may also find a sample workflow process for a clinic visit in Figure B.1, “Sample Office Visit Workflow Diagram (HITRC, 2011)”.

6.1. Run a Pilot Test or Sample Data Set

Evaluators may need to conduct a pilot test before completing the main assessment or evaluation.

SMARTForm Use Case: Pilot Study

The team decided to have one participant for a pilot study. They found that the procedure worked well, except that the SMARTForm froze during testing as the participant was talking aloud. No other objective was affected. The technical issues were fixed. The team decided that the data from this pilot study would be included with the main study although the interaction time would need to be edited to account for the technical issue.

6.2. Collect Data

The use case provides an example of the data collection steps.

SMARTForm Use Case: Collect the Data

Effectiveness—(a) A report from the IT team identified the SMARTForm usage across the institution and its completeness across clinicians; (b) the team took notes on usability problems during interactions, and they entered the usability problems into a table similar to Table B.13, “Blank Use & Usability Issue Log (ONC, 2017)” in Appendix B, *ONC Open-Source Worksheets*.

Efficiency—The team captured interaction time via laptop (the first key pressed in the form started the timer and ended when the clinician exited the form).

Patient & ProcessOutcomes—The team worked with the IT department to retrieve patient incident reports for the first week after the implementation of the CDS intervention. This subset of data was analyzed to see if the search criteria needed to be refined. The criteria were refined before the main collection was completed.

Chapter 7. Analyze Data

The first step in data analysis is to determine the type of data being analyzed: (a) numerical, such as task times, scores on instruments, or number of errors (called interval level data); (b) counts for types of data, such as types of errors or severity (categorical data); and (c) comments (qualitative data). Each is analyzed differently. If evaluators want to perform statistical analyses beyond basic descriptive statistics or if they are doing data analytics on large volume data sets, they will want to collaborate with a researcher, statistician, or expert in data analytic techniques. For more details on data analyses, readers are referred to the Analyze Data sections in the Assessment Protocol sections 6.4, 7.4, and 8.4. (DVA, 2017a).

Evaluators may decide to use less formal data analysis methods like text summaries. For example, ONC Worksheet 9-5 (Table B.18, "CDS Program Enhancement Plans (HITEQ, 2017)" in Appendix B, *ONC Open-Source Worksheets*) summarizes the CDS goal, clinical objective, effectiveness, issues and usability summary, and recommendations for enhancements. The use case describes this step.

SMARTForm Use Case: Data Analyses

Effectiveness: Percentages were calculated for form usage across the institution. Simple counts were calculated for the number of usability problems, the number of abnormal clinical values (determined by the evaluators, for example, elevated A1Cs). Text was used to describe the types of usability problems and the problems were categorized into heuristic violations. Text was used to describe the kinds of critical values clinicians identified and missed.

Efficiency: Descriptive statistics were used to describe the task times.

Patient and Process Outcomes: Simple counts were used to summarize the number of incidences. The team categorized the patient incidences into low, moderate, and severe patient impact (the severity related to missed follow-up items on the SMARTForm).

Chapter 8. Synthesize and Communicate Findings

The final step in the assessment process is to synthesize and communicate findings.

8.1. Synthesize Findings

As evaluators synthesize material, they will want to determine congruencies, discrepancies, and gaps in the findings across objectives. Because most evaluations will have several objectives, evaluators will want to determine how the findings for each objective relate to each other and what the implications of the separate and synthesized findings might be. Table B.15, “Blank Performance Against Objectives Worksheet (ONC, 2017)” and Table B.17, “Blank Decision Log (ONC, 2017)”can be used to track the original CDS intervention goal(s) against actual performance and to track decisions and actions, respectfully. This step is important because findings across objectives may not be congruent. For example, clinicians may be highly dissatisfied with a CDS intervention but their performance times may be excellent. Evaluators would then think about what might be next steps in the process to improve satisfaction and what steps the organization needs to take.

8.2. Generate a Report

The final step is the generation of a report that documents the process and findings of the assessment or evaluation. Evaluators may find guidance in NIST 7742 helpful for generating reports after usability testing is completed.

The NIST 7742 report format is condensed and adapted in Appendices C, D, and E of the Assessment Protocol (DVA, 2017a) may be tailored to any CDS intervention evaluation or assessment.

Depending upon the CDS intervention assessment, evaluators may choose a text summary of the assessment or evaluation. For example, a short text summary highlighting goal effectiveness and required enhancements could accompany Section B.11, “Worksheet 9-5—CDS Program Enhancement Plans” (Appendix B, *ONC Open-Source Worksheets*). The use case shows an example of a short report on findings from a SMARTForm assessment or evaluation.

SMARTForm Use Case: Report for Separation from Active Duty SMARTForm

Date of CDS Intervention Assessment: 3/10/1–4/1/17

Date of Report: April 7, 2017

Report Prepared By: Best Quality Person, CQI, Portland VA

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Summary

An evaluation of the CDS Intervention for the Separation from Active Duty SMARTForm, version 2.3 (eHMP) was conducted in March 2017 in the Portland VA. The purpose of this evaluation was to determine the effectiveness, efficiency, and patient and process outcomes of the CDS intervention after initial fielding using several methods: (a) a report on usage and completeness of the form across the institution, (b) a usability assessment on efficiency satisfaction, (c) identification of usability problems, and (d) patient and process outcomes (patient incidences related to a missed follow-up).

- **Description:**The SMARTForm has been implemented for 1 month. The purpose of this CDS intervention is to describe the health status of Veterans as they leave active duty and to identify health issues for follow-up in the VA. The target users are clinicians. The stakeholders are clinicians in internal medicine; primary care; and the director of quality, safety, and value.

- **Goals:** (a) Determine initial adoption (use) rate of the SMARTForm, and (b) determine any usage issues (e.g., usability or productivity problems). This evaluation focused on the clinician and organization aspects of the CDS goals.

- **Objective on Effectiveness:** (a) Determine the use rate of the SMARTForm by all clinicians (percent); (b) determine the completeness of all fields to date across clinicians; (c) in the usability testing component, determine critical items for follow-up; and (d) identify usability problems that may interfere with either efficiency or effectiveness.

- **Objective on Efficiency:** Determine if the SMARTForm takes less time to complete than the clinician-set benchmark of 3 minutes.

- **Objectives on Patient and Process Outcomes:** Identify the number and severity of patient incidents due to missed follow-up related to the fields in the SMARTForm versus the overall total of patient incidents.

Participants

Five healthcare clinicians were participants. Table 8.1, “Participant Characteristics (n = 17)” summarizes participant characteristics.

Table 8.1. Participant Characteristics (n = 17)

Participant Characteristics	Number	Mean	SD	Range
Gender				
Female	2			
Male	3			
Age	52	52	2.5	30–65
Education				
High School				
Bachelor’s Degree				
Master’s Degree	1			
Doctorate				
MD	4			
Specialty				
Internal Medicine	1			
Orthopedics	1			
Primary Care	3			
SMARTForm Use	5	3 weeks	.5	2–4

Setting

The assessment was completed in a quiet setting near the participant’s work area.

Scenario and Tasks

The evaluators developed and validated the previous scenario for this CDS intervention. The scenario included information about a pulmonologist completing the form. The evaluators defined representative tasks related to the scenario and the CDS intervention. The specific tasks are:

- Access the SMARTForm.
- Enter the provided data into the SMARTForm.
- Find abnormal values (pre-populated with information from DoD).
- Find items for follow-up.

Measures

Various recommended measures were used in this evaluation, including and beyond participant interactions.

- Percent of usage;
- Percent of completed forms, missing critical fields (of 10 total);
- Number of patient care incidents related to missed follow-up during the transition from DoD to VA;
- Time to complete the tasks;
- Number and types of abnormal values found in pre-populated data;
- Number and types of items for follow-up participants found;
- Participant's overall satisfaction with the CDS using the SUS;
- Number and types of usability problems; and
- Subjective comments about the SMARTForm and areas needing improvement.

Procedure

For usage and patient incidents, the VA IT team compiled required data. For participant-related objectives, the assessment procedure was as follows. Each participant was greeted by the moderator who introduced the assessment and instructed participants to complete a demographic form. Participants read the scenario, and then completed a series of tasks one at a time. Participants were asked to verbalize the start and end of tasks. The moderator timed the tasks and recorded usability issues during the interactions.

Data Analyses

For data analyses, all participant data was de-identified. Descriptive statistics were used to analyze usage data and performance data. Content analysis was used to analyze participant comments and other subjective data. The patient incidents were counted and they were categorized into low, moderate, and severe impact.

Results: Usage Rates and Patient Incident Reports

The SMARTForm is used by an average of 60% of eligible clinicians. The team found an average of 3 missing critical fields (of 10 possible). The most common missing fields were related to recreational drug use.

Patient and Process Outcomes (Patient Incidents): The team found five patient incident reports related to missed follow-up during patients' transitions from DoD to the VA. Four were moderate patient impact and one was severe.

Performance Data

Participants completed the assessments in an average of 10 minutes. Performance data are summarized in Table 8.2, “Performance Data by Task Type”.

Table 8.2. Performance Data by Task Type

Task	Task Success	Task Times	
	Mean (SD)	(SD)	Range
Enter data	7.5 minutes	1.5	3–15
Find abnormal data	1.3	.5	.75–3
Find items for follow-up	1.7	.75	.75–3.2

The task taking the longest time was finding items for follow-up. Participants completed the task on finding abnormal data in the shortest amount of time.

Usability Problems

The team found a total of 35 usability problems. The most common heuristic violation was for Match with the Real World. The least was for Help and Documentation. Three problems were rated as catastrophic, 10 were major, and the remainder were minor. An example of a catastrophic usability problem was that the abnormal values were difficult to collate across the sections in the form because users had to scroll over all sections to find abnormal values (e.g., labs, physical exam, etc.).

Hint to Evaluators: Screen shots could be included to illustrate the problem and for examples of how evaluators might display usability problem data, please see the Assessment Protocol (DVA, 2017a), section 6.4, Analyze Data, and section 6.5.1, Generate a Report, for heuristic evaluations.

Participant Comments

In addition to the performance (interaction) data, the following qualitative comments were included:

- The participants liked the layout of the SMARTForm and said that it was easy to navigate.
- The SMARTForm needs to be organized to fit with the way clinicians think about health problems. For example, five participants suggested a head-to-toe organization. Health problems from the DoD should automatically populate in the problem list.
- Participants indicated the SMARTForm is an improvement over past electronic notes once its design issues are resolved.

Discussion

This evaluation was on the Separation from Active Duty SMARTForm. The evaluation addressed the effectiveness (usage rates, completeness, ability to find abnormal values and follow-up items, and usability problems); efficiency (task times); and patient and process outcomes (patient incident reports and severity) after 1 month of use. The findings indicate a low usage rate to date at 60%. The six patient incidents (missed follow-up) were related to clinicians who did not yet use the form. For performance data, the most common missing fields are on recreational drug use. The task times are beyond the set benchmarks at nearly double the indicated rate of 3 minutes. The team found 35 usability problems. The catastrophic heuristic violations were primarily in the category of Match with the Real World in that the form does not match the way clinicians think about a health history.

The qualitative findings indicate that the form needs to be reorganized into a format such as a head to toe assessment. Health problems from the DoD should automatically populate the problem list. Abnormal values should have improved highlighting and be collated into a synthesized list for easy viewing and review.

The next steps are several: (a) Reorganize the form to improve its flow, (b) redesign the form to auto-populate the problem list with the indicated health issues, (c) streamline the form to reduce the number of screens (to reduce the time to complete the form), and (d) highlight any missing field(s) when end users save the document. Additional improvements need to be completed with clinicians to improve adoption rates especially for current late adopters. The CQI team plans to work with the communications team on this effort and to follow-up with the training team to analyze past training efforts on the form.

Chapter 9. Conclusion

This document outlines a step-by-step impact evaluation process for post-implementation CDS interventions. The process integrates the General Model with available open-source worksheets that VA evaluators can use for the evaluation. The six-step impact evaluation process begins with defining goals in an iterative fashion. It includes gathering existing information about the CDS intervention, using guidelines to refine initial goals, and then writing specific objectives. The most time-consuming step is creating a plan for the evaluation with numerous considerations to help evaluators thoroughly think through the process. Evaluators then collect and analyze data based upon the plan, and finally, write a report that synthesizes findings.

The benefits of using the process in this document are several. It provides a consolidated set of materials previously unavailable, an expanded view of possible evaluation categories and measures, and a structured approach to CDS intervention evaluations. The process can be applied to any type of CDS intervention and can be used by those newer to the research process, as well as those who are more familiar with it.

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Appendix B. ONC Open-Source Worksheets

B.1. Worksheet 2-2—Checklist for CDS Goal Charter

This worksheet documents the necessary foundational components for a CDS program. This, of course, can be customized to suit specific needs, but most elements should be addressed. In many ways, this is the outline for a CDS charter, and each of these elements work together to form a successful program.

Table B.1. Sample Checklist for CDS Goal Charter (ONC, 2017)

Check	Section	Details
	1. Overview	N/A
	a. Purpose Statement	What are the reasons for addressing this goal? For example, antibiotics given to patients who are allergic to them result in significant morbidity and mortality.
	b. Goals, Objectives & Expected Outcome(s)	What are expected returns from addressing this goal/objective? They need to be important and worthwhile! For example, prevent patients from getting antibiotics to which they are allergic and reap corresponding returns.
	c. Scope	What are the boundaries for this project? For example: Actions from this initiative will affect major nodes in the medication management process—Prescription, Dispensing, Administration; will only focus on antibiotic medications; and non-antibiotic medications will not be considered, although we may favor actions that are scalable to other medication groups.
	d. Critical Success Factors	What are factors needed for success? For example: Education to all, especially to frontline stakeholders; easy CDS system use with minimal disruption of current workflow; and quantifiable reduction in preventable adverse events.
	e. Assumptions	What are assumptions related to the technology, resource, scope, expectation, or timeline assumptions for addressing this goal/objective? For example: Adverse events from antibiotics are detectable and preventable; and we have statistical methods that can determine whether our actions are effective, even if the event rate is very low.
	f. Constraints	What are the constraints related to budget, resources, timeline, and technology? For example: This project needs to be completed within 12 months; action plan must be efficient for frontline stakeholders; and leadership support is critical.
	2. Authority & Milestones	N/A
	a. Funding Authority	Who or what is funding efforts toward this goal? For example, this project is funded by the hospital capital budget.
	b. Oversight Authority	What committee is responsible for this goal/objective? For example, the quality improvement, patient safety, and/or P&T committee could be the oversight authority for an objective that focuses on decreasing preventable allergic reactions. It is important that the CDS Committee not take full authority for all interventions. Involving more stakeholders at the front lines will increase acceptance.
	c. Major Milestones	What are the major points of success and deliverables that will define progress toward this objective? For example: Get buy-in from oversight authority and executive committee; define feasible data management strategy; formulate action strategy and timeline; execute action strategy; and analyze and interpret results.
	3. Organization	N/A
	a. Committee Structure	Graphically represent committees pertinent to this goal/objective and their interaction.
	b. Roles & Responsibilities	Construct a three-column table stating the member, their role, and responsibilities.
	4. Facilities & Resources	What are the facilities and resources needed? For example, office space, computers, personnel.
	5. Points of Contact	Who is the primary and back-up contact for the project?
	6. Glossary	Define all terms and acronyms used in the project charter.
	7. Revision History	Track all changes to the charter document.
	8. Appendices	Include any additional relevant information (e.g., charts, tables, lists).

Table B.2. Blank CDS Goal Charter Checklist (ONC, 2017)

Check	Section	Details
	1. Overview	
	a. Purpose Statement	
	b. Goals, Objectives & Expected Outcome(s)	
	c. Scope	
	d. Critical Success Factors	
	e. Assumptions	
	f. Constraints	
	2. Authority & Milestones	
	a. Funding Authority	
	b. Oversight Authority	
	c. Major Milestones	
	3. Organization	
	a. Committee Structure	
	b. Roles & Responsibilities	
	4. Facilities & Resources	
	5. Points of Contact	
	6. Glossary	
	7. Revision History	
	8. Appendices	

B.2. Worksheet 3-1—Clinical Information System (CIS) Inventory

When approaching the development of a CDS intervention to achieve a particular goal, readers will find it useful to examine alternative methods by which it will be implemented. Understanding the clinical information systems that are available can help identify resources to implement the intervention as well as identify potential gaps in information systems that must be filled prior to embarking on development. In other cases, systematically identifying available CIS resources may shed insight into how a particular problem might be solved without relying on a CDS intervention.

Table B.3. Sample CIS Inventory (HITEQ, 2017)

Information System (IS) Type	System Name	System Type	CDS-Related Functionality	Information Types (Coding System)	Users	Usage (%)	Notes
Ordering	N/A	N/A	N/A	N/A	N/A	N/A	See Clinical Records
Clinical Records & Patient Management	Better Care Inc.	Inpatient EHR and computerized patient order entry (CPOE)	• Order sets • Documentation templates • Relevant data display • Alerts	• Diagnosis information (ICD-10) • Order Information (CPT) • Lab results (LOINC) • Imaging Results (home-grown scheme)	Nurses, Doctors, Pharmacists	50% of physicians are currently using	Uses drug knowledge base from [XYZ Corp] for drug interaction and allergy alerting
Clinical Records & Patient Management	Outpatient Computer Corp.	N/A	• Order sets • Documentation templates • Relevant data display • Alerts	• Visit diagnosis (ICD-10) • Problem lists (ICD-1O) • Medication lists (National Drug Code (NDC) • Visit notes (Text)	Outpatient clinics, mostly primary care	25%	Not yet exchanging data well with inpatient system
Clinical Records & Patient Management	Given Meds Corp.	N/A	• Order sets • Documentation templates • Relevant data display • Alerts	• Date/time for medication administration • Medications (NDCl) • Dose administered	Nurses at two hospitals	100%	Linked to hand-held devices
Departmental Data Management	Get Your Labs, Inc.	N/A	• Relevant data display • Alerts	• Lab results (LOINC) • Anatomic pathology results (Text)	Nurses, Doctors, Pharmacists	Frequently	N/A
Clinical Content	Know-It-All Reference	N/A	Disease and drug reference for info-buttons capability	• Disease management info (ICD-9) • Drug reference info (NDC)	Nurses, Doctors, Pharmacists	Frequently	Linked to hand-held devices

Table B.4. Blank CIS Inventory (HITEQ, 2017)

Information System (IS) Type	System Name	System Type	CDS-Related Functionality	Information Types (Coding System)	Users	Usage (%)	Notes

B.3. Worksheet 3-2—Workflow Process Mapping Elements

This worksheet is a high-level template that shows some of the elements of workflow mapping. This tool is useful for visualizing processes as they relate to individual stakeholders. It is also helpful to document changes to existing workflows as a CDS intervention is implemented, as it may reveal unintended consequences of the intervention. Further examples can be found in the Workflow Assessment Health IT Toolkit on HealthIT.gov [https://healthit.ahrq.gov/health-it-tools-and-resources/workflow-assessment-health-it-toolkit/all-workflow-tools/flowchart].

Figure B.1. Sample Office Visit Workflow Diagram (HITRC, 2011)

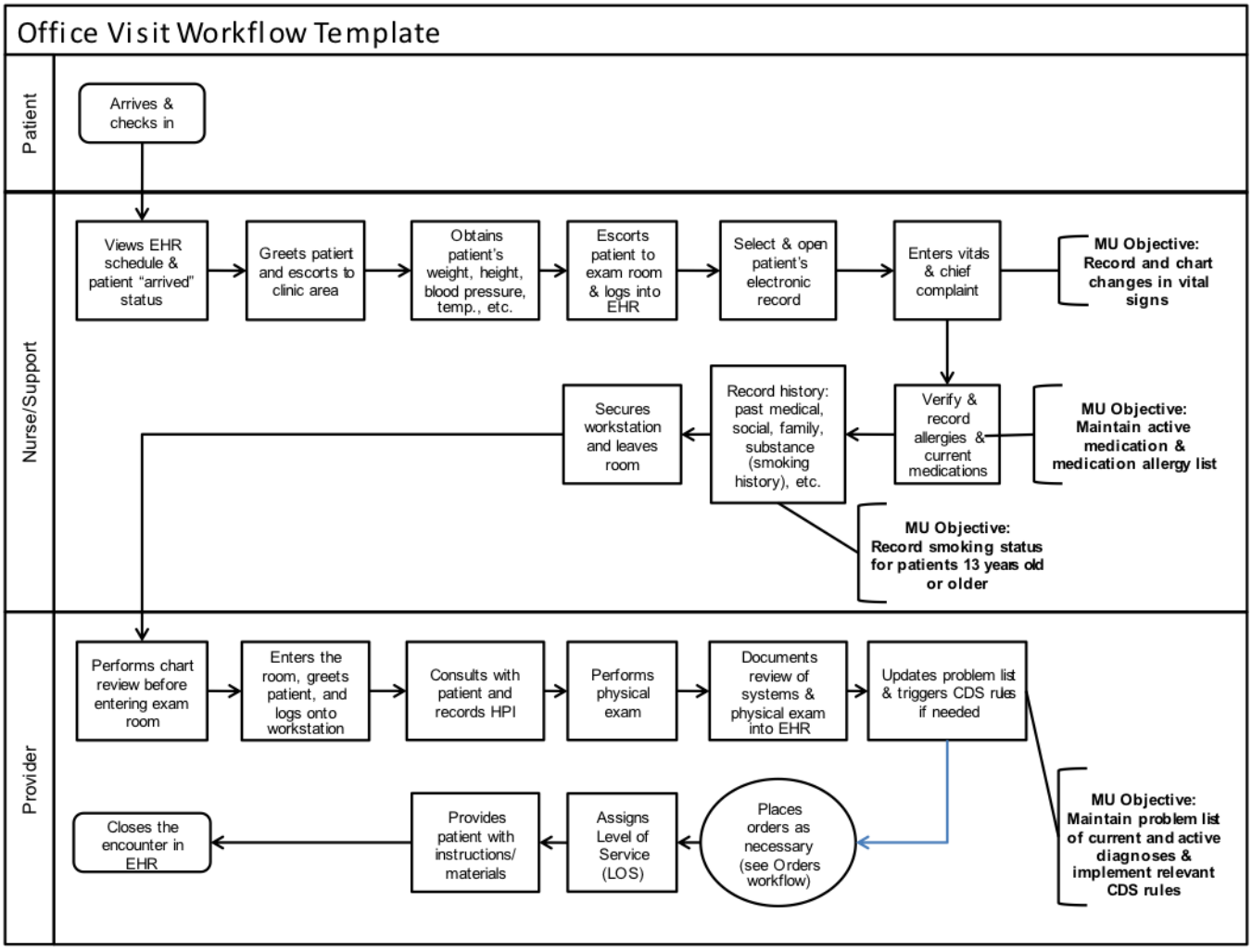
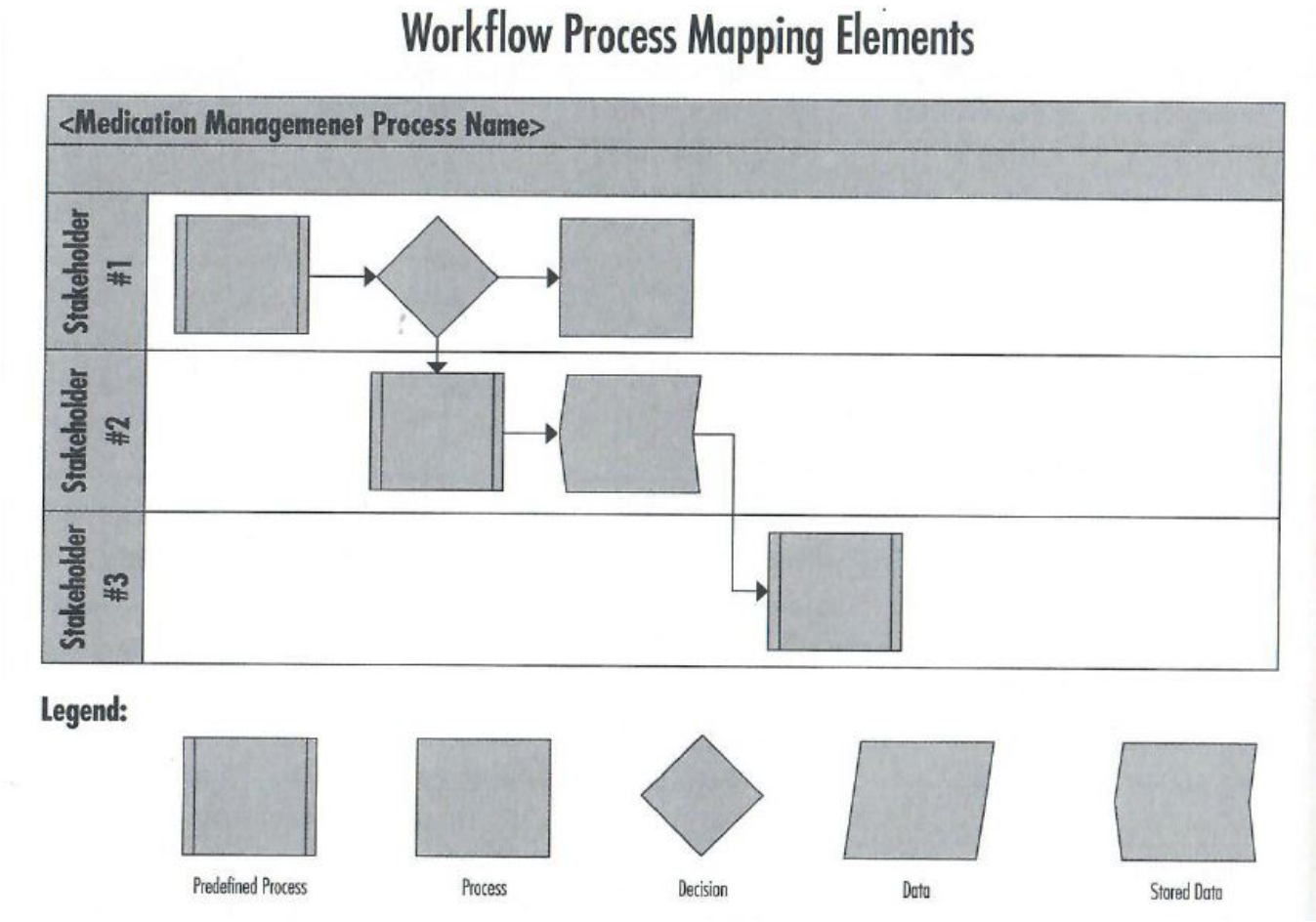


Figure B.2. Workflow Process Mapping Elements Blank Diagram (ONC, 2017)



B.4. Worksheet 5-1—Selecting and Prioritizing CDS Goals

In an environment of constrained resources, simultaneously implementing all CDS goals is difficult. This worksheet serves to document CDS goals for the organization to provide the essential information needed to prioritize goals—so that an organization's resources can be targeted appropriately. This also provides a central repository to identify goals that may be similar (or identical) to reduce duplication of effort.

Table B.5. Goal Selection and Prioritization Worksheet (HITEQ, 2017)

Target	Rationale	Priority	Baseline Performance (%)	Desired Outcome (%)	Notes
Increase appropriate use of venous thromboembolism (VTE) prophylaxis	Part of P4P contract; VTE is a hospital-acquired condition for which CMS is not providing additional reimbursement	1	76% appropriate prophylaxis use	90% appropriate use within 12 months	Coordinate CDS efforts with major organizational Pl effort on this topic
Prevent patients from getting medications to which they are allergic	Recent high-profile sentinel event; significant documented costs associated with this preventable ADE	2	3% of prescriptions are to allergic patients	0% of prescriptions are to allergic patients within 12 months	Coordinate CDS approach with recent launch of CPOE and electronic medication administration record (eMAR) system

Table B.6. Blank CDS Goal Selection and Prioritization Worksheet (HITEQ, 2017)

Target	Rationale	Priority	Baseline Performance (%)	Desired Outcome (%)	Notes

B.5. Worksheet 5-2—Objectives to Achieve Goals

Table B.7. Sample Objectives to Achieve Goals Worksheet for the Clinical Goal to Use Anticoagulation Drugs More Safely and Effectively (HITEQ, 2017)

CDS Goal	Clinical Objective	Desired Action	Baseline Performance (%)	Desired Outcomes (%)	Notes
Increase appropriate use of venous thromboembolism (VTE) prophylaxis	Improve adherence post-op heparin prophylaxis recommendations	Entry of physician order for subcutaneous heparin	Reviewing inpatient order entry data reveals approximately 62% compliance on the three surgical wards	100% compliance for appropriate patients, defined as no history of neurosurgery or other major bleeding risk and no history of heparin-related allergy or problem in the past	Objective is big push for quality officer; lots of time and attention being devoted to the gap; interest in exploring CDS to help make current improvement approach more efficient and effective
Increase appropriate use of venous thromboembolism (VTE) prophylaxis	Improve prothrombin time (PTT) monitoring for anticoagulant effect on a timely and regular basis	Order for PTT entered by physician	88% of reviewed patients have PTT ordered within the first 6 hours	100% compliance	
Increase appropriate use of venous thromboembolism (VTE) prophylaxis	Improve PTT monitoring for anticoagulant effect on a timely and regular basis	Collection of PTT by nursing	66% of reviewed patients had PTT collected within the first 6 hours	100% compliance	Some wards are not staffed with nursing assistants, leading to delays in drawing the PTT
Increase appropriate use of venous thromboembolism (VTE) prophylaxis	Improve PTT monitoring for anticoagulant effect on a timely and regular basis	Abnormal PTT posted by lab acknowledged and addressed by clinical staff	39% of inappropriate PTT values [define thresholds] addressed within 6 hours	75% compliance, allow for some delay based on time of day and lab reporting schedule, but only 1-hour leeway	Shift changes seem to have a big effect on the delay in addressing inappropriate PTT values
Increase appropriate use of venous thromboembolism (VTE) prophylaxis	Improve compliance with care guideline for enoxaparin	Order for enoxaparin in patients admitted with deep vein thrombosis (DVT) without embolism	75% of hospitalized patients with DVT still receive IV heparin	100% compliance with enoxaparin and DVT policy	

Table B.8. Blank Objectives to Achieve [Clinical Goal] Worksheet (HITEQ, 2017)

Clinical Objective	Desired Action	Baseline Performance (%)	Desired Outcomes (%)	Notes

B.6. Worksheet 6-1—Determining the Best CDS Type for Your Objective

Table B.9. Blank Determine the Best CDS Type for [Objective] Worksheet (HITEQ, 2017)

Core Action Areas	Your Details	Likely Workflows	Likely CDS Types
Recognize Patterns[1]		Pre-encounter, RN & MD history/assessment	Data-triggered alerts, Smart documentation forms, calculators, clinical scores, Relevant data summaries, Predictive analytics, Expert system
Formulate Plan[2]		RN & MD history/ assessment,Formulate plan of care	Filtered reference Reference info in order sets / care plans Expert workup advisors
Execute Plan[3]		Documentation, Orders/ Rx, Order handling / medication dispensing, Therapies / procedures	Order sets / care plans (suggested doses, protocols), Parameter guidance, Critiques/ warnings (“immediate alerts”), Smart documentation forms/checklists, Filtered reference information
Monitor, Detect, and Handle Events[4]		Results and new events, Post-visit home care	Event-driven alerts, Multi-patient monitors, Time-driven reminders, Retrospective analytics
Communicate[5]		Consult requests, Discharge and referrals	Filtered reference information, Smart documentation forms (with messaging links)

[1] Is there need for help to recognize promptly that a particular situation, diagnosis, or presentation exists? What data are needed to recognize this?

[2] Is there need for help in choosing the best therapies and/or diagnostic studies for this condition, symptom, or diagnosis?

[3] Is there need for specific help to: (a) create orders or care plans correctly, completely, and without errors; (b) perform relevant procedures; and (c) carry out orders or administer medications?

[4] Is there a need to help detect new events that could be hazardous or require a change in plan on: (a) A single patient, or (b) an entire service? Is there a need to monitor performance over time? Is there a need to monitor patient self-care at home?

[5] Is there a need to help to: (a) Decide on the need for consultation or referral, (b) notify other caregivers about the patient’s status, (c) provide proper information to the consultant, or (d) engage and inform the patient or their family?

B.7. Worksheet 9-1—Metric Selection and Use

Table B.10. Metrics Selection & Use, CDS Objective: Prevent Prescription of Medication to Allergic Patients Intervention Name: Prescription Allergy Alert Window (HITEQ, 2017)

Outcome Category	Check Those That Apply	Metric Type	Metric Owner	Measurement Schedule	Collection Method
Quality		Mortality rate	PI coordinator	Monthly	Existing adverse event reporting process
Quality		Morbidity rate (including ADEs and reactions)	PI coordinator	Monthly	Existing adverse event reporting process
Quality		Length of stay changed?	Sam D. (medical records)	Monthly	Chart-review, semi-automated
Quality		NCC MERP outcome metrics	Jean S. (pharmacist)	Monthly	Chart review
Quality		Effects of CDS on number, class, and type of medications ordered	Jean S. (pharmacist)	Monthly	Existing pharmacy database
Safety[6]		Prescribing	PI coordinator	Monthly	Existing adverse event reporting process
Safety		Transcribing	N/A	N/A	N/A
Safety		Dispensing	PI coordinator	Monthly	Existing adverse event reporting process
Safety		Administering	PI coordinator	Monthly	Existing adverse event reporting process
Safety		Each NCC MERP category (B to I)?	Jean S. (pharmacist)	Monthly	Existing adverse event reporting process
Safety		Are there unintentional adverse effects?	James V. (CDS Team / evaluation	Monthly x 6	Walk rounds, focus groups with clinicians to assess qualitative alert responses
Efficiency		By how much has time taken to use system increased or decreased?	PI coordinator	Weekly x 4	Silent observer, system logs
Efficiency[7]		Prescribing	PI coordinator	Weekly x 4	Silent observer, system logs
Efficiency		Transcribing	N/A	N/A	N/A
Efficiency		Dispensing	N/A	N/A	N/A
Efficiency		Administering	N/A	N/A	N/A
Cost		Resource management changes due to CDS implementation—cost/benefit ratios	Joan R. (billing)	Monthly	Query current billing system
Cost		Change in prescribed medication costs pertinent to CDS interventions	Joan R. (billing)	Monthly	Query current billing system

[6] Are the number of errors reduced at each of the listed medication management nodes?

[7] How has efficiency been affected at the medication management process nodes?

Table B.11. Blank Metrics Selection & Use for [CDS Objective] [Intervention Name] (ONC, 2017)

Outcome Category	Check Those That Apply	Metric Type	Metric Owner	Measurement Schedule	Collection Method
Efficiency					
Quality					
Safety					
Cost					

B.8. Worksheet 9-2—Use and Usability Issue Log

Table B.12. Sample Use & Usability Log (HITEQ, 2017)

Intervention Name	Usage	Usability Issue	Source	Channel	Date Noted	Remediation Plan	Responsible Party	Date Resolved	Priority
Heparin post-op alert	Avg. 20 firings/day	• 97% rejection rate • High user dissatisfaction	Anne M., intervention owner	EHR	1 Mar	Analysis in progress to add in better data on contraindications for heparin therapy. Alert removed from production awaiting resolution.	N/A	5 Mar	Medium
PTT order set	Avg. 16 uses/day	• None • Good user satisfaction	Robert V., intervention owner	CPOE	1 Apr	N/A	N/A	N/A	NA
PTT alert	Avg. 50 firings/day	• 80% rejection rate • Nurses do not feel that it is accurate and don't have time to contact physicians after it fires	George F., CNO	EHR	1 Apr	Consider removal	N/A	N/A	High
Heparin post-op order set	Avg. 13 uses/day	None	Glenda J., intervention owner	CPOE	1 Apr	N/A	N/A	N/A	N/A

Table B.13. Blank Use & Usability Issue Log (ONC, 2017)

Intervention Name	Usage	Usability Issue	Source	Channel	Date Noted	Remediation Plan	Responsible Party	Date Resolved	Priority

B.9. Worksheet 9-3—Performance Against Objectives

Table B.14. Sample Performance Against Objectives Worksheet (HITEQ, 2017)

Clinical Objective	Organizational Priority	Desired Action	Intervention Name	Baseline Performance	Target Performance	Actual Performance	Other Effects
Improve heparin prophylaxis in post-op patients	Quality & Safety: Reduction in VTE events	Increase orders for post-op heparin prophylaxis	Heparin post-op order set	62% compliance	98% for patients without contraindications	85% compliance in follow up (not yet able to reliably exclude patients with contraindications	Users indicated intervention had a positive effect on workflow; complained when it was briefly unavailable
Improve heparin prophylaxis in post-op patients	Quality & Safety: Reduction in VTE events	Increase orders for post-op heparin prophylaxis	Heparin post-op alert	71% compliance	95% compliance	90% compliance	Users dislike the alert so that many more have begun to use the order set
Improve monitoring of heparin for patients on IV heparin	Safety & Efficiency: Avoid ADEs timely lab use (minimize STAT labs)	Increase routine PTT orders for patients prescribed IV heparin	PTT order set	88% compliance	100% compliance when indicated	92% compliance	None
Improve monitoring of heparin for patients on IV heparin	Safety & Efficiency: Avoid ADEs timely lab use (minimize STAT labs)	Increase timely PTT collection by nursing	PTT alert	66% compliance	95% of specimens collected within 1 hour of specified time	84% compliance	Alert has been accompanied by training and workflow enhancements that have improved compliance

Table B.15. Blank Performance Against Objectives Worksheet (ONC, 2017)

Clinical Objective	Organizational Priority	Desired Action	Intervention Name	Baseline Performance	Target Performance	Actual Performance	Other Effects

B.10. Worksheet 9-4—Decision Log

Table B.16. Sample Decision Log (HITEQ, 2017)

CDS Objective	Decision Name	Decision Description	Decision Date	Owner	Critical Decision Factors	Impact	Follow-up/ Comments
Reduce preventable allergic reactions	Interruptive allergy alert override	Make coded alert override reason a mandatory field when prescriber overrides an allergy alert	4/25	CPOE alerts committee	Coded reasons necessary to rapidly process data; plan reviewed with end user champions and stakeholders, who agreed to trail this approach to enhance safety	May still get pushback from some physicians, but approach consistent with alerting plan. Will provide communications/support before/during go-live	Revisit user response and log data in 3 months and re-evaluate whether mandatory override reason still necessary

Table B.17. Blank Decision Log (ONC, 2017)

CDS Objective	Decision Name	Decision Description	Decision Date	Owner	Critical Decision Factors	Impact	Follow-up/ Comments

B.11. Worksheet 9-5—CDS Program Enhancement Plans

Table B.18. CDS Program Enhancement Plans (HITEQ, 2017)

High-Level Clinical Goal	Clinical Objective	Intervention Name	Effectiveness Summary	Issues & Usability Summary	Enhancement Plans
Improve anticoagulation use safety and effectiveness	N/A	N/A	N/A	N/A	Given success of initial interventions, will add better adherence to enoxaparin guidelines as objective for next round CDS
Improve anticoagulation use safety and effectiveness	Improve Heparin prophylaxis in post-op patients	Heparin post-op order set	Moderate—9% improvement	N/A	None
Improve anticoagulation use safety and effectiveness	Improve Heparin prophylaxis in post-op patients	Heparin post-op alert	High—19% improvement	N/A	Add the prophylaxis order to the alert; the action and the alert may improve user satisfaction
Improve anticoagulation use safety and effectiveness	Improve PTT monitoring in patients on IV Heparin	PTT order set	Low—4% but baseline was relatively high	N/A	Add header above the PTT order to make it easier to see
Improve anticoagulation use safety and effectiveness	Improve PTT monitoring in patients on IV Heparin	PTT alert	Very high—28% improvement	N/A	Improvements may have been related to increased awareness and in-services; remove alert for now, with careful monitoring of compliance

Table B.19. Blank CDS Program Enhancement Plans (ONC, 2017)

High-Level Clinical Goal	Clinical Objective	Intervention Name	Effectiveness Summary	Issues & Usability Summary	Enhancement Plans

Appendix C. Glossary

Adverse Drug Events	An injury resulting from medical intervention related to a drug. This includes medication errors, adverse drug reactions, allergic reactions, and overdoses.
CDS Impact	The measurable change(s) in the quality (i.e., effectiveness, efficiency, safety, and satisfaction) of health care generated by the introduction of CDS interventions
CDS Intervention	The delivery of information to enhance decisions and actions related to health and healthcare delivery
Clinical Decision Support	A process to enhance health-related decisions and actions with pertinent, organized clinical knowledge and patient information to improve health and healthcare delivery
Computer Patient Order Entry	A module in health IT supporting electronic orders management
Controlled Observation	Observation conducted outside the users' work environment, typically in a quiet room or lab, that involves an observer evaluator, who captures issues through note-taking or analyses of recordings, and participant, who is a representative CDS user and interacts with the target CDS intervention while talking aloud
Effectiveness	In relationship to a CDS intervention, the product is based on scientific knowledge and performs its designed task effectively
Efficiency	In relationship to a CDS intervention, the product avoids waste and performs its designed task efficiently
Electronic Medication Administration Record	A module in an electronic health record that supports activities for patient medications administration
Heuristic Evaluation	An expert method to inspect software where those trained in the technique (or usability experts) use tasks to interact with and evaluate a CDS intervention to: (a) find usability problems, (b) assign the problems to a specific category of heuristic, and (c) rate each problem by severity
Hospital Consumer Assessment of Healthcare Clinicians and Systems	A patient satisfaction survey required by CMS
Institutional Review Board	Some reasonable definition here.
Nautralistic Observation	Observation conducted in a user's actual work environment that involves an observer evaluator, who captures issues through note-taking or analyses of recordings, and participant, who is a representative CDS user and interacts with the target CDS intervention while talking aloud
Observer	The evaluator in research (e.g., during a user observation)
Summative Usability Testing	Evaluation of a product with representative users and tasks designed to measure the effectiveness, efficiency and satisfaction of the complete or nearly complete product
Usability	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

User Satisfaction	User perception about a CDS intervention related to its effectiveness and efficiency within a particular context
Workflow	Sequence of steps in a process typically within a particular context