Chapter 6
Best Practices for Implementation of Clinical Decision Support

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Abstract Implementation of clinical decision support (CDS) is the process by which knowledge about appropriate practice is integrated with systems that are designed to influence provider behavior. We describe a systematic and replicable approach to implementation of knowledge that proceeds from knowledge synthesis that defines ideal care through a knowledge formalization phase in which that knowledge is transformed so it can be processed by computers. Next the knowledge is fitted to local needs, capabilities, and constraints. Finally, new knowledge gained from the implementation completes a feedback loop to inform future decision support activities.

Keywords Decision support • Implementation • Knowledge synthesis • Knowledge formalization • Knowledge localization

Implementation of clinical decision support (CDS)is the process by which knowledge about appropriate practice is integrated with systems that are designed to influence provider behavior. CDS design and implementation considerations are closely interrelated [1]. CDS implementation requires attention to the socio-technical and cognitive aspects of care delivery, as well as organizational function, human-computer interaction, and workflow analysis and reengineering. Implementation is increasingly regarded as a science in its own right that borrows from and contributes to these disciplines.

We describe three phases of CDS development and implementation—knowledge synthesis, knowledge formalization, and knowledge localization—in which knowledge about best clinical practice is captured, transformed into computable format, and embedded in health care systems (Fig. 6.1) [2]. Clinicians and policy makers increasingly speak of a "learning healthcare system" in which a cycle is created by feeding back the results of using CDS to promote advances in patient care, health care delivery processes, and implementation science [3].

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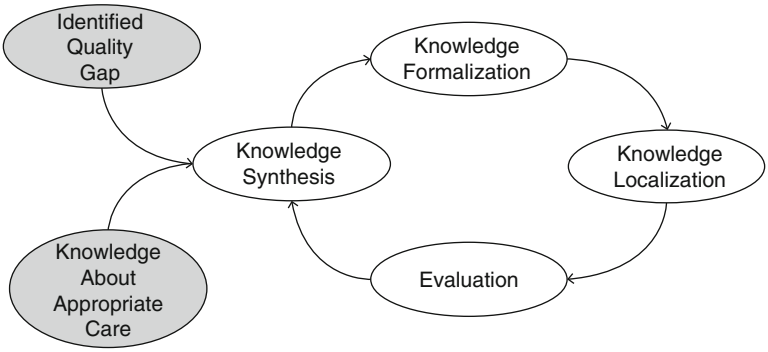

Fig. 6.1 Phases of CDS development and implementation in a learning healthcare system

6.1 Knowledge Synthesis

CDS is intended to improve the quality and safety of health care. Therefore, implementation begins with recognition and acknowledgement of a gap between current processes (and outcomes) of care and ideal care. Raw knowledge about appropriate care is derived from journal articles, monographs, book chapters, meta-analyses of individual studies, and the experience and expertise of subject matter experts. To be useful, this knowledge must be captured, organized, codified, and represented in a manner that can be manipulated by computers.

Knowledge synthesis is the process of combining the results of systematic review of the biomedical literature with the experience and expertise of experts to create recommendations about best practice [2]. *Clinical practice guidelines* represent a particularly rich source of knowledge about best practice. Current, evidence-based practice guidelines are developed and sanctioned by trusted professional societies, government entities, and healthcare delivery organizations. Guideline authoring teams strive to identify and organize unstructured knowledge into a narrative format that includes recommendations about appropriate care.

The 2011 Institute of Medicine report *Clinical Practice Guidelines We Can Trust* provides standards for development of guidelines [4]. According to the IOM, "trustworthy guidelines" should:

- Be based on a systematic review of the existing evidence;
- Be developed by a knowledgeable, multidisciplinary panel of experts from key affected groups;
- Consider important patient sub-groups and patient preferences;
- Be based on an explicit and transparent process that minimizes distortions, biases, and conflicts of interest;
- Be informed by an assessment of anticipated benefits and harms of alternative care options;

- Provide a clear explanation of the logical relationships between alternative care options and health outcomes, and provide ratings of both the quality of evidence and the strength of recommendations; and
- Be reconsidered and revised as appropriate when important new evidence warrants modification of recommendations [4].

To date, there has been considerable variability in the processes employed to develop practice guidelines. Some organizations apply consistent and rigorous methodologies to their development activities with careful evaluation of the evidence-base, while others rely on imprecise capture of expert opinion—sometimes referred to as GOBSAT (Good Old Boys Sitting Around the Table). In an effort to codify successful approaches and make the guideline development process more systematic and replicable, we developed BRIDGE-Wiz (Building Recommendations In a Developer's Guideline Editor), a software application that leads guideline authors through a series of steps intended to improve the clarity and transparency of guidelines and help assure that the guidelines can be implemented [5]. BRIDGE-Wiz focuses first on clearly specifying the recommended actions to be undertaken and the precise circumstances under which these actions are to occur. Next, it asks authors to document anticipated benefits, risks, harms, and costs that may be expected if the recommendation is executed. Finally, it standardizes the language of obligation in which the recommendations are articulated commensurate with the quality of evidence that supports each recommendation and the authors' judgment about the balance of anticipated benefits and harms. Additional tools have been used to help measure guideline quality and implementability of guideline statements, including COGS, [6] AGREE II, [7] NEATS (personal communication, Jane Jue), and eGLIA [8]. The COGS (Conference on Guideline Standardization) and AGREE (Appraisal of Guidelines for Research and Evaluation) are instruments intended to measure guideline quality based on longstanding indicators. The NEATS instrument (National Guideline Clearinghouse Extent Adherence to Trustworthy Standards) is more current and based on the IOM standards for trustworthy guidelines. eGLIA (Electronic Guidelines Implementability Appraisal) examines individual guideline recommendations to highlight potential obstacles to successful implementation.

The product of the Knowledge Synthesis phase of CDS development is an unstructured narrative document containing recommendations about appropriate care and meta-information about how those recommendations were derived and how they should be applied.

6.2 Knowledge Formalization

*Knowledge formalization*is the process of translating narrative guidelines into structured knowledge that can be implemented consistently in CDS applications [2]. Early work in CDSS design showed that knowledge engineers tasked with

transforming guideline knowledge into CDSS developed idiosyncratic systems that provided different advice when tested against the same standardized patients [9, 10]. This unfortunate finding emphasizes the importance of transparency of knowledge transformation. Ideally an audit trail should be available to help assure fidelity of the decision support to the original knowledge source.

To help assure accuracy of knowledge translation and auditability of the formalization process, we translate the narrative guideline documents into an intermediate knowledge representation expressed in the eXtensible Markup Language (XML). XML is a multiplatform, Web-based, open standard. Users parse the text of a document (such as a guideline) into chunks delineated by meaningfully labeled "tags", for example:

<guidelineTitle>Hypertension Management</guidelineTitle>.

XML is human-readable, yet can be processed by computers. The process of parsing guideline content into XML can be performed by non-programmers.

The Guideline Elements Model (GEM) schema is a standard model of the content of clinical practice guidelines in XML. It includes 167 tags to describe and characterize textual components of narrative guidelines. The model is hierarchical with the following top-level elements [11]:

- Identity (containing information about title, release date, companion documents, status)
- Developer (including sponsoring organization, names of committee members, funding, conflict of interest declarations)
- Purpose (including focus, objective, and rationale for creating a guideline)
- Intended audience (including users and care settings in which the guideline may be implemented)
- Target Population (including inclusion and exclusion criteria)
- Method of Development (including description of evidence collection and combination, rating schemes for evidence quality and recommendation strength)
- Testing and Revision plans
- Implementation Plan
- Knowledge Components [11]

GEM works well as a knowledge representation intermediate between a narrative guideline and a formally specified CDSS. Most valuable to CDS implementers are the elements in the Knowledge Components hierarchy. In GEM, these elements include definitions of terms used in the guideline, algorithms (flowchart representations of procedural logic), and the guideline's recommendations about appropriate care. The <recommendation> subtree of the GEM hierarchy includes the <conditional> element, which, in turn, comprises:

- <decisionVariable>: the condition(s) under which a recommendation is appropriate, and
- <action>: the appropriate activities to be carried out.

Decision variables and actions together can be used to create IF…THEN rules to represent guideline recommendations.

Other elements in the <KnowledgeComponents> subtree provide tags for the <reason> (why the recommendation was developed and what it is intended to accomplish), <evidenceQuality>, and <recommendationStrength>, among others.

GEM Cutter is an XML editor (available from http://gem.med.yale.edu) that facilitates markup of guideline documents and their transformation from narrative text to a semi-structured format. The user interface provides three side-by-side panels. A user imports the narrative guideline into the leftmost panel. The middle panel provides an expandable list view of the GEM hierarchy. The rightmost panel provides a window for editing and iterative refinement of the guideline text. The user selects relevant text from the leftmost panel, determines where it belongs in the GEM hierarchy, and clicks a button that moves the text into the middle panel visually and adds the text to an evolving XML file.

In many cases, the decision variables and actions are stated in a vague and underspecified manner; occasionally they are frankly ambiguous. To achieve a semiformal representation, relevant concepts are iteratively clarified and appropriate codes are identified in relevant standardized vocabularies, e.g., diagnosis codes in SNOMED-CT or ICD-10, laboratory results codes in LOINC, drug codes in RxNorm. Further, the logical relationships between and among decision variables and actions are defined using ANDs, ORs, NOTs, and grouped with parentheses. As these refinements are undertaken, the Guideline Elements Model maintains the original text of the recommendation statement to provide an audit trail against which the final edited recommendation may be compared with the original knowledge source.

Several proposals for a semi-formal representation are being developed by standards development organizations, which include Arden Syntax, HQMF, FHIR, and Health eDecisions. The product of knowledge formalization is one or more IF-THEN rules with decidable conditions and executable actions. In addition, concepts are represented in a standardized vocabulary.

There is a limit to how far centralized guideline development teams, such as those supported by professional societies or healthcare delivery organizations, can go in implementing CDS. Ideally, one would wish that a transformed module could simply be plugged into a local electronic health record system and shared. Unfortunately, many site-specific considerations must be addressed before a recommendation can be instantiated in a CDSS.

6.3 Knowledge Localization

The next step in the development of a decision support rule is one of the more complex ones. Once the recommendations have been expressed in statement logic (IF… THEN format) using structured vocabulary, those statements need to be translated into actionable decision support [12].

Knowledge localization encompasses the activities in which formalized knowledge about appropriate care is introduced into the systems that influence care [2]. Knowledge localization takes into account local resource constraints, workflow analysis, functional capabilities of the electronic health record, and the choice of CDS modality. Localization, by its very nature, cannot be fully standardized. Nonetheless, many implementation considerations may be generalized.

6.3.1 Resource Constraints

Implementation often takes a backseat to design and development of a CDSS. Failure to budget for implementation is common and in many cases, implementation makes use of resources that are left over, rather than allocated when the system is first specified. Clearly, early consideration of implementation needs is critical to project success.

A CDS governance structure that can assure the availability of necessary resources and help to prioritize an implementation plan is critical to CDSS success. Clinical leadership must provide support for introduction of all new technology, including CDS. In planning for adoption, implementers should consider incentives to use the systems, having champions on the ground, and integration of performance measurements. An example of an incentive includes having a form autopopulated that allows school and child care to administer medications when those medications are determined to be appropriate by the CDSS [12]. Likewise, a tablet-based device that collects information relevant to decision making in Spanish or Arabic and transmits its English equivalent into the CDSS facilitates use of the CDS and saves time for providers.

6.3.2 Workflow

Effective deployment and integration of CDSS requires analysis and understanding of current and anticipated workflows. Personnel roles and responsibilities vary greatly from facility to facility. Also, the sequence of activities to achieve a goal is often site-specific as are the resources available. Optimal implementation of CDSS requires careful attention to how and by whom information is collected, processed, and acted upon. Often, reengineering of workflow results in enhanced CDS function. Likewise, failure to optimize workflow can result in project failure.

It is also important to use multiple methods to analyze workflow. Individuals may not always be aware of their own processes or may choose not to share "workarounds" when asked to describe their workflow. Direct observation of processes, though time-consuming, can often provide valuable information. For instance, when implementing CDS that was intended to be used at the point-of-care, we found that documentation necessary to trigger the CDS often did not occur until the

end of the clinic session when the patient had gone home. We addressed that problem by encouraging patients to directly enter relevant data into the CDS. In order to avoid having to repeat data gathering, the clinician would have to open the CDS while the patient was present.

6.3.3 EHR Functionality

Wright et al. have demonstrated that the technical capability of commercial EHRs to deliver CDS varies widely [13]. Triggers to invoke decision support and the types of data that can be used to make inferences may work well in one system but may be unavailable in another.

Even though formalization represents critical CDS elements in standardized vocabularies, many EHR vendors maintain their own proprietary coding systems into which concepts must be re-coded. This recoding provides opportunities to subvert the intent of the original knowledge sources.

6.3.4 CDSS Design

Careful attention to human factors design principles can help to assure that information is presented in a manner that optimizes information transfer and user acceptance. A set of best practices for CDS design is emerging [14, 15]. These standards call for design consistency, concise and unambiguous language, careful selection of modes for providing advice, and organization of information by problem and clinical goal. Since access to appropriate data for evaluation is a key challenge, implementers should plan to incorporate these elements during design.

In 2009 researchers analyzed more than one thousand randomly selected guideline recommendations and found that the actions could be reliably classified into the following 13 categories: “test, inquire, examine, monitor, conclude, prescribe, perform procedure, refer/consult, educate/counsel, prevent, dispose, advocate, and prepare facility/modify structure of care” [16]. They described how these categories of action types for guideline statements can be used to provide design strategies for implementation. For example, design of systems to implement a “test” action might consider presentation of test options/alternatives, test costs, scheduling options, interpretation aids, patient education about the test, requirements for preparation for the test, and a “tickler” follow-up system. Likewise, a “prescribe” recommendation might be supported by presenting the clinician with drug information, safety alerts (drug-allergy, drug-drug interaction), dosage calculation, pharmacy transmission, and corollary orders. Attention to these recurring themes can enhance CDSS design [16].

Strategies for delivery of decision support differ. While primary care clinicians dealing with an unfamiliar problem may welcome a prescriptive approach to CDS

delivery (e.g., "The patient has moderate to severe Condition X for which Drug Y is indicated"), specialists managing a condition with which they are familiar often prefer a critiquing approach in which advice is only provided when a clinician's proposed care differs from actions recommended by the CDSS.

6.3.5 CDS Modalities

CDS can be provided by several modalities. Perhaps the most familiar modality is the *alert or reminder*. If one or more conditions are satisfied, the alert fires within the CDSS. Recent work has indicated that many alerts are perceived as distracting noise by busy clinicians and contribute to a condition known as "alert fatigue" [17]. These users are liable to bypass alerts without heeding the information they contain which has the potential to compromise effective care or patient safety. Care should be taken in employing interruptive alerts and in display of reminders to maximize user acceptance and safe use. Implementers should avoid intrusive CDSS designs wherever possible.

Order sets comprise another frequently used CDS modality. Order sets group information for display and facilitate appropriate choices as CDS users are formulating plans and writing orders. This type of CDS can be highly interactive and display information conditionally based on the user's actions. Order sets have been demonstrated in numerous studies to improve processes and outcomes of care [18]. There is usually a need to get agreement among clinician users as to what orders should be part of an order set. Although this can be time-consuming, it is worth the effort as the order sets can make subsequent use of the system more efficient. For instance, in our GLIDES project, we chose highly respected guidelines published by the National Heart Lung and Blood Institute and in other work, we chose guidelines from trusted professional associations [12].

Visual summaries of recent relevant findings help to organize complex data. Tierney et al. showed that simply presenting physicians with the results of previous tests reduced the ordering of those tests [19]. Likewise, *documentation templates* cue the user to collect and record appropriate information. *Hypertext links* to additional information serve an educational purpose. The *Infobutton* is an HL7 standard that facilitates user-initiated requests for additional information in a context-sensitive manner [20]. *Calculators* can be used to promote accuracy of numeric operations, e.g., calculating a drug dosage in mg/kg or intravenous drip rate. Alternatively, calculators can calculate scores on survey instruments and categorize disease severity based on symptom scores.

6.3.6 *Level of Enforcement*

The level of enforcement of an alert should be tied to the importance of the information being delivered. Guideline-specified *recommendation strength* can be useful to implementers in determining appropriate levels of enforcement. For example, prescribing a drug to a patient known to be allergic to that drug might result in an alert with a high level of enforcement—a hard stop in which further progress is not possible without burdensome data entry or communication with an authorizer. Hard stops should be reserved for uncommon and potentially serious situations. Lower levels of enforcement might simply require the user's acknowledgement of the alert in order to move forward. Finally, some reminders might simply be informational not requiring any activity on the part of the user.

6.3.7 *Participatory Design*

End users should participate in CDSS design and development activities from the outset. Importantly, they should recognize that they represent a class of users and should serve as a bilateral communication medium, bringing subject matter expertise to the implementers and explanation of the evolving CDSS to stakeholders.

Providing users with a benefit for using the CDS helps to gain their acceptance. For example, an asthma decision support system was designed to automatically create and populate a permission form for the use of a rescue inhaler at school or camp. Likewise, we developed decision support for improving prescription of opioids for chronic pain. Once a provider indicates an intent to prescribe an opioid, s/he is reminded about non-pharmacologic interventions (e.g., physical therapy, acupuncture, cognitive behavioral therapy, etc.) and referral is facilitated. In addition, the CDSS provides a link to the guidelines that provide the evidence base for the recommendations and another to the state Prescription Drug Monitoring Program, "Making it easy to do it right" is a useful mantra for implementers to follow [21].

6.4 Evaluation and Learning

CDSS success should be measured against the goals originally identified during Knowledge Synthesis. Once tested and deployed, the implementation team should collect data regarding effectiveness, usefulness,and usability of the CDSS. Use of CDS to guide care results in the generation of new data about how adhering to existing recommendations affects health and healthcare. CDSS evaluation helps to shape new recommendations about appropriate care.

Implementers also learn about the usability of the CDSS by planned evaluation activities. Evaluation can include formal or informal observation of users interacting with the CDSS as well as user surveys to assess system usefulness, ease of use, ease of learning and general satisfaction. Chapter 9 discusses other strategies for CDSS evaluation.

A learning health system effectively captures this information and loops it back to be synthesized with indicators of effectiveness [3]. These new data inform future CDSS design and deployment decisions.

6.5 Summary and Conclusions

Clinical decision support has great promise to improve the health of individuals and to improve the delivery of healthcare across populations. In order to do so, CDSS must be based on the best knowledge available systematically and replicably transformed into formats that computers can process. Careful consideration of local needs and resource constraints determines the ultimate success or failure of the system. Knowledge about best clinical practice must be combined with knowledge about effective implementation.

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