

# Focus on **Implementing Guidelines**

# JAMIA

## Model Formulation ■

## A Design Model for Computer-based Guideline Implementation Based on Information Management Services

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**Abstract** Clinical practice guidelines must be implemented effectively if they are to influence the behavior of clinicians. The authors describe a model for computer-based guideline implementation that identifies eight information management services needed to integrate guideline-based decision support with clinical workflow. *Recommendation* services determine appropriate activities in specific clinical circumstances. *Documentation* services involve data capture. *Registration* services integrate demographic and administrative data. *Explanation* services enhance the credibility of automated recommendations by providing supportive evidence and rating the quality of evidence. *Calculation* services measure time intervals, suggest medication dosages, and perform other computational tasks. *Communication* services employ standards for information transfer and provide data security. Effective *presentation* services facilitate understanding of complex data, clarify trends, and format written materials (including prescriptions) for patients. *Aggregation* services associate outcomes with specific guideline interventions. The authors provide examples of the eight services that make up the model from five evidence-based practice parameters developed by the American Academy of Pediatrics.

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Effective implementation of clinical practice guidelines requires strategies that encourage clinicians to follow recommendations. Mere publication of guidelines usually fails to change the behavior of clinicians.<sup>1–4</sup> Other reasons for failed guideline implementation efforts include flaws intrinsic to some prose guidelines, the inertia of clinician–user behaviors, and defects in implementation strategies.<sup>5</sup>

This paper addresses guideline implementation strategies. Some guideline implementations involve education and feedback outside the clinical encounter setting.<sup>6</sup> However, Grimshaw and Russell<sup>7</sup> found that providing patient-specific advice at the time and place of consultation correlated best with implementation success. While the importance of integrating guideline knowledge with clinical workflow has been docu-

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mented,<sup>8-11</sup> a systematic framework for accomplishing this has been lacking. We have developed a model of information management *services* for implementers to consider in maximizing the usefulness of automated clinical guideline applications. Current approaches often omit one or more of these services.<sup>12</sup>

## Development of a Model to Promote Guideline Workflow Integration

Our model design evolved from three primary activities.

- The Guidelines Review Group (GRG) of the Yale Center for Medical Informatics has collaborated with the American Academy of Pediatrics (AAP) since the fourth quarter of 1996 to analyze and critique the AAP's practice parameters prior to publication or revision. Faculty and postdoctoral fellows of the GRG have expertise in various clinical specialties, in informatics, and in epidemiology, public health, and preventive medicine. The GRG examines guidelines for clarity, comprehensiveness, and consistency; rigor of development; linkages among recommendations and sources of evidence; and potential difficulties in implementation. Examples of AAP guidelines include Office Management of Acute Exacerbations of Asthma in Children (ASTHM),<sup>13</sup> Otitis Media with Effusion in Young Children (OME),<sup>14</sup> Management of Acute Gastroenteritis in Young Children (GASTRO),<sup>15</sup> Management of Hyperbilirubinemia in the Healthy Term Newborn (BILI),<sup>16</sup> and Neurodiagnostic Evaluation of the Child with a First Simple Febrile Seizure (FEB SZ).<sup>17</sup>
- Two authors (R.N.S. and Y.L.) helped design, develop, and evaluate a hand-held computer system that implements a national guideline for outpatient management of childhood asthma.<sup>18</sup>
- The authors performed a systematic review of published, computer-based guideline interventions.<sup>12</sup>

## The Information Management Services Model

We have identified eight critical information management services that can promote guideline integration into clinical workflow, including recommendation, documentation, explanation, calculation, communication, presentation, registration, and aggregation.

### Recommendation

Recommendation services determine the appropriate guideline-specified activities that should occur under

specific clinical circumstances. Ideally, guideline statements can be represented as multiple *if . . . then* rules. Each rule specifies antecedent decision variables and their corresponding states that, when present in aggregate, initiate one or more system or end-user actions—e.g., performing procedures, concluding a diagnosis, or determining a patient's eligibility or unsuitability for specific interventions.

Faithful translation of guideline prose into computer-executable statements is often complex and arduous, because guideline developers may not plan for algorithmic implementation.<sup>19,20</sup> Guideline statements may not address all possible situations comprehensively, or they may provide multiple alternative actions for the same antecedents. For example, the OME guideline covers management of bilateral middle ear effusions but not the relatively common chronic unilateral effusion. The asthma guideline lists three different cut-off values for "acceptable" peak expiratory flow rate (PEFR) measurements, without apparent reason. Some guideline decision variables may be vague or require significant clinical experience to interpret (A and B below); in others, the actions may be ambiguous or absent (C and D below), as these phrases, quoted directly from the guidelines, show: A) "no previously diagnosed major organ system disorders" (GASTRO); B) "a neurologically healthy child with a first simple febrile seizure" (FEB SZ); C) "a child who has had fluid in both middle ears for a total of 3 months should undergo hearing evaluation. Before 3 months of effusion, hearing evaluation is an option" (OME); D) "in a child between 12 and 18 months, a lumbar puncture should be considered . . ." (FEB SZ).

Often, guideline recommendations must be adapted to local resources or needs. The Institute of Medicine noted that "even well-developed guidelines . . . may not foresee significant local objectives or constraints."<sup>21</sup> Conversely, guidelines should not be adapted to protect arbitrary professional or local habits or to service economic self-interests. National guideline developers should openly define acceptable bounds within which local adaptations would be considered appropriate.

In implementing guideline recommendations, the medium may be as important as the message. Dynamically generated alerts and reminders—mechanisms documented as being effective for decision support<sup>22</sup>—represent the most common form of automated guideline implementation. Alternatively, simply providing prompts for recording specific data can remind clinicians to act in accord with guideline recommendations, e.g., to measure PEFR in children with

asthma or to perform pneumatic otoscopy in OME. A critiquing model can allow users to submit a management plan and have it evaluated for guideline adherence.<sup>23,24</sup> Consultation, through which users initiate a request for information from a guideline knowledge source, is less intrusive, but this approach relies on the users' initiative and may prove impractical in busy clinical settings.

Implementers of guidelines must consider how stringently each assertion should be enforced. The strength of scientific evidence that supports each recommendation may sometimes be used to determine the degree of enforcement,<sup>25</sup> as described in the "Explanation" section below.

### Documentation

Documentation services provide for the collection, recording, and storage of observations, assessments, and interventions related to clinical care. One of the grand challenges of medical informatics has been finding ways to promote direct documentation of clinical activities in computer-accessible format by health care professionals.<sup>26</sup> Many current guideline implementation systems utilize paper-based data recording by clinicians and subsequent manual data entry by clerical personnel.<sup>27-30</sup> This "minimally-intrusive" approach fails to provide an opportunity for clinicians to interact with the computer in a manner that supports real-time clinical decision making.

Selection of appropriate data entry modalities to match clinicians' needs and preferences constitutes a critical design issue. How users are prompted to comply with a guideline and the degree to which captured data are structured to optimize automated processing (i.e., avoiding open-ended, free-text responses) influence guideline effectiveness. On-screen graphical entry tools (checkboxes, listboxes, radio buttons) and more sophisticated (e.g., Web-based Java) data collection templates can offer standardized, efficient means for recording data in a structured format. Whatever the data capture mechanism, it is important to ensure that eligibility and exclusion criteria are met.

### Registration

Registration services record and store administrative and demographic data, identifying the patient, provider(s), and encounter, in contrast to clinical data. Registration services are necessary to provide patient-specific data collection and advice. Providing registration functions often requires special efforts, including interfaces to legacy systems and to health plan eligibility data.

### Explanation

Users may be less likely to accept guideline recommendations if they do not understand their components or agree with the rationale underlying them.<sup>31</sup> At the same time, system designers must be wary of overloading users with information that is not perceived to be useful.

Explanation services provide definitions, examples, costs, and measures of quality for guideline decision variables and for recommended actions. Explanation services also explain the rationale for the guideline (e.g., evidence from expert panels and literature citations). Evidence-based guidelines should explicitly link recommendations with assessments of evidence quality. In many cases, however, quality of evidence is not the sole determinant of the imperative power of a recommendation.<sup>32</sup>

Explanation services can be used to define rule antecedents and actions uniformly and thereby enhance consistent clinical practice. Increasingly, evidence-based guidelines describe test characteristics in a quantitative manner, as in this example from the OME guideline:

The positive predictive value for middle ear effusion of a flat (Type B) tympanogram (i.e., the likelihood that an effusion is present if the tympanogram is abnormal) has been found to be between 49 and 99 percent. . . .

Explanation services may also provide pragmatic information about carrying out an intervention, as in the ASTHM:

There are different methods of administering aerosol therapy which significantly alter the dose administered. These include the amount of diluent used with the  $\beta$ -agonist. It is generally recommended that the final volume should be between 2 and 3 mL. . . .

### Calculation

Clinicians perform a variety of mathematical operations that can be time-consuming and, when completed manually, can introduce errors. Automated calculation services can efficiently and accurately determine temporal intervals (e.g., duration of middle ear effusion as the difference between initial presentation and current encounter dates), suggest medication dosages (e.g., based on a child's weight or body surface area), and perform more complex calculations. For example, the rate of rise in serum bilirubin is important in selecting appropriate therapy for neonatal

hyperbilirubinemia, and the predicted PEF, used for determining the severity of an asthma exacerbation, is a third degree polynomial function of height.

### Communication

Communication services provide rapid, accurate, and widely accessible electronic message transfers that facilitate information exchange among clinicians (e.g., referring physician and consultant), between the laboratory and clinicians, and among administrative entities. In a guideline implementation application, recommended actions often translate into the preparation of medical orders (e.g., prescriptions), device orders, and return-appointment requests. Limitations imposed by managed care must be handled (choice of medications, testing facilities, care providers). Standards for message passing and common vocabularies are essential. For example, the BILI guideline requires ordering measurements of an infant's total serum bilirubin, Coombs testing, tests for hemolysis, and a review of maternal blood type. These may be performed at any of several hospital or free-standing laboratories, each of which may use a wide variety of software and computing platforms. To be interpreted correctly, the results of these studies must be returned to the clinician and integrated with information about the child's age and clinical status. Because the use of paper records remains pervasive in the current health care environment, guideline implementers may need to provide reliable transfer and entry of paper-based information via document scanning, facsimile transmission capture and conversion, and similar means. Finally, communication services must secure confidential information while facilitating necessary communication tasks.<sup>33</sup> Technologic security services can provide for authentication, access control, and audit trails to promote the security of individual health data.

### Presentation

Presentation services facilitate understanding of complex data, clarify trends, and format written materials (including prescriptions) for patients. A body of accumulated research is available to help designers facilitate data visualization.<sup>34,35</sup> Effective presentations may include graphic plots of laboratory test results (e.g., line graphs to portray the effectiveness of phototherapy in reducing serum bilirubin in newborns) or flowcharts (e.g., illustrating the degree of hearing deficit over time by associating physical findings, tympanometric results, and audiometric measurements in patients with otitis media with effusion). Similarly, creating frequently used report templates (e.g., for prescriptions or aftercare instructions for parents of children with acute gastroenteritis) can both facilitate clinical care and enhance data capture.

### Aggregation

Aggregation services associate outcomes with specific guideline interventions. Aggregation derives population-based information from individual patient data and can help validate (or invalidate) guideline assertions or profile the adherence of providers to specific guidelines. The data required for functional status assessment are often distinct from the clinical observations required to trigger guideline logic and from those necessary for completion of a clinical note. It is important to collect data on disease-specific physiologic outcomes, health-related quality-of-life variables, and economic information.<sup>36</sup> For example, an understanding of outcomes following an asthma exacerbation may require data collection regarding the number of missed school days and the child's ability to participate in sports activities—historical items that may not be collected routinely.

Several AAP guideline development committees noted that the evidence base for certain guidelines was incomplete. Providing aggregation functionality can help researchers better understand the outcomes associated with guideline-recommended processes of care.

### Discussion

Elson<sup>37</sup> notes that "Just as the three most important considerations in real estate are 'location, location and location', the three most important determinants of implementation success are 'workflow, workflow and workflow'." We believe that designing computer applications that provide effective recommendation, explanation, calculation, communication, documentation, registration, presentation, and aggregation information management services will promote workflow integration and improve the likelihood of a successful guideline implementation strategy.

The services model can be used as a checklist for developers of computer-based guideline implementation solutions. Alternatively, the model provides constructs by which guideline implementations can be evaluated.<sup>12</sup> A questionnaire based on information management services is currently being used to analyze satisfaction with AsthMonitor, a computer-based asthma-guideline implementation application.

The information management services model does not represent an exhaustive listing of requisites for an effective guideline implementation system, but it offers a framework to promote workflow integration for development and evaluation of computer-based guideline implementations.

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