

Editorial Comments ■

Pragmatics of Implementing Guidelines on the Front Lines

LEMUEL R. WAITMAN, PhD, RANDOLPH A. MILLER, MD

■ *J Am Med Inform Assoc.* 2004;11:436–438. DOI 10.1197/jamia.M1621.

We commend Shiffman and colleagues (“Bridging the Guideline Implementation Gap: A Systematic, Document-Centered Approach to Guideline Implementation”¹) for highlighting the challenges of integrating guidelines into clinical practice and proposing pragmatic mechanisms for addressing them. We note, however, that the approach advocated by Shiffman et al., as well as by numerous other groups recently,^{2–8} is fundamentally a document-centric model. This approach may lead others to assume that representing a guideline correctly as a “computer-readable” document is the majority of the work required for implementation success. Although the “understanding” and representation of the clinical content of a guideline are a *sine qua non* for its local implementation, the document-centric approach leaves a substantial gap between the idealized document model and any specific guideline implementation in a local clinical system. This considerable gap is not unlike the “curly braces” problem documented for the Arden Syntax a decade ago.^{3,5} We estimate that 90% of the effort required for successful guideline implementation is (and must be) local, and the remaining 10% of the effort involves “getting the document right.”

We believe that an alternative approach to local guideline implementation is to focus on the guideline’s recommended actions; on the capabilities of the local care provider order entry (CPOE) or electronic health record (EHR) system that will serve as the “effector mechanism” for the guideline; on locally available computational and clinical resources; and on the guideline’s required “clinical infrastructure.” We believe that guidelines should be implemented locally and directly (with a systematic approach, as described below) via local clinical systems (as opposed to a quasi-automatic implementation using a computer-readable, nationally disseminated document). The goal of both the “document-centric” and the “locally customized and guided” approaches is the same: implemen-

tation of locally effective guidelines that appropriately influence clinical decision making, resulting in desirable actions that improve patient outcomes.

Local guideline implementation requires the following understanding, resources, and efforts:

1. **A local, clinically expert champion (or group of champions) who will customize the national guideline to be compatible with local capabilities and practices and, more importantly, take ownership of guideline evolution locally over time.** While national-level guidelines should form the basis of evidence-based practice, the unfortunate truth is that national guideline developers rarely reconvene to systematically update guidelines in a timely manner. Unless local experts take responsibility for guideline implementation in the present, and for future updates, the institution where a national guideline is implemented over time becomes at risk of practicing “the ‘perfect’ medicine of bygone eras” (e.g., national standards from 5 to 10 years ago).
2. **A locally developed consensus among clinicians across services on how to implement each guideline** (e.g., across Medicine, Surgery, Obstetrics/Gynecology, Pediatrics, Emergency Department). This may include modifying the national guideline in various ways:
 - a. **Guideline distillation and presentation.** What are the resulting local actions (orders) of the guideline? After focusing on the orders, determine whether the conditional statements qualifying the orders lend themselves to explanatory text or whether a more sophisticated “advisor” program with complex calculations is required. The choices may result in implementation of a simple guideline (e.g., evidence-based “pick-lists” specifying care options for a patient admitted with acute coronary syndrome) as an “order set.”⁹ Order sets for the most part leave “branching logic” choices up to the end user by providing textual instructions over each subsection of orderables (e.g., “Select one of the following beta-blockers that is most appropriate for the patient from the list below.”). In contrast, another, more complex guideline might require implementation as a programcode-based algorithm (“advisor”) that calculates patient-specific doses and recommendations based on known patient demographics, clinical parameters (e.g., renal function, current orders, clinical diagnoses, weight, height), and laboratory results (e.g., coagulation studies, renal function tests, serological results). For example, Web-based advisors are helpful for

Affiliations of the authors: Department of Biomedical Informatics, Vanderbilt University Medical Center, Nashville, TN.

The authors thank Elizabeth Madsen of Vanderbilt University for her editorial expertise in proofreading and editing this manuscript.

Correspondence and reprints: Lemuel R. Waitman, PhD, B003 Eskind Biomedical Library, 2209 Garland Avenue, Vanderbilt University Medical Center, Nashville, TN 37232-8340; e-mail: <russ.waitman@vanderbilt.edu>.

Received for publication: 06/08/04; accepted for publication: 06/09/04.

ordering multicomponent total parenteral nutrition in a neonatal intensive care unit, which requires careful balancing of electrolytes, fluids, caloric sources, and involves many patient-specific "rules." Web-based advisors are also helpful for combining complex textual instructions with patient-specific calculations such as for antibiotic selection and dosing based on clinical indications. Note, however, that hardware and software issues locally may influence guideline implementation choices. An old MS-DOS® character-based interface cannot support the bandwidth for complex advisors that a Web-based, multitiered architecture can support, but the former may be at least as good for implementing simple pick-lists.

- b. **Guideline interpretation/translation locally.** How are radiology procedures and the pharmacy formulary represented locally in contrast to the text in the guideline? What orderables inferred in the guideline can actually be ordered in the local clinical system? (e.g., if Doppler studies of the legs are suggested in a guideline for "diagnosis and treatment of suspected deep venous thrombosis," does the local system allow unilateral or bilateral Doppler ordering and in a manner that is consistent with guideline recommendations?) Do new orderables need to be added or will comments or additional parameters within existing orders suffice to fulfill guideline requirements?
- c. **Guideline creation based on informed decision making about optimal local methods.** Having decided on the appropriate orderables (actions) and whether to create the guideline as an order set or an advisor, what additional details must be specified? If the guideline is best implemented via order sets, should there be a single order set or several linked (nested) order sets (e.g., a main order set and another order set for medications that might already have been created for a different purpose)? If the guideline is more complex, and a multifaceted "advisor" is necessary, can the advisor be simple and one pass (e.g., total parenteral nutrition ordering in a neonatal intensive care unit) or will it involve multistage "component" advisors? For example, for an "anticoagulation advisor," the initial phase might consist of ordering deep venous thrombosis prophylaxis for "normal" patients at bed rest. The next phase might involve ordering the correct diagnostic procedures, baseline laboratory tests, and "coverage" anticoagulants for patients with "suspected deep venous thrombosis." The next phase should advise users how to initiate "definitive therapy" per national guidelines once a diagnosis of "deep venous thrombosis" is firmly established. Finally, the last phase might consist of adjusting heparin (or low molecular weight heparin) doses per national guidelines after initial therapy was ordered, based on follow-up information (such as activated partial thromboplastin test results for monitoring heparin dosing). Such multistage protocols must "recognize" the previous state of the patient in the sequence of the protocol, as well as be able to "trigger" the next step on appropriate cues. Often, for such complex guidelines, the code underlying the clinical system may also have to be modified to handle such convoluted, multistage protocols if they are "new and unique" in the experience of the

CPOE or EHR system. The approach taken will depend on the resources available, the style of the institution, and the capabilities/flexibilities of the clinical system.

3. **A host of reference material supporting guideline implementation.** With respect to run-time guideline activation, many reluctant clinicians take a "show-me" stance. In such settings, helpful "educational" links explaining both the rationale for the guideline's suggestions (i.e., the "evidence base" for the guideline) as well as detailed explanations of the procedural steps involved in implementing the guideline, including explicit displays of the calculations/logic performed by the program in a patient-specific manner (e.g., dose calculations) are required. Internet and intranet links to national Web sites, locally maintained "expert" monographs, and documents that describe local hospital policy and procedures must support local guideline implementation. Such references require local maintenance above and beyond any "national" guideline content maintenance per se.
4. **An organized set of ancillary "EHR system-based" information relevant to clinicians' thought processes to support their attempts to follow a guideline.** For example, if the information related to the guideline requires concurrent awareness of active orders, medication doses, laboratory results, etc. (as might occur for a heparin therapy advisor), how will the information be obtained and displayed in "real time" using the underlying CPOE or EHR system as part of the "guideline display page" so that the clinician has "one stop shopping" for guideline-related decision making? There are no pragmatics at the national level for how to do this in individual local systems.
5. **A method for advertising the availability/applicability of the guideline for appropriate user groups.** This might consist of
- Placing a guideline order set (if it exists in this form) in the default list of selectable order sets for nursing units** on which the guideline is likely to be applicable.
 - Automatically triggering** the order set or advisor based on when the user enters specific orders or when specific real-time laboratory results occur. This ability is dependent on the flexibility of the clinical system.
6. **A set of parameters and methods for tracking and measuring guideline effectiveness.** If the CPOE (local guideline implementation) system does not distinguish in its "log files" (system database) which orders were entered "free hand," which orders were entered via which "order set," and which orders were created using a specific "advisor program," then determining the situations in which guideline suggestions were being followed may become difficult or impossible. Guideline implementers must be able to determine both when a user was prompted to follow a guideline and whether the user chose to do so (and optimally to record why a guideline suggestion was not followed through user-generated explanatory text). The mechanics of doing so are dependent almost wholly on the local system and cannot be specified as part of a nationally distributed "reference guideline document" that is quasi-automatically incorporated into a system (although this might be possible for groups of users using the same clinical system). In addition, because a published guideline

is a snapshot in time, local changes in practice and expertise may lead to subsequent customization of some guidelines, so a mechanism for "versioning" both guidelines and their effector order sets and advisors is required in the local clinical system.

The above-described tasks highlight the guideline disseminators' and guideline implementers' mutual problem: Although there is a desire to have a "top down," document-centric representation that fully describes each guideline, such representations cannot offer pragmatic, easily assimilated, maintainable, and actionable mechanisms for guideline incorporation into local production systems, nor can they do so in a manner that effectively integrates the guideline into local workflows. Pryor and Hripcsak's¹⁰ sharing of "rather simple" Arden syntax medical logic modules (MLM) between two institutions a decade ago began to reveal the magnitude of effort required for local integration. In their example, seven MLMs required 43 modifications to be translated between two systems that had already "adopted" the ASTM-standard MLM. A decade later, their conclusion is still applicable: "Standards can be of great assistance in sharing the work of many, but the routine sharing of medical knowledge may be delayed until common standards exist not only in the description of the logic but in all aspects of the medical information system."

As Bates¹¹ suggests, simplicity in implementation often is most effective. Clinical end users sometimes resent overly complex, multiple-screen advisors even when they convey best practices. In implementing clinical systems, it is important to remember that the clinician-user is both more intelligent and more knowledgeable and understanding of the patient's condition than is the clinical computer system. If one relies on the intelligence of the end user (clinician) as a component of guideline implementation and execution, very simple guideline representations, such as order sets, may suffice. Additionally, clinicians should have the ultimate discretion in patient care, including guideline implementation. There are more exceptions than rules in clinical practice. As long as clinicians are made aware of relevant guidelines "just in time" during patient care activities, "optimal" guideline compliance rates may be 80% and not 100% due to patient-specific factors not considered by guideline developers. Effective guideline implementation is hopelessly intertwined with considerations based on local clinical applications, local clinical practices, and local control of procedures and policies as they evolve over time.

National document-centric representations of guidelines, although helpful and important, must be seen as supporting the local pragmatics of implementing guidelines on the front

lines, and increasing emphasis should be placed on the latter. The situation is not hopeless in that the work that local institutions must do to adopt and maintain guidelines can sometimes be shared "locally" among hospitals and clinics belonging to a conglomerate "system" that share a common information system infrastructure or "locally" among the "user group" of a national vendor with multiple install sites, all of whom presumably share the same implementation platform. The best methods for evolving and supporting guidelines, once they are "installed" will remain an active area of both research and practical interest as EHR and CPOE systems become more ubiquitous.

References ■

1. Shiffman RN, Michel G, Essaihi A, Thornquist E. Bridging the guideline implementation gap: a systematic, document-centered approach to guideline implementation. *J Am Med Inform Assoc.* 2004;11:418-26.
2. Peleg M, Boxwala AA, Tu S, et al. The InterMed approach to sharable computer-interpretable guidelines: a review. *J Am Med Inform Assoc.* 2004;11:1-10.
3. Sutton DR, Fox J. The syntax and semantics of the PROforma guideline modeling language. *J Am Med Inform Assoc.* 2003;10:433-43.
4. Maviglia SM, Zielstorff RD, Paterno M, Teich JM, Bates DW, Kuperman GJ. Automating complex guidelines for chronic disease: lessons learned. *J Am Med Inform Assoc.* 2003;10:154-65.
5. Peleg M, Tu S, Bury J, et al. Comparing computer-interpretable guideline models: a case-study approach. *J Am Med Inform Assoc.* 2003;10:52-68.
6. Shiffman RN, Karras BT, Agrawal A, Chen R, Marengo L, Nath S. GEM: a proposal for a more comprehensive guideline document model using XML. *J Am Med Inform Assoc.* 2000;7:488-98.
7. Shiffman RN, Liaw Y, Brandt CA, Corb GJ. Computer-based guideline implementation systems: a systematic review of functionality and effectiveness. *J Am Med Inform Assoc.* 1999;6:104-14.
8. Patel VL, Allen VG, Arocha JF, Shortliffe EH. Representing clinical guidelines in GLIF: individual and collaborative expertise. *J Am Med Inform Assoc.* 1998;5:467-83.
9. Payne TH, Hoey PJ, Nichol P, Lovis C. Preparation and Use of Preconstructed Orders, Order Sets, and Order Menus in a Computerized Provider Order Entry System. *J Am Med Inform Assoc.* 2003;10:322-9.
10. Pryor TA, Hripcsak G. Sharing MLM's: an experiment between Columbia-Presbyterian and LDS Hospital. *Proc Annu Symp Comput. Appl Med Care.* 1993:399-403.
11. Bates DW, Kuperman GJ, Wang S, et al. Ten commandments for effective clinical decision support: making the practice of evidence-based medicine a reality. *J Am Med Inform Assoc.* 2003;10:523-30.