

# Standards-Based Sharable Active Guideline Environment (SAGE): A Project to Develop a Universal Framework for Encoding and Disseminating Electronic Clinical Practice Guidelines

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## ABSTRACT

*A multi-site, collaborative, research and development project has been initiated to develop a standards-based, comprehensive technology infrastructure that will enable encoding and dissemination of interoperable, electronic clinical practice guidelines. The goal of this project is to provide technologies with which 1) Health care organizations can author and encode guidelines in a standard electronic format, and 2) Health care organizations throughout the nation can deploy those guidelines easily within any standards-conforming clinical information system. Three key deliverables of this large scale (\$18M), 3-year project include: An interoperable guideline model, a guideline authoring/encoding workbench, and a guideline deployment system. Our approach will be to employ (and extend where necessary) existing informatics standards, and to collaborate closely with standards development organizations. The project methodology will build on earlier efforts in this field, and will be driven by requirements specific to supporting active deployment of guideline content within clinical information system workflow.*

## Problems with the Quality of U.S. Healthcare

The Institute of Medicine (IOM) defines quality of care as “the degree to which health services for individuals and populations increase the likelihood of desired health care outcomes and are consistent with current professional knowledge.”<sup>1</sup> As we enter the 21<sup>st</sup> century, a growing body of literature<sup>2,3,4,5,6</sup> describes problems related to the quality of health care delivered in the United States. Overuse and underuse of services, combined with errors and variability

in health care contribute to disappointingly low ratings<sup>7</sup> of U.S. healthcare on Year 2000 World Health Organization assessments. In 2001, IOM recommendations<sup>8</sup> to address healthcare quality included a “comprehensive program aimed at making scientific evidence more useful and accessible to clinicians and patients”, accompanied by an infrastructure that supported dissemination of evidence and guidelines and decision support tools to assist clinicians in applying the evidence.

## Clinical Practice Guidelines

Clinical practice guidelines (CPG's) are “systematically developed statements to assist practitioner and patient decisions about appropriate health care for specific clinical circumstances.”<sup>9</sup> CPG's have become an important tool for a new paradigm of clinical practice known as evidence-based medicine (EBM), which integrates best research evidence with clinical expertise and patient values. Guidelines have attracted intense interest from various sectors of the U.S. and international health care industry because of the widespread belief that they can improve patient safety, improve the quality of care, reduce the variability of care, and reduce the costs of care.

Despite a substantial level of interest, CPG's have yet to realize their potential to improve patient safety, improve quality, and reduce costs because they have failed to influence clinician behavior significantly<sup>10,11,12,13</sup>. Infrastructure-related reasons for this are:

1. Most guideline content today is distributed in the form of electronic (or worse, hardcopy) *documents*, (e.g., PDFs, text, flowcharts). To access these documents, clinicians must interrupt their

normal workflow to locate, read, assess, and act upon them.

2. Wide-spread distribution of computable CPG content (i.e., guideline content that could be instantiated through clinical information system (CIS) functions) is currently prevented by severe infrastructure challenges such as lack of standards for representation of medical knowledge and wide disparity among clinical information systems throughout the country.

### **Interoperable, Computerized Clinical Guidelines: The Potential and the Challenge**

Reviews of the effectiveness of various methods of dissemination of guidelines show that computer-based, patient-specific CPG content integrated into the clinician's workflow achieve the strongest impact<sup>14,15,16,17</sup>. For example, a systematic review of 68 controlled trials confirmed that computerized decision support systems could significantly enhance clinical performance in the areas of drug dosing, preventive medicine, and other areas of medical care.<sup>18</sup>

Organizations that have demonstrated that patient-specific, computer-generated guidance can improve physician compliance with guidelines have done so only on a local basis. Some commercially available software packages for electronic medical records can generate simple rule-based patient-specific reminders, but the technology is rudimentary in the following aspects:

- "Guidelines" implemented with computer-generated reminders tend to be simple, often consisting of a single if-then statement.
- Implementation of even simple guidelines requires hospitals to enlist experts that can program in high-level software languages.
- There is no simple method to import guidelines authored by outside institutions. No institution can, for example, import guidelines from the National Guideline Clearinghouse into its clinical information system.
- There is no easy way for a hospital to adjust or update an imported guideline.

As a result, very few medical organizations (approximately 1%) have implemented computer-based guidelines.

Efforts to date have been less-than-successful in having substantial effects on national care-quality indicators in part because they have typically been undertaken in the absence of a comprehensive

framework for the creation, dissemination and deployment of CPGs.

What might such a comprehensive CPG infrastructure framework look like? Consider the following 'scenario':

1. A guideline author or editor collects the source material required for the guideline to be rendered into electronic, distributable form. This may comprise textbooks, research papers, textual guidelines, paper-based flowcharts, etc.
2. The author/editor, perhaps with assistance of a knowledge engineer, uses a "guideline editor's workbench", to encode an electronic version of the guideline(s) envisaged. This workbench would provide assistance, such as guiding the author to correct logical inconsistencies or workflow 'dead ends.'
3. The guideline, once encoded, would be stored in a designated location, such as a website, managed by a not-for-profit organization, a professional body (such as a medical specialty college), or perhaps a commercial organization.
4. An individual or team of clinical practice specialists at a specific healthcare delivery organization would 'download' one or more guidelines. The guidelines would be clearly comprehensible to 'computer-disinterested' clinicians, and free of the gratuitous hieroglyphics that sometimes plague computer-based representations of clinical knowledge. The dependencies of the guideline on specific enterprise resources (e.g., 24 hour access to emergency MRI or cardiac echo services) that may render the guideline difficult to implement in, for example, remote rural locations would be explicit.
5. Upon local approval of the guideline, (according to the clinical governance structures of the local organization) the guideline may need to be adapted prior to deployment. This may entail substantive changes to the clinical content of the guideline. It may also entail adaptation of nomenclature (e.g., use of trade names for drugs rather than generic names) or specific local terms for laboratory investigations. In addition, adaptation to the particular local clinical information services may be required. For example, the local CIS may not support features anticipated by the guideline, such as automatic messaging to pagers, or physician order entry. Local adaptation of guidelines would be undertaken using a tool simi-

lar to the workbench used for the ‘central, initial’ guideline creation; adapted to support certain local requirements, such as the maintenance of ‘libraries’ of local terminologies etc. Upon conclusion of the local adaptation of the guideline, the guideline would be ‘installable’ into the local CIS environment.

6. After ‘upload’ to the local CIS, the CPG(s) would be ‘activated,’ such that they would begin to have a potential clinical impact, through such mechanisms as providing alerts and reminders, order-critiquing, etc. Ideally, the guidelines would be deployed in a manner that automatically recorded each time the guideline ‘intervened,’ and the consequences of the intervention (recommendations accepted, ignored, etc) to facilitate subsequent guideline evaluation.
7. The impact of the guideline(s) would be evaluated, and where necessary the guideline may be adjusted locally. Version management services would be necessary, both within the local workbench, and within the local CIS.
8. A feedback mechanism would be necessary, to enable local evaluations of guideline impact to be reported to the ‘central’ organization, whether that was a not-for-profit or a commercial enterprise.

The components of the framework needed to enable this vision to become a reality are illustrated in Figure 1. This requires the simultaneous and integrated solution of three significant challenges in clinical informatics: (1) Creation, (2) Representation, and (3) Deployment of shared clinical knowledge in the form of computer-interpretable guidelines. Additionally, we must devise informatics-based information system solutions that will allow true “interoperability” of clinical guidelines, to enable widespread dissemination of guidelines and their adoption, adaptation, and use by individual health care delivery organizations using disparate clinical information systems.

### Description of the SAGE Project

The goal of the SAGE project is to enable the interoperability of computerized clinical practice guidelines. Specifically, we will develop infrastructure and software technologies with which:

- Health care organizations can author and encode CPG’s in a standard electronic format.
- Health care organizations throughout the nation can deploy those CPG’s easily within any standards-conforming clinical information system.

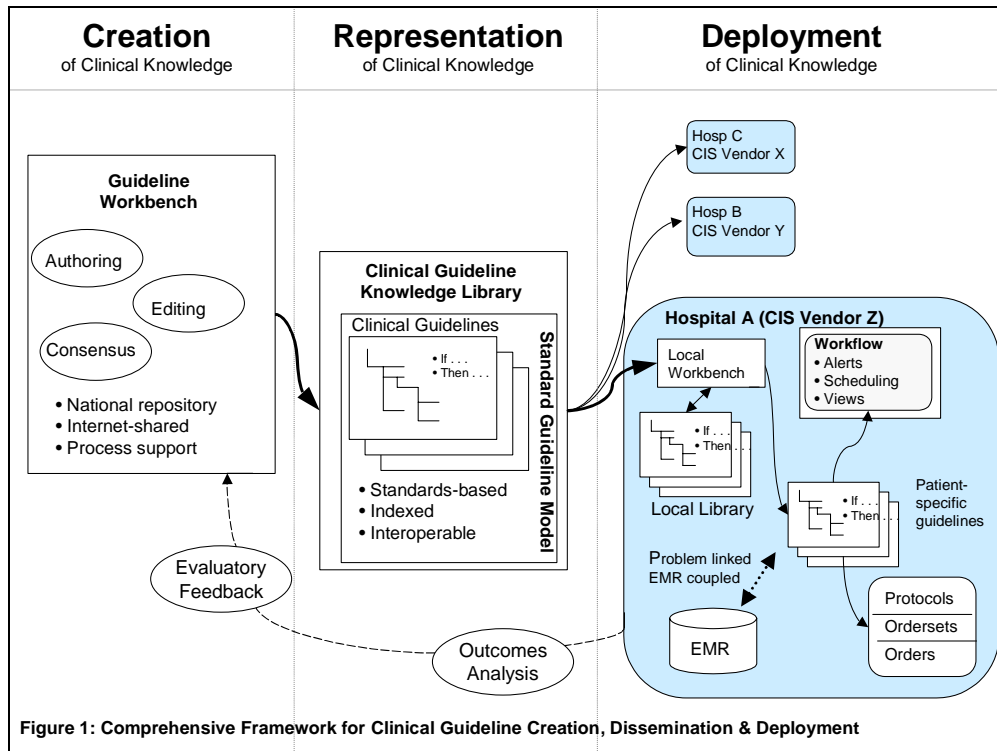
The SAGE infrastructure will support guidelines ranging from the simple (e.g., “check potassium level prior to administering Digoxin”) to complex (e.g., a guideline for management of complicated diabetes that maintains knowledge of a patient state across multiple visits). It will model and deploy guidelines spanning a breadth of domains, including acute care, chronic care, and clinical trial protocols. The SAGE infrastructure will present guidelines to clinicians through active recommendations, such as sets of clinical orders, or assessment-based care plans, and will also support access to explanatory flow-chart views and guideline-specific evidence-based rationale. To achieve this goal, the SAGE technology infrastructure will comprise three main components:

1. An *interoperable Guideline Model*, a standard, computable format for representing CPG content (including logic, goals, rationale, references, etc). Our approach will be to build on the strong foundation of earlier efforts in this area (e.g., Intermed/GLIF<sup>19</sup>, EON<sup>20</sup>, Prodigy<sup>21</sup>), driven by a focus on what is required in a guideline model to support active deployment of CPG content within CIS workflow. Our interoperable guideline model will therefore incorporate standards-based representation of generic CIS functions. We will also employ (and extend where necessary) existing informatics standards (e.g., SNOMED, LOINC) for representation of medical knowledge, and collaborate closely with standards development organizations (e.g., HL7), in this effort.

2. An *interoperable Guideline Workbench*, a software tool for authoring, editing, encoding, and maintaining guidelines in the format of the guideline model. In this area as well, we will build on earlier work, such as the Protégé knowledge-authoring environment.<sup>22</sup> Functions of the guideline workbench will include:

- Knowledge data acquisition
- Resource (knowledge base) library management
- CPG version control and library management
- Encoding/decoding of CPG content
- Consensus management
- Rule verification and integrity checking

3. *Interoperable Guideline Deployment Software*, which will enable a commercial CIS to receive and execute interoperable guidelines. The deployment system comprises two main components, an Administrative Subsystem – CIS independent, and an Execution Subsystem – software that will be specific to a particular CIS. To support our goal of interoperability, we will seek to maximize CIS independent components of SAGE infrastructure.



Planned key components of the Administrative Sub-system include:

- a) An execution server client– providing guideline administration and operation services.
- b) A guideline local editor – to allow modification of guideline content required by local conditions or constraints.
- c) A guideline mapping module – which maps resources (e.g., data, concepts, logic) represented in the guideline to resources available in the local CIS.

Planned key components of the Execution Subsystem include:

- a) A guideline compiler – to transform CPG instructions from standard interoperable guideline format to CIS-specific “language” and messages.
- b) An execution server – which will communicate with the guideline compiler and control execution of CIS functions necessary to operationalize the guideline.
- c) A resource manager – to provide access to local databases and tables in the target CIS.

### Project Progress to Date

In general the four main phases of the 3-year project will be: 1) Requirements and technical specifications, 2) Guideline Model, 3) Guideline Workbench, 4) Guideline Deployment System.

A substantial part of the effort in Year 1 (2002) of the SAGE project has been directed to a comprehensive, tiered requirements definition process<sup>23</sup>. We have employed an innovative approach to requirements, in which the first tier is a use-case analysis of the experience of the “clinical” user when a CPG is in operation. Subsequent requirements analysis tiers connect each specific instance of a guideline interaction with:

- a) The CIS functions required to enable that interaction.
- b) The guideline model elements required to inform the specific CIS function.
- c) The guideline workbench functions required to encode the specific guideline model elements.

In this manner, requirements for the guideline model and the guideline workbench are driven by the initial analysis of the needs for instantiating a guideline within a clinical information system.

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