GDSI: A Web-Based Decision Support System to Facilitate the Efficient and Effective Use of Clinical Practice Guidelines

Douglas C. Stahl*, Layla Rouse, Dave Ko, and Joyce C. Niland
Division of Information Sciences, City of Hope National Medical Center Duarte, CA 91010
dstahl@coh.org, lrouse@coh.org, dko@coh.org, jniland@coh.org

Abstract
Clinical Practice Guidelines (CPGs) are systematically developed healthcare recommendations designed to improve quality and control costs by reducing errors, minimizing practice variability, and promoting best practices. Although considerable effort and resources have been applied to CPG design, development, and deployment, the impact of CPGs on clinician behavior is inconsistent at best. The biomedical literature suggests that CPG efficacy could be improved using information systems that make CPGs and related patient-specific decision support functions available and easier to use at the point of care. This approach also depends upon the ability to integrate CPG information systems into the clinician workflow.

Based on an analysis of the barriers to efficient and effective guideline use, researchers from City of Hope National Medical Center’s Division of Information Sciences were motivated to develop a Web-based expert system to facilitate CPG utilization in a variety of clinical environments.

The resulting Graphical Decision Support Interface (GDSI) employs a relational database-driven state machine architecture adapted from an instrument control system developed by one of the authors. The user interface was designed to facilitate clinician interaction with large, complex decision hierarchies. As users enter information about an individual patient, the system computes additional derived values and provides context-specific recommendations. It also documents when and why clinicians intentionally deviate from guideline recommendations to assist with organizational benchmarking and CPG modification efforts. This report describes the GDSI prototype and our experience with the translation of breast cancer treatment guidelines into algorithms with explicit states and decision points. It also describes a pilot study of the system at two Southern California cancer treatment facilities. Preliminary results suggest that the GDSI system is well received among clinicians and is capable of making a positive contribution toward CPG development and use. Lessons learned and directions for future research are also discussed.

1. Introduction
Clinical practice guidelines (CPGs) are systematically developed statements designed to assist practitioners and patients with decisions about appropriate healthcare for specific clinical circumstances [1]. Over the last several decades, the need to improve patient care outcomes, reduce practice variability, and control costs has motivated the development of a large number and variety of CPGs [2], many of which are now publicly available on the Internet [3]. Although the promise of CPGs, especially automated ones, to reduce practice variability and improve outcomes is great [4], there continues to be considerable variation in the effectiveness of CPGs to bring about change in the behavior of clinicians [2,4,5]. Despite the considerable effort and resources invested in CPG development and dissemination, many clinicians still ignore them [5].

A medical error is defined as the failure of a planned action to be completed as intended or the use of an incorrect plan to achieve an aim [6]. A 1999 Institute of Medicine report entitled To Err is Human: Building a Safer Health System attributes over a million injuries and 44,000 to 98,000 deaths per year in the U.S. to medical errors. Other costs include lost income, expense of additional care resulting from the errors, and loss of confidence in the healthcare system. Since the goal of safe, high-quality, cost efficient care is shared among clinicians, payers, and policymakers, and since information technology has the potential to improve evidence-based practice through computer-based delivery of and interaction with CPGs, a more detailed analysis of the barriers to CPG use is presented in the following section.
2. Barriers to the Use of Clinical Practice Guidelines

It is important to note that some of the barriers to CPG usage cannot be addressed directly with information technology. These barriers include [4,7]:

- Gaps and inconsistencies in the literature supporting one guideline over another.
- Differences in the biases and perspectives of guideline authors, resulting in guidelines of variable quality and conflicting recommendations.
- Physician disagreement.
- Inertia associated with traditional practice behavior.
- Lack of incentives (or disincentives) to change.
- Noncompliance associated with lack of education, cost, and / or side effects of recommended treatments.

In addition to these “non-technical” issues, problems with the dissemination of CPGs are frequently cited as a major reason for their failure to impact practice [2]. Even when acceptable to providers and patients, guideline content must be easily accessible at the point of care. If CPGs are accessed after the fact, the benefit may be lost once a patient leaves the office [4]. Since clinicians at the point of care may not accept CPG recommendations at face value, the rationale for each CPG should be clearly stated with supporting references. Although this knowledge is often implicit in the guideline itself, making it explicit can improve acceptability among clinicians [2].

Another frequently cited reason for poor compliance with guidelines is difficulty with the application of CPGs designed for populations of patients to the case of a particular patient [2]. Searching pages of text to locate a recommendation for a specific individual is not considered to be practical in today’s healthcare environment. CPG systems must therefore be easy to use and no more time consuming than traditional methods. Workflow integration is also critical for effective CPG implementation. To be accepted, guideline systems should provide something of value (e.g. patient handouts, references to the medical literature, reports, patient-specific reminders) to offset the inconvenience of using them [4,5].

3. Strategies for Minimizing the Barriers

Reviews of the effectiveness of various guideline dissemination methods show that the maximum benefit is achieved when CPGs are made accessible through computer-based, patient-specific reminders that are integrated into the clinician workflow [2,5]. However, when describing “computerized” CPGs, there is still a lack of consensus about what “computerized” means [4]. In general, the level of information technology that can be applied to CPG automation depends upon organizational culture, the characteristics of individual clinicians, and the organization’s information technology infrastructure [2].

At the most basic level, CPG automation describes access to electronic versions of text-based guidelines. Such access can now be made widely available to an entire practice or institution via an intranet or more globally on the Internet. For example, the U.S. Agency for Healthcare Research and Quality (AHRQ) maintains a comprehensive publicly accessible online database containing nearly 1,100 evidence-based clinical practice guidelines [3]. One noteworthy benefit of Web technology for CPG automation is the ability to hyperlink recommendations and related documents to the evidence that supports them [5]. This approach solves the basic problem of guideline accessibility, but searching for knowledge embedded in the guideline can be problematic when the guideline is long and complex, and when the answer to a specific question is needed quickly [2].

The next level of automation and decision support occurs when the computer can make use of the patient’s clinical data, follow its own algorithm, and present only the information relevant to the current clinical situation [2]. An obstacle to achieving this goal is the ambiguous language with which most text-based guidelines are composed. Eligibility criteria and disease / symptom severity often are not explicitly defined. When they are, the definitions may not map to computable data within an electronic medical record (EMR). The process of translating ambiguous guideline statements into equivalent ones that use available coded data is onerous and carries the risk of distorting the intent and spirit of the original guideline [2]. Another obstacle to achieving this goal is the requisite level of technology infrastructure for integrating CPG systems with other organizational sources of patient-specific information.

Greens, et al. have identified the following five essential characteristics or “desiderata” for computer-based guidelines, the relative importance of which depend upon the specific application setting and use [8]:

- **Definition and structure** – all decision criteria and actions must be correct and expressed with unambiguous terminology.
- **Eligibility** – specific eligibility criteria are required to facilitate the retrieval of guidelines that are relevant to a particular clinical situation.
**Adaptation to local characteristics** – organizational culture, technology infrastructure, and other unique local characteristics must be considered.

**Mapping to host platform** – the ability to interact with an EMR and / or other organizational sources of electronic information must be considered if applicable.

**User Interface** – Various healthcare delivery settings have specific user interface requirements (e.g. Web, handheld device).

To be effective, CPG information systems must also be adequately integrated into the clinician workflow. Toward that end, Shiffman et al. identified the following eight information management services that promote workflow integration [5]:

- **Recommendation** - determination of appropriate guideline-specified activities that should occur under specific clinical circumstances.
- **Documentation** - the collection, recording, and storage of observations, assessments, and interventions related to clinical care.
- **Explanation** - the provision of background information on decision variables, guideline-specified actions, and the supporting rationale for CPG recommendations, including evidence and literature citations.
- **Presentation** - the creation of useful output from internal data stores.
- **Registration** - the recording and storage of administrative and demographic data to uniquely identify patients, providers, and encounters.
- **Communication** - the transmission and receipt of electronic messages between the clinician and other information providers.
- **Calculation** - the manipulation of numeric and / or temporal data to derive required information.
- **Aggregation** - the derivation of population-based information from individual patient data.

Each service adds value to a CPG application that can increase its probability for success, and the service model itself provides a structure with which to compare and evaluate CPG systems [5].

Assuming that CPGs are implemented and used, process and outcome data (including when and why clinicians intentionally deviate from guideline recommendations) must be collected, analyzed, and combined with updated knowledge to assist with organizational benchmarking and CPG modification efforts. Although the incorporation of new knowledge may require substantial revision of the guideline recommendations and underlying algorithms, it is essential to ensure that outdated or invalid CPGs do not become embedded in an organization’s clinical practice [2].

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**4. Study Environment - City of Hope National Medical Center (COH)**

City of Hope National Medical Center and Beckman Research Institute, located in Duarte, California, is a nonprofit biomedical research and patient care facility specializing in cancer, HIV / AIDS, diabetes, and other life-threatening diseases. Established in 1913, City of Hope (COH) is one of only 39 National Cancer Institute (NCI) – designated Comprehensive Cancer Centers in the U.S [9]. The 112-acre COH campus includes a 165-bed hospital and an outpatient clinic that supports over 115,000 outpatient visits annually. At any given time, COH is conducting 300-400 clinical trial investigations into new drugs and therapeutic approaches. COH also has partnership arrangements with a number of community-based cancer treatment facilities in the Southern California area.

**5. National Comprehensive Cancer Network (NCCN)**

The National Comprehensive Cancer Network (NCCN) is a nonprofit organization established in 1995 to create an alliance among the nation’s leading cancer centers and to develop programs that enhance the efficiency and effectiveness of cancer care. A map of the NCCN member centers and their locations is shown in Figure 1. Shortly after its inception, the NCCN began to develop a comprehensive set of diagnostic, treatment, and supportive care guidelines to enhance clinical decision-making [10]. Each guideline consists of an algorithm or decision pathway that allows a clinician to use disease stage, tumor size, and other relevant clinical information to produce recommendations for primary treatment, adjuvant treatment, and follow-up. The NCCN Practice Guidelines in Oncology have become the recognized standard reference for appropriate practice in the field of oncology [11]. The paper-based NCCN breast cancer CPG is over 50 pages long, with many guideline pathways continued across multiple pages. An example of one page from the NCCN breast cancer CPG is shown in Figure 2.

**6. Relationship Between COH and the NCCN**

A strong relationship between COH and the NCCN exists at several levels. COH joined the NCCN as one of its founding members in 1995, and the COH Division of Information Sciences serves as the National
Figure 1 - Map of NCCN member centers. COH is the National Data Coordinating Center for the ongoing NCCN outcomes research study.

Figure 2 - Representative section of the NCCN CPG for systematic adjuvant treatment of invasive breast cancer.
Data Coordinating Center for the ongoing NCCN outcomes research study. In this role, COH responsibilities include the design, development, and deployment of a Web-enabled outcomes database, along with systems and processes used to receive and analyze outcomes data from all participating centers [12,13]. The NCCN outcomes research study measures clinician adherence to NCCN CPGs, and provides clinical and other outcomes data to evaluate the quality of cancer care. The outcomes research project was launched on July 1, 1997 at five NCCN institutions that treat over 7,000 new breast cancer patients each year. Since that time, the system has been expanded to include breast cancer outcomes data from nearly 15,000 patients submitted by 12 participating centers.

7. Study Objectives

Our analysis of NCCN breast cancer outcomes data on a national scale led to observations about guideline adherence variability among participating clinicians. This in turn increased our interest in the development of systems to facilitate the efficient and effective use of NCCN breast cancer CPGs at the point of care. A specific question of interest related to COH community-based affiliates and their adherence to NCCN breast cancer treatment guidelines. To study this issue and to evaluate our ability to extend the NCCN outcomes research project into the community oncology setting, the authors applied for and received a small one-year grant from the NCI in 2001 as a supplement to the COH Cancer Center Support Grant. The project, entitled “Outcomes Research in the Community Oncology Setting (ORCOS)” funded the extension of NCCN outcomes research into two community-based treatment facilities, and also funded development of the Web-based decision support system (GDSI) described in this study.

The ORCOS study was designed with several specific objectives in mind:

- Analysis of the quality and completeness of data collected in the community setting was expected to provide a better understanding of the time, effort, and resources required to extend NCCN outcomes research into this setting.
- Analysis of the community population relative to the population at risk was expected to yield insights about the design of future studies in settings geared toward specific patient groups and underserved populations.
- The GDSI, if successful, was expected to improve data collection and decision support in the community setting, and could eventually be extended into the Cancer Center setting and elsewhere throughout COH and the NCCN.

8. COH Community-Based Affiliates

After a review of five COH community-based affiliate organizations, the following two were selected for participation in the ORCOS study based on their interest, patient population, and technology infrastructure.

Mission Hospital Regional Medical Center (MHRMC): MHRMC is a 271-bed acute care facility that has provided medical care to families in Southern Orange County since 1971. The facility offers a wide range of special programs and services and is accredited by the American College of Surgeons as a Comprehensive Community Hospital Cancer Program. Approximately 750 new cancer cases are diagnosed and treated at the Center each year, the majority of which are breast cancers.

Antelope Valley Cancer Center (AVCC): AVCC is an outpatient treatment facility dedicated to the delivery of medical oncology and radiation oncology services in the Antelope Valley. The facility currently provides approximately 70% of the cancer care in the community, treating 60-70 new cancer cases each year. Breast cancer is the leading disease diagnosed and treated at the Center.

9. System Architecture

In an unrelated COH research program, one of the authors developed a system and method for automating the control of analytical instrumentation [14]. The approach was successfully applied to a number of protein and peptide characterization problems requiring complex interactions between high-performance liquid chromatography (HPLC) systems, tandem mass spectrometers, and computers, to interactively analyze data and transmit revised instrument control instructions [15]. Given the success of this approach in a different decision support environment, the authors decided to adapt it for CPG automation in this study. The approach is based on a state machine architecture in which the NCCN CPGs were decomposed into states, inputs, and the possible relationships among them.

In general terms, each “state” in the CPG state machine describes an analytical situation. The state machine begins in an initial state and waits to receive user input. When received, the rules associated with
that state evaluate the data, initiate all required actions, and select the next state. Each state behaves in a similar fashion until an exit state is reached at a CPG terminus. Prior to technical implementation, the authors modeled each of the NCCN breast cancer guidelines into a more detailed representation as shown in Figure 3 to identify and resolve any ambiguities.

Figure 3. Generic representation of NCCN Breast Cancer Treatment Guidelines developed for use with the GDSI state machine.

During this modeling process, several “dead end” branches of this CPG hierarchy were identified that did not lead to specific recommendations. After some additional research, we learned that the NCCN employs a “5% rule” during their guideline construction process. As a rule of thumb, if a clinical scenario represents less than 5% of presentations for a particular condition, the NCCN does not attempt to derive a unique pathway for that scenario unless there are very significant clinical implications [11]. Using this information, we modified each terminus of this type to state the absence of a specific NCCN recommendation for these rare conditions.

We also recognized that the GDSI’s inability to reach a treatment recommendation could also be caused by a logic error in the state machine. When an unexpected dead end is encountered, the user is notified of the condition, the CPG path that caused the condition is written to the database, and the event is presented in a GDSI administrative application for review and resolution. In other words, the GDSI is designed to assist with the repair and maintenance of its own knowledge base.

10. Technical Implementation

The GDSI Web application was developed using Microsoft Active Server Page (ASP) technology and deployed using Microsoft’s Internet Information Server (IIS). The server (Web and database) hardware consists of two Dell 1650 servers with dual 1.4 GHz processors and 512 MB RAM. Each question and each recommendation (terminus) in the 2002 NCCN Breast Cancer Treatment Guidelines was modeled as a state in the GDSI state machine. A Microsoft SQL Server 2000 relational database was used to relate each state with its corresponding initialization, transition, status, and action rules. User responses to each question and the order in which they were received were stored in a similar fashion. If a user elects to revise an answer to an earlier question, the answers to all subsequent questions are deleted. For example, if a clinician arrives at step eight of a 10-step guideline, and decides to revise the answer to a question at step six, the end of the pathway (steps 6-10) can be re-traversed while leaving the earlier section (steps 1-5) intact. This allows the GDSI to be used in a “what if” fashion to observe how the CPGs change in response to different clinical situations.

11. Application Features

The application is password protected and uses Secure Sockets Layer (SSL) technology for server authentication and data encryption. Once authenticated, users are provided with an overview of the NCCN Breast Cancer Treatment Guidelines and how to interpret them, along with disclaimers and warnings concerning appropriate application use. Once accepted, the GDSI allows users to define patients to the system or select a patient that has already been defined. For this initial study, patient information consisted of date of birth, date of first presentation, and optional text entries for past medical history, Gail risk estimate, and radiology / pathology findings. At this point the user receives a system-generated identification number, and the clinician is reminded to record the GDSI ID for future reference. Individually identifiable health information was intentionally kept to a minimum in light of recent federal Health Insurance Portability and Accountability Act (HIPAA) regulations concerning individually identifiable health information.

Once a patient has been entered and selected, the user is presented with the first guideline question as shown in Figure 4. As the user scrolls down below the information shown, two additional panels of information are maintained as shown in Figure 5. On the left side, all known information about the patient is readily available for use during the guideline traversal.
Figure 4. Initial GDSI data entry screen for NCCN Breast Cancer Treatment Guidelines

Figure 5. Additional GDSI status information including patient-specific data and guideline traversal status.

Figure 6. The GDSI user interface approach for presenting CPGs in a consistent fashion.

Figure 7. A GDSI-generated treatment recommendation. Information about the user's intent to follow guideline recommendations is collected for review during the guideline development and modification process.
process. A summary of the user’s previous answers in the guideline traversal path is maintained on the right. This panel can also be used to jump directly to a previously answered question.

To facilitate guideline traversal within a Web application, the GDSI employs a consistent GUI approach that always shows the following basic elements from left to right as illustrated in Figure 6:
- The previous question answered
- All possible answers to the previous question
- The user’s answer to the previous question
- The current question with all relevant answer options
- All of the states (next question or terminus) that depend upon the answer to the current question

The example in Figure 6 shows that the answer to the previous question regarding hormone receptor status was answered “positive” (instead of negative or unknown) leading to the current question about antiestrogen therapy within the last year. Based on the user’s answer to this question, the next state to be processed by the GDSI state machine will either be a treatment recommendation or another question concerning menopausal status. By displaying all state transitions in a consistent fashion, the GDSI can present a uniform and intuitive user interface regardless of the length or complexity of the guideline being traversed.

At the end of each computable CPG pathway, a recommendation is provided as shown in Figure 7, along with its NCCN Category of Consensus to designate the strength of the evidence behind the recommendation and the degree of consensus about its inclusion in the guidelines. NCCN Consensus Category values range from Category 1 (recommendation based on high-level evidence with near unanimous consensus among CPG developers) to Category 3 (recommendation has engendered major disagreement among CPG developers with links to information to explain the nature of the controversy) [11].

At this point, the clinician is also asked to declare his or her intention to follow the guideline recommendations. If s/he answers in the affirmative, the application proceeds directly to the creation of a printable summary and records the patient-specific recommendations in the database. If the user does not intend to follow the recommendation(s), the application requests a rationale and additional supporting information if applicable. This information is collected for submission to the NCCN to assist with construction of future versions of the guidelines.

### 12. GDSI Pilot Study in the Community Setting

The first version of the GDSI was completed in February 2002 and tested at COH by the authors and NCCN data management staff. The recommendation to identify and capture information regarding intentional deviations from CPG recommendations resulted from this phase of testing and was added to the system along with several other minor user interface modifications. In May 2002, the modifications were complete and the pilot study began at MHRMC and AVCC.

Over a period of approximately six months, nine clinicians at the two community sites used the GDSI and/or its printed summary reports to generate patient-specific NCCN breast cancer treatment recommendations on 39 different patients. Users included study coordinators and physicians at each site who used the GDSI for individual patient care purposes and for case presentation at interdisciplinary tumor board meetings. GDSI usage at the two community sites was evaluated using three survey instruments: a case-specific survey which was completed after each patient was entered into the GDSI, a general observation/tumor board summary survey which recorded GDSI-related comments from the tumor board meetings, and a clinician survey which described overall user satisfaction, perceived accuracy, and perceived benefits.

Case specific surveys were completed for 21 of the 39 patients evaluated at the two community centers. Results indicate that each case required approximately 10 minutes to enter and that 90% (19/21) produced a treatment recommendation. In 79% (15/19) of cases where a treatment recommendation was reached, the clinician was “totally confident” in its accuracy, with the remaining 21% (4/19) being “generally confident”. When asked about ease of GDSI navigation, all but one case was completed without navigation difficulties.

Comments summarized from the tumor board meetings indicated that 2/3 of clinicians who interacted with the GDSI in any way (direct data entry and/or use of GDSI printed reports) were likely to continue using the system at the point of care and at tumor board meetings. The remaining 1/3 rated themselves as “moderately likely” to continue using the system.

The clinician overall survey results were generally favorable and also included some constructive feedback and opportunities for improvement, including:
- Navigation improvement in the areas related to tumor staging. The GDSI asks multiple sets of staging questions in series but the staging questions could be presented as a group since the answers for each set do not impact the others.
• Other general comments requesting additional data elements, rewording and/or reordering of some questions, larger fonts on the printed summary reports, ability to view an entire treatment branch, ability to derive the Gail risk estimate, and the ability to save partial records for completion at a later time.

13. Limitations of the Study

Although the GDSI application described in this study was shown to be capable of providing decision support at the point of care by facilitating clinician interaction with complex CPGs, the authors recognize several limitations of the study. First and foremost, the short study period and small sample size (users and participating centers) limit the generalizability of the results. An advantage was gained by starting with NCCN breast cancer treatment guidelines since they are developed as algorithms that are relatively easy to automate when compared with many other CPGs containing ambiguous statements such as “in certain circumstances”, “under some conditions”, and “some experts advise”. Efforts to fill in these gaps in order to produce a more computable algorithm are tantamount to amending the guideline and must therefore proceed with caution [2].

There are several other major research initiatives and technical approaches for guideline representation (ARDEN, Asbru, EON, GEM, GLIF, Protégé), each with relative strengths and weaknesses that should be considered by others attempting to develop CPG decision support systems. We recognize that our approach to guideline construction is not standard and it is relatively difficult to incorporate new knowledge and edit existing CPGs in the current state machine implementation. Efforts are underway to improve this aspect of the GDSI. The primary emphasis in this study was clinician interaction with a specific set of guidelines using an established automation approach from another discipline. Others have emphasized the representation of CPGs in a standardized and sharable fashion. We plan to evaluate these other guideline definition approaches and incorporate them as applicable.

14. Lessons Learned and Directions for Future Research

An important lesson learned from this study is that information technology can be used to further streamline interaction with CPGs without changing their meaning. The NCCN breast cancer CPGs begin with the assumption that tumor staging has already taken place. In an effort to provide additional decision support for GDSI users, the authors attempted to add support for tumor staging using the well-established standard staging criteria from the American Joint Committee on Cancer (AJCC). Although GDSI users considered the AJCC tumor staging criteria to be accurate, tumor staging was considered to be the most lengthy and awkward aspect of the GDSI traversal process due to the large number of clicks and screens required to traverse it. Several opportunities to create “multi-question” input screens to minimize the number of steps required were overlooked, and efforts are currently underway to identify these opportunities as part of the guideline modeling process.

An obvious direction for future research involves deployment of the GDSI at COH and throughout the NCCN. The current Web-based version of the GDSI can be tested at any site with an Internet connection, and it was designed to be usable in small clinics and regional treatment facilities. However, we also plan to expand the system to interact with other databases to obtain patient specific information and obviate the need for redundant data entry. This level of automation would probably be limited to larger organizations with more sophisticated EMR systems, but it would provide clinicians at those organizations with additional incentive to use it. An advantage of the state machine approach is that once a CPG is modeled and represented, states can be added or expanded to include additional functionality such as database queries, additional computations, and messaging. As described in the literature, we also plan to add links to related resources, such as patient handouts and references to the medical literature to further promote patient and clinician use [4].

The unique relationship between COH and the NCCN makes it possible to design more robust research studies that measure the GDSI’s impact on outcomes across multiple organizations and treatment settings. As the GDSI captures intentional deviations from CPGs and the reasons behind them, an important feedback loop will be established that should benefit the guideline construction process.

15. Conclusions

The ORCOS study as a whole yielded useful results for all three of its primary study objectives. Analysis of the quality and completeness of collected data suggested that support from trained data managers or clinical research assistants would be required to facilitate the extension of NCCN outcomes research into the community setting. Comparisons between the community-based patient populations and other “at-
risk” populations yielded no significant differences upon which the design of future studies could be based.

The purpose of the GDSI project was to develop, deploy, and evaluate a Web-based decision support system to facilitate the efficient and effective use of clinical practice guidelines. A well recognized, widely used, and rigorously developed set of breast cancer treatment guidelines was represented to the system, and the system was evaluated by a number of clinicians in two different community-based practice settings. Preliminary results indicated that the GDSI prototype was well received among clinicians and is capable of making a positive contribution toward CPG development and use. User feedback obtained during the pilot study also contained additional insights about how to further improve and enhance the system.

16. Acknowledgements

The authors would like to acknowledge Janet Nikowitz, Dinusha Perris, and Lei Chen (COH Division of Information Sciences) for their assistance with various aspects of this study. We also wish to acknowledge Mission Hospital Regional Medical Center and Antelope Valley Cancer Center for their participation. This project was supported in part by a grant (CA33572-S3) from the National Cancer Institute.

17. References


