Users’ Evaluation of ONCO DOC,
a Breast Cancer Therapeutic Guideline Delivered at the Point of Care
B. Séroussi†, M.D., Ph.D., J. Bouaud†, Ph.D., E.-C. Antoine‡, M.D.
†Service d’Informatique Médicale, AP–HP & Département de Biomathématiques,
Université Paris 6, Paris, France
‡Service d’Oncologie Médicale, Groupe Hospitalier Pitié-Salpêtrière, Paris, France

Despite the dissemination of computer-based “clinical practice guidelines” as decision support systems, low practical compliance rates are still observed. The reason commonly invoked is that such recommendations, suited to average patients, are not rules for all the patients. Rather than providing automatic decision support, ONCO DOC allows the clinician to operationalize the implemented breast cancer therapeutic expertise through his hypertextual reading of the knowledge base. In this way, he has the opportunity to interpret the information provided in the context of his patient therefore controlling his categorization to the closest appropriate “average patient”. After a four-month real-life experimentation of the system, a survey was conducted among the users. The observed compliance, significantly higher than the best figures found in the literature, and the clinicians objective and subjective evaluation of the system reinforced the implementation choices adopted in ONCO DOC.

INTRODUCTION

The need to reduce variations in patterns of clinical practice and to improve the care for the same medical problem across providers, institutions and regions has founded the recent development of computer-based clinical practice guideline (CPG) systems. These systems are expected to provide uniform optimal approaches to problem-focused care delivery, although locally adapted. However, despite the proliferation of such decision support systems, there is still little evidence of any change in physician prescribing habits. Additional developments such as computer-generated reminders or individualized feedbacks to clinicians have been shown to enhance guidelines utilization. But yet, median compliance remains very low, even when users positively evaluate decision support systems.

The reason commonly invoked to explain that fact is that such recommendations, suited to average patients, are not rules for all the patients. Although CPGs may point out the best research evidence to guide the care of formal patients, they are not a substitute for clinical judgment, which should be applied to each actual individual patient. CPG information has to be interpreted in accordance with its intended meaning by a given physician for a given patient. Medical knowledge, mainly expressed in natural language, is often subject to contextual interpretation to generate acceptable inferences. This property limits the formalization of such knowledge that hardly accounts for all possible contexts. This may explain low compliance rates with implemented CPG systems.

ONCO DOC is a CPG system elaborated in a document-based paradigm with a knowledge-based approach. Rather than providing automated decision support for guideline-based medical care, the system involves the physician in an active medical reasoning process. As opposed to usual fully computerized approaches, the clinician explores an explicit decision tree like a flowchart and has thus the opportunity to control the knowledge operationalization by his free interpretation of the information provided. He can therefore participate to the therapeutic decision by categorizing his patient in an appropriate clinical context.

This choice of CPG implementation has been tested in a real-life experimentation. Routinely used at the point of care by the oncologists of the Service d’Oncologie Médicale Pitié-Salpêtrière (SOMPS) in the management of breast cancer patients, OncoDoc demonstrated significantly high scores of compliance. At the end of the experimentation, we sent a questionnaire to the different physicians involved. The aim of the survey was to evaluate the effectiveness of ONCO DOC approach, both qualitatively and quantitatively, and analyze the user requirements for a CPG system they will use and comply to.
ONCODOC APPROACH

Background
Clinicians need simple, patient-specific, user-friendly guidelines, but much of the recommendations presented in formal overviews, although comprehensive and valid, is not in a form directly relevant to individual patient care. Formalized CPGs are indeed unable to anticipate all possible contexts, necessarily unattainable at design time, and to offer sufficient flexibility in interpreting guideline knowledge. The reason why is that CPGs are mostly expressed in natural language. This mode of expression, suited for human to human communication, allows interpretation variations depending on the actual context in which the knowledge is applied. Such a property allows for flexibility in CPG use, that, by essence, formal computer-based models cannot afford.

General principles
In order to preserve the flexibility in interpreting CPGs, the methodology we adopted in ONCODOC’s design9 aims at delegating the knowledge interpretation task to the physician at the time it is needed when the context of an actual patient is available. Our proposal is halfway between knowledge representation and literary writing. The clinician is proposed a structured knowledge base (KB) encoded as a decision tree which formal properties guarantee completeness in coverage and uniqueness of solutions. This KB is not run on data, but read by the clinician who has the opportunity of interpreting this knowledge for a given patient through a hypertextual traversal of the decision tree. The physician is then involved in the categorization process of his patient which he keeps control over and he is responsible of. At the leaf level, he can then choose among the proposed therapeutic recommendations.

Architecture
ONCODOC has been implemented in a document-based paradigm (Fig. 1). A generic SGML structure for decision trees, the Document Type Definition, or DTD, has been designed. The CPG knowledge has been encoded as an SGML document which is an instance of this DTD. Then a set of programs, SDTMP1, using Perl, Tcl, Cost, HTML++ scripts, operates transformations on the SGML resource and maintains a version and validation database. It generates a “validation booklet” to be printed on paper and which is the expansion of all the decision tree paths, and a set of HTML pages, which constitutes the hypertextual version of the original decision tree. Then, the KB can be disseminated on standard computer networks and browsed from any web browser.

![Figure 1: OncoDoc architecture.](image)

METHOD

Pilot-site experiment
Current ONCODOC’s application provides recommendations for breast cancer therapy. A real-life experimentation of ONCODOC has been carried out at the SOMPS and lasted 4 months from December 15th, 1997 to April 15th, 1998. Installed on an intranet web server and used from 6 client PCs located in medical consultation offices, it involved the 8 department residents and attendings. The experiment protocol was presented at the department weekly meeting. There was no training. For each breast cancer therapeutic decision, clinicians had to use ONCODOC to get the appropriate CPG recommendations for his patient.

Protocol
To estimate how clinicians were in theoretical agreement with the CPG recommendations (the “intention” agreement of Advani et al.) and how they complied in practice to the CPG recommendations, we have introduced two different types of validation: a theoretical validation carried out through the evaluation of how appropriate is each therapeutic proposition to the “average” patient, a practical validation carried out through the evaluation of how appropriate is each therapeutic proposition to the “actual” patient. Figure 2 shows the experiment form that clinicians had to fulfill after each actual decision.

The quantitative aspect of theoretical and practical validations has allowed the definition of two different criteria: adherence, defined as the frequency of physicians theoretical agreement with the CPG recommendations, and compliance, as the frequency with which physicians actually followed the recommendations. Adherence evaluates the relevance of guideline knowledge out of any context, compliance, its ability to be applied in actual particular contexts.

1SDTMP stands for “SGML Decision Tree Management Programs”.
At the end of the experimentation, we sent to the involved clinicians a questionnaire. There were 7 categories of items to evaluate (i) clinicians aptitude in handling computers, (ii) ONCODOC presentation and clinicians’ comprehension of the experimentation protocol, (iii) the use of the system at the point of care, (iv) CPG knowledge modeling, (v) medical contents assessment, and (vi) context account. There were a total of 84 items. Qualitative judgments were ranked on a five-point Likert scale where 1 and 5 correspond to extreme values and 3 to the median value.2

RESULTS

Seven questionnaires were returned corresponding to 87.5% of responses.

Clinicians aptitude in handling computers

Clinicians estimated they are rather familiar with computers (3.7 [never use; use very often]) though non experts (2.4 [novice; expert]). They rarely use computers to access on-line documentation, e.g., Medline, etc., (2.4 [never; very often]), but 85% of them have a PC at home. However ONCODOC was unanimously found user-friendly (5.0 [very complicated to use; very simple to use]). Mouse-clicking to select answers is satisfying (4.9 [non satisfying; satisfying]) and the best choice of interaction in front of tactile screen, vocal command, and keyboard use, this latter being considered as a true disadvantage.

ONCODOC presentation and clinicians’ comprehension of the experimentation protocol

The presentation of the system at the department weekly meeting as well as the demo on an actual patient record were judged enough to understand how to use the system (4.0 [insufficient; enough]). Using ONCODOC was rather easy and 71.5% of clinicians acknowledge that no training was necessary. There was no need for a user’s manual; no technical problem was reported.

ONCODOC utilization at the point of care

In 77% of the cases, clinicians used the system during the encounter, while the patient was being seen. Re-
response delays are quick (4.0 [long;short]) and the time spent to use the system is short (4.0 [long;short]). Clinicians estimation for one navigation is between 2 and 5 minutes, with a mean value of 3 minutes.

**CPG knowledge modeling**
With regards to the decision tree modeling and its “operationalization” through a hypertextual navigation, the proposed model is considered suited to the dissemination of recommendations (4.7 [no;yes]). CPG textual equivalents are not preferred (1.4 [no;yes]). The reasoning process adopted within the system is unanimously described as comprehensible (5.0 [no;yes]) and appropriate (4.7 [no;yes]). The order in which the decision parameters are presented is well suited to the building of a coherent clinical context (4.6 [accessory;essential]) and appropriate to the medical reasoning process progress. The terminology used for parameters and values appeared to be clear (4.9 [ambiguous;clear]). In case of ambiguity, the additional definitions (either general or local) were found essential (4.6 [accessory;essential]) and they practically often allow disambiguation (4.0 [never;always]).

**Medical contents assessment**
The precision level of patient categories is almost sufficient (4.0 [insufficient;sufficient]) to allow therapeutic recommendations. Clinicians estimate at 25%, the proportion of situations where this level of details is not enough. The proposed parameters are considered moderately suited (3.4 [unsuited;suited]) to describe the clinical reality of a patient. As a result, the ability of the system to cover every clinical context is considered scarcely sufficient (3.7 [insufficient;sufficient]). The frequency of the situations in which clinicians did not find acceptable answers to the questions asked would be of 18%. However, the set of values for each decision parameter is rather relevant (4.6 [no;yes]).

Despite these restrictions, ONCODOC is nearly considered as an expert (4.4 [incompetent;expert]) on its competence domain that it shares with its users. This distortion in judgment is confirmed with an estimated adherence of 92%, higher than the estimated compliance of 80%.

**Context account**
As for the consideration of the context, the presentation of the “recapitulative” of previous choices is ranked essential (4.9 [accessory;essential]) at the node level during the hypertextual navigation, thus showing the importance of the recall of the clinician’s involvement in the knowledge operationalization. To the item “The fact that therapeutic recommendation is given from your own interpretation of the clinical situation (e.g. cardiac function) and not from raw patient data (e.g. ejection fraction) is in your opinion rather (1) a disadvantage, or (5) an advantage”, the answers are disparate and distributed along the scale, even if slightly in favor of the advantage (3.7).

However, in the hypothesis of a running electronic medical record which would contain all decision parameters values, clinicians prefer to keep control over data interpretation to handle decision tree navigation and recommendation selection (4.6 [no;yes]). Their preference for prescription automatization has been ranked 1.9. Data entry in a single step is not preferred as opposed to the sequential traversal of the decision tree (1.7 [no;yes]). For our clinicians, knowing and understanding the structure that conducts the decision process is considered essential (4.9 [accessory;essential]). They estimate they would not have the same attitude with an “expert system” (2.0 [no;yes]) where implemented knowledge is not totally explicit.

**DISCUSSION**

The study we conducted at the SOMPS shows that users will more naturally comply to computer-based CPG systems if those are easy to use and allow clinicians to gain time (patient-centered, and providing a simple and rapid access to the relevant information). The results of the survey show that the implementation choices adopted in ONCODOC meet all these requirements, and that there was no difficulty for clinicians to appropriate the KB contents and its underlying utilization model.

Apart from implementation features, the differences between the figures actually computed and estimated by clinicians for adherence, compliance and average session time prove that clinicians are really confident in the system’s recommendations and consider that the delivered therapeutic knowledge is relevant (see table 1). For instance, they were surprised in 13% of cases, as they were suggested treatment plans they had not thought about and that they found more adapted to their patient.

<table>
<thead>
<tr>
<th></th>
<th>Observations</th>
<th>Estimations</th>
</tr>
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<tbody>
<tr>
<td>Adherence</td>
<td>96.60%</td>
<td>92.00%</td>
</tr>
<tr>
<td>Compliance</td>
<td>64.28%</td>
<td>80.00%</td>
</tr>
<tr>
<td>Session time</td>
<td>1 minute 30 s</td>
<td>3 minutes</td>
</tr>
</tbody>
</table>

More important, the survey illustrates that the generic
knowledge encoded in the decision tree, while considered relevant and accurate (high score of adherence), may not apply to every specific case (lower compliance). This conclusion was already known as the previously pointed out difference between the average patient to whom CPGs by construction apply and the actual patient that may need a specific customized treatment. As opposed to usual approaches, ONCODOC does not rely on the automatic matching of both average and actual patients, on the basis of out-of-context patient data, which may lead to inappropriate results that clinicians most of the time disagree with, explaining the traditionally low compliance figures. On the contrary, ONCODOC allows the user, from his own interpretation of a given clinical context built from his level of expertise and his perception of the physiopathological reality of the actual patient, to control his categorization to the closest average patient and to choose the most appropriate among the recommendations. Preserving their autonomy, clinicians are favorable to CPG systems as decision supports that bring knowledge to their mouse but let them control knowledge operationalization and medical reasoning.

CONCLUSION

The approach developed in ONCODOC addresses some problems usually strongly criticized by clinicians resulting in CPG low compliance results. The study conducted at the SOMPS after the four-month experimentation reinforces our choices of implementation: ease of use (no type writing), no loss of time, contextualization of generic knowledge, and user-controlled identification of the best (closest) average patient. One argument proving the good fit of ONCODOC to users needs is that the system is still used over the long term with around 5 navigations per month (against 20 during the experiment).

Since the experimentation, the ONCODOC has been further refined to extensively cover the management of breast cancer patients: all types of breast cancers are now included as well as the recent guidelines for chemotherapy and hormone therapy schemes leading to a potential compliance of 80%. In the last version, ONCODOC uses 64 decision parameters organized in a tree of 2,314 leaves. At this level of complexity, the exhaustive validation of the KB which was previously handled through the manual review of the paper-based validation booklet was no more appropriate. Computer-based tools allowing an on-line validation of the KB have been developed. Beyond managing the KB versions, these tools provide a direct access to the no more valid paths of the decision tree (because of recent modifications), and allow to flip through the electronic version of the validation booklet from one invalid path to another.

References