Supporting multidisciplinary staff meetings for guideline-based breast cancer management: a study with OncoDoc2

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In order to reduce practice variations and offer cancer patients the best treatments according to reference guidelines, therapeutic decisions have to be taken, in France, by “multidisciplinary staff meetings” (MSMs) as patient-specific care plans which are then implemented by cancer specialists. OncoDoc2 is a CDSS implementing CancerEst guidelines, a “local reference guideline”, on breast cancer management. The system has been assessed in a pragmatic before/after study. The intervention consisted in the routine use of OncoDoc2 during MSMs of Tenon hospital. The MSM decision compliance rate with the reference guideline was significantly higher in the after period, increasing from 79% to 93%. MSM decision analysis showed that missing steps in treatment plans were the main cause of noncompliance during the before period. This cause was drastically reduced in the after period.

INTRODUCTION

Even in developed countries, there is a qualitative inequality in the management of cancers, especially of breast cancer, which is the most frequent female cancer. In year 2003, a long term political action, known as “Cancer Plan”, has been initiated in France. In order to guarantee best patient-specific care, therapeutic decisions should now be taken by multidisciplinary staff meetings (MSMs) according to Clinical Practice Guidelines (CPGs). CPGs would preferably be evidence-based and nationwide, but when evidence and national consensus are lacking, then “local reference guidelines” can be applied.

Despite the organization of MSMs, therapeutic variability remains. The international Effective Practice and Organisation of Care Group of the Cochrane Collaboration has reviewed the literature on intervention studies designed to improve health professional practice. The simple dissemination of documents, whatever electronic or paper, has nearly no impact on physician behavior. Among the different means that influence medical prescription, reminders, defined as an intervention that takes place at the time a decision is made, are considered as the most efficient. Clinical Decision Support Systems (CDSSs), issuing “computerized reminders” are considered appropriate tools to promote CPG use by their ability to take into account situation-specific information and deliver patient-centered recommendations. In a systematic review, Garg et al. confirmed the impact of CDSSs on medical practice, although limited when applied to diagnostic tasks.

If many CDSSs have been developed for years, few are routinely used. Since CPGs are produced, how guideline recommendations could be integrated in CDSSs is the focus of many research. Several CPG-dedicated formalisms and tools have been proposed to represent all aspects of guideline-based care. However, in spite of these developments, those tools have not been yet widespread in actual clinical settings. Many organizational and technical barriers limit their use in a multidimensional care process environment. Thus implementing guideline-based CDSSs in routine remains today a challenge.

OncoDoc is a guideline-based CDSS providing patient-specific recommendations in the management of breast cancer. In order to harmonize their practices, cancer specialists of CancerEst (the union of 4 university hospitals of the Eastern Paris, including the Tenon hospital) have drawn up local reference guidelines for the management of several cancers including non-metastatic breast cancer. A new version of OncoDoc, OncoDoc2, has been developed. Knowledge bases (KBs) have been extended to account for CancerEst CPGs. Additional functionalities have been developed to handle the management of MSMs. OncoDoc2 has been implemented in a pragmatic uncontrolled be...
fore/after study in a real clinical setting. The aim was to evaluate how the use of OncoDoc2 during MSMs could improve the compliance rate of MSM therapeutic decisions with the system recommendations.

MATERIAL AND METHODS

OncoDoc2 for modeling CancerEst CPGs

CancerEst CPGs are developed as narrative textual guidelines, disseminated on both paper and web support, a format that we know does not help physicians to characterize the recommendation that applies to a given patient. OncoDoc2 is an updated version of OncoDoc that implements CancerEst CPGs. KBs have been extended to cover all therapeutic modalities of breast cancer management (including surgery procedures such as reexcisions for inadequate margins, sentinel node procedure, etc.), as opposed to OncoDoc which was more focused on the chemotherapeutic management of breast cancer.

Like OncoDoc, OncoDoc2 has been developed according to the documentary paradigm of decision support. This approach allows physicians to contextualize both guideline medical knowledge and patient information thus improving the flexible use of guidelines for any given patient and optimizing the patient-specificity of the recommended therapeutic propositions. Like in automatically executable guideline systems, OncoDoc2 relies on a formalized KB structured as a decision tree. But unlike these systems, OncoDoc2’s KB is designed to be browsed, thus delegating the control of knowledge execution to the physician user. From the root of the decision tree, the physician is asked to characterize her patient clinical profile by clicking at each tree level of the KB to select the appropriate value of the decision node (medical history, clinical examination, pathology results, etc.). While navigating through the KB, all instantiated patient characteristics are collected to incrementally build a summary which corresponds to the “formal patient” derived from the actual patient. When completing the navigation, the physician finally comes to the recommended therapeutic propositions associated to the “formal patient”.

OncoDoc2 represents recommended care plans as ordered sequences of therapeutic actions, denoted \( D_{CPG} = (e_1, e_2, \ldots, e_n) \), where each therapeutic action \( e_i \) is expressed at the lowest level of abstraction. For instance, \( e_i = '4xAC60, D1-D15' \) specifies the number of cures (4), the name of the drug association (AC), the drug dosage (60), and the rhythm of chemotherapy courses (every 2 weeks).

OncoDoc2 for managing MSMs

Tenon breast cancer MSMs occur every Thursday morning. All medical specialists involved in breast cancer management (surgeons, radiologists, oncologists, radiotherapists, pathologists, oncogeneticists, etc.) are attending the meeting. This is the place where physicians conjointly determine patient-specific care plans for all discussed clinical cases. The different steps of care plans are then implemented by the medical specialists concerned. Physicians present their clinical cases: they are responsible for the accuracy of patient parameters they are reporting. On the basis of these parameters, the decision is collectively taken but the meeting coordinator is responsible for the MSM therapeutic decision. Depending on the physicians attending the meeting, the MSM decision, denoted \( D_{MSM} = (E_1, E_2, \ldots, E_k) \), is more or less abstract, from \( E_i = '4xAC60, D1-D15' \), to \( E_i = 'chemotherapy' \).

To enable the use of OncoDoc2 and facilitate its acceptance, additional functionalities have been developed to help in the administrative management of MSMs (display of the list of patients to be discussed, dynamically updated list of attending physicians, specific user interfaces, etc.). In case the final MSM therapeutic decision is one of OncoDoc2 propositions, it is automatically inserted in the MSM decision window with the compliant status (green) (Figure 1). In case of non-compliance, the MSM therapeutic decision has to be typed, which automatically instantiates the noncompliant status (red) of the decision. Deviations have to be justified. For each patient case, a MSM report including patient data, the summary of the navigation, OncoDoc2 therapeutic propositions, the therapeutic decision of the MSM, the list of attending physicians, the name of the physician in charge of the patient, and the name of the coordinator of the MSM is automatically generated to be signed by the two responsible parties.

Guideline compliance definition

There is scarce literature about guideline compliance definition. Most of the time, it seems to be a binary variable, although there are examples with three modalities, the usual two values “with deviations” and “without deviations” being expanded in “with minor deviations”, “with critical deviations”, and “without deviation”.

Deviation or compliance are usually categorized by experts and the basis of this categorization is often unclear. Let \( D_{MSM} = (E_1, E_2, \ldots, E_k) \) denote the ordered therapeutic sequence decided by the MSM and \( D_{CPG} = (e_1, e_2, \ldots, e_n) \) denote the ordered therapeutic sequence proposed by OncoDoc2. A MSM’s decision is defined as compliant with CancerEst guidelines thus OncoDoc2 propositions, which is denoted \( D_{MSM} \equiv D_{CPG} \), if:

\[ D_{MSM} = (E_1, E_2, \ldots, E_k) \]
Figure 1: Recording the MSM decision in OncoDoc2

- \( k = n \) and \( \forall i, E_i = e_i \).
  In this case \( D_{MSM} = D_{CPG} \)
- \( k = n \) and \( \forall i, E_i \supseteq e_i \), which indicates that \( E_i \) subsumes \( e_i \), i.e. \( E_i \) is more abstract than \( e_i \).
  In this case, \( D_{MSM} \) is more general than \( D_{CPG} \), which is denoted \( D_{MSM} \sim D_{CPG} \).

As a consequence, noncompliance patterns for MSM decisions are three-fold:
- \( k < n \), there is at least one missing step (e.g. a forgotten radiotherapy)
- \( k > n \), there is at least one extra step (e.g. an additional chemotherapy is prescribed, although not recommended),
- \( k = n \) and \( \exists i / \neg(E_i \supseteq e_i) \), there is at least one inappropriate step (e.g. a surgery decided instead of a neoadjuvant chemotherapy recommended).

For each therapeutic modality, surgery, chemotherapy, radiotherapy and hormonotherapy, a subsumption taxonomy (figure 2) represents treatment levels of abstraction.

**Figure 2**: Excerpt of the subsumption taxonomy for chemotherapy treatments

The study took place between 2005 and 2006. Among all patients whose cases were discussed during MSMs, only those matching inclusion criteria (female non-metastatic invasive breast cancers) were enrolled. Table 1 reports the number of included patients and therapeutic decisions considered in each period.

In each group, patients were compared on age, menopausal status, hormonal receptors, axillary status, and prior breast cancer treatments. Decisions were compared according to the last administered treatment before the current MSM. MSM members were the same in both periods. Statistical analyses (not reported...
Table 1: Number of inclusions (patients and decisions) by period.

<table>
<thead>
<tr>
<th>Period</th>
<th>Duration</th>
<th># patients</th>
<th># decisions</th>
</tr>
</thead>
<tbody>
<tr>
<td>Before</td>
<td>6 m.</td>
<td>139</td>
<td>226</td>
</tr>
<tr>
<td>After</td>
<td>6 m.</td>
<td>177</td>
<td>241</td>
</tr>
<tr>
<td>Total</td>
<td>12 m.</td>
<td>316</td>
<td>467</td>
</tr>
</tbody>
</table>

here) allowed us to consider both groups of decisions homogeneous and thus comparable.

Compliance rates

Compliance rates were compared in each group using the compliance definition of the “Methods” section and are reported in table 2. The compliance rate was significantly higher in the after period ($p < 10^{-5}$; Fisher’s exact test), increasing from 79.2% to 93.4%.

Table 2: Compliance rates in each period.

<table>
<thead>
<tr>
<th>Period</th>
<th># decisions</th>
<th>Compliant decisions</th>
<th>Compliance rate</th>
</tr>
</thead>
<tbody>
<tr>
<td>Before</td>
<td>226</td>
<td>179</td>
<td>79.2%</td>
</tr>
<tr>
<td>After</td>
<td>241</td>
<td>225</td>
<td>93.4%</td>
</tr>
</tbody>
</table>

Noncompliant decisions

Noncompliant decisions were analyzed using the categories previously described (Figure 3).

In the before period, the main cause of noncompliance is a missing step which represents more than 2/3 of all deviations (33/47) and nearly 15% of all decisions (33/226). Those missing steps are made of 42.5% of radiotherapies, 24.2% of hormonotherapies, 24.2% of surgeries, and 9.1% of chemotherapies. In the after period, 16 decisions on 241 remain deviant. Missing steps have fallen from 15% to less than 2% of all decisions. Extra steps were divided by 2 to reach 1.7%, and inappropriate steps frequency remains similar.

We also considered noncompliant decisions from the point of view of the therapeutic modality involved in the “faulty” step: surgery, chemotherapy, radiotherapy, or hormonotherapy. Figure 4 reports the distribution of each type as a percentage of all decisions. In the before period, deviations on surgical steps represents 34% of all deviations, radiotherapies 28%, hormonotherapies 19%, and chemotherapies 13%. In the after period, the noncompliance frequency of each therapeutic modality has decreased and is below the 2% threshold of all decisions, except for surgeries.

DISCUSSION AND CONCLUSION

Noncompliance analysis

The comparison of noncompliance causes (Figure 3) shows that the main difference between the 2 periods is that the number of missing steps drastically decreased, while the other causes of deviation do not seem to be impacted and remain at comparable levels. Thus, the fall of those “forgotten” steps explains 90% of the compliance increase (+14.2%) between the 2 periods. This would suggest that the intervention had a “reminder” effect on the MSM members.

In the before period, missing steps are essentially forgotten radiotherapies and hormonotherapies. These steps are always the last steps of a patient care plan and may not be considered by MSM members as a priority in a decision focused on the first steps. Besides, these missing steps are often added, apart from MSM decisions, by the medical specialists in charge of implementing the first steps of the therapeutic plan. In other situations ($\approx 1/3$), the omission corresponds to missed reexcisions, axillary node dissections, or adjuvant chemotherapy. Those missing steps are at the beginning of the treatment plan and, unfortunately, might not be recovered, which worsens the patient prognosis.
The 16 deviations of the after period are composed of 4 missing steps (3 radiotherapies for patients older than 90, 1 adjuvant chemotherapy), 4 extra steps (2 hormone therapies despite negative hormonal receptors, 1 third line of neoadjuvant chemotherapy while a maximum of two lines is recommended, and an extra radiotherapy) and 8 inappropriate steps (essentially concerning surgery). Unlike the deviations of the before period, these 16 deviations are conscious and assumed by MSM participants. The reasons why they did not comply range from unavoidable very particular cases (e.g., surgery refused by the patient, lymph node dissection contraindicated, prophylactic mastectomy for BRCA1 mutation, very old patients...), to risk overestimation leading to more aggressive treatments than recommended (e.g., extra radiotherapy, lymph node dissection instead of sentinel node procedure...) or risk underestimation (e.g., tumorectomy instead of mastectomy, hormonotherapy instead of chemotherapy...). These cases of noncompliance with CPGs in the after period exemplify limits of CPGs to cover all clinical cases and problems of threshold in patient categorization. Unlike objective parameters which are not context-sensitive, variations in evaluating subjective parameters have been observed. Similar borderline cases have been categorized differently depending on the coordinator of the MSM while navigations have been handled taking into account in the same way the “reality” of patient parameters.

Limitations of the study
Randomized controlled trials constitute the gold standard but they are difficult to implement for intervention studies. Since there is no controlled arm in the design of the study, the observed difference in compliance rates, although significant, cannot be strictly considered as an impact of the system. Nevertheless, our study could be related to a “proof of concept study” (defined for drug trials) which aims at validating the relevance of “in vivo preclinical models” (real clinical settings and actual patients). The assessment of the system acceptance by clinicians would correspond to a phase I trial, whereas compliance rate increase is a first assessment of the ability of the system to produce some effect as in phase II trials. To prove the actual impact of the intervention, a solution could be to stop the intervention (back to MSMs without OncoDoc2) as in time series design. But, clinicians involved in MSMs have clearly rejected the idea and wanted to continue using the system routinely. This additional impact of the system cannot be put into question.

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