Agreement between oncology guidelines and clinical practice in Italy: the ‘right’ program. A project of the Italian Association of Medical Oncology (AIOM)

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On behalf of the AIOM Guidelines Task Force
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Background: RIGHT (Research for the Identification of the most effective and highly accepted clinical guidelines for the cancer Treatment) is a project promoted by the Italian Association of Medical Oncology (AIOM) to measure the concordance between oncology guidelines and clinical practice. The goal of this pilot phase was to develop and test a reliable process to measure this concordance nationwide.

Materials and methods: Twenty Italian centers participated to the survey. Breast cancer (BC) and colorectal cancer (CRC): guidelines issued by AIOM in 2003 were selected. A total of 29 indicators linked to the process of care were abstracted. Patients who had their first visit at the oncology center between February 2004 and June 2005, with a diagnosis of invasive BC (stage 1 or 2), colon cancer (stage 3), rectal cancer (stage T3–4 or N1–2) or advanced CRC were enclosed.

Results and conclusion: One hundred and sixty-one patients (80%) were analyzed. On average, 93% of BC and 80.3% of colorectal patients received recommended care. These first results indicate that the RIGHT system provides a valid measurement of oncology care to assess agreement with guidelines. A second larger phase of this nationwide monitoring program will enable results to be generalized.

Key words: breast cancer, colon cancer, guidelines adherence, Italian guidelines, process indicators

Introduction

Oncology is one of the medical fields where research is most advanced. Well-designed trials have provided diagnostic and therapeutic strategies for many types of cancer and guidelines have been developed to allow their application in clinical practice. A strategy with proven efficacy may, however, not be effective and translate into a tangible patient’s benefit [1]. Some guidelines have been criticized on the ground that they are not applicable to clinical practice [2]. The adoption of guidelines is influenced by individual factors (e.g. knowledge, skill and motivation), social factors (e.g. reactions of patients, colleagues and recognized authorities) and organizational factors (e.g. available resources and organizational climate) [2, 4, 5]. The active involvement of health professionals is an important strategy for the implementation of guidelines in clinical practice [6]. The evaluation of the ability of guidelines to change professional behavior and improve patient’s outcomes is thus a central strategy for evaluating their effectiveness.

Following the recommendations of the Italian National Health System [7] and the experience of other Institutions, such as the American Institute of Medicine and the American Association of Clinical Oncology [8–10], the Italian Association of Medical Oncology (AIOM) instituted a Guidelines Task Force (GTF) in 2002 to develop a method that could monitor and improve the quality of delivered cancer care based on the principles of clinical audit.

According to the National Institute of Excellence, a quality improvement process can be implemented through a cycle called ‘clinical audit’ which plays a central role in the evaluation of the application of guidelines in clinical practice and consists of four steps: (i) establishing best practice, (ii) measuring care against agreed criteria, (iii) taking action to improve care and (iv) monitoring to sustain improvement [11].

RIGHT (Research for the Identification of the most effective and highly accepted clinical guidelines for the cancer Treatment) program is the first Italian project promoted by a Scientific Society as the Italian AIOM with the aim of evaluating how AIOM guidelines are applied in clinical practice.

In this paper, we report about the design and results of the RIGHT pilot study focused mainly to test the ability of the system to measure current practice in oncology centers.
**materials and methods**

**preliminary AIOM membership survey**

Before starting with the pilot phase of this program, a preliminary survey was conducted among a convenience sample of 1000 AIOM members in July 2004. The survey aimed at evaluating: (i) knowledge of AIOM guidelines; (ii) interest in applying them; (iii) opinion about their relevance, clarity and updatedness. Three hundred and fifty-two (35%) of the 1000 selected AIOM members (on basis of the e-mail address availability) replied to the questionnaire. Ninety-one percent of the respondents were medical oncologists, 1% radiation oncologists, 2% surgical oncologists, 1% nurses and 6% had other roles. Ninety-eight percent of the respondents were aware of AIOM guidelines, 95% were interested in them and 99% considered guidelines from moderately important to important for clinical practice. Moreover, 96% of them judged AIOM guidelines updated, 97% clear and 98% useful. Eighty-seven percent of respondents were available to participate in AIOM initiatives regarding guideline development and implementation.

**development of a system to evaluate care in oncology centers**

A convenience sample of 23 Oncology centers specialized in breast cancer (BC), colon cancer, rectal cancer and advanced colorectal cancer (CRC) care were selected to assess the validity of the method developed to monitor clinical guidelines into clinical practice. Following this preliminary pilot test, the aim will be to evaluate the agreement between clinical practice and AIOM guidelines.

A system of measurement was developed to identify deviations from recommended care and reasons for lack of compliance [12–14]. The system was developed in five steps: (i) definition of the audience and purpose of measurement; (ii) definition of the research teams; (iii) overview of available evidence and choice of clinical indicators; (iv) design of indicators and (v) pilot study [16, 17].

The audience of measurement were AIOM centers and the purpose was the identification of deviations from recommended care for stage 1 and 2 invasive BC, stage 3 colon cancer, stage T3–4/N1–2 rectal cancer or advanced CRC.

Two research teams were established, one for BC and one for CRC. The two teams were coordinated by the AIOM GTF coordinators and were aided by epidemiologists (Appendix 1).

The choice of indicators emphasized quality of evidence and validity [15, 18]. A preliminary set of indicators was obtained from existing AIOM guidelines [19, 20] on the basis of the level of evidence and the strength of recommendations [21]. The measurements were reviewed by the team members who excluded indicators not routinely available in clinical practice.

The final set included nine indicators for BC, eight for colon cancer, eight for rectal cancer and four for advanced CRC. Each indicator was accompanied by a multiple choice indicator specifying the reason for lack of implementation. The choices included some prespecified answers (patient refusal, organizational limitations, clinical reasons, complications of surgical or medical treatment) and a blank space for further reasons.

The possibility to measure an agreement between clinical practice and AIOM guidelines was evaluated retrospectively on a random sample medical records. Patients who had their first visit at the oncology center between February and June 2004 were eligible for the study if they satisfied the following criteria: (i) age <70 years with stage 1 or 2 invasive BC and followed by the study center for ≥12 months after diagnosis; (ii) stage 3 colon cancer without urgent surgery and followed by the study center for ≥12 months after diagnosis; (iii) stage T3–4/N1–2 rectal cancer without urgent surgery and followed by the study center for ≥12 months after diagnosis; (iv) patients stage 3 CRC with liver metastases and without extrahepatic localizations followed regularly by the study center.

Data collection was performed using a Web-based interface. After receipt of invitation e-mail, the physician in charge of data entry at each center inputs the patients’ anonymous data. Data input involved: (i) general variables, (ii) cancer-related variables such as staging, diagnosis and treatment, (iii) waiting times and (iv) care indicators.

The main outcome measure was the proportion of patients following recommended guidelines for each indicator. In order to avoid a possible underestimation of the percentage of agreement, for each indicator were considered only the ‘eligible events’ defined as a subgroup of patients for which the application of the recommended procedures did not have any other clinical contraindications (i.e. comorbidities, personal decision, other barrier limits). The average (percentage of) agreement for indicators was also calculated for each of two considered cancers (BC versus CRC).

Medical records that were wrongly included as satisfying the eligibility criteria, but did not, were not analyzed.

**results**

**evaluation of care in oncology centers**

Twenty (87%) of the 23 selected AIOM centers participated to the survey. Eleven centers were specialized in BC and nine in CRC care. Seventy-five percent of the centers were located in Northern Italy, 15% in Central Italy and 10% in Southern Italy (Appendix 2).

The centers collected the medical records of 106 BC and 72 CRC patients between July and August 2005 (Table 1). Ninety percent of all cases had all the data needed for analysis.

The 96 BC patients yielded a total of 590 measurements organized in nine categories. On average, 93% of patients received recommended care. The greatest adherence to guidelines (100%) was detected for diagnosis, presurgery and surgery categories and the lowest adherence (63%) for the time elapsed between surgical and radiation therapy (Table 2).

<table>
<thead>
<tr>
<th>Table 1. Characteristics of historical cohort</th>
</tr>
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<tbody>
<tr>
<td></td>
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</tr>
<tr>
<td>BC</td>
</tr>
<tr>
<td>CC</td>
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<tr>
<td>RC</td>
</tr>
<tr>
<td>Advanced CRC</td>
</tr>
</tbody>
</table>

SD, standard deviation; BC, breast cancer; NA, not available; CC, colon cancer; RC, rectal cancer; CRC, colorectal cancer; - , not available.
The 65 CRC patients yielded a total of 383 eligible events organized in 21 categories. On average, 80.3% of these patients received the recommended care. The greatest adherence to guidelines (100%) was detected for treatment of advanced colon cancer with fluoropyrimidine and the minimum adherence (64%) for the domains of presurgical and surgical therapy (Tables 3, 4 and 5). For colon cancer and rectal cancer patients separately, the best agreement was obtained for the proportion of cases that had a colonoscopy or barium enema at the time of diagnosis (92.0% and 89.5%, respectively). Among the colon cancer patients, the lowest adherence (64%) was for surgical procedure within 4 weeks from the time of diagnosis. The execution of radiotherapy and/or chemotherapy before the intervention registered the minimum adherence (64%) about management of rectal cancer patients (Tables 3 and 4).

**Discussion**

The RIGHT pilot study aimed at developing and evaluating a system to measure the agreement between clinical practice and AIOM guidelines for the care of BC and CRC patients as performed by specialized oncology centers.

Although a minority (35%) of AIOM members replied to the anonymous Web-based questionnaire, all were interested in guideline implementation. A response bias is clearly possible, however, because AIOM members who answered to the questionnaire are more likely to be interested in guidelines than those who did not respond to the invitation. Within this limitation, the judgment of AIOM members about guidelines was very good for all categories (clarity, interest and updatedness) in virtually all cases.

Our data agree with those obtained by similar studies. For instance, in the survey of the Quality Oncology Practice Initiative (QOPI), 86% of BC patients and 78% of CRC patients received recommend care [22]. These percentages are similar to those obtained by us despite some differences in study design. First, we abstracted data from medical records without direct involvement of the patients. Secondly, our entry criteria were different from those of QOPI. Thirdly, because we studied a convenience sample of BC and CRC centers, our data are not representative of general care and cannot be used to perform between-center comparisons. Interestingly, as reported also by QOPI [22], despite the good agreement between recommended and actual care, nearly half (47%) of the indicators scored values <85%.

Our study has some limitations. The main limitation is that it was performed in a convenience sample of selected oncology centers with a possible overestimation of the adherence rates to guidelines. Moreover, a possible underestimation of the performance of care indicators had to be taken into account. To reduce this effect, we collected data about the applicability of a specific procedure in a particular context, to check for the

### Table 2. BC process indicators

<table>
<thead>
<tr>
<th>Domains</th>
<th>BC process indicator</th>
<th>Strength of recommendations</th>
<th>Eligible events</th>
<th>Adherence (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Diagnosis</td>
<td>D1 Proportion of patients underwent Rx-mammography</td>
<td>A</td>
<td>96</td>
<td>100</td>
</tr>
<tr>
<td></td>
<td>S1 Proportion of patients treated with complete axillary dissection or with axillary level I and II dissections</td>
<td>A</td>
<td>32</td>
<td>100</td>
</tr>
<tr>
<td></td>
<td>S2 Proportion of patients with tumor size $&lt;3$ cm underwent sentinel lymph node biopsy</td>
<td>A(^a)</td>
<td>57</td>
<td>88</td>
</tr>
<tr>
<td>Therapy</td>
<td>T1 Proportion of patients treated with radiation therapy after breast-conservation surgery</td>
<td>A</td>
<td>87</td>
<td>93</td>
</tr>
<tr>
<td></td>
<td>T2 Proportion of patients who after mastectomy received radiation therapy for the following tumor characteristics: tumor size $&gt;5$ cm or 4 (or more) involved lymph nodes</td>
<td>B</td>
<td>21</td>
<td>100</td>
</tr>
<tr>
<td></td>
<td>T3 Proportion of patients who started radiotherapy within 12 weeks after surgery if adjuvant systemic chemotherapy is not used</td>
<td>B(^b)</td>
<td>27</td>
<td>63</td>
</tr>
<tr>
<td></td>
<td>T4 Proportion of patients with positive hormone receptors who received adjuvant hormonal therapy</td>
<td>A</td>
<td>78</td>
<td>94</td>
</tr>
<tr>
<td></td>
<td>T5 Proportion of patients with positive lymph nodes who received adjuvant systemic therapy</td>
<td>A</td>
<td>96</td>
<td>100</td>
</tr>
<tr>
<td>Follow-up</td>
<td>F1 Proportion of patients who, in absence of symptoms, underwent follow-up with only Rx-mammography as diagnostic test</td>
<td>A</td>
<td>96</td>
<td>95</td>
</tr>
</tbody>
</table>


\(^a\)Only if exist adequate know-how in the hospital.

\(^b\)Not specified on the guidelines, rated by AIOM GTF Consensus.

BC, breast cancer.
possible restrictions. These restrictions were taken into account by a specification defined as ‘eligible events’ for each indicator.

The selection of process-based indicators was dictated firstly to satisfy the need to use routinely collected data from the existing medical charts.

In fact, the first aim of this pilot project was to test the feasibility of a monitoring system which could provide a practical tool to use at clinical practice level. As new treatments or quality standards evolve, the RIGHT system goal will be to update the clinical performance measures frequently.

To meet this target, we adopted a very easy to use Web-based tool system, containing questionnaires where the items were chosen mainly to allow only binary status assignments.

In conclusion, the RIGHT pilot study developed and validated a system of measurement of oncology care to allow comparison with AIOM guidelines. The next phase of the RIGHT study will be the application of this system to a nationwide sample of oncology centers and the evaluation of the agreement between actual and recommended care in Italy.
The following investigators in Appendix 1 and Appendix 2 are coauthors of article.

**Appendix 1.**

AIOM Guidelines Task Force Coordinators
S. Giovanni Rotondo (Maiello E), Treviglio (Barni S).

Breast Cancer Guidelines Task Force
Negrar (Venturini M), Perugia (Gori S), Verona (Molino A), Torino (Donadio M).

Colorectal Cancer Guidelines Task Force
Bergamo (Labianca R), Brescia (Beretta GD), Milano (Carnaghi C), Milano (Valvo F), Roma (Cosimelli M), Torino (Faggiuolo R).

Epidemiological and data analysis Unit
Modena (Sgarbi S, Simoni L, Fiori G).

**Appendix 2. List of participating centers**

Colorectal Cancer Study Group
Alessandria (Fusco V), Ancona (Scartozzi M), Catanzaro (Molica S), Milano (Martignoni G), Napoli (Catalano G), Novara (Miraglia S), Parma (Pucci F), Roma (Tonini G), Torino (Pochettino P).

Breast Cancer Study Group
Belluno (Giovanni P), Bologna (Rimondini S), Brescia (Simoncini E), Camposampiero (D'Alessio A), Candiolo (Montemurro F), Ivrea (Manzini E), Parma (Di Blasio B), Reggio Emilia (Bisagni G), Roma (Nisticò C), Torino (Pedani F), Trento (Ferro A).

**Acknowledgements**
This study was supported also by an educational grant from Novartis and Roche, Italy.

**References**


**Table 5. Advanced CRC process indicator**

<table>
<thead>
<tr>
<th>Domains</th>
<th>Advanced CRC process indicator</th>
<th>Strength of recommendations&lt;sup&gt;a&lt;/sup&gt;</th>
<th>Eligible events</th>
<th>Adherence (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Therapy T1</td>
<td>Proportion of patients considered for a possible surgical intervention</td>
<td>A&lt;sup&gt;b&lt;/sup&gt;</td>
<td>14</td>
<td>85.7</td>
</tr>
<tr>
<td>Therapy T2</td>
<td>Proportion of patients treated with folic acid, fluorouracil (5-FU) associated with oxaliplatin or irinotecan</td>
<td>A</td>
<td>21</td>
<td>95.2</td>
</tr>
<tr>
<td>Therapy T3</td>
<td>Proportion of patients not treated with oral fluoropyrimidine</td>
<td>B</td>
<td>21</td>
<td>100.0</td>
</tr>
<tr>
<td>Therapy T4</td>
<td>Proportion of patients who were not treated with biological drugs</td>
<td>_</td>
<td>21</td>
<td>80.9</td>
</tr>
</tbody>
</table>

<sup>a</sup>Source: AIOM Colorectal Cancer Guidelines 2003.<br>
<sup>b</sup>Not specified on the guidelines, rated by AIOM GTF Consensus.

CRC, colorectal cancer; _, not available.

**Annals of Oncology symposium article**

Volume 18 | Supplement 6 | June 2007
doi:10.1093/annonc/mdm252 | vii185

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