

DEFINING EVIDENCE-BASED CLINICAL ONCOLOGIC CARES QUALITY INDICATORS



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INTRODUCTION

Using clinical indicators for quality assessment represents a fundamental approach to document the quality of the care delivered. The implementation of process of care measures implies the development of quality indicators (QIs) rigorously constructed. Quality of Cancer Care (QoCC) studies and structured programmes on specific quality indicators (QIs) have been developed in USA, Canada and Europe since the late '90s [1,2,4-7], showing both a continuous improvement of oncologic care, provided by the clinical structures involved, and an increased availability of specialized care in the considered areas. Most of these studies have been implemented at the regional level on a territory with uniform legislative, health and geographical characteristics, increasing the likelihood of recruitment of involved clinicians. So far, in Switzerland no population-based study on QoCC with a prospective design has been developed. We, therefore, implemented the QC₃ project, a prospective descriptive population-based study on the QoCC, at the Ticino Cancer Registry, during a 3-year time period (2011-2013) on the territory of Canton Ticino (Southern Switzerland), focusing on tumours of colon-rectum, prostate, uterus, ovary and lung.

One of the aims of the QC₃ study is to define evidence-based QoCC indicators for the tumour localizations above cited, in order to favour an improvement of the short-term oncologic diagnostic-therapeutic process.

METHODS -

The QIs development process implies a *planning phase*, which means organizing a selected working group (WG); a *development phase*, were QIs are prioritized on an evidence-based scientific source and selected on a Delphi-process bases by the WG; a *validation phase*, where QIs are validated by a panel of recognized experts; a *data collection phase*, where the data regarding the studied population are collected.

The initial cancer-specific list of QC₃ QIs, derived from a comprehensive literature search on PubMed/MEDLINE of relevant peer-reviewed articles, is proposed to the WG's in an in-person meeting. Each WG offers a multidisciplinary perspective on practice, including specialists, professionals, clinicians and researchers of all concerned disciplines (pathology, surgery, oncology, radiology, radiation oncology, nuclear medicine, gastroenterology, gynaecology, urology, pneumology) coming from both public and private hospitals and clinical cancer care services of Canton Ticino [8-10]. Thus individual and collective interests of the essential groups as well as key contents areas are adequately represented. The participants are asked to select those Qls considered pertinent for the QCCC measurement and eventually to suggest additional Qls not already included. After this initial revision, the list of Qls is formatted as a questionnaire and distributed to the WGs in two separate rounds, using to a 2-step modified Delphi process [11,12]; respondents have to rate each Ql adopting the RAND Appropriateness technique (scale 1 to 9, 1= extremely inappropriate; 9= extremely appropriate) or the megatrends method (response yes/no to the suitability of each Ql) according to its association with quality and patient outcomes [13]. Furthermore, the list of selected cancer-specific Qls derived from the two Delphi rounds, is then submitted to an independent international multidisciplinary cancer-specific Advisory Board (AB), in order to get an additional evaluation and to define a final approved list of Qls.

The final selected QIs are applied to the regional routine oncologic care, so to evaluate the performance of the currently used pattern of care according to the international guidelines.



Fig. 1 - QC, QIs SELECTION

RESULTS

Here we present a selection of the preliminary QIs results about the colorectal cancer (CRC). The initial QIs list (n=149) was submitted to a preliminary revision by the CRC WG and the selection (n=104) underwent to a 2-step modified Delphi process, shortening the QIs candidates to 89. The AB revised them and extracted the final 74 QIs (Fig.1).

In **Tab. 1** is represented a selection of the final QIs. For each QI is described its own *denominator*, i.e. the population on whom the QI is calculated, and the literature used to define it (**G**= guidelines; **R**= reviews; **M**= meta-analysis; **PBS**= population-based studies; **CCS**= case-control or cohort studies).

Tab. 1 - CRCs QC₃ QIs SELECTION

QUALITY INDICATORS (QI)	DENOMINATORS	LITERATURE
Proportion of patients evaluated by preoperative colonoscopy	Patients with colorectal cancer undergoing surgery (n=200)	CCS, R, G
Proportion of patients with preoperative staging according to the AJCC TNM 7 th ed.	Patients with colorectal cancer undergoing surgery (n=200)	G
Proportion of patients undergoing rectal- sigmoidoscopy /colonscopy	Patients with rectal cancer (n=76)	P, CCS, R, M
Proportion of patients undergoing biopsy	Patients with rectal cancer (n=76)	P, CCS, R, M
Proportion of patients with description of the clinical-endoscopic visit, particularly of the tumour localization (distance ab ano)	Patients with rectal cancer (n=76)	CCS, R
Proportion of patients with definitive pathological report including the number of lymph nodes retrieved	Patients with colorectal cancer undergoing surgery (n=200)	CCS, R, G, PBS
Proportion of patients with definitive pathological report including the margin status	Patients with colorectal cancer undergoing surgery (n=200)	G
Proportion of patients with definitive pathological report including the pTNM classification	Patients with colorectal cancer undergoing surgery (n=200)	ccs, G
Proportion of patients operated in emergency	Patients with colorectal cancer undergoing surgery (n=200)	ccs
Proportion of patients operated on with free margins	Patients with colorectal cancer undergoing surgery (n=200)	CCS, G, M
Proportion of patients NOT undergoing neoadjuvant RT or RT-CT, with a number of resected lymph nodes ≥ 12	Patients with colon cancer and patients with rectal cancer undergoing primary surgery (n=183)	CCS, R, G, PBS
Proportion of patients with clinical stage from I (T2N0M0) to III (every T,N1-2M0) undergoing an extensive surgical resection with anastomosis	Patients with AJCC stage I (from T2N0M0) - III colorectal cancer (n=173)	G
Proportion of patients with metastases for which the first line of systemic therapy was planned on the basis of molecular factors (KRAS, BRAF, etc)	Patients with colorectal cancer with unresectable metastases undergoing chemotherapy (n=28)	CCS, R, G
Proportion of patients with single pulmonary metastasis or hepatic metastases undergoing immediate/synchronous metastasectomy	Patients with colorectal cancer with hepatic or singular pulmonary metastases (n=30)	G
Proportion of patients with protective stoma before neo-adjuvant RT-CT	Patients with rectal cancer undergoing neo-adjuvant radio- chemotherapy (n=20)	ccs
Proportion of patients with locally advanced tumours undergoing neo- adjuvant RT±CT	Patients with locally advanced rectal cancer (n=24)	CCS, R, G

CONCLUSIONS

The QC₃ study is instrumental to draw a population-based picture of the QoCC currently in use in the territory of Canton Ticino and to open new perspectives on quality-related issues in oncology. In addition, the systematic trend analysis of QI allows to assess immediate changes and improvements in the diagnostic-therapeutic process that could be translated in a shortterm benefit for patient, without waiting for survival analysis typically needed some years to be produced because of the patients follow-up. The prospective design allows the production of up-to-date results, reproducing the currently used pattern of care. The population-based design implies the inclusion of the elderly patients usually excluded from RCTs. The study favours the rationalization of data transmission modalities to Cancer Registries and, furthermore, it increases the expectations of Cancer Registry data system, moving from the static retrospective evaluation of cancer treatment outcomes to dynamic interventions to monitor and to ensure optimal multidisciplinary cancer care. Moreover, in a second step, for each QI the minimum and the target requirement at a regional level will be proposed. Using QIs for quality assessment represents an important approach to documenting the quality of care. QI are mandatory not only for the clinicians, but also for the stakeholders all around and for the patients. This underlines that the QI should be defined, developed and tested with scientific evidence-based rigor in a careful and transparent manner.

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