Screenee perception and health-related quality of life in colorectal cancer screening: A review

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**ABSTRACT**

Screening for colorectal cancer (CRC) has become established to varying degrees in several Western countries for the past 30 years. Because of its effectiveness, screening has been adopted or is planned in a number of other countries. In most countries, the screening method (e.g., fecal occult blood test [FOBT], sigmoidoscopy) is followed by colonoscopy, for verification. In other countries (e.g., United States, Germany), colonoscopy is the preferred first-line investigation method. However, because colonoscopy is considered to be invasive, might be poorly tolerated, and can be associated with complications, the idea of adopting colonoscopy as the primary screening method suffers. Negative effects of screening methods can reduce participation in programs and thereby negate the desired effect on individual and societal health. At present, there is no generally accepted method either to assess the perception and satisfaction of patients screened or the outcome of the screening procedures in CRC. In this review, we discuss the past development and present availability of instruments to measure health-related quality of life (HRQoL), the scarce studies in which such instruments have been used in screening campaigns, and the findings. We suggest the creation of a specific instrument for the assessment of HRQoL in CRC screening.

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**Introduction**

Incidence of colorectal cancer (CRC) has increased sharply in the Western world since 1970 [1]. In the United States, CRC is the third most common cancer in terms of incidence and the third leading cause of cancer death after lung cancer, prostate cancer in men, and breast cancer in women [2,3]. In Europe, CRC is the second most frequent cancer and the third leading cause of cancer death after lung and breast cancers in men and women [3]. A steady increase of environmental risk factors for CRC (obesity, smoking, low physical activity, poor diet) has created the need for CRC prevention not only in Western countries but recently also in Asia [4]. This need has resulted in an appeal from the European Commission to its member states to establish CRC screening programs nationwide. At present, this recommendation has been followed to varying degrees—with a certain eagerness of some Eastern European countries in which the level of CRC incidence was particularly high [5], and with hesitation and slowness in some Western European countries with a similar incidence [1].

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Fecal occult blood test (FOBT) traditionally has been the most common test used in CRC screening, but in later years sigmoidoscopy and colonoscopy have become increasingly popular choices. In the United States and Germany, colonoscopy is strongly promoted as the first-line screening method, whereas prescreening with FOBT is recommended in other countries, such as the United Kingdom. An overview of the characteristics of currently recommended CRC screening tools is given in Table 1 [6]. However, no reliable data are available at present about the actual cost of various screening methods in relation to the gain of quality-adjusted life years (QALYs), as those will very much depend on the management methods presently used to assess HRQoL in general. Thereafter, a review is provided of the limited number of attempts to assess and describe participants’ perceptions of screening and their HRQoL before and after various CRC screening methods and procedures. Some characteristics necessary for a specific HRQoL instrument to be used in CRC screening are also mentioned.

### General Instruments for the Assessment of Health-Related Quality of Life

#### Background and history

Quality of life (QoL) is a notion that has been discussed, in various guises, throughout the history of philosophy. The notion of QoL appears in the health care sector quite early, and in the 1960s, the health-related literature started showing interest for this concept [8,9].

According to Apolone [10], we can distinguish three outcome categories in health management: clinical/epidemiological, humanistic, and economic (Table 2). The components of the first type of outcome are measured by objective indicators derived by diagnostic procedures and clinical events, such as recurrences and mortality. The economic outcome assessment measures both direct and indirect costs, such as hospitalization, examinations, resource consumption, lost working hours, and productivity reduction. The category of humanistic outcomes contains the measures that will mainly be addressed in this review: severity of symptoms, functional impact of disease, well-being and QoL. These elements synthesize the main part of the variety that reflects different approaches of health-related quality of life (HRQoL).

According to Spilker et al., HRQoL represents the functional effects of disease and therapeutic actions on the patient, in the way the patient defines them [11], and is therefore considered to be one of the primary indicators of outcome [12]. The World Health Organization (WHO) defines QoL as the subjective perception that an individual has of his position in life, in

### Table 1 – Characteristics of primary colorectal cancer (CRC) screening tools currently in use [6].

<table>
<thead>
<tr>
<th>Characteristics</th>
<th>Fecal occult blood test (FOBT)</th>
<th>Sigmoidoscopy</th>
<th>Colonoscopy (CS)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Invasiveness/discomfort</td>
<td>Noninvasive, minimal discomfort*</td>
<td>Moderate invasiveness and discomfort†</td>
<td>Invasive</td>
</tr>
<tr>
<td>Risk of complications</td>
<td>No risk of complications‡</td>
<td>Complications are rare‡</td>
<td>Sedation useful/necessary§</td>
</tr>
<tr>
<td>Sensitivity</td>
<td>Low sensitivity for target lesions (25%–50%)</td>
<td>Lower sensitivity than CS (70%–80%)</td>
<td>Complications are possible (bleeding/perforations)§</td>
</tr>
<tr>
<td></td>
<td>Fails to detect most polyps and some cancers</td>
<td>Only rectum and left part of the colon are examined‡</td>
<td>High sensitivity (95%–100%)</td>
</tr>
<tr>
<td></td>
<td>False-positive results are possible‡</td>
<td></td>
<td>Allows exploration of rectum and entire colon§</td>
</tr>
<tr>
<td>Need for additional procedures and/or</td>
<td>Requires CS if positive and hazardous without annual or biannual repetition§</td>
<td>Requires CS if positive and hazardous without annual or biannual repetition§</td>
<td>Additional procedures not required</td>
</tr>
<tr>
<td>repetition</td>
<td></td>
<td></td>
<td>Biopsies can be performed and precancerous polyps removed during the test</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Repetition every 5 years‡</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Effectiveness in reducing CRC mortality has not yet been proved in RCT‡</td>
</tr>
<tr>
<td>Reduction of CRC mortality</td>
<td>Annual/biannual FOBT in ages 50–80 years can reduce CRC mortality by 15%–33%‡</td>
<td>Repetition every 5 years‡</td>
<td>Additional procedures not required</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Effectiveness in reducing CRC mortality has not yet been proved in RCT‡</td>
</tr>
</tbody>
</table>

* Indirect evidence available.
†, low; ‡, medium; §, high; RCT, randomized controlled trials.
a cultural setting and in a set of values in which he lives, in
relation to his aims, expectations, and worries [13].

Many authors have provided a definition of HRQoL that takes
into account only one particular component, such as functional
abilities [14], general satisfaction [15], well-being, and needs.
Such definitions have been translated into measures through
standardized or semistandardized questionnaires [10].

In 1996, the American Society of Clinical Oncology (ASCO)
declared the HRQoL as one of the most important elements to
be measured in patients with cancer [16]. Clinical studies of-
ten undervalue the severity of patients’ symptoms, but in re-
cent years, more trials have incorporated HRQoL as a key end
point [17,18]. In general, most questionnaires that measure
the HRQoL focus on physical, social, and emotional function-
ing [17], sometimes including the pain dimension and the so-

### Approaches and instruments to measure HRQoL

Instruments of HRQoL can focus on one or numerous areas,
adopting different approaches (Table 3).

A first approach considers the symptoms perception. A
symptom can be defined as the perception of an abnormal
situation from a physical point of view (pain, urgency, dis-
comfort), an emotional point of view (associated with a
mental or psychological status, and with concern, worry,

<table>
<thead>
<tr>
<th>Table 2</th>
<th>Examples of outcome measures [10].</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Outcome</strong></td>
<td><strong>Events</strong></td>
</tr>
<tr>
<td>Clinical/epidemiological</td>
<td>Clinical events</td>
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<tr>
<td></td>
<td>Physical, laboratory measures</td>
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<tr>
<td></td>
<td>Mortality</td>
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<tr>
<td>Humanistic</td>
<td>Symptoms</td>
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<td></td>
<td>Functional status</td>
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<td></td>
<td>Health status</td>
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<tr>
<td></td>
<td>Well-being</td>
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<td></td>
<td>QALY</td>
</tr>
<tr>
<td>Economic</td>
<td>Direct medical aspects</td>
</tr>
<tr>
<td></td>
<td>Indirect medical aspects</td>
</tr>
</tbody>
</table>

ADL, activities of daily living; NHP, Nottingham Health Profile; SF-36, short form 36-item questionnaire; SIP, Sickness Impact Profile.

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situation from a physical point of view (pain, urgency, dis-
comfort), an emotional point of view (associated with a
mental or psychological status, and with concern, worry,
frustration), and a cognitive aspect (memory, concentration) [19]. Symptoms appear in questionnaires to measure HRQoL in three ways:

- as frequency and intensity scales (symptoms checklist);
- as symptoms scales linked with questions about the degree of bother;
- as direct components of HRQoL.

The questionnaires using this type of approach include the symptoms checklist [20], the Gastrointestinal Symptom Rating Scale (GSRS) [21], the Kupperman Index [22], and the Asthma Quality of Life Questionnaire (AQLQ) [23]. The most used questionnaire to measure pain is the McGill Pain Questionnaire [24].

A second approach values the HRQoL according to the physical functions and the related functional disability. The most common scale to measure disability is the Barthel Index [25]. Another is the frequently used Karnofsky Performance Index [26], with the ECOG score (also called the WHO or Zubrod score) for quantifying cancer patients’ general well-being [27]. Examples of instruments to assess daily activities include the activities of daily living (ADL) scale [28] and the Townsend scale [29].

A third approach, developed in the late 1970s, is the survey of global satisfaction with HRQoL, which is based on the assumption that the sum of physical, psychological, and social components is of greatest importance [30]. The instruments developed in this period are defined as general measures of HRQoL, as they can be applied in any type of disorder. The Sickness Impact Profile (SIP) [31], the Nottingham Health Profile (NHP) [32], the Short Form 36-Item Health Survey (SF-36) [33], and its shortened form, the SF-12 [34], are the most diffused examples.

Other approaches to measure the HRQoL take into account the patient’s limits in the realization of personal expectations, for example, the Repertory Grid Technique (RGT) [35] and the Schedule for the Evaluation of Individual Quality of Life (SEIQOL) [36]. The wellness approach, developed in the 1990s, takes into account psychological wellness and personal satisfaction. The Beck Depression Inventory [37], the Affect-Balance Scale [38], the Delighted-Terrible Scale [39], and the Psychological General Well-Being Index [40] are all used frequently for psychological disturbances.

One last approach is mainly based on utility. It captures the implications of a new concept of health, in terms of value of life. This approach is based on the assumption that individuals make rational choices and express preferences comparing their health status with a hypothetical health status. One such instrument is the Health Utility Index (HUI) [41], which is used mainly in economic cost-utility analysis.

Also the EuroQol [13] represents the attempt to develop a general, standardized instrument to describe and evaluate the HRQoL independently from the specific disease. Another instrument of this type is the WHO Quality of Life (WHOQOL) [42]. The Quality of Life Inventory (QoLI) [43] evaluates the HRQoL assuming that general satisfaction is a result of the sum of the satisfaction in specific areas of life that the individual believes to be important.

From this description of the main instruments to measure the HRQoL some reflections can be derived. Any attempt to integrate more dimensions automatically increases the number of items, thereby potentially limiting the effectiveness of the instruments. The multiplicity of instruments described above also highlights that there is no common agreement on what is “quality of life.”

At present, it might be advisable to use general instruments, like the SF-36, for a comparison with other health care situations or disorders, and to add validated disease-specific instruments, if they exist. However, in previously noncovered fields of health care, innovative approaches are needed, including the design of new purpose-tailored approaches.

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**Screenee Perception and Health-Related Quality of Life in Colorectal Cancer Screening**

**Background and past experiences**

CRC ideally meets the criteria for screening because of its high prevalence, its long asymptomatic phase, and the existence of treatable precancerous lesions [44]. Several screening methods have been evaluated, such as FOBT [45,46], sigmoidoscopy [47,48], colonoscopy [49], and, recently, CT-colonography [50]. Colonoscopy has become the preferred test for physicians—and particularly gastroenterologists—because of its possibility to visualize the entire large bowel, to take histological specimens from lesions suspicious of cancer, and to directly remove clinically significant precancerous lesions—adenomas—with the aim of reducing the future incidence of CRC [51]. Nevertheless, colonoscopy is less accepted as a primary screening method for CRC than the various types of FOBTs and the less invasive sigmoidoscopy [52].

The barriers hindering the widespread diffusion of colonoscopy-based primary screening campaigns include worries of the potential screenee (e.g., pain, other discomfort, potential complications connected with the procedure) and the cumbersome and poorly tolerated cleansing preparation necessary for an optimal result of the screening procedure.

Despite the evident benefits of CRC prevention, screenee’s potential negative perceptions and impaired HRQoL still have to be considered. Moreover, it is important to recall that the lifetime risk of CRC is about 6% and, therefore, even if colonoscopy were completely effective in eliminating CRC, 94% of the screened patients would not benefit from screening [44]. Little is known about the psychological impact on healthy individuals of receiving an invitation for a screening test, about the worry associated with the screening procedure itself, the receiving of positive (pathological) results, and the presumed benefit of a negative result. What follows here is a review of the data published so far. Currently, most tests used to measure HRQoL are generic and not designed for a specific disorder or health condition (Table 4).

In the general population the worry about CRC is low or nonexistent [53,54], in contrast to persons with a family history of cancer. Among the latter, the perception of cancer risk is increased and seems to improve the adherence to screening [55]. Thus, there are two possibilities regarding cancer worry: it may facilitate or inhibit screening participation. Both theories have received support by
had received the invitation letter but had not attended the screening). The control group consisted of persons who did not attend the screening, a telephone or personal interview was conducted to assess the worry in the case group (individuals attending the screening). The results influenced the trial adherence positively, as subjects with a new cancer diagnosis were excluded from the analysis. A total of 176 subjects were enrolled in the study. The data reported a significantly more participants had better vitality scores and significantly more participants had better vitality scores and mental health scores after colonoscopy. On the contrary, no improvement in the physical health domains of the SF-36 was seen, irrespective of the screening results.

Another Scandinavian work addressed the psychological effect of attending a colonoscopy screening program. In this study, subjects participating in the Telemark (Norway) screening program for detection and removal of polyps received two questionnaires by mail: the Goldberg’s General Health questionnaire and the Hospital Anxiety and Depression Scale. Subjects completed the questionnaire 15 days, 3 months and 17 months after colonoscopy. A control group of subjects not attending the screening program also completed the questionnaires. The score for both the questionnaires was lower in the group of subjects attending the screening, indicating a lowered level of psychiatric distress.

In another study, the HRQoL of 225 subjects participating in a colonoscopy-screening campaign was measured using the SF-36 questionnaire. The participants completed the questionnaire before and after undergoing colonoscopy. Significantly more participants had better vitality scores and mental health scores after colonoscopy. On the contrary, no improvement in the physical health domains of the SF-36 was seen, irrespective of the colonoscopy results.

A study in Gothenburg, Sweden, assessed the worries associated with CRC screening using a specifically designed questionnaire to get a measure of the amount of worry following an invitation to a mass FOBT-screening program. After screening, a telephone or personal interview was conducted to assess the worry in the case group (individuals attending the screening). The control group consisted of persons who had received the invitation letter but had not attended the screening program. A total of 3548 persons were analyzed: 54% of participants reported that they were "not worried at all" after receiving the invitation letter. However, severe worry was expressed by 13% of the men and 19% of the women in the participants’ group, with similar data in the nonparticipants’ group (10% and 19%, respectively). Moreover, about 65% of the participants and 78% of the nonparticipants reported that their daily life was affected to various extents after the start of the screening campaign. Lower education level was associated with higher level of worry. Worry disappeared in the majority of the patients after endoscopy and 98% of the subjects appreciated the possibility to participate in the screening campaign. The results showed that, despite the increased worry, most of participants did not experience an increase in anxiety. In addition, the endoscopic procedure had a positive effect on reducing worry.

HRQoL studies have referred to screening campaigns for prostate, breast, or cervical cancer and shown limited negative effects on general anxiety (even in case of false-positive results) that tend to diminish with a long-standing follow-up. The National Cancer Institute’s prostate, lung, colorectal, and ovarian (PLCO) cancer screening trial is a long-lasting project focused on the effects of screening for these cancers. As part of the trial, an ancillary study was conducted to assess the impact on HRQoL of receiving normal or abnormal screening results. The SF-12 questionnaire was used to assess the HRQoL, and four items from the seven-item Intrusion Subscale of the Impact of Event Scale (IES) were added to assess cancer specific distress and to evaluate the participants’ responses to the screening test. Subjects with a new cancer diagnosis were excluded from the analysis. A total of 176 subjects were enrolled in the study. The data reported a better QoL in participants than in the general population, irrespective of the screening results (normal or abnormal; abnormal results were mainly due to an abnormal sigmoidoscopy). Older patients and those with a first-degree relative with cancer reported a better HRQoL score than younger persons and those without family history of cancer. Normal results influenced the trial adherence positively, as subjects without pathological findings were encouraged to continue their participation.

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In a recent paper the emotional reactions to a positive FOBT result were evaluated as a part of a CRC screening pilot program in the United Kingdom [76]. Subjects were eligible for the study after they had completed all the screening steps (FOBT and colonoscopy). Three adapted questionnaires were used: the IPQ-R (Revised Illness Perception Questionnaire) was used to define cognitive and emotional representation of illness [77]; the WCQ (Ways of Coping Questionnaire) was used to analyze the strategies to manage the positive FOBT result [78]; and the State-Trait Anxiety Inventory was used to assess the anxiety level [74]. The data were analyzed according to the presence of cancer, adenoma, or negative screening outcome. Cancer patients reported their diagnosis as more distressing than patients with polyps or negative results, but they held stronger beliefs in the efficacy of treatment than the other two groups. Moreover, the patients in the cancer group were less likely to attribute their disease to personal lifestyle factors. State anxiety did not differ with screening outcome between the groups, suggesting that anxiety may be an individual characteristic. This study concluded that the presence of colonic neoplasm was in general not associated with escape-avoidance strategies but resulted in positive self-change behavior.

Globally, the data show that screening for CRC has a positive psychological effect even in subjects with a positive (i.e., pathological) result. However, no conclusive answer exists for possible negative consequences of screening activities for specific cancer forms. Even if the initial data coming from the big screening trials using FOBT have shown a reduction in CRC mortality [45,46,79], an increased mortality from cardiac disease has been suggested in the follow-up of individuals that underwent screening colonoscopy [80]. This data might point to adverse psychological effects. Hoff et al. (2001) reported the long-term results of a sigmoidoscopy screening program, showing that, after the initial screening procedure, the incidence of CRC was lower in the group that underwent the screening than in the non-screened control group [81]. However, the overall survival rate in the screening group was similar to that in the control group because of an excess mortality for nonmalignant disorders (mainly coronary heart disease). Moreover, they found a trend toward a higher increase in body mass index (BMI) for patients without polyps and a reduction of smoking for subjects with polyps. The same authors analyzed the changes in lifestyle variables (BMI, smoking habits, physical activity, and vegetable consumption) in the screened group and in the control group; they found an undesirable lifestyle change associated with CRC screening [82]. These observations suggest that the positive psychological effect of screening could inversely affect the attention to negative lifestyle factors. However, the concerns about such a “complacency effect” in persons who received a favorable screening outcome, leading to deterioration in general health behavior, were contradicted by the data of Miles et al. [83]. In their study, the authors evaluated health attitudes and practices (such as eating fruit, avoiding fatty food, taking regular exercise, smoking status, and participation in cervical and breast screening) in a group of subjects attending the UK sigmoidoscopy trial. The results showed a positive change for the majority of the health attitudes and practices and no differences in the health behaviors between subjects with a negative screening test result compared to those with pathological findings.

Thus, participants’ perception and HRQoL in CRC screening have rarely been addressed in the past and often used a combination of general HRQoL questionnaires and nonvalidated elements (Table 4). Nonspecific and validated questionnaires—comparable to the Inflammatory Bowel Disease Questionnaire (IBDQ) [84]—are presently not available to assess HRQoL during CRC screening.

A specific instrument with the purpose to assess the perception and the HRQoL of CRC screening participants is still lacking. Such an instrument could primarily serve clinical and public health studies at a national and international level in order for screening providers to audit the quality of their own activities and to compare them with those obtained by others. The instrument should cover all phases of the screening process from invitation onward, including the period when screening results are reported to the screenees, as well as a certain period of follow-up, independent of a positive (lesion found and treated) or negative outcome. Psychological anticipations and reactions of the participants should be addressed as much as the technical quality of the screening method and organizational details of the screening.

The findings reported here provide insights into the impact of CRC screening in HRQoL and give arguments in favor of screening programs. The HRQoL seems to be positively influenced by attending screening independently by its outcome. This is a crucial point as most subjects undergoing screening test will not have the disease and will not benefit directly from the test. The observed beneficial effect on HRQoL could be a persuasive argument to increase the attendance rate to screening for CRC.

**Summary and Conclusions**

In this overview, after a review of the general instruments for the assessment of HRQoL and the outcome of some more specific surveys associated with CRC screening, we have pointed out the elements that should be part of a questionnaire-instrument to be used in various forms of CRC screening. HRQoL has become ubiquitously implemented over the past 30 years in the outcome assessment of health care processes, diagnostics, treatment, and organization. Initially, HRQoL was seen as an important outcome in disorders in which therapeutic interventions could be very demanding and even more detrimental to patients than the disorder itself (like the chemotherapy of malignancies) and therefore limiting the applicability of such measures. More recently, HRQoL has been useful in more benign disorders and has been accepted as one of the parameters contributing to decisions of health care providers, insurers, and national and international drug agencies (e.g., the FDA and EMA) to license certain interventions.

Prevention is widely accepted as an important part of the management of benign and malignant diseases; therefore, it is reasonable that screening processes and procedures should undergo objective audits of their quality. As a con-
sequence, the HRQoL of screening participants should be assessed. Until now, this type of assessment in CRC screening has been used only sporadically, mainly applying traditional generic instruments or nonvalidated questionnaire constructs. An internationally accepted instrument does not yet exist and should therefore be created. Because the perceived HRQoL is an important self-reported outcome in the community, it is conceivable that positive reports can be an incentive for the potential screening population to adhere to calls for screening.

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