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An International Collaborative Standardizing a Comprehensive Patient-Centered Outcomes Measurement Set for Colorectal Cancer

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IMPORTANCE Global health systems are shifting toward value-based care in an effort to drive better outcomes in the setting of rising health care costs. This shift requires a common definition of value, starting with the outcomes that matter most to patients.

OBJECTIVE The International Consortium for Health Outcomes Measurement (ICHOM), a nonprofit initiative, was formed to define standard sets of outcomes by medical condition. In this article, we report the efforts of ICHOM's working group in colorectal cancer.

EVIDENCE REVIEW The working group was composed of multidisciplinary oncology specialists in medicine, surgery, radiation therapy, palliative care, nursing, and pathology, along with patient representatives. Through a modified Delphi process during 8 months (July 8, 2015 to February 29, 2016), ICHOM led the working group to a consensus on a final recommended standard set. The process was supported by a systematic PubMed literature review (1042 randomized clinical trials and guidelines from June 3, 2005, to June 3, 2015), a patient focus group (11 patients with early and metastatic colorectal cancer convened during a teleconference in August 2015), and a patient validation survey (among 276 patients with and survivors of colorectal cancer between October 15, 2015, and November 4, 2015).

FINDINGS After consolidating findings of the literature review and focus group meeting, a list of 40 outcomes was presented to the WG and underwent voting. The final recommendation includes outcomes in the following categories: survival and disease control, disutility of care, degree of health, and quality of death. Selected case-mix factors were recommended to be collected at baseline to facilitate comparison of results across treatments and health care professionals.

CONCLUSIONS A standardized set of patient-centered outcome measures to inform value-based health care in colorectal cancer was developed. Pilot efforts are under way to measure the standard set among members of the working group.

Related article

Supplemental content

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Group Information: A list of the Colorectal Cancer Working Group of the International Consortium for Health Outcomes Measurement (ICHOM) is provided at the end of this article.

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Colorectal cancer (CRC) is the third leading cancer in men and the second leading cancer in women globally, with 1.2 million new cases and 600 000 deaths per year.[1] Existing treatment options include surgery, radiation therapy, and chemotherapy, each with trade-offs between disease treatment and quality of life (QOL). Within each treatment modality, significant variation exists in the quality of care delivered across institutions, suggesting that there is opportunity for standardization to ensure high-value health care for all patients.[2]

Value-based health care is a conceptual framework that is guiding global health system reform and will grow in importance with recent health care policy changes.[3] It is founded on the principle of measuring and making decisions on the outcomes of care relative to the total cost of care.[4] In this instance, outcomes are patient-centered outcomes that include not only survival but also the ability to lead productive lives free of the symptoms of disease or treatment. Value-based health care is a framework that guides internal improvement efforts and system-level policies, such as reimbursement, market transparency, and comparative effectiveness research.[5-7] The foundation for these efforts is a common definition of value, starting with outcomes.

Outcomes measurement efforts in CRC exist.[8,9] However, to our knowledge, no measurement initiative includes patient-reported outcomes and is accepted internationally. This lack of standardized measurement impedes a widespread attainment of value-based care for patients with CRC. To inform the development of value-based initiatives,[10] the International Consortium for Health Outcomes Measurement (ICHOM) secured funding to develop a comprehensive patient-centered outcomes measurement set for this patient group.

Methods

The development of a standard set was initiated by ICHOM (http://www.ichom.org). ICHOM is a nonprofit organization that has developed standardized sets of pertinent outcomes for multiple medical conditions, including cancers of the prostate[11,12] and lung.[13] No institutional review board approval or informed consent was required for this study.

Working Group

ICHOM assembled a diverse team of experts (all authors except J. Lippa) and formulated a working group (WG), including representatives from patient advocacy groups, palliative care, oncology nursing, pathology, epidemiology, and radiation, surgical, and medical oncology from Europe, Australia, Asia, and the United States. A smaller project team (PT) (J.A.Z., M.G.S., A.C.M.V., C.S., C.J.V., and R.T.) guided the efforts of the larger group.

Development of the CRC Cancer Standard Set

The WG convened via 8 teleconferences between July 8, 2015, and February 29, 2016, and proceeded through a structured process similar to that described for prior cancer standard sets.[11,12,14-16] The development of the standard set involved several phases, shown in detail in the eFigure in the Supplement.

Development of Potential Outcomes List

The PT performed a structured PubMed (June 3, 2005, to June 3, 2015) literature review to identify clinical and patient-reported outcomes and measures of health-related QOL in men and women with CRC (eTable 1 in the Supplement). The literature review identified 1042 randomized clinical trials and guidelines. Three individuals (including J.A.Z.) reviewed citations until a saturation of outcomes was observed at 310 citations. Existing CRC registries were also reviewed, and the WG was asked to identify pertinent sources.

An international focus group of 11 patients (including authors D.B., J. Lloyd, P.K.M., and K.R.) with early and metastatic CRC was convened during a teleconference in August 2015. Through a semi-structured interview, participants provided their input on patient-centered outcomes for CRC, including which outcomes mattered most to them or other patients with CRC, what affected them most in day-to-day activities, and during what period. They were asked about outcomes in the categories of survival and disease control, complications, and degree of health. Findings from the literature review and the focus group were used to guide and inform the content of the WG teleconference discussions.

Modified 2-Round Delphi Method to Prioritize Outcomes and Case-Mix Variables

After each teleconference, each WG member voted anonymously for inclusion or exclusion of each outcome or case-mix variable. A similar process was used to agree on outcome definitions or, in the case of patient-reported outcomes measurements (PROMs), the measurement tool to be recommended.

Two rounds of a modified Delphi process were conducted. As per prior outcome development,[17-19] inclusion for all proposed outcomes and case-mix variables required consensus by at least 70% of the WG members rating the item as very important (score of 7-9 on a 9-point Likert-type scale) in either round (eTable 2 and eTable 3 in the Supplement). The items had to score between 7 and 9 by at least 50% to 70% in the second voting round to be brought to a final vote. The items were included in the standard set when at least 70% of WG members voted for inclusion in this final vote. Members of ICHOM maintained the data and conducted the surveys, but neither ICHOM nor its funders influenced voting.

Validation of Outcomes

The final list of outcomes as defined by the WG was validated in a larger group of patients with and survivors of CRC. Patients were recruited via several CRC patient organizations (Bowel Cancer Australia, Colon Cancer Alliance, Fight Colorectal Cancer, and the Association of Cancer Online Resources Colon Discussion List) to complete an anonymous online survey. Through social media recruitment, participants were asked to rate the importance of outcomes on a 9-point Likert-type scale. Participants had the option of including additional missing outcomes in a free-text box (eTables 4, 5, and 6 in the Supplement).

PROM Tools Selection

After finalizing the list of outcomes, the corresponding PROMs were identified. The PROMs' psychometric qualities were evaluated by the PT according to the International Society for Quality of Life Research Standards (eTable 7 in the Supplement).[20] A mapping of outcomes to PROMs was presented to guide WG members in decision making (eTable 8 in the Supplement).

External Input

The final standard set was presented to key stakeholders and others with an interest in outcomes measurement to review the set and provide feedback via an online survey. They were asked to rate their confidence on a 9-point Likert-type scale on several elements of the set (eg, completeness of the outcomes list and implementation feasibility), with an open field for comments (eTable 9 in the Supplement).

Results

Project Scope

The PT defined the scope of the project as all patients with invasive, American Joint Committee of Cancer stage I to IV colon or rectal cancer regardless of type or intent of treatment received, including those who did not receive therapy. Patients undergoing treatment with investigational agents were excluded because such studies have their own specific outcome assessments.

Outcomes

After consolidating findings of the literature review and focus group meeting, a list of 40 outcomes was presented to the WG and underwent voting (eTable 2 in the Supplement). Outcomes were grouped into the following 4 categories: survival and disease control, disutility of care (short-term treatment complications), degree of health (QOL, functioning, and long-term adverse effects), and quality of death. The final 31 outcomes are listed in **Table 1** and are discussed below. Of the 276 patients participating in the patient validation survey between October 15, 2015 and November 4, 2015, 223 (80.8%) believed that this list captured the most important outcomes and that no additional outcomes had to be included (eTable 6 in the Supplement). Some respondents suggested additional outcomes, which are discussed below. The timeline for outcome assessment was determined by the WG to achieve a balance between the clinically relevant times when outcomes may be expected to change and the pragmatic concerns that institutions and practices face in data collection (**Figure 1**).

Survival and Disease Control

The following measures were included for survival and disease control: overall survival, disease-specific survival, recurrence, and progression-free survival. For patients with rectal cancer receiving neoadjuvant therapy or surgery, pathological complete response and margin status, respectively, were included because they may serve as intermediary outcomes, proxies of survival, and short-term indicators of surgical quality.[21] The recommended time frame for collection of data was 1 year after treatment and, if possible, annually up to 10 years.

Disutility of Care

Care disutility measures focused on short-term complications of treatment, including type and severity. An algorithm to determine severity was developed based on the grading systems of the Clavien-Dindo classification for surgical complications[22] and the Common Terminology Criteria for Adverse Events, version 4.0 for radiation therapy and chemotherapy.[23]

Degree of Health (QOL, Functioning, and Symptoms)

The final QOL, functioning, and symptoms measures are listed in Table 1. Although social functioning, dietary restrictions, and vaginal symptoms were excluded after the second Delphi round (eTable 2 in the Supplement), they were reconsidered in the final voting because of their high rating of importance by focus group patients, on the patient validation survey, and by the WG.

PROMs were used to assess the degree of health outcomes. After relevant outcomes were selected, corresponding reliable and valid measurement tools were reviewed (eTables 7 and 8 in the Supplement). PROM tools were researched based on the outcome coverage, psychometric quality, clinical interpretability, and feasibility to assess and implement the PROMs in daily practice. After extensive evaluation and discussion, the WG recommended the European Organisation for Research and Treatment of Cancer (EORTC) Quality of Life C30 tool[24] to capture overall QOL and the EORTC Quality of Life CR29 tool[25] to capture CRC-specific outcomes. To capture outcomes not directly assessed in the EORTC measurement tools, the Memorial Sloan Kettering Cancer Center Bowel Function dietary subscale[26] and a single item of the EORTC Quality of Life LM21 tool[27] were selected to assess dietary issues and neuropathy, respectively, for patients who received chemotherapy. All PROMs were recommended for collection at baseline, 6 months and 1 year after treatment, and annually up to 10 years, if possible. The use of recommended PROMs is encouraged at more frequent time points during the treatment process to support communication and clinical decision making.

Quality of Death

Several reports have outlined outcomes related to the quality of end-of-life (EOL) care.[28,29] Because research suggests that EOL hospitalization may be preventable and may indicate poor quality of care,[28] the WG decided to include the outcome of more than 1 hospital admission in the last 30 days of life for patients with advanced disease. Place of death was included, with response options that are internationally comparable and easy to obtain.[30] The patient's preference for place of death was also included because patients often have individualized EOL care preferences and needs that necessitate assessment and documentation.[29] A measure on hospice use was included given evidence showing its benefit at the EOL, in part due to providing less aggressive care.[28] We recommend reviewing the records of deceased patients on an annual basis for EOL outcomes.

Case-Mix Variables

Case-mix variables were included for baseline collection to allow for cross-treatment and cross-center comparison (**Table 2**). These variables included demographic factors, baseline clinical factors, and baseline tumor factors.

Demographic factors included age, sex, race/ethnicity, educational level, and relationship status. Because racial/ethnic disparities have been demonstrated in CRC treatment and outcomes,[31] the WG determined that race/ethnicity was also important to include. However, because there is no standardized method to assess racial/ethnic subgroups internationally, we recommend using national or regional classification systems instead. While socioeconomic status is predictive of health outcomes in patients with CRC,[32] it is difficult to accurately assess. Educational level, defined as the highest

Table 1. Summary of Outcomes for the ICHOM Colorectal Cancer Standard Set

Patient Population	Measure	Details	Data Sources[a]
Survival and Disease Control			
All patients	Overall survival	Date of death	Administrative data (death registry or claims data)
	Cause of death	Death attributed to colorectal cancer	
Patients with curative intent	Recurrence-free survival	Local, regional, or distant recurrence	Clinical abstraction
Patients with advanced disease	Progression-free survival	Disease progression	
Patients with rectal cancer receiving neoadjuvant therapy	Pathological or clinical complete response	No sign of residual invasive cancer of resected specimen or on diagnostic evaluation	
Patients with rectal cancer receiving surgery	Margin status	Evidence of circumferential margin involvement	
Disutility of Care			
All patients with treatment	Short-term complications of treatment[b]	Any complication leading to an intervention, prolonged hospitalization, unplanned readmission, intensive care (unit) management, discontinuation of treatment, reduced dosing, limiting self-care activity of daily living,[c] or death	Clinical abstraction
Degree of Health			
All patients	Overall well-being	Tracked via EORTC Quality of Life C30	Patient-reported sources
	Physical functioning		
	Emotional functioning		
	Social functioning		
	Mobility		
	Depression		
	Pain		
	Fatigue		
	Sexual functioning	Tracked via EORTC Quality of Life CR29	
	Bowel functioning		
Patients with surgery or radiation therapy	Dietary issues	Tracked via MSKCC Bowel Function dietary subscale	NA
	Fecal leakage	Tracked via EORTC Quality of Life CR29	
	Stool frequency		
	Diarrhea		
	Gastrointestinal symptoms		
	Erectile dysfunction		
	Vaginal symptoms		
Patients with systemic therapy	Neuropathy	Tracked via EORTC Quality of Life LM21 (1 item)	NA
Patients with surgery	Presence of stoma (colostomy or ileostomy)	If yes, report ostomy functioning, as well as via EORTC Quality of Life CR29	Clinical and, if applicable, patient reported
Quality of Death			
Patients with advanced disease	Hospital admission at end of life	Admission to the hospital >1 time in the last 30 d of life	Clinical abstraction
	Hospice care	Hospice care at time of death	Administrative or clinical abstraction
	Place of death	Where patient died (home, hospital, or nursing home or care home)	Administrative data (death registry or claims data)
	Preference for place of death	Where patient preferred to die (home, hospital, or nursing home or care home)	Clinical abstraction

Abbreviations: EORTC, European Organisation for Research and Treatment of Cancer; ICHOM, International Consortium for Health Outcomes Measurement; MSKCC, Memorial Sloan Kettering Cancer Center; NA, not applicable.

[a] The data source reflects the way outcomes are collected and was determined as clinical (eg, physician report), patient reported (eg, EORTC Quality of Life C30), or administrative (with a combination of ways in some cases).

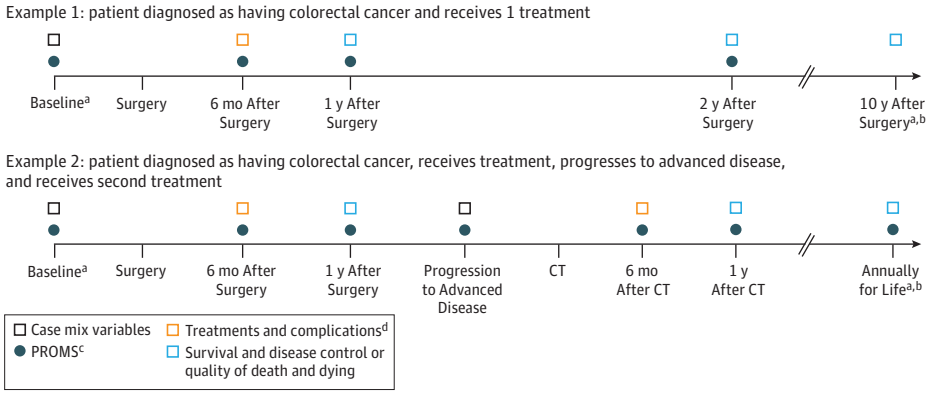
[b] Collection of short-term complications is recommended when the patient is undergoing treatment or within 90 days after initiation of treatment. The type of short-term complication is also to be recorded specific to treatment type, including surgery (leakage, breakdown of anastomosis, wound infection, thromboembolic, hematoma, stoma-related complication, and incontinence), radiation therapy (skin desquamation, dysuria, dehydration, weight loss, and neurotoxicity), chemotherapy (febrile neutropenia, neutropenic sepsis, and mucositis), and targeted therapy (skin toxicity). Full details of definitions may be found in the online reference guide available at http://www.ichom.org/medical-conditions/colorectal-cancer.

[c] Self-care activities of daily living refer to bathing, dressing and undressing, feeding self, using the toilet, taking medications, and not being bedridden.

level of schooling attained, is reported to serve as a good surrogate for socioeconomic status and is easily obtainable and internationally comparable.[33] Relationship status was included because it is considered to be an important aspect of social support, which is independently associated with survival.[34]

Baseline clinical factors prioritized for inclusion were Eastern Cooperative Oncology Group performance status, comorbidities, cognitive status, and disorders with predisposed CRC risk. The patient-reported, modified Self-Administered Comorbidity Questionnaire[35] was selected for comorbidity reporting because it

Figure 1. Sample Timelines Showing When Outcomes and Baseline Factors Should Be Collected for Patients With Colorectal Cancer



These timelines are intended to represent the outcome data collection points for possible treatment paths a patient could take and do not advocate a particular treatment approach. Most baseline factors should be collected at the time of initiation of the colorectal cancer standard set, although several (eg, pathological stage) are collected after treatment. CT indicates chemotherapy; PROMs, patient-reported outcomes measurements.

[a]At first physician visit.

[b]Distinction for long-term follow-up: patients with local disease should receive follow-up for up to 10 years, and patients with advanced disease should receive follow-up annually for life.

[c]All PROMs will be collected at baseline, 6 months after treatment, and then annually.

[d]Collection of short-term complications is recommended when the patient is undergoing treatment or within 90 days after initiation of treatment.

has been shown to predict functional outcomes equally as well as the Charlson Comorbidity Index.[36]

Several baseline tumor factors were included, such as tumor location, clinical and pathological TNM stage, and treatment intent (Table 2). If there is more than 1 primary tumor, tumor factors of the tumor with the highest clinical TNM stage should be collected. Urgency of procedure was also included according to the United Kingdom's National Confidential Enquiry Into Peri-operative Deaths classification.[37]

Treatment Variables

To provide a standardized terminology of treatment options among heterogeneous health care delivery institutions, the most commonly used treatment types in daily practice were included for local and systemic therapy, with free-text options for other treatment delivered. These variables are listed in Table 2.

Reference Guide

A reference guide, which includes sample questionnaires and timelines, is freely available on the ICHOM website (http://www.ichom.org/medical-conditions/colorectal-cancer). The website also contains a data dictionary for all variables in the standard set.

External Input

A total of 28 health care professionals from different specialties participated in an open review period and shared feedback via an online survey. The respondents were confident (mean score, 6.8 on a 9-point Likert-type scale) about the comprehensiveness of the standard set and the feasibility of data collection in clinical practice (eTable 9 in the Supplement). Main concerns raised were related to the duration of follow-up and the number of PROMs questions and data items, which could influence feasibility. One additional case-mix variable related to the tumor distance from the anal verge was included based on the feedback survey.

Discussion

An international, multidisciplinary WG convened during 8 months to develop a standardized and comprehensive patient-centered outcomes measurement set for patients with CRC. Through the use of extensive patient input, a literature review, and expert consensus, the WG defined a final standard set, which we propose will facilitate institutions and practices in adapting to a restructuring of health care delivery and reimbursement that focuses on value (outcomes relative to cost).

We recognize that this standard set is not inclusive of all outcomes that may matter to patients. To balance the aims of the WG with the development of a product that would be practical to implement in clinical practice, the WG sought to construct a parsimonious data set. Centers are encouraged to collect additional information outside of the standard set, if desired. ICHOM has appointed a steering committee, composed of members of this working group, to convene annually and update the standard set based on feedback from implementers and other developments in the field of CRC treatment.

Limitations and Future Directions

The standard set is limited by its integration of multiple PROMs. While most of the PROMs (59 of 64 [92.2%]) are from 2 well-tested instruments (EORTC Quality of Life C30 and CR29), the use of a single question from the EORTC Quality of Life LM21 and the addition of a module from the Memorial Sloan Kettering Cancer Center Bowel Function dietary subscale have not been tested in this context. These additional questions were added to inform outcomes that were prioritized by patients but not collected within the EORTC measurement system. Each recommended instrument or question has been individually validated, but further work is required to understand how to interpret these instruments within a single set of outcomes. The

Table 2. Summary of Case-Mix Factors and Treatment Approaches for the ICHOM Colorectal Cancer Standard Set

Patient Population	Measure	Details	Data Sources[a]
Demographic Factors			
All patients	Date of birth	NA	Patient-reported sources
	Sex		
	Body mass index	Height and weight	Clinical abstraction
	Race/ethnicity	Determined by country	Patient-reported sources
	Educational level	Level of schooling completed according to ISCED[b]	
	Relationship status	Relationship status	
Baseline Clinical Factors			
All patients	Performance status	ECOG or WHO scale for performance status	Clinical abstraction
	Comorbidities	Modified SCQ[c]	Patient-reported sources
	Cognitive status	Evidence of cognitive disorder	Clinical abstraction
	Familial adenomatosis polyposis	Presence of *APC* mutation (OMIM 611731)	
	Lynch syndrome or hereditary nonpolyposis colon cancer	Presence of *MMR* (OMIM 276300) or *EPCAM* (OMIM 185535) mutation	
	IBD	Clinical documentation of IBD diagnosis	
Baseline Tumor Factors			
All patients	Date of diagnosis	Initial date of histological diagnosis	Clinical abstraction
	Synchronous primary tumor	Presence of >1 primary tumor[d]	
	Tumor location	NA	
	Clinical stage	Clinical stage per AJCC editions 5-7	
Patients with rectal cancer receiving surgery or radiation therapy	Location of rectal tumor	Distance from anal verge (in millimeters)	
Patients with surgery or biopsy	Tumor grade	Histological grade of tumor	
	BRAF status	Presence of *BRAF* (OMIM 164757) mutation	
	RAS status	Presence of *RAS* (OMIM 164790, 190070, 190020) mutation	
	MSI or DNA mismatch repair	Presence of *MSI* (OMIM 276300) mutation	
Patients with surgery	Pathological stage	Pathological stage per AJCC editions 5-7	
	No. of lymph nodes resected	NA	
	No. of lymph nodes involved		
	Lymphovascular invasion of tumor	Presence of lymphovascular invasion of tumor	
	Perineural invasion of tumor	Presence of perineural invasion in resected tumor	
	Completeness of surgical resection	Presence of residual disease after surgery according to TNM	
Baseline Treatment Factors			
Patients with surgery	Urgency of procedure	According to NCEPOD score[e]	Clinical abstraction
All patients	Perforation	Presence of perforation of the bowel at site of the tumor	
	Treatment intent	Curative or palliative treatment intent	
Treatment Approaches			
All patients	Surgery	Type and method of surgical procedure	Clinical abstraction
	Radiation therapy	Type of radiation therapy	
	Chemotherapy	Type of chemotherapy	
	Targeted therapy	Type of targeted therapy	
	No treatment	NA	

Abbreviations: AJCC, American Joint Committee on Cancer; APC, adenomatous polyposis coli; ECOG, Eastern Cooperative Oncology Group; EORTC, European Organisation for Research and Treatment of Cancer; EPCAM, epithelial cell adhesion molecule; IBD, inflammatory bowel disease; ICHOM, International Consortium for Health Outcomes Measurement; ISCED, International Standard Classification of Education; MMR, mismatch repair; MSI, microsatellite instability; NA, not applicable; NCEPOD, National Confidential Enquiry Into Peri-operative Deaths; SCQ, Self-Administered Comorbidity Questionnaire; WHO, World Health Organization.

[a] The data source reflects the way outcomes are collected and was determined as clinical (eg, physician report), patient reported (eg, EORTC Quality of Life C30), or administrative (with a combination of ways in some cases).

[b] Level of schooling was defined in each country according to the ISCED.

[c] Have you ever been told by a physician that you have any of the following? I have no other disease, heart disease (eg, angina, heart attack, or heart failure), high blood pressure, leg pain when walking due to poor circulation, lung disease (eg, asthma, chronic bronchitis, or emphysema), diabetes, kidney disease, liver disease, problems caused by stroke, disease of the nervous system (eg, Parkinson disease or multiple sclerosis), other cancer (within the last 5 y), depression, or arthritis (select all that apply).

[d] If yes, please collect information on the tumor with the highest TNM stage.

[e] Elective (operating room at a time that suits surgeon and patient), scheduled (operating room within 3 weeks, early surgery preferred, and not life saving), urgent (operating room within 24 hours or as soon as possible after resuscitation), or emergency (operating room within 2 hours, immediate operating room, or resuscitation simultaneous with operating room).

Figure 2. Sample Institutional Implementation Plan for the Colorectal Cancer Standard Set

	1. Patient-reported data	2. Structured clinical data	3. Linked data
Key portions of data set	PROMs (eg, EORTC Quality of Life C30, CR29, and LM21 and MSKCC Bowel Function dietary subscale)	Case mix variables (eg, baseline clinical, tumor, and treatment factors) and complications of treatment	Survival and disease control (eg, disease recurrence, overall survival, date of death, place of death, and cause of death)
Operational requirements	Tablet-based, patient-reported outcome data collection software for use in clinic with real-time scoring[a]	Manual medical record abstractors, scribes, or Smart Forms built into the hospital's electronic medical record system	Unique patient identifiers, privacy laws that support linkages, facilitated by interoperability standards[b]
Example use cases	Better monitoring of symptom burden, better communication between patients and care professionals	Quality improvement, benchmarking, value-based payment programs	Comparative effectiveness research

EORTC indicates European Organisation for Research and Treatment of Cancer; MSKCC, Memorial Sloan Kettering Cancer Center; and PROMs, patient-reported outcomes measurements.

[a]Increasingly available in standard electronic medical record systems.

[b]Linkage capabilities are often constrained by national health information technology infrastructure and patient privacy policies; in their absence, institutions are encouraged to follow up patients according to their best ability and resources.

WG recognizes that 64 total questions represent a significant respondent burden; however, there is evidence that questions of strong salience to patients that are integrated into the clinical interaction can outweigh increased respondent burden.[38] Experience collecting these outcomes in practice will inform whether any of these domains can be eliminated while retaining the standard set's usefulness. We anticipate that respondent burden will also be reduced through future development of item banks and computer-adaptive testing, which allow for modular selection of outcome domains and more precise measurement within a given domain.[39]

We recognize that this recommendation will stretch the capabilities of most institutions. Routine collection of patient-reported outcomes is rare in most organizations, and much of the recommended clinical data are unstructured, making it difficult to extract for analysis. There are larger trends actively changing these capabilities. Major electronic medical record vendors and many third-party tools exist to support patient-reported data collection and integration into the electronic medical record.[40,41] These same vendors are also creating structured data fields within specialty-specific templates.[42] These changes are being driven by demands from payers and government for structured, standardized data elements to facilitate reporting of outcomes directly or through quality registries.

Collection of this data set could also be limited by the existing national infrastructure for following up patients. In some countries, through linkages made possible by national patient identifiers,[43] cancer recurrence can be tracked over time. In other countries, this data collection is not possible, and in the absence of resources for manual tracking, follow-up will likely be limited to those patients who remain longitudinally at their initial treating institution.

In light of these challenges, we recommend that institutions take a stepwise approach to implementation (**Figure 2**), beginning with patient-reported outcomes. Evidence suggests that the use of patient-reported outcomes in cancer treatment can improve patient-physician communication, QOL, and survival while reducing emergency department visits and hospitalizations.[44,45] Incorporating patient-reported outcomes into clinical practice is also typically simpler than collecting structured clinical data, which requires specially trained medical record abstractors or redesign of clinical workflows. However, clinical data are necessary for quality improvement or value-based payment applications.

Alongside improvements in technical infrastructure, successful implementation of the standard set will require a significant change in clinical attitudes and workflow,[46] starting with the desire to incorporate the patients' perspective more systematically into the care process. To help guide organizations through this process, ICHOM has developed a framework that comprises 4 phases (eTable 10 in the Supplement). It was designed to engage the organization and enable change as well as sustain and build on results. This framework has been successfully used across a range of conditions and settings.

ICHOM's near-term implementation goal for this standard set is to partner with select members of the WG to implement the set as a proof of concept, to inform revision by the steering committee, and to pave the way for broader adoption and endorsement by national policy and regulatory bodies. This approach has been successfully used for the localized prostate cancer standard set, facilitated by the Movember Foundation.[47]

Conclusions

The goal of this project was to develop a standardized set of patient-centered outcome measures to inform value-based health care efforts in CRC care. This article describes the process by which a novel comprehensive standard set was developed to meet this need.

ARTICLE INFORMATION

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