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Quality Indicator Selection for The Canadian Partnership Against Cancer (CPAC) Rectal Cancer Project: A Modified Delphi Study

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ABSTRACT

Aim: It is well established that (i) magnetic resonance imaging (MRI), (ii) Multidisciplinary Cancer Conference (MCC), (iii) pre-operative radiotherapy, (iv) Total Mesorectal Excision (TME) surgery and (v) pathologic assessment as described by Quirke are key processes necessary for high quality, rectal cancer care. The objective was to select a set of

multidisciplinary, quality indicators to measure the uptake of these clinical processes in clinical practice.

Method: A multidisciplinary panel was convened and a modified, two phase Delphi method was used to select a set of quality indicators. Phase 1 included a literature review with written feedback from the panel. Phase 2 included an in-person workshop with anonymous voting. The selection criteria for the indicators were: strength of evidence, ease of capture and usability. Indicators for which ≥90% of the panel members voted "to keep" were selected as the final set of indicators.

Results: During Phase 1, 68 potential indicators were generated from the literature and an additional 5 indicators were recommended by the panel. During Phase 2, these 73 indicators were discussed and 48 indicators met the 90% inclusion threshold and included 8 pathology, 5 radiology, 11 surgical, 6 radiation oncology and 18 MCC indicators.

Conclusion: A modified Delphi method was used to select 48 multidisciplinary, quality indicators to specifically measure the uptake of key processes necessary for high quality care of patients with rectal cancer. These quality indicators will be used in future work to identify and address gaps in care in the uptake of these clinical processes.

What does this paper add to the literature?

This study is important because it provides a set of 48 multidisciplinary, quality indicators that can be used to measure the uptake in order to identify and address gaps in care for key processes of high quality, rectal cancer care.

INTRODUCTION

Quality in healthcare is defined as the degree to which health services for individuals and

populations increase the likelihood of desired health outcomes and are consistent with current professional knowledge[1]. With growing demand for services and increasingly constrained resources, improving the quality of healthcare delivery has emerged as a priority for institutions and health systems[2].

Quality indicators are standardized, evidence-based measures that represent a means to gauge clinical performance and therefore measure quality[3]. Quality indicators have several possible applications. They may be used to evaluate the care received by individuals or administered by institutions[4]. Measured over several centers, they may then be used to develop benchmarks[5, 6]. Finally, they may be used to identify evidence-to-practice gaps to be targets for knowledge translation and further inform quality improvement initiatives[7].

Traditionally, quality indicators have been categorized as structure, process or outcome measures[8-10]. Structural measures focus on attributes and facilities of health care, process measures focus on the specific steps that lead to a particular outcome and outcome measures focus on the effects of healthcare on the patient or the system. Additionally, indicators may be classified as generic measures, relevant to all disease's states, or disease-specific measures that describe the quality of care related to a specific diagnosis[3]. Within cancer care, data from disease-specific quality indicator compliance has been successfully used in several multi-institution and national audits to make comparisons over time, set priorities for the organization of care, support accountability, and inform quality initiatives with the goal of improving care delivery[11-16].

In rectal cancer care, it is established that (i) pre-operative staging with magnetic resonance imaging (MRI), (ii) implementation of multidisciplinary cancer conferences (MCC), (iii) appropriate use of pre-operative radiotherapy, (iv) Total Mesorectal Excision (TME) surgery and (v) pathologic assessment as described by Quirke, are key components of high-quality care[17-27]. These clinical processes and strategies have been widely supported in the literature and have led to improved patient outcomes. However, their implementation has been challenging, with several studies from North America and Europe demonstrating considerable variation in their uptake across clinical practice[16, 28-38].

The Canadian Partnership Against Cancer (CPAC) Rectal Cancer Project is a multi-year knowledge translation (KT) initiative. A full protocol of the CPAC rectal cancer project has been published previously[39]. The objective of this current study reflects the first stage of the CPAC Rectal Cancer Project which is to systematically select a set of multidisciplinary, quality indicators to measure the uptake of these established key components of high quality rectal cancer care.

METHODS:

Study Setting and Community of Practice:

As part of the CPAC Rectal Cancer Project, opinion leaders in surgery, radiology, medical oncology, radiation oncology and pathology from 8 high volume rectal cancer centres across Canada were invited to form a multidisciplinary community of practice (CoP) and to select a set of quality indicators that would measure the uptake of the established processes necessary for high quality rectal cancer care using a modified Delphi method.

Delphi Method:

The Delphi Method is an iterative technique designed to congregate expert opinion through a series of iterative questionnaires or "rounds", with the goal of coming to a group consensus[40]. In the modified Delphi approach, instead of open-ended questions, the process begins with a set of carefully selected items and it incorporates a face-to-face meeting of expert participants[41]. In this study, a 2-phase modified Delphi approach was applied to systematically select clinically relevant multidisciplinary quality indicators.

Delphi Phase 1: Literature Review and Feedback

The guiding principles used by the CoP to develop a comprehensive set of potential indicators were that the indicator was evidence based and directly measures one of the key processes of high quality rectal cancer care, including (i) magnetic resonance imaging (MRI), (ii) Multidisciplinary Cancer Conference (MCC,) (iii) pre-operative radiotherapy, (iv) Total

Mesorectal Excision (TME) surgery and (v) Quirke method pathologic assessment as described by Quirke.

Potential quality indicators were identified by the investigative team through review of previously published indicators in the literature or by national bodies such as the American Society of Clinical Oncology (ASCO), the National Comprehensive Cancer Network (NCCN), the National Initiative on Cancer Care Quality (NICCQ), the Quality Oncology Practice Initiative (QOPI), the BC Cancer Agency, Cancer Care Ontario (CCO) and the Florida Initiative for Quality Cancer Care (FIQCC). This was supplemented by a scoping review of PubMed/MEDLINE to identify further potentially relevant publications. Backward and forward snowballing of references and citations respectively was performed until saturation was reached. To supplement the literature review, specialty members of the CoP were also approached and invited to suggest further potential quality indicators.

Once generated, identified indicators were grouped as either pathology, radiology, surgery, radiation oncology, multidisciplinary cancer conference (MCC) or pre-operative indicators. The collated list was then sent electronically to CoP members via email survey for review. Members were asked to rate proposed indicators on a 5-point scale based on clinical relevance, with low scoring indicators (rating 1or 2) removed from consideration. At this time, members were also encouraged to provide written feedback via the electronic survey and suggest additional potential indicators for final review.

Delphi Phase 2: In-person Workshop and Iterative Voting

An in-person planning workshop was held on May 23rd, 2014 in Toronto ON, Canada. At the workshop, the potential indicators from Phase 1 were presented with review of associated evidence, followed by a moderated multidisciplinary discussion. An anonymous vote followed to include/exclude proposed indicators. To be eligible for selection, indicators were required to (i) be evidence based, (ii) directly measure one of the key processes of high quality rectal cancer care, (iii) be easily captured by document review and (iv) be actionable. Indicators for which 90% or more of the CoP voted "to keep" based on these criteria were included in the final set of indicators. A high consensus threshold of 90% was selected in order to ensure widespread acceptance of the selected indicators from future study participants during the data collection and quality improvement stages of the project.

Recommended Measurement Tools for Data Capture

After completion of the Delphi method, the CoP was asked to recommend specific tools that were currently being successfully used at their own centres that could be easily modified and/or implemented at other centres to assist with the data capture of this newly selected set of indicators.

RESULTS:

Thirty-two out of the forty invited individuals agreed to participate in the CoP meeting. This consisted of 4 individuals from each centre and 8 individuals from surgery, radiology, radiation oncology and pathology. None of the invited medical oncologists agreed to participate in the CoP. The reasons that medical oncologists provided to the investigative team were that the specific issues being addressed at the CoP were not a "high enough" priority. Subsequently, two additional medical oncologists were invited on an ad hoc basis and participated in the CoP meeting.

A summary of the indicator selection process is shown in Figure 1. During Phase 1 of the modified Delphi method, 68 potential indicators were identified during the literature review and an additional 5 were recommended by the CoP (2 pathology, 1 radiology, 1 radiation oncology, 1 surgery). None of the initial indicators were removed. In total, 73 potential indicators were identified during Phase 1 and included 13 surgery, 12 radiology, 13 pathology, 9 radiation oncology, 18 MCC and 8 pre-operative indicators.

For Phase 2 of the modified Delphi method, 31 of 32 (88.9%) CoP members, representing all 8 participating sites, participated in the in-person workshop. Representation by specialty included 6 pathologists, 9 radiologists, 8 surgeons, 6 radiation oncologists and 2 clinicians who did not specify specialty. Following voting, 48 of 73 indicators (65.7%) met the inclusion threshold of 90% and were included in the final set of indicators. This final set of indicators included 6 pre-operative, 5 radiology, 5 surgery, 8 pathology, 6 radiation oncology, and 18 MCC indicators (Table 1). Table 2 shows a list of the 25 indicators that were excluded. At the time of the meeting, the CoP decided not to include any indicators with a specified time

frame as there were significant concerns that these indicators were more of a reflection on resource constraints as opposed to the quality of clinical care. Furthermore, since the dates of the reports would be included in the data collection, these time indicators could be reviewed outside the context of the study. There was considerable discussion around re-staging MRI, however this was excluded since re-staging MRI was not being performed as routine practice at all of the participating centres.

Based on the final set of indicators, the CoP recommended measurement tools currently being used at their own centres that would help facilitate data capture. The College of American Pathologist (CAP) checklist[42], BC Cancer Agency Rectal Cancer Surgery Checklist[43], Cancer Care Ontario synoptic MRI report[44] and the Radiation Oncology Peer Review Checklist (appendix A) were identified as existing clinical tools that could be used to facilitate data capture for most proposed quality indicators.

DISCUSSION:

For this study, a multidisciplinary CoP was convened, and a modified Delphi method was used to select a set of indicators to measure the uptake of processes and strategies necessary for high quality rectal cancer care. In total, 48 indicators were selected and represented the multidisciplinary care of rectal cancer including specific indicators for pathology, radiology, surgery, radiation oncology, multidisciplinary cancer conference (MCC) and pre-operative care.

Several colorectal cancer specific quality indicators have already been proposed in the literature, with a recent systematic review identifying 349 unique indicators from 12 consensus-based publications[45] (Table 3). While similar to our study in that most were selected using combined literature review and consensus methodology, most of these studies focused primarily on combined colorectal and surgical indicators. In contrast, our group was able to develop a set of indicators specifically for rectal cancer that were evaluated by a multidisciplinary CoP. Our experience was consistent with the evidence that suggests that compared to single discipline panels, multi-disciplinary groups tend to reach consensus on a differing set of quality indicators[46]. For example, while initially the surgeons did not feel strongly that a synoptic OR report should be included as an indicator, the radiologists and pathologists provided feedback

that a synoptic OR report would help them complete their reports more accurately and this led to a unanimous vote by the CoP to include a synoptic OR report as an indicator for the study.

European programs have successfully evaluated quality indicators and outcomes as part of national audits with demonstrated improvements in rectal cancer care[47-51]. More recently, the European Registration of Cancer Care (EURECCA), an outcome-based, multidisciplinary audit registry consisting of pooled data from 9 national audits and 11 countries, was established to reduce systematic variance by standardizing and harmonizing care in Europe[52]. Based on European success, in the US the Commission on Cancer Rectal Cancer Accreditation Program was recently established to standardize and improve rectal multidisciplinary cancer care through setting of quality indicator benchmarks[53, 54]. Similarly, we plan to use the developed indicators to evaluate the quality of rectal cancer care on a national level. The selected indicators will be measured prospectively, and we plan to use longitudinal measurements of selected quality indicators to set preliminary benchmarks for participating institutions. We also plan to validate selected indicators against both short and long term oncologic outcomes. Additionally, we plan to evaluate the effectiveness of knowledge translation initiatives on improving the quality of care. We expect that high quality of care will be associated with improved outcomes and improvements in quality to correlate with improvement in outcome. We believe the results of the project will be generalizable to other tertiary care centers within Canada considering the geographic diversity of participating institutions.

There are several limitations to this study. First of all, this set of indicators was developed specifically for the CPAC Rectal Cancer study for which our group has recently completed data collection for 5 year outcomes for a prospectively collected cohort of 600 patients with Stage I-III rectal cancer treated with TME surgery. Clearly, over this time period, there have been secular trends (i.e., non-operative management [NOM], total neoadjuvant therapy [TNT]) and therefore updating this indicator set would be necessary in order to reflect both these secular trends and the specific goals of future projects. For example, at the time of our CoP meeting, we could not achieve consensus to include re-staging MRI as an indicator as it was not considered to be a routine practice, however if we were to update these indicators it is quite likely that consensus would be achieved to include re-staging MRI as an indicator given the increased uptake of NOM and TNT.

Furthermore, at the time of our initial CoP meeting we were not able to actively engage our medical oncology colleagues to commit to the time requirements of this project. As a result, we did not formally include any medical oncology indicators because we did not have any local champions to lead the implementation of medical oncology quality initiatives. However, we did capture medical oncology data including receipt of chemotherapy and time of initiation of chemotherapy from surgery. It is quite likely that if we had initiated this study today, we would have been more successful at engaging our medical oncology colleagues given the increased uptake of TNT and that this would result in a change in some of the selected indicators. For instance, the MCC indicator indicating that the medical oncologist attendance at MCC would likely increase to 100% rather than 50% which was based on Cancer Care Ontario MCC Standards at the time of the study.

An additional limitation of the study was that the quality indicator selection relied on the CoP membership consisting of Canadian rectal cancer experts working at tertiary care hospitals. Also, patient preferences in quality indicator selection were not incorporated. This may bias the external validity of our findings in non-Canadian, non-academic settings. Finally, limitations of the Delphi method must also be considered. Most notably, that there are no agreed upon definitions for consensus, there is limited evidence of reliability (i.e., two panels receiving the same question may not come to the same consensus), and that independence of participant responses may be influenced by determined individuals during voting [40, 55]. This was addressed in our study through use of stringent consensus criteria (90%), the restriction of the CoP to content experts whose opinions would likely reflect best practices of the time and use of electronic and anonymous voting. Despite these limitations, we believe the outlined methods provide a useful framework for other societies and regions to create their own quality indicators and that the selected indicators will still provide the foundation for further assessments of quality in rectal cancer care.

CONCLUSION:

A multidisciplinary CoP participated in a modified Delphi method to select a set of quality indicators to measure the uptake of processes and strategies necessary for high quality rectal cancer care. These selected indicators will be used and validated as part of the CPAC Rectal Cancer Project to measure the current quality of rectal cancer care and identify gaps in

care in order to inform future knowledge translation initiatives to improve the quality of rectal cancer care across Canada.

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Table 1: Final process indicators

Process Indicators	Evidence
Pre-operative Assessment	
1. Pre-operative CEA testing	56-61

2. Pre-operative staging workup with CT abdomen/pelvis	
3. Pre-operative staging chest imaging (CXR or CT; CT preferred)	
4. Pre-operative endoscopy	
5. Pre-operative local staging (MRI or TRUS; MRI preferred)	17, 62, 63
6. Presentation at MCC	64-73
Radiology	
1. MRI protocol meets minimum MERCURY criteria	74
2. MRI report in synoptic format	42, 75-79
3. Complete MRI report: - *Assessment of mesorectal lymph nodes documented* - *Assessment of distance to the MRF documented* - *Assessment of distance of lower extent of tumor relative to anal verge* - *Assessment of extramural depth of venous invasion* - *Assessment of relationship of tumor to anterior peritoneal reflection* - *Assessment of distance from top of the puborectalis sling to the lower extent of tumor*	44, 80-83
4. Percentage agreement between MRI and pathology for MRF/CRM within 1mm	74
5. Percentage agreement between MRI and pathology for T stage	17
Surgery	
1. Pre-operative marking by a stoma RN when applicable (planned stoma)	56
2. OR report in synoptic format	42, 76-78
3. Documentation of distance from anal verge to lowest extent of tumour	56
4. Documentation of rationale for APR	56
5. Unplanned return to OR within 30 days	84
Pathology	
1. Pathologic assessment using Quirke method	23, 27, 85
2. Assessment of quality of the total mesorectal excision specimen (complete, near complete, incomplete)	27
3. Assessment of circumferential resection margin (CRM)	85
4. Assessment of extramural venous invasion	86
5. Pathology report created in synoptic format	42
6. Pathology report contains mandatory data elements of the CAP checklist	42, 76-78
7. Proportion of cases containing >5 tumor blocks	Expert opinion
8. Assessment of pathologic response to neoadjuvant therapy performed	87
Radiation Oncology	
1. Radiation plan meets criteria for dose distribution	88, 89

2. Documentation of rationale if radiation pan does not meet dose distribution criteria	89
3. Radiation plan is peer reviewed	90
4. Radiation therapy note is in synoptic format	42, 76-78
5. Image guided set-up for radiation plan	Expert opinion
6. Radiation therapy note is complete: - Planned/delivered dose and fractionation - Technique (field-based, 3D conformal, IMRT) - Start date/completion date documented - Delay/disruption in treatment (any reason) - Documentation of acute side effects	Expert opinion
Multidisciplinary Case Conference (MCC)	
1. MCC held at least every 2 weeks	73, 91
2. MCC coordinator to organize rounds	
3. MCC chair to facilitate rounds	
4. Representation from surgery 100% of rounds	
5. Representation from radiology 100% of rounds	
6. Representation from radiation oncology 100% of rounds	
7. Representation from pathology 75% of rounds	
8. Representation from medical oncology 50% of rounds	
9. Sessions attended by at least one treatment physician for each case	
10. Clinical case reviewed for 100% of cases	
11. Radiology imaging reviewed for 100% of cases	
12. Discussion of new findings for 100% of cases	
13. MCC report issued	
14. MCC report dictated by treating physician	
15. MCC report includes attendance by specialty	
16. MCC report includes treatment recommendation	
17. MCC report includes rationale for treatment recommendation	
18. Proportion of rectal cancers reviewed at MCC	

Table 2: Excluded Indicators

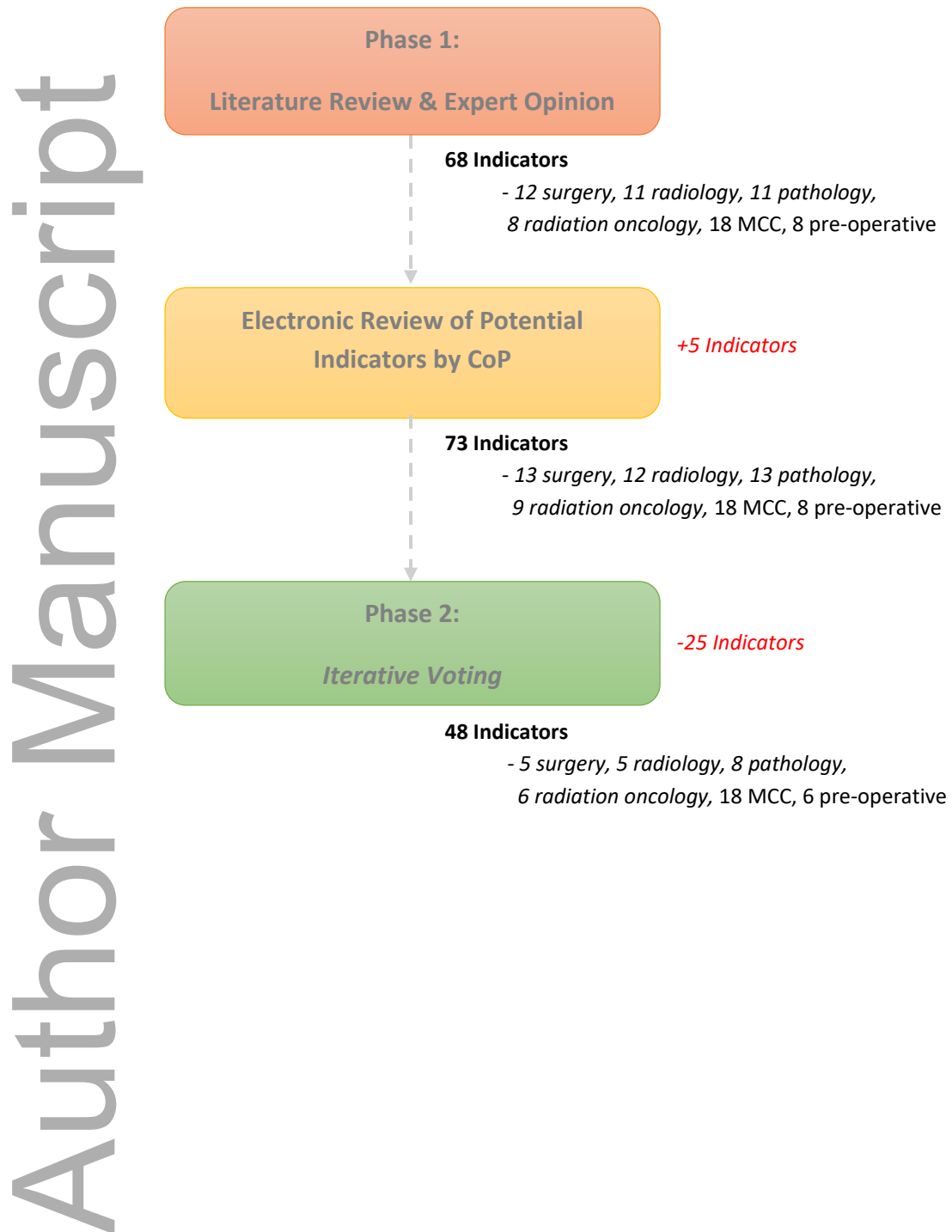| Category	Description
Radiology Process Indicators	
1)	MRI dictated within 2 business day of procedure
2)	Time in days from MRI to issue of final report
3)	Time to MRI from initial consultation (in days)
4)	Routine restaging MRI following chemoradiation
5)	Restaging MRI must include:
	- *Tumor regression grade*
	- *Distance to MRF*
6)	- Percentage agreement between MRI and pathology for tumor regression grade
7)	- Percentage agreement between MRI and pathology for EMVI
Surgical Process Indicators	
1)	Length of stay
2)	Reconstructive surgery performed (APR Rate)
3)	Laparoscopic or laparoscopic assisted procedure
4)	Diverting ileostomy performed
5)	Operative note dictated on same day of procedure

6)	Time (in days) from date of OR to issue of OR note	
7)	Documentation of surgical checklist on synoptic report	
8)	Documentation of SSI and DVT prophylaxis on synoptic report	
Pathology Process Indicators		
1)	Specimens are re-examined routinely if <12 lymph nodes identified	
2)	Routine testing for microsatellite instability (MSI)	
3)	Pathology report issued within two weeks of surgery	
4)	Time (in days) from surgery to issue of final pathology	
5)	Elastin stains performed on all slides in which there is a suspicion of venous invasion	
Radiation Oncology Process Indicators		
1)	Radiation note dictated within 3 days of completion	
2)	Image guided set up at each fraction specified	
3)	Radiation note dictated within 3 days of completion of treatment	
Multidisciplinary Case Conference (MCC) Process Indicators		
1)	All patients with primary rectal cancer must be presented at MCC at baseline	
2)	MCC report in synoptic format	

Table 3: Published Consensus-based Quality Indicators *(adapted from L Keikes et al)*

[92]**Young JM et al**	2014	-Literature Review - 2 stage Delphi Method	16	- Family Medicine - Gastroenterology - Medical Oncology - Nursing

| | | | | - Radiation Oncology |
				- Surgery
[93]**Ludt S et al**	2013	- RAND/UCLA appropriateness method	52	- Epidemiology - Family medicine - Gastroenterology - Genetics - Medical oncology -Psychotherapy - Pathology - Radiotherapy - Surgery
[94]**Jackson GL et al**	2013	-Guideline Review -Expert Panel	34	- Surgery - Oncology
[95]**Bianchi V et al**	2013	-Literature Review - Modified Delphi Method	27	- Gastroenterology - Medical oncology - Nuclear medicine - Pathology - Radiology - Radiotherapy - Surgery
[11]**Chung KP et al**	2010	-Literature Review - Modified Delphi Method	17	- Gastroenterology - Medical oncology - Pathology - Radiotherapy - Surgery
[96]**Dixon E et al**	2009	-Literature Review - Modified Delphi Method	18	- Anesthesia - Gastroenterology - Medical oncology - Palliative care - Pathology - Surgery
[97]**Habib MR et al**	2009	-Literature Review	16	- Not Defined
[98]**Malafa MP et al**	2009	-Guideline Review - Expert Panel	50	- Not Defined
[99]**Desch CE et al**	2008	-Literature Review	4	- Not Defined

		-Expert Panel			
[100]**Jacobsen PB et al**	2007	-Guideline Review	8	-	Not Defined
[101]**McGory ML et al**	2006	-RAND/UCLA appropriateness method	92	-	Surgery
[12]**Gagliardi AR et al**	2005	-Literature Review -Modified Delphi Method	15	- - - - -	Medical oncology Nursing Radiotherapy Pathology Surgery

Figure 1: Indicator selection process

Phase 1:

Literature Review & Expert Opinion

68 Indicators
- 12 surgery, 11 radiology, 11 pathology,
8 radiation oncology, 18 MCC, 8 pre-operative

Electronic Review of Potential Indicators by CoP

+5 Indicators

73 Indicators
- 13 surgery, 12 radiology, 13 pathology,
9 radiation oncology, 18 MCC, 8 pre-operative

Phase 2:

Iterative Voting

-25 Indicators

48 Indicators
- 5 surgery, 5 radiology, 8 pathology,
6 radiation oncology, 18 MCC, 6 pre-operative

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