

BMJ Open

BMJ Open is committed to open peer review. As part of this commitment we make the peer review history of every article we publish publicly available.

When an article is published we post the peer reviewers' comments and the authors' responses online. We also post the versions of the paper that were used during peer review. These are the versions that the peer review comments apply to.

The versions of the paper that follow are the versions that were submitted during the peer review process. They are not the versions of record or the final published versions. They should not be cited or distributed as the published version of this manuscript.

BMJ Open is an open access journal and the full, final, typeset and author-corrected version of record of the manuscript is available on our site with no access controls, subscription charges or pay-per-view fees (<http://bmjopen.bmj.com>).

If you have any questions on BMJ Open's open peer review process please email info.bmjopen@bmj.com

BMJ Open

Patient-centered outcomes for gastrointestinal cancer care: a scoping review protocol

Journal:	<i>BMJ Open</i>
Manuscript ID	bmjopen-2022-061309
Article Type:	Protocol
Date Submitted by the Author:	23-Jan-2022
Complete List of Authors:	<p>Yang, Joanna; University of Toronto Temerty Faculty of Medicine, Barabash, Tori; Sunnybrook Research Institute Evaluative Clinical Sciences Platform, Cancer Program</p> <p>Rajendran, Luckshi; University of Toronto Department of Surgery</p> <p>Mahar, Alyson; University of Manitoba Faculty of Health Sciences, Hsu, Amy; Ottawa Hospital Research Institute, Clinical Epidemiology Program; Bruyere Research Institute</p> <p>James, Paul; University Health Network, Department of Medicine</p> <p>Gotlib Conn, Lesley; Sunnybrook Research Institute Evaluative Clinical Sciences Platform, Tory Trauma Research Program; University of Toronto Institute of Health Policy Management and Evaluation</p> <p>Wright, Frances; Sunnybrook Research Institute Evaluative Clinical Sciences Platform, Cancer Program; Odette Cancer Centre, Division of Surgical Oncology</p> <p>Ludwig, Claire; University of Ottawa School of Nursing</p> <p>Kosyachkova, Ekaterina; Stomach Cancer Foundation of Canada</p> <p>Deleemans, Julie; University of Calgary Cumming School of Medicine, Division of Psychosocial Oncology</p> <p>Coburn, Natalie G.; Sunnybrook Research Institute Evaluative Clinical Sciences Platform, Cancer Program; Odette Cancer Centre, Division of Surgical Oncology</p> <p>Hallet, Julie; Sunnybrook Research Institute Evaluative Clinical Sciences Platform, Cancer Program; Odette Cancer Centre, Division of Surgical Oncology</p>
Keywords:	ONCOLOGY, Adult oncology < ONCOLOGY, Gastrointestinal tumours < ONCOLOGY, Hepatobiliary tumours < ONCOLOGY, Colorectal surgery < SURGERY, Hepatobiliary surgery < SURGERY

SCHOLARONE™
Manuscripts

Patient-centered outcomes for gastrointestinal cancer care: a scoping review protocol

Joanna Yang¹, Tori Barabash², MSc; Luckshi Rajendran³, MD; Alyson L. Mahar⁴, PhD; Amy Hsu^{5,6}, PhD; Paul D. James⁷, MD MSc; Lesley Gotlib Conn^{8,9,10} PhD; Frances C. Wright^{1,2,3,11}, MD MED; Claire Ludwig¹², RN PhD(c); Ekaterina Kosyachkova¹³, CPA; Julie Deleemans¹⁴, PhD(c) Natalie Coburn^{1,2,3,11}, MD MPH; Julie Hallet^{1,2,3,11}, MD MSc

1. Temerty Faculty of Medicine, University of Toronto, Toronto, Ontario, Canada.
2. Cancer Program, Evaluative Clinical Sciences, Sunnybrook Research Institute, Toronto, Ontario, Canada.
3. Department of Surgery, University of Toronto, Toronto, Ontario, Canada.
4. Department of Community Health Sciences, University of Manitoba, Winnipeg, Manitoba, Canada.
5. Ottawa Hospital Research Institute, Ottawa, Ontario, Canada.
6. Bruyère Research Institute, Ottawa, Ontario, Canada.
7. Department of Medicine, University Health Network, Toronto, Ontario, Canada.
8. Tory Trauma Research Program, Evaluative Clinical Sciences, Sunnybrook Research Institute, Toronto, Ontario, Canada.
9. Department of Anthropology, University of Toronto, Toronto, Ontario, Canada.
10. Institute of Health Policy, Management, and Evaluation, University of Toronto, Toronto, Ontario, Canada.
11. Division of Surgical Oncology, Odette Cancer Centre, Sunnybrook Health Sciences Centre, Toronto, Ontario, Canada.
12. School of Nursing, Faculty of Health Sciences, University of Ottawa, Ottawa, Ontario, Canada.
13. Stomach Cancer Foundation of Canada, Toronto, Ontario, Canada.
14. Cumming School of Medicine, Division of Psychosocial Oncology, University of Calgary, Calgary, Alberta, Canada.

Corresponding author:

Dr. Julie Hallet

2075 Bayview Avenue, T2-102, Toronto, Ontario, Canada, M4N 3M5

T. 416-480-4774; F. 416-480-6002; E. Julie.hallet@sunnybrook.ca

Word count: 1932

ABSTRACT

Introduction: Following a cancer diagnosis, patients and their caregivers face crucial decisions regarding goals of care and treatment which have consequences that can persist throughout their cancer journey. To foster informed and value-driven treatment choices, evidence-based information on outcomes relevant to patients is needed. Traditionally, clinical studies have largely focused on a few concrete and easily measurable outcomes such as survival, disease progression, and immediate treatment toxicities. These outcomes do not capture other important factors that patients consider when making treatment decisions. Patient-centered outcomes reflect the patients' individual values, preferences, needs, and circumstances that are essential to directing meaningful and informed healthcare discussions. Often, however, these outcomes are not included in a standardized and practical fashion in research protocols. This scoping review will summarize the existing literature on patient-centered outcomes in gastrointestinal (GI) cancer care as well as the tools used to assess these outcomes. A comprehensive list of these patient-centered outcomes will be generated for future efforts to develop a core outcome set.

Methods and analysis: This scoping review will follow Arksey and O'Malley's expanded framework for scoping reviews. We will systematically search Medline, Embase, CINAHL, Cochrane Library, and APA PsycINFO databases for studies examining patient-centered outcomes in the context of GI cancer. Two authors will independently perform two rounds of screening to select studies for inclusion. The data from full texts will be extracted, charted, and summarized both quantitatively and qualitatively.

1
2
3 **Ethics and dissemination:** No ethics approval is required for this scoping review. Results will
4
5 be disseminated through scientific publication and presentation at relevant conferences.
6
7
8
9

10 **KEYWORDS:** cancer, patient-centered outcomes research, health outcomes, scoping review
11
12
13

14 **STRENGTHS AND LIMITATIONS**

- 15
16
17 • This will be the first scoping review to systematically search patient-centered outcomes
18 for patients with cancers of the gastrointestinal tract along the cancer care continuum.
- 19
20
21 • Stakeholders including patients with lived experience of cancer will be consulted and
22 engaged throughout the study process.
- 23
24
25 • As this is a scoping review, quality assessment and grading of articles will not be
26 performed, limiting the ability to provide clinical recommendations.
- 27
28
29 • Studies published in all geographies will be included.
30
31
32
33
34
35
36
37
38
39
40
41
42
43
44
45
46
47
48
49
50
51
52
53
54
55
56
57
58
59
60

INTRODUCTION

Cancers of the gastrointestinal (GI) tract represent a leading cause of morbidity and mortality worldwide, with an estimated 4.8 million new cases and 3.4 million deaths in 2018.(1)

Management usually requires a multi-modal approach and may involve surgery, radiotherapy, chemotherapy, targeted therapy, and survivorship care. Each patient trajectory is unique in terms of prognosis, potential complications, and choice of therapies. Moreover, the side effects and long-term consequences can vary greatly and impact the patient experience throughout the care continuum. Thus, many complex considerations must be taken into account when making treatment decisions.

Patient-centered care (PCC) is recognized by the World Health Organization as a core competency for healthcare providers (HCPs) and a key component of healthcare systems and care quality.(2) PCC is a model of care in which HCPs are encouraged to partner with patients to co-design and deliver personalized care through shared decision-making.(3-6) Under these tenets, cancer care should address the individual needs, values, and preferences of each patient through effective communication and collaboration. These factors determine which outcomes are prioritized when designing treatment plans at each point along the cancer care continuum. This process relies on both patients and HCPs having accessible and understandable data on care options, evidence, and their benefits and harms with regards to relevant patient-centered outcomes (PCOs). However, evidence is often lacking for these outcomes.

1
2
3 PCOs reflect the beliefs, preference, and needs of patients.(7) They are used to amplify patients'
4 voices when assessing the value of healthcare options. PCOs may represent priorities that are
5 less obvious to non-patients when considering treatment choices, such as the impact on function
6 rather than survival. Importantly, PCOs may include, but differ from, patient-reported outcomes,
7 which are measures completed by patients themselves. Traditional clinical trials and studies in
8 cancer care focus on endpoints deemed important by physicians and researchers.(8)
9
10 Consequently, available evidence is mostly centered on survival and other clinical events such as
11 recurrence, disease progression, and immediate treatment toxicities. While this information is
12 significant for some clinical decisions, they do not capture the personal and social factors that are
13 important to patients when evaluating management options.(9, 10) Overall, little information
14 exists regarding PCOs in the setting of GI cancer care and patients often feel they do not have a
15 sufficient understanding of their condition, their options, and of the impact of proposed therapies.
16 Without such information, patients may not be able to meaningfully engage in their care, which
17 can lead to decisional conflict and decision-regret.(11-13) Decision-regret is associated with
18 patient dissatisfaction, increased use of health resources, and high health care cost. Thus,
19 establishing an understanding of the outcomes most relevant to patients is essential to minimize
20 decision-regret, improve patient experiences, and reduce health care costs.
21
22
23
24
25
26
27
28
29
30
31
32
33
34
35
36
37
38
39
40
41
42
43
44

45 While the importance of integrating PCOs into cancer care is recognized, the question remains,
46 which PCOs should be focused on and what approaches to measurement of such outcomes
47 should be implemented? Different types of PCOs have been described, each highlighting certain
48 domains of the patient experience. These broad categories include patient satisfaction, decision
49 regret, patient preference, and health-related quality of life (HRQOL).(14) PCOs may involve
50
51
52
53
54
55
56
57
58
59
60

1
2
3 specific long-term complications, adverse events, or functional status post-treatment. When
4 incorporating PCOs into cancer research, it is important to remain cognizant of the practical
5 limits of data collection in study designs. A core outcome set (COS) comprised of a short,
6 standardized list of PCOs would be conducive to developing prediction tools and decision-aids
7 for systematic use in clinical trials and comparisons of treatments, while minimizing the burden
8 of data collection and interpretation on HCPs and researchers. (15, 16)
9
10
11
12
13
14
15
16
17
18

19 This study will systematically map and synthesize the evidence on PCOs for GI cancer care. We
20 will outline existing literature and generate a comprehensive list of previously studied PCOs and
21 their potential measurement strategies to guide the development of a COS which will be used to
22 direct future research efforts.
23
24
25
26
27
28
29

30 **METHODS**

31 A scoping review methodology will be used to explore the literature describing the use of PCOs
32 in GI cancer care and research following the expanded Arksey and O'Malley framework for
33 scoping reviews. (17-19) Reporting will adhere to the Preferred Reporting Items for Systematic
34 Reviews and Meta-Analysis Extension for Scoping Reviews (PRISMA-ScR). (20)
35
36
37
38
39
40
41
42
43
44

45 **Objectives**

46 The scoping review will answer the following research questions:

- 47 1) With a focus on GI cancers, what PCOs have been described to study cancer care
48 interventions or guide treatment decisions?
49
50
51
52
53
54
55
56
57
58
59
60

- 1
2
3 2) What measures have been described to assess these PCOs in the context of GI
4 cancer research?
5
6
7
8
9

10 **Eligibility criteria**

11 Table 1 outlines the inclusion and exclusion criteria. GI cancers will include any solid
12 malignancy of the GI tract, including the esophagus, stomach, small intestine, colon, rectum,
13 pancreas, and biliary system.
14
15
16
17
18
19
20
21
22
23
24
25
26
27
28
29
30
31
32
33
34
35
36
37
38
39
40
41
42
43
44
45
46
47
48
49
50
51
52
53
54
55
56
57
58
59
60

Table 1. Summary of inclusion and exclusion criteria to be applied to citations identified through the literature search

	Inclusion Criteria	Exclusion Criteria
Outcome	Measurement or discussion of ≥ 1 PCO <ul style="list-style-type: none"> • Use of validated/existing or original outcome measures • Use of patient-reported outcome measures (PROMs) • Quality of life measures 	<ul style="list-style-type: none"> • No measurement or discussion of specific PCOs • Measurement or discussion of the following outcomes only: <ul style="list-style-type: none"> ○ Survival ○ Progression free survival ○ Cost to healthcare system
Exposure	Interventions for any aspect(s) of GI cancer care or all solid cancers <ul style="list-style-type: none"> • Treatment (i.e. medical, radiation, surgical) • Supportive care • Cancer-related morbidity and complications • Cancer survivorship 	<ul style="list-style-type: none"> • Interventions outside the context of cancer only • Interventions for non-GI cancer subtypes only (i.e. breast, prostate, etc.) • Interventions for screening or diagnosis of cancer
Population	<ul style="list-style-type: none"> • Age ≥ 18 years (all participants) • Active or previous diagnosis of solid malignancy (all participants) 	<ul style="list-style-type: none"> • Age < 18 years (any participants) • No cancer diagnosis (any participants) • Non-GI cancer subtypes only • Hematologic malignancies (any participants)
Study details	<ul style="list-style-type: none"> • Randomized and non-randomized interventional trials • Prospective and retrospective observational studies • Reviews and narrative studies • Case series of 10 or more subjects • Qualitative and quantitative studies • Published after 2000 • All languages and geographies 	<ul style="list-style-type: none"> • Editorials, opinion pieces, case-reports, dissertations, conference abstracts, protocols • Published before 2000

Outcome

PCOs are outcomes that are important to the patient and are inclusive of their individual values, preferences, autonomy, and needs. (7, 21) While the broad definition overlaps with some elements of traditional clinical research, it also involves unique patient priorities that are often not captured in most conventional cancer studies. Thus, for the purpose of this review, the definition of PCOs will exclude those established endpoints commonly measured in such studies, including survival, progression free survival, disease recurrence, and healthcare cost. We will include all studies that involve measurement of or discussion of any other PCOs.

Exposure

We will consider all cancer interventions for any aspect of the cancer care continuum. This will include interventions for disease treatment, management of cancer-related morbidity and complications, supportive care, and cancer survivorship. These interventions must be applicable to any GI cancers specifically or to all solid malignancies.

Population

This review will focus on patient-centered care in adults diagnosed with GI cancer, along the cancer care continuum. Accordingly, any studies with participants under the age of 18 or without a cancer diagnosis will be excluded. Studies involving only participants with any GI cancer will be included. Studies pertaining to solid malignancies inclusive of GI cancers (not site or subtype specific) will also be included. Studies addressing exclusively non-GI cancer (e.g. management of breast cancer) will be excluded. Studies involving any hematologic malignancies will be excluded as the approach to management of these cancers is different entirely.

Study details

We will include clinical trials, observational studies, reviews, narrative studies, qualitative and quantitative studies, and case series of 10 or more subjects published in or after the year 2000.

Those published before the year 2000 will be excluded as the approach to cancer care and research has since evolved with regards to PCOs. Studies published in all languages will be included, however search terms will only be executed in English, and no limitations will be placed on the geographic region of the study population.

Search strategy and information sources

The search strategy was developed for Medline with consultation from a health sciences librarian at the University of Toronto and adapted to other search engines including Embase, Cochrane Library, CINAHL, and APA PsycINFO. The search will identify studies under the intersection of three search concepts: “GI cancer”, “patient-centeredness”, and “outcome assessment”, through use of relevant *MeSH* terms and *textword* searches. The full search strategy for Medline is seen in Table 2. A preliminary search identified 1,141 potential citations between all databases after removing 373 duplicates.

Table 2. Medline search strategy

#	Searches
1	Neoplasms/
2	exp Digestive System Neoplasms/
3	((anal or bile duct* or biliar* or gastrointestin* or GI or neuroendocrin* or stomach* or gastric* or colon or colorectal or rectal* or rectum* or duoden* or esophag* or gastroesophag* or gallbladder* or liver* or hepat* or pancrea* or bowel* or intestin* or digestive*) adj3 (neoplasm* or adenocarcinoma* or cancer* or tumor* or tumour* or metasta* or oncolog*)).tw,kf.
4	1 or 2 or 3
5	Patient-Centered Care/
6	Decision Making, Shared/
7	(patient centered or patient centred or person centered or person centred or patient focused or patient oriented).tw,kf.
8	(patient adj3 (priorit* or preference* or value* or expectation* or need* or relevan*)).tw,kf.
9	5 or 6 or 7 or 8
10	Outcome Assessment, Health Care/
11	Patient Outcome Assessment/
12	Patient Reported Outcome Measures/
13	(patient outcome* adj3 (measure* or assessment*)).tw,kf.
14	((patient centered or patient centred or person centered or person centred or patient focused or patient oriented or patient reported) adj3 outcome*).tw,kf.
15	(core outcome set* or standard set*).tw,kf.
16	10 or 11 or 12 or 13 or 14 or 15
17	4 and 9 and 16
18	limit 17 to yr="2000 -Current"

Study selection

We will use a two-stage study selection process. The first stage will be a review of titles and abstracts for inclusion using the Covidence systematic review software (Veritas Health Innovation, Melbourne, Australia), independently performed by two reviewers. In the second stage, two reviewers will independently conduct a full-text review to determine whether each article meets the inclusion criteria. Disagreements will be resolved with discussion between the two reviewers, and by a third reviewer if necessary to reach consensus. As per recommendations by Levac et al., the study selection criteria will be pilot tested with an initial review of a random sample of 25 titles and abstracts. (19) Subsequently, the team will meet to discuss discrepancies and make modifications to the eligibility criteria as needed. Screening will only start once a minimum of 80% agreement is achieved. Moreover, study selection will be an iterative process whereby inclusion and exclusion criteria may evolve as data are retrieved, with meetings between reviewers throughout the process to refine inclusion criteria.

Data items

Key information from the selected studies will be extracted and charted in a form with fields as suggested by Peters et al. (21) A preliminary charting table with included variables to be abstracted is summarized in Table 3. This will provide the reader with a logical and descriptive summary of the results that are relevant to the research question as previously described. As per Levac et al., data charting will too be an iterative process, with fields updated as needed as data are abstracted. (19) The form will be pilot tested for the first 10 articles, which will be charted independently by two reviewers who will then reconvene with the other authors to ensure that the extracted data are relevant to the research questions.

Table 3. Summary of charting table fields

1. Article information:		
a)	Author(s)	
b)	Year of publication	
c)	Source origin/country of origin	
d)	Aims/purpose	
e)	Study population and sample size (if applicable)	
f)	Methodology	e.g. RCT, cohort study, qualitative, systematic review, etc.
g)	Intervention type and comparator (if applicable)	
h)	Duration of the intervention (if applicable)	
2. Key findings related to scoping review question:		
a)	Cancer type(s) and subtype(s)	
b)	Patient-centered outcomes measured	e.g. cognitive functioning
c)	How patient-centered outcomes are measured	e.g. validated/existing vs. original scoring system; if existing system, state system (i.e. EORTC QLQ-C30)
d)	How patient-centered outcomes are collected	e.g. clinical (i.e. physician report), patient-reported, administrative (i.e. death registry)
e)	Times of assessment of patient-centered outcomes	e.g. at baseline, during intervention, follow-up
f)	Rationale for measuring specific outcomes	
g)	Study findings on patient-centered outcomes	

Data Synthesis

Results will be summarized both quantitatively and qualitatively to provide a description of the collected data. A conceptual framework patient-centered care will be used to provide an overview of the breadth of the literature. (22) We will include both descriptive numerical summary analysis, presented using tables and charts, and qualitative thematic analysis. Descriptive statistics of key outcomes such as frequencies of specific outcomes, outcome measures, cancer types, and reported rationales will also be reported. In keeping with scoping review methodology, an evaluation of study quality will not be performed. Finally, a master list of all PCOs and their measurement strategies described in the literature for GI cancer care will be reported.

Patient and Public Involvement

Stakeholder engagement is known to enhance the relevance, validity, and quality of research. (23-25) Following the patient and service users engagement framework, we will partner with patients, service users, HCPs, and health decision-makers to obtain additional sources of information and unique insights into the illness experience to guide research plans and outputs. (26) Three patient partners with lived experience of cancer (CL, EK, JD) are members of the research team who have been involved from inception and will participate in all parts of the study to ensure clinical relevance and applicability. Consultations with stakeholders will also be utilized to share preliminary findings, validate and identify gaps in our findings, and inform future research efforts.

Ethics and Dissemination

1
2
3 This scoping review protocol outlines a method to systematically search and map the literature
4 on PCOs used in GI cancer care and research. Since this review will include only published data,
5
6 ethics approval will not be sought. As outlined above, this review will constitute the first stage of
7
8 the development of a COS for use in GI cancer PCC and research. Following the identification of
9
10 existing PCOs in the literature, we will conduct semi-structured interviews with patients and
11
12 HCPs. A series of Delphi surveys will be used to prioritize and obtain consensus on the most
13
14 relevant PCOs for GI cancer care. Ultimately, this COS will support the development of
15
16 predictive tools and decision-aids for personalized GI cancer care delivery. This is necessary to
17
18 create tools that go beyond typical prognostication and provide patients with a spectrum of
19
20 information on outcomes they value and that influence decision-making. (27-30) These aids for
21
22 shared decision-making will facilitate patient education, improve clinical outcomes, and reduce
23
24 delivery of care that is incongruent with patients' values and wishes. (31-33) Furthermore, this
25
26 information can be used by health systems, patient organizations, researchers, and HCPs to plan
27
28 cancer care, guide clinical trials, and assess health services by measuring outcomes aligned with
29
30 the values, needs, and priorities of patients and other stakeholders.
31
32
33
34
35
36
37
38
39
40
41
42
43
44
45
46
47
48
49
50
51
52
53
54
55
56
57
58
59
60

FOOTNOTES

Contributors: JY, JH, NC, TB, LR conceived of the idea, developed the research questions and study methods, and contributed to the drafting of the protocol. JY and TB conceived of and executed the search strategy. JH, NC, ALM, AH, PDJ, LGC, FCW, CL, EK, and JD contributed meaningfully to the editing and critical review of this protocol and approved the final manuscript.

Funding: This work was supported by Canadian Health Research Institutes grant number 459694.

Competing interests: None declared.

Patient consent for publication: Not required.

REFERENCES

1. Arnold M, Abnet CC, Neale RE, Vignat J, Giovannucci EL, McGlynn KA, et al. Global Burden of 5 Major Types of Gastrointestinal Cancer. *Gastroenterology*. 2020;159(1):335-49.e15.
2. Professional competence – standards. World Health Organization; 2005.
3. Bardes CL. Defining "patient-centered medicine". *N Engl J Med*. 2012;366(9):782-3.
4. Elwyn G, Frosch D, Thomson R, Joseph-Williams N, Lloyd A, Kinnersley P, et al. Shared decision making: a model for clinical practice. *J Gen Intern Med*. 2012;27(10):1361-7.
5. Barry MJ, Edgman-Levitan S. Shared decision making--pinnacle of patient-centered care. *N Engl J Med*. 2012;366(9):780-1.
6. Barry MJ. Shared decision making: informing and involving patients to do the right thing in health care. *J Ambul Care Manage*. 2012;35(2):90-8.
7. Establishing the Definition of Patient-Centered Outcomes Research: Patient-Centered Outcomes Research Institute; 2014 [Available from: <https://www.pcori.org/research-results/about-our-research/patient-centered-outcomes-research/establishing-definition>].
8. Frank L, Basch E, Selby JV, Institute P-COR. The PCORI perspective on patient-centered outcomes research. *JAMA*. 2014;312(15):1513-4.
9. (PCORI) MCotP-CORI. Methodological standards and patient-centeredness in comparative effectiveness research: the PCORI perspective. *JAMA*. 2012;307(15):1636-40.
10. Gabriel SE, Normand SL. Getting the methods right--the foundation of patient-centered outcomes research. *N Engl J Med*. 2012;367(9):787-90.
11. Brehaut JC, O'Connor AM, Wood TJ, Hack TF, Siminoff L, Gordon E, et al. Validation of a decision regret scale. *Med Decis Making*. 2003;23(4):281-92.
12. Becerra Pérez MM, Menear M, Brehaut JC, Légaré F. Extent and Predictors of Decision Regret about Health Care Decisions: A Systematic Review. *Med Decis Making*. 2016;36(6):777-90.
13. Calderon C, Ferrando PJ, Lorenzo-Seva U, Higuera O, Ramon Y Cajal T, Rogado J, et al. Validity and Reliability of the Decision Regret Scale in Cancer Patients Receiving Adjuvant Chemotherapy. *J Pain Symptom Manage*. 2019;57(4):828-34.
14. Oliver A, Greenberg CC. Measuring outcomes in oncology treatment: the importance of patient-centered outcomes. *Surg Clin North Am*. 2009;89(1):17-25, vii.

15. Ramsey I, Eckert M, Hutchinson AD, Marker J, Corsini N. Core outcome sets in cancer and their approaches to identifying and selecting patient-reported outcome measures: a systematic review. *J Patient Rep Outcomes*. 2020;4(1):77.
16. Williamson PR, de Ávila Oliveira R, Clarke M, Gorst SL, Hughes K, Kirkham JJ, et al. Assessing the relevance and uptake of core outcome sets (an agreed minimum collection of outcomes to measure in research studies) in Cochrane systematic reviews: a review. *BMJ Open*. 2020;10(9):e036562.
17. Arksey H, O'Malley L. Scoping studies: towards a methodological framework. *International Journal of Social Research Methodology*. 2005;8(1):19-32.
18. Colquhoun HL, Levac D, O'Brien KK, Straus S, Tricco AC, Perrier L, et al. Scoping reviews: time for clarity in definition, methods, and reporting. *J Clin Epidemiol*. 2014;67(12):1291-4.
19. Levac D, Colquhoun H, O'Brien KK. Scoping studies: advancing the methodology. *Implement Sci*. 2010;5:69.
20. Tricco AC, Lillie E, Zarin W, O'Brien KK, Colquhoun H, Levac D, et al. PRISMA Extension for Scoping Reviews (PRISMA-ScR): Checklist and Explanation. *Ann Intern Med*. 2018;169(7):467-73.
21. Peters MD, Godfrey CM, Khalil H, McInerney P, Parker D, Soares CB. Guidance for conducting systematic scoping reviews. *Int J Evid Based Healthc*. 2015;13(3):141-6.
22. Santana MJ, Manalili K, Jolley RJ, Zelinsky S, Quan H, Lu M. How to practice person-centred care: A conceptual framework. *Health Expect*. 2018;21(2):429-40.
23. Barber R, Boote JD, Parry GD, Cooper CL, Yeeles P, Cook S. Can the impact of public involvement on research be evaluated? A mixed methods study. *Health Expect*. 2012;15(3):229-41.
24. Domecq JP, Prutsky G, Elraiyah T, Wang Z, Nabhan M, Shippee N, et al. Patient engagement in research: a systematic review. *BMC Health Serv Res*. 2014;14:89.
25. Bowen SJ, Graham ID. From knowledge translation to engaged scholarship: promoting research relevance and utilization. *Arch Phys Med Rehabil*. 2013;94(1 Suppl):S3-8.
26. Shippee ND, Domecq Garces JP, Prutsky Lopez GJ, Wang Z, Elraiyah TA, Nabhan M, et al. Patient and service user engagement in research: a systematic review and synthesized framework. *Health Expect*. 2015;18(5):1151-66.
27. Ngiam KY, Khor IW. Big data and machine learning algorithms for health-care delivery. *Lancet Oncol*. 2019;20(5):e262-e73.

- 1
2
3 28. Rabin BA, Gaglio B, Sanders T, Nekhlyudov L, Dearing JW, Bull S, et al. Predicting
4 cancer prognosis using interactive online tools: a systematic review and implications for
5 cancer care providers. *Cancer Epidemiol Biomarkers Prev.* 2013;22(10):1645-56.
6
7 29. Stacey D, Légaré F, Lewis K, Barry MJ, Bennett CL, Eden KB, et al. Decision aids for
8 people facing health treatment or screening decisions. *Cochrane Database Syst Rev.*
9 2017;4:CD001431.
10
11 30. Stacey D, Légaré F, Lewis KB. Patient Decision Aids to Engage Adults in Treatment or
12 Screening Decisions. *JAMA.* 2017;318(7):657-8.
13
14 31. McAlpine K, Lewis KB, Trevena LJ, Stacey D. What Is the Effectiveness of Patient
15 Decision Aids for Cancer-Related Decisions? A Systematic Review Subanalysis. *JCO*
16 *Clin Cancer Inform.* 2018;2:1-13.
17
18 32. Ziebland S, Chapple A, Evans J. Barriers to shared decisions in the most serious of
19 cancers: a qualitative study of patients with pancreatic cancer treated in the UK. *Health*
20 *Expect.* 2015;18(6):3302-12.
21
22 33. Gillespie J, Kacikanis A, Nyhof-Young J, Gallinger S, Ruthig E. Information Needs of
23 Hepato-Pancreato-Biliary Surgical Oncology Patients. *J Cancer Educ.* 2017;32(3):589-
24 95.
25
26
27
28
29
30
31
32
33
34
35
36
37
38
39
40
41
42
43
44
45
46
47
48
49
50
51
52
53
54
55
56
57
58
59
60

Preferred Reporting Items for Systematic reviews and Meta-Analyses extension for Scoping Reviews (PRISMA-ScR) Checklist

SECTION	ITEM	PRISMA-ScR CHECKLIST ITEM	REPORTED ON PAGE #
TITLE			
Title	1	Identify the report as a scoping review.	
ABSTRACT			
Structured summary	2	Provide a structured summary that includes (as applicable): background, objectives, eligibility criteria, sources of evidence, charting methods, results, and conclusions that relate to the review questions and objectives.	
INTRODUCTION			
Rationale	3	Describe the rationale for the review in the context of what is already known. Explain why the review questions/objectives lend themselves to a scoping review approach.	
Objectives	4	Provide an explicit statement of the questions and objectives being addressed with reference to their key elements (e.g., population or participants, concepts, and context) or other relevant key elements used to conceptualize the review questions and/or objectives.	
METHODS			
Protocol and registration	5	Indicate whether a review protocol exists; state if and where it can be accessed (e.g., a Web address); and if available, provide registration information, including the registration number.	
Eligibility criteria	6	Specify characteristics of the sources of evidence used as eligibility criteria (e.g., years considered, language, and publication status), and provide a rationale.	
Information sources*	7	Describe all information sources in the search (e.g., databases with dates of coverage and contact with authors to identify additional sources), as well as the date the most recent search was executed.	
Search	8	Present the full electronic search strategy for at least 1 database, including any limits used, such that it could be repeated.	
Selection of sources of evidence†	9	State the process for selecting sources of evidence (i.e., screening and eligibility) included in the scoping review.	
Data charting process‡	10	Describe the methods of charting data from the included sources of evidence (e.g., calibrated forms or forms that have been tested by the team before their use, and whether data charting was done independently or in duplicate) and any processes for obtaining and confirming data from investigators.	
Data items	11	List and define all variables for which data were sought and any assumptions and simplifications made.	
Critical appraisal of individual sources of evidence§	12	If done, provide a rationale for conducting a critical appraisal of included sources of evidence; describe the methods used and how this information was used in any data synthesis (if appropriate).	
Synthesis of results	13	Describe the methods of handling and summarizing the data that were charted.	



SECTION	ITEM	PRISMA-ScR CHECKLIST ITEM	REPORTED ON PAGE #
RESULTS			
Selection of sources of evidence	14	Give numbers of sources of evidence screened, assessed for eligibility, and included in the review, with reasons for exclusions at each stage, ideally using a flow diagram.	
Characteristics of sources of evidence	15	For each source of evidence, present characteristics for which data were charted and provide the citations.	
Critical appraisal within sources of evidence	16	If done, present data on critical appraisal of included sources of evidence (see item 12).	
Results of individual sources of evidence	17	For each included source of evidence, present the relevant data that were charted that relate to the review questions and objectives.	
Synthesis of results	18	Summarize and/or present the charting results as they relate to the review questions and objectives.	
DISCUSSION			
Summary of evidence	19	Summarize the main results (including an overview of concepts, themes, and types of evidence available), link to the review questions and objectives, and consider the relevance to key groups.	
Limitations	20	Discuss the limitations of the scoping review process.	
Conclusions	21	Provide a general interpretation of the results with respect to the review questions and objectives, as well as potential implications and/or next steps.	
FUNDING			
Funding	22	Describe sources of funding for the included sources of evidence, as well as sources of funding for the scoping review. Describe the role of the funders of the scoping review.	

JBI = Joanna Briggs Institute; PRISMA-ScR = Preferred Reporting Items for Systematic reviews and Meta-Analyses extension for Scoping Reviews.

* Where *sources of evidence* (see second footnote) are compiled from, such as bibliographic databases, social media platforms, and Web sites.

† A more inclusive/heterogeneous term used to account for the different types of evidence or data sources (e.g., quantitative and/or qualitative research, expert opinion, and policy documents) that may be eligible in a scoping review as opposed to only studies. This is not to be confused with *information sources* (see first footnote).

‡ The frameworks by Arksey and O'Malley (6) and Levac and colleagues (7) and the JBI guidance (4, 5) refer to the process of data extraction in a scoping review as data charting.

§ The process of systematically examining research evidence to assess its validity, results, and relevance before using it to inform a decision. This term is used for items 12 and 19 instead of "risk of bias" (which is more applicable to systematic reviews of interventions) to include and acknowledge the various sources of evidence that may be used in a scoping review (e.g., quantitative and/or qualitative research, expert opinion, and policy document).

From: Tricco AC, Lillie E, Zarin W, O'Brien KK, Colquhoun H, Levac D, et al. PRISMA Extension for Scoping Reviews (PRISMA-ScR): Checklist and Explanation. *Ann Intern Med.* 2018;169:467–473. doi: [10.7326/M18-0850](https://doi.org/10.7326/M18-0850).



St. Michael's

Inspired Care.
Inspiring Science.

For peer review only - <http://bmjopen.bmj.com/site/about/guidelines.xhtml>

BMJ Open

Patient-centered outcomes for gastrointestinal cancer care: a scoping review protocol

Journal:	<i>BMJ Open</i>
Manuscript ID	bmjopen-2022-061309.R1
Article Type:	Protocol
Date Submitted by the Author:	26-May-2022
Complete List of Authors:	Yang, Joanna; University of Toronto Temerty Faculty of Medicine, Barabash, Tori; Sunnybrook Research Institute Evaluative Clinical Sciences Platform, Cancer Program Rajendran, Luckshi; University of Toronto Department of Surgery Mahar, Alyson; University of Manitoba Faculty of Health Sciences, Hsu, Amy; Ottawa Hospital Research Institute, Clinical Epidemiology Program; Bruyere Research Institute James, Paul; University Health Network, Department of Medicine Gotlib Conn, Lesley; Sunnybrook Research Institute Evaluative Clinical Sciences Platform, Tory Trauma Research Program; University of Toronto Institute of Health Policy Management and Evaluation Wright, Frances; Sunnybrook Research Institute Evaluative Clinical Sciences Platform, Cancer Program; Odette Cancer Centre, Division of Surgical Oncology Ludwig, Claire; University of Ottawa School of Nursing Kosyachkova, Ekaterina; Stomach Cancer Foundation of Canada Deleemans, Julie; University of Calgary Cumming School of Medicine, Division of Psychosocial Oncology Coburn, Natalie G.; Sunnybrook Research Institute Evaluative Clinical Sciences Platform, Cancer Program; Odette Cancer Centre, Division of Surgical Oncology Hallet, Julie; Sunnybrook Research Institute Evaluative Clinical Sciences Platform, Cancer Program; Odette Cancer Centre, Division of Surgical Oncology
Primary Subject Heading:	Surgery
Secondary Subject Heading:	Oncology, Patient-centred medicine
Keywords:	ONCOLOGY, Adult oncology < ONCOLOGY, Gastrointestinal tumours < ONCOLOGY, Hepatobiliary tumours < ONCOLOGY, Colorectal surgery < SURGERY, Hepatobiliary surgery < SURGERY

SCHOLARONE™
Manuscripts

1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25
26
27
28
29
30
31
32
33
34
35
36
37
38
39
40
41
42
43
44
45
46
47
48
49
50
51
52
53
54
55
56
57
58
59
60

Patient-centered outcomes for gastrointestinal cancer care: a scoping review protocol

Joanna Yang¹, Tori Barabash², MSc; Luckshi Rajendran³, MD; Alyson L. Mahar⁴, PhD; Amy Hsu^{5,6}, PhD; Paul D. James⁷, MD MSc; Lesley Gotlib Conn^{8,9,10} PhD; Frances C. Wright^{1,2,3,11}, MD MED; Claire Ludwig¹², RN PhD(c); Ekaterina Kosyachkova¹³, CPA; Julie Deleemans¹⁴, PhD(c) Natalie Coburn^{1,2,3,11}, MD MPH; Julie Hallet^{1,2,3,11}, MD MSc

1. Temerty Faculty of Medicine, University of Toronto, Toronto, Ontario, Canada.
2. Cancer Program, Evaluative Clinical Sciences, Sunnybrook Research Institute, Toronto, Ontario, Canada.
3. Department of Surgery, University of Toronto, Toronto, Ontario, Canada.
4. Department of Community Health Sciences, University of Manitoba, Winnipeg, Manitoba, Canada.
5. Ottawa Hospital Research Institute, Ottawa, Ontario, Canada.
6. Bruyère Research Institute, Ottawa, Ontario, Canada.
7. Department of Medicine, University Health Network, Toronto, Ontario, Canada.
8. Tory Trauma Research Program, Evaluative Clinical Sciences, Sunnybrook Research Institute, Toronto, Ontario, Canada.
9. Department of Anthropology, University of Toronto, Toronto, Ontario, Canada.
10. Institute of Health Policy, Management, and Evaluation, University of Toronto, Toronto, Ontario, Canada.
11. Division of Surgical Oncology, Odette Cancer Centre, Sunnybrook Health Sciences Centre, Toronto, Ontario, Canada.
12. School of Nursing, Faculty of Health Sciences, University of Ottawa, Ottawa, Ontario, Canada.
13. Stomach Cancer Foundation of Canada, Toronto, Ontario, Canada.
14. Cumming School of Medicine, Division of Psychosocial Oncology, University of Calgary, Calgary, Alberta, Canada.

Corresponding author:

Dr. Julie Hallet

2075 Bayview Avenue, T2-102, Toronto, Ontario, Canada, M4N 3M5

T. 416-480-4774; F. 416-480-6002; E. Julie.hallet@sunnybrook.ca

Word count: 1965

ABSTRACT

Introduction: Following a cancer diagnosis, patients and their caregivers face crucial decisions regarding goals of care and treatment which have consequences that can persist throughout their cancer journey. To foster informed and value-driven treatment choices, evidence-based information on outcomes relevant to patients is needed. Traditionally, clinical studies have largely focused on a few concrete and easily measurable outcomes such as survival, disease progression, and immediate treatment toxicities. These outcomes do not capture other important factors that patients consider when making treatment decisions. Patient-centered outcomes (PCOs) reflect the patients' individual values, preferences, needs, and circumstances that are essential to directing meaningful and informed healthcare discussions. Often, however, these outcomes are not included in a standardized and practical fashion in research protocols. This scoping review will summarize the existing literature on patient-centered outcomes in gastrointestinal (GI) cancer care as well as the tools used to assess these outcomes. A comprehensive list of these patient-centered outcomes will be generated for future efforts to develop a core outcome set.

Methods and analysis: This scoping review will follow Arksey and O'Malley's expanded framework for scoping reviews. We will systematically search Medline, Embase, CINAHL, Cochrane Library, and APA PsycINFO databases for studies examining PCOs in the context of GI cancer. We will include studies published in or after the year 2000 up the date of the final searches, with no language restrictions. Studies involving adult patients with GI cancers and discussion of any PCOs will be included. Opinion pieces, protocols, case reports, and abstracts will be excluded. Two authors will independently perform two rounds of screening to select

1
2
3 studies for inclusion. The data from full texts will be extracted, charted, and summarized both
4
5 quantitatively and qualitatively.
6

7 **Ethics and dissemination:** No ethics approval is required for this scoping review. Results will
8
9 be disseminated through scientific publication and presentation at relevant conferences.
10
11

12
13
14 **KEYWORDS:** cancer, patient-centered outcomes research, health outcomes, scoping review
15
16

17 18 19 **Strengths and limitations of this study** 20

- 21 • A broad and comprehensive search of relevant studies will be performed in several
22 academic research databases with the guidance of a health sciences librarian.
23
- 24 • Stakeholders including patients with lived experience of cancer will be consulted and
25 engaged throughout the study process.
26
- 27 • As this is a scoping review, quality assessment and grading of articles will not be
28 performed, limiting the ability to provide clinical recommendations.
29
- 30 • Studies published in all geographies will be included.
31
32
33
34
35
36
37
38
39
40
41
42
43
44
45
46
47
48
49
50
51
52
53
54
55
56
57
58
59
60

INTRODUCTION

Cancers of the gastrointestinal (GI) tract represent a leading cause of morbidity and mortality worldwide, with an estimated 4.8 million new cases and 3.4 million deaths in 2018.(1)

Management usually requires a multi-modal approach and may involve surgery, radiotherapy, chemotherapy, targeted therapy, and survivorship care. Each patient trajectory is unique in terms of prognosis, potential complications, and choice of therapies. Moreover, the side effects and long-term consequences can vary greatly and impact the patient experience throughout the care continuum. Thus, many complex considerations must be taken into account when making treatment decisions.

Patient-centered care (PCC) is recognized by the World Health Organization as a core competency for healthcare providers (HCPs) and a key component of healthcare systems and care quality.(2) PCC is a model of care in which HCPs are encouraged to partner with patients to co-design and deliver personalized care through shared decision-making.(3-6) Under these tenets, cancer care should address the individual needs, values, and preferences of each patient through effective communication and collaboration. These factors determine which outcomes are prioritized when designing treatment plans at each point along the cancer care continuum. This process relies on both patients and HCPs having accessible and understandable data on care options, evidence, and their benefits and harms with regards to relevant patient-centered outcomes (PCOs). However, evidence is often lacking for these outcomes.

PCOs reflect the beliefs, preference, and needs of patients.(7) They are used to amplify patients' voices when assessing the value of healthcare options. PCOs may represent priorities that are

1
2
3 less obvious to non-patients when considering treatment choices, such as the impact on function
4 rather than survival. Importantly, PCOs may include, but differ from, patient-reported outcomes,
5 which are measures completed by patients themselves. Traditional clinical trials and studies in
6
7
8 cancer care focus on endpoints deemed important by physicians and researchers.(8)
9

10
11 Consequently, available evidence is mostly centered on survival and other clinical events such as
12
13 recurrence, disease progression, and immediate treatment toxicities. While this information is
14
15 significant for some clinical decisions, they do not capture the personal and social factors that are
16
17 important to patients when evaluating management options.(9, 10) Overall, little information
18
19 exists regarding PCOs in the setting of GI cancer care and patients often feel they do not have a
20
21 sufficient understanding of their condition, their options, and of the impact of proposed therapies.
22
23 Without such information, patients may not be able to meaningfully engage in their care, which
24
25 can lead to decisional conflict and decision-regret.(11-13) Decision-regret is associated with
26
27 patient dissatisfaction, increased use of health resources, and high health care cost. Thus,
28
29 establishing an understanding of the outcomes most relevant to patients is essential to minimize
30
31 decision-regret, improve patient experiences, and reduce health care costs.
32
33
34
35
36
37
38
39

40 While the importance of integrating PCOs into cancer care is recognized, the question remains,
41
42 which PCOs should be focused on and what approaches to measurement of such outcomes
43
44 should be implemented? Different types of PCOs have been described, each highlighting certain
45
46 domains of the patient experience. These broad categories include patient satisfaction, decision
47
48 regret, patient preference, and health-related quality of life (HRQOL).(14) PCOs may involve
49
50 specific long-term complications, adverse events, or functional status post-treatment. When
51
52 incorporating PCOs into cancer research, it is important to remain cognizant of the practical
53
54
55
56
57
58
59

1
2
3 limits of data collection in study designs. A core outcome set (COS) comprised of a short,
4
5 standardized list of PCOs would be conducive to developing prediction tools and decision-aids
6
7 for systematic use in clinical trials and comparisons of treatments, while minimizing the burden
8
9 of data collection and interpretation on HCPs and researchers. (15, 16)
10
11
12
13

14
15 This study will systematically map and synthesize the evidence on PCOs for GI cancer care. We
16
17 will outline existing literature and generate a comprehensive list of previously studied PCOs and
18
19 their potential measurement strategies to guide the development of a COS which will be used to
20
21 direct future research efforts.
22
23
24
25

26 **METHODS AND ANALYSIS**

27
28 A scoping review methodology will be used to explore the literature describing the use of PCOs
29
30 in GI cancer care and research following the expanded Arksey and O'Malley framework for
31
32 scoping reviews. (17-19) Reporting will adhere to the Preferred Reporting Items for Systematic
33
34 Reviews and Meta-Analysis Extension for Scoping Reviews (PRISMA-ScR). (20)
35
36
37
38
39

40 **Objectives**

41
42 The scoping review will answer the following research questions:
43
44

- 45 1) With a focus on GI cancers, what PCOs have been described to study cancer care
46
47 interventions or guide treatment decisions?
48
- 49 2) What measures have been described to assess these PCOs in the context of GI
50
51 cancer research?
52
53
54
55
56
57
58
59
60

Eligibility criteria

Table 1 outlines the inclusion and exclusion criteria. GI cancers will include any solid malignancy of the GI tract, including the esophagus, stomach, small intestine, colon, rectum, pancreas, and biliary system.

For peer review only

Table 1. Summary of inclusion and exclusion criteria to be applied to citations identified through the literature search

	Inclusion Criteria	Exclusion Criteria
Outcome	Measurement or discussion of ≥ 1 PCO <ul style="list-style-type: none"> • Use of validated/existing or original outcome measures • Use of patient-reported outcome measures (PROMs) • Quality of life measures 	<ul style="list-style-type: none"> • No measurement or discussion of specific PCOs • Measurement or discussion of the following outcomes only: <ul style="list-style-type: none"> ○ Survival ○ Progression free survival ○ Cost to healthcare system
Exposure	Interventions for any aspect(s) of GI cancer care or all solid cancers <ul style="list-style-type: none"> • Treatment (i.e. medical, radiation, surgical) • Supportive care • Cancer-related morbidity and complications • Cancer survivorship 	<ul style="list-style-type: none"> • Interventions outside the context of cancer only • Interventions for non-GI cancer subtypes only (i.e. breast, prostate, etc.) • Interventions for screening or diagnosis of cancer
Population	<ul style="list-style-type: none"> • Age ≥ 18 years (all participants) • Active or previous diagnosis of solid malignancy (all participants) 	<ul style="list-style-type: none"> • Age < 18 years (any participants) • No cancer diagnosis (any participants) • Non-GI cancer subtypes only • Hematologic malignancies (any participants)
Study details	<ul style="list-style-type: none"> • Randomized and non-randomized interventional trials • Prospective and retrospective observational studies • Reviews and narrative studies • Case series of 10 or more subjects • Qualitative and quantitative studies • Published during or after 2000 • All languages and geographies 	<ul style="list-style-type: none"> • Editorials, opinion pieces, case-reports, dissertations, conference abstracts, protocols • Published before 2000

Outcome

PCOs are outcomes that are important to the patient and are inclusive of their individual values, preferences, autonomy, and needs. (7, 21) While the broad definition overlaps with some elements of traditional clinical research, it also involves unique patient priorities that are often not captured in most conventional cancer studies. Thus, for the purpose of this review, the definition of PCOs will exclude those established endpoints commonly measured in such studies, including survival, progression free survival, disease recurrence, and healthcare cost. We will include all studies that involve measurement of or discussion of any other PCOs.

Exposure

We will consider all cancer interventions for any aspect of the cancer care continuum. This will include interventions for disease treatment, management of cancer-related morbidity and complications, supportive care, and cancer survivorship. These interventions must be applicable to any GI cancers specifically or to all solid malignancies.

Population

This review will focus on patient-centered care in adults diagnosed with GI cancer, along the cancer care continuum. Accordingly, any studies with participants under the age of 18 or without a cancer diagnosis will be excluded. Studies involving only participants with any GI cancer will be included. Studies pertaining to solid malignancies inclusive of GI cancers (not site or subtype specific) will also be included. Studies addressing exclusively non-GI cancer (e.g. management of breast cancer) will be excluded. Studies involving any hematologic malignancies will be excluded as the approach to management of these cancers is different entirely.

Study details

We will include clinical trials, observational studies, reviews, narrative studies, qualitative and quantitative studies, and case series of 10 or more subjects published in or after the year 2000, up to the date of the final searches. Those published before the year 2000 will be excluded as the approach to cancer care and research has since evolved with regards to PCOs. Studies published in all languages will be included, however search terms will only be executed in English, and no limitations will be placed on the geographic region of the study population.

Search strategy and information sources

The search strategy was developed for Medline with consultation from a health sciences librarian at the University of Toronto and adapted to other search engines including Embase, Cochrane Library, CINAHL, and APA PsycINFO. The search will identify studies under the intersection of three search concepts: “GI cancer”, “patient-centeredness”, and “outcome assessment”, through use of relevant *MeSH* terms and *textword* searches. The full search strategy for Medline is seen in Table 2. The full search strategies for all included databases are shown in Supplemental Appendices A-E.

Table 2. Medline search strategy

#	Searches
1	Neoplasms/
2	exp Digestive System Neoplasms/
3	((anal or bile duct* or biliar* or gastrointestin* or GI or neuroendocrin* or stomach* or gastric* or colon or colorectal or rectal* or rectum* or duoden* or esophag* or gastroesophag* or gallbladder* or liver* or hepat* or pancrea* or bowel* or intestin* or digestive*) adj3 (neoplasm* or adenocarcinoma* or cancer* or tumor* or tumour* or metasta* or oncolog*)).tw,kf.
4	1 or 2 or 3
5	Patient-Centered Care/
6	Decision Making, Shared/
7	(patient centered or patient centred or person centered or person centred or patient focused or patient oriented).tw,kf.
8	(patient adj3 (priorit* or preference* or value* or expectation* or need* or relevan*)).tw,kf.
9	5 or 6 or 7 or 8
10	Outcome Assessment, Health Care/
11	Patient Outcome Assessment/
12	Patient Reported Outcome Measures/
13	(patient outcome* adj3 (measure* or assessment*)).tw,kf.
14	((patient centered or patient centred or person centered or person centred or patient focused or patient oriented or patient reported) adj3 outcome*).tw,kf.
15	(core outcome set* or standard set*).tw,kf.
16	10 or 11 or 12 or 13 or 14 or 15
17	4 and 9 and 16
18	limit 17 to yr="2000 -Current"

Study selection

We will use a two-stage study selection process. The first stage will be a review of titles and abstracts for inclusion using the Covidence systematic review software (Veritas Health Innovation, Melbourne, Australia), independently performed by two reviewers. In the second stage, two reviewers will independently conduct a full-text review to determine whether each article meets the inclusion criteria. Disagreements will be resolved with discussion between the two reviewers, and by a third reviewer if necessary to reach consensus. As per recommendations by Levac et al., the study selection criteria will be pilot tested with an initial review of a random sample of 25 titles and abstracts. (19) Subsequently, the team will meet to discuss discrepancies and make modifications to the eligibility criteria as needed. Screening will only start once a minimum of 80% agreement is achieved. Moreover, study selection will be an iterative process whereby inclusion and exclusion criteria may evolve as data are retrieved, with meetings between reviewers throughout the process to refine inclusion criteria.

Data items

Key information from the selected studies will be extracted and charted in a form with fields as suggested by Peters et al. (21) A preliminary charting table with included variables to be abstracted is summarized in Table 3. This will provide the reader with a logical and descriptive summary of the results that are relevant to the research question as previously described. As per Levac et al., data charting will too be an iterative process, with fields updated as needed as data are abstracted. (19) The form will be pilot tested for the first 10 articles, which will be charted independently by two reviewers who will then reconvene with the other authors to ensure that the extracted data are relevant to the research questions.

Table 3. Summary of charting table fields

1. Article information:		
a)	Author(s)	
b)	Year of publication	
c)	Source origin/country of origin	
d)	Aims/purpose	
e)	Study population and sample size (if applicable)	
f)	Methodology	e.g. RCT, cohort study, qualitative, systematic review, etc.
g)	Intervention type and comparator (if applicable)	
h)	Duration of the intervention (if applicable)	
2. Key findings related to scoping review question:		
a)	Cancer type(s) and subtype(s)	
b)	Patient-centered outcomes measured	e.g. cognitive functioning
c)	How patient-centered outcomes are measured	e.g. validated/existing vs. original scoring system; if existing system, state system (i.e. EORTC QLQ-C30)
d)	How patient-centered outcomes are collected	e.g. clinical (i.e. physician report), patient-reported, administrative (i.e. death registry)
e)	Times of assessment of patient-centered outcomes	e.g. at baseline, during intervention, follow-up
f)	Rationale for measuring specific outcomes	
g)	Study findings on patient-centered outcomes	

Data synthesis

Results will be summarized both quantitatively and qualitatively to provide a description of the collected data. A conceptual framework patient-centered care will be used to provide an overview of the breadth of the literature. (22) We will include both descriptive numerical summary analysis, presented using tables and charts, and qualitative thematic analysis. Descriptive statistics of key outcomes such as frequencies of specific outcomes, outcome measures, cancer types, and reported rationales will also be reported. In keeping with scoping review methodology, an evaluation of study quality will not be performed. Finally, a master list of all PCOs and their measurement strategies described in the literature for GI cancer care will be reported.

Patient and public involvement

Stakeholder engagement is known to enhance the relevance, validity, and quality of research. (23-25) Following the patient and service users engagement framework, we will partner with patients, service users, HCPs, and health decision-makers to obtain additional sources of information and unique insights into the illness experience to guide research plans and outputs. (26) Three patient partners with lived experience of cancer (CL, EK, JD) are members of the research team who have been involved from inception and will participate in all parts of the study to ensure clinical relevance and applicability. Consultations with stakeholders will also be utilized to share preliminary findings, validate and identify gaps in our findings, and inform future research efforts.

ETHICS AND DISSEMINATION

1
2
3 This scoping review protocol outlines a method to systematically search and map the literature
4 on PCOs used in GI cancer care and research. Since this review will include only published data,
5
6 ethics approval will not be sought.
7
8

9
10 Results of this scoping review will be disseminated through scientific publication and
11 presentation at relevant conferences.
12
13

14
15 As outlined above, this review will constitute the first stage of the development of a
16 COS for use in GI cancer PCC and research. Following the identification of existing PCOs in the
17 literature, we will conduct semi-structured interviews with patients and HCPs. A series of Delphi
18 surveys will be used to prioritize and obtain consensus on the most relevant PCOs for GI cancer
19 care. Ultimately, this COS will support the development of predictive tools and decision-aids for
20 personalized GI cancer care delivery. This is necessary to create tools that go beyond typical
21 prognostication and provide patients with a spectrum of information on outcomes they value and
22 that influence decision-making. (27-30) These aids for shared decision-making will facilitate
23 patient education, improve clinical outcomes, and reduce delivery of care that is incongruent
24 with patients' values and wishes. (31-33) Furthermore, this information can be used by health
25 systems, patient organizations, researchers, and HCPs to plan cancer care, guide clinical trials,
26 and assess health services by measuring outcomes aligned with the values, needs, and priorities
27 of patients and other stakeholders.
28
29
30
31
32
33
34
35
36
37
38
39
40
41
42
43
44
45
46
47
48
49
50
51
52
53
54
55
56
57
58
59
60

FOOTNOTES

Contributors: JY, JH, NC, TB, LR conceived of the idea, developed the research questions and study methods, and contributed to the drafting of the protocol. JY and TB conceived of and executed the search strategy. JH, NC, ALM, AH, PDJ, LGC, FCW, CL, EK, and JD contributed meaningfully to the editing and critical review of this protocol and approved the final manuscript.

Funding: This work was supported by Canadian Health Research Institutes grant number 459694.

Competing interests: None declared.

Patient consent for publication: Not required.

REFERENCES

1. Arnold M, Abnet CC, Neale RE, Vignat J, Giovannucci EL, McGlynn KA, et al. Global Burden of 5 Major Types of Gastrointestinal Cancer. *Gastroenterology*. 2020;159(1):335-49.e15.
2. Professional competence – standards. World Health Organization; 2005.
3. Bardes CL. Defining "patient-centered medicine". *N Engl J Med*. 2012;366(9):782-3.
4. Elwyn G, Frosch D, Thomson R, Joseph-Williams N, Lloyd A, Kinnersley P, et al. Shared decision making: a model for clinical practice. *J Gen Intern Med*. 2012;27(10):1361-7.
5. Barry MJ, Edgman-Levitan S. Shared decision making--pinnacle of patient-centered care. *N Engl J Med*. 2012;366(9):780-1.
6. Barry MJ. Shared decision making: informing and involving patients to do the right thing in health care. *J Ambul Care Manage*. 2012;35(2):90-8.
7. Establishing the Definition of Patient-Centered Outcomes Research: Patient-Centered Outcomes Research Institute; 2014 [Available from: <https://www.pcori.org/research-results/about-our-research/patient-centered-outcomes-research/establishing-definition>].
8. Frank L, Basch E, Selby JV, Institute P-COR. The PCORI perspective on patient-centered outcomes research. *JAMA*. 2014;312(15):1513-4.
9. (PCORI) MCotP-CORI. Methodological standards and patient-centeredness in comparative effectiveness research: the PCORI perspective. *JAMA*. 2012;307(15):1636-40.
10. Gabriel SE, Normand SL. Getting the methods right--the foundation of patient-centered outcomes research. *N Engl J Med*. 2012;367(9):787-90.
11. Brehaut JC, O'Connor AM, Wood TJ, Hack TF, Siminoff L, Gordon E, et al. Validation of a decision regret scale. *Med Decis Making*. 2003;23(4):281-92.
12. Becerra Pérez MM, Menear M, Brehaut JC, Légaré F. Extent and Predictors of Decision Regret about Health Care Decisions: A Systematic Review. *Med Decis Making*. 2016;36(6):777-90.
13. Calderon C, Ferrando PJ, Lorenzo-Seva U, Higuera O, Ramon Y Cajal T, Rogado J, et al. Validity and Reliability of the Decision Regret Scale in Cancer Patients Receiving Adjuvant Chemotherapy. *J Pain Symptom Manage*. 2019;57(4):828-34.
14. Oliver A, Greenberg CC. Measuring outcomes in oncology treatment: the importance of patient-centered outcomes. *Surg Clin North Am*. 2009;89(1):17-25, vii.

15. Ramsey I, Eckert M, Hutchinson AD, Marker J, Corsini N. Core outcome sets in cancer and their approaches to identifying and selecting patient-reported outcome measures: a systematic review. *J Patient Rep Outcomes*. 2020;4(1):77.
16. Williamson PR, de Ávila Oliveira R, Clarke M, Gorst SL, Hughes K, Kirkham JJ, et al. Assessing the relevance and uptake of core outcome sets (an agreed minimum collection of outcomes to measure in research studies) in Cochrane systematic reviews: a review. *BMJ Open*. 2020;10(9):e036562.
17. Arksey H, O'Malley L. Scoping studies: towards a methodological framework. *International Journal of Social Research Methodology*. 2005;8(1):19-32.
18. Colquhoun HL, Levac D, O'Brien KK, Straus S, Tricco AC, Perrier L, et al. Scoping reviews: time for clarity in definition, methods, and reporting. *J Clin Epidemiol*. 2014;67(12):1291-4.
19. Levac D, Colquhoun H, O'Brien KK. Scoping studies: advancing the methodology. *Implement Sci*. 2010;5:69.
20. Tricco AC, Lillie E, Zarin W, O'Brien KK, Colquhoun H, Levac D, et al. PRISMA Extension for Scoping Reviews (PRISMA-ScR): Checklist and Explanation. *Ann Intern Med*. 2018;169(7):467-73.
21. Peters MD, Godfrey CM, Khalil H, McInerney P, Parker D, Soares CB. Guidance for conducting systematic scoping reviews. *Int J Evid Based Healthc*. 2015;13(3):141-6.
22. Santana MJ, Manalili K, Jolley RJ, Zelinsky S, Quan H, Lu M. How to practice person-centred care: A conceptual framework. *Health Expect*. 2018;21(2):429-40.
23. Barber R, Boote JD, Parry GD, Cooper CL, Yeeles P, Cook S. Can the impact of public involvement on research be evaluated? A mixed methods study. *Health Expect*. 2012;15(3):229-41.
24. Domecq JP, Prutsky G, Elraiyah T, Wang Z, Nabhan M, Shippee N, et al. Patient engagement in research: a systematic review. *BMC Health Serv Res*. 2014;14:89.
25. Bowen SJ, Graham ID. From knowledge translation to engaged scholarship: promoting research relevance and utilization. *Arch Phys Med Rehabil*. 2013;94(1 Suppl):S3-8.
26. Shippee ND, Domecq Garces JP, Prutsky Lopez GJ, Wang Z, Elraiyah TA, Nabhan M, et al. Patient and service user engagement in research: a systematic review and synthesized framework. *Health Expect*. 2015;18(5):1151-66.
27. Ngiam KY, Khor IW. Big data and machine learning algorithms for health-care delivery. *Lancet Oncol*. 2019;20(5):e262-e73.

- 1
2
3 28. Rabin BA, Gaglio B, Sanders T, Nekhlyudov L, Dearing JW, Bull S, et al. Predicting
4 cancer prognosis using interactive online tools: a systematic review and implications for
5 cancer care providers. *Cancer Epidemiol Biomarkers Prev.* 2013;22(10):1645-56.
6
7
8 29. Stacey D, Légaré F, Lewis K, Barry MJ, Bennett CL, Eden KB, et al. Decision aids for
9 people facing health treatment or screening decisions. *Cochrane Database Syst Rev.*
10 2017;4:CD001431.
11
12 30. Stacey D, Légaré F, Lewis KB. Patient Decision Aids to Engage Adults in Treatment or
13 Screening Decisions. *JAMA.* 2017;318(7):657-8.
14
15 31. McAlpine K, Lewis KB, Trevena LJ, Stacey D. What Is the Effectiveness of Patient
16 Decision Aids for Cancer-Related Decisions? A Systematic Review Subanalysis. *JCO*
17 *Clin Cancer Inform.* 2018;2:1-13.
18
19 32. Ziebland S, Chapple A, Evans J. Barriers to shared decisions in the most serious of
20 cancers: a qualitative study of patients with pancreatic cancer treated in the UK. *Health*
21 *Expect.* 2015;18(6):3302-12.
22
23 33. Gillespie J, Kacikanis A, Nyhof-Young J, Gallinger S, Ruthig E. Information Needs of
24 Hepato-Pancreato-Biliary Surgical Oncology Patients. *J Cancer Educ.* 2017;32(3):589-
25 95.
26
27
28
29
30
31
32
33
34
35
36
37
38
39
40
41
42
43
44
45
46
47
48
49
50
51
52
53
54
55
56
57
58
59
60

Supplemental Material

Appendix A. Medline search strategy

#	Searches
1	Neoplasms/
2	exp Digestive System Neoplasms/
3	((anal or bile duct* or biliar* or gastrointestin* or GI or neuroendocrin* or stomach* or gastric* or colon or colorectal or rectal* or rectum* or duoden* or esophag* or gastroesophag* or gallbladder* or liver* or hepat* or pancrea* or bowel* or intestin* or digestive*) adj3 (neoplasm* or adenocarcinoma* or cancer* or tumor* or tumour* or metasta* or oncolog*)).tw,kf.
4	1 or 2 or 3
5	Patient-Centered Care/
6	Decision Making, Shared/
7	(patient centered or patient centred or person centered or person centred or patient focused or patient oriented).tw,kf.
8	(patient adj3 (priorit* or preference* or value* or expectation* or need* or relevan*)).tw,kf.
9	5 or 6 or 7 or 8
10	Outcome Assessment, Health Care/
11	Patient Outcome Assessment/
12	Patient Reported Outcome Measures/
13	(patient outcome* adj3 (measure* or assessment*)).tw,kf.
14	((patient centered or patient centred or person centered or person centred or patient focused or patient oriented or patient reported) adj3 outcome*).tw,kf.
15	(core outcome set* or standard set*).tw,kf.
16	10 or 11 or 12 or 13 or 14 or 15
17	4 and 9 and 16
18	limit 17 to yr="2000 -Current"

Appendix B. EMBASE Search Strategy

#	Searches
1	neoplasm/
2	solid malignant neoplasm/
3	exp digestive system cancer/
4	exp digestive system carcinoma/
5	((anal or bile duct* or biliar* or gastrointestin* or GI or neuroendocrin* or stomach* or gastric* or colon or colorectal or rectal* or rectum* or duoden* or esophag* or gastroesophag* or gallbladder* or liver* or hepat* or pancrea* or bowel* or intestin* or digestive*) adj3 (neoplasm* or adenocarcinoma* or cancer* or tumor* or tumour* or metasta* or oncolog*)).tw,kw.
6	1 or 2 or 3 or 4 or 5
7	patient preference/
8	(patient centered or patient centred or person centered or person centred or patient focused or patient oriented).tw,kw.
9	(patient adj3 (priorit* or preference* or value* or expectation* or need* or relevan*)).tw,kw.
10	7 or 8 or 9
11	outcome assessment/
12	patient-reported outcome/
13	(patient outcome* adj3 (measure* or assessment*)).tw,kw.
14	((patient centered or patient centred or person centered or person centred or patient focused or patient oriented or patient reported) adj3 outcome*).tw,kw.
15	(core outcome set* or standard set*).tw,kw.
16	11 or 12 or 13 or 14 or 15
17	6 and 10 and 16
18	limit 17 to yr="2000 -Current"

Appendix C. CINAHL Search Strategy

#	Query
S17	S4 AND S9 AND S16 Limiters - Published Date: 20000101-
S16	S10 OR S11 OR S12 OR S13 OR S14 OR S15
S15	TI (core outcome set* or standard set*) OR AB (core outcome set* or standard set*)
S14	TI ((patient centered or patient centred or person centered or person centred or patient focused or patient oriented or patient reported) N3 (outcome*)) OR AB ((patient centered or patient centred or person centered or person centred or patient focused or patient oriented or patient reported) N3 (outcome*))
S13	TI ((patient outcome*) N3 (measure* or assessment*)) OR AB ((patient outcome*) N3 (measure* or assessment*))
S12	(MH "Patient-Reported Outcomes")
S11	(MH "Outcome Assessment Information Set")
S10	(MH "Outcome Assessment")
S9	S5 OR S6 OR S7 OR S8
S8	TI ((patient) N3 (priorit* or preference* or value* or expectation* or need* or relevan*)) OR AB ((patient) N3 (priorit* or preference* or value* or expectation* or need* or relevan*))
S7	TI (patient centered or patient centred or person centered or person centred or patient focused or patient oriented) OR AB (patient centered or patient centred or person centered or person centred or patient focused or patient oriented)
S6	(MH "Patient Centered Care")
S5	(MH "Patient Preference")
S4	S1 OR S2 OR S3
S3	TI ((anal or bile duct* or biliar* or gastrointestin* or gi or neuroendocrin* or stomach* or gastric* or colon or colorectal or rectal* or rectum* or duoden* or esophag* or gastroesophag* or gallbladder* or liver* or hepat* or pancrea* or bowel* or intestin* or digestive*) N3 (neoplasm* or adenocarcinoma* or cancer* or tumor* or tumour* or metasta* or oncolog*)) OR AB ((anal or bile duct* or biliar* or gastrointestin* or gi or neuroendocrin* or stomach* or gastric* or colon or colorectal or rectal* or rectum* or duoden* or esophag* or gastroesophag* or gallbladder* or liver* or hepat* or pancrea* or bowel* or intestin* or digestive*) N3 (neoplasm* or adenocarcinoma* or cancer* or tumor* or tumour* or metasta* or oncolog*))
S2	(MH "Digestive System Neoplasms+")
S1	(MH "Neoplasms")

Appendix D. APA PsycINFO Search Strategy

#	Searches
1	Neoplasms/
2	((anal or bile duct* or biliar* or gastrointestinal* or GI or neuroendocrin* or stomach* or gastric* or colon or colorectal or rectal* or rectum* or duoden* or esophag* or gastroesophag* or gallbladder* or liver* or hepat* or pancrea* or bowel* or intestin* or digestive*) adj3 (neoplasm* or adenocarcinoma* or cancer* or tumor* or tumour* or metastas* or oncolog*)).tw.
3	1 or 2
4	Patient Centered Care/
5	(patient centered or patient centred or person centered or person centred or patient focused or patient oriented).tw.
6	(patient adj3 (priorit* or preference* or value* or expectation* or need* or relevan*)).tw.
7	4 or 5 or 6
8	"Treatment Process and Outcome Measures"/
9	Patient Reported Outcome Measures/
10	(patient outcome* adj3 (measure* or assessment*)).tw.
11	((patient centered or patient centred or person centered or person centred or patient focused or patient oriented or patient reported) adj3 outcome*).tw.
12	(core outcome set* or standard set*).tw.
13	8 or 9 or 10 or 11 or 12
14	3 and 7 and 13
15	limit 14 to yr="2000 -Current"

Appendix E. Cochrane Library Search Strategy

#	Search
1	MeSH descriptor: [Neoplasms] this term only
2	MeSH descriptor: [Digestive System Neoplasms] explode all trees
3	((anal or bile duct* or biliar* or gastrointestin* or GI or neuroendocrin* or stomach* or gastric* or colon or colorectal or rectal* or rectum* or duoden* or esophag* or gastroesophag* or gallbladder* or liver* or hepat* or pancrea* or bowel* or intestin* or digestive*) NEAR/3 (neoplasm* or adenocarcinoma* or cancer* or tumor* or tumour* or metasta* or oncolog*)):ti,ab,kw (Word variations have been searched)
4	#1 OR #2 OR #3
5	MeSH descriptor: [Patient Preference] this term only
6	MeSH descriptor: [Patient-Centered Care] this term only
7	("patient centered" or "patient centred" or "person centered" or "person centred" or "patient focused" or "patient oriented"):ti,ab,kw (Word variations have been searched)
8	(patient NEAR/3 (priorit* or preference* or value* or expectation* or need* or relevan*)):ti,ab,kw (Word variations have been searched)
9	#5 OR #6 OR #7 OR #8
10	MeSH descriptor: [Outcome Assessment, Health Care] this term only
11	MeSH descriptor: [Patient Outcome Assessment] this term only
12	MeSH descriptor: [Patient Reported Outcome Measures] this term only
13	("patient outcome*" NEAR/3 (measure* or assessment*)):ti,ab,kw (Word variations have been searched)
14	((("patient centered" or "patient centred" or "person centered" or "person centred" or "patient focused" or "patient oriented") NEAR/3 outcome*)):ti,ab,kw (Word variations have been searched)
15	("core outcome set*" or "standard set*"):ti,ab,kw (Word variations have been searched)
16	#10 OR #11 OR #12 OR #13 OR #14 OR #15
17	#4 AND #9 AND #16

Preferred Reporting Items for Systematic reviews and Meta-Analyses extension for Scoping Reviews (PRISMA-ScR) Checklist

SECTION	ITEM	PRISMA-ScR CHECKLIST ITEM	REPORTED ON PAGE #
TITLE			
Title	1	Identify the report as a scoping review.	
ABSTRACT			
Structured summary	2	Provide a structured summary that includes (as applicable): background, objectives, eligibility criteria, sources of evidence, charting methods, results, and conclusions that relate to the review questions and objectives.	
INTRODUCTION			
Rationale	3	Describe the rationale for the review in the context of what is already known. Explain why the review questions/objectives lend themselves to a scoping review approach.	
Objectives	4	Provide an explicit statement of the questions and objectives being addressed with reference to their key elements (e.g., population or participants, concepts, and context) or other relevant key elements used to conceptualize the review questions and/or objectives.	
METHODS			
Protocol and registration	5	Indicate whether a review protocol exists; state if and where it can be accessed (e.g., a Web address); and if available, provide registration information, including the registration number.	
Eligibility criteria	6	Specify characteristics of the sources of evidence used as eligibility criteria (e.g., years considered, language, and publication status), and provide a rationale.	
Information sources*	7	Describe all information sources in the search (e.g., databases with dates of coverage and contact with authors to identify additional sources), as well as the date the most recent search was executed.	
Search	8	Present the full electronic search strategy for at least 1 database, including any limits used, such that it could be repeated.	
Selection of sources of evidence†	9	State the process for selecting sources of evidence (i.e., screening and eligibility) included in the scoping review.	
Data charting process‡	10	Describe the methods of charting data from the included sources of evidence (e.g., calibrated forms or forms that have been tested by the team before their use, and whether data charting was done independently or in duplicate) and any processes for obtaining and confirming data from investigators.	
Data items	11	List and define all variables for which data were sought and any assumptions and simplifications made.	
Critical appraisal of individual sources of evidence§	12	If done, provide a rationale for conducting a critical appraisal of included sources of evidence; describe the methods used and how this information was used in any data synthesis (if appropriate).	
Synthesis of results	13	Describe the methods of handling and summarizing the data that were charted.	

SECTION	ITEM	PRISMA-ScR CHECKLIST ITEM	REPORTED ON PAGE #
RESULTS			
Selection of sources of evidence	14	Give numbers of sources of evidence screened, assessed for eligibility, and included in the review, with reasons for exclusions at each stage, ideally using a flow diagram.	
Characteristics of sources of evidence	15	For each source of evidence, present characteristics for which data were charted and provide the citations.	
Critical appraisal within sources of evidence	16	If done, present data on critical appraisal of included sources of evidence (see item 12).	
Results of individual sources of evidence	17	For each included source of evidence, present the relevant data that were charted that relate to the review questions and objectives.	
Synthesis of results	18	Summarize and/or present the charting results as they relate to the review questions and objectives.	
DISCUSSION			
Summary of evidence	19	Summarize the main results (including an overview of concepts, themes, and types of evidence available), link to the review questions and objectives, and consider the relevance to key groups.	
Limitations	20	Discuss the limitations of the scoping review process.	
Conclusions	21	Provide a general interpretation of the results with respect to the review questions and objectives, as well as potential implications and/or next steps.	
FUNDING			
Funding	22	Describe sources of funding for the included sources of evidence, as well as sources of funding for the scoping review. Describe the role of the funders of the scoping review.	

JBI = Joanna Briggs Institute; PRISMA-ScR = Preferred Reporting Items for Systematic reviews and Meta-Analyses extension for Scoping Reviews.

* Where *sources of evidence* (see second footnote) are compiled from, such as bibliographic databases, social media platforms, and Web sites.

† A more inclusive/heterogeneous term used to account for the different types of evidence or data sources (e.g., quantitative and/or qualitative research, expert opinion, and policy documents) that may be eligible in a scoping review as opposed to only studies. This is not to be confused with *information sources* (see first footnote).

‡ The frameworks by Arksey and O'Malley (6) and Levac and colleagues (7) and the JBI guidance (4, 5) refer to the process of data extraction in a scoping review as data charting.

§ The process of systematically examining research evidence to assess its validity, results, and relevance before using it to inform a decision. This term is used for items 12 and 19 instead of "risk of bias" (which is more applicable to systematic reviews of interventions) to include and acknowledge the various sources of evidence that may be used in a scoping review (e.g., quantitative and/or qualitative research, expert opinion, and policy document).

From: Tricco AC, Lillie E, Zarin W, O'Brien KK, Colquhoun H, Levac D, et al. PRISMA Extension for Scoping Reviews (PRISMA-ScR): Checklist and Explanation. *Ann Intern Med.* 2018;169:467–473. doi: [10.7326/M18-0850](https://doi.org/10.7326/M18-0850).



St. Michael's

Inspired Care.
Inspiring Science.

For peer review only - <http://bmjopen.bmj.com/site/about/guidelines.xhtml>