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Clinical Prediction Tools for Patient-Reported Outcomes in Gastrointestinal Cancer: A Scoping Review Protocol

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Keywords:	Gastrointestinal tumours < ONCOLOGY, Patient Reported Outcome Measures, Clinical Decision-Making

Title: Clinical Prediction Tools for Patient-Reported Outcomes in Gastrointestinal Cancer: A Scoping Review Protocol

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Keywords: Patient reported outcome, PROM, prediction model, gastrointestinal cancer, GI cancer

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Abstract:

Background: Gastrointestinal (GI) cancers are among the most significant contributors to the global cancer burden, causing substantial physical and emotional distress. Effective management of patient-reported outcomes (PROs) is essential for enhancing quality of life and overall survival in cancer care. Despite significant advances in cancer care, understanding PROs and their integration into clinical practice remains limited. Prediction models for PROs have the potential to support patient-centered care by improving shared decision-making and informing care plans. However, the development and application of clinical tools that predict PROs in GI cancer patients have not been systematically explored. This scoping review aims to explore clinical prediction tools for PROs and quality of life in GI cancer patients, identifying current tools, predictors, and outcomes, as well as evaluating their clinical usability and equity considerations.

Methods and Analysis: A scoping review methodology, guided by the JBI Manual for Evidence Synthesis and the Arksey and O'Malley framework, will be used. The review will include studies of adult patients with primary GI cancer that developed or validated clinical prediction tools for PROs or quality of life. Inclusion criteria require the use of self-reported PRO measures. A systematic search of Ovid Medline, Embase, and CINAHL will be conducted, complemented by hand-searching references. Data extraction will focus on tool characteristics, predictors, statistical methods, and equity considerations. Findings will be synthesized descriptively, mapping trends, identifying gaps, and highlighting areas for future research.

Ethics and Dissemination: Ethical approval is not required for this literature-based study. Results will be disseminated through peer-reviewed publications, conferences, and patient advocacy networks to maximize the impact on research, policy, and clinical practice.

Article Summary:

Strengths and limitations of this study:

- Novel Focus: First review exploring clinical tools for predicting PROs in gastrointestinal cancer, addressing a significant gap in the literature.
- Rigorous and Comprehensive Approach: Employs systematic search methods and established frameworks (JBI, TRIPOD) to ensure transparency and replicability, alongside a broad search strategy spanning multiple databases to enhance the review's depth and diversity of findings.
- Patient-Centered: Direct involvement of patient partners and healthcare providers ensures the relevance and real-world applicability of outcomes.
- Actionable Insights: Identifies critical gaps and provides guidance for developing future tools, advancing patient-centered care in GI cancer.
- Exclusion of grey literature: Limiting the review to published studies may omit relevant but unpublished tools.

Background:

Cancer poses a significant burden on global health. Gastrointestinal (GI) cancers account for 26% of the global cancer incidence and 35% of all cancer-related deaths.[1] Cancer diagnosis and treatment can cause significant physical and emotional distress,[2] which if not appropriately addressed, can lead to diminished quality of life.[3] Timely identification and appropriate management of patient reported symptoms has been shown to improve patient's quality of life and overall survival as it promote patient-centered care, a core component of cancer care.[4,5]

The National Cancer Institute defines Patient-Reported Outcomes (PROs) as Information about a patient's health that comes directly from the patient.[6] Examples include a patient's description of their symptoms, their satisfaction with care, and how a disease or treatment affects their physical, mental, emotional, spiritual, and social well-being. Patient-Reported Outcome Measures (PROMs) are "measurement tools that patients use to provide information on aspects of their health status that are relevant to their quality of life, including symptoms, functionality, and physical, mental and social health."[7] Patient-reported outcomes (PROs) are important to understanding whether health care services and procedures make a difference to patients' health status and quality of life. They also provide insight on the effectiveness of care from the patient's perspective.

With advancement in cancer care, PROs are increasing recognized as providing valuable and essential information in achieving health system goals and outcomes.[7] Incorporation of PROs and PROMs into clinical care not only enhances patient-provider communication and shared-decision making, but also informs health services programming, planning and policies.[7,8]

Prognostic prediction models play an important role in cancer care. Innumerable decision made by patients, family members, oncologists, surgeons and other care providers depend on assessing the probability of future events. Over the recent years, significant efforts have been made to improve and formalize prediction models based on statistical methods to provide a quantitative estimate of the probability of a specific event for an individual patient.[9] Such prediction models have a goal to improve information sharing and shared decision making with cancer patients, while supporting synthesis of complex information for care plan for individual patients. To date, there is a wealth of literature and prediction models for cancer patients of all diagnosis, with a focus survival and recurrence. There is, however, a lack of knowledge in if and how PROMs are used in prediction model for cancer patients. Therefore, the aim of this review is to explore prediction tools for patient reported outcomes (PROs) and quality of life in adult patients with gastrointestinal cancer. The intent is to identify all studies that developed or validated a clinical prediction tool for patient reported outcomes and quality of life in GI cancer.

Methods and analysis

A scoping review methodology will be used to explore the literature describing clinical prediction tools for patient-reported outcomes in GI cancer patients. This review will follow the guidelines outlined in the JBI Manual for Evidence Synthesis and the expanded Arksey and O'Malley framework for scoping reviews Arksey, H., & O'Malley, L. (2005).[10,11] Reporting will align with the Preferred Reporting Items for Systematic Reviews and Meta-Analysis Extension for Scoping Reviews.[12]

Objectives:

The scoping review protocol will answer the following research questions:

1. What clinical prediction tools have been developed and their characteristics for patient-reported outcomes (PROs) and quality of life for adult patients diagnosed with GI cancer?

2. Which outcomes and predictors are used by these prediction tools?
3. How has clinical usability, applicability, and equity been assessed in these prediction tools?

Eligibility criteria

Studies will be eligible for inclusion if they include adults >/=18 years with primary gastrointestinal cancer diagnosis and developed or validated a clinical prediction **tool for patient reported outcomes or quality of life** (table 1). Patient reported outcome is defined as any "measure that patients use to provide information on aspects of their health status that are relevant to their quality of life, including symptoms, functionality, and physical, mental and social health."

To ensure the outcomes reflect the patient's perspective, only studies using self-reported PROMs will be included, where information is reported directly by the patient or, if necessary, by a relative or proxy. This does not include outcomes solely assessed or interpreted by a physician or clinician. Additionally, studies must provide information on the specific PROM used, such as the survey or questionnaire, along with details on how the outcome was assessed to confirm it aligns with the definition of self-reported PROs.

Table 1: inclusion and exclusion criteria

	Inclusion	Exclusion
Outcome	• A patient reported outcome, quality of life or equivalent. • Reported by patients or (relative/proxies)	• No measure of PRO, quality of life, or equivalent • Outcome solely on Health Care provider's perspective (i.e. physician, nurse)
Intervention	Any study that developed, validated, or updated a clinical prediction model based on a statistical method and produced a readily useable clinical tool (i.e. scoring system, nomogram, or online calculator) designed for individual patient risk calculation	• Nonclinical tool (Not readily useable in the clinical setting) • Includes predictors that is not readily clinically available • Model not based on a statistical method (i.e. consensus statements) • Inappropriate analytic purpose (i.e. multivariate modeling not aimed at prognostication, development of novel statistical methods) • Studies that only investigated single variables
Population	Age >/=18 Active or prior diagnosis of GI cancer	Age <18 No GI cancer diagnosis
Study details	• Prospective and retrospective cohort studies.	• Editorials, opinion pieces, case reports, dissertations,

	• Case series of 10 or more subjects. • All languages and geographies.	conference abstracts and protocols. • Reviews and narrative studies • Non-english studies

Population

The population of interest include adults (≥18 years) diagnosed with Gastrointestinal cancer, defined as solid malignancy in the oesophagus, stomach, small intestine, colon, rectum, pancreas and biliary system.

Context:

To capture literature developing, validating and/or updating a clinical prediction tool for any patient - reported outcomes or quality of life measures for patients diagnosed with GI cancer. For this study, a PRO is any information reported by a patient or their proxy about a patient's health. It includes any measure of symptoms, their satisfaction with care, and how a disease or treatment affects their physical, mental, emotional, spiritual, and social well-being.

Study details

A broad list of study designs will be included. Any study that includes the development or validation of a clinical prediction tool will be included, regardless of statistical methods and patient recruitment strategies. Grey literature will be excluded. All geographical regions will be included. However, for the purposes of this review, we will only include studies published in English.

Search Strategy and information sources:

In consultation with a senior Health Sciences librarian at the University of Toronto, we developed a search strategy that included keywords and medical subject headings (MeSH) for gastrointestinal cancer, patient reported outcomes, and prediction tool. Each set of search terms was modified for the specific search engine. The search strategy for Ovid Medline is illustrated below (Table 2). To ensure thoroughness, we will systematically search Ovid Medline, Embase, and CINAHL, and we plan to hand-search key article reference lists and reviews for additional relevant citations. No age filters will be applied due to potential limitations in sensitivity, and no language restrictions will be set . Grey literature will be excluded. A previous systematic review evaluating trends in PROMs within healthcare found that publication of PROM literature began emerging in the 1990s. [13] As such, a temporal limit of 1990 was set to the search strategy. [13] We will use the search holdings of University of Toronto, University of Western Ontario Libraries, and Queen's University, as well as 3 Hospitals Network libraries (Sunnybrook Health Sciences, University Health Network, and Unity Health Toronto) to obtain full test. Reference will be managed with using the Covidence, a systematic review software.

Study selection

Study selection will follow the guidelines set out by the JBI manual for Evidence Synthesis and the expanded Arksey and O'Malley framework.[10,11,14,15] A pilot phase for testing eligibility criteria will be conducted using a random sample of 50 titles and abstracts, evaluated independently by two reviewers. The reviewers will then compare their selections, resolve any discrepancies through discussion, and adjust the eligibility criteria as needed. Study selection will officially commence once an inter-rater reliability of at least 75% is reached. We will follow a two-stage study selection process. In the first stage, titles and abstracts will be screened independently and in duplicate (i.e. two reviewers). In the second stage, full

texts of any potentially relevant citation for inclusion will also be screened independently and in duplicate. At all phases of the review, disagreement will be resolved by consensus and adjudicated by a third reviewer. The inclusion and exclusion criteria will be reviewed and may be modified following the pilot testing phase and iteratively throughout the search during research team meetings.

Table 2: Search strategy OVID MEDLINE

Database: Ovid MEDLINE(R) ALL <1946 to May 17, 2024>

Search Strategy:

1 Gastrointestinal Neoplasms/ or Digestive System Neoplasms/ (24374)

2 (Gastrointestinal adj2 (cancer* or tumor* or tumour* or neoplasm* or malignancy or carcinoma)).tw,kf,ti,ab. (30738)

3 Esophageal Neoplasms/ or Stomach Neoplasms/ or Pancreatic Neoplasms/ or Intestinal Neoplasms/ or Colorectal Neoplasms/ or rectal neoplasms/ or anus neoplasms/ or Biliary Tract Neoplasms/ or liver neoplasms/ or Colonic Neoplasms/ (650057)

4 (((digestive or esophageal or esophagus or gastric or stomach or pancreas or pancreatic or intestinal or intestine* or colon* or colorectal or bowel or liver or hepatic or rectal or rectum or biliary or cholangio* or hepatocellular) adj3 (adenocarcinoma or carcinoma or cancer* or tumor* or tumour* or neoplasm* or malignancy)) or (hepatoma or hepatocarcinoma or cholangiocarcinoma)).tw,kf,ti,ab. (760505)

5 1 or 2 or 3 or 4 (944472)

6 models, statistical/ or likelihood functions/ or linear models/ or logistic models/ or nomograms/ or proportional hazards models/ (441472)

7 clinical decision rules/ (960)

8 (((statistical or linear or logistic or hazard*) adj2 model*) or (nomogram* or (table* adj2 partin)) or (likelihood adj2 function*)).tw,kf,ti,ab. (349427)

9 ((rule* adj3 clinical adj3 (decision* or predict*)) or (predict* adj3 tool)).tw,kf,ti,ab. (21831)

10 6 or 7 or 8 or 9 (723974)

11 Patient Outcome Assessment/ or Patient Reported Outcome Measures/ (21258)

12 health care surveys/ or "quality of life"/ or Diagnostic Self Evaluation/ or "Surveys and Questionnaires"/ (829143)

13 Outcome Assessment, Health Care/ or Symptom Assessment/ (90346)

14 (((patient reported or self reported or self-reported or patient or self) adj3 (outcome* or symptom* or survey or health or measure* or assessment* or experience or perspective)) or ((patient outcome* or symptom) adj3 (measure* or assessment*))).tw,kf,ti,ab. (413806)

15 (HRQoL or health related quality of life or (quality adj2 life) or (wellbeing or nausea or pain or depression or anxiety or fatigue or shortness of breath or appetite or drowsiness or tiredness or bowel function or quality-of-life)).tw,kf,ti,ab. (1868962)

16 (PRO or PROM or QOL or HRQoL or HRQL or ePROM or e-PROM).tw,kf,ti,ab. (353046)

17 11 or 12 or 13 or 14 or 15 or 16 (2935837)

18 5 and 10 and 17 (3380)

19 limit 18 to yr= “1990-current” (3378)

Data extraction

Data extraction will be performed using standardized extraction tables designed by the research team, informed by the JBI Manual for Evidence Synthesis, Arksey and O’Malley’s framework, and the TRIPOD statement for prediction models.[10,11] [16] These tables will be aligned with the research objectives to ensure the collection of relevant information, including study characteristics (e.g., design, setting, sample

size), PROs assessed, predictors included, statistical methods used, and the performance of the prediction models.

A pilot data extraction will be conducted on the first 10 studies by two independent reviewers to test and refine the extraction tables.[11,14] Any discrepancies identified during the pilot phase will be resolved through discussion, with input from a third reviewer if necessary. Adjustments to the extraction tables will be made iteratively throughout the review to accommodate unanticipated data or insights that emerge. [11,14] Final extracted data will be reviewed by the research team to ensure consistency and completeness.

Table 3a: Draft data extraction table, study characteristics

First/Last Author (publication year)	Country	Study Design	Data source	Recruitment Period	Follow-up Period	Population	Outcome

Table 3b: Draft data extraction table, model details

First/Last Author (publication year)	Modeling method	Prediction Tool	Sample size	Outcome	Key predictors	Model Performance	Validation Technique (Internal/ External)

Data Analysis

The extracted data will be analyzed descriptively, with a focus on mapping trends, identifying gaps, and summarizing the characteristics of prediction tools for PROs and quality of life in gastrointestinal cancer. The following steps will guide the data analysis:

1. Descriptive synthesis: A narrative summary will describe the study characteristics, prediction models, and patient-reported outcomes. This will help identify patterns in the use of PROMs across studies.
2. Categorization of PROs: PROs will be grouped into broad domains (e.g., physical, mental, emotional, and social well-being) to explore which domains are most predicted.
3. Analysis of predictors: The predictors included in the models will be compared across studies to identify common factors and explore their clinical relevance.
4. Mapping of statistical methods: Identifying and mapping of statistical techniques used for model development
5. Equity considerations: We will assess whether the populations used to develop and validate each model represent the broader GI cancer population, evaluate if equity was incorporated in model methods, and identify factors allowing stratification by subgroups (e.g., socioeconomic status, race, ethnicity).
6. Trend analysis: Trends in the development and validation of prediction models over time will be explored, including changes in statistical methodologies, the use of PROMS, and any equity considerations.

The findings will be synthesized to provide an overview of key insights on the use of PROMs in prediction models, identify gaps in the current literature, and suggest directions for future research. Where applicable, we will reference the TRIPOD guidelines to ensure our review thoroughly addresses essential aspects of prediction models, facilitating the synthesis of relevant literature. While TRIPOD is not specifically designed for scoping reviews, its components can be adapted to enhance the rigor and

transparency of our analysis. By using TRIPOD as a guide, we can ensure that our scoping review effectively covers critical elements of prediction models, thereby identifying important areas for future exploration. [16]

Patient and public involvement

This study recognizes the importance of involving patients and stakeholders to ensure the research is relevant, meaningful, and aligned with real-world needs. Engaging individuals with lived experience brings unique perspectives that enrich the study and ensure that outcomes resonate with those affected by gastrointestinal cancer. Following best practices in patient and public involvement we actively integrated feedback from patient partners, healthcare providers, and decision-makers at key stages of this review.

Two patient partners with lived experience of gastrointestinal cancer (EK and TT) are core members of the research team. Their involvement began at the project's inception, ensuring that the study objectives and design align with the needs and concerns of patients. They will continue to contribute throughout the entire study, including data analysis, interpretation of findings, and dissemination of results, ensuring clinical relevance and patient-centeredness. We will also conduct consultations with healthcare providers and other stakeholders to validate our preliminary findings, identify any gaps, and gather feedback to refine the results. These engagements will help ensure that the review outputs are relevant to clinical practice and can guide future research initiatives.

Ethics and Dissemination

As this study involves a review of existing literature, formal ethical approval is not required. This review is the first to explore prediction models for PROs in GI cancer. The findings will provide valuable insights into existing prediction tools and serve as a foundation for future model development, guiding the creation of clinically relevant tools that integrate patient-centered outcomes. The results will be disseminated through a peer-reviewed publication and presented at relevant academic and clinical conferences. We will also engage with patient advocacy groups, healthcare professionals, and decision-makers to share key findings, ensuring they inform both practice and policy. Patient partners involved in this study will co-author publications and participate in presentations, ensuring the patient perspective is reflected in all communications.

In addition, we will use non-academic channels, including newsletters and social media, to reach patients, caregivers, and the general public. This multi-faceted dissemination strategy aims to maximize the impact of our findings, promoting the integration of PROs into future prediction models and supporting shared decision-making in GI cancer care.

Contributors: AZ, KYI, JH and NGC conceived the idea and developed the research questions and study methods. AZ drafted the protocol. AZ and KYI conceived and executed the search strategy. AZ, KYI, AM, ATH, PJ, EK, TT, JH and NGC contributed meaningfully to the editing and critical review of this protocol and approved the final manuscript.

Funding: This work was supported by a Team Grant from the Canadian Institutes of Health Research (FRN#459694).

Data availability statement: No data are available. Not applicable.

Patient and public involvement: Patients and the public were involved in the design, conduct, reporting or dissemination plans of this research. Refer to the Methods and analysis section for further details.

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Abstract:

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- Rigorous and Comprehensive Approach: Employs systematic search methods and established frameworks (JBI, TRIPOD) to ensure transparency and replicability, alongside a broad search strategy spanning multiple databases to enhance the review's depth and diversity of findings.
- Patient-Centered: Direct involvement of patient partners and healthcare providers ensures the relevance and real-world applicability of outcomes.
- Actionable Insights: Identifies critical gaps and provides guidance for developing future tools, advancing patient-centered care in GI cancer.
- Exclusion of grey literature: Limiting the review to published studies may omit relevant but unpublished tools.
- Given the objective of scoping reviews, this study will not conduct a comparative analysis of prediction tool performance metrics or evaluate data quality, limiting its ability to inform clinical practice.

Background:

Cancer poses a significant burden on global health. Gastrointestinal (GI) cancers account for 26% of the global cancer incidence and 35% of all cancer-related deaths.[1] Cancer diagnosis and treatment can cause significant physical and emotional distress,[2] which if not appropriately addressed, can lead to diminished quality of life.[3] Timely identification and appropriate management of patient reported symptoms has been shown to improve patients' quality of life and overall survival as it promote patient-centered care, a core component of cancer care.[4,5]

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Prognostic prediction models play an important role in cancer care. Innumerable decision made by patients, family members, oncologists, surgeons and other care providers depend on assessing the probability of future events. Over the recent years, significant efforts have been made to improve and formalize prediction models based on statistical methods to provide a quantitative estimate of the probability of a specific event for an individual patient.[9] Such prediction models have a goal to improve information sharing and shared decision making with cancer patients, while supporting synthesis of complex information for care plan for individual patients. To date, there is a wealth of literature and prediction models for cancer patients of all diagnosis, with a focus survival and recurrence. There is, however, a lack of knowledge regarding if and how PROMs are used in prediction models for cancer patients. Therefore, the aim of this review is to identify and describe clinical prediction tools developed for PROs and quality of life in adult patients diagnosed with GI cancer, examine the outcomes and predictors utilized within these prediction tools, and assess how clinical usability, applicability, and equity have been evaluated in relation to these tools.

Methods and analysis

A scoping review methodology will be used to explore the literature describing clinical prediction tools for patient-reported outcomes in GI cancer patients. This review will follow the guidelines outlined in the JBI Manual for Evidence Synthesis and the expanded Arksey and O'Malley framework for scoping reviews Arksey, H., & O'Malley, L. (2005).[10,11] Reporting will align with the Preferred Reporting Items for Systematic Reviews and Meta-Analysis Extension for Scoping Reviews.[12]

Objectives:

The scoping review protocol will answer the following research questions:

1. What clinical prediction tools have been developed and their characteristics for patient-reported outcomes (PROs) and quality of life for adult patients diagnosed with GI cancer?
2. Which outcomes and predictors are used by these prediction tools?
3. How has clinical usability, applicability, and equity been assessed in these prediction tools?

Eligibility criteria

Studies will be eligible for inclusion if they include adults >/=18 years with primary gastrointestinal cancer diagnosis and developed or validated a clinical prediction **tool for patient reported outcomes or quality of life** (table 1). Patient reported outcome is defined as any "measure that patients use to provide information on aspects of their health status that are relevant to their quality of life, including symptoms, functionality, and physical, mental and social health."

To ensure the outcomes reflect the patient's perspective, only studies using self-reported PROMs will be included, where information is reported directly by the patient or, if necessary, by a relative or proxy. This does not include outcomes solely assessed or interpreted by a physician or clinician. Additionally, studies must provide information on the specific PROM used, such as the survey or questionnaire, along with details on how the outcome was assessed to confirm it aligns with the definition of self-reported PROs.

Table 1: inclusion and exclusion criteria

	Inclusion	Exclusion
Outcome	• A patient reported outcome, quality of life or equivalent. • Reported by patients or (relative/proxies)	• No measure of PRO, quality of life, or equivalent • Outcome solely on Health Care provider's perspective (i.e. physician, nurse)
Intervention	Any study that developed, validated, or updated a clinical prediction model based on a statistical method and produced a readily useable clinical tool (i.e. scoring system, nomogram, or online calculator) designed for individual patient risk calculation	• Nonclinical tool (Not readily useable in the clinical setting) • Includes predictors that is not readily clinically available • Model not based on a statistical method (i.e. consensus statements) • Inappropriate analytic purpose (i.e. multivariate modeling not aimed at prognostication, development of novel statistical methods) • Studies that only investigated single variables
Population	Age >/=18 Active or prior diagnosis of GI cancer	Age <18 No GI cancer diagnosis

Study details	• Prospective and retrospective cohort studies. • Case series of 10 or more subjects. • .	• Editorials, opinion pieces, case reports, dissertations, conference abstracts and protocols. • Reviews and narrative studies • Non-English studies

Population

The population of interest include adults (≥18 years) diagnosed with Gastrointestinal cancer, defined as solid malignancy in the oesophagus, stomach, small intestine, colon, rectum, pancreas and biliary system.

Context:

To capture literature developing, validating and/or updating a clinical prediction tool for any patient - reported outcomes or quality of life measures for patients diagnosed with GI cancer. For this study, a PRO is any information reported by a patient or their proxy about a patient's health. It includes any measure of symptoms, their satisfaction with care, and how a disease or treatment affects their physical, mental, emotional, spiritual, and social well-being.

Study details

A broad list of study designs will be included. Any study that includes the development or validation of a clinical prediction tool will be included, regardless of statistical methods and patient recruitment strategies. Grey literature will be excluded. All geographical regions will be included. However, for the purposes of this review, we will only include studies published in English. The search strategy was first developed on May 17, 2024, and will be updated periodically to ensure the review remains current. The planned completion date for the study is July 1, 2025.

Search Strategy and information sources:

In consultation with a senior Health Sciences librarian at the University of Toronto, we developed a search strategy that included keywords and medical subject headings (MeSH) for gastrointestinal cancer, patient reported outcomes, and prediction tool. Each set of search terms was modified for the specific search engine. The search strategy for Ovid Medline is illustrated below (Table 2). To ensure thoroughness, we will systematically search Ovid Medline, Embase, and CINAHL, and we plan to hand-search key article reference lists and reviews for additional relevant citations (Appendix S1 for full search strategies). No age filters will be applied due to potential limitations in sensitivity. Language restrictions will be applied solely during the selection stage, rather than at the literature search phase, to address challenges related to accessibility and the accuracy of translating non-English PROMs. Grey literature will be excluded. A previous systematic review evaluating trends in PROMs within healthcare found that publication of PROM literature began emerging in the 1990s. [13] As such, a temporal limit of 1990 was set to the search strategy. [13] We will use the search holdings of University of Toronto, University of Western Ontario Libraries, and Queen's University, as well as 3 Hospitals Network libraries (Sunnybrook Health Sciences, University Health Network, and Unity Health Toronto) to obtain full test. Reference will be managed with using the Covidence, a systematic review software.

Study selection

Study selection will follow the guidelines set out by the JBI manual for Evidence Synthesis and the expanded Arksey and O'Malley framework.[10,11,14,15] A pilot phase for testing eligibility criteria will be conducted using a random sample of 50 titles and abstracts, evaluated independently by two reviewers. The reviewers will then compare their selections, resolve any discrepancies through discussion, and adjust the eligibility criteria as needed. Study selection will officially commence once an inter-rater reliability of at least 75% is reached. We will follow a two-stage study selection process. In the first stage, titles and abstracts will be screened independently and in duplicate (i.e. two reviewers). In the second stage, full texts of any potentially relevant citation for inclusion will also be screened independently and in duplicate. At all phases of the review, disagreement will be resolved by consensus and adjudicated by a third reviewer. The inclusion and exclusion criteria will be reviewed and may be modified following the pilot testing phase and iteratively throughout the search during research team meetings.

Table 2: Search strategy OVID MEDLINE

Database: Ovid MEDLINE(R) ALL <1946 to May 17, 2024>

Search Strategy:

1 Gastrointestinal Neoplasms/ or Digestive System Neoplasms/ (24374)

2 (Gastrointestinal adj2 (cancer* or tumor* or tumour* or neoplasm* or malignancy or carcinoma)).tw,kf,ti,ab. (30738)

3 Esophageal Neoplasms/ or Stomach Neoplasms/ or Pancreatic Neoplasms/ or Intestinal Neoplasms/ or Colorectal Neoplasms/ or rectal neoplasms/ or anus neoplasms/ or Biliary Tract Neoplasms/ or liver neoplasms/ or Colonic Neoplasms/ (650057)

4 (((digestive or esophageal or esophagus or gastric or stomach or pancreas or pancreatic or intestinal or intestine* or colon* or colorectal or bowel or liver or hepatic or rectal or rectum or biliary or cholangio* or hepatocellular) adj3 (adenocarcinoma or carcinoma or cancer* or tumor* or tumour* or neoplasm* or malignancy)) or (hepatoma or hepatocarcinoma or cholangiocarcinoma)).tw,kf,ti,ab. (760505)

5 1 or 2 or 3 or 4 (944472)

6 models, statistical/ or likelihood functions/ or linear models/ or logistic models/ or nomograms/ or proportional hazards models/ (441472)

7 clinical decision rules/ (960)

8 (((statistical or linear or logistic or hazard*) adj2 model*) or (nomogram* or (table* adj2 partin)) or (likelihood adj2 function*)).tw,kf,ti,ab. (349427)

9 ((rule* adj3 clinical adj3 (decision* or predict*)) or (predict* adj3 tool)).tw,kf,ti,ab. (21831)

10 6 or 7 or 8 or 9 (723974)

11 Patient Outcome Assessment/ or Patient Reported Outcome Measures/ (21258)

12 health care surveys/ or "quality of life"/ or Diagnostic Self Evaluation/ or "Surveys and Questionnaires"/ (829143)

13 Outcome Assessment, Health Care/ or Symptom Assessment/ (90346)

14 (((patient reported or self reported or self-reported or patient or self) adj3 (outcome* or symptom* or survey or health or measure* or assessment* or experience or perspective)) or ((patient outcome* or symptom) adj3 (measure* or assessment*))).tw,kf,ti,ab. (413806)

15 (HRQoL or health related quality of life or (quality adj2 life) or (wellbeing or nausea or pain or depression or anxiety or fatigue or shortness of breath or appetite or drowsiness or tiredness or bowel function or quality-of-life)).tw,kf,ti,ab. (1868962)

16 (PRO or PROM or QOL or HRQoL or HRQL or ePROM or e-PROM).tw,kf,ti,ab. (353046)

17 11 or 12 or 13 or 14 or 15 or 16 (2935837)

18 5 and 10 and 17 (3380)

19 limit 18 to yr= "1990-current" (3378)

Data extraction

Data extraction will be performed using standardized extraction tables designed by the research team, informed by the JBI Manual for Evidence Synthesis, Arksey and O'Malley's framework, and the TRIPOD statement for prediction models.[10,11] [16] These tables will be aligned with the research objectives to ensure the collection of relevant information, including study characteristics (e.g., design, setting, sample size), PROs assessed, predictors included, statistical methods used, and the performance of the prediction models (Table 3).

A pilot data extraction will be conducted on the first 10 studies by two independent reviewers to test and refine the extraction tables.[11,14] Any discrepancies identified during the pilot phase will be resolved through discussion, with input from a third reviewer if necessary. Adjustments to the extraction tables will be made iteratively throughout the review to accommodate unanticipated data or insights that emerge. [11,14] Final extracted data will be reviewed by the research team to ensure consistency and completeness.

Table 3a: Draft data extraction table, study characteristics

First/Last Author (publication year)	Country	Study Design	Data source	Recruitment Period	Follow-up Period	Population	Outcome

Table 3b: Draft data extraction table, model details

First/Last Author (publication year)	Modeling method	Prediction Tool	Sample size	Outcome	Key predictors	Model Performance	Validation Technique (Internal/ External)

Data Analysis

The extracted data will be analyzed descriptively, with a focus on mapping trends, identifying gaps, and summarizing the characteristics of prediction tools for PROs and quality of life in gastrointestinal cancer. The following steps will guide the data analysis:

1. Descriptive synthesis: A narrative summary will describe the study characteristics, prediction models, and patient-reported outcomes. This will help identify patterns in the use of PROMs across studies.
2. Categorization of PROs: PROs will be grouped into broad domains (e.g., physical, mental, emotional, and social well-being) to explore which domains are most predicted.
3. Analysis of predictors: The predictors included in the models will be compared across studies to identify common factors and explore their clinical relevance.
4. Mapping of statistical methods: Identifying and mapping of statistical techniques used for model development.
5. Examination of model performance measures: review of model performance measures, as well as methods employed for both internal and external validation (where applicable)
6. Equity considerations: We will assess whether the populations used to develop and validate each model represent the broader GI cancer population, evaluate if equity was incorporated in model methods, and identify factors allowing stratification by subgroups (e.g., socioeconomic status, race, ethnicity).

7. Trend analysis: Trends in the development and validation of prediction models over time will be explored, including changes in statistical methodologies, the use of PROMS, and any equity considerations.

The findings will be synthesized to provide an overview of key insights on the use of PROMs in prediction models, identify gaps in the current literature, and suggest directions for future research. The results will be summarized using tables, figures and a narrative format, based on cancer types allowing more targeted insighted. Subgroup analysis by cancer type will be performed as necessary. Where applicable, we will reference the TRIPOD guidelines to ensure our review thoroughly addresses essential aspects of prediction models, facilitating the synthesis of relevant literature. While TRIPOD is not specifically designed for scoping reviews, its components can be adapted to enhance the rigor and transparency of our analysis. By using TRIPOD as a guide, we can ensure that our scoping review effectively covers critical elements of prediction models, thereby identifying important areas for future exploration. [16]

Patient and public involvement

This study recognizes the importance of involving patients and stakeholders to ensure the research is relevant, meaningful, and aligned with real-world needs. Engaging individuals with lived experience brings unique perspectives that enrich the study and ensure that outcomes resonate with those affected by gastrointestinal cancer. Following best practices in patient and public involvement we actively integrated feedback from patient partners, healthcare providers, and decision-makers at key stages of this review.

Two patient partners with lived experience of gastrointestinal cancer (EK and TT) are core members of the research team. Their involvement began at the project's inception, ensuring that the study objectives and design align with the needs and concerns of patients. They will continue to contribute throughout the entire study, including data analysis, interpretation of findings, and dissemination of results, ensuring clinical relevance and patient-centeredness. We will also conduct consultations with healthcare providers and other stakeholders to validate our preliminary findings, identify any gaps, and gather feedback to refine the results. These engagements will help ensure that the review outputs are relevant to clinical practice and can guide future research initiatives.

Ethics and Dissemination

As this study involves a review of existing literature, formal ethical approval is not required. This review is the first to explore prediction models for PROs in GI cancer. The findings will provide valuable insights into existing prediction tools and serve as a foundation for future model development, guiding the creation of clinically relevant tools that integrate patient-centered outcomes. The results will be disseminated through a peer-reviewed publication and presented at relevant academic and clinical conferences. We will also engage with patient advocacy groups, healthcare professionals, and decision-makers to share key findings, ensuring they inform both practice and policy. Patient partners involved in this study will co-author publications and participate in presentations, ensuring the patient perspective is reflected in all communications.

In addition, we will use non-academic channels, including newsletters and social media, to reach patients, caregivers, and the general public. This multi-faceted dissemination strategy aims to maximize the impact of our findings, promoting the integration of PROs into future prediction models and supporting shared decision-making in GI cancer care.

Contributors: AZ, KYI, JH and NGC conceived the idea and developed the research questions and study methods. AZ drafted the protocol. AZ and KYI conceived and executed the search strategy. AZ, KYI, AM, ATH, PJ, EK, TT, JH and NGC contributed meaningfully to the editing and critical review of this protocol and approved the final manuscript. NGC is guarantor.
Funding: This work was supported by a Team Grant from the Canadian Institutes of Health Research (FRN#459694).
Data availability statement: No data are available. Not applicable.
Patient and public involvement: Patients and the public were involved in the design, conduct, reporting or dissemination plans of this research. Refer to the Methods and analysis section for further details.

Reference :

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4 World Health Organization. People-Centred Health Care: A POLICY FRAMEWORK.

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9 Vickers AJ. Prediction models in cancer care. *CA: A Cancer Journal for Clinicians*. 2011;61:315–26. doi: 10.3322/caac.20118

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11 JBI Manual for Evidence Synthesis - JBI Global Wiki. https://jbi-global-wiki.refined.site/space/MANUAL (accessed 15 October 2024)

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13 Churruca K, Pomare C, Ellis LA, *et al.* Patient-reported outcome measures (PROMs): A review of generic and condition-specific measures and a discussion of trends and issues. *Health Expect*. 2021;24:1015–24. doi: 10.1111/hex.13254

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16 Collins GS, Reitsma JB, Altman DG, *et al.* Transparent reporting of a multivariable prediction model for individual prognosis or diagnosis (TRIPOD): the TRIPOD Statement. *BMC Medicine*. 2015;13:1. doi: 10.1186/s12916-014-0241-z

Database: Embase Classic+Embase <1947 to 2024 May 20>

Search Strategy:

1 digestive system cancer/ or gastrointestinal cancer/ or gastrointestinal tumor/ (45317)

2 (Gastrointestinal adj2 (cancer* or tumor* or tumour* or neoplasm* or malignancy or carcinoma)).tw,kf,ti,ab. (45382)

3 stomach cancer/ or esophagus cancer/ or pancreas cancer/ or intestine cancer/ or colon cancer/ or colorectal cancer/ or colon carcinoma/ or rectum cancer/ or anus cancer/ or bile duct cancer/ or biliary tract cancer/ or gallbladder cancer/ or liver cancer/ (589495)

4 (((digestive or esophageal or esophagus or gastric or stomach or pancreas or pancreatic or intestinal or intestine* or colon* or colorectal or bowel or liver or hepatic or rectal or rectum or biliary or cholangio* or hepatocellular) adj3 (adenocarcinoma or carcinoma or cancer* or tumor* or tumour* or neoplasm* or malignancy)) or (hepatoma or hepatocarcinoma or cholangiocarcinoma)).tw,kf,ti,ab. (1105763)

5 1 or 2 or 3 or 4 (1273648)

6 statistical model/ or regression model/ or nomogram/ or clinical decision rule/ or proportional hazards model/ or multivariate analysis/ (471271)

7 clinical decision rules/ (824)

8 (((statistical or linear or logistic or hazard*) adj2 model*) or (nomogram* or (table* adj2 partin)) or (likelihood adj2 function*)).tw,kf,ti,ab. (501956)

9 ((rule* adj3 clinical adj3 (decision* or predict*)) or (predict* adj3 tool)).tw,kf,ti,ab. (32744)

10 6 or 7 or 8 or 9 (882726)

11 patient-reported outcome/ (61612)

12 outcome assessment/ or health care survey/ or "quality of life"/ or self evaluation/ or health survey/ (1767570)

13 Symptom Assessment/ (12809)

14 (((patient reported or self reported or self-reported or patient or self) adj3 (outcome* or symptom* or survey or health or measure* or assessment* or experience or perspective)) or ((patient outcome* or symptom) adj3 (measure* or assessment*))).tw,kf,ti,ab. (618965)

15 (HRQoL or health related quality of life or (quality adj2 life) or (wellbeing or function or quality-of-life or depression or anxiety or fatigue or pain or appetite or quality-of-life)).tw,kf,ti,ab. (5805839)

16 (PRO or PROM or QOL or HRQoL or HRQL or ePROM or e-PROM).tw,kf,ti,ab. (558510)

17 11 or 12 or 13 or 14 or 15 or 16 (7501137)

18 5 and 10 and 17 (9835)

19 limit 18 to yr="1990 -Current" (9818)

Database: Ovid MEDLINE: Epub Ahead of Print, In-Process & Other Non-Indexed Citations, Ovid MEDLINE® Daily and Ovid MEDLINE® <1946-Present >

Search Strategy:

1 Gastrointestinal Neoplasms/ or Digestive System Neoplasms/ (24377)

2 (Gastrointestinal adj2 (cancer* or tumor* or tumour* or neoplasm* or malignancy or carcinoma)).tw,kf,ti,ab. (30757)

3 Esophageal Neoplasms/ or Stomach Neoplasms/ or Pancreatic Neoplasms/ or Intestinal Neoplasms/ or Colorectal Neoplasms/ or rectal neoplasms/ or anus neoplasms/ or Biliary Tract Neoplasms/ or liver neoplasms/ or Colonic Neoplasms/ (650246)

4 (((digestive or esophageal or esophagus or gastric or stomach or pancreas or pancreatic or intestinal or intestine* or colon* or colorectal or bowel or liver or hepatic or rectal or rectum or biliary or cholangio* or hepatocellular) adj3 (adenocarcinoma or carcinoma or cancer* or tumor* or tumour* or neoplasm* or malignancy)) or (hepatoma or hepatocarcinoma or cholangiocarcinoma)).tw,kf,ti,ab. (760829)

5 1 or 2 or 3 or 4 (944822)

6 models, statistical/ or likelihood functions/ or linear models/ or logistic models/ or nomograms/ or proportional hazards models/ (441576)

7 clinical decision rules/ (961)

8 (((statistical or linear or logistic or hazard*) adj2 model*) or (nomogram* or (table* adj2 partin)) or (likelihood adj2 function*)).tw,kf,ti,ab. (349672)

9 ((rule* adj3 clinical adj3 (decision* or predict*)) or (predict* adj3 tool)).tw,kf,ti,ab. (21837)

10 6 or 7 or 8 or 9 (724268)

11 Patient Outcome Assessment/ or Patient Reported Outcome Measures/ (21283)

12 health care surveys/ or "quality of life"/ or Diagnostic Self Evaluation/ or "Surveys and Questionnaires"/ (829441)

13 Outcome Assessment, Health Care/ or Symptom Assessment/ (90359)

14 (((patient reported or self reported or self-reported or patient or self) adj3 (outcome* or symptom* or survey or health or measure* or assessment* or experience or perspective)) or ((patient outcome* or symptom) adj3 (measure* or assessment*))).tw,kf,ti,ab. (414071)

15 (HRQoL or health related quality of life or (quality adj2 life) or (wellbeing or nausea or pain or depression or anxiety or fatigue or shortness of breath or appetite or drowsiness or tiredness or bowel function or quality-of-life)).tw,kf,ti,ab. (1869779)

16 (PRO or PROM or QOL or HRQoL or HRQL or ePROM or e-PROM).tw,kf,ti,ab. (353239)

17 11 or 12 or 13 or 14 or 15 or 16 (2937094)

18 5 and 10 and 17 (3382)

19 limit 18 to yr="1990 -Current" (3378)

Search Strategy: CINAHL May 18, 2024

#	Query	Limiters/Expanders	Last Run Via	Results
S15	S12 AND S13 AND S14	Expanders - Apply equivalent subjects Search modes - Boolean/Phrase	Interface - EBSCOhost Research Databases Search Screen - Advanced Search Database - CINAHL Ultimate	1,551
S14	S8 OR S9 OR S10 OR S11	Expanders - Apply equivalent subjects Search modes - Boolean/Phrase	Interface - EBSCOhost Research Databases Search Screen - Advanced Search Database - CINAHL Ultimate	350,555
S13	S5 OR S6 OR S7	Expanders - Apply equivalent subjects Search modes - Boolean/Phrase	Interface - EBSCOhost Research Databases Search Screen - Advanced Search Database - CINAHL Ultimate	268,476
S12	S1 OR S2 OR S3 OR S4	Expanders - Apply equivalent subjects Search modes - Boolean/Phrase	Interface - EBSCOhost Research Databases Search Screen - Advanced Search Database - CINAHL Ultimate	169,723
S11	(MH "Symptoms") OR (MH "Symptom Burden") OR (MH "Symptom Distress") OR (MH "Cancer Fatigue") OR (MH "Symptom Distress Scale") OR (MH "Psychiatric Symptom Index") OR (MH "Symptom Severity (Iowa NOC)") OR (MH "Symptom Status (Iowa NOC)")	Expanders - Apply equivalent subjects Search modes - Boolean/Phrase	Interface - EBSCOhost Research Databases Search Screen - Advanced Search Database - CINAHL Ultimate	13,214
S10	(MH "Cancer Pain")	Expanders - Apply equivalent subjects Search modes - Boolean/Phrase	Interface - EBSCOhost Research Databases Search Screen - Advanced Search Database - CINAHL Ultimate	6,380

S9	(MH "Quality of Life") OR "quality of life" OR (MH "Psychological Well-Being") OR (MH "Well-Being (Iowa NOC)") OR (MH "Psychological Well-Being (Iowa NOC)") OR (MH "Spiritual Well-Being (Iowa NOC)") OR (MH "Family Member Well-Being Index")	Expanders - Apply equivalent subjects Search modes - Boolean/Phrase	Interface - EBSCOhost Research Databases Search Screen - Advanced Search Database - CINAHL Ultimate	279,689
S8	(MH "Patient-Reported Outcomes") OR (MH "Outcome Assessment") OR "patient reported outcome"	Expanders - Apply equivalent subjects Search modes - Boolean/Phrase	Interface - EBSCOhost Research Databases Search Screen - Advanced Search Database - CINAHL Ultimate	65,692
S7	(MH "Prediction Models") OR (MH "Predictive Research") OR (MH "Clinical Prediction Rules") OR (MH "Predictive Value of Tests") OR (MH "Predictive Validity")	Expanders - Apply equivalent subjects Search modes - Boolean/Phrase	Interface - EBSCOhost Research Databases Search Screen - Advanced Search Database - CINAHL Ultimate	71,271
S6	"nomogram"	Expanders - Apply equivalent subjects Search modes - Boolean/Phrase	Interface - EBSCOhost Research Databases Search Screen - Advanced Search Database - CINAHL Ultimate	4,488
S5	(MH "Clinical Assessment Tools") OR "prognostic tool"	Expanders - Apply equivalent subjects Search modes - Boolean/Phrase	Interface - EBSCOhost Research Databases Search Screen - Advanced Search Database - CINAHL Ultimate	199,269

S4	"pancreas neoplasm" OR (MH "Colonic Neoplasms") OR (MH "Esophageal Neoplasms") OR (MH "Stomach Neoplasms") OR (MH "Abdominal Neoplasms") OR (MH "Colorectal Neoplasms") OR (MH "Sigmoid Neoplasms") OR (MH "Liver Neoplasms") OR (MH "Pancreatic Neoplasms") OR (MH "Rectal Neoplasms") OR (MH "Jejunal Neoplasms") OR (MH "Ileal Neoplasms") OR (MH "Gastrointestinal Neoplasms") OR (MH "Gallbladder Neoplasms") OR (MH "Retroperitoneal Neoplasms") OR (MH "Intestinal Neoplasms") OR (MH "Duodenal Neoplasms") OR (MH "Cecal Neoplasms") OR (MH "Biliary Tract Neoplasms") OR (MH "Bile Duct Neoplasms") OR (MH "Digestive System Neoplasms")	Expanders - Apply equivalent subjects Search modes - Boolean/Phrase	Interface - EBSCOhost Research Databases Search Screen - Advanced Search Database - CINAHL Ultimate	106,674
S3	"pancreas cancer"	Expanders - Apply equivalent subjects Search modes - Boolean/Phrase	Interface - EBSCOhost Research Databases Search Screen - Advanced Search	12,044

			Database - CINAHL Ultimate	
S2	(MH "Cancer Patients") OR (MH "Cancer Survivors")	Expanders - Apply equivalent subjects Search modes - Boolean/Phrase	Interface - EBSCOhost Research Databases Search Screen - Advanced Search Database - CINAHL Ultimate	66,049
S1	(MH "Gastrointestinal Neoplasms+")	Expanders - Apply equivalent subjects Search modes - Boolean/Phrase	Interface - EBSCOhost Research Databases Search Screen - Advanced Search Database - CINAHL Ultimate	76,228