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What patient reported outcomes and patient reported outcome measures have been applied in individuals undergoing colorectal cancer surveillance: Scoping review protocol

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ADMINISTRATIVE INFORMATION

Support - No.

Review Stage at time of this submission - The review has not yet started.

Conflicts of interest - None declared.

INPLASY registration number: INPLASY202480008

Amendments - This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 02 August 2024 and was last updated on 22 August 2024.

INTRODUCTION

Review question / Objective The aim of this scoping review is to assess patient reported outcomes and patient reported outcome measures that have been applied in individuals undergoing colorectal cancer surveillance.

Moreover, the scoping review will aim to answer the following sub-questions:

- 1. What patient reported outcomes have been assessed in individuals undergoing colorectal cancer surveillance?
- 2. What patient reported outcome measures have been applied in individuals undergoing colorectal cancer surveillance?
- 3. What are the domains of patient reported outcome measures that have been applied in individuals undergoing colorectal cancer surveillance?
- 4. What are the differences in the applied patient reported outcome measures based on various risk factors of individuals undergoing colorectal cancer surveillance?

5. What are the differences in the applied patient reported outcome measures relative to the timing of colonoscopy in individuals undergoing colorectal cancer surveillance?

Background Colorectal cancer ranks as the third most prevalent cancer and is the second leading cause of cancer-related fatalities globally (Jarab et al., 2024). The increasing burden of colorectal cancer underscores the need for appropriate clinical care for individuals identified at elevated risk for colorectal cancer, through ongoing colonoscopy surveillance to reduce incidence rates and death.

However, undergoing regular surveillance colonoscopy is associated with risks to the patients. This includes certain problems related to bowel preparation, such as discomfort, pain, the risk of bleeding, the possibility of perforation during colonoscopy procedures, and psychological impacts that affect quality of life depending on the delivery of care (Cheong et al., 2023). This can be evaluated by an assessment of patient reported

outcomes (PROs) and patient reported outcome measures (PROMs).

Assessing PROs in these elevated risk individuals, during and after colonoscopy surveillance, is valuable to ensure the positive outcome of the delivery of care (Cuenant et al., 2019). PROs is a report of the status of one's health condition obtained directly from the individual without any report by health professionals (Burke et al., 2006). Commonly assessed PROs include health-related quality of life (HRQoL), symptoms, pain, depression, health behaviours, functional status, and social wellbeing (Hahn et al., 2015).

Rationale Undergoing colorectal cancer surveillance can have both short-term and longterm impacts related to procedure-related discomfort, and psychological, social and emotional impact, respectively. These health outcomes can be evaluated using standard PROs and validated PROMs. However, there is a lack of summarised information on what PROs are important and what PROMs have been used to assess them in populations undergoing colorectal cancer surveillance. Studies have predominantly assessed HRQoL in surveillance populations using different PROMs, including the generic EQ-5D-5L (Shah et al., 2018), the cancer-specific European Organisation for Research and Treatment of Cancer Quality of Life Core Questionnaire (EORTC QLQ-C30) (Ahmedzai et al., 1993) and the Functional Assessment of Cancer Therapy-Colorectal (FACT-C) questionnaire (Hahn et al., 1999).

This scoping review will summarise what PROs and PROMs have been used in this population. Understanding the relevant PROs and PROMs will inform the assessment of outcomes in clinical practice to provide patient-centred care, improve clinical decision-making for follow-up care, and enhance overall health outcomes.

Condition being studied Assessment of PROs and PROMs in elevated risk populations undergoing surveillance for colorectal cancer.

METHODS

Search strategy Search strategy: Peer-reviewed publications will be searched using five databases, including Medline (OVID), Scopus, Web of Science, CINAHL, and PsycINFO (OVID). The search strategy will be prepared by using key words and Medical Subject Headings (MeSH) related to the study question. The review question will use the general terms; individuals undergoing colorectal cancer surveillance (population), PROs (concept), and PROMs applied in a colorectal cancer

surveillance population (context). The text words in the titles and abstracts of relevant studies will be used for the search.

Participant or population Populations at elevated risk for colorectal cancer, such as individuals with a significant family history of colorectal cancer, and individuals with a prior colorectal neoplasia (adenoma, serrated lesion or colorectal cancer) will be included. Populations with a confirmed or suspected genetic cause for elevated colorectal cancer will also be included (e.g. Lynch syndrome, adenomatous polyposis conditions, juvenile polyposis syndrome, Peutz-Jeghers syndrome and serrated polyposis syndrome).

Intervention Colorectal cancer surveillance.

Comparator There is no comparator.

Study designs to be included Experimental studies (randomized and non-randomized), analytical observational studies (prospective and retrospective cohort studies), case-control studies, cross-sectional studies (descriptive and analytical), case series, and individual case reports.

Eligibility criteria The participants are populations at elevated-risk for colorectal cancer undergoing regular colonoscopy surveillance. The studies assessing PROs, such as health-related quality of life, health status, descriptions of symptoms, satisfaction, physical, emotional, mental, spiritual, social well-being, and other health outcomes, will be included. Studies that are written in English will be included without restriction by time. Comments, editorial letters, news, reviews, conference proceedings, conference abstracts, and case reports will be excluded.

Information sources The sources of the literature will include Medline (OVID), Scopus, Web of Science, CINAHL, and PsycINFO (OVID). The title and abstract will be screened by the two research members independently, with a third reviewer to resolve any disagreements. The selected studies will also continue through a full-text review, which will be completed by two independent reviewers, with disagreements resolved by a third reviewer. All reasons for the exclusion of studies at the full text review will be recorded and reported. The reporting of the review will follow the PRISMA guidelines.

Main outcome(s) Available PROs and PROMs for elevated risk populations undergoing colorectal cancer surveillance.

Additional outcome(s) Timing of PROs assessment and the domains assessed by each PROM, relative to the colonoscopy procedure.

Data management The result from each database will be imported into the reference manager software EndNote 21 (Clarivate Analytics, version 21.2.0.17387, January 2022, USA) to facilitate data management. Covidence will be used to remove duplications and for screening.

Quality assessment / Risk of bias analysis Not applicable.

Strategy of data synthesis A narrative summary will be conducted. Finally, the data will be presented in the graph and tables.

Subgroup analysis Yes.

Sensitivity analysis No.

Language restriction English language.

Country(ies) involved Australia.

Keywords Above average risk population, Colorectal cancer; Patient reported outcomes; Patient reported outcome measures; Surveillance colonoscopy; Surveillance.

Dissemination plans The review will be disseminated through both local and international conference presentations. The final report will be published in a peer-reviewed journal.

Contributions of each author

Author 1 - Wudneh Simegn Belay - Conceptualisation, review of literature, draft of the manuscript, and review of the final manuscript.

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