

# BMJ Open Mapping the literature on decision regret in patients with non-communicable diseases (NCDs): a scoping review protocol

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## ABSTRACT

**Introduction** Decision regret refers to feelings of remorse or dissatisfaction with a decision made regarding the treatment. Mapping the meaningful aspects of decision regret in patients with non-communicable diseases (NCDs) is necessary to provide a comprehensive understanding of the phenomenon and inform the development of effective interventions to address it. For this reason, this protocol aimed to describe the methodological aspects of a scoping review focused on mapping all the meaningful aspects of decision regret in patients with NCDs and provide a conceptual and comprehensive framework of the phenomenon.

**Methods and analysis** The study described in this protocol will be performed following the Joanna Briggs Institute (JBI) methodology for scoping reviews. The anticipated starting time is July/August 2023 and the anticipated end of the review is June 2024. This scoping review will include quantitative, qualitative, primary and secondary literature, as well as grey literature on decision regret in patients with NCDs. The systematic search will be performed by consulting PubMed, Embase, Scopus, CINAHL, the Cochrane Library and Google Scholar. English-language articles from any context will be eligible for inclusion. Two independent reviewers will take part in an iterative process of evaluating literature, choosing papers and extracting data. Disagreements among reviewers will be solved through consensus meetings. Results will be presented in relation to the review question by employing tables, figures and narrative summaries.

**Ethics and dissemination** This scoping review did not require ethical approval since it involves a literature review and does not include new data collection from human participants. The results of the review will provide a summary of the available literature on decision regret experienced by patients with NCDs, which is crucial for developing preventive educational interventions in situations where multiple therapeutic options are available.

## INTRODUCTION

Most medical decisions for managing non-communicable diseases (NCDs) represent a tradeoff between multiple therapeutical options for managing a given chronic condition.<sup>1</sup> NCDs are chronic conditions that are

## STRENGTHS AND LIMITATIONS OF THIS STUDY

- ⇒ The scoping review methodology allows for a comprehensive and systematic search of the literature on decision regret in patients with non-communicable diseases.
- ⇒ The search strategy includes only a limited number of databases and may therefore miss relevant studies that are not indexed in those databases or in grey literature.
- ⇒ The use of two independent reviewers for study selection and data extraction reduces the potential for bias and improves the reliability of the review.
- ⇒ The scoping review methodology does not include a formal quality assessment of the included studies, which may limit the ability to draw strong conclusions about the quality of the evidence.

not spread from person to person. According to the WHO,<sup>2</sup> NCDs are a leading cause of death worldwide, accounting for approximately 71% of all deaths globally. Patients with NCDs often face complex treatment decisions, as multiple therapeutic options are available. These decisions can be influenced by various factors, including patients' personal preferences, their health literacy and the information and support provided by healthcare providers.

Decision regret is a complex and multifaceted concept that involves a range of negative emotions that patients may experience after making a decision, such as disappointment, dissatisfaction and self-blame. Decision regret typically refers to a sense of remorse or distress over a decision and is a significant indicator of treatment decision efficacy and may emerge when patients feel that they could have had a better outcome if they had chosen a different treatment.<sup>1</sup> In general, regret requires imagining possibilities other than the current state being experienced, where individuals reflect on choices, processes and



outcomes generated and consider potential outcomes had the choice has been different.<sup>3,4</sup>

One specific type of decision regret is outcome regret, which involves regretting the consequences of a past decision. It occurs when individuals compare the actual outcome of a decision to a better outcome that could have been achieved if a different choice had been made. According to previous studies, the proximity of the counterfactual alternative outcome, the action-non-action component and the perception of responsibility are the three most important factors for developing outcome regret.<sup>1</sup> When an alternative outcome is readily available and easy to imagine, such as when one came very close to obtaining a better outcome, it can trigger emotions like outcome regret. These emotions can also arise when the negative outcome is due to inappropriate or irrational decisions or actions.<sup>1</sup> In addition to outcome regret, there are other types of decision regret, such as process regret and chosen option regret. Process regret refers to regretting the decision-making process itself, such as not gathering enough information or seeking advice from others. Chosen option regret, on the other hand, is regretting the option chosen among the available alternatives. Several factors, such as uncertainty about the decision, conflicting values or priorities or lack of information or support, can trigger these negative emotions. Understanding the different components of decision regret, including outcome, process and chosen option regrets, is important for developing effective interventions to prevent or manage regret in patients with NCDs.<sup>5-7</sup> Additionally, as emotional amplification might be experienced by patients with NCDs, clinicians and healthcare providers should be aware of these types of regret and how they might affect patients.<sup>3,4</sup>

One specific field where several studies have established that patients can experience substantial regret relates to cancer-related decisions, with most studies focusing on patients with breast or prostate cancer.<sup>5-7</sup> This feeling is due to the evidence that the various surgical treatments available for these diseases have similar efficacy, making it essential for the decision process to reflect the preferences, values and expectations of the patients.<sup>3,4</sup> Patients can also experience decision regret in other non-cancer conditions (eg, gastro-oesophageal reflux disease, GERD), highlighting the importance of making informed choices. In general, decision regret is more frequent among patients with NCDs because the likelihood of facing situations where multiple therapeutic options are available is higher.<sup>8</sup> Understanding the factors contributing to decision regret among this population is important to improve patient outcomes and quality of care. Without patients' active and early involvement, some regrets about the decided option might be experienced even years after the decision, undermining a safe follow-up and adherence to the scheduled plans.<sup>8</sup> Unsatisfactory treatment outcomes may harm the relationship between patients and their healthcare providers, such as distrust and low satisfaction with physicians.<sup>1</sup> For these

reasons, preventing decision regret in patients with NCDs is important for improving their well-being and reducing healthcare costs.<sup>9,10</sup>

Engagement strategies like the shared decision-making (SDM) approach could mitigate patients' decisional regret.<sup>11</sup> SDM requires that clinicians and patients make decisions together using the best available evidence, and patients are encouraged to think about the available screening and management options to achieve the best decision.<sup>12</sup> In this regard, SDM keeps the patient engaged from the earliest phases of the clinical pathway and could help to mitigate regrets. Understanding what people experience with NCDs when a decision regret occurs is still under-described, although it could be useful for developing predictive models using retrospective data.

Increasing awareness and the definition of a theoretical framework to guide clinicians, educators and researchers is needed. Healthcare providers require evidence-based guidance for planning adequate research and educational activities for mitigating the onset of decision regret and its consequences.<sup>8</sup> The literature on this topic is still fragmented due to the lack of reliable tools to assess decision regret, and very little information is available on the strategies to prevent and mitigate decision regret in people with NCDs.<sup>11</sup> These aspects undermine the possibility of defining a theoretical framework to guide clinicians, educators and researchers. The awareness about this specific negative feeling that may be experienced in several NCDs is still underoptimal among healthcare educators, researchers and clinical specialists. In this regard, scoping reviews are typically helpful to systematically collect and synthesise information to (a) clarify key concepts and definitions in the literature, (b) explore and define knowledge gaps on the subject, (c) provide a comprehensive and up-to-date overview for nurses, researchers and educators and (d) facilitate future research and development, as described by Arksey and O'Malley, Levac *et al* and Peters *et al*.<sup>13-15</sup>

A scoping review employs a broader search strategy while maintaining reproducibility, transparency and reliability: Scoping reviews are an excellent tool for determining the extent (or coverage) of a body of literature on a specific and nuanced topic and for providing a clear indication of the volume of literature and studies available, as well as an overview of the real phenomenon focus.<sup>16</sup> Moreover, Munn *et al* described scoping reviews as an advantageous way for examining emerging evidence when it is still unclear what other, more specific questions can be posed,<sup>16</sup> making this kind of review the ideal method to respond to the aims and objectives of this study. The proposed review will be performed in accordance with the Joanna Briggs Institute (JBI) methodology for scoping reviews.<sup>17</sup> The aim of this scoping review is to systematically map the literature on decision regret in patients with NCDs.

## METHODS AND ANALYSIS

Considering that the literature on decision regret in patients with NCDs has not been systematically mapped yet, the authors recognised the scoping review process as an adequate approach to summarise the literature in this regard.<sup>13–15</sup> The anticipated starting time is July/August 2023, and the anticipated end of the review is June 2024.

### Review questions

The main question for the proposed scoping review is: ‘What existing literature exists about decision regret in NCDs?’. The following sub-questions are also posed to guide the study:

- ▶ What are the specific populations in which the phenomenon has been described?
- ▶ How can decision regret be measured in patients with NCDs?
- ▶ What are the characteristics of the tools developed to assess decision regret in NCDs?
- ▶ What antecedents and consequences have been described in relation to decision regret?

### Search strategy

An initial limited search of Medline (PubMed) and CINAHL was undertaken to identify articles on the topic and define the keywords. The text words contained in the titles and abstracts of relevant articles and the index terms used to describe the articles were used to develop a complete search strategy (see online supplemental appendix 1). The final search strategy will aim to locate both published and unpublished studies in PubMed, Embase, Scopus, CINAHL, the Cochrane Library, and Google Scholar. The search strategy, including all identified keywords and index terms, will be adapted for each included information source. All the eligible records published up to June 2023 will be considered in the search strategy.

### Population

Studies focused on patients with NCDs will be considered. This scoping review will seek to include patients with specific conditions such as Brca1 and Brca2 mutations, non-cancer conditions (eg, GERD, cancer, heart failure and diabetes), and broadly populations with NCDs where patients might benefit from alternative and valid therapeutic approaches (see online supplemental appendix 1). The literature included in this scoping review will specifically focus on adult populations aged 18 years and above, encompassing individuals of all genders and diverse sociodemographic backgrounds. This approach will ensure a comprehensive analysis of decision regret in adult patients with NCDs, taking into account the potential influence of age, gender, and other sociodemographic factors.

### Concept

The concept guiding the development of the search strategy will be decision regret. This concept will also be searched in relation to patient-reported outcome

measures (PROMs) to better understand what people experience when a decision regret happens. Incorporating PROMs into the data analysis will provide valuable insights into decision-making, decision regret and potential interventions to mitigate regret. PROMs are assessments that capture information directly from patients about their health status, symptoms, functioning and quality of life. PROMs are valuable in healthcare research and practice as they provide insights into the patient’s perspective, help monitor treatment effectiveness, inform SDM and evaluate the impact of interventions on patient outcomes.

The use, promotion, and also sharing of PROMs are crucial to determining a framework to better define, prevent and mitigate decision regret. Many disease-specific PROMs have been developed for benign upper gastrointestinal and oesophageal diseases, including GERD and Barrett’s oesophagus;<sup>17</sup> also, in oncological surgery, PROMs are broadly applied, and it has been shown that PROMs enhance patient–clinician communication, patient satisfaction and quality of care.<sup>18</sup> PROMs, on the one hand, let healthcare professionals have a crucial and unique niche in patient management; on the other hand, PROMs provide a global vision regarding the healthcare experience of patients with NCDs.<sup>18</sup> Both these aspects are theoretically determinants of possible situations of regrets regarding a therapeutic choice.<sup>18</sup> However, generic PROMs are used to provide comparisons between diseases or to compare data with normative population values, not to evaluate specific patient populations.<sup>19</sup> Therefore, selecting PROMs is a complex but essential process, and it is also important to look for input from the target patient population early when developing valid and reliable measurements for PROMs in a population-specific framework.<sup>19 20</sup>

### Context

The context examined will include all primary, secondary, and tertiary healthcare settings. This broad approach will allow authors to identify the relevant literature referred to the research question.

### Study selection

All identified articles will be collected and uploaded to the reference manager Zotero,<sup>21</sup> and duplicates will be removed after the search. Two independent reviewers will then screen titles and abstracts for assessment against the review inclusion criteria using Rayyan.<sup>22</sup> Two independent reviewers will assess the full text of selected papers in detail against the inclusion criteria. Reasons for the exclusion of full-text studies that do not meet the inclusion criteria will be recorded and reported in the scoping review. Reviewer disagreements will be addressed by discussion until a consensus is established or, if necessary, through consultation with the study team. The search results will be reported in full in the final scoping review and presented in the Preferred Reporting Items for

Systematic reviews and Meta-Analyses (PRISMA) extension for Scoping Reviews (PRISMA-ScR).<sup>23</sup>

### Data extraction

Data will be extracted from papers included in the scoping review by two independent reviewers using a data extraction tool developed by the reviewers. The data extracted will include specific details about the population, concept, context, study methods, and key findings relevant to the review objective. The draft data extraction tool will be modified and revised as necessary during the process of extracting data from each included study. Modifications will be detailed in the full scoping review report. Any disagreements that arise between the reviewers will be resolved through discussion or consultation with the study team. Authors of papers will be contacted to request missing or additional data, where required.

### Data presentation and synthesis

As indicated in the JBI guidelines, the extracted data will be presented in diagrammatic or tabular form in a manner that aligns with the objective of this scoping review. Data will be descriptively summarised and focused on organising results to reflect the review question and the specific subquestions. A narrative summary will accompany the tabulated and/or charted results and describe how the results relate to the review aims and objectives. The Mixed Methods Appraisal Tool (MMAT) will be used to appraise the quality of each included study.<sup>24</sup> The MMAT is specifically designed for the appraisal stage of systematic mixed studies reviews, including qualitative, quantitative and mixed methods studies. The MMAT allows researchers to assess the methodological quality of studies across qualitative research, randomised controlled trials, non-randomised studies, quantitative descriptive studies and mixed-method studies. It therefore provides a systematic approach to evaluating the quality of studies from diverse designs, enabling researchers to critically appraise the included studies and consider their strengths and limitations. Even though it is not mandatory in scoping reviews, this approach will provide additional information to the results.

### Patient and public involvement

There was no patient or public involvement in the design of this scoping review protocol.

### Ethics and dissemination

The proposed scoping review does not involve the collection of new data from human participants; instead, it is based on a literature review. As a result, there are no ethical concerns related to this study, and ethical approval is not required. All data used in the review will be previously collected and publicly available. The emerging results could be useful for guiding future empirical studies on decision regret. The dissemination strategy will involve peer-reviewed publications and conference proceedings.

## DISCUSSION

This scoping review will map all the meaningful aspects of decision regret in patients with NCDs and synthesise the studies concerning the phenomenon, providing a conceptual and comprehensive framework. In general, scoping review protocols are a crucial component of the research process and publishing protocols is important to give a recorded account of a structured plan of action, outlining the rationale, methods and analysis in advance. Therefore, this study will examine decision regret in patients with NCDs across various domains, including treatment choices, diagnostic decisions, lifestyle modifications and healthcare utilisation. Specific dimensions of decision regret that will be explored include the factors influencing regret, such as information availability, decision-making processes and patient involvement in decision-making when available. In addition, the review will focus on understanding the prevalence and severity of decision regret in different subgroups of patients with NCDs, considering factors such as age, gender, socioeconomic status and comorbidities by keeping into account potential antecedents and consequences of decision regret, including its impact on treatment adherence, patient-provider relationships and PROMs.

The conduct of this study does not require ethical approval. For the proposed scoping review, only previously collected information will be examined. The findings will be published in a peer-reviewed journal and disseminated at conferences and/or seminars. This protocol aims to be informative to the nursing scientific community and, more broadly, to the researchers interested in studying decision regret in patients with NCDs. In this sense, along with the implications regarding the transparency pursued by publishing a study protocol, the current protocol also has an educative metaimplication due to the availability of peer-reviewed protocols that might represent a benchmark for researchers who wish to perform a study with similar methods.

The implications of mapping decision regret in patients with NCDs are several. First, obtaining a state-of-the-art understanding of decision regret is crucial in guiding the efforts of decision-makers, researchers and clinicians to prevent and address episodes of decision regret. In this regard, a scoping review can provide a comprehensive overview of the current state of knowledge on decision regret in people with NCDs. Second, having a summary of which valid and reliable tools are useful for assessing decision regret could be helpful in assessing decision regret in clinical contexts; this aspect supports evidence-based practice and informs decision-making in clinical settings. Third, a description of how decision regret is prevalent in different subgroups and the main determinants of decision regret could guide future studies. Finally, the most important understanding is how decision regret can be influenced, defining the more susceptible factors that can be included, for example, in implementing

organisational interventions within a precise framework to guide practice. Overall, this scoping review could help identify research gaps and provide direction for future research in the field.

While this scoping review aims to provide a comprehensive overview of decision regret in patients with NCDs, it is important to acknowledge some potential limitations. First, the search strategy, although carefully designed and implemented, may still have some limitations in capturing all relevant literature. Despite our efforts to include appropriate databases and search terms, it is possible that some relevant studies may have been missed. However, by conducting a rigorous and systematic search, we aim to minimise this potential bias. Second, the quality and heterogeneity of the included studies may pose challenges in data synthesis and interpretation. As this scoping review will encompass studies of diverse designs, there may be variations in methodological rigour and reporting standards across the included studies. Therefore, it is essential to consider the potential limitations and variability in the quality of evidence when interpreting the findings. Finally, it is important to note that this scoping review will rely on existing literature and does not involve primary data collection. While this approach allows for a broad exploration of the topic, it is limited to the available information and may be influenced by the biases and limitations present in the original studies.

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