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**Interventions to optimise medication prescribing and adherence in older people with cancer:
A systematic scoping review (protocol)**

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Abstract

Background: Older adults with cancer often require multiple medications including cancer-specific treatments and supportive care medications (e.g. analgesics), as well as medications for pre-existing medical conditions. Increasing numbers of medications pose risks of potentially inappropriate prescribing, drug-drug interactions and drug-disease interactions. The burden of treatment (i.e. the workload of healthcare and its impact on patient functioning and well-being) may also negatively affect the way patients take their medications. Non-adherence to medication in patients with cancer is associated with treatment failure and increased healthcare costs. Therefore, it is crucial that medicines are optimised for older adults with cancer to enhance appropriate prescribing, reduce the complexity of treatment regimens and minimise the risk of non-adherence.

Objective: To provide an overview of evaluations of interventions aimed at optimising medication prescribing and/or adherence in older adults with cancer.

Methods: A systematic scoping review will be undertaken. Four databases will be searched from inception: PubMed, EMBASE, CINAHL and PsycINFO. In order to meet inclusion criteria, studies must evaluate an intervention seeking to improve medication prescribing and/or adherence in older adults (aged ≥ 65 years) with an active cancer diagnosis using a comparative evaluation (e.g. inclusion of a control group). Two reviewers will independently screen titles and abstracts for inclusion and extract data relating to study population, intervention characteristics, outcome assessments and key findings. Extracted data will be collated using tables, figures and accompanying descriptive summaries. The review will be reported using the Preferred Reporting Items for Systematic reviews and Meta-Analyses extension for Scoping Reviews (PRISMA-ScR) guidelines.

Project impact: The scoping nature of this review will serve to provide an overview of the existing literature on interventions aimed at optimising medication prescribing and adherence in older adults with cancer. The review findings will help to identify research gaps and highlight areas to explore further in future research.

Key words: cancer, oncology, older adults, intervention, prescribing, adherence

54 **Abbreviations:**

55 ADE: adverse drug event

56 EPOC: Effective Practice and Organisation of Care

57 PIP: potentially inappropriate prescribing

58 PRISMA-ScR: Preferred Reporting Items for Systematic Reviews and Meta-Analyses extension
59 for Scoping Reviews

60 RCT: randomised controlled trial

61 STOPP/START: Screening Tool of Older Person's Prescriptions / Screening Tool to Alert doctors
62 to Right Treatment

63

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Introduction

The population is ageing and by 2050, it is predicted that 17% of the global population will consist of individuals aged ≥ 65 years (conventionally described as “older”) (1). Advancing age is a major risk factor for cancer (2). In 2012, 48% of all cancer diagnoses worldwide occurred in older adults and, by 2038, this is expected to rise to 58% (2). At diagnosis, older patients with cancer often have existing health conditions necessitating the use of polypharmacy, which is commonly defined as the prescribing of five or more medications (3-5). The reported prevalence of polypharmacy in older patients with cancer ranges from 13% to 92% (6). Polypharmacy contributes to patients’ overall treatment burden (i.e. the workload of healthcare and its impact on patient functioning and well-being) (7). Treatment burden may be further increased by cancer-specific treatments and any additional supportive care medications (e.g. analgesics) that are required. Consequently, interventions aimed at optimising treatment regimens in cancer patients are required.

Medicines optimisation is an approach to care that aims to ensure the greatest clinical benefits for patients, through the safe and effective use of medicines (10). Medicines optimisation is individual to each patient and accounts for their specific needs, preferences and values (11). Optimising prescribing involves examining potentially inappropriate prescribing, as well as encouraging the appropriate use of medications in a way that the patient is willing to adhere to (12). The concept of medicines optimisation is particularly relevant to older adults as observational studies have highlighted associations between polypharmacy and potentially inappropriate prescribing (PIP), as well as negative clinical consequences, such as adverse drug events (ADEs) (8). This has also been observed in oncology settings, whereby a high proportion (21%) of admissions to cancer services among older patients are related to adverse drug reactions arising from both the use of systemic anticancer treatments and non-cancer specific treatments (9).

The term PIP encompasses a range of suboptimal prescribing practices, including inappropriate doses or durations of medication, prescribing medications associated with high risks of ADEs and

errors of omission (13). Various criteria have been developed and validated to assess and optimise medication prescribing in the general older population (14-17). These criteria can largely be classified as explicit (criterion-based, e.g. Screening Tool of Older Person's Prescriptions/Screening Tool to Alert doctors to Right Treatment (STOPP/START) (17, 18)) or implicit (judgement-based, e.g. Medication Appropriateness Index (19)). Application of these criteria in clinical settings has been shown to improve the appropriateness of prescribing for older people (20). However, the applicability of these criteria to older patients with cancer is often limited, as prescribing for this patient cohort requires additional considerations, such as life expectancy and time until treatment benefit (21). In addition, these tools frequently recommend the cessation or avoidance of drugs that may be clinically appropriate for older adults with cancer (e.g. non-steroidal anti-inflammatory drugs can be of particular benefit for various forms of cancer pain) (22, 23). A deprescribing guideline has been developed that is specific to cancer populations at the palliative stage of illness (24). However, the extent of its clinical impact has yet to be determined.

The challenges that polypharmacy present are not limited to prescribing. Increasing numbers of medications may negatively impact the way in which patients take their medications. The World Health Organisation defines adherence as “the extent to which a person’s behaviour-taking medication, following a diet, and/or executing lifestyle changes, corresponds with agreed recommendations from a healthcare provider” (25). Rates of medication adherence in patients with cancer vary widely, ranging from 46% to 100% (26). Previous studies have indicated that polypharmacy and complex medication regimens negatively impact on medication adherence (25, 27). Non-adherence to medication in patients with cancer has been associated with treatment failure, poor clinical outcomes, and increased healthcare costs (28, 29). Therefore, it is crucial that medicines are optimised in older adults with cancer to reduce the complexity of treatment regimens, minimise the risk of non-adherence and, ultimately, improve clinical outcomes.

Several systematic reviews have examined interventions to improve the appropriate use of polypharmacy in older adults across a variety of settings (13, 20, 30, 31). However, none of these reviews have focussed specifically on older adults with cancer. For example, a Cochrane review on interventions to improve appropriate prescribing of polypharmacy for older people specifically excluded studies of interventions targeting patients with terminal illnesses and patients receiving chemotherapy (20). This has implications in terms of the generalisability of existing evidence to older patients with cancer. Furthermore, relatively few of the included studies (5/32 studies) assessed adherence as an outcome.

A scoping review will be undertaken of interventions, evaluated to date, that have focussed on two key aspects of medicines optimisation for older people with cancer: appropriate prescribing and medication adherence. As the aim of this review is to provide a broad overview of the existing literature, a scoping review is preferable to a systematic review. Systematic reviews tend to be more specific in nature and normally focus on a more precise review question (32). Scoping reviews aim to identify and map the key concepts underpinning a research area (33). Additionally, they can help to identify research gaps and to highlight areas to explore further in future research (34). The objectives of this scoping review are to:

1. Identify the types of interventions aimed at optimising medication prescribing and/or adherence in older adults with cancer.
2. Characterise key features of the interventions (i.e. content, delivery, setting).
3. Examine the intervention development process (i.e. underpinning evidence and theory).
4. Characterise the study populations.
5. Identify the outcome measures that have been used to evaluate the interventions.
6. Establish key findings of the evaluations.

Methods

This review protocol has been developed in accordance with relevant methodological guidance (34, 35). The final review will be reported using the Preferred Reporting Items for Systematic Reviews and Meta-Analyses extension for scoping reviews (PRISMA-ScR) guidelines (36).

Search strategy

Searches of the following electronic databases will be conducted using established search methods for scoping reviews: PubMed, EMBASE, CINAHL and PsycINFO (34). All databases will be searched from inception. The search strategy will comprise three stages:

1. Preliminary searches of each database will be conducted to identify relevant keywords and index terms.
2. A comprehensive search strategy for each electronic database will be developed with input from a research librarian.
3. Following database searching, reference lists of all included studies and any relevant review articles will be screened for additional studies.

The initial search terms will include combinations of terms such as: “cancer”, “older adults”, “prescribing” and “adherence”, as well as relevant variants and synonyms. This will inform the development of a comprehensive search strategy. The full search strategy will be included in the final review manuscript.

Inclusion criteria

Types of participants

This review will include studies involving older adults (≥ 65 years) with an active cancer diagnosis. Eligible studies will not be limited by the number or types of medicines prescribed, nor will they be restricted to patients with any specific type of cancer or patients who are receiving treatment in any particular healthcare setting. Studies which also involve other patient groups (e.g. patients < 65 years, patients with other medical conditions) will be eligible for inclusion provided that data for the subgroup of older cancer patients are available separately (either as published study data or available separately from the study authors).

Types of interventions

This review will include interventions seeking to optimise medication prescribing or adherence in older adults (aged ≥ 65 years) with an active cancer diagnosis. Interventions must align with key principles of medicines optimisation which will be broadly categorised as: interventions to optimise prescribing and interventions to improve medication adherence (10). For the purpose of this review, interventions to optimise prescribing will include interventions that target any of the following: misprescribing (prescribing that significantly increases the risk of ADEs, including incorrect dosing, frequency or duration), overprescribing (prescribing in the absence of a clinical indication) and underprescribing (omission of medications for specific clinical indications aimed at either treatment or prevention) (37). Interventions aimed at improving medication adherence will include any intervention that seeks to promote adherence to prescribed medication in older patients with cancer. Eligible interventions can be targeted at the level of healthcare professional or patient. In order to meet inclusion criteria, interventions must specifically target medication prescribing or adherence in individuals aged ≥ 65 years or a study population with a mean age of ≥ 65 years.

Types of outcome measures

Due to the lack of an existing review of evaluations of interventions aimed at optimising medication prescribing and adherence in older adults with cancer, all outcomes for studies that meet the above inclusion criteria will be included in the review. This will allow for an overview to be provided of the range of outcomes that have been evaluated on this topic to date.

Types of studies

In order to meet inclusion criteria, studies must have included some form of comparative evaluation (e.g. inclusion of a control group or use of a controlled before/after design). Only full-text manuscripts published in English will be eligible for inclusion. Published conference abstracts will not be included in the review.

Study selection

Following deduplication, two reviewers will independently screen titles and abstracts for inclusion. If an abstract appears to meet inclusion criteria or cannot be excluded based on the title or abstract alone, the full-text article will subsequently be retrieved and assessed for inclusion by both reviewers independently. Any disagreements will be resolved through discussion and consultation with a third reviewer if necessary.

Data extraction

Two reviewers will independently perform data extraction (commonly referred to as 'charting the results' in the scoping review literature) using a data extraction form that has been developed in accordance with relevant methodological guidance (Appendix A) (34). The data extraction form will be piloted on one study that meets inclusion criteria and amended if necessary. Data will be extracted relating to each of the following:

1. *Study*: Authors, year of publication, country of origin, study design, study setting, study aims/purpose.
2. *Population*: Sample size, patient demographics (e.g. age, gender, type of cancer, stage of cancer, life expectancy, other medical conditions, numbers and types of medicines).
3. *Intervention details*: Intervention category (classified according to the Effective Practice and Organisation of Care (EPOC) taxonomy i.e. 'Delivery arrangements', 'Financial arrangements', 'Governance arrangements', 'Implementation strategies' (38)); intervention targets/recipients and deliverers, mode of intervention delivery, intervention duration, intervention costs/resource requirements.
4. *Intervention development*: details of any underpinning evidence base/theory base for the intervention.
5. *Outcome measures used to evaluate the intervention*: Reported outcomes, assessment methods and assessment time points.
6. *Key findings*: summary details of key results.

Any inconsistencies in terms of data extraction will be resolved through discussion and consultation with a third reviewer if necessary.

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Data appraisal and synthesis

As the aim of a scoping review is to provide a broad overview of the existing literature, formal assessments of methodological quality of included studies are not routinely undertaken (34). Data collation will focus on summarising the information presented across included studies. A narrative synthesis will be undertaken in accordance with established guidance (40). This will involve the following key steps (40):

- (1) Developing a preliminary synthesis of findings of included studies: study characteristics and findings will be tabulated to summarise key study information and describe patterns across the studies in terms of direction and size of intervention effects.
- (2) Exploring relationships in the data: extracted study data will be reviewed to identify factors that might help to explain differences in the direction and size of intervention effects across the included studies.
- (3) Assessing the robustness of the synthesis: the findings of the synthesis process will be critically reviewed by the review team, in terms of the evidence on which it is based and potential sources of bias from the evidence sources, as well as any discrepancies and uncertainties identified relating to study outcome assessments. This process will help to identify and highlight any gaps in the existing literature as part of the review.

Presentation of results

In accordance with methodological guidance on scoping reviews (34), it is recommended that a proposed plan for presenting results should be developed at the time of protocol development. The findings of this review will be presented under the following headings to enable a logical and descriptive summary to be presented that aligns with the review's objectives:

- Search results
- Study designs
- Study aims/objectives
- Study populations

- Interventions
- Outcomes recorded
- Key findings

A PRISMA-ScR flow diagram will be used to depict study selection. Tables of the characteristics of included studies (Appendix B) and key study findings, together with accompanying descriptive summaries will be used to outline the data charted from included studies.

Discussion

Given the growing burden of cancer diagnoses among the older population, interventions targeting medicines optimisation are of considerable importance in terms of ensuring appropriate prescribing and use of medicines, and maximising their clinical benefits for patients. This review will examine interventions aimed at optimising medication prescribing and/or adherence in older adults with cancer in any healthcare setting. The scoping nature of the review will serve to map existing literature on interventions that have been evaluated to date (e.g. in terms of how interventions were developed, delivered and assessed). The review's findings will lay important foundations in establishing current available evidence and informing future research on developing and evaluating interventions to improve the care of older patients with cancer in line with established methodological guidance (41).

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Conflicts of interest

None

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424 **Appendices**

425 Appendix A: Data extraction form (outline)

426 Appendix B: Table of characteristics of included studies (key components)

427

428 **Appendix A: Data extraction form (outline)**

429 Data extraction fields

430 1. Author(s)

431 2. Year of publication

432 3. Country

433 4. Study design

434 5. Study aims/objectives

435 6. Study duration

436 7. Study population, setting and sample size

437 8. Intervention type

438 9. Details of intervention development

439 10. Assessment of intervention

440 11. Outcome measures

441 12. Results

442

443

444 **Appendix B: Table of characteristics of included studies (key components)**

445 1. Author, year of publication, country

446 2. Study design

447 3. Study duration

448 4. Study population, setting and sample size

449 5. Intervention type and comparison

450 6. Assessment of intervention

451 7. Outcome measures

452 8. Results