Current management of adults receiving oral anti-cancer medications: A scoping review protocol [version 4; peer review: 2 approved, 1 approved with reservations]

Janice P. Richmond1, Mary Grace Kelly1, Alison Johnston1, Lisa Hynes2, Patrick J. Murphy1, Andrew W. Murphy2

1Oncology Department, Letterkenny University Hospital, Letterkenny, Co Donegal, Ireland
2HRB Primary Care Clinical Trials Network Ireland, Discipline of General Practice, NUI Galway, Galway, Ireland

Abstract

Oncology has been undergoing a profound transition in the last ten years with the increased usage in oral anti-cancer medication. Approximately 25% of all anti-cancer medication is now designed for oral use and this is likely to increase prospectively. These treatments are convenient for patients and are often preferred by them, yet there are similar safety and toxicity concerns as there are to intravenous treatment. Oral anti-cancer medications (OAMs) have the potential to alleviate capacity issues in cancer treating units as patients receive their treatment at home, however there remains a requirement for safe and efficient assessment and care. Consequently, the management of patients on OAMs is of paramount importance. The optimum setting, whether within primary or secondary care, in addition to the appropriate health care professional to carry out patient assessment and monitoring needs to be established.

This paper presents a protocol for a scoping review which aims to systematically and comprehensively map the literature on the current management of adults receiving OAMs. The review will follow the published guidance to direct the various steps involved. The protocol will be guided by the Preferred Reporting Items for Systematic Reviews and Meta-Analyses Extension for Scoping Reviews (PRISMA-ScR) framework to ensure methodological and reporting quality. Independent full text review will be performed by two reviewers and any disagreements resolved through discussion with a third reviewer. The process will be iterative in nature.
This scoping review will provide a narrative synthesis and map the literature on the management of individuals receiving OAMs. This work is an appropriate initial stage in presenting the literature to inform the subsequent steps in a multi-phased research study which aims to establish and analyse the safety and efficacy of an integrated care model for the management of patients receiving OAM in the community by an advanced practitioner.

**Keywords**
cancer, oral anticancer medications, care, management, assessment

This article is included in the [HRB Primary Care CTNI gateway](https://www.hrb.ie/primary-care-tni/). Any reports and responses or comments on the article can be found at the end of the article.

---

**Corresponding author:** Janice P. Richmond ([janicep.richmond@hse.ie](mailto:janicep.richmond@hse.ie))

**Author roles:** **Richmond JP:** Conceptualization, Funding Acquisition, Investigation, Methodology, Writing – Original Draft Preparation; **Kelly MG:** Conceptualization, Funding Acquisition, Investigation, Methodology, Writing – Original Draft Preparation; **Johnston A:** Formal Analysis, Investigation, Methodology, Writing – Original Draft Preparation; **Hynes L:** Formal Analysis, Investigation, Methodology, Writing – Original Draft Preparation; **Murphy PJ:** Formal Analysis, Investigation, Methodology, Writing – Original Draft Preparation; **Murphy AW:** Formal Analysis, Funding Acquisition, Investigation, Methodology, Writing – Original Draft Preparation

**Competing interests:** No competing interests were disclosed.

**Grant information:** This study is funded by The Irish Cancer Society [CNRA19RIC] in collaboration with the Health Research Board (HRB), the National Cancer Control Programme (NCCP), and the Office of the Nursing & Midwifery Services Director (ONMSD). The funders had no role in study design, data collection and analysis, decision to publish, or preparation of the manuscript.

**Copyright:** © 2022 Richmond JP et al. This is an open access article distributed under the terms of the [Creative Commons Attribution License](https://creativecommons.org/licenses/by/4.0/), which permits unrestricted use, distribution, and reproduction in any medium, provided the original work is properly cited.

**How to cite this article:** Richmond JP, Kelly MG, Johnston A et al. Current management of adults receiving oral anti-cancer medications: A scoping review protocol [version 4; peer review: 2 approved, 1 approved with reservations] HRB Open Research 2022, 4:7 [https://doi.org/10.12688/hrbopenres.13208.4](https://doi.org/10.12688/hrbopenres.13208.4)

**First published:** 28 Jan 2021, 4:7 [https://doi.org/10.12688/hrbopenres.13208.1](https://doi.org/10.12688/hrbopenres.13208.1)
Introduction

The introduction of novel oral anti-cancer medications (OAM) is a paradigm shift in cancer care and these are being approved at a record-setting pace (Meier et al., 2018) with almost 20 new approvals in oncology in the three years preceding 2019 (U.S. Food & Drug Administration, 2018). Oral anticancer medications are a sub-set of systemic anti-cancer treatments (SACT) and have a narrow therapeutic window with a unique mechanism of action which includes pro-drugs and targeted therapies, and excludes endocrine therapy (National Cancer Institute, 2020). The National Cancer Control Programme (NCCP) (2018) defines OAMs as all medications with direct anti-tumour activity administered by mouth (enteral route) for the treatment of cancer. They are increasingly common; a review of the NCCP website shows more than 50 different OAMs are currently in use alongside a suite of guidelines for Health Care Professionals (HCP) to direct safe and standardised patient care.

OAMs have the same benefits and risks as SACT given parenterally in terms of positive disease outcomes, treatment-related toxicities or potential for serious medication errors leading to patient harm (NCCP, 2018). Consequently individuals receiving OAMs require frequent (at least monthly) holistic patient assessment, and serum and/or urine analysis. While these medications are convenient for individuals, it shifts the responsibility for medication management from the oncology healthcare professionals to the patient. Consequently there are concerns regarding adherence and management of toxicities or adverse effects (Greer et al., 2016; Hammond et al., 2012; NCCP, 2018; Paolella et al., 2018; Wood, 2012). Evidence suggests that current health care practices globally do not ensure safe administration or patient adherence (Griffiths & Pasco, 2014; LeFebvre & Felice, 2016; Le Saux et al., 2018; Redelico et al., 2018; Zerillo et al., 2015). A review of OAM practices in North America, Zerillo et al. (2015) identified unmet patient needs of 43–49% for patient education and 19–25% for adherence/toxicity monitoring. Individuals prescribed OAMs often experience a high burden of cancer related symptoms which corresponds to reduced adherence and quality of life (Jacobs et al., 2019).

Due to the potential toxicity of these medications and associated safety challenges, the care and monitoring of patients receiving OAMs remains largely within the acute hospital setting by specialist health care teams (Department of Health, 2017; Hammond et al., 2012; Kinnair et al., 2019; NCCP, 2018). A medication safety review in Ireland noted a recurring theme of diversity and often lack of processes for the management of OAM (Heckmann et al., 2014). Furthermore, anecdotal evidence from the authors suggest that in the hospital environment individuals on OAMs receive disproportionately less input than those on parenteral treatment as the former are incorrectly perceived as being less acute and as the medication is administered at home there is less requirement to expediently progress their care at their hospital visit. To try to maximise the safety of OAMs and improve hospital efficiency, the National Cancer Strategy (Department of Health, 2017) recommended the development of a model of care for OAM. Subsequently a guidance document for this was published by the NCCP (2018). The NCCP (2018) made 16 recommendations for the care of individuals receiving OAMs in an attempt to maximise safe practice. The focus was on safe and efficient care of individuals rather than prescriptive directions for which location that care should be delivered or by which HCP. The authors of the NCCP (2018) report recognised that there was a requirement for change within the Irish health care service to fully realise the recommendations. There is scope for these to be built upon to standardise and improve safe practice for the care of individuals receiving OAMs.

There is universal consensus in international healthcare policy documents regarding the crucial and central role which primary care should play in health care delivery. Systems with strong primary care have better health outcomes at lower costs (House of the Oireachtas, 2017; Randall et al., 2017; Starfield, 1998; World Health Organisation, 2018). Within Ireland, a shift from hospital to community-based care is being strongly promoted with the aim of delivering care closer to the person’s home within an integrated care context. This is evident in the Sláintecare health reform programme (Government of Ireland, 2018) which endorses efforts to transform health care to maximise hospital efficiency and patient convenience. The nursing profession is recognised as critical to implementing this shift from hospital to community-based care. Specifically, nurse-led clinics for management of chronic diseases have emerged as an ideal means to achieve improved organisation in the health service (Government of Ireland, 2018; Randall et al., 2017).

Patient satisfaction levels are high with specialist or advanced practice in nursing clinics (Liljeroos & Stromberg, 2019; Linedale et al., 2020). In Ireland, Advanced Nurse Practitioners (ANP) have scope for physical examination and medicinal prescribing (Department of Health, 2019). They have the required expertise and skills to undertake caseload management of a cohort of patients requiring advance level decision making, such as those receiving OAMs. Currently, however advanced nursing assessment in cancer care is largely performed within a hospital context. Of particular relevance is a recent systematic review which assessed the impact of community-based nurse-led clinics on patient outcomes, and none of the studies included in the final review were oncological (Randall et al., 2017) indicating that oncology nurse-led care in the community is in its’ infancy. This review concluded that community-based nurse-led clinics have largely shown positive impact on patient outcomes, patient satisfaction and access to care despite the evidence base for such a key universal policy aim being limited. Extrapolating this to more specific care of individuals receiving OAMs, community-based care or integrated care models...
for this cohort of patients do not appear to be well established in national or international healthcare landscapes.

The coronavirus 2019 (COVID-19) pandemic has brought into sharp focus the requirement to reduce unnecessary hospital visits (Cucinotta & Vanelli, 2020). This is especially pertinent to individuals receiving cancer treatment due to potential immunosuppression and concomitant risk of infection. Those patients being treated with OAM require on-going assessment and monitoring but this does not necessarily require them to repeatedly attend the hospital. Consequently, within the COVID-19 context this is an opportune time to transform the care of this cohort of patients. This would be in line with the transformative vision of a shift beyond the acute hospital, yet at the same time implement the NCCP recommendations (2018). The document by the NCCP (2018), the Sláintecare health reform programme (Government of Ireland, 2018), the context of the COVID-19 pandemic alongside other literature promoting robust OAM patient monitoring provides the opportunity for a nurse-led integrated model of care to be developed for this patient cohort.

To consider the management of this subset of cancer patients, it is necessary to initially identify the specific aspects that constitute their assessment and care. The NCCP (2018) outlined five stages for generic SACT care which include: decision to treat, prescribing, dispensing, medication administration and patient monitoring (Figure 1). For parental SACT these stages are all performed within the hospital setting but for OAM, dispensing is performed by the community pharmacy and medication administration is within the patients’ home. Similarly Zerillo et al. (2018) outlines the care delivery domains for oral chemotherapy care process in their systematic review on the safety and quality of OAM. The authors do not specifically identify decision to treat as a specific stage and they include patient education occurring prior to drug administration which is a logical inclusion. Furthermore, storage and disposal are added as a final aspect of care (Zerillo et al., 2018) (Figure 2).

For the purposes of this scoping review, the processes outlined by the NCCP (2018) and Zerillo et al. (2018) will be used as a framework to guide the analysis and categorisation of literature. There will be a particular emphasis on literature pertaining to prescribing, dispensing, patient education and patient monitoring as these are encompassed within the concept of patient management. Treatment decision is a baseline initial assessment based on the individuals’ suitability for treatment to commence and is not part of the daily ongoing management of care and consequently will be excluded from this review.

**Aim**

A preliminary search of relevant databases, CINAHL, Medline and Web of Science was conducted, and no published systematic reviews on the overall management or continued monitoring of individuals receiving OAM were identified. Therefore, the aim of this scoping review is to identify how patients receiving OAM are currently managed from an international perspective.

**Objectives**

The specific objectives of the review are to:

- Complete a systematic search of the literature to explore the current clinical management practices for the ongoing assessment and monitoring of patients receiving OAM.
- Map existing patient management practices for those receiving OAMs with a focus on prescribing, dispensing, patient education and patient monitoring.

![Figure 1. Generic systemic anti-cancer treatments (SACT) processes (NCCP, 2018).](image1)

![Figure 2. Oral anti-cancer medications (OAM) Care (Zerillo et al., 2018).](image2)
• From the research literature, identify any best-practice patient care recommendations that exist within current frameworks of OAM management.

This organization of information is the initial stage in a multi-phased research study which aims to establish and analyse the safety and efficacy of an integrated care model for the management of patients receiving OAM by an ANP. The scope of the review will be deliberately broad so as not to exclude the identification of best practice from any one HCP group or any country/health service. In addition, the iterative nature of this work allows for a replicable process that can be adapted to ensure it is fit for the desired endpoint. Guidance produced by Peters et al. (2015) will be used to direct the various stages of this scoping review. The Preferred Reporting Items for Systematic Reviews and Meta-Analyses Extension for Scoping Reviews (PRISMA-ScR) checklist will be followed throughout (Tricco et al., 2018).

Protocol design
A search will be conducted for published and appropriate literature on the research subject. The PCC mnemonic will be used as a guide to frame the scoping review question and refers to Population, Concept and Context (Joanna Briggs Institute, 2019). In this scoping review adult cancer patients are the population, ‘oral anticancer medications’ are the concept and the context is management of care.

The three-step method for searching for studies will be applied as recommended by the Joanna Briggs Institute (2019). The databases CINAHL, Medline and Web of Science will be used for this scoping review as they collectively contain a vast range of medical, nursing and allied health literature; enabling this review to be comprehensive by capturing the majority of relevant references. The search will also include the reference lists of included papers as well as searching relevant grey literature in government reports, policy statements and conference proceedings in order to minimise the risk of publication bias. The keywords with Medical Subject Headings (MeSH) and proximity operators will be identified appropriate for each database.

An initial limited search will be conducted in these databases, followed by an analysis of text in the title and abstract, and of the index terms used to describe the article. A comprehensive search strategy will be formulated, in consultation with a university librarian, to identify relevant studies. The search strategy, including English language, identifying keywords and index terms, will be adapted for each included database as syntax of search strategies are database specific. A second search using all identified keywords and index terms will then be undertaken across all included databases. No specific search fields will be applied and all study designs will be included to keep the search broad. The third search will be of the reference list of all identified articles that are relevant to identify any potential additional further studies. Search results will be imported into a reference management software programme and duplicates removed. Any deviation from the protocol will be made clear and explained in the complete scoping review report as advocated by the Joanna Briggs Institute (2019).

Search selection
The inclusion and exclusion criteria for this review are shown in Table 1. Only English language articles published in the years 2010–2020 will be included; justification for this being English is the vernacular of the authors and OAM are a recent development (NCCP, 2018). The systematic review by Zerillo et al. (2018) of OAM safety and quality encompassed the past 20 years but all included articles were published after 2007 with 75% (n = 12) in the last 3 years. The authors note that the types of OAM medications have become more diverse over time and most of the earlier publications focused on capecitabine in patients with breast or colorectal cancers. Therefore, as this scoping review aims to consider contemporary management of care for this patient population who are receiving all OAMs it is sufficient to focus on studies published from 2010–2020 inclusive.

The search terms that are to be used are outlined in Table 2 using the PCC. Three reviewers (JR, MGK, AJ) will independently review the retrieved articles for inclusion based on title and abstract. The articles selected at this stage will then undergo a further independent full text review by the reviewers (JR, MGK) to determine relevance. Any disagreement will be resolved through discussion with a third reviewer (AJ). As quality assessment does not form part of a scoping review our study will not include assessment of methodological quality of the included papers (Arksey & O’Malley, 2005).

Throughout the scoping review however, the authors will review and report the salient aspects of the studies reviewed. This will include the quantity of the different types of articles reviewed and will allow descriptive expansion on the items listed in the data extraction table below (Table 3), in particular the methodologies, study populations, sample size, HCP involved and models of care utilised as this has direct relevance to the subject under review.

Data extraction
Data extraction will be performed by two reviewers independently. Microsoft Excel 2010 will be used for the management of the screening, duplicate removal and data extraction stages of the scoping review. Endnote will be used for reference management. A data extraction table (Table 3) will be used to capture the characteristics relating to the aims and objectives of the scoping review. Pre-testing with a pilot of up to five studies will be performed by three reviewers (JR, MGK, AJ) to evaluate the appropriateness and suitability of the headings used in the data extraction tool. The data extraction table will structure the review of each study and enable the authors to standardise the reporting of work reviewed. Furthermore, it will focus the authors to search for and report on the relevant aspects of each study to ensure detailed and accurate review. This is especially pertinent when more than one individual is performing the review and facilitates the sharing of findings from the scoping review between the research team members.
Table 1. Inclusion and exclusion criteria.

| Inclusion criteria                                                                 |
|-----------------------------------------------------------------------------------|
| English language articles                                                          |
| Articles published 2010–2020                                                        |
| Adults: individuals of 18 years old or more                                         |
| • Allow inclusion of relevant studies with mean age over 18 years of age           |
| Studies pertaining to the ongoing management of adults receiving oral anti-cancer medication. |

| Exclusion criteria                  |
|------------------------------------|
| Non-human studies                  |

Table 2. Search terms used for scoping review of the current Management of Cancer Care for Patients Receiving OAMs.

| Population: (Cancer) patients | Concept: Oral anticancer medicine | Context: Cancer Care management |
|-------------------------------|-----------------------------------|-------------------------------|
| Cancer                        | Oral anticancer*                  | Care                          |
| Oncolog*                      | (Oral anticancer drug*)           | Management                    |
| Neoplasm*                     | (Oral anticancer agent*)          | Model*                        |
| Patient*                      | (Oral anticancer medic*)          | Clinic*                       |
| (NOT child/paediatric/adolescent) | (Oral anticancer therap*)     | Unit*                         |
| (Oral anticancer treatment*)   | (Health) Service*                | "Delivery of health care"    |
| (Oral antineoplastic*)         |                                   |                               |
| (Oral antineoplastic drug*)    |                                   |                               |
| (Oral antineoplastic agent*)   |                                   |                               |
| (Oral antineoplastic medic*)   |                                   |                               |
| (Oral antineoplastic therap*)  |                                   |                               |
| (Oral antineoplastic treatment*) |                                   |                               |
| Oral chemotherap*              |                                   |                               |
| (Oral chemotherapeutic drug*)  |                                   |                               |
| (Oral chemotherapeutic agent*) |                                   |                               |
| (Oral chemotherapeutic medic*) |                                   |                               |
| Medication therapy management  |                                   |                               |

Data analysis
Descriptive numerical summaries and narrative synthesis, that aligns with the scoping review aim and objectives, will be presented in appropriate formats e.g. maps, tables. Narrative synthesis refers to an approach to the systematic review and synthesis of findings from multiple studies that relies primarily on the use of words and text to summarise and explain the findings and utilises a textual approach to ‘tell the story’ of the findings from included studies (Popay et al., 2006). Search results, selection process results, additions from reference searching, etc. and the final number of included sources will be presented in a PRISMA-ScR flow chart.

Dissemination of information
The result of the scoping review is critical as a means to gather the relevant evidence base and inform further aspects
of the study. As the research team plan to produce a nurse-led community model for care of individuals on OAMs, the scoping review will provide an overview of the current management of this cohort of patients and identify essential aspects of care required for safe practice. Furthermore, any recommendations for practice identified by existing literature will be included to enable the model of care developed by this work to conform to best practice standards. Once the scoping review has been completed, the findings will be disseminated in two ways. Firstly the results will be presented to a study advisory panel, consisting of the collaborators and invited national experts to discuss models of potential processes and outcomes, and produce a proposal for an ANP integrated oncology care model in the community. Furthermore, the results will be disseminated by publication in a peer-reviewed journal.

Study status
At the time of publication of this protocol, informal preliminary searches of the literature have been commenced primarily to help to identify key search terms.

Discussion
The scoping review protocol is an essential component in the process of performing a scoping review of a chosen topic (Moloney et al., 2020) and provides an outlined method for exploring and mapping relevant literature (Lafferty et al., 2019). Individuals being treated with OAM require on-going assessment and monitoring (NCCP, 2018) yet with increasing numbers of patients on OAMs there is a requirement to improve hospital efficiency and reduce overcrowding in cancer units yet provide safe, appropriate and timely patient care. The knowledge obtained in this scoping review will be presented to an advisory panel and will help inform the subsequent steps in a multi-phased research study which aims to establish and analyse the safety and efficacy of an integrated care model for the management of patients receiving OAM in the community by an ANP.

Data availability
Underlying data
No data are associated with this article.

References

| Table 3. Definitions for data extraction. |
|------------------------------------------|
| **Descriptive term** | **Definition for the purpose of the scoping review** |
| Author(s) | Name of individual(s) writing the paper |
| Year | Year paper was published |
| Country/countries | Country/countries in which the paper was published |
| Publication type | List whether it is paper, conference presentation, website or other |
| Aims | List the aims of the paper |
| Type of study/methodology | List the method used to gather the data-e.g. Randomised controlled trial, ethnographic, interventional, descriptive etc. |
| Study population | Type of malignant pathology that the paper primarily focuses on for the study population
  - Select if the cancer(s) studied is haematological (non-solid) or oncology (solid) or both.
  - For solid malignancies select the best option to describe the primary cancer as breast/colorectal/prostate/gastric/variety of cancers or unspecified |
| Sample size | Number of participants in the study |
| HCP primarily involved | The HCP primarily involved in the study (e.g. nurse/medical/pharmacist/variety) |
| Model of care identified | Is a defined or established framework for delivery care identified? |
| Patient monitoring | Is on-going scheduled monitoring/assessment of patients on OAMs described or outlined? |
| Recommendation(s) | Identify any recommendation(s) for improvement of patient care on OAMs |

Arksey H, O'Malley L: Scoping studies: towards a methodological framework. Int J Soc Res Methodol. 2005; 8(1): 19–32. Publisher Full Text

Cucinotta D, Vanelli M: WHO declares COVID-19 a pandemic. Acta Biomed. 2020; 91(1): 157–160. PubMed Abstract | Publisher Full Text | Free Full Text
Evaluation of an education program to facilitate adherence management in patients on oral anticancer medications. A review on adherence management in patients on oral chemotherapy. Nursing application of oral chemotherapy safety standards: An informal survey. Administration of oral chemotherapy: adherence, symptoms, and quality of life. Identifying over-adherence to capecitabine: a potential safety issue in breast and colorectal cancer patients. Assessing the impact of a care pathway. Introducing nurse-led heart failure clinics in Swedish primary care settings. Over-adherence to cepaclitabin: a potential safety issue in breast and colorectal cancer patients. Cancer Chemother Pharmacol. 2018; 83(3): 319–327.

References

Department of Health, Ireland: National Cancer Strategy 2017-2026. Last accessed 10 December 2020, 2019.

Department of Health: Policy on the development of graduate to advanced nursing and midwifery practice. Department of Health; Dublin. Last accessed 10 December 2020, 2019.

Government of Ireland: Slaintecare Implementation Strategy. Last accessed 01 December 2020, 2018.

Greer JA, Amoyal N, Nisotel L et al.: A Systematic Review of Adherence to Oral Antineoplastic Therapies. Oncologist. 2016; 21(3): 354–376.

Griffiths T, Pascoe E: Evaluation of an education program to facilitate patient adherence, toxicity monitoring and promote safety and well-being in the self-administration of oral chemotherapy in the home setting: an Australian study. Australian Journal of Cancer Nursing. 2014; 15(2): 30–38.

Hammond L, Marsden E, O’Hanlon N et al.: Identification of risks associated with the prescribing and dispensing of oral anticancer medicines in Ireland. Int J Clin Pharm. 2012; 34(6): 893–901.

Heckmann P, McCarthy T, Walsh O et al.: NCCP Oncology Medication Safety Review Report. Dublin. 2014.

House of the Oireachtas: Committee on the future of Healthcare: Slaintecare Report. Last accessed 10 November 2020, 2017.

Jacobs JM, Ream ME, Pensak N et al.: Patient experiences with oral chemotherapy: adherence, symptoms, and quality of life. J Natl Compr Canc Netw. 2019; 17(2): 221–228.

Joanna Briggs Institute Reviewers Manual: Joanna Briggs Institute template study details, characteristics and results extraction instrument. Last accessed 10 October 2020, 2019.

Kinner LM, Decoene E, Van Heck A et al.: Collaborative network to take responsibility for oral anticancer therapy (CONTACT): Study-protocol investigating the impact of a care pathway. J Adv Nurs. 2019; 75(12): 3720–3739.

Kraaijkamp K, Post S, van der Veer M et al.: Patient experiences with oral chemotherapy: adherence, symptoms, and quality of life. J Natl Compr Canc Netw. 2019; 17(2): 221–228.

Lafferty A, Phillips D, Paul G et al.: Stage 1 Registered Report: A scoping review protocol to map the evidence on family carers who combine work with care [version 1; peer review: 2 approved]. HRB Open Res. 2019; 2: 7.

Le Febvre KB, Felice TL: Nursing application of oral chemotherapy safety standards: An informal survey. Clin J Oncol Nurs. 2016; 20(3): 258–262.

Le Saux O, Bourmaud A, Rioufol C et al.: Over-adherence to cepaclitabin: a potential safety issue in breast and colorectal cancer patients. Cancer Chemother Pharmacol. 2018; 82(3): 319–327.

Liljeroos M, Strömberg A: Introducing nurse-led heart failure clinics in Swedish primary care settings. Eur J Heart Fail. 2019; 21(1): 103–9.

Linedale EC, Mikocka-Walus A, Gibson PR et al.: The Potential of Integrated Nurse-Led Models to Improve Care for People With Functional Gastrointestinal Disorders: A Systematic Review. Gastroenterol Nurs. 2020; 43(1): 53–64.

Meier J, Bergsbaken J, Suzuki S: Initiatives to improve safety of oral anticancer agents as delivered by community pharmacists. European Medical Journal. 2018; 3(20): 60–68.

Moynihan B, Kroll T, Lafferty A: An exploration of young carers’ experiences in school and their perceptions regarding their future career—a scoping review protocol [version 1; peer review: 2 approved]. HRB Open Res. 2020; 3: 41. Last accessed 03 November 2020.

National Cancer Control Programme: Oral Anti-Cancer Medicines Model of Care Recommendations. 2018. Last accessed 14 September 2020.

National Cancer Institute: Targeted Cancer Therapies. 2020. Last accessed 10 September 2020.

Paolella GA, Boyd AD, Wirth SM et al.: Adherence to Oral Anticancer Medications: Evolving Interprofessional Roles and Pharmacist Workforce Considerations. Pharmacy (Basel). 2018; 6(1): 23. Last accessed 10 December 2020.

Peters MJ, Godfrey CM, Khalil H et al.: Guidance for conducting systematic scoping reviews. Int J Evid Based Healthc. 2015; 13(3): 141–6.

Pogay J, Roberts H, Sowden A et al.: Guidance on the Conduct of Narrative Synthesis in Systematic Reviews: A Product from the ESRC Methods Programme. 2006. Last accessed 09 December 2020.

Randall S, Crawford T, Currie J et al.: Impact of community based nurse-led clinics on patient outcomes, patient satisfaction, patient access and cost effectiveness: A systematic review. Int J Nurs Stud. 2017; 73: 24–33.

Redelico TJ, Walton SM, LaFollette J et al.: Assessment of Provider Adherence to Recommended Monitoring Parameters for Oral Anticancer Medications. J Oncol Pract. 2018; 14(7): e446–e450.

Starfield B: Primary Care: Balancing Health Needs, Services, and Technology. New York: Oxford University Press; 1998; 448.

Tricco AC, Lillie E, Zarin W et al.: PRISMA Extension for Scoping Reviews (PRISMA-ScR): Checklist and Explanation. Ann Intern Med. 2018; 169(7): 467–473. Last accessed 26 October 2020.

U.S. Food & Drug Administration: Hematology/Oncology (Cancer) Approvals & Safety Notifications. U.S. Food & Drug Administration, 2018.

Wood L: A review on adherence management in patients on oral cancer therapies. Eur J Oncol Nurs. 2012; 16(4): 432–438.

World Health Organisation: Global declaration of Astana. 2018; Last accessed 14 November 2020.

Zerillo JA, Pham TH, Kadiupek P et al.: Administration of oral chemotherapy: results from three rounds of the quality oncology practice initiative. J Oncol Pract. 2015; 11(2): e255–62.

Zerillo JA, Goldenberg BA, Kotecha RR et al.: Interventions to improve oral chemotherapy safety and quality: A systematic review. JMM Oncol. 2016; 4(1): 105–117.
Open Peer Review

Current Peer Review Status: ✔️ ✔️ ✔️

Version 4

Reviewer Report 09 March 2022

https://doi.org/10.21956/hrbopenres.14757.r31626

© 2022 Dalby M. This is an open access peer review report distributed under the terms of the Creative Commons Attribution License, which permits unrestricted use, distribution, and reproduction in any medium, provided the original work is properly cited.

✔️ Melanie Dalby

Barts Health NHS Trust, London, UK

I have no further comments to make.

Competing Interests: No competing interests were disclosed.

Reviewer Expertise: Cancer pharmacy, oral anti-cancer medications, patient experience, cancer in the community, oncology, haematology.

I confirm that I have read this submission and believe that I have an appropriate level of expertise to confirm that it is of an acceptable scientific standard.

Version 3

Reviewer Report 24 February 2022

https://doi.org/10.21956/hrbopenres.14733.r31491

© 2022 Dalby M. This is an open access peer review report distributed under the terms of the Creative Commons Attribution License, which permits unrestricted use, distribution, and reproduction in any medium, provided the original work is properly cited.

✔️ Melanie Dalby

Barts Health NHS Trust, London, UK

I am happy to amend the status to Approved. I have just one further comment, please remove the word ‘between’ in bold below:
This is especially pertinent when more than one individual is performing the review and facilitates the sharing of findings between from the scoping review between the research team members.

**Competing Interests:** No competing interests were disclosed.

**Reviewer Expertise:** Cancer pharmacy, oral anti-cancer medications, patient experience, cancer in the community, oncology, haematology.

I confirm that I have read this submission and believe that I have an appropriate level of expertise to confirm that it is of an acceptable scientific standard.

---

**Version 2**

**Reviewer Report 28 January 2022**

https://doi.org/10.21956/hrbopenres.14485.r31164

© 2022 Dalby M. This is an open access peer review report distributed under the terms of the Creative Commons Attribution License, which permits unrestricted use, distribution, and reproduction in any medium, provided the original work is properly cited.

**Melanie Dalby**

Barts Health NHS Trust, London, UK

This study protocol has been well prepared and written. I just have a few comments for you to consider.

1. It would be useful if you could include the search terms you are planning to use.

2. Sentence starting: ‘Furthermore, anecdotal evidence from the authors ... less input that those...’ please change that to than.

3. I understand that a quality assessment of each paper will not be completed but will you report on the quantity of different article types i.e. number of randomised controlled trials, observational studies, etc.?

4. For the aim can you add whether this is locally, nationally, or internationally?

5. Please can you explain how the data extraction table will be used in a bit more detail?

6. Sentence: ‘...indicating that oncology nurse-led care in the community is in its’ infancy.’ Can you remove the apostrophe?

7. Sentence starting: ‘The search strategy, including English language, identified keywords ...’ I think it would read better if you said ‘identifying’ rather than ‘identified’, please have a look.

Is the rationale for, and objectives of, the study clearly described?
Yes

**Is the study design appropriate for the research question?**
Yes

**Are sufficient details of the methods provided to allow replication by others?**
Partly

**Are the datasets clearly presented in a usable and accessible format?**
Not applicable

**Competing Interests:** No competing interests were disclosed.

**Reviewer Expertise:** Cancer pharmacy, oral anti-cancer medications, patient experience, cancer in the community, oncology, haematology.

I confirm that I have read this submission and believe that I have an appropriate level of expertise to confirm that it is of an acceptable scientific standard, however I have significant reservations, as outlined above.

Reviewer Report 14 July 2021

https://doi.org/10.21956/hrbopenres.14485.r29740

© 2021 Furlong E et al. This is an open access peer review report distributed under the terms of the Creative Commons Attribution License, which permits unrestricted use, distribution, and reproduction in any medium, provided the original work is properly cited.

Andrew Darley 🚀
School of Medicine, University College Dublin, Dublin, Ireland

Eileen Furlong 🚀
School of Nursing, Midwifery and Health Systems, University College Dublin, Dublin, Ireland

Thank you for considering and including our suggestions and comments. We have no further comments to make on this revised article.

**Is the rationale for, and objectives of, the study clearly described?**
Not applicable

**Is the study design appropriate for the research question?**
Not applicable

**Are sufficient details of the methods provided to allow replication by others?**
Not applicable

**Are the datasets clearly presented in a usable and accessible format?**
Not applicable

**Competing Interests:** No competing interests were disclosed.

**Reviewer Expertise:** Cancer care; patient outcomes; integrated care; scoping reviews

We confirm that we have read this submission and believe that we have an appropriate level of expertise to confirm that it is of an acceptable scientific standard.

---

**Reviewer Report 30 March 2021**

https://doi.org/10.21956/hrbopenres.14360.r29033

© 2021 Tralongo P. This is an open access peer review report distributed under the terms of the [Creative Commons Attribution License](https://creativecommons.org/licenses/by/4.0/), which permits unrestricted use, distribution, and reproduction in any medium, provided the original work is properly cited.

**Paolo Tralongo**  
Medical Oncology Unit, Ospedale Umberto I, RAO, Siracusa, Italy

The paper on the protocol proposed belongs to a fascinating and important issue in the oncology field and daily debated.

1. The rationale and objectives of the study are clearly described. However, the aim of making any recommendations for the clinicians should undergo to a valid and shared by scientific community method, to assess and grading quality of evidence and strength of any potential recommendation.

2. The study design appears appropriate for the research question. However I would modify the exclusion criteria, they should not be only the opposite of inclusion criteria.

3. I would suggest to gather and summarize the findings of the studies included, categorizing them by the quality and strength of the evidence, through the type of studies (i.e. randomized controlled trial, observational studies, etc.).

4. The manuscript is extremely concise and it does not provide all details of the proposed research.

**Is the rationale for, and objectives of, the study clearly described?**  
Partly

**Is the study design appropriate for the research question?**  
Partly

**Are sufficient details of the methods provided to allow replication by others?**
Yes

Are the datasets clearly presented in a useable and accessible format?
Yes

**Competing Interests:** No competing interests were disclosed.

**Reviewer Expertise:** Medica oncologist

I confirm that I have read this submission and believe that I have an appropriate level of expertise to confirm that it is of an acceptable scientific standard, however I have significant reservations, as outlined above.
o Clearly state the research question of the scoping review.

o Consider changing “This approach” to “The knowledge obtained in this review could...”

o Please specify the patient management practices as mentioned in the Objectives.

**Methodology**

o Are you using a screening tool e.g., Covidence?

o How will study selection be recorded? Is this being done through Excel or are the authors using a reference manager?

o Will duplicates be removed manually by the author team?

o In the abstract it states that the review will be performed by two reviewers and checked by a third reviewer, however on P8 that ‘any disagreement will be resolved through discussion with a third reviewer’. Please confirm the process.

o Provide more specific detail on “relevant grey literature” and justify why it is being included. It would be helpful if the authors provided the search strategy for the grey literature and how it will be limited. e.g. search terms, sources.

o Consider using initials of the author team when referring to the reviewers.

o Statement regarding “desired endpoint” – consider using “replicable” process rather than repetitive.

o Consider removing “crucially” in Protocol Design.

o Consider changing “natural language” to “English”.

o Reword sentence beginning with “To keep the search broad...”

o Did the authors consider using SCOPUS in their search?

o Will the authors conduct a quality appraisal on the identified studies? If not, provide justification.

o Consider including Limitations of the studies reported in Table 2, which will help analysis.

o Please use “A nurse-led...” not “an”.

**Conclusion**

o Consider reframing the final two sentences to address the value of this scoping review in light of the aims and objectives.

**Is the rationale for, and objectives of, the study clearly described?**

Yes
Is the study design appropriate for the research question?
Yes

Are sufficient details of the methods provided to allow replication by others?
Partly

Are the datasets clearly presented in a useable and accessible format?
Not applicable

Competing Interests: No competing interests were disclosed.

Reviewer Expertise: Cancer care; patient outcomes; integrated care; scoping reviews

We confirm that we have read this submission and believe that we have an appropriate level of expertise to confirm that it is of an acceptable scientific standard, however we have significant reservations, as outlined above.