

Why you should read this article:

- To enhance your understanding of the benefits of a nurse-led clinic for patients receiving PARP inhibitors and other systemic anticancer treatments
- To recognise that those responsible for leading and delivering a nurse-led service require the relevant training and competencies
- To appreciate the importance of creating a business case when setting up a nurse-led clinic

Developing a nurse-led clinic for patients receiving PARP inhibitors

Laura Appadu, Lynn Buckley, Sandeep Chahal et al

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Correspondence

laura.appadu@rmh.nhs.uk

Conflict of interest

Laura Appadu, Lynn Buckley, Sandeep Chahal, Helen Manderville, Tina Mills-Baldock, Nafisa Patel and Lisa Young are on the GSK UK Nurse Council. Laura Appadu has worked with AstraZeneca, Sandeep Chahal has worked with AstraZeneca and Clovis Oncology, and Lisa Young has served on GSK advisory panels (UK and European). Katy Leonard is an employee of GSK. Funding was provided by GSK

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Abstract

Nurse-led chemotherapy clinics are an essential part of UK oncology services. The approval of oral poly (adenosine diphosphate (ADP)-ribose) polymerase (PARP) inhibitors as maintenance treatment for people with platinum-responsive advanced ovarian cancer has provided patients with a new treatment option. However, due to their side effect profile, patients on these treatments require additional monitoring which can necessitate changes to the design of outpatient services. Nurse-led clinics designed specifically for patients receiving PARP inhibitors have been effective in addressing the additional monitoring requirements. This article provides a practical guide to developing a nurse-led clinic for patients receiving PARP inhibitors for advanced ovarian cancer and other systemic anticancer treatments.

Author details

Laura Appadu, advanced nurse practitioner, gynaecology, The Royal Marsden NHS Foundation Trust, London, England; Lynn Buckley, Macmillan gynaecology oncology clinical nurse specialist, Hull University Teaching Hospitals NHS Trust, Hull, England; Sandeep Chahal, Macmillan gynae-oncology clinical nurse specialist, University Hospital, Coventry, England; Katy Leonard, lead medical science liaison, GSK, Brentford, England; Helen Manderville, Macmillan gynae-oncology clinical nurse specialist, Queen Elizabeth Hospital Gateshead, Gateshead, England; Tina Mills-Baldock, senior research nurse, cancer clinical trials, Queen's Hospital, Barking Havering Redbridge University Hospitals NHS Trust, Romford, England; Nafisa Patel, Macmillan gynae-oncology clinical nurse specialist, University Hospitals of Leicester NHS Trust, Leicester, England; Lisa Young, Macmillan lead gynaecological cancer clinical nurse specialist, University Hospital Southampton NHS Foundation Trust, Southampton, England

Keywords

cancer, cancer treatments, chemotherapy, clinical, gynaecological cancer, innovation, nurse-led clinics, ovarian cancer, professional

Introduction

Recent developments have provided further treatment options for patients with advanced ovarian cancer, defined here as cancer arising in the ovaries, peritoneum (primary peritoneal) or fallopian tube (Rimel et al 2020). Poly (adenosine diphosphate (ADP)-ribose) polymerase (PARP) inhibitors are oral medicines recommended as a daily maintenance treatment following complete or partial response to platinum-based chemotherapy in patients with advanced epithelial ovarian cancer (Joint Formulary

Committee 2022). The use of PARP inhibitors in the maintenance treatment of patients with advanced ovarian cancer is associated with substantial benefits for long-term survival (Hao et al 2021, Scott 2021).

PARP inhibitors are recommended to be taken until they become ineffective at preventing relapse or until unacceptable toxicity is reached. Unacceptable toxicity occurs when patients cannot manage the side effects of a treatment. Although tolerability to PARP inhibitors usually improves after a few months of treatment (La Fargue et al 2019), some patients

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find it challenging to manage side effects such as nausea, vomiting and fatigue in the first few months. Other side effects include hypertension and myelosuppression, which require close monitoring for the first few treatment cycles. Patients receiving PARP inhibitor maintenance treatment or other systemic anticancer therapies (SACTs) require ongoing monitoring, such as full blood count and blood pressure (BP) checks, and potentially management of side effects and toxicities (Liu et al 2018, Moore et al 2018, Joint Formulary Committee 2022).

Before the approval of PARP inhibitors in the UK, patients with advanced ovarian cancer did not receive oral maintenance treatments and were monitored for disease progression every two to four months for the first two years, then every three to six months for three further years, with no other treatment unless their cancer returned (Ray-Coquard et al 2020). The advent of maintenance treatment with PARP inhibitors has radically changed the advanced ovarian cancer follow-up pathway, meaning that more patients require regular follow-up and monitoring (Liu et al 2018). This has in turn increased the demands placed on healthcare services (Jupp et al 2020). As such, there is considerable value in providing specific clinics for patients with ovarian cancer who are receiving maintenance treatment. These clinics can be led by nurses and allied health professionals such as pharmacists.

This article provides practical guidance and advice for nurses working in gynaecological oncology who are planning to set up a clinic for patients to receive PARP inhibitors. The guidance may also be relevant for nurses and allied health professionals seeking to set up clinics for patients receiving other types of SACTs.

PARP inhibitors

PARP is a family of enzymes that repairs damaged deoxyribonucleic acid (DNA) in cancer cells. Inhibiting PARP means that cancer cells are less able to repair themselves, resulting in an antineoplastic effect. Three PARP inhibitors have been approved to treat patients with advanced epithelial ovarian cancer in the UK – olaparib, niraparib and rucaparib (Joint Formulary Committee 2022). Figure 1 shows the role of PARP inhibitors in the treatment pathway for advanced ovarian cancer based on their licensed indications in the UK.

Benefits of nurse-led clinics

The benefits of nurse-led clinics in oncology have been widely documented. Patients

managed via nurse-led clinics have reported high levels of satisfaction with holistic continuity of care, quality of life and symptom control (Faithfull et al 2001, Allan 2018). Nurse-led clinics can reduce patient waiting times and the burden on outpatient services, and may be more cost-effective than medically managed care (Faithfull et al 2001, Allan 2018, Lai et al 2018).

Telephone support is frequently used in nurse-led clinics and some evidence has suggested that this can reduce treatment-related toxicities in patients with advanced cancers (Menjak et al 2021). Similarly, a combined online and phone-based home monitoring system for chemotherapy symptom and toxicity management, which was linked to a homecare nursing service, was shown to be effective for patients with a variety of solid tumours who were receiving routine SACT (Rasschaert et al 2021). Patients using this system reported that they felt in control of their treatment and appreciated the system's responsive nature.

Nurse-led telephone clinic

In 2019, staff at the Royal Marsden NHS Foundation Trust in Sutton, south-east England, set up a dedicated telephone-based clinic for patients receiving maintenance treatment for gynaecological cancers. The clinic was led by nurses and pharmacists, with oncology consultant supervision. It was established initially for patients receiving PARP inhibitors and bevacizumab (another drug administered as a maintenance treatment for patients with gynaecological cancers), although patients could be seen in person if required; for example, if they developed mild disease-related symptoms or mild treatment-related toxicity (Jupp et al 2020).

Box 1 outlines important considerations when setting up a PARP inhibitor clinic.

Patient and staff feedback

The clinic was initially introduced as a pilot which ran from August 2019 to February 2020. During the pilot period 36 patients were prescribed a PARP inhibitor or bevacizumab, 25 of whom were moved onto the nurse-led telephone clinic. The remaining 11 patients continued to attend face-to-face clinics. Patients and staff surveys were conducted at the end of the pilot; 19 out of 23 patient surveys and ten out of 13 staff surveys (five doctors, four nurses, one pharmacist) were completed and returned (Jupp et al 2020).

Overall, the pilot received positive feedback, with patients and clinicians reporting high levels of satisfaction. All 19 patients reported that there was no waiting time for their telephone

appointment, that they felt very confident or confident in the healthcare practitioner who was leading the telephone consultation and that they felt very comfortable or comfortable discussing side effects with them.

All ten staff reported that they believed the telephone clinic had supported management of face-to-face clinics while nine reported that they felt very confident in the healthcare professionals who were leading the telephone consultations (Jupp et al 2020).

These findings are supported by previous evidence where patients with ovarian cancer reported that nurse-led follow up by telephone was particularly useful for psychosocial support during treatment (Cox et al 2008).

Overall, the pilot showed that the telephone-based format was effective, therefore the PARP inhibitor nurse-led clinic was introduced into the trust permanently from February 2020 (Jupp et al 2020).

Effects of coronavirus disease 2019 (COVID-19) pandemic

The forced move to remote patient management during the coronavirus disease 2019 (COVID-19) pandemic emphasised potential challenges for the clinic in monitoring patients, for example when they needed to be seen in person following abnormal blood test results or for visual assessment of toxicities with symptoms such as rashes.

Research into patients receiving cancer treatment during COVID-19, including a study of patients with gynaecological cancers (Moran et al 2020), demonstrated varied experiences with remote support (Drury et al 2021). Some studies reported that patients had concerns about not being listened to properly and not being provided with adequate support, and found it challenging to discuss specific physical concerns with healthcare staff without face-to-face contact (Moran et al 2020, Drury et al 2021). Conversely, a study of 55 patients with cancer receiving telephone consultations due to COVID-19 reported that 60% ($n=33$) were willing to continue with telephone clinics (Dalby et al 2021). However, the researchers found that some patients preferred face-to-face clinics and believed it was challenging to assess side effects and physical concerns remotely.

Pandemic-related staff shortages have also posed challenges in relation to running remote clinics, while some patients are unfamiliar with remote technology or lack equipment or an internet connection (Aapro et al 2020). In the future, a combined approach of face-to-face and virtual contact may be required. Decisions

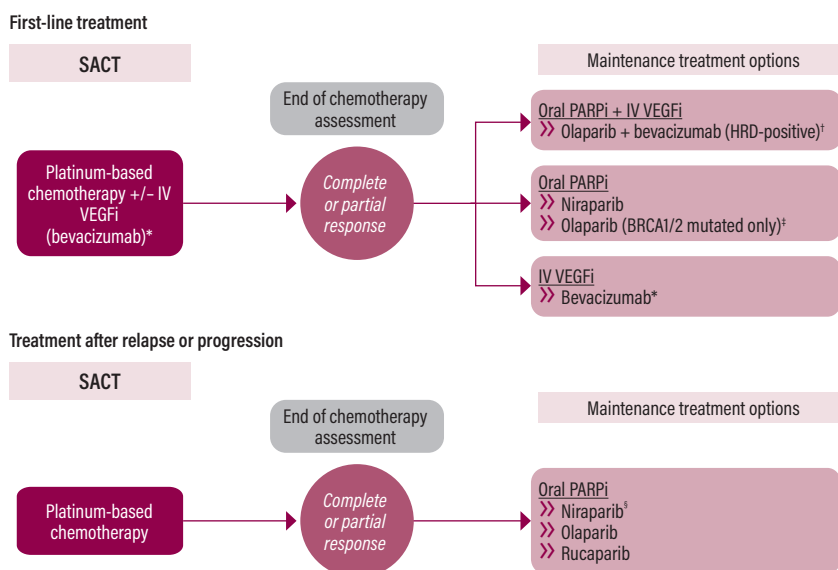
about how a nurse-led telephone clinic should operate and the appropriate combination of remote and face-to-face contact should be made at the planning stage and should consider patients' and clinicians' needs.

Homecare services external to hospital-based nurse-led gynaecology and oncology clinics, and involving scheduled community nurse visits, could also benefit patients receiving oral SACTs. A nationwide homecare service initiated during the COVID-19 pandemic included patients with ovarian cancer receiving certain PARP inhibitors (Keep up with Cancer and Cancer 52 2021). Patients received home nurse visits for medicines delivery, phlebotomy and BP monitoring, which were provided by an external service partnered with the NHS and funded by GSK. The service was initially intended to be available for the duration of the pandemic but having received positive feedback from patients and clinicians and reduced the burden on the NHS it is being made permanent (Keep up with Cancer and Cancer 52 2021).

Training, competencies and professional development

When planning to implement a nurse-led clinic it is important to ensure that those responsible

Figure 1. Role of poly (adenosine diphosphate (ADP)-ribose) polymerase (PARP) inhibitors in the treatment pathway for advanced ovarian cancer based on their licensed indications in the UK



*Bevacizumab only for patients naïve to bevacizumab or other anti-VEGF/anti-VEGF-receptor treatments; †HRD-positive defined as BRCA1/2-mutated and/or with genomic instability; ‡Germline and/or somatic; §Indication is for serous epithelial ovarian cancer only in the relapsed setting

HRD=homologous recombination deficiency; PARPi=poly (ADP ribose) polymerase inhibitor; SACT=systemic anticancer treatment; VEGFi=vascular endothelial growth factor inhibitor

(Adapted from Joint Formulary Committee 2022)

Key points

- Nurse-led clinics for patients receiving PARP inhibitors or other oral systemic anticancer treatments can reduce patient waiting times and the burden on outpatient services
- Nurse-led clinics can enhance patient confidence and satisfaction in continued care
- Nurses leading and involved in delivering nurse-led clinics must have the relevant recommended training, education and competencies
- It is essential to develop a structured and comprehensive business case when setting up a nurse-led clinic
- Involvement in developing and managing nurse-led clinics can support nurses' career development and revalidation

for leading and delivering the service have the recommended qualifications. The Royal College of Nursing (RCN), in conjunction with the UK Oncology Nursing Society, provides detailed guidance for training and education requirements in cancer nursing (RCN 2022). Essential and recommended skills for nurses leading or undertaking a patient's chemotherapy review are shown in Table 1 (Lennan et al 2012).

For nurses who intend to implement a PARP inhibitor clinic, the five important skill areas recommended are:

- » Assessment.
- » Experience with PARP inhibitors.
- » Experience with requesting and interpreting investigations.
- » Prescribing.
- » Self-directed education.

Nurse and/or allied health professional prescribers are not essential for running a PARP inhibitor clinic – such clinics can also be run by non-prescribing nurses or allied health professionals – but the involvement of prescribers is considered the gold standard (Lennan et al 2012).

Box 1. Important considerations when setting up a poly (adenosine diphosphate (ADP)-ribose) polymerase inhibitor clinic

Clinic structure may vary across hospitals and trusts depending on resource and skill availability

Management and staffing

Staffing options include:

- » Nurse and/or pharmacist
- » Clinical nurse specialist
- » Consultant and/or allied health professional in a shared-care agreement (joint service shared between a consultant and other allied health professional)
- » Clinic cover and rescheduling considerations if the nurse and/or allied health professional is absent

Referral criteria

- » Who?
- » What?
- » When?
- » Where?
- » How?

Structure

Clinic structure options include:

- » Telephone clinic
- » Face-to-face clinic
- » Hybrid clinic

Scheduling

For example, the patient's regular clinician might review them at treatment cycles 1-3 (PARP inhibitors), then the patient would be referred to the nurse-led clinic at cycle 4 with review alternating back to the regular clinician at every other cycle

If nurse prescribers are part of the clinic, an important consideration is the maintenance of their professional standards and required education (Hatchett 2008, 2016).

The UK Oncology Nursing Society (2019) recommends that nurses who administer SACTs should hold a university accredited SACT course, accredited at higher education institution level 6 (BSc Hons) or level 7 (MSc), and should be employed in a band 5 role or higher. Although nurses should meet the essential requirements for administering SACT and leading a chemotherapy review, the required level of non-essential but highly recommended skills, such as prescribing, in a clinic may vary. Further, some nurses will not require initial skills training because they already possess competencies such as chemotherapy administration, disease and treatment knowledge and advanced communication skills.

Continuing professional development (CPD) is important in a nurse-led clinic and may include formal learning, shadowing or mentoring by more experienced staff (Hatchett 2008, Hatchett 2016). An example of a CPD exercise related to PARP inhibitors might be a nurse's reflective account of how a change in a patient's blood results was addressed. Developing links with a nearby university's faculty of healthcare can also be useful for nurses to gain an in-depth understanding of PARP inhibitors' mode of action and thereby enable them to provide informed patient education (Hatchett 2008). In addition, for nurses who set up or lead a clinic the variety of professional activities involved can contribute significantly to their Nursing and Midwifery Council (NMC) (2021) revalidation requirements.

Protocols should be developed clearly laying out all processes required in the clinic and related staff responsibilities. For a PARP inhibitor clinic, protocols related to patient eligibility, consent and onboarding, medicines administration, patient assessment (for example, blood count and BP monitoring), adverse event monitoring and management and patient referral should be developed based on the summary of medicinal product characteristics (SmPC) (Liu et al 2018, Moore et al 2018, Joint Formulary Committee 2022). Checking for updates to the SmPC monitoring requirements should be a planned task undertaken at appropriate intervals. Protocols should be evaluated and approved by local quality improvement partner panels (QuIPPs) to ensure they meet the quality, innovation, productivity and prevention criteria (NHS England 2018).

Developing a business case

Developing a business case is vital when setting up a nurse and/or allied health professional-led clinic and should clearly outline the clinic's aims and objectives, which can then be used as measurable goals (Hatchett 2008, Farrell 2015, Hatchett 2016). A business case should identify the following elements (Lennan et al 2012):

- » Current pressures – for example, patient numbers, specialist nursing and/or medical staff shortages and waiting times.
- » Future pressures – for example, changes in indication such as an extension to the type of patients eligible for treatment or increased monitoring requirements.
- » Contingency planning – for example, staff availability.

The important components of a business case are outlined in Table 2. The lead nurse for the clinic should be responsible for leading the initial development of the business plan and for regular updates (Lennan et al 2012).

Since a nurse-led clinic is part of each patient's overall healthcare pathway, it is important to discuss the clinic with the wider multidisciplinary team before starting the set-up, including staff who may refer patients to the service (Hatchett 2008, Hatchett 2016). The logistical and administrative requirements for setting up the clinic are likely to vary from trust to trust, in terms of the details and those responsible for clinic set-up. However, requirements are likely to include the submission of a request to the clinic feasibility committee. This will need to emphasise the important points of the clinic, including its ability to reduce the time patients spend in hospital, improve waiting times for treatment and reduce the number of patients requiring appointments in the outpatient department.

Practically, when setting up a PARP inhibitor clinic, the lead nurse will need to identify the patient population (those receiving maintenance treatment) and determine whether the clinic will be incorporated into existing nurse-led chemotherapy clinics or will be a standalone service. The lead nurse must then establish the requirements of the clinic in terms of clinical observations, imaging requirements and the procedure for offering face-to-face appointments. A pilot clinic should be set up, with important roles identified within the service and information provided to referring teams. Trust guidelines should be updated and patient information leaflets and information on the trust website should be developed.

Table 1. Essential and recommended skills for nurses leading or undertaking a patient's chemotherapy review

Educational attainment	Essential or recommended
Recognised qualification and/or extensive competency-based experience in chemotherapy	Essential
History taking	Essential
Physical examination	Recommended*
Advanced assessment skills (for example, synthesising history and physical assessment)	Essential
Completion of a recognised course in advanced communication skills	Recommended*
Non-medical prescribing	Recommended*

*The UK Oncology Nursing Society regards these educational attainments as gold standard (Lennan et al 2012)
(Adapted from Lennan et al 2012)

Table 2. Important components of a business case

Section	Description
Executive summary	» Provide an overall 'snapshot' of the business case, incorporating the aim, rationale and benefits and placed in the wider context of the trust » Useful for those who may not read the full document
Proposal aims and objectives	» State what the clinic is aiming to achieve and why
Introduction	» Identify the need driving the change and provide evidence to support the rationale of the clinic. Sub-sections may include: — Current situation and shortfalls — Demographic information on who the clinic will serve — Feedback from patients, data from audits to support the rationale — Objectives – these should be specific, measurable, attainable, relevant and time-bound (SMART) » Assumptions and constraints
Details and options	» Detail the options available and the benefits and risks of each » Show evidence that risk assessments have been undertaken » Resources – who will be needed to establish and maintain the clinic; which products and equipment will be required? » Professional standards – how will these be maintained? Consider competency, professional development and mentoring » What is the timescale for establishment, for example receiving funding, setting up and recruitment?
Financial	» How will the clinic be sustained? » What are the wage costs and non-wage-related costs (for example, equipment, training and marketing)? » What is the income and projected return on investment? » Funding details » Cost-benefit versus alternative options
Conclusion	» State the preferred option » State the next steps if the proposal is accepted

(Adapted from Carter 2017)

Publicity for the clinic should begin at the planning stage so that adjustments based on feedback can be made to the service before it opens (Hatchett 2008). The clinic can be publicised through the trust website, leaflets, posters, group discussions or face-to-face appointments with those who may be eligible (Hatchett 2008). When patients are invited to their initial appointment, invitation letters should provide information about what to expect (Hatchett 2008).

A nurse-led review of the clinic once it has been set up must include systems to ensure that national protocols for care quality and safety are implemented and regularly audited (Lennan et al 2012). Services such as a PARP inhibitor clinic should also be aligned with relevant local policies. Further, the lead nurse should assess local chemotherapy provision as a whole to ensure that a specific nurse-led chemotherapy clinic does not interfere with existing services (Lennan et al 2012).

The UK Oncology Nursing Society SACT competency passport (an online learning

document that records nurses' competence in administering SACT) should be completed by staff involved in a PARP inhibitor clinic (UK Oncology Nursing Society 2017).

Conclusion

A nurse-led clinic service can be an effective and efficient way of managing patients receiving PARP inhibitors and other oral SACTs. When planning to implement a nurse-led clinic it is important to ensure that those responsible for leading and delivering the service have the recommended qualifications. It is also vital to develop a business case which should clearly outline the clinic's aims and objectives, which can then be used as measurable goals. Additionally, involvement in the management of such clinics can be beneficial for nurses' career development and revalidation. Nurse-led clinics have the potential to reduce hospital waiting times and enhance patient confidence and satisfaction in continued care.

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