

The
Health Policy
Partnership
[research, people, action]

Health system readiness for radioligand therapy in the UK

Governance

Working paper

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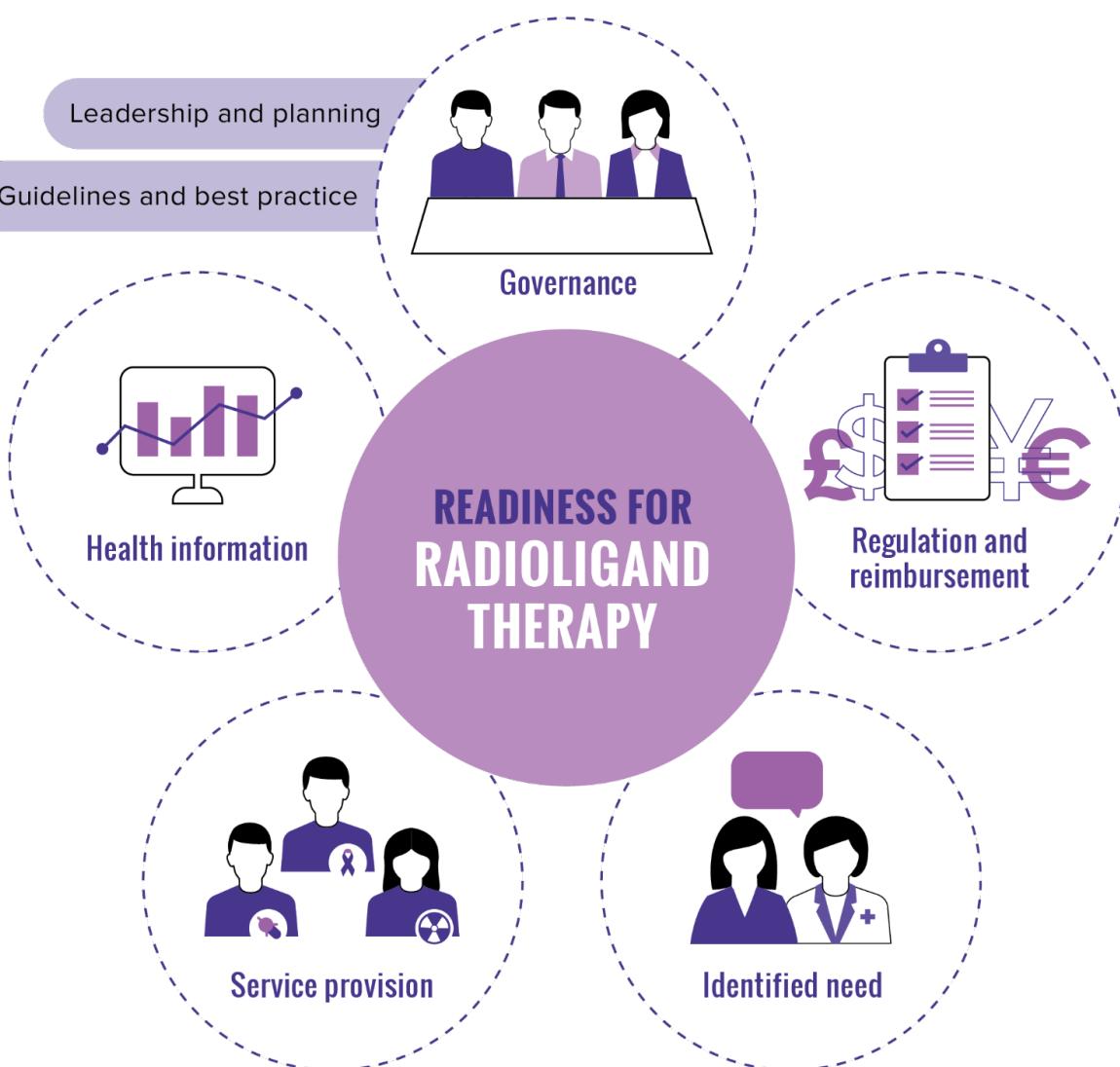
About this working paper

This working paper is part of a broader piece of work aiming to define what is needed to establish system-level readiness for radioligand therapy in the UK. It explores current integration and future readiness for the approach as it relates to governance, one of the five domains of the Radioligand Therapy Readiness Assessment Framework (*Figure 1*). The working paper provides answers to questions from the framework, with key findings from relevant subdomains outlined in a summary assessment at the start of each section. We focus on the situation in neuroendocrine neoplasms, lymphoma and prostate cancer in England, though we also include examples from across the devolved nations. Many of the findings in this paper may be applicable across the UK and in other areas of cancer care.

- This working paper is supported by other documents on health system readiness for radioligand therapy in the UK. For more details, please visit:
www.radioligandtherapy.com/framework/UK

This working paper uses the term **radioligand therapy**, but there are various terms used for the approach, including: peptide-receptor radionuclide therapy (PRRT), systemic radiation therapy, targeted radionuclide therapy, targeted radiotherapy and molecular radiotherapy. When the ligand used is an antibody, the approach is known as radioimmunotherapy.

Figure 1. Domains of the Radioligand Therapy Readiness Assessment Framework



What is governance?

Strong governance reflects and shapes a health system's priorities and practices. Governance is shaped by a country's specific context and history. It is an essential pillar of a well-functioning health system, and provides a system of values within which to act.¹ NHS England describes governance as 'the system through which NHS organisations are accountable for continuously improving the quality of their services and safeguarding high standards of care by creating an environment in which clinical excellence will flourish'.²

The governance of a health system has direct impact on the availability, accessibility and standards of delivery for any therapy, ultimately influencing health outcomes. In cancer care, governance is the means by which services are organised and managed at the macro level.^{3 4} It includes national health strategies and plans that set a clear direction and targets for cancer care, as well as guidelines and protocols informing best practice.

What does good governance look like?

Effective governance for radioligand therapy requires strategic recognition and national leadership, careful planning and well-defined guidance. Planning for radioligand therapy involves establishing national health plans and strategies that consider the approach as a current component of cancer care and commit to its appropriate integration and funding. Plans and strategies should outline short-, medium- and long-term priorities for the use of the therapy, and delineate how greater integration is to be achieved through implementation and monitoring measures. Progress should be regularly assessed, audited and reported in the public domain to ensure accountability. Planning for effective integration of radioligand therapy also involves including it in clinical guidance, which should be actively used in practice.

1 Leadership and planning

Summary assessment

Indicators	Assessment
Is there national leadership and political support for radioligand therapy?	Leadership for radioligand therapy mainly comes from patient organisations and the nuclear medicine and neuroendocrine clinical communities. Political awareness and understanding of radioligand therapy remain very limited.
Are there any cancer strategies or plans in place in the UK that include, or could include, radioligand therapy?	<i>Achieving world-class cancer outcomes: a strategy for England 2015 – 2020</i> commits to further research into radioligand therapy. <i>The NHS Long Term Plan</i> , which builds on the cancer strategy, does not mention radioligand therapy but does commit to providing more personalised care and investing in safer and more precise cancer treatments.
Are there any disease-specific strategies or plans in place in the UK that include, or could include, radioligand therapy?	Neuroendocrine neoplasms (NENs): There are no national plans or strategies for NENs. England's cancer strategy, the <i>UK Strategy for Rare Diseases</i> and <i>The NHS Long Term Plan</i> do not mention NENs, and seldom consider rare and less common cancers. Lymphoma: There are no national plans or strategies for haematological cancers. Lymphoma is briefly mentioned in England's cancer strategy and in <i>The NHS Long Term Plan</i> , but neither mentions treatment of this indication. Prostate cancer: There are no national plans or strategies for prostate cancer. However, prostate cancer is included in England's cancer strategy and in <i>The NHS Long Term Plan</i> ; the former considers treatments, although not radioligand therapy, and the latter does not make reference to prostate cancer treatment.

1.1 National leadership and political support

Leadership for radioligand therapy exists but political commitment to its wider introduction into cancer care is still lacking. Patient organisations play an important role in starting discussions about radioligand therapy. For example, Neuroendocrine Cancer UK has organised educational sessions for healthcare professionals on eligibility criteria and administration of radioligand therapy.⁵ The charity is also campaigning to ensure that all

people with neuroendocrine neoplasms (NENs) receive the most appropriate care,⁶ which may include radioligand therapy. The nuclear medicine community is also active in bringing radioligand therapy to the fore. It has established a dedicated committee to support education and clinical development of radioligand therapy,⁷ prompting consideration of the approach for all people with cancer who may benefit from it. Some referring physicians are aware of radioligand therapy,^{8 9} particularly among the neuroendocrine cancer community. However, awareness remains limited among policymakers and decision-makers.¹⁰

- For more information on healthcare professional awareness of radioligand therapy, read the working paper on [identified need](#).

Multi-sectoral collaboration will help raise the profile of radioligand therapy and facilitate its integration into clinical care. The current lack of political recognition and support contributes to limited funding for the approach and its limited acknowledgement within national cancer priorities. One example of a therapy which has gained widespread political recognition is radiotherapy. Its success demonstrates that political support can be instrumental in facilitating greater integration of a therapy into cancer care (*Real-world example 1*). As occurred in the case of radiotherapy, raising the profile of radioligand therapy needs to be a collaborative effort between all actors involved in cancer care. It requires patient involvement, clinical buy-in and policy engagement. Establishing partnerships with local NHS Cancer Alliances is also important, as these drive change in cancer care and provide local leadership.

Real-world example 1. Radiotherapy as a leading policy priority in cancer care

In 2014, NHS England and Cancer Research UK published a 10-year *Vision for Radiotherapy*,¹¹ a document which has served as a foundation for many successful initiatives, expanding radiotherapy's availability and incorporating it into healthcare policy. It was used to develop a new NHS England service specification for radiotherapy¹² and national policy on access to proton beam therapy for children and young adults.¹³ It has also supported the development of the All-Party Parliamentary Group for Radiotherapy (APPGRT), which brings together MPs and its secretariat, Action Radiotherapy, to support use of radiotherapy and improve access to and funding for the approach.¹⁴ Political support facilitated a 1.5% increase of the national radiotherapy budget by Parliament.¹⁵

The progressive agenda around radiotherapy has enabled the creation of a learning healthcare system for the approach.¹⁶ The system, built by NHS England and 15 partner organisations in 2019, operates a top-down approach in which commissioners are responsible for ensuring that clinical research is translated into policy change.

Political support for radiotherapy has also contributed to its prioritisation in national cancer ambitions. The *NHS Long Term Plan* states it will 'reform specialist commissioning payments for radiotherapy'.¹⁷ As a result, £130 million has been invested in replacing or upgrading over 80 radiotherapy machines across England so far.¹⁸

National service specifications for radioligand therapy can be a source of cohesion, laying out how services will be governed, and by whom, in years to come. In 2013, NHS England developed service specifications for radioligand therapy, which clarify its use in a number of indications, including NENs and lymphoma.¹⁹ The specifications did not include any mention of governance for radioligand therapy services, creating uncertainty around how these services are to be led and by whom. However, the 2019 service specifications for England's Radiotherapy Operational Delivery Networks describe key governance functions and include radioligand therapy in the networks' scope of care provision (*Real-world example 2*).¹² They provide clarity over how radioligand therapy services will be governed within the context of each regional network, thus helping facilitate planning and readiness for the approach.

Real-world example 2. Governance of Radiotherapy Operational Delivery Networks

England's 11 networks for radiotherapy, established in 2019, aim to support the delivery of radiotherapy, including brachytherapy and radioligand therapy.¹² Networks provide system leadership and fulfil NHS England's vision and ambitions for radiotherapy. Each network is governed by an oversight group, which represents stakeholders from the wider cancer system and is chaired by a board member of a local Cancer Alliance. The oversight group is responsible for preparing and delivering annual work programmes, which include a review of current radioligand therapy services and consideration of future service planning requirements. The operational lead for each network is known as a Program Manager. Program Managers from each network meet to discuss and share good practice from their local region.²⁰

1.2 Plans and strategies

England's national cancer strategy commits to further research into radioligand therapy. *Achieving world-class cancer outcomes: a strategy for England 2015 – 2020*²¹ acknowledges the predicted rise in demand for cancer therapies and the complexity of planning for and delivering them – with reference to surgery, radiotherapy, interventional radiology, chemotherapy and systemic treatments. The strategy mentions radioligand therapy, but only in calling for further research investment into the approach.²¹ As radioligand therapy was only approved in the UK in 2018,²² this somewhat limited reference appears appropriate. It is unclear whether further investment was allocated to implement this research ambition.

The NHS Long Term Plan does not mention radioligand therapy but provides opportunities for future inclusion. *The NHS Long Term Plan* is a 10-year strategy, published by NHS England, to make England's health system fit for the future. It builds on recommendations made in England's cancer strategy. One of its ambitions is that 'from 2028, 55,000 more people each year will survive their cancer for at least five years after diagnosis'.¹⁷ Radioligand therapy could support this ambition, as it has been shown to improve overall and progression-free survival as well as quality of life for people with certain cancers.²³⁻²⁸ The plan does not cover specific therapeutic approaches, but it does commit to providing more personalised care and investing in safer and more precise cancer

treatments. This investment could someday include radioligand therapy, which is considered a precision cancer therapy as it delivers radiation directly to specific cells.²⁹

The National Institute for Health and Care Excellence's (NICE) strategy for 2021 to 2026 prioritises rapid evaluation of innovative technologies, which could include radioligand therapy. The five-year plan acknowledges the rapidly evolving health landscape and outlines how NICE will adapt its health technology assessment and guidance development processes to reflect this new environment.³⁰ It highlights that innovative approaches to treatment may need to be evaluated differently from traditional medicinal products. Radioligand therapy is not specifically mentioned; however, a more flexible regulatory environment may help ensure that it is regulated appropriately. The strategy also discusses the growing use of certain personalised and diagnostic medicines, which could include radioligand therapy. The strategy commits to early collaboration with industry, academia and government to help ensure that these innovative therapies can be reviewed appropriately and efficiently.³⁰

- For more information on current regulation of radioligand therapy, read the working paper on [regulation and reimbursement](#).

1.2.1 Neuroendocrine neoplasms

NENs are not included in any national plans or strategies, therefore they receive limited national support in clinical practice. *The NHS Long Term Plan* does not mention NENs.¹⁷ Rare cancers are seldom mentioned within overarching strategies, which means they receive very limited support in clinical practice. In addition, there is no specific national plan for NENs and they are not mentioned in the *UK Strategy for Rare Diseases*,³¹ further limiting policy awareness of people living with this type of cancer.

1.2.2 Lymphoma

Lymphoma is acknowledged in national plans and strategies, but no reference to its treatment is made. England's cancer strategy and *The NHS Long Term Plan* only briefly reference lymphoma. The documents describe survival rates in lymphoma alongside other cancers, indicating that life expectancy and five-year survival are slightly higher in lymphoma than the average of the other cancers shown.^{17 21} Investment in innovative treatments in lymphoma will likely remain limited if this indication is not prioritised in national plans.

1.2.3 Prostate cancer

Prostate cancer has received recognition in all relevant plans and strategies, but the most recent national healthcare plan does not cover specific therapies for prostate cancer. England's 2015 cancer strategy extensively references prostate cancer therapy.²¹ By contrast, none of the ambitions for prostate cancer laid out in *The NHS Long Term Plan*, published in 2019, relate to therapy.¹⁷ The plan aims to support a timed diagnostic pathway for prostate cancer, collect data on people with prostate cancer, and establish a stratified follow-up approach in all NHS trusts. The absence of ambitions for prostate cancer therapy in the plan may act as a barrier to integrating radioligand therapy into prostate cancer care if it is licensed for use in that indication.

1.3 Impact of Brexit

Following Brexit, the European Union's approach to healthcare no longer applies in the UK. For example, the UK is not represented in Europe's Beating Cancer Plan.³² The plan outlines strategies and funding for overcoming cancer and includes reference to radioisotopes.³² Following Brexit, the UK did not contribute to the development of this strategy, and is not committed to enacting the plan. International initiatives can provide valuable representation and funding which may not be available at a national level, particularly for rare cancers such as NENs.³³ Cancer research organisations and charities have emphasised the uncertainty that Brexit poses to collaboration on European research projects.³⁴

- For more information on the impact of Brexit on European research, read the working paper on [health information](#).

2 Guidelines and best practice

Summary assessment

Indicators	Assessment
<p>Do national disease-specific guidelines, published by any UK professional society or health body, include radioligand therapy?</p>	<p>Neuroendocrine neoplasms (NENs): The UK and Ireland Neuroendocrine Tumour Society (UKINETs) recommends that clinicians use the 2017 European Neuroendocrine Tumor Society (ENETS) guidelines for managing NENs. The NICE appraisal published in 2018 provides guidance for the use of radioligand therapy in certain types of NENs; however, the most commonly used guidelines are those from ENETS.</p> <p>Lymphoma: Guidelines published by the British Society for Haematology in 2020 recommend consideration of radioligand therapy in relapsed or refractory follicular lymphoma. However, the most recent 2016 NICE guidelines do not include radioligand therapy, as NICE has never assessed it in this indication.</p> <p>Prostate cancer: Clinical guidelines for the management of prostate cancer, published in 2013 by the British Uro-oncology Group and the British Association of Urological Surgeons' Section of Oncology, do not mention radioligand therapy. Likewise, the 2019 NICE clinical guidelines do not mention radioligand therapy as it has not been approved for use in prostate cancer.</p>
<p>Is there guidance for the delivery of radioligand therapy across clinical indications published centrally by any UK professional societies or other health bodies?</p>	<p>In 2019, the Intercollegiate Standing Committee on Nuclear Medicine developed guidance for the delivery of radioligand therapy in relevant indications, aimed at clinicians. Also in 2019, the British Nuclear Medicine Society developed guidelines aimed at hospital departments and commissioners.</p>

2.1 Neuroendocrine neoplasms

Radioligand therapy is included in European guidelines for NENs and is well established as a treatment in practice in the UK. The 2017 ENETS guidelines are recommended by the UKINETs to guide NENs care as they provide the most comprehensive and up-to-date detail on the management of NENs.³⁵⁻³⁷ These guidelines recommend radioligand therapy for people with inoperable, metastatic, lower-grade NENs, and state that those with higher-grade NENs should also be considered for the approach.³⁷ Other guidelines recommend radioligand therapy for NENs, such as the 2018 NICE technology appraisal guidance for radioligand therapy³⁸ and the European Society for Medical Oncology (ESMO) guidelines.³⁹ However, the ENETS guidelines remain the most commonly used guidelines in the UK.

There is a lack of clarity in national care pathways regarding who should be referred for radioligand therapy and at what point in their care. Care pathways clarify diagnoses, referrals and treatment sequencing. There is no NICE pathway for NENs; however, the UKINETs ‘bitesize’ pathways provide a good indication of when radioligand therapy should be considered for some types of NENs. Formal NICE endorsement of this pathway may help improve national consistency in the use and availability of the therapy.^{40 41}

2.2 Lymphoma

The use of radioligand therapy is addressed in relevant professional clinical guidelines for lymphoma, but the approach is not mentioned in NICE clinical guidance. Professional guidelines for the management of follicular lymphoma were updated by the British Society for Haematology in 2020.⁴² They recommend that radioligand therapy be considered for management of relapsed or refractory follicular lymphoma. However, NICE’s 2016 lymphoma guidelines do not reference radioligand therapy,⁴³ as NICE has never assessed it in this indication.⁴⁴ The absence of radioligand therapy from NICE guidelines, and subsequent lack of NHS funding, has contributed to the decline in its use across England.⁸

Changes in regional guidelines demonstrate the decreasing prominence of radioligand therapy within lymphoma therapy paradigms. Prior to the publication of NICE’s 2016 lymphoma guidance, radioligand therapy was included in certain regional guidelines. For example, the most recent Kent and Medway Cancer Collaborative

guidelines, published in 2014, recommend radioligand therapy as a first-line therapy that can be used in exceptional circumstances or where necessary funding has been approved.⁴⁵ However, the approach is not included in some more recent regional guidelines, such as the 2018 Pan-London Haemato-Oncology Clinical Guidelines and the 2019 Greater Manchester Lymphoma Guidelines.^{46 47} The exclusion of radioligand therapy from regional guidelines coincides with publication of NICE's 2016 guidance and pharmaceutical companies' decreased interest in promoting the approach in lymphoma care.⁸ This demonstrates the importance of national guidance and commercial interest to ensure successful integration of therapies into clinical care.

2.3 Prostate cancer

Radioligand therapy has not been licensed for use in prostate cancer in the UK and is not included in professional or NICE guidelines. This is to be expected as the therapy is still under investigation in prostate cancer, and NICE does not include non-licensed therapies in its guidance. As with all NICE guidance, the prostate cancer guidance is scheduled to be assessed every five years to determine whether it needs updating.⁴⁸ In between these assessments, NICE tracks ongoing studies and research to enable quick reactions to changes in evidence.⁴⁸ In its strategy for 2021–26, NICE further commits to developing and updating guidance more quickly.³⁰ This commitment should help ensure that radioligand therapy is incorporated into guidelines relatively rapidly if approved. In contrast, the British Uro-oncology Group and the British Association of Urological Surgeons' Section of Oncology guidelines were most recently published in 2013. They do not usually include non-licensed therapies, and therefore do not include radioligand therapy.⁴⁹ Should radioligand therapy be licensed in prostate cancer, it will be important that these professional guidelines are updated to reflect that.

European clinical guidelines, which refer to radioligand therapy in an investigational context, are used in prostate cancer care in the UK. Prostate cancer guidelines developed by the European Association of Urology, European Association of Nuclear Medicine, European Society for Radiotherapy and Oncology, European Society of Urogenital Radiology and International Society of Geriatric Oncology in 2020 refer to radioligand therapy for investigational use, and state that it could be used as second-line

therapy to treat metastatic prostate cancer.⁵⁰ Where clinicians rely on both European and national guidelines, differences in guidance may result in inconsistent care.

2.4 Guidance for the delivery of radioligand therapy

Nuclear medicine groups have developed guidance for the delivery of radioligand therapy in NENs, lymphoma and prostate cancer, among other indications. In 2019, the Intercollegiate Standing Committee on Nuclear Medicine (ICSCNM) developed clinical guidelines for healthcare professionals on the delivery of radioligand therapy.⁵¹ The guidelines define training, roles and responsibilities of professionals involved in delivering the therapy and describe requirements for ensuring appropriate infrastructure. The same year, the British Nuclear Medicine Society (BNMS) published guidelines for radioligand therapy to help hospital departments formulate local protocols and commissioners establish quality and performance standards.⁵² These guidelines define the roles and responsibilities of professionals involved in the approach, as well as dosimetry, radioactive waste management, patient preparation and workforce training. Both guidance documents were developed after significant experience delivering radioligand therapy in the UK and are therefore expected to be up to date with the most recent scientific advances. Their existence will help ensure consistent and safe delivery of radioligand therapy as the approach is approved in new indications.

Upcoming changes to the NHS support multidisciplinary collaboration, which may ease integration of radioligand therapy into clinical practice. As evident in the BNMS and ICSCNM guidelines, delivery of radioligand therapy requires the collaboration of numerous clinical specialties, from diagnosis through to delivery and post-therapy care. To enable this collaboration, we need overarching clinical structures that support multidisciplinary working. In a recent white paper, the Department of Health and Social Care outlined changes to the NHS that aim to support greater collaboration across specialisms.⁵³ The increased integration of different specialists into care pathways has the potential to improve delivery of radioligand therapy.

- For more information on available radioligand therapy data, read the working paper on [health information](#).
- For more information on the roles of healthcare professionals involved in radioligand therapy, read the working paper on [service provision](#).

Conclusion

Radioligand therapy is relatively well integrated into certain areas of system governance, but a number of important barriers need to be addressed. Radioligand therapy is, or could readily be, integrated into certain aspects of the health system's governance. For example, leadership for the approach exists and *The NHS Long Term Plan* commits to more personalised care and precise cancer treatment, which could eventually include radioligand therapy. However, there are important governance-related system deficiencies to be considered, such as limited political awareness and understanding of radioligand therapy in NENs and lymphoma. This contributes to limited acknowledgement of the approach within national cancer priorities and general lack of investment.

Establishing readiness for radioligand therapy will require greater political recognition of the approach and its value in cancer care. Multidisciplinary collaboration and consensus on the optimal use of radioligand therapy for different indications is needed to make a compelling case to policymakers and decision-makers for its greater integration into cancer care. Learning from the success of multidisciplinary care in NENs and leveraging the prioritisation of personalised and multidisciplinary care already present within England's NHS reform may help. The combination of efforts may facilitate its inclusion in national cancer ambitions and, as a result, its implementation in clinical practice.

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