



NATIONAL OPTIMAL PATHWAY FOR LUNG CANCER: 2nd EDITION (2022)

Point of Suspicion to First Definitive Treatment in Adults (aged 16 and over)

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FOREWORD

The NHS Wales National Optimal Pathways (NOPs) have been developed as part of the Single Cancer Pathway (SCP) programme of work. They aim to establish consistent generic and site-specific pathways that describe all routes of entry, from the point of suspicion (PoS) of cancer. They describe good practice diagnostic and treatment pathways, the diagnostic pathway, including staging, should be performed within 28 days from PoS; and definitive treatment commenced within 21 days from date of Decision to Treat (DTT). The pathways also describe where patients should receive consistent information and support, tailored to meet their needs.

The NOPs aim to provide a platform to standardise care, reduce unwarranted variation and drive improvement whilst increasing quality across each of the cancer pathways in order to:

- meet the SCP cancer waiting time of 62 days for patients presenting with a suspicion of cancer,
- improve cancer patient experience, and,
- improve cancer patient outcomes throughout Wales to that comparable with the best outcomes in Europe.

The Lung Cancer NOP is designed to help lung cancer service providers and their commissioners see the basic structure of an effective and efficient lung cancer pathway. It has adopted many of the recommendations made in the UK National Optimal Lung Cancer Pathway (NOLCP), developed following wide stakeholder consultation by the Clinical Expert Group for Lung Cancer, NHSE in 2017¹. In essence, it is about ensuring that each stage of the pathway happens quickly, that communications with patients are effective and that the entire lung team works in a coordinated but flexible way, focusing always on the patient's journey. It is recognised that the introduction of the National Optimal Pathway for Lung Cancer may present challenges for the Lung Cancer multidisciplinary teams. However, introducing a nationally agreed, clinically endorsed pathway will support service improvement. They will also provide clarity and consistency for primary care around the referral process into secondary care, including access to diagnostics, to ensure the patients move through the system in a timely manner.

GROUP CONSULTATION

The first edition of the National Optimal Pathway for Lung Cancer (2019) was developed and led by Dr Gareth Collier and Dana Knoyle. This standardised approach to the management of patients with lung cancer was developed with representation from the full range of professionals involved in delivering lung cancer services. Workshops were held with the Clinical Nurse Specialists (CNS) and Allied Health Professional (AHP) members to embed rehabilitation and Person-Centred Care (PCC) into the pathway, ensuring all patient's needs are assessed and met in a timely manner. Wider consultation was sought in May and June 2019 from NHS Wales's stakeholders, including National Imaging and Pathology Networks and the third sector prior to a final version being issued in July 2019. Initially published in July 2019, the NOPLC has been firmly embedded into a working pathway for Lung Cancer MDTs across Wales.

This second edition (2022) of the NOLCP reflects the changing developments in the treatment of lung cancer since the NOLCP was first described. A standardised approach to molecular and genetic testing of biopsies allows patients with both early and advanced stage lung cancer to benefit from an increasing range of novel therapies and improve access to clinical trials.

Dr Craig Dyer (CSG Lead Clinician)

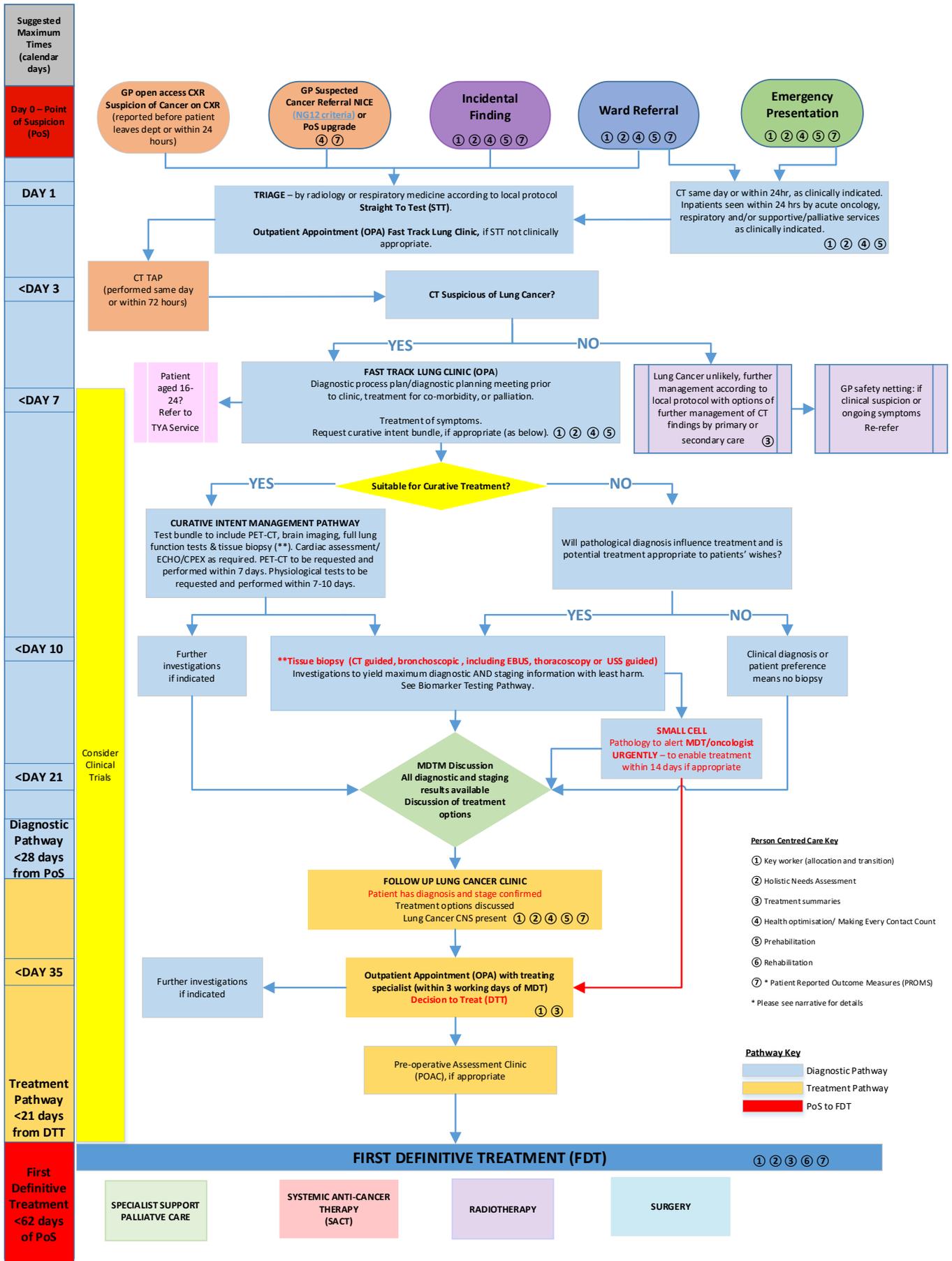
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Date 01/02/2022

¹ https://www.cancerresearchuk.org/sites/default/files/lung_cancer_implementation_guide_august_2017.pdf

National Optimal Cancer Pathway for suspected and confirmed Lung Cancer: Point of Suspicion (PoS) to First Definitive Treatment (FDT) for adult patients (aged 16 and over)



BIOMARKER TESTING PATHWAY

At the time of drafting the first version of the NOPLC in 2019, standard practice recommended biomarker testing at the point of diagnosis for locally advanced or metastatic NSCLC adenocarcinomas. This allowed MDTs to select the most appropriate systemic treatment. At the time of writing the initial document, testing was limited to a relatively small number of biomarkers (PDL1 and genomic testing to include EGFR, ALK, and ROS1).

This second edition of the NOPLC recognises the subsequent rapid development in biomarker testing and treatments available. The number of clinically actionable variants in NSCLC has rapidly increased (EGFR, KRAS, BRAF, ALK, ROS1, RET, MET, NTRK^{2,3,4}), with a range of new targeted therapies available to be fast-tracked for approval in routine clinical care and genomic-enabled clinical trials are opening for patient recruitment at pace^{2,3}. Biomarker testing is indicated in patients undergoing radical treatment as both targeted therapies and immunotherapy are now systemic treatment options in the adjuvant setting^{4,5,6}. The National Genomic Test Directory sets out the recommendations for genomic testing within the NHS⁷ and all lung cancer patients in Wales can now access state-of-the-art 500 gene DNA and RNA Next Generation Sequencing (NGS) panels, enabling comprehensive molecular testing and future-proofing the testing service as and when new targets become clinically relevant⁸.

The move towards personalised medicine is a welcome development in this second edition of the NOPLC. It aims to help improve outcomes for Welsh patients diagnosed with lung cancer and aligns local practice with international recommendations^{9,10}. The aim of a well-defined biomarker testing strategy is to standardise practice across the country, recognising that reflex genomic testing at the point of diagnosis regardless of tumour stage is an integral part of the NOPLC and wider NHS plans for cancer care¹¹. Benefits include improved equity of patient access to testing, treatment and clinical trials as well as guiding discussions regarding prognosis, treatment sequencing and follow-up strategies.

This is the first step in an ongoing programme of work to address the resource requirements and turnaround times associated with biomarker testing. It is anticipated that this pathway will provide clarity to individual MDTs and act as national benchmark to continue develop best practice.

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Date 01/02/2022

² Kerr et al. The evolving landscape of biomarker testing for non-small cell lung cancer in Europe. *Lung Cancer*. 2021; 154:161-175.

³ Medicines and Healthcare products Regulatory Agency. Guidance on Project Orbis. 2020. Retrieved from: <https://www.gov.uk/guidance/guidance-on-project-orbis>

⁴ NICE. Durvalumab for treating locally advanced unresectable non-small-cell lung cancer after platinum-based chemoradiation. Technology appraisal guidance [TA578]. 2019. Retrieved from: <https://www.nice.org.uk/guidance/ta578/chapter/1-Recommendations>

⁵ FDA. FDA approves atezolizumab as adjuvant treatment for non-small cell lung cancer. 2021. Retrieved from: <https://www.fda.gov/drugs/resources-information-approved-drugs/fda-approves-atezolizumab-adjuvant-treatment-non-small-cell-lung-cancer>

⁶ NICE. Osimertinib for adjuvant treatment of EGFR mutation-positive non-small-cell lung cancer after complete tumour resection. Technology appraisal guidance [TA761]. 2022. Retrieved from: <https://www.nice.org.uk/guidance/ta761/chapter/1-Recommendations>

⁷ NHS England. National Genomic Test Directory for cancer. 2021. Retrieved from: <https://www.england.nhs.uk/publication/national-genomic-test-directories/>

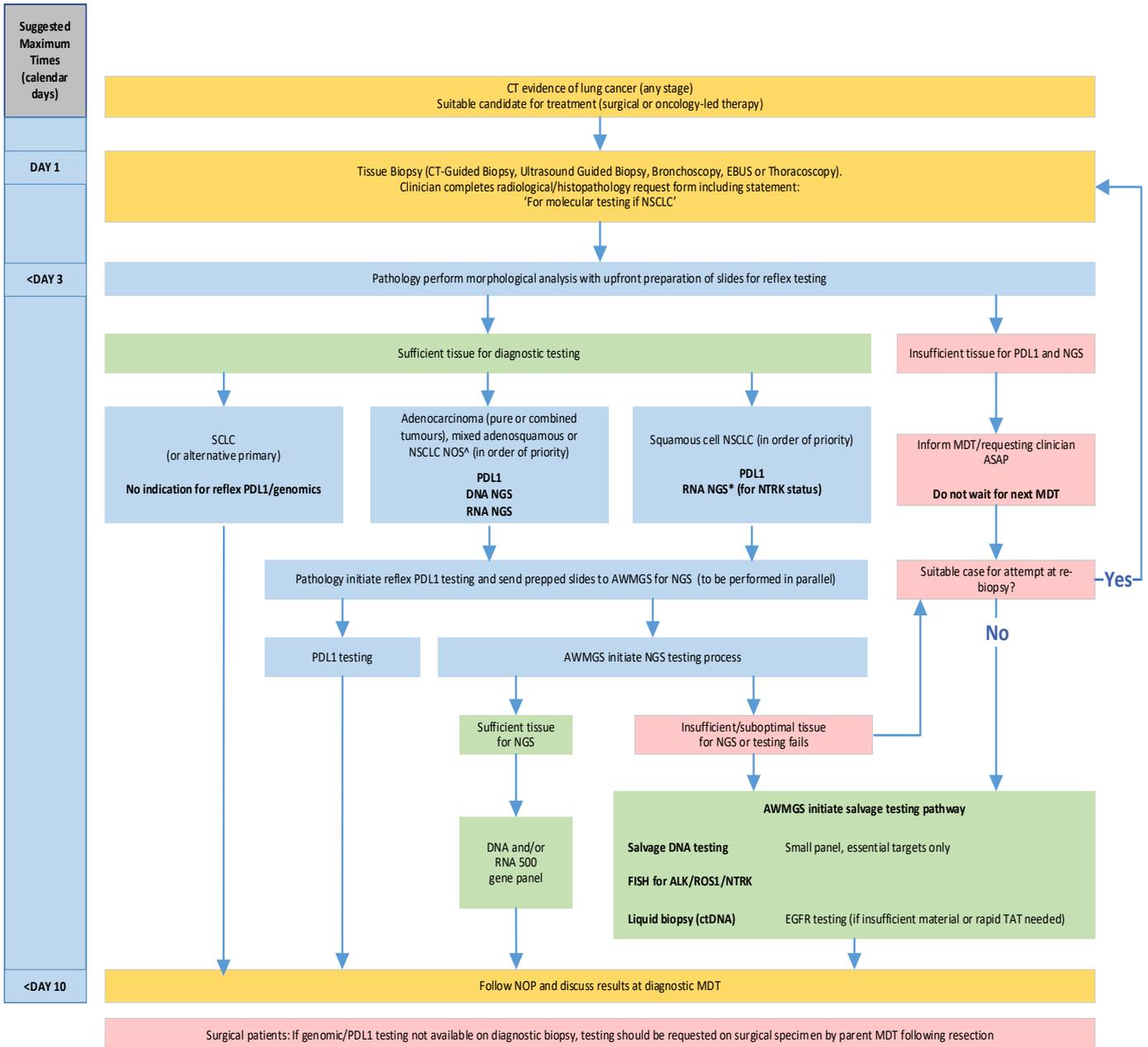
⁸ All Wales Medical Genomics Service. CYSGODI Service Information Sheet. 2021. Retrieved from: <https://medicalgenomicswales.co.uk/images/CYSGODI/PD-GEN-CYSGODIinfo.pdf>

⁹ Mosele et al. Recommendations for the use of next-generation sequencing (NGS) for patients with metastatic cancers: a report from the ESMO Precision Medicine Working Group. *Ann Oncol*. 2020 Nov;31(11):1491-1505. doi: 10.1016/j.annonc.2020.07.014. Epub 2020 Aug 24. PMID: 32853681.

¹⁰ Aggarwal et al. Molecular testing in stage I-III non-small cell lung cancer: Approaches and challenges. *Lung Cancer*. 2021; 162:42-53.

¹¹ Department of Health and Social Care. Genome UK: 2021-2022 implementation plan. Retrieved from: <https://www.gov.uk/government/publications/genome-uk-2021-to-2022-implementation-plan/genome-uk-2021-to-2022-implementation-plan#pillar-1-diagnosis-and-personalised-medicine>

Biomarker Testing Pathway



*DNA NGS should be considered if clinical characteristics associated with high probability of driver mutation (never or minimal smokers, young age)

^aBoth DNA and RNA NGS should be considered in any pure or combined tumours with adenocarcinoma e.g. large cell neuroendocrine tumour with adenocarcinoma features

DEFINITIONS

Decision to Treat	<p>The DATE on which a Decision To Treat is made. For the cancer data sets, the DECISION TO TREAT DATE is the DATE that the consultation between the PATIENT and the clinician took place and a Planned Cancer Treatment was agreed.</p> <p>Source: NHS Data Dictionary</p>
Direct to Test	<p>GPs have direct access to diagnostic endoscopy, ultrasound, MRI, X-ray and CT for people suspected of cancer.</p> <p>Source: National Institute for Health and Care Excellence, Quality Standard 2016 (QS 124)</p>
First Definitive Treatment	<p>First Definitive Treatment is the first CLINICAL INTERVENTION intended to manage a PATIENT's disease, condition or injury and avoid further CLINICAL INTERVENTIONS. What constitutes First Definitive Treatment is a matter of clinical judgement in consultation with others, where appropriate, including the PATIENT.</p> <p>Source: NHS Data Dictionary</p>
Next Generation Sequencing (NGS)	<p>The advent of next generation sequencing (NGS) technology has revolutionised the scale at which genetic testing can be performed, enabling the analysis of many more genes within the same assay. This allows multiple variants (mutations) to be detected per sample. Large gene panel tests (>500 genes) for cancer testing are rapidly being adopted in the UK.</p> <p>Source: Genome UK: the future of healthcare 2020</p>
Safety Netting	<p>“Safety netting is a management strategy of patients, tests and referrals used in the context of diagnostic uncertainty in healthcare. It aims to ensure patients are monitored until signs and symptoms are explained or resolved.”</p> <p>Source: Royal College General Practitioners</p>
Straight to Test	<p>“Following clear referral criteria into secondary care (usually NICE guidance) the secondary care clinician (defined as per local protocol) will arrange a diagnostic procedure as the first episode of care in place of an outpatient episode. The clinician will retain clinical responsibility for the result including acting on the result.”</p> <p>Source: Delivering Cancer Waiting Times NHSE</p>
Teenagers and Young Adults (TYA) Service	<p>Young people (aged 16-24 years) with cancer have their diagnosis treatment and support agreed and delivered by a cancer-site specific multidisciplinary team and a teenage and young adult multidisciplinary team.</p> <p>Source: National Institute for Health and Care Excellence (NICE), 2014. Cancer services for children and young people (QS55)</p>

CLINICAL EVIDENCE

<p>Point of Suspicion/ Referral</p>	<p>Single Suspected Cancer Pathway Definitions (December 2018)</p> <p>National Institute for Health and Care Excellence (NICE) NG12 Suspected Cancer Referral Guidance</p> <p>Cancer Risk Assessment Tool (RAT)</p> <p>Q Cancer Risk Assessment Tool</p>
<p>Diagnosis and Management</p>	<p>National Institute for Health and Care Excellence (NICE) NG122 guidance for investigation and management of lung cancer</p> <p>Improving diagnostic pathways for patients with suspected lung cancer. Final report. Accelerate, Coordinate, Evaluate (ACE) Programme</p> <p>Straight to CT - Quick reference guide. Accelerate, Coordinate, Evaluate Programme (ACE)</p> <p>United Kingdom Lung Cancer Coalition: Millimetres Matter – Implementing the UK National Optimal Lung Cancer Pathway (November 2018)</p> <p>United Kingdom Lung Cancer Coalition: Molecules Matter – Turning the Science of Molecular Diagnostics in Lung Cancer into Practical Service for All Patients</p>

PERSON CENTRED CARE

Person-centred cancer care is culturally embedded and supported by a common approach to assessing and managing people’s needs and care should be Co-produced to ensure people affected by cancer to achieve the outcomes that matter to them’ (Cancer Quality Statement, 2021).

<p>Key Worker</p>	<p>QS 14: Patients are made aware of who to contact, how to contact them and when to make contact about their ongoing healthcare needs. National Institute for Health & Care Excellence (NICE, 2012) CG138 Clinical Guideline: Patient Experience in adult NHS services</p> <p><i>A cancer key worker is “a person who, with the patient’s consent and agreement, takes a key role in coordinating the patient’s care and promoting continuity, ensuring the patient knows who to access for information and advice”.</i></p> <ol style="list-style-type: none"> 1. All cancer patients must have an allocated key worker 2. Allocation / Review of key worker to take place at key time points including: <ol style="list-style-type: none"> a. Around the time of diagnosis <i>*please note: allocation of key worker may occur earlier than time of diagnosis, if there is a very high level of suspicion of cancer e.g. evidence obtained via pathology, radiology, endoscopy.</i> b. Commencement of treatment 3. When not under active management by the cancer MDT, the Key worker would be a member of the primary care team. This involvement is critical as many patients living with cancer also live with 2 or more other chronic conditions. <p>Key workers for cancer patients (Welsh Health Circular /2014/001) GOV.WALES Welsh Government. Cancer Delivery Plan for Wales 2016-2020.</p>
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<p>Holistic Needs Assessment and Associated Care Plan</p>	<p>QS 4: Patients have opportunities to discuss their health beliefs, concerns and preferences to inform their individualised care.</p> <p>QS 10: Patients have their physical and psychological needs regularly assessed and addressed, including nutrition, hydration, pain relief, personal hygiene and anxiety. National Institute for Health & Care Excellence (NICE, 2012) CG138 Clinical Guideline: Patient Experience in adult NHS services</p> <p>Assessment and discussion of patients’ needs for physical, psychological, social, spiritual and financial support should be undertaken at key points including:</p> <ul style="list-style-type: none"> • Around diagnosis <i>*please note: undertaking a Holistic Needs Assessment may occur earlier than time of diagnosis, if there is a very high level of suspicion of cancer e.g. evidence obtained via pathology, radiology, endoscopy; and it is supported by professional judgement.</i> • At commencement, during, and at the end of treatment. <p>National Institute for Clinical Excellence (NICE, 2004) CSG4 Improving Supportive & Palliative care for adults with cancer</p> <p>Ideally Holistic Needs Assessments should be undertaken electronically. Welsh Government. Cancer Delivery Plan for Wales 2016-2020. The Macmillan eHNA is <i>one</i> tool which is both valid and reliable. Snowden A & Fleming M (2015) Validation of the electronic HNA.</p>
<p>Health Optimisation / MECC</p>	<p>QS 9: Patients experience care that is tailored to their needs and personal preferences, taking into account their circumstances, their ability to access services and their coexisting conditions. National Institute for Health & Care Excellence (NICE, 2012) CG138 Clinical Guideline: Patient Experience in adult NHS services</p> <p>Health Optimisation refers to a proactive approach to supporting people who present to NHS services with concurrent comorbid health conditions (e.g. anaemia, diabetes), or health risk behaviours (e.g. smoking, physical inactivity). Welsh Government (2018) A Healthier Wales. Welsh Government (2015) Wellbeing of Future Generations Act.</p> <p>Making Every Contact Count (MECC), is a behaviour change approach that helps health and social care professionals to help people to improve their health and wellbeing through prevention and early intervention. Public Health Wales Strategic Plan 2018-2021</p> <p><i>Lifestyle advice / resources are available from Making Every Contact Count (MECC)</i></p> <p><i>*Please note: Whilst addressing concurrent comorbidities and health risk behaviours is the responsibility of all health and social care professionals, at every contact throughout the pathway; earliest possible intervention may impact on cancer treatment choices / outcomes (especially in respect to tobacco smoking).</i> National Institute for Clinical Excellence (NICE, 2018) NG92 NICE Guideline Stop Smoking Interventions and services.</p>
<p>Prehabilitation</p>	<p>Patients should have the opportunity to take part in evidence-based education and rehabilitative activities, including self-management programmes, <i>where available</i>, that promote their ability to manage their own health if appropriate. National Institute for Health & Care Excellence (NICE, 2012) CG138 Clinical Guideline: Patient Experience in adult NHS services Welsh Government (2018) A Healthier Wales. Welsh Government (2015) Wellbeing of Future Generations Act. The Quality Statement for Cancer.</p>

<p>Rehabilitation</p>	<p>All patients will have their needs for rehabilitation services assessed, with referral to an appropriate level of rehabilitative support, throughout the patient pathway.</p> <p><i>*Please note: not all patients will require specialist cancer rehabilitation services. Referral into non-cancer rehabilitation, self-management, and fitness services may be suitable to meet some patients' needs.</i></p> <p>National Standards for Rehabilitation of Adult Cancer Patients (2010) GOV WALES National Institute for Health and Care Excellence (NICE) CSG4 (2004) resources for improving supportive and palliative care for adults with cancer.</p>
<p>Patient Reported Outcome Measures (PROMs) / Patient Reported Experience Measures (PREMs)</p>	<p>Patient Reported Outcome Measures (PROMs) are questionnaires that patients are asked to complete before and after treatment to assess the impact on health and wellbeing.</p> <p><i>Some</i> of the Cancer Site Groups (CSGs) have been working with the International Collaboration for Health Outcome Measurement (ICHOM), Value Based Healthcare Team, National PROMS, PREMS, & Effectiveness Programme (NPP&EP) and other partners, to pilot tools and data capture methods, which will inform a consistent approach to PROMS & PREMS for cancer. The Quality Statement for Cancer</p> <p><i>*Please note: there are outstanding questions relating to tool selection, data capture intervals, data capture methods and data analysis / reporting which may prevent the implementation of PROMS & PREMS across all pathways at this time. PROMS & PREMS have been included in the pathways, in recognition of this work, and will be updated pending further advice from the CSGs.</i></p> <p>Patient Reported Experience Measures (PREMs) are questionnaires that patients are asked to complete at any time during their pathway to help professionals to understand their experience of NHS services. This information is crucial to understanding the value of healthcare as perceived by patients. Welsh Government (2018/19). Chief Medical Officer Annual Report</p> <p><i>*Please Note: Whilst it is good practice to collect PREMS throughout the pathway, there is no current standard for cancer PREMS in Wales; further advice regarding this will be sought via the CSGs in due course.</i></p>