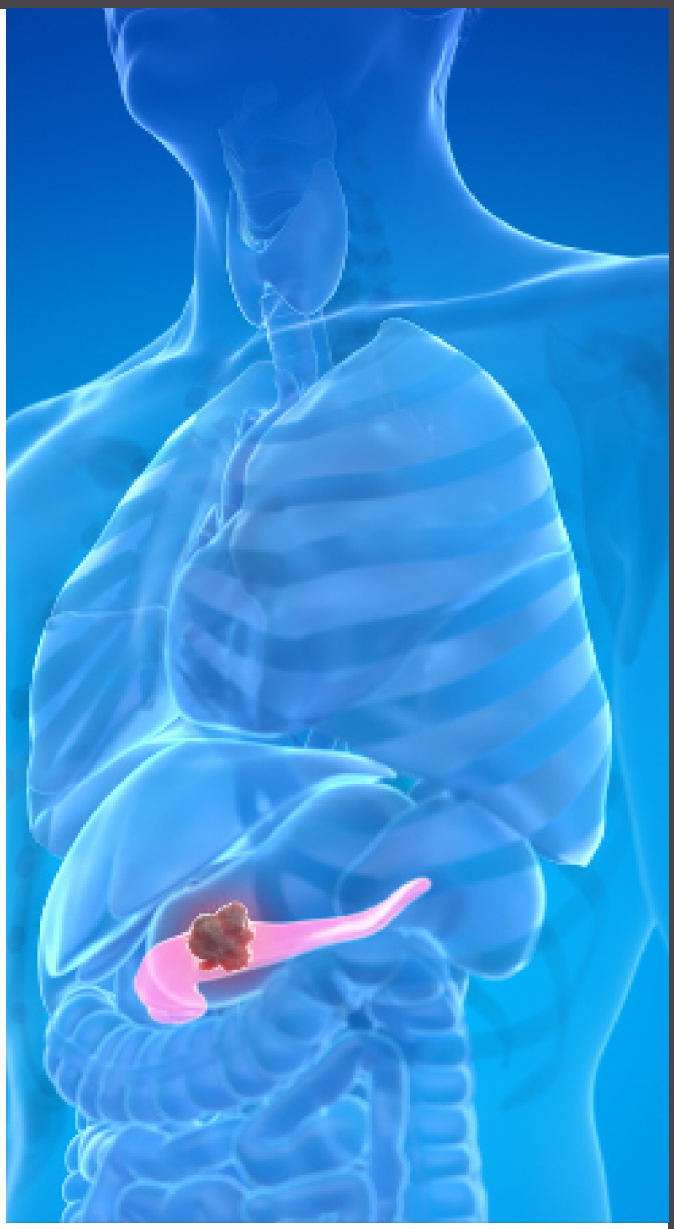
NPaCA
National Pancreatic Cancer Audit

National Pancreatic Cancer Audit

Scoping Document

November 2023



NATCAN
National Cancer Audit Collaborating Centre

Royal College of Surgeons of England
ADVANCING SURGICAL CARE

LONDON SCHOOL of HYGIENE &TROPICAL MEDICINE

NHS England

HQIP
Healthcare Quality Improvement Partnership

NDRS
NATIONAL DISEASE REGISTRATION SERVICE

GIG CYMRU NHS WALES
Rhwydwaith Canser Cymru
Wales Cancer Network

NPaCA
National Pancreatic Cancer Audit

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HQIP
Healthcare Quality Improvement Partnership

The National Cancer Audit Collaborating Centre (NATCAN) is commissioned by the Healthcare Quality Improvement Partnership (HQIP) as part of the National Clinical Audit and Patient Outcomes Programme (NCAPOP). NATCAN delivers national cancer audits in non-Hodgkin lymphoma, bowel, breast (primary and metastatic), oesophago-gastric, ovarian, kidney, lung, pancreatic and prostate cancers. HQIP is led by a consortium of the Academy of Medical Royal Colleges, the Royal College of Nursing, and National Voices. Its aim is to promote quality improvement in patient outcomes, and in particular, to increase the impact that clinical audit, outcome review programmes and registries have on healthcare quality in England and Wales. HQIP holds the contract to commission, manage and develop the National Clinical Audit and Patient Outcomes Programme (NCAPOP), comprising around 40 projects covering care provided to people with a wide range of medical, surgical, and mental health conditions. The programme is funded by NHS England, the Welsh Government and, with some individual projects, other devolved administrations and crown dependencies.
https://www.hqip.org.uk/national-programmes

Executive summary

The National Pancreatic Cancer Audit (NPaCA) has been commissioned to evaluate pancreatic cancer care delivered in NHS hospitals across England and Wales. It aims to help NHS organisations to benchmark their pancreatic cancer care against measurable standards, to identify unwarranted variation in care, and to provide tools to help services improve quality of care for people with pancreatic cancer.

To develop the scope of the audit and identify priority areas for quality improvement, the NPaCA team carried out 1) a review of clinical guidelines, existing audits/registries and literature relevant to pancreatic care, and 2) consultations with key stakeholders, including clinical experts, allied health professionals, patient groups and charities, and representatives from NHS England and NHS Wales. These activities built on a feasibility study conducted by the National Oesophago-Gastric Cancer Audit in 2022, which comprised a stakeholder survey and review of potential quality indicators for an audit of pancreatic cancer.

Based on this work, NPaCA proposes to include all adults diagnosed with exocrine pancreatic cancer in England and Wales (including those with radiologic or clinical diagnoses), plus those with tumours of the extrahepatic bile duct and ampulla of Vater. The audit will cover the care pathway from first diagnosis of pancreatic cancer to the end of primary treatment, including treatments with and without curative intent. Treatment pathways will be reported by intent, and type of treatment where appropriate.

Several areas for quality improvement along the pancreatic cancer care pathway were identified during the scoping exercise. The following were highlighted as potential priorities for the audit to address:

- Reducing variation in use of diagnostic procedures
- Reducing time between diagnosis and start of treatment
- Understanding current treatment patterns
- Reducing variation in access to palliative / non-surgical treatment
- Improving consistency in provision of supportive care.

These QI priorities will inform the development of NPaCA's Healthcare Improvement Plan, alongside further consultation with key stakeholders via the audit's Clinical Reference Group and Patient & Public Involvement Forum.

Table of Contents

1. Introduction

This document sets out the scope of the National Pancreatic Cancer Audit (NPaCA), including:

- **Clinical scope:** inclusion criteria to determine patient eligibility and the parts of the patient pathway that will be covered by the audit.
- **Quality improvement:** potential priority areas for quality improvement in pancreatic cancer care, to inform the development of healthcare improvement goals.

The NPaCA is one of six new national cancer audits that will be delivered by the National Cancer Audit Collaborating Centre (NATCAN), which was established to strengthen National Health Service (NHS) cancer services across England and Wales (Appendix 1).

The audit will support NHS organisations to benchmark their practice against measurable standards, identify unwarranted variation in practice and provide tools to help NHS pancreatic cancer services to improve the quality of care received by patients. It will publish annual State of the Nation reports, which present an overall picture of care and outcomes as measured by the audit performance indicators. In addition, to support ongoing local quality improvement, the audit will publish quarterly online dashboards presenting the audit performance indicator findings for all NHS organisations in England and Wales who provide pancreatic cancer services.

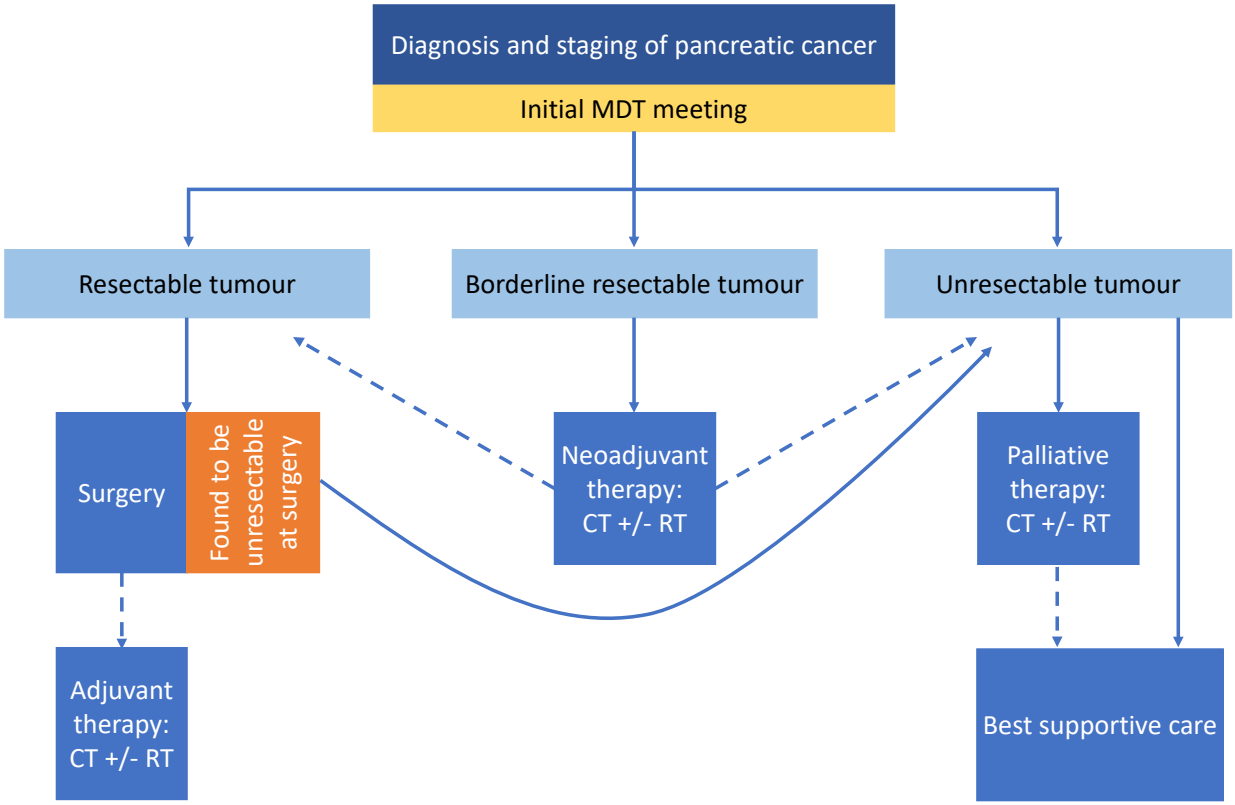
To develop the scope of the audit and identify priorities for the audit, the NPaCA Team (Appendix 2) has carried out a review of pertinent guidelines and relevant literature, as well as consulting with key stakeholders. This has extended an earlier feasibility study on an audit of pancreatic cancer undertaken by the National Oesophago-Gastric Cancer Audit (Appendix 3).

2. Background on pancreatic cancer

Pancreatic cancer is the 10th most common cancer in the UK, with approximately 10,500 people diagnosed each year.[1]

Early stage pancreatic cancer does not typically produce symptoms. Consequently, pancreatic cancer is often diagnosed at a late stage (III or IV) and only 25% of patients will survive for at least one year after they are diagnosed.[2]

The management of pancreatic cancer is becoming increasingly complex and involves a variable sequence of treatments which are individualised to each patient (Figure 1). Patients who are diagnosed with a tumour that has not spread beyond the pancreas (and does not involve important local blood vessels) will have surgery, if fit, followed by systemic anti-cancer therapy (such as chemotherapy) with or without radiotherapy. A tumour can be classified as borderline resectable (if local ateries and veins are involved). In this scenario patients may receive systemic therapy with or without radiotherapy (with the aim of shrinking the tumour) prior to surgery. Patients who have advanced disease (precluding surgery) may receive treatments aimed at extending life and/or managing symptoms caused by the cancer.



CT: chemotherapy; MDT: Multi-disciplinary team; PS: performance status; RT: radiotherapy

NOTE: Dashed lines indicate variations or alternative steps in pathways; some patients may not proceed along these routes

Figure 1: Sequence of steps in common pancreatic cancer pathway, from diagnosis to treatment, in English and Welsh NHS organisations

Pancreatic cancer care in England and Wales is organised around specialist centres, where specialist multidisciplinary teams review new diagnoses of pancreatic cancer, plan treatment, and conduct surgical resections for eligible patients. There are 23 specialist hepatopancreaticobiliary (HPB) centres in England, and one surgical and two oncology specialist centres in Wales.[3] This centralised service model was implemented following the publication of national guidance in 2001, which recommended that specialist teams for pancreatic cancer serve populations of two to four million, to ensure the teams reach minimum treatment volumes associated with improved outcomes.[4]

Preliminary analyses of Hospital Episode Statistics data by the NPaCA team confirmed that almost all pancreatic cancer surgeries in England (99.7%) take place at one of the 23 specialist centres.

2.1 Guidelines on the management of pancreatic cancer care

There are several UK-specific guidelines relevant to pancreatic cancer care, which were reviewed as part of the set-up of NPaCA and are referenced where applicable within this scoping document:

- NICE Guideline NG85: "Pancreatic cancer in adults: diagnosis and management" [5]
- NICE Quality Standard QS177: "Pancreatic cancer quality standard" [6]
- NICE Guideline NG12: "Suspected cancer: recognition and referral" [7]

- NHS England Clinical Commissioning Policy Statement: “Stereotactic ablative body radiotherapy for patients with locally advanced, inoperable, non-metastatic pancreatic carcinoma”. [8]

Clinical guidelines have been regularly updated to reflect the evolution of pancreatic cancer care, which may involve a combination of modalities: surgery, systemic anti-cancer therapy, radiotherapy, endoscopic treatments, and pancreatic enzyme replacement therapy (PERT). There are ongoing developments within each of the different modalities. For example, the range of available systemic anti-cancer therapies is expanding, with new targeted therapies being developed for individualised genetic and molecular tumour profiles. Other changes include an increasing use of neoadjuvant systemic anti-cancer therapy over the last decade.

Guidance is also available on the organisation of services. In Wales, the NHS Wales National Optimal Pathways (NOPs) programme produced guidance to support pancreatic cancer services in establishing an effective and efficient pancreatic cancer pathway.[9] It covers the pathway from diagnosis, staging and the various treatment options, as well as highlighting when patients should receive information and support to meet their individual needs.

The NPaCA team identified a number of existing pancreatic cancer audits and registries, including projects in Scotland, Northern Ireland, the Netherlands, Sweden, Germany, and the USA. Please see Appendix 3 for more information.

2.2 Evidence of variation in the care of pancreatic cancer

Patterns of care provided to patients with pancreatic cancer have been reported to vary across England and Wales. [10] The National Pancreatic Cancer Audit has been commissioned as part of NATCAN (Appendix 1) to support NHS organisations to benchmark their practice, identify underlying causes of variation, and plan ways to improve the quality of care received by patients with pancreatic cancer.

In its 2020 report [11], the charity Pancreatic Cancer UK (PC-UK) highlighted the results from the global surveillance of trends in cancer survival 2000–14 (CONCORD-3), [12] which noted the UK was ranked 29th out of 33 countries for five-year survival for pancreatic cancer and that other countries had a greater proportion of patients diagnosed with early stage (1 or 2) disease. The PC-UK report went on to highlight:

- regional variation in the distribution of disease stage,
- low rates of surgery with curative intent,
- regional variation in the proportion of patients who had chemotherapy after surgery, and
- regional variation in the proportion of patients who received palliative chemotherapy.

While these figures relate to care delivered before 2020, the evidence highlights various areas of concern.

The COVID-19 pandemic had a major impact on routine care pathways for cancer patients. For patients diagnosed with pancreatic cancer, an evaluation by Lemanska et al. [13] highlighted that the

number of patients diagnosed over time was not affected by the pandemic, but they estimated that the observed proportion of patients having a surgical resection (6 for every 100 people diagnosed) was lower than predicted had the pandemic not occurred (8-9 per 100 people diagnosed).

Variation in prescribing of PERT, a treatment that is recommended for all patients with unresectable pancreatic cancer to manage problems with digesting and absorbing food caused by pancreatic cancer, has been found in two recently published studies. In a prospective study by the RICOCHET Study Group, rates of PERT prescribing in the UK were 74.4% in patients with potentially resectable disease and 45.3% in patients with unresectable disease in 2018.[14] A second study using a primary care database in England estimated prescribing rates in England were far below the expected 100% level, at only 48% nationally in December 2022.[15] Regional rates ranged from approximately 30 to 60%.

3. Stakeholder engagement

The scope of the audit was developed by the NPaCA team in consultation with a range of stakeholders. The following approaches were taken:

- **A feasibility study** for an audit of pancreatic cancer was conducted in 2022 by the National Oesophago-gastric Cancer Audit (NOGCA) team. The study comprised an online stakeholder survey and review of potential quality indicators. Responses were received from a range of stakeholders including medical professionals and the charity Pancreatic Cancer UK. A summary of the results is provided in section 3.1. Full details can be found in Appendix 3.
- **Consultation meeting with the Clinical Reference Group (CRG).** The group was formed for NPaCA, with representation from surgery, medical oncology, clinical oncology, radiology, gastroenterology, palliative care, cancer nurse specialists, HPB specialist dietitians, patient groups, NHS England, and NHS Wales. The first meeting of this group was held in July 2023 and formed part of the audit's scoping exercise. The minutes of this scoping meeting can be seen in Appendix 4.
- **Consultation with the patient charity** Pancreatic Cancer UK to hear about the experience of their members and understand their priorities.

3.1 Summary of stakeholder survey results

During February 2022, an online survey was distributed to various stakeholders identified through NOGCA's clinical networks and contacts. Responses were received from 59 stakeholders, with participants representing surgery, oncology, gastroenterology, clinical nurse specialists, and a national pancreatic cancer charity.

Among survey respondents, there was broad support for the scope of an audit that extended from the point of diagnosis to the end of initial treatment. There were a range of views on how the patient eligibility criteria might be defined; the majority of respondents supported a broad approach, with the audit including pancreatic ductal adenocarcinoma (PDAC) and periampullary tumours. There was little support for the inclusion of neuroendocrine tumours. The survey results

did not give a clear indication on whether the audit would include patients with suspected pancreatic cancers or whether it should be limited to patients with a histological diagnosis.

When asked "What areas of care should be a focus of the audit?", respondents identified various specific areas of care. A summary is given in Box 1.

Box 1: Areas of care that the NPaCA could assess, as reported by the survey respondents

Duration and types of symptoms / GP attendances prior to diagnosis Route to diagnosis Time from referral to diagnosis
Access to investigations (imaging: PET-CT, endoscopic: EUS, ERCP) Number and sequence of investigations and MDT reviews Attempt(s) at histological diagnosis Classification of extent of disease (including venous involvement) Treatment intent after MDT review Definition of borderline versus resectable cases Treatment variation of borderline cases with resectable disease
Time from diagnosis to MDT review Time from diagnosis to (first) treatment
Prehabilitation before resectional surgery Rates of surgical resection Patterns of neoadjuvant therapies received Short-term surgical outcomes Pathological outcomes
Types of palliative chemotherapy / radiotherapy regimens used Short-term outcomes of palliative chemotherapy / radiotherapy Use of biliary drainage procedures Access to / use of specialist dietician Prevalence of pancreatic exocrine insufficiency (PEI) Use of pancreatic enzyme replacement therapy (PERT)
Access to specialist palliative care service – specialist input, setting and timing Access to / participation in clinical trials

4. Proposed scope of the audit

4.1 Inclusion criteria

The inclusion criteria were agreed by the audit team in consultation with key stakeholders via the CRG. It was proposed that the audit includes adults (≥18 years of age) diagnosed and/or treated in England or Wales by NHS hospital services for pancreatic cancer, as defined using the ICD-10 codes listed in Table 1.

Patients are eligible if they have a radiologic or clinical diagnosis; eligibility is not limited to patients with a histological diagnosis because a large proportion of patients with pancreatic cancer are too unwell to undergo biopsy for histological diagnosis. We note that neuroendocrine tumours can be identified on imaging and so could be excluded.

Table 1. ICD-10 diagnosis codes for defining which patients are eligible for inclusion

Inclusion criteria	**Rationale**
Diagnosis is one of the following: • C25.x Malignant neoplasm of pancreas • C24.0 Extrahepatic bile duct • C24.1 Malignant neoplasm of ampulla of Vater	The diagnostic and treatment pathways are very similar for patients with pancreatic cancer, Ampulla of Vater, and (most) tumours covered by the code for extrahepatic bile duct tumours.
Exclusion criteria	**Rationale**
Diagnosis is one the following: • C25.4 Pancreatic neuroendocrine tumour • C24.8 Overlapping lesion of biliary tract • C24.9 Unspecified biliary tract tumours • C23.x Gallbladder tumours • C22.1 Intrahepatic bile duct tumours • C17.0 Duodenal tumours	• Neuroendocrine tumours have a different treatment pathway from exocrine pancreatic cancers • While patients with the other ICD-10 codes listed may receive some of the treatments received by patients with pancreatic tumours, their inclusion may complicate the interpretation of results.

4.2 Coverage of care pathway

The audit will cover the pathway from first diagnosis of pancreatic cancer through to the end of primary treatment.

Primary treatment will include planned treatments with and without curative intent. Treatments may be multimodal and include any of surgery, chemotherapy (CT), radiotherapy (RT), or best supportive care. Interventions aimed at relief of symptoms, such as a stent or PERT, will not be considered primary treatment unless they are part of best supportive care.

Surgical and non-surgical treatment pathways will be reported separately. Non-surgical pathways may be further sub-categorised into 1) borderline resectable cancers treated with CT +/- RT and 2) metastatic disease treated with palliative CT +/- RT or best supportive care.

Compared to some other tumour types, pancreatic cancer has relatively few known biomarkers and targeted therapies. However, the audit will monitor emerging personalised medicine approaches in pancreatic cancer and report on system factors that support personalisation.

4.3 Priorities for quality improvement

The audit's scoping exercise identified several potential priority areas for quality improvement along the pancreatic cancer care pathway, which are summarised in Table 2.

Among the main issues in pancreatic cancer care are the following:

- The high percentage diagnosed as an emergency presentation
- Variation in diagnostic work-up, including use of endoscopic ultrasound (EUS), timing / access to staging imaging (inc. PET), timing of biliary drainage (where relevant), tissue diagnosis (where relevant) and number of multi-disciplinary team (MDT) meetings per patient
- Delays to diagnosis and treatment decision due to access to diagnostic tests, procedures such as EUS and administrative processes (MDT meetings)
- Variation in the availability of treatment based on geography, how it impacts time to first treatment (either oncological treatment, best supportive care, or surgery)
- Inconsistency in supportive care, including variations in PERT prescriptions and specialist end of life support.

The audit will continue to engage with medical associations, patient charities and other stakeholders to develop specific health care improvement goals.

4.4 Potential indicators and methodological considerations

The feasibility study identified a suite of performance indicators that have been used by other studies and / or clinical audits in various countries. The process of selecting these for the audit will involve consultation with relevant medical professionals and patient charities, and we expect this process to have two steps: (1) identifying a set of desirable indicators, and (2) an assessment of the feasibility and validity of the indicators. There will be constraints imposed on the audit by the availability and quality of data within the national cancer datasets collected in England and Wales (for more information, see the Feasibility Study described in Appendix 3).

The audit team will formulate a communication strategy that includes activities to reassure clinicians and patients that the national data are sufficiently complete and accurate to support the production of valid organisational level indicators.

Table 2. Potential quality improvement areas for NPaCA

QI area	Relevant guidance / standards[1]
Route to diagnosis	
Reducing time between referral and diagnosis and/or start of treatment; reducing proportion diagnosed via emergency admission	Cancer waiting times standards (Updated from 1 October 2023)[16]
Diagnosis process	
Reducing variation in diagnostic procedures, e.g. use of EUS	NICE NG85: • Offer a pancreatic protocol CT scan • If diagnosis unclear, offer FDG-PET/CT and/or EUS with EUS-guided tissue sampling. If cytology or histological samples are needed, offer EUS with EUS-guided tissue sampling. Take a biliary brushing for cytology if ERCP is being used to relieve the biliary obstruction and there is no tissue diagnosis NICE QS177: Statement 1 - Adults with suspected pancreatic cancer have their diagnosis and care agreed by a specialist pancreatic cancer multidisciplinary team (MDT) NICE QS177: Statement 2 - Adults with localised pancreatic cancer on CT have staging using FDG-PET/CT before they have surgery, radiotherapy, or systemic therapy
Curative treatments	
Understanding current treatment patterns (e.g. use of neoadjuvant chemotherapy, timing of biliary drainage, use of radiotherapy);	NICE NG85: • Neoadjuvant therapy: only consider for people with resectable or borderline resectable pancreatic cancer as part of a clinical trial • Surgery: for head of pancreas cancer, consider pylorus-preserving resection if the tumour can be adequately resected; standard rather than extended lymphadenectomy

[1] Included: NICE Guideline 85 (NG85); NICE Quality Statement 177 (QS177); NHS Clinical Commissioning Policy Statement; Cancer Waiting Times Standards

QI area	Relevant guidance / standards[1]
Understanding complications associated with different treatment patterns, e.g. surgery first vs. biliary drainage followed by surgery	• Adjuvant treatment: Start therapy as soon as they are well enough to tolerate all 6 cycles NICE QS177: Statement 3 - Adults with resectable pancreatic cancer and obstructive jaundice have resectional surgery rather than preoperative biliary drainage (unless the drainage is specifically indicated)
Non-curative treatments	
Reducing variation in treatment and access to palliative / non-surgical treatment; use of biliary drainage in those with advanced disease; admissions in the last months of life	NICE NG85: For locally advanced pancreatic cancer: • Offer systemic combination chemotherapy to people who are well enough to tolerate it For Metastatic pancreatic cancer: • First-line treatment: - Offer FOLFIRINOX to those with ECOG performance status of 0 to 1 - Consider gemcitabine combination therapy for people who are not well enough to tolerate FOLFIRINOX - Offer gemcitabine to people who are not well enough to tolerate combination chemotherapy NHS Clinical Commissioning recommendation: • Use of stereotactic ablative body radiotherapy (SABR) as a treatment option for adults with locally advanced, inoperable, non-metastatic pancreatic carcinoma where the disease remains localised following systemic chemotherapy
Other supportive care	
Promoting consistency in supportive care provided, including access to PERT and specialist end of life support	NICE NG85: Recommendations on nutritional management, pain management NICE QS177: Statement 4 - Adults with unresectable pancreatic cancer are prescribed enteric-coated pancreatin

5. Future steps

5.1 Development of Healthcare Improvement Strategy

Building on the QI priorities identified in the scoping exercise, the audit will develop its Healthcare Improvement Strategy. As part of this process, the audit will undertake several activities, in consultation with key stakeholders via its Clinical Reference Group and Patient and Public Involvement Forum, including:

- Development of five quality improvement goals for the audit over the next audit cycle
- Analysis of national cancer data to identify key performance indicators for annual and quarterly reporting, and mapping of these to the quality improvement goals
- Development of methods and activities to support local quality improvement and implementation of audit recommendations
- Plans for monitoring and evaluation of the audit's impact.

5.2 Communication and dissemination activities

Key activities relating to communication and dissemination include:

- NPaCA newsletters: distributed to key stakeholders on a quarterly basis, and published on the audit website
- Website: development and regular review/update of website content and design (https://www.natcan.org.uk/audits/pancreatic/)
- Social media: regular posts on X (formerly Twitter) about the audit's activities, outputs and plans, and reposting of content of relevance to followers
- Publications & presentations: audit results will be presented at national conferences, and specific topics will be evaluated in further depth in articles submitted to peer-reviewed journals.

Further detail about these activities will be set out in NPaCA's Communications Strategy.

6. References

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7. Appendices

Appendix 1 – The National Cancer Audit Collaborating Centre (NATCAN)

The National Pancreatic Cancer Audit is part of the National Cancer Audit Collaborating Centre (NATCAN), a national centre of excellence launched on 1st October 2022 to strengthen NHS cancer services by looking at treatments and patient outcomes in multiple cancer types across the country. The centre was commissioned by the Healthcare Quality Improvement Partnership (HQIP) on behalf of NHS England and the Welsh Government with funding in place for an initial period of three years.

NATCAN is based within the Clinical Effectiveness Unit (CEU), the academic partnership between the Royal College of Surgeons of England (RCS Eng) and the London School of Hygiene & Tropical Medicine. The CEU is recognised as a national centre of expertise in analytic methodology and the development of administrative and logistic infrastructure for collating and handling large-scale data for assessment of health-care performance.

Prior to the launch of NATCAN, the CEU was already the sole provider of national cancer audits in the NHS in England and Wales, incorporating audits in prostate, lung, bowel, and oesophago-gastric cancers, and recently completed an audit of breast cancer in older patients. These audits have helped provide a wider understanding of cancer treatments across England and Wales and have improved services and infrastructure leading to improved outcomes for patients. By consistently placing quality improvement (QI) at the centre of all audits, initiatives which promote QI within NHS cancer services have been developed and areas of best practice identified.

Alongside the National Pancreatic Cancer Audit, NATCAN delivers five other audits in ovarian, kidney, primary and metastatic breast cancer, and non-Hodgkin Lymphoma. The aim of these audits is to:

1. Provide regular and timely evidence to cancer services of where patterns of care in England and Wales may vary.
2. Support NHS services to increase the consistency of access to treatments and help guide quality improvement initiatives.
3. Stimulate improvements in cancer detection, treatment and outcomes for patients, including survival rates.

The audits which the CEU already provided have joined NATCAN (bowel, oesophago-gastric and prostate) or will, in the near future (lung), bringing the number of NATCAN audits to ten. This critical mass of knowledge and expertise enable it to respond to the requirements of the funders and stakeholders.

Key features of NATCAN's audit approach

The design and delivery of the audits in NATCAN has been informed by the CEU's experience delivering national audits, built up since its inception in 1998. Key features of all audit projects within the CEU include:

- Close clinical-methodological collaboration
- Use of national existing linked datasets as much as possible
- Close collaboration with data providers in England (National Disease Registration Service [NDRS, NHSE] and Wales (Wales Cancer Network [WCN], Public Health Wales [PHW])
- A clinical epidemiological approach, informing quality improvement activities.
- "Audit" informed by "research".

All these features will support NATCAN's focus on the three "Rs", ensuring that all its activities are clinically relevant, methodologically robust, and technically rigorous.

Organisational structure of NATCAN

Centre Board

NATCAN has a multi-layered organisational structure. NATCAN's Board provides top-level governance and oversees all aspects of the delivery of the contract, ensuring that all audit deliverables are produced on time and within budget and meet the required quality criteria. The Board also provides the escalation route for key risks and issues. It will also consider NATCAN's strategic direction. The Board will meet at 6-monthly intervals and will receive regular strategic updates, programme plans, and progress reports for sign-off. Risks and issues will be reported to the NATCAN Board for discussion and advice.

Executive Team

NATCAN's Executive Team is chaired by the Director of Operations (Dr Julie Nossiter) and includes the Clinical Director (Dr Ajay Aggarwal), the Director of the CEU (Prof David Cromwell), the Senior Statistician (Dr Kate Walker), and the Senior Clinical Epidemiologist (Prof Jan van der Meulen) with support provided by NATCAN's project manager (Ms Verity Walker). This Executive Team is responsible for developing and implementing NATCAN's strategic direction, overseeing its day-to-day running, and coordinating activities across the cancer audits. This group meets weekly. The Executive Team provide 6-monthly updates to NATCAN's Board.

Advisory groups

The Executive Team will be supported by two external groups. First, the Technical Advisory Group including external senior data scientists, statisticians, and epidemiologists as well as representatives of the data providers (NDRS, NHSD and WCN, PHW), co-chaired by NATCAN's Senior Statistician and Senior Epidemiologist, will advise on national cancer data collection, statistical methodology, development of relevant and robust performance indicators to stimulate QI, and communication to practitioners and lay audiences.

Second, the Quality Improvement Team includes national and international experts who have extensive experience in QI and implementation research. This team will provide guidance on the optimal approaches to change professional and organisational behaviour. It will be chaired by NATCAN's Clinical Director and managed by the Director of Operations.

This set up will provide a transparent and responsive management structure allowing each audit to cater for the individual attributes of the different cancer types, while also providing an integrated and consistent approach across the NATCAN audits. The integrated approach will result in efficient production of results through sharing of skills and methods, a common "family" feel for users of audit outputs, and a shared framework for policy decisions and, project management.

Audit Project Teams

Audit development and delivery is the responsibility of each Project Team. The Project Team works in partnership to deliver the objectives of the audit and is responsible for the day-to-day running of the audit and producing the deliverables. It will lead on the audit design, data collection, data quality monitoring, data analysis and reporting.

Each cancer audit Project Team is jointly led by two or three Clinical Leads representing the most relevant professional organisations, and senior academics with a track record in health services research, statistics, data science and clinical epidemiology, affiliated to the London School of Hygiene and Tropical Medicine. In addition, each audit will have a clinical fellow, who contributes to all aspects of the audits, reinforcing the audits' clinical orientation and contributing to capacity building.

The delivery of the audit is coordinated by an audit manager who is supported by NATCAN's wider infrastructure. Data scientists with experience in data management and statistics and methodologists with experience in performance assessment and QI work across audits.

Audit Clinical Reference Groups

Each audit has a Clinical Reference Group representing a wide range of stakeholders. This group will act as a consultative group to the Project Team on clinical issues related to setting audit priorities, study methodology, interpretation of audit results, reporting, QI, and implementation of recommendations.

Effective collaboration within the centre and across audits facilitates the sharing of expertise and skills in all aspects of the delivery process, notably: designing the audits, meeting information governance requirements, managing and analysing complex national cancer data to produce web-based indicator dashboards / state of the nation reports, and supporting quality improvement.

This organisation creates "critical mass" and audit capacity that is able to respond to the requirements of the funders (NHS England and Welsh Government) and the wider stakeholder "family".

Audit PPI Forums

Patients and patient charities are involved in all aspects of the delivery of the cancer audits. Each audit will also have a standalone Patient and Public Involvement (PPI) Forum to provide insight from a patient perspective on strategic aims and specific audit priorities. This will include shaping the development of each audit's quality improvement initiatives by ensuring this work is relevant from a patient perspective. A key activity of the PPI Forums will be to actively participate in the production of patient-focussed audit outputs (including patient and public information, patient summaries of reports, infographics and design and function of the NATCAN website), guiding on how to make this information accessible.

Data acquisition

The NATCAN Executive Team is working closely with data providers in England (NDRS, NHSE) and in Wales (WCN, PHW) to establish efficient "common data channels" for timely and frequent access to datasets, combining data needs for all cancers into a single request in each Nation and only using routinely collected data, thereby minimising the burden of data collection on provider teams.

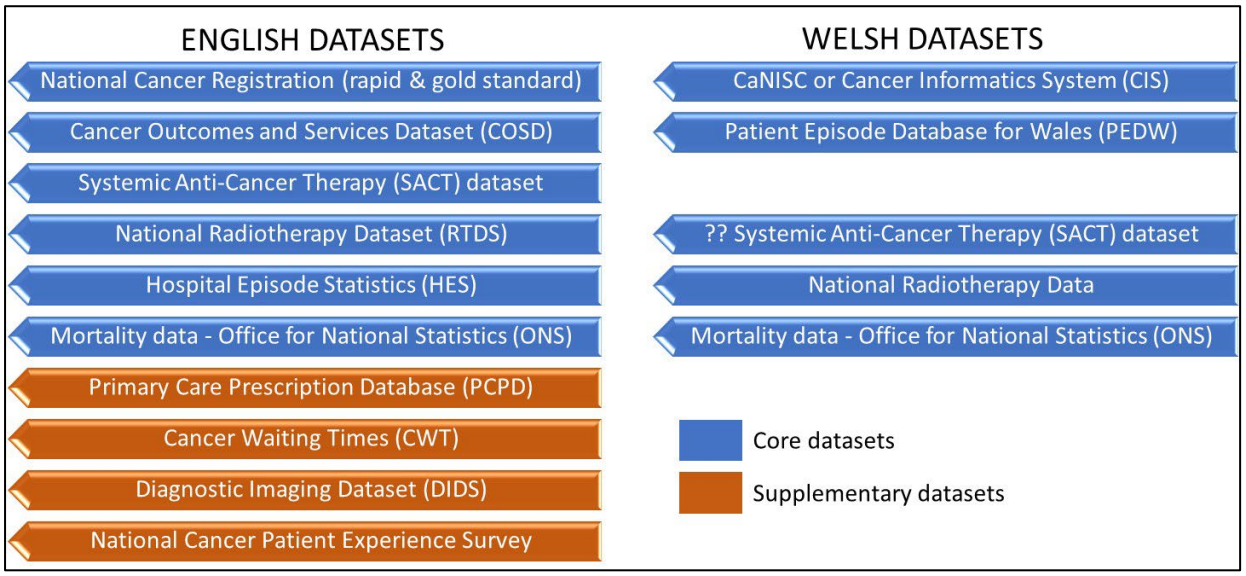
Annual and quarterly data

NATCAN will utilise two types of routinely collected data in England. First, an annual "gold-standard" cancer registration dataset, released on an annual basis with a considerable delay between the last recorded episode and the data being available for analysis, and second, a "rapid" cancer registration dataset (RCRD), released at least quarterly with much shorter delays (3 months following diagnosis). The CEU's recent experience with English rapid cancer registration data, in response to the COVID pandemic has demonstrated the latter's huge potential,[2] despite a slightly lower case ascertainment and less complete staging information.

NATCAN will utilise these data across all cancers linked to administrative hospital data (Hospital Episode Statistics/Systemic Anti-Cancer Therapy/Radiotherapy Data Set/Office for National Statistics among other routinely collected datasets, see Figure 1) for describing diagnostic pathway patterns, treatments received and clinical outcomes.

An equivalent data request will be made to the Wales Cancer Network (WCN)/Public Health Wales (PHW).

FIGURE 1. NATIONAL DATASETS AVAILABLE TO NATCAN



[2] Nossiter J, Morris M, Parry MG, Sujenthiran A, Cathcart P, van der Meulen J, Aggarwal A, Payne H, Clarke NW. Impact of the Covid-19 pandemic on the diagnosis and treatment of men with prostate cancer. BJU Int. 2022; doi: 10.1111/bju.15699.

Information governance

NATCAN will comply with legislation and good practice principles to ensure data security and patient confidentiality. The patient-level information received and managed by NATCAN is treated as confidential. When analysing data to produce information on patient care and outcomes, NATCAN audit teams use de-identified data and so individual patients are not identifiable.

HQIP and NHSE are joint data controller for the linked de-identified dataset that is supplied to NATCAN for analysis.

Reporting

Individual cancer audits will produce:

- Annual '*State of the Nation'* reports for NHS Trusts/Health Boards within England and Wales. These reports will highlight where local services should focus quality improvement activities.
- NHS organisational-level results (as well as national and regional results) as a dashboard on the NATCAN website. These dashboard results will be refreshed on a quarterly and annual basis, and the website will include the facility to download activity summaries and outcomes as short PDF documents and presentations.

These outputs will be supported by a range of tools that will support their use by local services and other stakeholders, including slide sets and QI resources. Additional outputs include peer-reviewed publications and presentations at national and international meetings. Newsletters will be disseminated to announce the publication of new results to clinical teams and audit stakeholders.

Summaries of the '*State of the Nation'* reports from each cancer audit will be prepared for patients and the general public and available on the NATCAN website, in addition to information for patients. Patient representatives in the PPI Forums and Clinical Reference/Advisory Groups of each cancer audit will provide input into the development of the audit outputs.

Publication of comparative local outcomes, along with the associated commentary, allow patients to understand the quality of care being offered and enable them to ask Trusts/Health Boards and clinical teams how they plan to put right any deficiencies identified via the audits.

Healthcare improvement

A priority for each audit in NATCAN is the development of a healthcare improvement plan that includes explicit QI goals aiming to improve cancer outcomes as well as the patient experience. These plans will be built around clinically relevant and methodologically robust performance indicators that each audit will develop and disseminate.[3]

The healthcare improvement plan will also set out the key drivers for each QI goal, alongside national and local improvement tools.[4] NATCAN will ensure that its healthcare improvement programme will be closely aligned with related activities implemented by other relevant

[3] Geary RS, Knight HE, Carroll FE, Gurol-Urganci I, Morris E, Cromwell DA, van der Meulen JH. A step-wise approach to developing indicators to compare the performance of maternity units using hospital administrative data. BJOG. 2018; 125(7):857-865. doi: 10.1111/1471-0528.15013.

[4] Foy R, Skrypak M, Alderson S, Ivers NM, McInerney B, Stoddart J, Ingham J, Keenan D. Revitalising audit and feedback to improve patient care. BMJ. 2020; 368:m213. doi: 10.1136/bmj.m213.

organisations (e.g., CQC and Getting it Right First Time in England, and NHS Quality Improvement and Patient Safety in Wales).

Each audit within NATCAN will complete at least one national QI initiative using the RCRD, aiming "to close the audit cycle" following an approach commonly referred to as the "plan-do-study-act" method.[5] This will be a first at national level and we envisage that it will become a core element of involvement for the NATCAN QI Team.

Again, NATCAN will build on the CEU's longstanding experience in targeting and designing QI implementation approaches, ensuring that the audit feedback information and recommendations truly reach the clinicians who can act on it, also incorporating specific action plans.

[5] Taylor MJ, McNicholas C, Nicolay C, Darzi A, Bell D, Reed JE. Systematic review of the application of the plan-do-study-act method to improve quality in healthcare. BMJ Qual Saf. 2014; 23(4):290-8. doi: 10.1136/bmjqs-2013-001862.

Appendix 2 – The NPaCA project team

The audit will be delivered by a team that combines clinical leadership, methodological expertise, and project management. The clinical leads are:

- Dr Ganesh Radhakrishna, Clinical Lead (Clinical Oncology)
- Mr Andrew Smith, Clinical Lead (Surgery)
- Prof Nigel Trudgill, Clinical Lead (Gastroenterology)

The other members of the audit team provide methodological, statistical, and project management expertise: Vikki Hart (Senior Project Manager), David Cromwell (Health Services Research), Min Hae Park (Health Services Research), and Amanda McDonell (Data Scientist). A Clinical Research Fellow will shortly join the team.

The Clinical Reference Group (CRG) will provide advice to the project team. It will usually convene twice a year to advise on the direction of the audit and feedback on interpretation of audit findings. The CRG will also help in the dissemination of audit findings. The CRG members represent patient organisations and healthcare professional groups, including: Pancreatic Cancer UK, Pancreatic Cancer Action, the Association of Upper Gastrointestinal Surgery, the Royal College of Radiologists (RCR), the British Society of Gastroenterology, and the Royal College of Surgeons of England (RCSEng).

The audit will also have a PPI forum whose members represent patients and carers with lived experience of pancreatic cancer.

NOGCA | National Oesophago-Gastric Cancer Audit

National Pancreatic Cancer Audit feasibility report

2022

Contents

Glossary

Common biliary duct – Carries bile from the gallbladder and liver in into the upper part of the small intestine and joins the pancreatic duct at the point where they enter the small intestine duct, known as the ampulla of Vater

Pancreas – An organ located behind the stomach that releases pancreatic enzymes into the digestive system and secretes pancreatic hormones into the bloodstream. Enzymes are released into the pancreatic duct which joins the common bile duct before the small intestine.

Pancreatic adenocarcinoma – most common type of pancreatic cancer in which tumours involve the cells lining the pancreatic duct.

Pancreatic neuroendocrine – pancreatic cancers that arise in neuroendocrine cells. In the pancreas, these cells produce hormones such as insulin that helps to control the sugar levels in the blood.

Periampullary tumours – these tumours occur near the ampulla of Vater, where the ducts from the liver and pancreas join and enter the small intestine

1. Background

Around 8,500 people in England and 500 people in Wales are diagnosed with pancreatic cancer every year, and the incidence of pancreatic cancer has been rising over the last two decades. There are two dominant forms:

- pancreatic adenocarcinoma, which accounts for about 85% of cases, and
- pancreatic neuroendocrine tumours, which make up around 5% of cases.

Early stage pancreatic cancer does not typically produce symptoms. Consequently, pancreatic cancers are often diagnosed at a late stage (III or IV), and only 1 in 4 patients with pancreatic adenocarcinoma survive 1 year after diagnosis.

A national clinical audit into pancreatic cancer care will be commissioned by the Healthcare Quality Improvement Partnership (HQIP) on behalf of NHS England and the Welsh Government. There are reports of variation in patterns of care provided to patients with pancreatic cancer across England and Wales [Exarchakou et al 2020], and the audit will support NHS organisations to benchmark their practice, identify the underlying causes of variation, and plan ways to improve the quality of care received by patients.

To inform the scope of the future pancreatic cancer audit, the National Oesophago-Gastric Cancer Audit (NOGCA) conducted a feasibility study that comprised a stakeholder survey and review of potential quality indicators. The results of this feasibility study are described in this report.

2. Stakeholder survey

2.1 Survey design

A survey was developed to collect the views of key stakeholders on the scope of a future national pancreatic cancer audit and to identify potential challenges in its design and delivery. The survey included questions about:

- Which parts of the care pathway and specific areas of care should be covered by the audit
- Eligibility criteria to define the patient cohort
- Existing studies or evaluations of pancreatic cancer care that could inform the future audit
- Limitations of current national cancer registration datasets

During February 2022, a link to the online survey was sent to a range of stakeholders identified through NOGCA's clinical networks, relevant professional bodies and charities, including representatives from: the Pancreatic Society of Great Britain & Ireland, Pancreatic Cancer UK, Great Britain & Ireland Hepato Pancreato Biliary Association, Association of Upper Gastrointestinal Surgery of Great Britain and Ireland, Association for Cancer Surgery, Royal College of Radiologists, British Society of Gastroenterology, and cancer nurse specialists (CNS).

2.2 Results

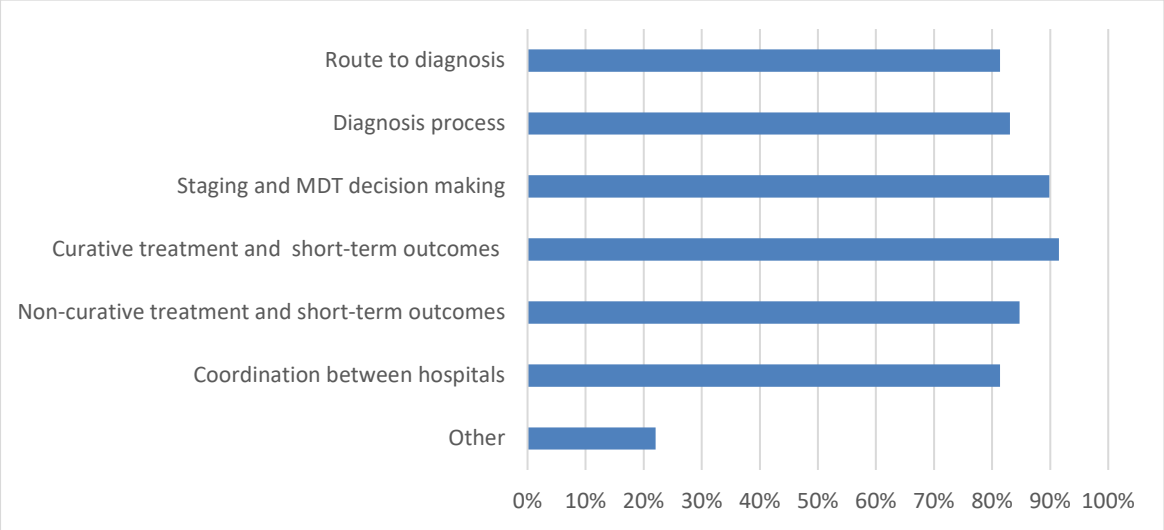
Responses were submitted from 59 stakeholders, with participants representing surgery (n=31), oncology (n=21), gastroenterology (n=4), clinical nurse specialists (CNS; n=2), and a national pancreatic cancer charity (n=1).

Which parts of the care pathway should the audit cover?

The first survey question asked about which parts of the care pathway were important for a future audit to evaluate. Figure 1 summarises the proportion of respondents who were in favour of including the care pathway elements (from the route to diagnosis to the end of initial treatment). Each element was selected by over 80% of respondents, and the majority of respondents (58%) felt that all six parts of the pathway should be covered by the audit.

Free text responses identified the following other aspects of care than might be covered: participation in trials, palliative and supportive care, and biomarker testing.

Figure 1: Which parts of the care pathway should the audit cover? (n=59 respondents)



Which patients should be included in the audit?

The next question explored the inclusion criteria that should be used to define the patient cohort. The 53 respondents identified a range of options:

- The majority of respondents stated that inclusion criteria should be broad, to include all patients with pancreatic cancer (57%), while a further 36% specified pancreatic ductal adenocarcinoma (PDAC)
- 38% specified that patients with periampullary tumours should be included, whilst 4% felt they should be excluded
- 30% specified that neuroendocrine tumours should be excluded, but 8% said that they should be included
- 28% of respondents felt that suspected pancreatic cancers should be included even if not histologically confirmed; 9% thought the audit should be limited to histological diagnoses.

Two respondents proposed inclusion criteria relating to the management of the cancer, suggesting the audit include: patients requiring pancreatic resection, or patients considered for surgery / oncology rather than those managed endoscopically.

What areas of care should be a focus of the audit in each part of the care pathway?

Details of the specific areas of care mentioned by respondents for each part of the care pathway are summarised in the supplementary material. In summary, respondents felt that a pancreatic audit should evaluate NHS services in relation to:

Duration and types of symptoms / GP attendances prior to diagnosis Route to diagnosis Time from referral to diagnosis
Access to investigations (imaging: PET-CT, endoscopic: EUS, ERCP) Number and sequence of investigations and MDT reviews Attempt(s) at histological diagnosis Classification of extent of disease (including venous involvement) Treatment intent after MDT review Definition of borderline versus resectable cases Treatment variation of borderline cases with resectable disease
Time from diagnosis to MDT review Time from diagnosis to (first) treatment
Prehabilitation before resective surgery Rates of surgical resection Patterns of neoadjuvant therapies received Short-term surgical outcomes Pathological outcomes
Types of palliative chemotherapy / radiotherapy regimens used Short-term outcomes of palliative chemotherapy / radiotherapy Use of biliary drainage / procedures Access to / use of specialist dietician Prevalence of pancreatic exocrine insufficiency (PEI) Use of pancreatic enzyme replacement therapy (PERT)
Access to specialist palliative care service – specialist input, setting and timing Access to / participation in clinical trials

3. Review of potential organisational-level indicators

A key function of the new clinical audit will be to select performance indicators that are accurate and reliable when produced at an organisational level. To achieve this requires an indicator to meet a number of conditions, including:

1. The volume of patients is sufficient to produce indicator values at an organisational-level that are not unduly influenced by random variation.
2. The data required for potential indicators are available in England and Wales; this might include the availability of data items in national cancer datasets and administrative health care datasets (HES / PEDW)

3.1 Performance indicators used in other settings for pancreatic cancer services

There are a number of recent studies that have evaluated the care delivered to patients with pancreatic cancer. Some of these were highlighted by respondents to the survey (indicated in the list below by (*)). These studies include:

- The UK Ricochet study into diagnostic and management pathways (*)
- The Dutch pancreatic cancer audit (*)
- The Swedish pancreatic cancer audit (*)
- The German DGAV StuDoQ Pancreas registry
- The American College of Surgeons National Surgical Quality Improvement Program for pancreatic surgery (*)

The RICOCHET study is a multicentre, prospective design that examined the care received by patients with suspected hepatopancreaticobiliary (HPB) malignancies during a 90 day period. It aimed to describe the care of patients from first presentation to the end of initial treatment and short-term outcomes. The indicators proposed by the RICOCHET team are summarised in the appendix, and can be seen to overlap with the indicators suggested by survey respondents. Results from the RICOCHET study are expected soon.

The four overseas audits / registries all focused on surgical treatment. A comparison of their results and study designs [Mackay et al, 2021] highlighted variation in the following areas of clinical practice: use of preoperative chemotherapy, use of minimally invasive surgery, median length of stay, reoperation rates, and postoperative in-hospital mortality. Importantly for this feasibility study, the work by Mackay et al produced recommendations for a set of core data items, although it was noted that 20 out of 55 (36.4%) core data items were not available in one or more of the four audits / registries.

Finally, we note that there was a review and consultation undertaken by NHS Scotland to produce a set of hepatobiliary and pancreatic (HBP) cancer quality performance indicators (QPIs). The resulting document provided detailed specifications for each of the indicators, which are helpful in highlighting to which patient subgroups the indicators relate. The process indicators for patients with pancreatic cancer are summarised in Table A3.1. The indicators proposed for the monitoring of outcomes were: (i) 90-day survival following diagnosis, and (ii) overall 1 and 2 year survival.

Table A3.1: The set of pancreatic cancer quality performance indicators (QPIs) that was proposed after a consultation by NHS Scotland. Some indicators had additional criteria to exclude specific patients (such as patients who died before first treatment). See report for full details

QPI	**Description:**	**Numerator:**	**Denominator:**
QPI 1	Proportion of patients with HPB cancer who are discussed at MDT meeting before definitive treatment.	Number of patients with HPB cancer discussed at the MDT before definitive treatment.	All patients with HPB cancer.
QPI 2-5	*For Hepatocellular Carcinoma (omitted)*		
QPI 6 -	Proportion of patients with pancreatic, duodenal or biliary tract cancer who undergo CT of the chest, abdomen and pelvis.	Number of patients with pancreatic, duodenal or biliary tract cancer who undergo CT of the chest, abdomen and pelvis.	All patients with pancreatic, duodenal or biliary tract cancer.
QPI 7	Proportion of patients with pancreatic, duodenal or distal biliary tract cancer undergoing non-surgical treatment who have a cytological or histological diagnosis	Number of patients with pancreatic, duodenal or distal biliary tract cancer undergoing non-surgical treatment who have a histological or cytological diagnosis	All patients with pancreatic, duodenal or distal biliary tract cancer undergoing non-surgical treatment.
QPI 8	Proportion of patients undergoing resection for pancreatic cancer receiving adjuvant chemotherapy.	Number of patients undergoing pancreatic cancer resection who receive adjuvant chemotherapy.	All patients undergoing resection for pancreatic cancer.
QPI 9 -	Proportion of patients who undergo resection for pancreatic, distal biliary tract or duodenal cancer	Number of patients with pancreatic, duodenal or distal biliary tract cancer who undergo resection.	All patients with pancreatic, duodenal or distal biliary tract cancer.
QPI 10	Average number of lymph nodes resected and pathologically examined for patients with pancreatic, duodenal or distal biliary tract cancer who undergo pancreatoduodenectomy performed by a specialist centre, over a 1 year period	Average number of lymph nodes per centre	
QPI 11 -	Proportion of patients undergoing surgical resection with curative intent for pancreatic, duodenal or distal biliary tract cancer who die within 30/90 days.	Number of patients with pancreatic, duodenal or distal biliary tract cancer undergoing surgical resection who die within 30/90 days of surgery	All patients with pancreatic, duodenal or distal biliary tract cancer undergoing surgical resection.
QPI 12	Number of surgical resections for pancreatic, duodenal or distal biliary tract cancer performed by a specialist centre, and surgeon, over a 1 year period	Number of surgical resections for pancreatic, duodenal or distal biliary tract cancer performed by each surgeon/centre in a given year	

3.2 Comments on performance indicator robustness

There was strong support among survey respondents for the new audit to cover the care pathway from presentation to the end of primary treatment. This is similar to existing HQIP commissioned national cancer audits, and will have many advantages. This perspective has implications for the design of the audit indicators, some of which are considered in this section.

Allocation of patients to NHS organisations

An important consideration is how to allocate patients to organisations. For indicators related to the care pathway around diagnosis and staging, one option is to allocate patients to the organisation of diagnosis. This may be at a specialist centre ("hub") or a "spoke" hospital. An alternative is to allocate patients to one of the 27 specialist centres at whose MDT their treatment was (or could have been) discussed (see Appendix for list of the current centres). This would have the advantage of simplifying the reporting and increasing the (minimum) number of cases on which indicator values were derived. However, recommendations and quality improvement activities around diagnosis and staging would need to engage all hospitals involved in these parts of the care pathway, and the latter approach would require the specialist centre to communicate clearly with the hospitals who refer it patients for review by the specialist MDT.

For indicators related to treatment (such as surgery), options for aggregation include the organisation of diagnosis or the organisation of treatment. For surgical indicators, the practice in NOGCA has been to report surgical practice and short-term surgical outcomes by the treating organisation, which is based on a recognition that it will be these surgical centres that will undertake quality improvement activities related to these indicators.

Patient volumes and indicator reliability

For indicators whose values are a proportion or rate, the precision of the organisational-level indicator value is determined by (1) the number of patients on which it is derived and (2) the overall indicator value for the cohort. If the overall indicator value is small (because there may be few events), the number of patients required to detect a difference between organisations will increase. The volume of cases for organisational-level indicators will vary across different elements of the care pathway, being largest for the indicators related to the process of diagnosis, staging and MDT planning that cover all pancreatic cancer patients. Treatment related indicators will have a denominator based on a subset of the patient cohort. For surgical indicators, this subset might be a small proportion of all patients diagnosed, given that many patients present with advanced pancreatic cancer. The NHS Scotland QPI illustrate the changing denominator for different indicators.

The pancreatic cancer audit team will need to assess how the indicators can be defined to ensure they have the statistical power to differentiate between good and poor performance. One option to improve statistical power will be to increase the time period over which data are analysed (i.e. to include patients treated over a period of several years), and this lead to the use of longitudinal charts (like a CUSUM) rather than cross-sectional charts (like a funnel plot) to ensure organisations are given performance information on their most recent activity. More information about the issues concerning indicator definitions and statistical power can be found in the various articles [Walker et al., 2013; Geary et al 2018].

3.3 Availability of required data items in national cancer / hospital datasets

The new pancreatic cancer audit will be designed to utilise existing national cancer datasets and other health care datasets to which these can be linked (eg, Hospital Episode Statistics / Patient Episode Dataset Wales). The evolution of these national datasets has seen them extended to provide richer information on tumour characteristics as well as patterns of care. In this section, the consequences of using national cancer datasets for the pancreatic cancer audit are considered.

A key requirement for the audit will be having data items that allow the characteristics of a patient's pancreatic cancer to be described sufficiently accurately to apply the desired inclusion criteria and define important patient subgroups for stratification / risk adjustment. The national cancer registration datasets do not always meet these requirements. For example, the NOGCA dataset includes a data item for tumour location that incorporates the widely used Siewert classification of junctional tumours but this is not available within the ICD-10 diagnosis codes that are used for tumour location in the cancer registration dataset.

The information available for defining pancreatic tumours in the national cancer datasets are:

- ICD-10 diagnosis codes: C25 for pancreatic cancer; C24 for biliary cancer (see appendix for details)
- Morphology codes (eg, adenocarcinoma, neuroendocrine)
- Tumour grade

These should be sufficient to allow the audit to define a workable set of inclusion criteria which are consistent with the options proposed by survey respondents. The data quality of these three variables is typically good, although problems can arise if the ICD-10 code for an "unspecified" type (ie, C25.9) is used for a sizeable proportion of patients. Another problem might be the extent of "unknown morphology" codes if a histological diagnosis cannot be made.

Various indicators will require data from the English COSD dataset. Some examples are given below:

- Date of MDT – CR0430; required for an indicator on what proportion of patients were discussed at MDT prior to treatment
- Clinical Nurse Indicator – CR2050; required for an indicator on what proportion of patients seen by a CNS
- Performance Status – CR0510; required for risk adjustment and patient subgroup selection, particularly in relation to the use of chemotherapy

The completeness of data items within COSD can be variable. However, work to improve data completeness means key variables such as cancer stage and performance status are often very high. The National Lung Cancer Audit reported that patients in the 2019 Rapid Cancer Registration Dataset had both performance status and clinical stage information for 85% of patients [RCP, 2022]. Data completeness for Wales was even higher, with performance status recorded in 99% of patients; disease stage was recorded in 99% of patients.

Survey respondents proposed several indicators related to the time taken by patients to travel along the care pathway. The data items required for these (date of GP referral, date of diagnosis, date of MDT discussion, date of first treatment) should be readily available and complete.

The cancer registration services have also an established algorithm to describe the route to diagnosis [Ellis-Brookes et al 2012]. For pancreatic cancer, it was reported that 50% of patients were

diagnosed after an emergency presentation, and another 27% came from a GP referral (either as a Two Week Wait or routine referral).

Variables related to the occurrence of cancer treatments, are generally well recorded, in Hospital Episodes Statistics (surgery), SACT (chemotherapy), and RTDS (radiotherapy). Both SACT and RTDS are capable of providing information on prescribed oncological regimens. Treatment completion can also be determined for the vast majority of patients receiving radiotherapy; this information is less complete for chemotherapy.

The national datasets are also capable of providing data for key outcome variables:

- The ONS death register has been used routinely by a number of existing national cancer audits for the derivation of survival
- Hospital Episode Statistics has proven capable of providing information on unplanned readmissions after surgery and oncological treatment
- Pathological data items are available in cancer registration and COSD datasets to collect information on nodes excised and nodes positive. Margin status after surgical resection is generally poorly completed, however.

An area of weakness continues to be the capture of cancer recurrence but this is unlikely to be the focus of the pancreatic cancer audit initially.

A question was included in the stakeholder survey about perceptions of using the national cancer registration datasets and linked treatment datasets[6]. The majority of respondents felt that these data sources are not sufficient. The most commonly cited issues were:

- poor data quality
- limited detail to capture complexity of pancreatic cancer care e.g. management decisions and routes to diagnosis
- limited details of therapy
- limited outcomes data
- time lag in data becoming available
- dataset too focused on surgery
- limited information on recurrence
- limited information about supportive/palliative care and patient experience

Of these various concerns, perhaps the most pressing issue is the time lag in data becoming available. The COVID-19 pandemic has severely disrupted the provision of the "gold-standard" English cancer registration datasets, with the last release being up to December 2019. The rapid cancer registration dataset (RCRD) provides more timely information but this has the weakness of (i) not capturing all patients and (ii) including only a subset of the variables available in the gold-standard dataset. Linkage of the RCRD to other national datasets including SACT and RTDS overcome some of the data item limitations.

[6] The question was: Are current national cancer registration data sources sufficient for an audit of pancreatic cancer in England and Wales?

4. Conclusion

This short report presents a sample of views from various stakeholders on how a national pancreatic cancer audit could be designed to support local NHS cancer services in their efforts to improve the quality of care received by patients with this disease.

The survey highlighted broad support for the scope of the audit extending from the point of diagnosis to the end of primary treatment. There were a range of views on how the patient eligibility criteria might be defined. There was general support a broad approach, with the audit including pancreatic ductal adenocarcinoma (PDAC) and periampullary tumours. There was little support for including neuroendocrine tumours. Further work will be required on clarifying whether or not the audit would include suspected pancreatic cancers (ie, those without a histological diagnosis).

The survey results also highlighted a range of possible process and outcome indicators, some of which had been adopted by other studies and / or audits in other countries. The team responsible for the design of the audit would benefit from undertaking an exercise with relevant medical professionals and patient representatives to select a set of audit indicators. This might be involve two steps, the first identifying a set of desirable indicators, followed by a second step in which the feasibility and validity of the indicators are assessed. This is likely to be necessary given the constraints imposed by the availability and quality of data within the cancer registration and associated national datasets. The results of this process could also address the concerns raised by survey respondents. In particular, it could form part of a communication strategy to demonstrate that the data are sufficiently complete and accurate to support the production of valid organisational level indicators.

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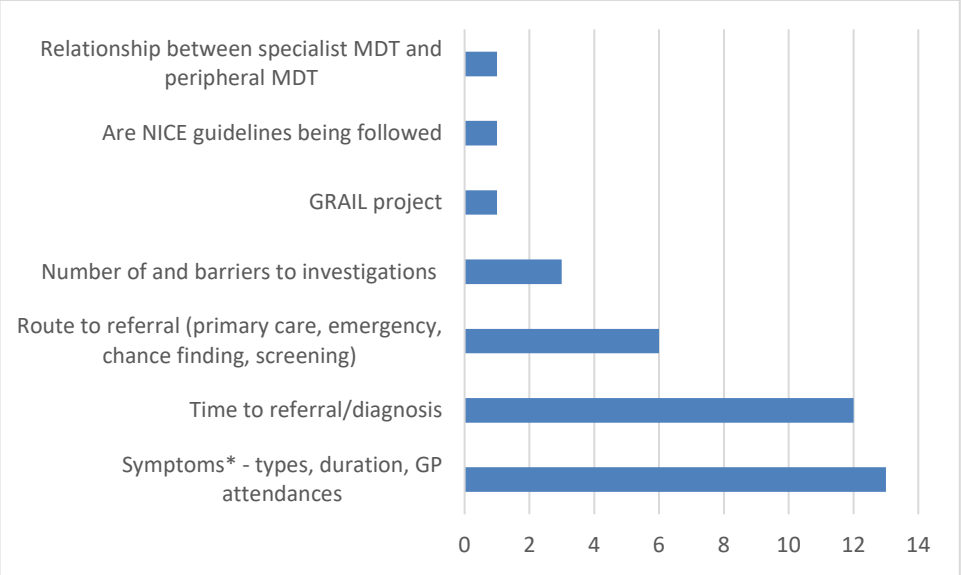
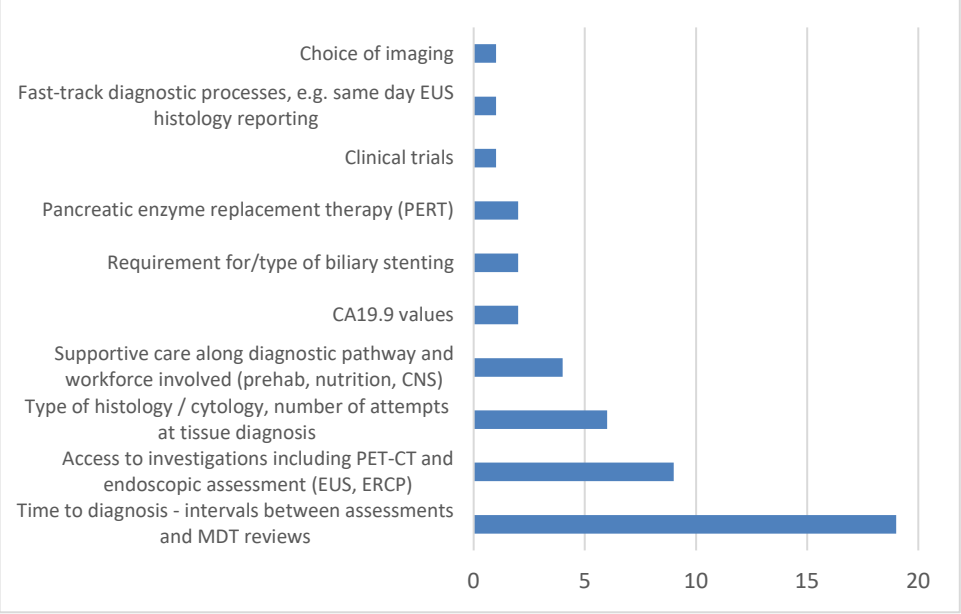
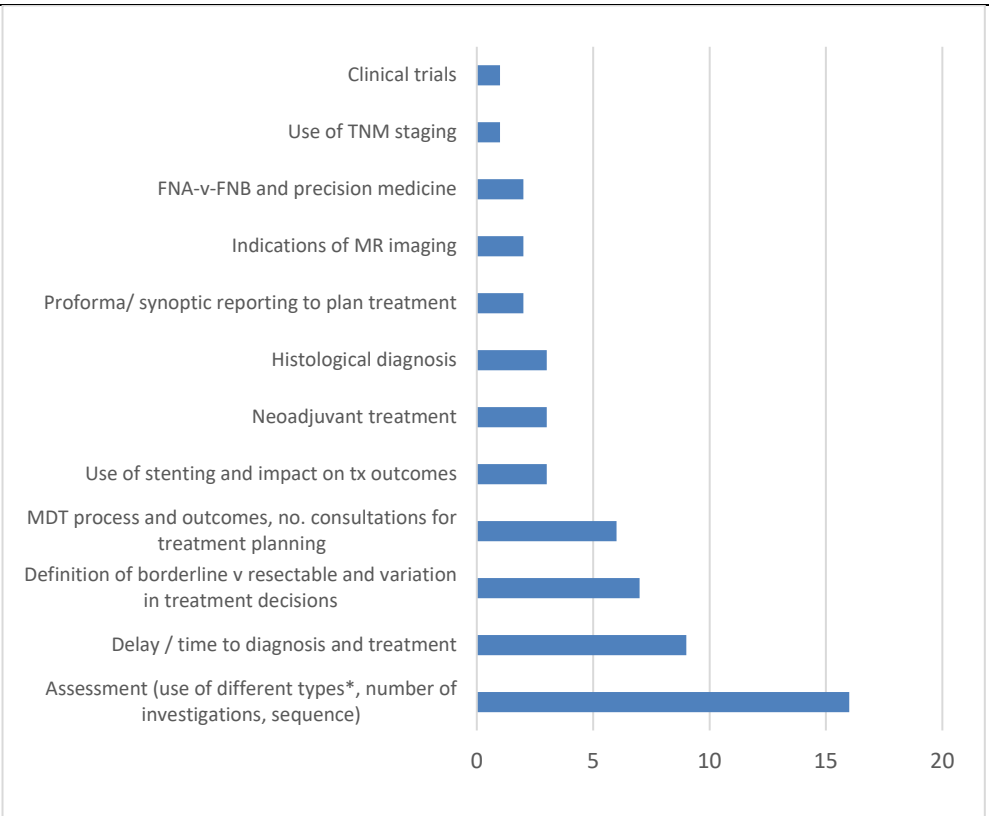
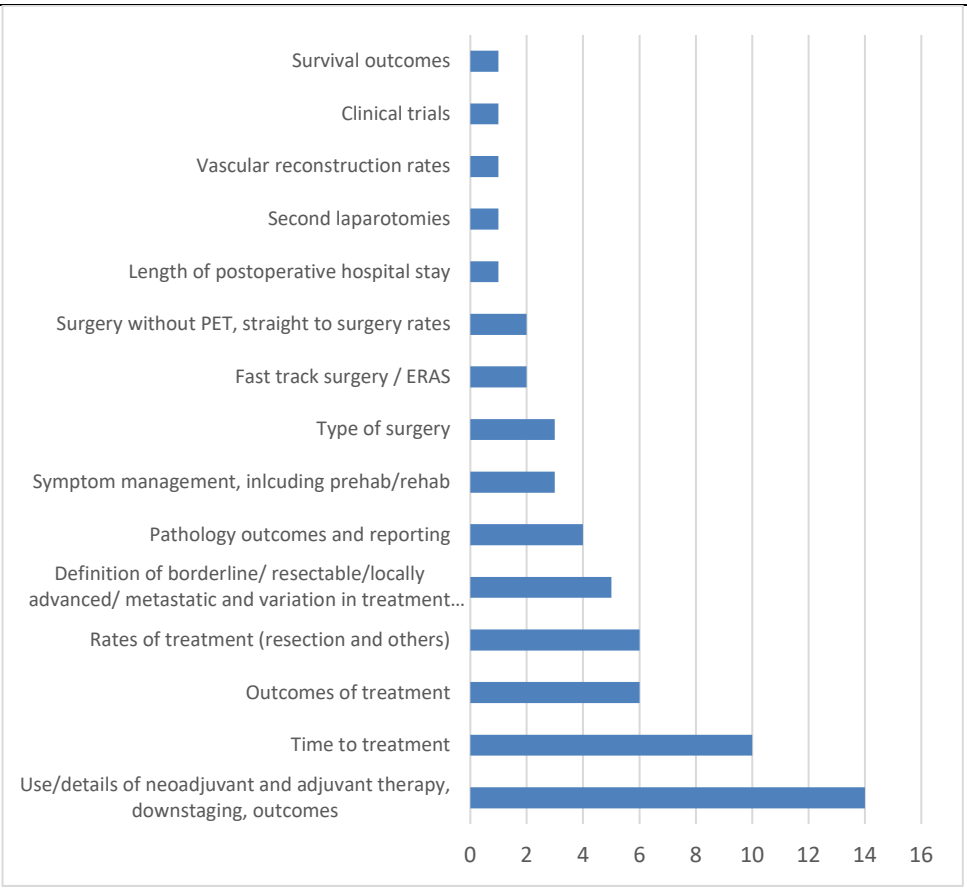
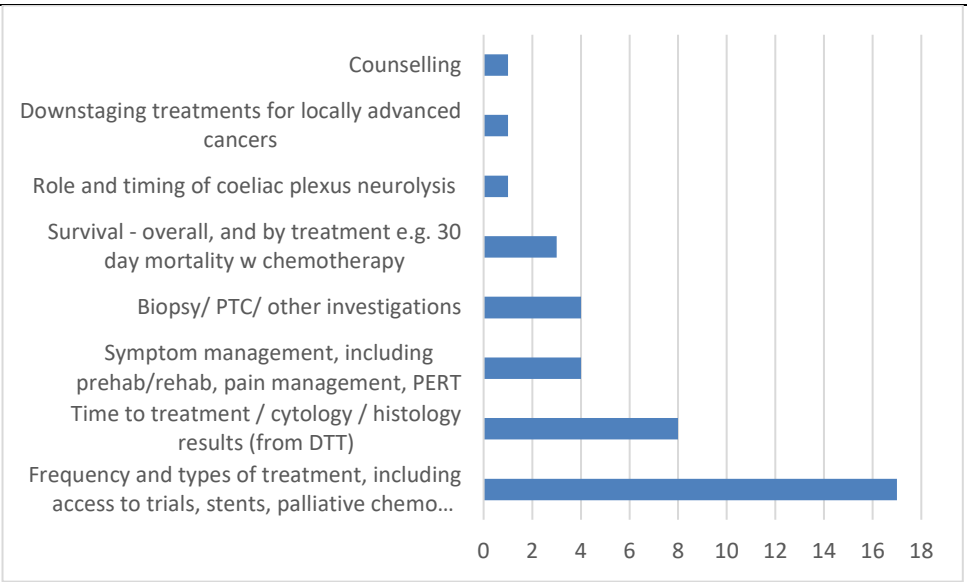
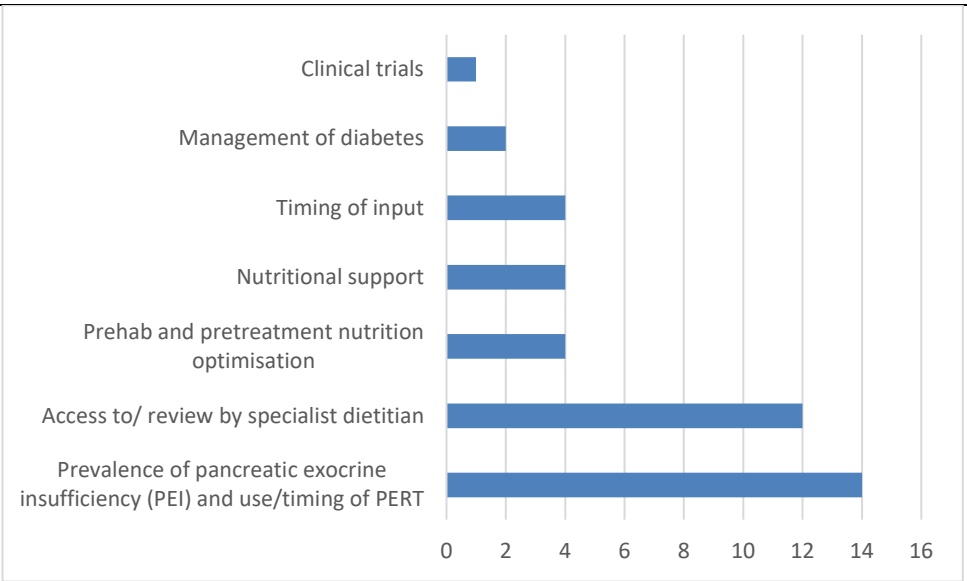
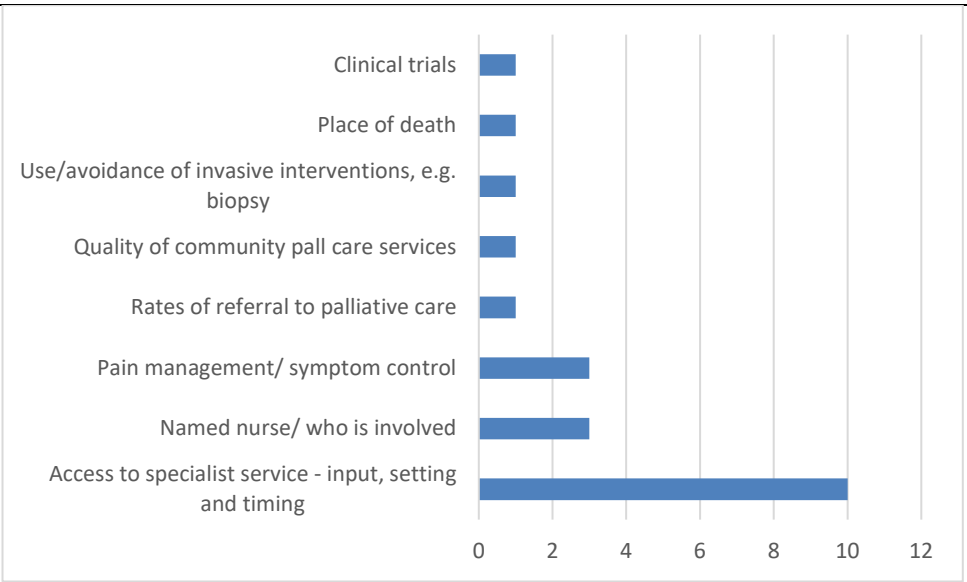
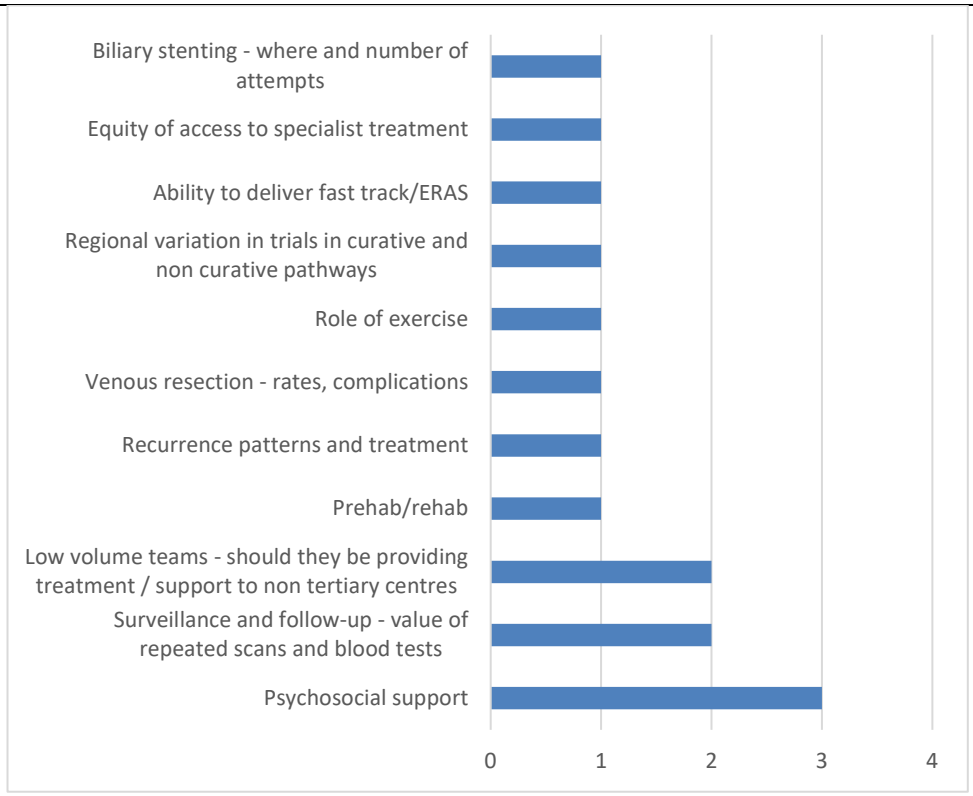
Supplementary material

Detail of survey responses

Route to diagnosis	 *n=4 specifically mentioned jaundice
Diagnosis process	

Staging and treatment planning	 *n=7 specifically mentioned access to PET, n=3 mentioned access to EUS
Curative treatment	

Non-curative treatment	
Nutritional management	
Palliative end-of-life care	

Other	 Biliary stenting - where and number of attempts Equity of access to specialist treatment Ability to deliver fast track/ERAS Regional variation in trials in curative and non curative pathways Role of exercise Venous resection - rates, complications Recurrence patterns and treatment Prehab/rehab Low volume teams - should they be providing treatment / support to non tertiary centres Surveillance and follow-up - value of repeated scans and blood tests Psychosocial support 0 1 2 3 4

27 regional NHS specialist centres for pancreatic cancer in England and Wales

Location	NHS organisation
Newcastle	Freeman Hospital in Newcastle.
Blackburn	East Lancashire Hospitals NHS Trust
Manchester	Surgery: Central Manchester Hospitals NHS Foundation Trust
	Oncology: The Christie NHS Foundation Trust
Liverpool	Royal Liverpool and Broadgreen University Hospitals NHS Trust
Hull	Hull and East Yorkshire Hospitals NHS Trust
Leeds	Leeds Teaching Hospitals NHS Trust
Sheffield	Sheffield Teaching Hospitals NHS Foundation Trust
Stoke on Trent	University Hospitals of North Midlands NHS Trust
Birmingham	University Hospitals Birmingham Foundation Trust
Coventry	University Hospitals Coventry and Warwickshire NHS Trust
Nottingham	Nottingham University Hospitals NHS Trust
Leicester	University Hospital of Leicester NHS Trust
Oxford	Oxford Radcliffe Hospitals NHS Trust
Cambridge	Cambridge University Hospitals NHS Foundation Trust
London – North West	Imperial College Healthcare NHS Trust
London – North	Royal Free Hampstead NHS Trust
London – North East	Barts and The London HPB Centre
London – South East	Kings College Hospital NHS Foundation Trust
London – South West	Royal Marsden NHS Foundation Trust
Guildford	Royal Surrey County Hospital
Southampton	Southampton University Hospitals NHS Trust
Plymouth	Plymouth Hospitals NHS Trust
Bristol	University Hospitals Bristol NHS Foundation Trust
North Wales	Royal Liverpool and Broadgreen University Hospitals NHS Trust
South Wales	Abertawe Bro Morgannwg University Health Board
Cardiff	Oncology centre, Velindre Cancer Centre
Swansea	Oncology centre, Singleton Hospital

Performance indicators proposed in the RICHOCHET study protocol

Principal care point	Was first presentation at a hub or spoke hospital?
Care by MDT	Was patient discussed at MDT meeting?
Imaging	Time from presentation to imaging
	Type of imaging received: USS, CT, MRI, and PET CT
Diagnostic tissue sampling	Timing of diagnostic sampling after presentation
Intervention domains	Use of EUS FNA, ERCP, PTC brushings, and tissue biopsy
Biliary decompression	Indication for decompression
	Treatment modality: ERCP, PTC, or other
	Complication rates after decompression intervention
	Treatment success as defined by successful biliary drainage
Neoadjuvant chemotherapy	Use of neoadjuvant chemotherapy
	Adverse outcomes after chemotherapy
Nutritional supplementation	Referral for specialist nutrition team input
	Use of pancreatic enzyme replacement prescription
Curative surgery	Time from presentation to surgery
	Patients who had surgery with curative intent
	Histological staging
	Surgical complication rates
Palliative therapy / end-of-life care planning	Rates of referral to hospital or community palliative care team if appropriate
	Proportion of patients seen by a CNS
	Proportion of patients where ceiling of care and resuscitation status was discussed

ICD10 codes for defining cancer of the pancreas and biliary tract

C25 Malignant neoplasm of pancreas

C25.0 Head of pancreas

C25.1 Body of pancreas

C25.2 Tail of pancreas

C25.3 Pancreatic duct

C25.4 Endocrine pancreas (Islets of Langerhans)

C25.7 Other parts of pancreas (Neck of pancreas)

C25.8 Overlapping lesion of pancreas [See note 5 at the beginning of this chapter]

C25.9 Pancreas, unspecified

C24 Malignant neoplasm of other / unspecified parts of biliary tract

(Excl.: intrahepatic bile duct (C22.1))

C24.0 Extrahepatic bile duct, (Biliary duct or passage, Common bile duct, Cystic duct, Hepatic duct)

C24.1 Ampulla of Vater

C24.8 Overlapping lesion of biliary tract

C24.9 Biliary tract, unspecified

Appendix 4 – Minutes from CRG scoping meeting

Below is an anonymised version of the section of the meeting minutes related to the scope of NPaCA, from the July 2023 CRG meeting.

1. <u>Scoping exercise: discussion</u>

The NPaCA project team provided an overview of the proposed audit scope and highlighted some key areas for discussion.

a. NPaCA inclusion criteria:

- It was noted that the NHS service specification for pancreatic cancer includes proximal duodenal tumours, and there was discussion about whether the audit should include these diagnoses for consistency. It was agreed that duodenal tumours should be excluded initially, to keep reporting and interpretation clear – this may be reviewed in future.
- There was general agreement that neuroendocrine tumours should be excluded.
- There was a question whether to restrict inclusion to only PDAC patients (excluding periampullary tumours) for simplicity; however, it was noted that there is a great deal of overlap in the diagnostic and surgical pathways for PDAC and periampullary tumours, and limiting the audit to PDAC may result in small surgery numbers at organisation level.
- It was agreed that both radiologic diagnoses and tissue diagnoses should be included.
- The NPaCA team observed that the approach for the audit would be to start off simply and to then build on the audit over time.
- The NPaCA team confirmed that only existing data sets would be accessed, to minimise the burden of audit for staff in hospitals. Some flows to cancer registry are not ideal and the audit would highlight areas to organisations where their data quality could be improved.

b. Pathway coverage:

- It was suggested the audit cover the whole pathway and consider reporting either 5-year or 10-year survival. The audit team noted that shorter-term survival (e.g. 1-3 years) tends to be reported in other audits, as long-term survival can be less informative about current practice given changes to standards of care and service levels over time.
- There was a request for the audit to clarify the use of "definitive treatment" when describing the care pathway. It was noted patients that this is typically used for curative treatment and many patients do not receive SACT or surgery (raised in the meeting and comments received via email).
- Time-based aspects of the pathway:
    - If possible, capturing time to diagnosis would be useful, including an understanding of what happens in primary care (e.g. number of GP appointments before referral, variation is use of early CT/ultrasound) – limitations of the primary care data available to the audit were discussed.
    - It was noted that time to EUS is important as prolonged waiting times are a barrier to starting treatment. Sequencing of investigations (multiple investigations in sequence rather that in parallel) was also identified as an important contributor to delays in treatment.

    - Time from referral to confirmed diagnosis, and time from diagnosis to start of first definitive treatment were mentioned as important aspects of the pathway to report.
- There was interest in the use of PERT, particularly for people waiting for the start of definitive treatment and/or for patients with poor performance status at diagnosis.
- There was interest in the type of biopsy done.
- There was interest in how chemotherapy regimens vary across NHS trusts, in particular for metastatic first-line treatment, and for adjuvant and neo-adjuvant treatment.

c. Quality Improvement (QI) priorities:

- It was noted that the suggested priorities are all important QI goals and it was appreciated that they focus on potential roadblocks in the pathway, which if addressed could lead to better patient experience and outcomes.
    - It was noted that it would be interesting to see information on access to specialist dietitians (this was also mentioned in comments via email). The NPaCA team noted that this information is not currently available in routine data, but potentially could be introduced into data collection, notably via COSD.
        - Post-meeting note: the NHSE GIRFT Pancreatic Cancer workstream is conducting a review of pancreatic cancer services in England, which will collect information on workforce, including the number of specialist dietitians in each network (Cancer Alliance) treating patients with pancreatic cancer.

Other comments received via email:

- There was interest in the use of biliary drainage / stent, particularly in those with advanced disease who may spend large amounts of time in hospital rather than being palliated in the community.
- Admissions in the last months of life may be an important quality indicator for end of life care.
- There were questions about how well enhanced supportive care services are identified in routine data, and how “access to specialist end of life care” (a small part of supportive and palliative care) is defined.
- It would be good to look at performance status and how this differs by treatment intent and stage at diagnosis.