

**Scottish Cancer Taskforce
National Cancer Quality Steering Group**

**HepatoPancreatoBiliary
Cancer Clinical Quality
Performance Indicators
Engagement Document**

January 2017

Contents Update Record

December 2016 (v3.0)

This document was updated following formal review of the Hepatopancreatobiliary (HPB) Cancer Quality Performance Indicators (QPIs) which took place following analysis of year 3 of the HBP cancer QPI data.

The following QPIs have been updated:

- QPI 2 - Diagnosis and Staging of HCC
- QPI 3 - Referral to Scottish Liver Transplant Unit
- QPI 7 - Pathological Diagnosis of Pancreatic, Duodenal or Biliary Tract Cancer
- QPI 10 - Lymph Node Yield
- QPI 11 - 30 and 90 Day Mortality After Treatment with Curative Intent
- QPI 12 - Volume of Cases per Centre / Surgeon

Please note the extant Clinical Trials has now been added into each tumour specific QPI document (see QPI 13: Clinical Trials).

As a result of the changes above, the contents page and page numbering differ from earlier version of this document. Sections 1 - 11 and the appendices have also been updated.

Please note that this version of the HPB Cancer QPI Document applies to cases diagnosed from 1st January 2016 onwards. Where amended or new QPIs require new data items for measurement, this will apply for patients diagnosed from 1st January 2017.

Previous Updates:

February 2015 (v2.1)

This document was updated following baseline review of the HPB Cancer QPIs which took place following analysis of year 1 of the HPB cancer QPI data. As a result, the following QPIs have been updated:

- QPI 2 – Diagnosis and Staging of HCC
- QPI 3 – Referral to Scottish Liver Transplant Unit
- QPI 4 – Palliative Treatment for HCC
- QPI 5 – 30 Day Mortality After Treatment for HCC Cancers
- QPI 6 – Radiological Diagnosis for Pancreatic, Duodenal or Biliary Tract Cancers
- QPI 10 – Lymph Node Yield
- QPI 12 – Volume of Cases per Centre/ Surgeon

Please note that this version of the HPB Cancer QPI Document applies to cases diagnosed from 1st January 2014.

November 2013

Please note that this document has been updated to include QPI 1 – Multi-Disciplinary Team (MDT) Meeting.

The overall QPI numbering, contents page and page numbering have been amended as a result and therefore differ from earlier versions of this document.

Contents Page

1. National Cancer Quality Programme	5
1.1 Quality Assurance and Continuous Quality Improvement	5
2. Quality Performance Indicator Development Process	5
3. QPI Formal Review Process	6
4. Format of the Quality Performance Indicators	6
5. Supporting Documentation	7
6. Quality Performance Indicators for HPB Cancer	8
QPI 1 – Multi-Disciplinary Team (MDT) Meeting	8
QPI 2 – Diagnosis and Staging of HCC	9
QPI 3 – Referral to Scottish Liver Transplant Unit	11
QPI 4 – Palliative Treatment for HCC	12
QPI 5 – 30 and 90 Day Mortality After Curative or Palliative Treatment	13
QPI 6 – Radiological Diagnosis of Pancreatic, Duodenal or Biliary Tract Cancer	14
QPI 7 – Pathological Diagnosis of Pancreatic, Duodenal or Biliary Tract Cancer	15
QPI 8 – Systemic Therapy for Pancreatic Cancer	16
QPI 9 – Resection Rate for Pancreatic, Duodenal or Biliary Tract Cancers	17
QPI 10 – Lymph Node Yield	18
QPI 11 – 30 and 90 Day Mortality After Treatment with Curative Intent	19
QPI 12 – Volume of Cases per Centre/Surgeon	20
QPI 13 – Clinical Trial Access	21
7. Survival	22
8. Areas for Future Consideration	22
9. Governance and Scrutiny	22
9.1 National	23
9.2 Regional – Regional Cancer Networks	23
9.3 Local – NHS Boards	23
10. How to participate in the engagement process	23
10.1 Submitting your comments	24
10.2 Engagement feedback	24
11. References	25
12. Appendices	27
Appendix 1: QPI Development Process	27
Appendix 2: HPB Cancer QPI Development Group Membership (2012)	29
Appendix 3: HPB Cancer QPI Formal Review Group Membership (2016)	30
Appendix 4: Clinical Trials Definitions	31

Appendix 5: 3 Yearly National Governance Process & Improvement Framework for Cancer Care	32
Appendix 6: Regional Annual Governance Process and Improvement Framework for Cancer Care	33
Appendix 7: Glossary of Terms	34

1. National Cancer Quality Programme

Better Cancer: Ambition and Action (2016)¹ details a commitment to delivering the national cancer quality programme across NHSScotland, with a recognised need for national cancer QPIs to support a culture of continuous quality improvement. Addressing variation in the quality of cancer services is pivotal to delivering improvements in quality of care. This is best achieved if there is consensus and clear indicators for what good cancer care looks like.

Small sets of cancer specific outcome focussed, evidence based indicators are in place for 18 different tumour types. These are underpinned by patient experience QPIs that are applicable to all, irrespective of tumour type. These QPIs ensure that activity is focused on those areas that are most important in terms of improving survival and individual care experience whilst reducing variation and supporting the most effective and efficient delivery of care for people with cancer. QPIs are kept under regular review and are responsive to changes in clinical practice and emerging evidence.

A programme to review and update the QPIs in line with evolving evidence is in place as well as a robust mechanism by which additional QPIs will be developed over the coming years.

1.1 Quality Assurance and Continuous Quality Improvement

The ultimate aim of the programme is to develop a framework, and foster a culture of, continuous quality improvement, whereby real time data is reviewed regularly at an individual Multi Disciplinary Team (MDT)/Unit level and findings actioned to deliver continual improvements in the quality of cancer care. This will be underpinned and supported by a programme of regional and national comparative reporting and review.

NHS Boards will be required to report against QPIs as part of a mandatory, publicly reported, programme at a national level. A rolling programme of reporting is in place, with approximately three national tumour specific reports published annually. National reports include comparative reporting of performance against QPIs at MDT/Unit level across NHSScotland, trend analysis and survival. This approach helps to overcome existing issues relating to the reporting of small volumes in any one year.

In the intervening years tumour specific QPIs are monitored on an annual basis through established Regional Cancer Network and local governance processes, with analysed data submitted to Information Services Division (ISD) for inclusion in subsequent national reports. This approach ensures that timely action is taken in response to any issues that may be identified through comparative reporting and systematic review.

2. Quality Performance Indicator Development Process

The QPI development process was designed to ensure that indicators are developed in an open, transparent and timely way. The development process can be found in appendix 1.

The HPB Cancer QPI Development Group was convened in June 2011, chaired by Dr Jennifer Armstrong (Senior Medical Officer, Scottish Government). Membership of this group included clinical representatives drawn from the three regional cancer networks, Healthcare Improvement Scotland, ISD and patient/carer representatives. Membership of the development group can be found in appendix 2.

3. QPI Formal Review Process

As part of the National Cancer Quality Programme a systematic national review process has been developed, whereby all tumour specific QPIs published are subject to formal review following 3 years analysis of comparative QPI data.

Formal review of the HPB Cancer QPIs was undertaken in September 2016.

A Formal Review Group was convened, chaired by Dr Sophie Barrett, Consultant Clinical Oncologist. Membership of this group included Clinical Leads from the three Regional Cancer Networks as well as the National Clinical Lead. Membership of this group can be found in appendix 3.

The formal review process is clinically driven with comments sought from specialty specific representatives in each of the Regional Cancer Networks for discussion at the initial meeting. This review builds on existing evidence using expert clinical opinion to identify where new evidence is available.

During formal review QPIs may be removed and replaced with new QPIs. Triggers for doing so include significant change to clinical practice, targets being consistently met by all Boards, and publication of new evidence.

Any new QPIs have been developed in line with the following criteria:

- **Overall importance** – does the indicator address an area of clinical importance that would significantly impact on the quality and outcome of care delivered?
- **Evidence based** – is the indicator based on high quality clinical evidence?
- **Measurability** – is the indicator measurable i.e. are there explicit requirements for data measurement and are the required data items accessible and available for collection?

4. Format of the Quality Performance Indicators

QPIs are designed to be clear and measurable, based on sound clinical evidence whilst also taking into account other recognised standards and guidelines.

- Each QPI has a **short title** which will be utilised in reports as well as a fuller **description** which explains exactly what the indicator is measuring.
- This is followed by a brief overview of the **evidence base and rationale** which explains why the development of this indicator was important.
- The measurability **specifications** are then detailed; these highlight how the indicator will actually be measured in practice to allow for comparison across NHSScotland.
- Finally a **target** is indicated, which dictates the level each unit should be aiming to achieve against each indicator.

In order to ensure that the chosen target levels are the most appropriate and drive continuous quality improvement as intended they are kept under review and revised as necessary, if further evidence or data becomes available.

Rather than utilising multiple exclusions, a tolerance level has been built into the QPIs. It is very difficult to accurately measure patient choice, co-morbidities and patient fitness therefore target levels have been set to account for these factors. Further detail is noted within QPIs where there are other factors which influenced the target level.

Where 'less than' (<) target levels have been set the rationale has been detailed within the relevant QPI. All other target levels should be interpreted as 'greater than' (>) levels.

5. Supporting Documentation

A national minimum core dataset and a measurability specification document have been developed in parallel with the indicators to support the monitoring and reporting of HPB Cancer QPIs. The updated document will be implemented for patients diagnosed with HPB Cancer on, or after, 1st January 2017.

6. Quality Performance Indicators for HPB Cancer

QPI 1 – Multi-Disciplinary Team (MDT) Meeting

QPI Title:	Patients with HepatoPancreatoBiliary (HPB) Cancer should be discussed by a multidisciplinary team prior to definitive treatment.
Description:	Proportion of patients with HPB cancer who are discussed at MDT meeting before definitive treatment.
Rationale and Evidence:	<p>Evidence suggests that patients with cancer managed by a multi-disciplinary team have a better outcome. There is also evidence that the multidisciplinary management of patients increases their overall satisfaction with their care².</p> <p>Discussion prior to definitive treatment decisions being made provides reassurance that patients are being managed appropriately.</p>
Specifications:	<p>Numerator: Number of patients with HPB cancer discussed at the MDT before definitive treatment.</p> <p>Denominator: All patients with HPB cancer.</p> <p>Exclusions:</p> <ul style="list-style-type: none"> • Patients who died before first treatment.
Target:	<p>95%</p> <p>The tolerance within this target is designed to account for situations where patients require treatment urgently.</p>

QPI 2 – Diagnosis and Staging of HCC

QPI Title:	Patients with Hepatocellular Carcinoma (HCC) should be appropriately diagnosed and staged.
Description:	<p>Proportion of patients with HCC who have undergone computerised tomography (CT) or Magnetic Resonance Imaging (MRI) and with full information recorded*.</p> <p>Please note: The specifications of this QPI are separated to ensure clear measurement of patients undergoing:</p> <ul style="list-style-type: none"> (i) CT or MRI; and (ii) CT or MRI with full information recorded
Rationale and Evidence:	<p>Management of HCC is determined by both the stage of HCC and presence/severity of underlying chronic liver disease. Complete information is required to enable correct management decisions to be made by the Multi-Disciplinary Team (MDT).</p> <p>Treatment options for patients with liver cancer are dependant on numerous factors, including the location, number and size of tumour(s)³.</p> <p>CT or MRI is the recommended imaging technique for the diagnosis of hepatocellular carcinoma⁴.</p>
Specification (i):	<p>Numerator: Number of patients with HCC undergoing either CT or MRI.</p> <p>Denominator: All patients with HCC.</p> <p>Exclusions:</p> <ul style="list-style-type: none"> • No exclusions.
Target:	<p>90%</p> <p>This target accounts for the fact that some patients may have significant co-morbidities or may not be fit for investigation and/or treatment.</p>
Specification (ii):	<p>Numerator: Number of patients with HCC undergoing either CT or MRI, and with full information recorded*.</p> <p>Denominator: All patients with HCC.</p> <p>Exclusions:</p> <ul style="list-style-type: none"> • No exclusions.
Target:	<p>90%</p> <p>This target accounts for the fact that some patients may have significant co-morbidities or may not be fit for investigation and/or treatment.</p>

* Full information requires the following to be recorded:

- No. of liver lesions
- Size of largest liver lesion
- Presence or absence of vascular invasion

- Presence or absence of chronic liver disease
- Cause of chronic liver disease
- Childs Pugh severity of chronic liver disease
- Alpha-Fetoprotein Quantification (AFP)

QPI 3 – Referral to Scottish Liver Transplant Unit

QPI Title:	Patients with early Hepatocellular Carcinoma (HCC) should be referred for consideration of liver transplantation.
Description:	Proportion of patients with HCC who meet the current UK listing criteria for orthotopic liver transplantation referred to the Scottish Liver Transplant Unit (SLTU) for consideration of liver transplantation.
Rationale and Evidence:	<p>Liver transplantation is associated with good long term outcome in selected patients with HCC^{5,6}. All patients with early HCC should be considered for liver transplantation and there should be equity of access to liver transplantation across Scotland.</p> <p>Current UK listing criteria, as defined by NHS Blood and Transplant (NHSBT), are based on the “Milan criteria” which are well validated selection criteria for liver transplantation in patients with HCC. Liver transplantation should be considered for all patients with HCC meeting the criteria. Failure to consider liver transplantation where appropriate may result in inequity of access to a successful therapeutic option^{4,6}.</p>
Specifications:	<p>Numerator: Number of patients with HCC meeting UK listing criteria that are referred to SLTU.</p> <p>Denominator: All patients with HCC meeting UK listing criteria (as defined by NHSBT)[*].</p> <p>Exclusions:</p> <ul style="list-style-type: none"> • Patients who refuse treatment. • Patients with evidence of vascular invasion. • Patients with extrahepatic disease.
Target:	<p>90%</p> <p>This target accounts for the fact that for some patients it may not be appropriate for referral to the SLTU, due to factors of patient fitness.</p>

^{*} Current UK listing criteria are:

- Single tumour ≤5cms diameter
- Up to 5 tumours all ≤3cms
- Single tumour 5-7cms which shows no significant progression over 6 months

QPI 4 – Palliative Treatment for HCC

QPI Title:	Patients with Hepatocellular Carcinoma (HCC) who are not suitable for curative treatment should receive palliative treatment.
Description:	Proportion of patients with HCC not suitable for treatment with curative intent (liver transplantation, resection or ablative therapies) that undergo specific treatment with palliative intent (Trans-arterial chemoembolisation (TACE) or Systemic Anti Cancer Therapy (SACT)).
Rationale and Evidence:	<p>TACE and SACT have been demonstrated to improve survival in patients with HCC and well compensated chronic liver disease that are not suitable for treatments with curative intent⁵.</p> <p>TACE is recommended as treatment for patients with inoperable advanced HCC, with chronic liver disease of Child's-Pugh grade A and B^{4,5}.</p>
Specifications:	<p>Numerator: Number of patients with HCC not undergoing treatment with curative intent who receive TACE or SACT.</p> <p>Denominator: All patients with HCC not undergoing treatment with curative intent (liver transplantation, resection or ablative therapies).</p> <p>Exclusions:</p> <ul style="list-style-type: none"> • Patients with decompensated chronic liver disease (Child's Pugh Grade C). • Patients who refuse treatment.
Target:	<p>40%</p> <p>This target accounts for the fact that some patients may have significant co-morbidities or fitness level which means that TACE or SACT is not appropriate. Additionally, this tolerance accounts for patients where synthetic function is not adequate to receive treatment.</p> <p>Please note: In order to ensure that the chosen target level is the most appropriate and drives continuous quality improvement as intended it will be kept under review and revised as necessary, once baseline data or further evidence becomes available.</p>

QPI 5 – 30 and 90 Day Mortality After Curative or Palliative Treatment

QPI Title:	30 and 90 day mortality following treatment for Hepatocellular Carcinoma (HCC) with either curative or palliative intent.
Description:	<p>Proportion of patients with HCC undergoing disease specific treatment, either curative (liver transplantation, resection or ablation) or palliative (Trans-arterial chemoembolisation (TACE) or Systemic Anti Cancer Therapy (SACT)) who die within 30 or 90 days of definitive treatment.</p> <p>Please note: The specifications of this QPI are separated to ensure clear measurement of both:</p> <ul style="list-style-type: none"> (i) Patients who die within 30 days of definitive treatment (with curative or palliative intent); and (ii) Patients who die within 90 days of treatment with curative intent
Rationale and Evidence:	<p>Disease specific interventions for HCC are delivered with either curative (liver transplantation, resection or ablation) or palliative (TACE or SACT) intent. In either case treatments should be performed safely with low rates of mortality. Similarly, disease specific treatment should only be undertaken in individuals that may benefit from treatment, that is, disease specific treatments should not be undertaken in futile situations.</p> <p>Treatment related mortality is a marker of the quality and safety of the whole service provided by the Multi Disciplinary Team (MDT)⁷.</p>
Specification (i):	<p>Numerator: Number of patients with HCC undergoing disease specific treatment (liver transplant, resection, ablation, TACE or SACT) that die within 30 days of definitive treatment.</p> <p>Denominator: All patients with HCC undergoing disease specific treatment (liver transplant, resection, ablation, TACE or SACT).</p> <p>Exclusions:</p> <ul style="list-style-type: none"> • No exclusions.
Specification (ii):	<p>Numerator: Number of patients with HCC undergoing disease specific treatment with curative intent (liver transplant, resection, or ablation) that die within 90 days of definitive treatment.</p> <p>Denominator: All patients with HCC undergoing disease specific treatment with curative intent (liver transplant, resection, or ablation).</p> <p>Exclusions</p> <ul style="list-style-type: none"> • No exclusions. <p>Please Note: This indicator will be reported by principal treatment modality, in the following hierarchy: liver transplant, resection, ablation, TACE, SACT.</p> <p>Mortality following SACT will be measured from date of commencement of therapy, as this particular treatment is taken over a prolonged period of time.</p>
Target:	<10%

QPI 6 – Radiological Diagnosis of Pancreatic, Duodenal or Biliary Tract Cancer

QPI Title:	Patients with pancreatic, duodenal or biliary tract cancers should undergo computerised tomography (CT) of the chest, abdomen and pelvis to evaluate the extent of disease.
Description:	Proportion of patients with pancreatic, duodenal or biliary tract cancer who undergo CT of the chest, abdomen and pelvis.
Rationale and Evidence:	<p>Accurate staging is important to ensure appropriate treatment is delivered and futile interventions avoided.</p> <p>The primary tumour and its local extent should be defined and the presence or absence of metastatic disease assessed. CT is recommended for the diagnosis of pancreatic cancer as it will accurately delineate tumour size, infiltration, and the presence of metastatic disease⁸.</p>
Specifications:	<p>Numerator: Number of patients with pancreatic, duodenal or biliary tract cancer who undergo CT of the chest, abdomen and pelvis.</p> <p>Denominator: All patients with pancreatic, duodenal or biliary tract cancer.</p> <p>Exclusions:</p> <ul style="list-style-type: none"> • Patients receiving supportive care only.
Target:	<p>80%</p> <p>This target accounts for factors of patient choice.</p>

QPI 7 – Pathological Diagnosis of Pancreatic, Duodenal or Biliary Tract Cancer

QPI Title:	Patients with pancreatic, duodenal or distal biliary tract cancers having non-surgical treatment should have a cytological or histological diagnosis.
Description:	Proportion of patients with pancreatic, duodenal or distal biliary tract cancer undergoing non-surgical treatment who have a cytological or histological diagnosis.
Rationale and Evidence:	<p>In patients who are being considered for anti-cancer therapy, definitive cytological or histological diagnosis is essential before chemotherapy to ensure full benefit of any treatment offered⁸.</p> <p>Even when no active treatment is being considered, a definitive diagnosis is valuable in helping to inform patients and carers about the nature of the disease and the likely prognosis.</p>
Specifications:	<p>Numerator: Number of patients with pancreatic, duodenal or distal biliary tract cancer undergoing non-surgical treatment who have a histological or cytological diagnosis (e.g. brush cytology, endoscopic or image guided biopsy).</p> <p>Denominator: All patients with pancreatic, duodenal or distal biliary tract cancer undergoing non-surgical treatment.</p> <p>Exclusions:</p> <ul style="list-style-type: none"> • No exclusions.
Target:	<p>75%</p> <p>This target takes account of the fact that it is not always appropriate, safe or possible to obtain a histological or cytological diagnosis due to the performance status of the patient or advanced nature of the disease. In addition it is intended to reflect factors relating to patient choice.</p>

QPI 8 – Systemic Therapy for Pancreatic Cancer

QPI Title:	Patients undergoing resection for pancreatic cancer should receive adjuvant chemotherapy, where appropriate.
Description:	Proportion of patients undergoing resection for pancreatic cancer receiving adjuvant chemotherapy.
Rationale and Evidence:	<p>Adjuvant chemotherapy is the accepted standard of care for patients with pancreatic cancer following surgical resection and is proven to have a survival benefit⁹.</p> <p>It is difficult to accurately and consistently measure whether patients have been considered for adjuvant chemotherapy. The number of patients who actually receive this treatment is therefore being utilised as a proxy measure of consideration for treatment.</p> <p>If available, clinical trials should be considered the preferred option for eligible patients.</p>
Specifications:	<p>Numerator: Number of patients undergoing pancreatic cancer resection who receive adjuvant chemotherapy.</p> <p>Denominator: All patients undergoing resection for pancreatic cancer.</p> <p>Exclusions:</p> <ul style="list-style-type: none"> • Patients who die post-operatively (within 60 days of surgery). • Patients who refuse chemotherapy.
Target:	<p>50%</p> <p>This target accounts for the fact that patients may have post-operative complications that preclude consideration of adjuvant therapy.</p> <p>Please note: In order to ensure that the chosen target level is the most appropriate and drives continuous quality improvement as intended it will be kept under review and revised as necessary, once baseline data or further evidence becomes available.</p>

QPI 9 – Resection Rate for Pancreatic, Duodenal or Biliary Tract Cancers

QPI Title:	Patients with localised pancreatic, distal biliary tract or duodenal cancer should have surgical resection.
Description:	Proportion of patients who undergo resection for pancreatic, distal biliary tract or duodenal cancer.
Rationale and Evidence:	<p>Surgical resection is the only potentially curative treatment for pancreatic cancer^{8,10}.</p> <p>Where surgical resection is not carried out the reason(s) should be clearly documented by the MDT.</p>
Specifications:	<p>Numerator: Number of patients with pancreatic, duodenal or distal biliary tract cancer who undergo resection.</p> <p>Denominator: All patients with pancreatic, duodenal or distal biliary tract cancer.</p> <p>Exclusions:</p> <ul style="list-style-type: none"> • No exclusions
Target:	<p>15%</p> <p>This target takes into consideration patient choice as well as patients who may develop pancreatitis or other complications during the pre-operative phase. It is intended as a composite measure of the entire diagnostic and staging pathway, but recognises that the majority of patients will have advanced disease at presentation.</p>

QPI 10 – Lymph Node Yield

QPI Title:	In patients undergoing surgery for pancreatic, duodenal or distal biliary tract cancer the number of lymph nodes examined should be maximised.
Description:	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.
Rationale and Evidence:	<p>Adequate lymph node yield is important for accurate staging and is a surrogate marker of adequacy of en-bloc cancer resection and diligence of the pathologist.</p> <p>Evidence suggests that pancreatoduodenectomy should yield a mean of at least 15 lymph nodes examined from the principal specimen¹¹.</p> <p>Within the measurement of this QPI, pancreatoduodenectomy is being utilised as a proxy measurement for all surgical resection, to ensure consistent and comparable measurement across NHS Scotland.</p>
Specifications:	<p>Average number of lymph nodes resected and pathologically examined for patients with pancreatic, duodenal or distal biliary tract cancer who undergo pancreatoduodenectomy by each centre in a given year.</p> <p>Exclusions:</p> <ul style="list-style-type: none"> • No exclusions.
Target:	<p>Average of 15 lymph nodes per centre.</p> <p>An average number is used rather than a minimum within this target as it is recognised that there may be cases where the surgery produces a smaller bulk of tissue and therefore less lymph nodes as a result.</p>

QPI 11 – 30 and 90 Day Mortality After Treatment with Curative Intent

QPI Title:	Mortality after surgery with curative intent [†] for pancreatic, duodenal or distal biliary tract cancer.
Description:	Proportion of patients undergoing surgical resection with curative intent for pancreatic, duodenal or distal biliary tract cancer who die within 30/90 days.
Rationale and Evidence:	<p>Mortality following resection for HPB cancer has fallen over the past 30 years and in specialist units should be less than 5%¹².</p> <p>Treatment related mortality is a marker of the quality and safety of the whole service provided by the Multi Disciplinary Team (MDT)⁷.</p>
Specifications:	<p>Numerator: Number of patients with pancreatic, duodenal or distal biliary tract cancer undergoing surgical resection who die within 30/90 days of surgery.</p> <p>Denominator: All patients with pancreatic, duodenal or distal biliary tract cancer undergoing surgical resection.</p> <p>Exclusions:</p> <ul style="list-style-type: none"> • No exclusions. <p>Please Note: This indicator will be reported separately as 30 day mortality and 90 day mortality, as opposed to a single figure.</p>
Target:	<5%

[†] Surgical resection with palliative intent may be undertaken in unique circumstances. For the purposes of this QPI, surgical resection with palliative intent has not been removed from the measurement due to the rare occurrence of these cases.

QPI 12 – Volume of Cases per Centre/Surgeon

QPI Title:	HPB resectional surgery should be performed in hospitals where there is an appropriate annual volume of such cases.
Description:	Number of surgical resections for pancreatic, duodenal or distal biliary tract cancer performed by a specialist centre, and surgeon, over a 1 year period.
Rationale and Evidence:	<p>Pancreatic resectional surgery should be performed by surgeons who work in a specialist Multi Disciplinary Team (MDT) in a specialist centre, with outcomes audited regularly and benchmarked nationally¹².</p> <p>Surgical resection should be confined to specialist centres to increase resection rates and reduce hospital morbidity and mortality⁸.</p> <p>The literature demonstrates that there is a relationship between increasing surgical volumes for major hepatopancreatobiliary resections and improved patients outcomes (mortality)¹³.</p>
Specifications:	<p>Number of surgical resections for pancreatic, duodenal or distal biliary tract cancer performed by each surgeon/centre in a given year.</p> <p>Exclusions:</p> <ul style="list-style-type: none"> • No exclusions
Target:	<p>Minimum 11 procedures per centre, with a minimum of 4 procedures per surgeon, in a 1 year period.</p> <p>This is a minimum target level and is designed to ensure that all surgeons performing pancreatic resection perform a minimum of 4 procedures per year.</p> <p>Please Note: Varying evidence exists regarding the most appropriate target level for surgical case volume. In order to ensure that the target level takes account of level 1 evidence and will drive continuous quality improvement as intended this performance indicator must be kept under regular review.</p> <p>It is recognised that multiple factors affect overall performance and that the end point focus must be clinical outcomes in what is a team delivered goal. It is recommended that where two consultants share an operation each should count the case in his/her numbers as this best reflects the partnership accountability of such shared procedures.</p>

Please note:

SMR01 data will be utilised to support reporting and monitoring of this QPI rather than clinical audit. This will maximise the use of data which are already collected and remove the need for any duplication of data collection. Standard reports are in place with direct access for each Board to run these reports to ensure nationally consistent analysis and reporting.

QPI 13 – Clinical Trial Access

QPI Title:	All patients should be considered for participation in available clinical trials, wherever eligible.
Description:	Proportion of patients with HPB cancer who are enrolled in an interventional clinical trial or translational research.
Rationale and Evidence:	<p>Clinical trials are necessary to demonstrate the efficacy of new therapies and other interventions. Furthermore evidence suggests improved patient outcomes from participation in clinical trials².</p> <p>Clinicians are therefore encouraged to enter patients into well-designed trials and to collect longer-term follow-up data.</p> <p>High accrual activity into clinical trials is used as a goal of an exemplary clinical research site.</p>
Specifications:	<p>Numerator: Number of patients with HPB cancer enrolled in an interventional clinical trial or translational research.</p> <p>Denominator: All patients with HPB cancer.</p> <p>Exclusions:</p> <ul style="list-style-type: none"> • No exclusions.
Target:	<p>Interventional clinical trials – 7.5%</p> <p>Translational research – 15%</p>

The clinical trials QPI will be measured utilising SCRN data and ISD incidence data, as is the methodology currently utilised by the Chief Scientist Office (CSO) and NCRI. The principal benefit of this approach is that this data is already collected utilising a robust mechanism. At present a 'clinical trial' data item is contained within all tumour specific datasets, however in order to avoid any duplication of effort, and focus resources appropriately, SCRN data is the preferred option.

Utilising SCRN data allows for comparison with CSO published data and ensures capture of all clinical trials recruitment, not solely first line treatment trials, as contained in the clinical audit data. Given that a significant proportion of clinical trials are for relapsed disease this is felt to be particularly important in driving quality improvement. This methodology utilises incidence as a proxy for all patients with cancer. This may slightly over, or underestimate, performance levels, however this is an established approach currently utilised by NHSScotland. For clinical trials definitions please see appendix 4.

The full Clinical Trials QPI document can be found at:

[Healthcare Improvement Scotland – Cancer Quality Performance Indicators](#)

7. Survival

Improving survival forms an integral part of the national cancer quality improvement programme. HPB cancer survival analysis will be reported and analysed on a 3 yearly basis by Information Services Division (ISD). The specific issues which will be addressed will be identified by an expert group ahead of any analysis being undertaken, as per the agreed national cancer quality governance and improvement framework.

The HPB Cancer QPI Group has identified, during the QPI development process, the following issues for survival analysis:

- 90 day survival following diagnosis
- Overall 1 and 2 year survival

To ensure consistent application of survival analysis, it has been agreed that a single analyst on behalf of all three regional cancer networks undertakes this work. Survival analysis will be scheduled as per the national survival analysis and reporting timetable, agreed with the National Cancer Quality Steering Group and Scottish Cancer Taskforce. This reflects the requirement for record linkage and the more technical requirements of survival analyses which would make it difficult for individual Boards to undertake routinely and in a nationally consistent manner.

8. Areas for Future Consideration

The HPB Cancer QPI Groups have not been able to identify sufficient evidence, or determine appropriate measurability specifications, to address all areas felt to be of key importance in the treatment of HPB cancer, and therefore in improving the quality of care for patients affected by HPB cancer.

The following areas for future consideration have been raised across the lifetime of the HPB Cancer QPIs.

- Surveillance and screening of patients with chronic liver disease for the development of hepatocellular carcinoma.
- Specialist pathology reporting for hepatocellular carcinoma.
- Palliative chemotherapy for pancreatic cancer.
- Surgical volumes for resection of primary liver cancer.
- Timing and outcomes of biliary intervention in patients with malignant biliary obstruction.
- Surgical margin rates

9. Governance and Scrutiny

A national and regional governance framework to assure the quality of cancer services in NHSScotland has been developed; key roles and responsibilities within this are set out below. Appendices 5 and 6 provide an overview of these governance arrangements diagrammatically. The importance of ensuring robust local governance processes are in place is recognised and it is essential that NHS Boards ensure that cancer clinical audit is fully embedded within established processes.

9.1 National

- Scottish Cancer Taskforce
 - Accountable for overall national cancer quality programme and overseeing the quality of cancer care across NHSScotland.
 - Advising Scottish Government Health and Social Care Directorate (SGHSCD) if escalation required.
- Healthcare Improvement Scotland
 - Proportionate scrutiny of performance.
 - Support performance improvement.
 - Quality assurance: ensure robust action plans are in place and being progressed via regions/Boards to address any issues identified.
- Information Services Division (ISD)
 - Publish national comparative report on tumour specific QPIs and survival for three tumour types per annum and specified generic QPIs as part of the rolling programme of reporting.

9.2 Regional – Regional Cancer Networks

- Annual regional comparative analysis and reporting against tumour specific QPIs.
- Support national comparative reporting of specified generic QPIs.
- Identify and share good practice.
- In conjunction with constituent NHS Boards identify regional and local actions required to develop an action plan to address regional issues identified.
- Review and monitoring of progress against agreed actions.
- Provide assurance to NHS Board Chief Executive Officers and Scottish Cancer Taskforce that any issues identified have been adequately and timeously progressed.

9.3 Local – NHS Boards

- Collect and submit data for regional comparative analysis and reporting in line with agreed measurability and reporting schedule (generic and tumour specific QPIs).
- Utilise local governance structures to review performance, develop local action plans and monitor delivery.
- Demonstrate continual improvements in quality of care through on-going review, analysis and feedback of clinical audit data at an individual multidisciplinary team (MDT) or unit level.

10. How to participate in the engagement process

In order to ensure wide inclusiveness of clinical and management colleagues from across NHSScotland, patients affected by HPB cancer and the wider public, several different methods of engagement are being pursued:

Professional groups, health service staff, voluntary organisations and individuals:

- Wide circulation of the draft documentation for comment and feedback.

Patient representative groups:

- Organised patient focus group sessions to be held.

10.1 Submitting your comments

You can submit your comments on the Revised HPB Cancer QPIs via the Scottish Government Consultation Hub (website link below):

<https://consult.scotland.gov.uk/nhs/review-of-hpb-cancer-qpis>

All responses should be submitted by 10 February **2017**.

If you require any further information regarding the engagement process please use the email address below.

Email: HPBQPIPpublicengagement@gov.scot

10.2 Engagement feedback

At the end of the engagement period, all comments and responses will be collated for review by the HPB Cancer QPI Formal Review Group. Those who have participated in the engagement process will receive an overview of the changes made and a copy of the final HPB Cancer QPI document.

11. References

1. Scottish Government (2016). Beating Cancer: Ambition and Action Available from: <http://www.scotland.gov.uk/Resource/Doc/242498/0067458.pdf>. (accessed December 2016)
2. NHS Quality Improvement Scotland (2008). Management of Core Cancer Services Standards [online]. Available from: http://www.healthcareimprovementscotland.org/our_work/cancer_care_improvement/cancer_resources/standards_for_cancer_services.aspx (accessed August 2013).
3. NICE (2009). Ex-vivo hepatic resection and reimplantation for liver cancer [online]. Available from: <https://www.nice.org.uk/guidance/ipg298> (accessed December 2016).
4. The Japan Society of Hepatology (2010). Clinical Practice Guidelines for Hepatocellular Carcinoma - The Japan Society of Hepatology 2009 update. Hepatology Research. 40(Suppl s1), 2-144 [online]. Available from: <http://onlinelibrary.wiley.com/doi/10.1111/hep.2010.40.issue-s1/issuetoc> (accessed August 2013).
5. Bruix J, Sherman M for the American Association for the Study of Liver Diseases (2010). Management of Hepatocellular Carcinoma: An Update [online]. 2010. Available from: https://www.aasld.org/sites/default/files/guideline_documents/HCCUpdate2010.pdf (accessed December 2016)
6. Brown DB, Bakal CW, Weintraub JL, Bass JC, Dickey KW, et al. for the American College of Radiology (2007). ACR Appropriateness Criteria. Hepatic malignancy [online]. Updated 2015 available from: <https://acsearch.acr.org/docs/69379/Narrative/> (accessed December 2016).
7. NHS Quality Improvement Scotland (2008). Clinical Standards for the Management of Bowel Cancer [online]. Available from: http://www.healthcareimprovementscotland.org/programmes/cancer_care_improvement/cancer_resources/standards_for_cancer_services.aspx (accessed August 2013).
8. Pancreatic Section of the British Society of Gastroenterology (2005). Guidelines for the management of patients with pancreatic cancer perampullary and ampullary carcinomas [online]. Available from: http://www.bsg.org.uk/pdf_word_docs/pan_cancer.pdf (accessed August 2013).
9. Jonker D, Boutell E, Kamra J, Spithoff K. (2007). Chemotherapy or radiotherapy for resectable pancreatic adenocarcinoma: clinical practice guidelines [online]. Available from: <http://www.cancercare.on.ca/common/pages/UserFile.aspx?serverId=6&path=/File%20Database/CCO%20Files/PEBC/pebc2-23s.pdf> (accessed August 2013).
10. Owens CA, Funaki BS, Ray CE Jr, Brown DB, Gemery JM, Greene FL, et al. for the American College of Radiology (2008). ACR Appropriateness Criteria. Percutaneous biliary drainage in benign and malignant biliary obstruction [online]. Available from: <http://www.guideline.gov/content.aspx?id=15731&search=biliary+tract+cancer> (accessed June 2011).

11. Royal College of Pathologists (2010). Dataset for the histopathological reporting of carcinomas of the pancreas, ampulla of Vater and common bile duct [online]. Available from: <https://www.rcpath.org/resourceLibrary/dataset-for-the-histopathological-reporting-of-carcinomas-of-the-pancreas--ampulla-of-vater-and-common-bile-duct.html> (accessed December 2016).
12. De Wilde, RF, Besselink, MG, van der Tweel, I. et al (2012). Impact of Nationwide Centralisation of Pancreaticoduodenectomy on Hospital Mortality. Br J Surg. 99(3), 404-410 [online]. Available from: <http://www.ncbi.nlm.nih.gov/pubmed/22237731> (accessed August 2013).
13. Association of Upper Gastrointestinal Surgeons of Great Britain and Ireland (2010). Guidance on Minimum Surgeon Volumes [online]. Available from: http://www.augis.org/wp-content/uploads/2014/05/AUGIS_recommendations_on_Minimum_Volumes.pdf (accessed December 2016).
14. NHS National Institute for Health Research (2011). Eligibility Criteria for NIHR Clinical Research Network Support. Available from: <http://www.nihr.ac.uk/funding-and-support/documents/Study-Support-Service/Eligibility/Eligibility%20Criteria%20for%20NIHRCRN%20support.pdf> (accessed December 2016)
15. NHS National Institute for Health Research. Clinical Trials Toolkit: Glossary [online]. 2013 [cited 2013 December 19]; Available from: <http://www.ct-toolkit.ac.uk/>
16. National Cancer Institute. Translational Research Working Group Definition of Translational Research. [online]. 2013. [cited 2013 December 19]; Available from: <https://www.cancer.gov/images/trwg/trwg-oct06rt-exsum-11-21-06.pdf>

12. Appendices

Appendix 1: QPI Development Process

Preparatory Work and Scoping

The preparatory work involved the development of a structured briefing paper by Healthcare Improvement Scotland. This paper took account of existing, high quality, clinical guidance and provided a basis for the development of QPIs.

The scope for development of HPB Cancer QPIs and a search narrative were defined and agreed by the HPB Cancer QPI Development Group. The table below shows the final, inclusion and exclusion criteria used in the literature search.

Inclusion	Exclusion
<p><i>Topics</i> (population/patient): primary liver, biliary tract, pancreatic cancers, cholangiocarcinoma</p> <p><i>Topics</i> (intervention): Diagnosis, staging, surgery, non-surgical management, treatment, palliative chemotherapy, radiotherapy and surgery.</p> <p>Adults only</p> <p><i>Date</i>: 2005 to present day</p> <p><i>Language</i>: all</p>	<p><i>Topics</i>: Communication/information, end of life care, pain management, prevention, screening and secondary liver cancer.</p>

Table 1: HPB Literature Search Criteria

A systematic search was carried out by Healthcare Improvement Scotland using selected websites and two primary medical databases to identify national and international guidelines.

Twenty seven guidelines were appraised for quality using the AGREE II instrument. This instrument assesses the methodological rigour used when developing a guideline. Six of the guidelines were not recommended for use. Of the remaining 21 guidelines, 12 were unreservedly recommended for use and 9 were recommended for use with consideration of their applicability or currency.

Indicator Development

The HPB QPI Development group defined evidence based, measurable indicators with a clear focus on improving the quality and outcome of care provided.

The Group developed QPIs using the clinical recommendations set out in the briefing paper as a base, ensuring all indicators met the following criteria:

- **Overall importance** – does the indicator address an area of clinical importance that would significantly impact on the quality and outcome of care delivered?
- **Evidence based** – is the indicator based on high quality clinical evidence?
- **Measurability** – is the indicator measurable i.e. are there explicit requirements for data measurement and are the required data items accessible and available for collection?

Engagement Process

A wide clinical and public engagement exercise was undertaken as part of development in April 2012 where the HPB Cancer QPIs, along with accompanying draft minimum core dataset and measurability specifications, were made available on the Scottish Government website. During the engagement period clinical and management colleagues from across NHSScotland, patients affected by HPB cancer and the wider public were given the opportunity to influence the development of HPB Cancer QPIs.

Draft documentation was circulated widely to professional groups, health service staff, voluntary organisations and individuals for comment and feedback.

Following the engagement period all comments and responses received were reviewed by the HPB Cancer QPI Development Group and used to produce and refine the final indicators.

Appendix 2: HPB Cancer QPI Development Group Membership (2012)

Name	Designation	Cancer Network/Base
Jennifer Armstrong	Senior Medical Officer (CHAIR)	Medical Director, NHS Greater Glasgow and Clyde
Dougal Adamson	Consultant Oncologist	NOSCAN (Ninewells Hospital)
Irfan Ahmed	Consultant Surgeon	NOSCAN (Aberdeen Royal Infirmary)
Rosanne Bate	Transplant Coordinator	SCAN (Edinburgh Royal Infirmary)
Andy Bathgate	Consultant Physician	SCAN (Edinburgh Royal Infirmary)
Chris Bellamy	Consultant Pathologist	SCAN (Edinburgh Royal Infirmary)
Andrew Fraser	Consultant Physician	NOSCAN (Aberdeen Royal Infirmary)
Alison Forrest	Clinical Services Manager	NOSCAN (Aberdeen Royal Infirmary)
Alan Foulis	Consultant Pathologist	WoSCAN (Glasgow Royal Infirmary)
Michele Hilton Boon	Programme Manager	Healthcare Improvement Scotland
Hedvig Karteszi	Consultant Radiologist	WoSCAN (Glasgow Royal Infirmary)
Jennifer Keatings	Information Officer	WoSCAN (Glasgow Royal Infirmary)
Derek Kerr	Patient Representative	
Lorraine Kirkpatrick	Cancer Nurse Specialist	SCAN (Edinburgh Royal Infirmary)
Maureen Lamb	Audit Facilitator	SCAN (Edinburgh Royal Infirmary)
Colin McKay	Consultant Surgeon; Lead Clinician National HPB Network	WoSCAN (Glasgow Royal Infirmary)
Brian Murray	Principal Information Development Manager	Information Services Division
James Powell	Consultant Surgeon	SCAN (Edinburgh Royal Infirmary)
Iona Scott	Project Manager	WoSCAN
Adrian Stanley	Consultant Physician	WoSCAN (Glasgow Royal Infirmary)
Evelyn Thomson	Regional Manager (Cancer)	WoSCAN

NOSCAN – North of Scotland Cancer Network

SCAN – South East Scotland Cancer Network

WoSCAN – West of Scotland Cancer Network

Appendix 3: HPB Cancer QPI Formal Review Group Membership (2016)

Name	Designation	Cancer Network
Sophie Barrett (CHAIR)	Consultant Clinical Oncologist	WoSCAN
Lorna Bruce	Cancer Audit Manager	SCAN
Anya Adair	HPB Lead Clinician	SCAN
Iain Tait	HPB Lead Clinician	NOSCAN
Euan Dickson	HPB Lead Clinician	WoSCAN
Evelyn Thomson	Regional Manager (Cancer)	WoSCAN
Steve Wigmore	National HPB Cancer Clinical Lead	SCAN
Jennifer Doherty	National Cancer Quality Programme Co-ordinator	WoSCAN
Lorraine Stirling	Project Officer	WoSCAN

Formal review of the HPB Cancer QPIs has been undertaken in consultation with various other clinical specialties.

Appendix 4: Clinical Trials Definitions

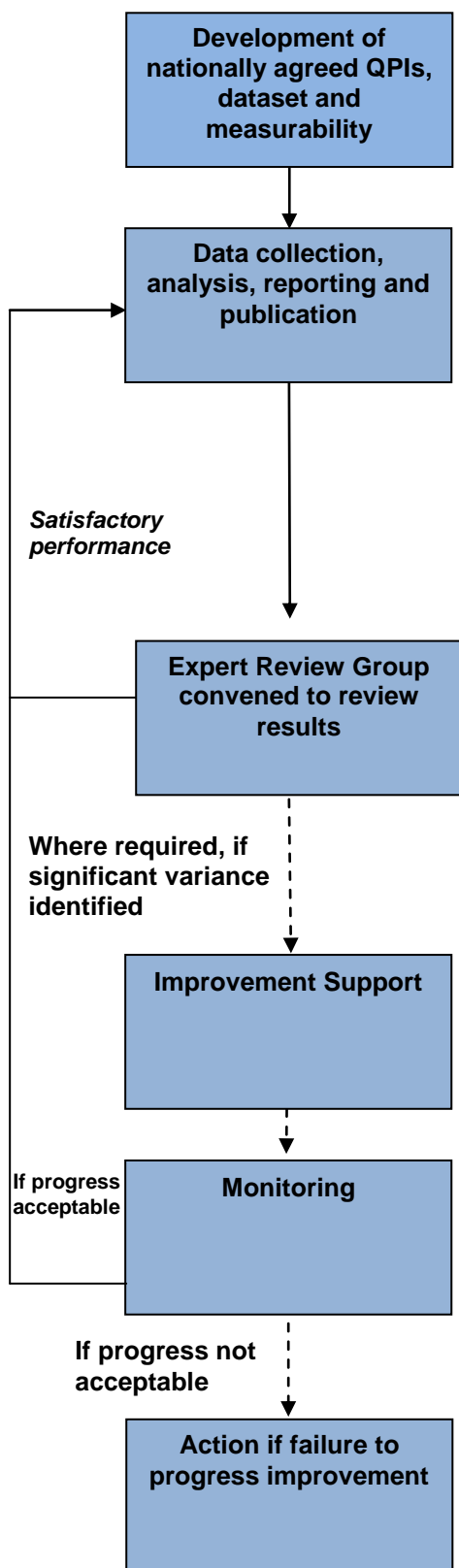
In order to ensure appropriate and nationally comparative measurement against QPIs developed it is of utmost importance to agree consistent definitions of the various terminologies utilised.

The Clinical Trial QPI SLWG has therefore agreed the following definitions:

Research	Research can be defined as the attempt to derive generalisable (i.e. of value to others in a similar situation) new knowledge by addressing clearly defined questions with systematic and rigorous methods. This excludes: audit; needs assessments; quality improvement and other local service evaluations. It also excludes routine banking of biological samples or data except where this activity is integral to a self-contained research project designed to test a clear hypothesis ¹⁴ .
Interventional Clinical Trial	A clinical study in which participants are assigned to receive one or more interventions (or no intervention) so that researchers can evaluate the effects of the interventions on biomedical or health-related outcomes. The assignments are determined by the study protocol. Participants may receive diagnostic, therapeutic, or other types of interventions ¹⁵ .
Translational Research	Translational research transforms scientific discoveries arising from laboratory, clinical, or population studies into clinical applications to reduce cancer incidence, morbidity, and mortality ¹⁶ . The development of the breast cancer drug trastuzumab (Herceptin) is an example for this kind of research. Researchers derived knowledge about the function and presence of a specific gene (HER) from laboratory studies. This information was then used to develop trastuzumab (Herceptin), which inhibits the growth of cancerous cells in patients whose cancers over express the protein coded by this gene.

Appendix 5: 3 Yearly National Governance Process & Improvement Framework for Cancer Care

This process is underpinned by the annual regional reporting and governance framework (see appendix 6).



1. National QPI Development Stage

- QPIs developed by QPI development groups, which include representation from Regional Cancer Networks, Healthcare Improvement Scotland, ISD, patient representatives and the Cancer Coalition.

2. Data Analysis Stage:

- NHS Boards and Regional Cancer Advisory Groups (RCAGs)* collect data and analyse on yearly basis using nationally agreed measurability criteria and produce action plans to address areas of variance, see appendix 6.
- Submit yearly reports to ISD for collation and publication every 3 years.
- National comparative report approved by NHS Boards and RCAGs.
- ISD produce comparative, publicly available, national report consisting of trend analysis of 3 years data and survival analysis.

3. Expert Review Group Stage (for 3 tumour types per year):

- Expert group, hosted by Healthcare Improvement Scotland, review comparative national results.
- Write to RCAGs highlighting areas of good practice and variances.
- Where required NHS Boards requested to submit improvement plans for any outstanding unresolved issues with timescales for improvement to expert group.
- Improvement plans ratified by expert group and Scottish Cancer Taskforce.

4. Improvement Support Stage:

- Where required Healthcare Improvement Scotland provide expertise on improvement methodologies and support.

5. Monitoring Stage:

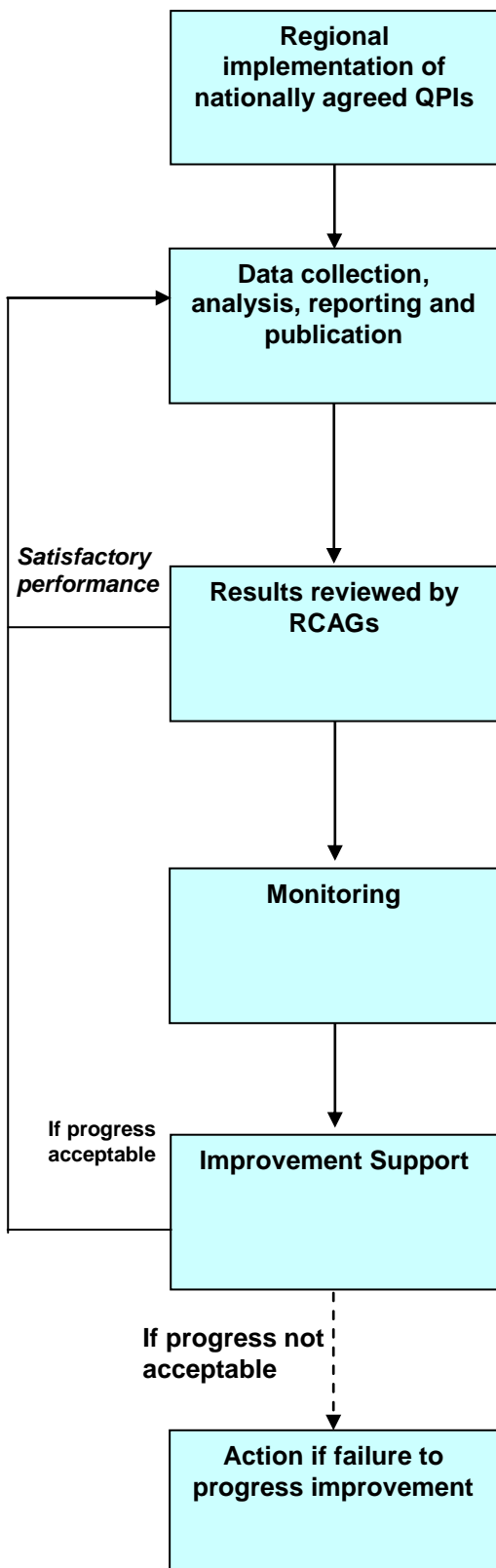
- RCAGs work with Boards to progress outstanding actions, monitor improvement plans and submit progress report to Healthcare Improvement Scotland.
- Healthcare Improvement Scotland report to Scottish Cancer Taskforce as to whether progress is acceptable.

6. Escalation Stage:

- If progress not acceptable, Healthcare Improvement Scotland will visit the service concerned and work with the RCAG and Board to address issues.
- Report submitted to Scottish Cancer Taskforce and escalation with a proposal to take forward to Scottish Government Health Department.

*In the South and East of Scotland Cancer Network (SCAN) the Regional Cancer Planning Group is the equivalent group to Regional Cancer Advisory Group (RCAG).

Appendix 6: Regional Annual Governance Process and Improvement Framework for Cancer Care



1. Regional QPI Implementation Stage:

- National cancer QPIs and associated national minimum core dataset and measurability specifications, developed by QPI development groups.
- Regional implementation of nationally agreed dataset to enable reporting of QPIs.

2. Data Analysis Stage:

- NHS Boards collect data and data is analysed on a yearly basis using nationally agreed measurability criteria at local/ regional level.
- Data/results validated by Boards and annual regional comparative report produced by Regional Networks.
- Areas of best practice and variance across the region highlighted.
- Yearly regional reports submitted to ISD for collation and presentation in national report every 3 years.

3. Regional Performance Review Stage:

- RCAGs* review regional comparative report.
- Regional or local NHS Board action plans to address areas of variance developed.
- Appropriate leads identified to progress each action.
- Action plans ratified by RCAGs.

4. Monitoring Stage:

- Where required, NHS Boards monitor progress with action plans and submit progress reports to RCAGs.
- RCAGs review and monitor regional improvement.

5. Improvement Support Stage:

- Where required Healthcare Improvement Scotland may be requested to provide expertise to NHS Boards/RCAGs on improvement methodologies and support.

6. Escalation Stage:

- If progress not acceptable, RCAGs will escalate any issues to relevant Board Chief Executives. If progress remains unacceptable RCAGs will escalate any relevant issues to Healthcare Improvement Scotland.

*In the South and East of Scotland Cancer Network (SCAN) the Regional Cancer Planning Group is the equivalent group to Regional Cancer Advisory Group (RCAG).

Appendix 7: Glossary of Terms

Abdominal ultrasound	An imaging procedure used to examine the internal organs of the abdomen.
Ablative therapies	See <i>Cryotherapy</i> and <i>Radiofrequency Ablation</i>
Active treatment	Treatment which is intended to improve the cancer and/or alleviate symptoms, as opposed to supportive care.
Adenocarcinoma	Cancer that begins in cells that line certain internal organs and that have gland-like properties.
Adjuvant Chemotherapy	The use of chemotherapy, after initial treatment by surgery to reduce the risk of recurrence of the cancer.
AFP (Alpha-fetoprotein)	A protein normally produced by a foetus. AFP levels are usually undetectable in the blood of healthy adult men or women (who are not pregnant). An elevated level of AFP suggests the presence of either a primary liver cancer or germ cell tumour.
Biliary tract	The organs and ducts that make and store bile (a fluid made by the liver that helps digest fat), and release it into the small intestine. The biliary tract includes the gallbladder and bile ducts inside and outside the liver. Also called biliary system.
Biopsy	Removal of a sample of tissue from the body to assist in diagnosis of a disease.
Brush Cytology	Examination of cells obtained from a mucosal surface using a cytological brush
Chemotherapy	The use of drugs that kill cancer cells, or prevent or slow their growth.
Childs Pugh	Is used to assess the prognosis of chronic liver disease, mainly cirrhosis. Although it was originally used to predict mortality during surgery, it is now used to determine the prognosis, as well as the required strength of treatment and the necessity of liver transplantation.
Chronic liver disease	Chronic liver disease in the clinical context is a disease process of the liver that involves a process of progressive destruction and regeneration of the liver parenchyma leading to fibrosis and cirrhosis.
Co-morbidity	The condition of having two or more diseases at the same time.
Computerised Tomography (CT)	An x-ray imaging technique, which allows detailed investigation of the internal organ of the body.
Cryotherapy	A treatment which aims to eradicate cancer by freezing.
Curative treatment	Treatment which is given with the aim of curing the cancer.
Cytological	The study of the structure and function of cells under the microscope, and of their abnormalities.
Diagnosis	The process of identifying a disease, such as cancer, from its signs and symptoms.
Duodenal	Refers to the duodenum, or the first part of the small intestine.
Dysplastic nodules	Abnormal development or growth of tissues, organs, or cells.
Endoscopic Ultrasound (EUS)	A procedure in which an endoscope is inserted into the body. A probe at the end of the endoscope is used to bounce high-energy sound waves (ultrasound) off internal organs to make a picture.
Hepatocellular Carcinoma (HCC)	A type of adenocarcinoma and the most common type of liver tumour.
Hepatopancreatobiliary (HPB) Cancer	Cancer of the liver, pancreas, gallbladder and biliary tract.

Histological/histopathological	The study of the structure, composition and function of tissues under the microscope, and their abnormalities
Immunohistochemistry (IHC)	A technique used to identify specific molecules in different kinds of tissue. The tissue is treated with antibodies that bind the specific molecule. These are made visible under a microscope by using a colour reaction, a radioisotope, colloidal gold, or a fluorescent dye. Immunohistochemistry is used to help diagnose diseases, such as cancer, and to detect the presence of micro organisms. It is also used in basic research to understand how cells grow and differentiate (become more specialised).
Inoperable	Describes a condition that cannot be treated by surgery.
Lesion	Tumour, mass, or other abnormality.
Liver	A large organ located in the upper abdomen. The liver cleanses the blood and aids in digestion by secreting bile.
Liver damage stages A and B	See <i>Childs Pugh</i>
Liver transplantation	Liver transplantation is a surgery that removes a diseased liver and replaces it with a healthy donor liver.
Lymph nodes	Small bean shaped organs located along the lymphatic system. Nodes filter bacteria or cancer cells that might travel through the lymphatic system.
Malignancy	Cancerous. Malignant cells can invade and destroy the tissue from which they originate and can spread to other sites in the body.
Metastatic	Spread of cancer away from the primary site to somewhere else via the bloodstream or the lymphatic system.
Milan Criteria	Criteria applied as a basis for selecting patients with cirrhosis and hepatocellular carcinoma for liver transplantation.
Mortality	Either (1) the condition of being subject to death; or (2) the death rate, which reflects the number of deaths per unit of population in any specific region, age group, disease or other classification, usually expressed as deaths per 1000, 10,000 or 100,000.
Multi-Disciplinary Team (MDT)	A meeting which is held on a regular basis, which is made up of participants from various disciplines appropriate to the disease area, where diagnosis, management, and appropriate treatment of patients is discussed and decided.
Orthotopic	Refers to something that occurs in the normal or usual place in the body. It is often used to describe tissue or an organ that is transplanted into its normal place in the body.
Palliative treatment	Anything which serves to alleviate symptoms due to the underlying cancer but is not expected to cure it.
Pancreas/Pancreatic	A glandular organ located in the abdomen. It makes pancreatic juices, which contain enzymes that aid in digestion, and it produces several hormones, including insulin. The pancreas is surrounded by the stomach, intestines, and other organs.
Pancreatitis	Inflammation of the pancreas.
Performance status	A measure of how well a patient is able to perform ordinary tasks and carry out daily activities. (PS WHO score of 0=asymptomatic, 4=bedridden).
Prognosis	An assessment of the expected future course and outcome of a person's disease.

R0 resection	A surgical procedure where the surgical margins are negative for cancer.
R1 resection	A surgical procedure where there are positive microscopic surgical margins.
Radio Frequency Ablation (RFA)	A procedure that uses radio waves to heat and destroy abnormal cells.
Resection	<i>See surgical resection</i>
Scottish Liver Transplant Unit (SLTU)	The Scottish Liver Transplantation Unit (SLTU) is funded to provide liver transplant services to the people of Scotland.
Staging	Process of describing to what degree cancer has spread from its original site to another part of the body. Staging involves clinical, surgical and pathology assessments.
Surgical resection	Surgical removal of the tumour/lesion.
Survival	The percentage of people in a study or treatment group who are alive for a certain period of time after they were diagnosed with or treated for a disease, such as cancer.
Systemic Anti Cancer Therapy (SACT)	Treatment of cancer using drugs which induce a reduction in tumour cell population, for example cancer chemotherapy or hormone therapy.
Trans-arterial Chemoembolisation (TACE)	Administration of chemotherapy directly to the liver tumour via a catheter. With this technique, the chemotherapy targets the tumour while sparing the patient many side effects of traditional chemotherapy that is given to the whole body
Tumour size	The size of a cancer measured by the amount of space taken up by the tumour.
Well-differentiated	Cancer in which the cells are mature and look like cells in the tissue from it arose. Differentiated cancers tend to be decidedly less aggressive than undifferentiated cancers composed of immature cells.
Whipple's resection	A type of surgery used to treat pancreatic cancer. The head of the pancreas, the duodenum, a portion of the stomach, and other nearby tissues are removed. Also called pancreatoduodenectomy.

Responding to this Consultation

We are inviting responses to this consultation by [Friday 10th February 2017](#)

Please respond to this consultation using the Scottish Government's consultation platform, Citizen Space. You view and respond to this consultation online at <https://consult.scotland.gov.uk/nhs/review-of-hpb-cancer-qpis>. You can save and return to your responses while the consultation is still open. Please ensure that consultation responses are submitted before the closing date of [Friday 10th February 2017](#).

If you are unable to respond online, please complete the Respondent Information Form (see "Handling your Response" below) to:

[Chris Booth](#)
[GER](#)
[St Andrew's House](#)
[Regent Road](#)
[Edinburgh](#)
[EH1 3DG](#)

Handling your response

If you respond using Citizen Space (<http://consult.scotland.gov.uk/>), you will be directed to the Respondent Information Form. Please indicate how you wish your response to be handled and, in particular, whether you are happy for your response to be published.

If you are unable to respond via Citizen Space, please complete and return the Respondent Information Form attached included in this document. If you ask for your response not to be published, we will regard it as confidential, and we will treat it accordingly.

All respondents should be aware that the Scottish Government is subject to the provisions of the Freedom of Information (Scotland) Act 2002 and would therefore have to consider any request made to it under the Act for information relating to responses made to this consultation exercise.

Next steps in the process

Where respondents have given permission for their response to be made public, and after we have checked that they contain no potentially defamatory material, responses will be made available to the public at <http://consult.scotland.gov.uk>. If you use Citizen Space to respond, you will receive a copy of your response via email.

Following the closing date, all responses will be analysed and considered along with any other available evidence to help us. Responses will be published where we have been given permission to do so.

Comments and complaints

If you have any comments about how this consultation exercise has been conducted, please send them HPBQIPublicEngagement@gov.scot.

Scottish Government consultation process

Consultation is an essential part of the policy-making process. It gives us the opportunity to consider your opinion and expertise on a proposed area of work.

You can find all our consultations online: <http://consult.scotland.gov.uk>. Each consultation details the issues under consideration, as well as a way for you to give us your views, either online, by email or by post.

Consultations may involve seeking views in a number of different ways, such as public meetings, focus groups, or other online methods such as Dialogue (<https://www.ideas.gov.scot>)

Responses will be analysed and used as part of the decision making process, along with a range of other available information and evidence. We will publish a report of this analysis for every consultation. Depending on the nature of the consultation exercise the responses received may:

- indicate the need for policy development or review
- inform the development of a particular policy
- help decisions to be made between alternative policy proposals
- be used to finalise legislation before it is implemented

While details of particular circumstances described in a response to a consultation exercise may usefully inform the policy process, consultation exercises cannot address individual concerns and comments, which should be directed to the relevant public body.



Review of HPB Cancer Quality Performance Indicators Consultation RESPONDENT INFORMATION FORM

Please Note this form **must** be completed and returned with your response.

Are you responding as an individual or an organisation?

- Individual
 Organisation

Full name or organisation's name

Phone number

Address

Postcode

Email

The Scottish Government would like your permission to publish your consultation response. Please indicate your publishing preference:

- Publish response with name
 Publish response only (without name)
 Do not publish response

Information for organisations:

The option 'Publish response only (without name)' is available for individual respondents only. If this option is selected, the organisation name will still be published.

If you choose the option 'Do not publish response', your organisation name may still be listed as having responded to the consultation in, for example, the analysis report.

We will share your response internally with other Scottish Government policy teams who may be addressing the issues you discuss. They may wish to contact you again in the future, but we require your permission to do so. Are you content for Scottish Government to contact you again in relation to this consultation exercise?

- Yes
 No



Scottish Government
Riaghaltas na h-Alba
gov.scot

© Crown copyright 2017

OGL

This publication is licensed under the terms of the Open Government Licence v3.0 except where otherwise stated. To view this licence, visit nationalarchives.gov.uk/doc/open-government-licence/version/3 or write to the Information Policy Team, The National Archives, Kew, London TW9 4DU, or email: psi@nationalarchives.gsi.gov.uk.

Where we have identified any third party copyright information you will need to obtain permission from the copyright holders concerned.

This publication is available at www.gov.scot

Any enquiries regarding this publication should be sent to us at
The Scottish Government
St Andrew's House
Edinburgh
EH1 3DG

ISBN: 978-1-78652-738-7 (web only)

Published by The Scottish Government, January 2017

Produced for The Scottish Government by APS Group Scotland, 21 Tennant Street, Edinburgh EH6 5NA
PPDAS261256 (01/17)

W W W . G O V . S C O T