Scottish Cancer Taskforce

Ovarian Cancer
Clinical Quality Performance Indicators

Engagement Document

November 2017

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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 indictors 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 Multidisciplinary 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 Ovarian Cancer QPI Development Group was convened in March 2012, chaired by Professor John Dewar (Consultant Clinical Oncologist, NHS Tayside). 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. Quality 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 Ovarian Cancer QPIs was undertaken in September 2017.

A Formal Review Group was convened, chaired by Ms Iona Reid (Consultant Breast Surgeon, NHS Greater Glasgow and Clyde). Membership of this group included Clinical Leads from the three Regional Cancer Networks. 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, this dictates the level which 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 will be 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 Ovarian Cancer QPIs. The updated document will be implemented for patients diagnosed with Ovarian Cancer on, or after, 1st October 2017.

6. Quality Performance Indicators for Ovarian Cancer

QPI 2 - Extent of disease assessed by Computed Tomography (CT) or Magnetic Resonance Imaging (MRI) prior to treatment

QPI Title:	Patients with epithelial ovarian cancer should have their stage of disease assessed by CT or MRI prior to treatment.	
Description:	Proportion of patients with epithelial ovarian cancer having a CT scan or MRI of the abdomen and pelvis performed to exclude the presence of metastatic disease prior to starting treatment.	
Rationale and Evidence:	It is necessary to fully image the pelvis and abdomen prior to starting any treatment in order to establish the extent of disease and minimise unnecessary treatment.[2]	
Specifications:	**Numerator:**	Number of patients with epithelial ovarian cancer having a CT scan or MRI of the abdomen and pelvis carried out prior to starting treatment.
	Denominator:	All patients with epithelial ovarian cancer.
	Exclusions:	• Patients who decline to undergo investigation. • Patients presenting for surgery as an emergency.
Target:	95% The tolerance allowed by the target reflects the fact that CA125 assessment and ultrasound scan does not always raise suspicion of cancer.	

Revisions:	***Target increased to 95%*** ***Removed 'definitive' from description and rationale.***

QPI 3 - Treatment planned and reviewed at a multi-disciplinary team meeting

QPI Title:	Patients with epithelial ovarian cancer should be discussed by a multidisciplinary team (MDT) prior to definitive treatment.
Description:	Proportion of patients with epithelial ovarian cancer who are discussed at a MDT meeting before definitive treatment.
Rationale and Evidence:	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 care.[3] Discussion prior to definitive treatment decisions being made provides reassurance that patients are being managed appropriately.
Specifications:	**Numerator:** Number of patients with epithelial ovarian cancer discussed at the MDT before definitive treatment. **Denominator:** All patients with epithelial ovarian cancer **Exclusions:** • Patients who died before first treatment.
Target:	95% The tolerance within this target accounts for situations where patients require treatment urgently.

Revisions:	***No changes to the QPI***

QPI 4 - Patients with early stage disease have an adequate staging operation

QPI Title:	Patients undergoing surgery for early stage epithelial ovarian cancer (FIGO Stage 1) have an adequate staging operation which includes Total Abdominal Hysterectomy (TAH), Bilateral Salpingo-Oophorectomy (BSO), omentectomy and washings.
Description:	Proportion of patients with early stage epithelial ovarian cancer (FIGO Stage 1) undergoing primary surgery for ovarian cancer, having their stage of disease adequately assessed (TAH, BSO, Omentectomy and washings), to determine suitability for adjuvant therapies.
Rationale and Evidence:	Stage of disease is an important prognostic factor influencing choice of therapy and quality of surgical staging is a key determinant of adjuvant chemotherapy.[4] Surgery is considered the initial treatment of choice for women with early stage epithelial ovarian cancer and will typically include TAH, BSO and omentectomy and may also involve assessment by palpation, visualisation and/or biopsy as indicated, of peritoneal surfaces, appendix and bowel mesentery and sampling of pelvic and para-aortic lymph nodes.[2]
Specifications:	**Numerator:** Number of early stage (FIGO Stage 1) epithelial ovarian cancer patients having primary surgery involving TAH, BSO, omentectomy and washings. **Denominator:** All early stage (FIGO Stage 1) epithelial ovarian cancer patients undergoing primary surgery. **Exclusions:** • Patients having fertility conserving surgery. • Patients presenting for emergency surgery.
Target:	90% The tolerance allows for the small number of patients who have undergone previous surgery (hysterectomy or unilateral oopherectomy).

Revisions:	***Removed specification (ii) regarding being operated on by a gynaecologist oncologist.*** ***Removed exclusion of patients with risk of malignancy index <200.*** ***Lowered the target from 95% to 90%.***

QPI 5 - No macroscopic residual disease following surgery for advanced disease

QPI Title:	Surgery, as first definitive treatment, for patients with advanced epithelial ovarian cancer (FIGO Stage 2 or higher) should achieve no macroscopic residual disease.
Description:	Proportion of patients with advanced epithelial ovarian cancer (FIGO Stage 2 or higher*) who have no macroscopic residual disease following surgery.
Rationale and Evidence:	Improved patient outcomes are observed in patients with no visible residual disease following surgical resection. The objective of performing surgery on women with epithelial ovarian cancer is complete resection of *all* macroscopic disease[5] although this is not always possible in patients with advanced disease because of widespread involvement of peritoneal surfaces, bowel mesentery and serosa of bowel. The tolerances allowed by the targets reflect this.
Specifications:	**Numerator:** Number of patients with advanced epithelial ovarian cancer (FIGO Stage 2 or higher) with no macroscopic residual disease following surgery. **Denominator:** All patients with advanced epithelial ovarian cancer (FIGO Stage 2 or higher) undergoing surgery. **Exclusions:** • Patients with FIGO Stage 4b disease.
Target:	50% The tolerance within this target accounts for the fact that due to widespread involvement of peritoneal surfaces, bowel mesentery and serosa of bowel in the majority of patients with advanced epithelial ovarian cancer it is frequently not possible to resect all visible disease.

Revisions:	***Removed specification (ii)regarding residual disease <1cm*** ***Focus now on no residual disease.*** ***Increased target from 30% to 50%. Changed exclusion from stage 4 to stage 4b only.***

*Final stage of disease as agreed by MDT

QPI 6 - Histopathology reports are complete and support clinical decision-making

QPI Title:	Histopathology reports relating to pelvic clearance surgery for patients with epithelial ovarian cancer contain all necessary information to inform treatment decision making.
Description:	Proportion of patients with epithelial ovarian cancer undergoing pelvic clearance surgery having a complete pathology report as defined by the Royal College of Pathologists.[6]
Rationale and Evidence:	Histopathological reporting provides prognostic indicators which inform treatment planning for women diagnosed with epithelial ovarian cancer. Using a standardised data set to report pathology specimens promotes completeness and the Royal College of Pathologists has agreed a minimum data set for reporting ovarian cancer.[6]
Specifications:	**Numerator:** Number of patients with epithelial ovarian cancer undergoing definitive cytoreductive surgery who have a complete pathology report that contains all data items as defined by the Royal College of Pathologists.[6] **Denominator:** All patients with epithelial ovarian cancer undergoing definitive cytoreductive surgery. **Exclusions:** • No exclusions
Target:	90% The tolerance within this target reflects situations where it is not possible to report all components of the data set due to poor quality of specimen.

Revisions:	***No changes to QPI***

QPI 7 - Histo/cytological diagnosis prior to starting neo-adjuvant chemotherapy

QPI Title:	Patients with epithelial ovarian cancer should have a histological diagnosis of their cancer prior to starting neo-adjuvant chemotherapy.	
Description:	Proportion of patients with epithelial ovarian cancer having a histological diagnosis obtained by percutaneous image-guided biopsy or laparoscopy prior to starting neo-adjuvant chemotherapy.	
Rationale and Evidence:	Before commencing neo-adjuvant cytotoxic chemotherapy, women with suspected advanced ovarian cancer should have their diagnosis confirmed by histology or by cytology if histology is not appropriate.[5] Where patients are being treated with chemotherapy prior to surgery, histology rather than cytology should be used to confirm the diagnosis[7].	
Specifications:	**Numerator**	Number of patients who have a diagnosis of epithelial ovarian cancer confirmed by histology prior to starting neo-adjuvant chemotherapy.
	Denominator	All patients with epithelial ovarian cancer undergoing neo-adjuvant chemotherapy.
	Exclusions:	• Patients for whom paracentesis, image guided biopsy or laparoscopy is considered not suitable.
Target:	80% The tolerance allowed by the target reflects that not all patients are suitable for histological confirmation of disease, e.g. where no targetable lesion identified on imaging and patient unsuitable for general anaesthetic/laparoscopy.	

Revisions:	***Removed specification (i) regarding having a diagnosis recorded.*** ***Focus is now solely on a diagnosis of ovarian cancer confirmed by histology.***

QPI 8 - Delayed primary surgery

QPI Title:	Delayed primary surgery, after neo-adjuvant chemotherapy for advanced epithelial ovarian cancer (FIGO Stage 3c or 4), should achieve no macroscopic residual disease.	
Description:	Proportion of patients with advanced epithelial ovarian cancer (FIGO Stage 3c or 4*) having delayed primary surgery following neo-adjuvant chemotherapy and where no macroscopic residual disease is achieved.	
Rationale and Evidence:	Improved patient outcomes are observed in patients with no visible residual disease following surgical resection. The objective of performing surgery on women with epithelial ovarian cancer, whether before chemotherapy or after neoadjuvant chemotherapy, is complete resection of all macroscopic disease[5] although this is not always possible in patients with advanced disease because of widespread involvement of peritoneal surfaces, bowel mesentery and serosa of bowel. Neo-adjuvant chemotherapy followed by surgery is a reasonable alternative to primary debulking surgery in stage 3c and 4 disease.[8]	
Specification (i):	**Numerator:**	Number of patients with advanced epithelial ovarian cancer (FIGO Stage 3c or 4) undergoing delayed primary surgery after neo-adjuvant chemotherapy.
	Denominator:	All patients with advanced epithelial ovarian cancer (FIGO Stage 3c or 4) having neo-adjuvant chemotherapy.
	Exclusions:	• No exclusions
Target:	75% The tolerances allowed by the target set reflect variance in individual patient response to chemotherapy, treatment associated morbidities and impact of these on individual patient fitness for surgery.	
Specification (ii):	**Numerator**	Number of patients with advanced epithelial ovarian cancer (FIGO Stage 3c or 4) undergoing delayed primary surgery after neo-adjuvant chemotherapy with no residual disease.
	Denominator	All patients with advanced epithelial ovarian cancer (FIGO Stage 3c or 4) undergoing delayed primary surgery after neo-adjuvant chemotherapy.
	Exclusions:	• No exclusions.
Target:	50% The tolerances allowed by the target set reflect variance in individual patient response to chemotherapy.	

*Final stage of disease as agreed by MDT

Revisions:	***Removed specification (ii) regarding delayed primary surgery with residual disease <1cm and replaced with NO residual disease.*** ***QPI Title and Description updated accordingly.***

QPI 9 - First-line Chemotherapy

Description:	Proportion of epithelial ovarian cancer patients who receive platinum-based chemotherapy, either in combination or as a single agent.
Rationale and Evidence:	First line chemotherapy treatment of epithelial ovarian cancer should include a platinum agent, either in combination or as a single agent. Carboplatin is the platinum drug of choice in both single and combination therapy and paclitaxel is recommended in combination where the potential benefits justify the toxicity of the therapy.[9,10] Patients who choose less toxic therapy or who are unfit for taxanes should be offered single agent carboplatin.[2]
Specifications:	**Numerator:** Number of epithelial ovarian cancer patients who receive chemotherapy treatment involving either paclitaxel in combination with a platinum-based compound or carboplatin only¥. **Denominator:** All epithelial ovarian cancer patients **Exclusions:** • Patients with low-grade serous disease. • Patients with FIGO stage 1a or 1b, low grade (G1) disease. • Patients with Stage 1a clear cell tumours. • Patients with Stage 1a endometrioid tumours. • Patients with low grade mucinous tumours. • Patients who decline chemotherapy treatment.
Target:	90% The tolerance allowed by the target recognises that there are a small number of patients who are not fit enough to undergo chemotherapy.

Revisions:	***Added exclusion categories for:*** ***Stage 1a endometrioid tumours*** ***Low grade mucinous tumours***

QPI 10 - Surgery for Advanced Disease

QPI Title:	Patients with advanced epithelial ovarian cancer (FIGO Stage 2 or higher) should undergo primary surgery, where appropriate.	
Description:	Proportion of patients with advanced epithelial ovarian cancer (FIGO Stage 2 or higher) undergoing primary surgery.	
Rationale and Evidence:	Evidence shows that most women with ovarian cancer present with advanced disease. Surgery along with chemotherapy remains the optimal treatment for women with advanced ovarian cancer.[7] Women with advanced stage ovarian cancers should be treated with debulking surgery with the aim of removing all macroscopic disease.[5,7]	
Specifications:	**Numerator:**	Number of patients with advanced epithelial ovarian cancer (FIGO Stage 2 or higher) undergoing primary surgery.
	Denominator:	All patients with advanced epithelial ovarian cancer (FIGO Stage 2 or higher).
	Exclusions:	• No exclusions
Target:	55% The tolerance within this target accounts for the fact that not all patients are suitable for surgery due to fitness levels and co-morbidities. **Please note:** varying evidence exists regarding the most appropriate target level therefore this may need redefined in the future, to take account of new evidence or as further data becomes available.	

NEW QPI

QPI 11 - BRCA1 and BRCA2 Sequencing in Epithelial Ovarian Cancer

QPI Title:	Patients with ovarian cancer should be offered genetic testing where appropriate.
Description:	Proportion of patients with epithelial ovarian cancer who undergo genetic testing.
Rationale and Evidence:	Genetic testing should be performed in patients with ovarian cancer where the combined risk of BRCA1 and BRCA2 mutation is ≥10%.[7] All women with non-mucinous ovarian cancer should be offered BRCA1 and BRCA2 mutation testing.[7] Various prediction models exist to assess the likelihood of a BRCA1 or BRCA2 mutation in a family. All patients with non mucinous ovarian cancer (any age) would be predicted to have mutation detection rate of between 6.2% and 17.5%.[7]
Specifications:	**Numerator:** Number of patients with epithelial ovarian cancer who undergo genetic testing. **Denominator:** All patients with epithelial ovarian cancer. **Exclusions:** • Patients with low grade serous disease • Patients with mucinous tumours
Target:	90% The target tolerance level accounts for factors of patient choice. **Please note:** varying evidence exists regarding the most appropriate target level therefore this may need redefined in the future, to take account of new evidence or as further data becomes available.

NEW QPI

QPI 12 - 30/90 Day Mortality after Treatment for Ovarian Cancer

QPI Title:	30/90 day mortality following treatment for ovarian cancer.
Description:	Proportion of patients with ovarian cancer who die within 30/90 days of treatment (surgery, and Systemic Anti Cancer Therapy (SACT)) for ovarian cancer.
Rationale and Evidence:	Treatment related mortality is a marker of the quality and safety of the whole service provided by the Multi Disciplinary Team (MDT)[11]. Outcomes of treatment, including treatment related morbidity and mortality should be regularly assessed. Treatment should only be undertaken in individuals that may benefit from that treatment, that is, treatments should not be undertaken in futile situations. This QPI is intended to ensure treatment is given appropriately, and the outcome reported on and reviewed.
Specifications:	**Numerator:** Number of patients with epithelial ovarian cancer who undergo treatment that die within 30/90 days of treatment. **Denominator:** All patients with epithelial ovarian cancer who undergo treatment (surgery, SACT). **Exclusions:** • No exclusions Please Note: This indicator will be reported by treatment modality, i.e. surgery and SACT as opposed to one single figure.
Target:	<5%

NEW QPI

QPI 13 - Clinical Trials and Research Study Access

This is QPI which is applicable to all tumour sites is currently undergoing final changes following review. The revised Clinical Trial Access QPI will be included with the final Ovarian Cancer QPI document.

7. Survival

Improving survival forms an integral part of the national cancer quality improvement programme. Ovarian 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 Ovarian Cancer QPI Group has identified, during the QPI development process, the following issues for survival analysis:

- 1 year or 5 year survival rates

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 Ovarian 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 ovarian cancer, and therefore in improving the quality of care for patients affected by ovarian cancer.

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

- BRCA1 (breast cancer susceptibility gene 1) and BRCA2 (breast cancer susceptibility gene 2) sequencing of high grade serous tumours.
- Surgery for recurrent ovarian cancer.

There is a proven link between BRCA1 and BRCA 2 gene mutations and increased risk of developing cancer of the ovary. Bilateral salpingo-oophorectomy reduces the risk of developing epithelial ovarian cancer, in these women, by at least 90%. Woman with BRCA1 and BRCA2 genetic mutations should be counselled regarding prophylactic oophorectomy and removal of fallopian tubes at the appropriate time.

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 ovarian 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 Ovarian Cancer QPIs via the Scottish Government Consultation Hub (website link below):

https://consult.gov.scot/nhs/ovarian-cancer-qpis

All responses should be submitted by **Wednesday 24th January 2017.**

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

Email: OvarianQPIPublicEngagement@gov.scot

10.2 Engagement feedback

At the end of the engagement period, all comments and responses will be collated for review by the Ovarian 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 Ovarian Cancer QPI document.

11. References

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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 ovarian cancer QPIs and a search narrative were defined and agreed by the Ovarian Cancer QPI Development Group. The table below shows the final search criteria used in the literature search.

Inclusion	Exclusion
Topics (**population/patient**): epithelial ovarian, fallopian tube, and primary peritoneal carcinomas Topics **(intervention)**: Diagnosis, staging, surgery, non-surgical management, treatment, chemotherapy, radiotherapy, intraperitoneal therapy, and hormone therapy. Adults only Date: 2005 to present day Language: English only	Topics: Related cancers, including: • Borderline ovarian carcinoma • Pseudomyxoma peritonei • Germ cell tumours of the ovary • Sex cord stromal tumours • Neuroendocrine tumours • Secondary ovarian cancers Communication/information, end of life care, pain management, prevention, and screening. Guidelines for the conduct of clinical trials (topic for generic QPI development).

Table 1 – Ovarian Cancer 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.

Seventeen remaining guidelines were appraised for quality using the AGREE II.[12] instrument. This instrument assesses the methodological rigour and precision used when developing a guideline. Twelve were recommended for use, three were not recommended, and two were consensus guidelines on management of ovarian cancer in pregnancy.

Indicator Development

The Group developed QPIs using the clinical recommendations set out in the briefing papar 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?

A wide clinical and public engagement exercise was undertaken as part of development in February 2013 where the Ovarian 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 ovarian cancer and the wider public were given the opportunity to influence the development of Ovarian 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 Ovarian Cancer QPI Development Group and used to produce and refine the final indicators.

Appendix 2: Ovarian Cancer QPI Development Group Membership (2013)

Name	Designation	Cancer Network/NHS Board
John Dewar	Consultant Clinical Oncologist	(CHAIR)
Elsa Armstrong	Data Manager	NOSCAN/NHS Grampian
Kevin Burton	Consultant Gynaecological Oncologist	WoSCAN/NHS Greater Glasgow and Clyde
Nancy Burns	Ward Manager	SCAN/NHS Lothian
John Burton	Consultant Radiologist	NOSCAN/NHS Tayside
Kevin Campbell	Project Manager	WoSCAN
Barbara Flont	Consultant Radiologist	NOSCAN/NHS Highland
Ros Glasspool	Consultant Medical Oncologist	WoSCAN/NHS Greater Glasgow and Clyde
Charley Gourley	Consultant Medical Oncologist	SCAN/NHS Lothian
Simon Herrington	Consultant Pathologist	NOSCAN/NHS Tayside
Michelle Hilton-Boon	Programme Manager	Health Improvement Scotland
Sue Lassman	Consultant Radiologist	WoSCAN/NHS Greater Glasgow and Clyde
Claire Mckenzie	Audit Facilitator	SCAN/NHS Lanarkshire
Ethel McLean	Audit Facilitator	WoSCAN/NHS Ayrshire and Arran
Wendy McMullan	Consultant Gynaecologist	NOSCAN/NHS Tayside
Cameron Martin	Consultant Gynaecologist	SCAN/NHS Lothian
Lorna Maule	Macmillan Gynaecology Clinical Nurse Specialist	WoSCAN/NHS Tayside
David Millan	Consultant Pathologist	WoSCAN/NHS Greater Glasgow and Clyde
Kathryn Morton	Consultant Pathologist	WoSCAN/NHS Greater Glasgow and Clyde
Brian Murray	Principal Information Development Manager	Information Services Division
David Parkin	Consultant Gynaecological Oncologist	NOSCAN/NHS Grampian
Nick Reed	Consultant Clinical Oncologist	WoSCAN/NHS Greater Glasgow and Clyde
Rae Roan	Gynaecological Clinical Nurse Specialist	WoSCAN/NHS Greater Glasgow and Clyde
Nadeem Siddiqui	Consultant Gynaecological Oncologist	WoSCAN/NHS Greater Glasgow and Clyde
Evelyn Thomson	Regional Manager (Cancer)	WoSCAN/NHS Greater Glasgow and Clyde
Radha Todd	Consultant Medical Oncologist	NOSCAN/NHS Grampian

Name	Designation	Cancer Network/NHS Board
Ewen Walker	Consultant Gynaecologist	WOSCAN/NHS Greater Glasgow and Clyde
Alistair Williams	Consultant Pathologist	SCAN/NHS Lothian

NOSCAN - North of Scotland Cancer Network
SCAN - South East Scotland Cancer Network
WoSCAN - West of Scotland Cancer Network

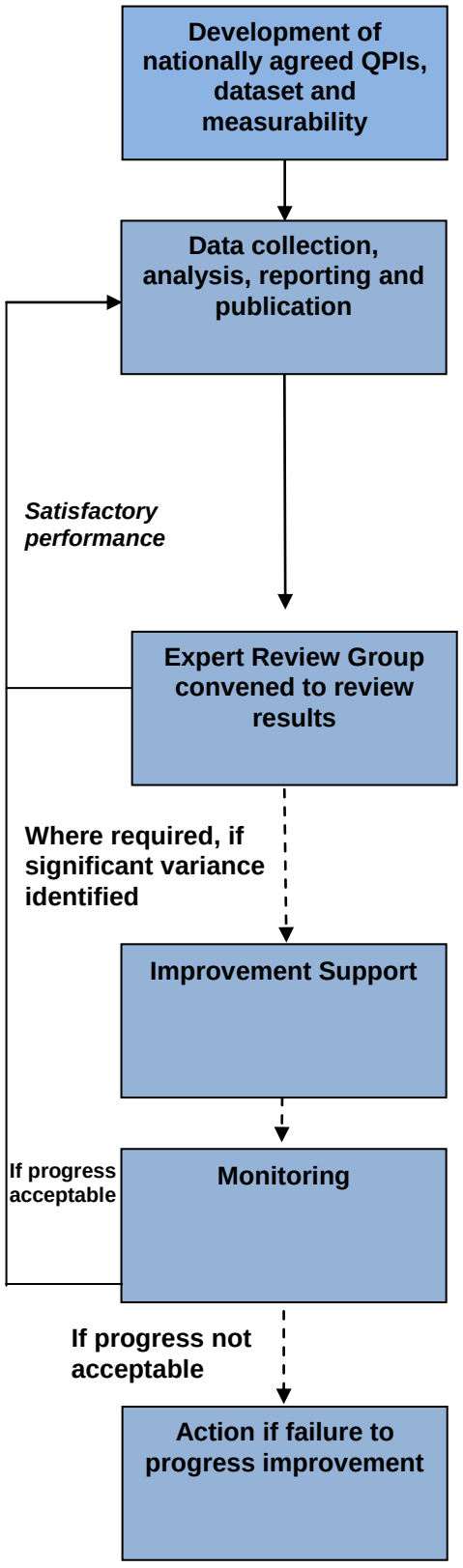
Appendix 3: Ovarian Cancer QPI Development Group Membership (2017)

Name	Designation	Cancer Network/NHS Board
Iona Reid	Consultant Breast Surgeon (CHAIR)	WoSCAN
Elsa Armstrong	Data Manager for Gynaecological Oncology	NOSCAN
Kevin Burton	Consultant Gynaecological Oncologist	WoSCAN
Kevin Campbell	MCN Manager	WoSCAN
Jennifer Doherty	National Cancer Quality Programme Co-ordinator	WoSCAN
Melanie Mackean	Consultant Medical Oncologist	SCAN
Mary Cairns	Consultant Gynaecological Oncologist	NOSCAN
Lorraine Stirling	Project Officer	WoSCAN
Chris Urquhart	Audit Manager	NOSCAN

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

Appendix 4: 3-Yearly National Governance Process & Improvement Framework for Cancer Care

This process is underpinned by the annual regional reporting and governance framework (see appendix 5).



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:

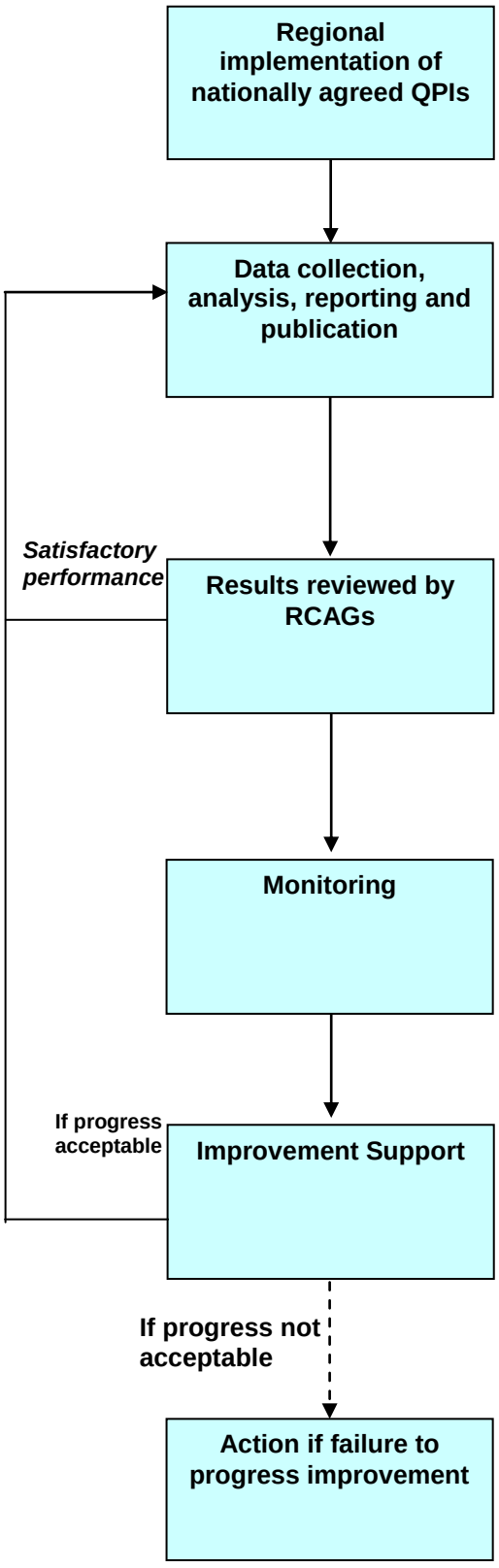
- RCAGs work with Boards to progress outstanding actions, monitor improvement plans and submit progress report to Healthcare Improvement Scotland.
- Healthcare Improvement Scotland report to Scottish Cancer Taskforce as to whether progress is acceptable**.**

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 5: 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 maybe 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 6: Glossary of Terms

Abdomen	The abdomen contains the stomach, liver, kidneys, bladder, in women it also contains the ovaries and uterus
Bilateral	Affecting both the right and left sides of the body.
Bilateral Salpingo–oophorectomy(BSO)	The term used to describe the removal of both ovaries and both fallopian tubes.
Biopsy	Removal of a sample of tissue from the body to assist in diagnosis of a disease.
BRCA1 (breast cancer susceptibility gene 1)**and BRCA2 mutation** (breast cancer susceptibility gene 2)	Specific genetic markers identifying an increased risk of breast and ovarian cancer.
CA125 (cancer antigen 125 or carbohydrate antigen 125)	The most frequently used biomarker for ovarian cancer detection The CA125 tumour marker or biomarker that may be elevated in the blood of some patients with ovarian cancer.
Carcinoma	Cancer that begins in the skin or in tissues that line or cover internal organs.
Chemotherapy	The use of drugs that kill cancer cells, or prevent or slow their growth.
Computed Tomography (CT)	An x-ray imaging technique, which allows detailed investigation of the internal organ of the body.
Contraindication/ Contraindicated	A symptom or medical condition that makes a particular treatment or procedure inadvisable because a person is likely to have a bad reaction.
Cytological/ Cytopathological	The study of the structure and function of cells under the microscope, and of their abnormalities.
Cytoreduction	A decrease in number of cells, as in a tumour.
Cytotoxic Treatment	Toxic to cells. This term is used to describe drugs which kill cancer cells or slow their growth.
Diagnosis/Diagnosed	The process of identifying a disease, such as cancer, from its signs and symptoms.
Elective/Elective Surgical Procedure	An elective procedure is one that is chosen by the patient or doctor that is advantageous to the patient but is not urgent.
Emergency Surgery	Unscheduled surgery performed promptly and often for lifesaving purposes.
Epithelial Ovarian Cancer	A disease in which malignant cancer cells form in the tissue covering the ovary.
Fallopian Tube	Also known as uterine tube or oviduct, either of a pair of long narrow ducts located in the female abdomen.
FIGO Stage	An international system of staging is used, and identifies the spread of the ovarian cancer at the point of diagnosis
First-line/Primary treatment	Initial treatment used to reduce or treat a cancer.
Histological/ Histopathogical/Histology	The study of the structure, composition and function of tissues under the microscope, and their abnormalities.
Invasive	Cancer that can or has spread from its histological original site.
Lesion	Tumour, mass, or other abnormality.
Locally advanced	Cancer that has spread from where it started to nearby tissue or lymph nodes.
Magnetic Resonance Imaging (MRI)	A procedure in which radio waves and a powerful magnet linked to a computer is used to create detailed pictures of areas inside the body. These pictures can show the difference between normal and diseased tissue.

Malignant	Cancerous. Malignant cells can invade and destroy nearby tissue and spread to other parts of the body.
Metastases / Metastatic disease	Spread of cancer away from the primary site to somewhere else via the bloodstream or the lymphatic system. Metastatic disease can be local (close to the area where the cancer is) or distant (in another area of the body).
Morbidity	How much ill health a particular condition causes.
Morphology	The science of the form and structure of organisms (plants, animals, and other forms of life).
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 meeting (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.
National Institute for Clinical Effectiveness (NICE)	An independent organisation responsible for providing NHS England with guidance on promoting good health and preventing and treating ill health.
Neoadjuvant therapy/ treatment	Drug treatment which is given before the treatment of a primary tumour with the aim of improving the results of surgery and preventing the development of metastases.
Omentum	A double layer of peritoneum attached to the stomach and linking it with other abdominal organs, such as the liver, spleen and intestine.
Omentectomy	The removal of all or part of the omentum.
Palliative	Anything which serves to alleviate symptoms due to the underlying cancer but is not expected to cure it.
Pathological	The study of disease processes with the aim of understanding their nature and causes. This is achieved by observing samples of fluid and tissues obtained from the living patient by various methods, or at post mortem.
Pathologist	A doctor who identifies diseases by studying cells and tissues under a microscope.
Pelvic/Pelvis	Having to do with the pelvis (the lower part of the abdomen located between the hip bones).
Percutaneous	Access to inner organs or tissue is carried out via 'needle puncture' to the skin rather than an open procedure.
Primary Tumour	The original tumour.
Prognosis	An assessment of the expected future course and outcome of a person's disease.
Prognostic indicators	Factors, such as staging, tumour type or deprivation that may influence treatment effectiveness and outcomes.
Progression	In medicine, the course of a disease, such as cancer, as it becomes worse or spreads in the body.
Prophylactic	To prevent the occurrence of disease.
Randomised Clinical Trials	A study to test a specific drug or other treatment in which people are randomly assigned to two (or more) groups: one (the experimental group) receiving the treatment that is being tested, and the other (the comparison or control group) receiving an alternative treatment, a placebo (dummy treatment) or no treatment. The two groups are followed up to compare differences in outcomes to see how effective the experimental treatment was. (Through randomisation, the groups should be similar in all aspects apart from the

	treatment they receive during the study.)
Resectable	Able to be removed (resected) by surgery.
Risk of Malignancy Index (RMI I)	RMI score derived from measure of serum CA125, ultrasound imaging and menopausal status RMI I = U x M x CA125
Risk Factor	Something that is known to increase your chances of getting a disease.
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.
Surgery/Surgical resection	Surgical removal of the tumour/lesion.
Surgical intervention	A surgical measure with the purpose of improving health or altering the course of disease.
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.
Symptomatic	Having to do with symptoms, which are signs of a condition or disease.
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.
Taxanes	A type of chemotherapy agent which includes paclitaxel and docetaxel.
Total Abdominal Hysterectomy (TAH)	A total abdominal hysterectomy is an operation to remove the womb (uterus) through an incision in the tummy known as a laparotomy.
Toxicity	The extent to which something is poisonous or harmful.
Treatment Intent	The reason for which treatment is given, that is, whether the treatment is intended to cure the disease or to alleviate symptoms.
Tumour size	The size of a cancer measured by the amount of space taken up by the tumour.
ug/l	Micrograms per litre.
Ultrasound	An imaging test that bounces sound waves off tissues and converts the echoes into pictures.