Scottish Cancer Taskforce
National Cancer Quality Steering Group

Cutaneous Melanoma
Clinical Quality Performance Indicators

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January 2022 (v4.0)
This document was updated following formal review (2nd cycle) of the Melanoma Quality Performance Indicators (QPIs) which took place after analysis of year 6 of the Melanoma cancer QPI data.

The following QPIs have been updated:

- QPI 3 – Multidisciplinary Team (MDT) Meeting
- QPI 6 – Wide Local Excisions
- QPI 7 – Time to Wide Local Excision
- QPI 8 – BRAF Status
- QPI 9 – Imaging for Patients with Advanced Melanoma
- QPI 10 – Systemic Therapy

The following QPIs have been archived:

- QPI 12 – Surgical Margins

The following new QPIs have been added:

- QPI 14 – Sentinel Lymph Node Biopsy
- QPI 15 - 30-Day Mortality following Systemic Anti-Cancer Therapy (SACT)

As a result of the changes above, the contents page and page numbering differ from earlier version of this document. Sections 1 – 10 and the appendices have also been updated.

Please note that this version of the Melanoma QPI Document applies to cases diagnosed from 1st July 2021 onwards.

August 2018 (v3.0)
This document was updated following formal review of the Melanoma Quality Performance Indicators (QPIs) which took place following analysis of year 3 of the Melanoma cancer QPI data.

The following QPIs have been updated:

- QPI 1 – Diagnostic Biopsy
- QPI 6 – Wide Local Excisions
- QPI 9 – Imaging for Patients with Advanced Melanoma

The following QPIs have been archived:

- QPI 11 – Access to Lymphoedema Service

The following new QPIs have been added:

- QPI 12 – Surgical Margins

Please note the Clinical Trial and Research Study Access has now been added into each tumour specific QPI document (see QPI 13 - Clinical Trial and Research Study Access).

As a result of the changes above, the contents page and page numbering differ from earlier version of this document. Sections 1 – 10 and the appendices have also been updated.

Please note that this version of the Melanoma QPI Document applies to cases diagnosed from 1st July 2017 onwards. Where amended or new QPIs require new data items for measurement, this will apply for patients diagnosed from 1st July 2018.

February 2016 (v2.0)
This document was updated following baseline review of the Melanoma QPIs which took place following analysis of year 1 of the Melanoma data. As a result, the following QPIs have been updated:

- QPI 1 – Excision Biopsy
- QPI 6 – Wide Local Excisions
- QPI 7 – Time to Wide Local Excision
- QPI 10 – Systemic Therapy

Please note that this version of the Melanoma QPI document applies to cases diagnosed from 1st July 2015.

Contents

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 19 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 is underpinned and supported by a programme of regional and national comparative reporting and review.

NHS Boards are 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 summary reports published annually. These reports highlight the publication of the QPIs in the Cancer QPI Dashboard which includes 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 Public Health Scotland (PHS) (previously ISD Scotland) for inclusion in the Cancer QPI Dashboard and subsequent national summary 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 Cutaneous Melanoma QPI Development Group was convened in February 2013, chaired by Mr Jim Docherty (Consultant Colorectal and General Surgeon). 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 Cutaneous Melanoma QPIs was undertaken for the first time in January 2018. A Formal Review Group was convened, chaired by Dr Carrie Featherstone, Consultant Clinical Oncologist. Membership of this group included Clinical Leads from the three Regional Cancer Networks. Membership of this group can be found in appendix 3.

The 2nd Cycle of Formal Review commenced in March 2021 following reporting of 6 years of QPI data. This cycle of review is more selective and focussed on ensuring the ongoing clinical relevance of the QPIs. A Formal Review Group was convened with Dr Carrie Featherstone, Consultant Clinical Oncologist, WoSCAN appointed as Clinical Advisor/Chair to the group. Membership of this group can be found in appendix 4.

The formal review process is clinically driven with proposals for change sought from specialty specific representatives in each of the Regional Cancer Networks. Formal review meetings to further discuss proposals will be arranged where deemed necessary. The review builds on existing evidence using expert clinical opinion to identify where new evidence is available, and a full public engagement exercise will take place where significant revisions have been made or new QPIs developed.

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. Where QPIs have been archived, for those indicators which remain clinically relevant, data will continue to be collected to allow local / regional analysis of performance as required.

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?

The Cutaneous Melanoma QPIs were made available on the Scottish Government Consultation Hub in October / November 2021, as part of a wide clinical and public engagement exercise. During the engagement period, clinical and management colleagues from across NHSScotland, patients affected by melanoma and the wider public were given the opportunity to influence the revised Melanoma QPIs.

Following the engagement period, all comments and responses received were reviewed by the Melanoma QPI Formal Review Group and used to produce and refine the final indicators (section 6).

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 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 report of Cutaneous Melanoma QPIs. The updated document will be implemented for patients diagnosed with Cutaneous Melanoma on, or after, 1st July 2021.

6. Quality Performance Indicators for Cutaneous Melanoma

QPI 1: Diagnostic Biopsy

QPI Title:	Patients with cutaneous melanoma should have their initial diagnostic biopsy carried out by a skin cancer clinician*.	
Description:	Proportion of patients with cutaneous melanoma who have their initial diagnostic biopsy carried out by a skin cancer clinician*. **Please note:** The specifications of this QPI are separated to ensure clear measurement of both patients who undergo: (i) Diagnostic excision biopsy as their initial procedure; and (ii) Diagnostic partial biopsy as their initial procedure.	
Rationale and Evidence:	The initial biopsy is important for both diagnosis and pathological staging[2-4]. Evidence has shown excisional biopsy to be the most appropriate procedure, because it allows accurate evaluation of tumour thickness and other prognostic factors[2, 5]. If melanoma is suspected an excision biopsy should be carried out to ensure the melanoma is completely removed, except in rare circumstances where an incision or shave biopsy may be a more appropriate initial procedure, due to location or size of lesion[6]. Patients suspected of having melanoma should be referred to secondary care to have their excisional biopsy carried out by someone with specialist experience in melanoma[4, 6, 7].	
Specification (i):	**Numerator:**	Number of patients with cutaneous melanoma undergoing diagnostic excision biopsy as their initial procedure who had this carried out by a skin cancer clinician*.
	Denominator:	All patients with cutaneous melanoma undergoing diagnostic excision biopsy as their initial procedure.
	Exclusions:	• No exclusions.

(continued overleaf….)

* A skin cancer clinician can be defined as a:

- Dermatologist,
- Plastic Surgeon,
- Oral and Maxillofacial Surgeon, or
- A locally designated clinician with a special interest in skin cancer, who is also a member (or under the supervision of a member) of the melanoma MDT.

QPI 1: Diagnostic Biopsy (cont…..)

Specification (ii):	**Numerator:**	Number of patients with cutaneous melanoma undergoing diagnostic partial biopsy as their initial procedure who had this carried out by a skin cancer clinician*.
	Denominator:	All patients with cutaneous melanoma undergoing diagnostic partial biopsy as their initial procedure.
	Exclusions:	• No exclusions.
Target:	90% The tolerance accounts for situations where lesion is not clinically suspicious of melanoma before excision and for factors relating to patient choice.	

QPI 2: Pathology Reporting

QPI Title:	Surgical pathology reports for patients with cutaneous melanoma should contain full pathology information to inform treatment decision making.
Description:	Proportion of patients with cutaneous melanoma who undergo diagnostic excision biopsy where the surgical pathology report contains a full set of data items (as defined by the current Royal College of Pathologists dataset).
Rationale and Evidence:	To allow treatment planning to take place for patients diagnosed with cutaneous melanoma, prognostic information from the primary excision biopsy is needed. The use of datasets 'improves the 'completeness' of data' in pathology reports[4, 6, 8]. The Royal College of Pathologists have agreed a minimum dataset[8]. The dataset is available from: Royal College of Pathologists - minimum dataset Cutaneous Melanoma
Specifications:	**Numerator:** Number of patients with cutaneous melanoma undergoing diagnostic excision biopsy where the surgical pathology report contains a full set of data items (as defined by the current Royal College of Pathologists dataset). **Denominator:** All patients with cutaneous melanoma undergoing diagnostic excision biopsy. **Exclusions:** • No exclusions.
Target:	90% The tolerance level within this target is designed to account for situations where there is insufficient tissue to perform additional testing.

QPI 3: Multi-Disciplinary Team Meeting (MDT)

QPI Title:	Patients with cutaneous melanoma should be discussed by a multidisciplinary team.	
Description:	Proportion of patients with cutaneous melanoma who are discussed at a MDT meeting. **Please note:** The specifications of this QPI are separated to ensure clear measurement of both: (i) Patients with stage IA cutaneous melanoma who are discussed at a MDT meeting; and (ii) Patients with stage IB and above cutaneous melanoma 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[9]. Discussion prior to definitive treatment decision provides reassurance that patients are being managed appropriately.	
Specification (i):	**Numerator:**	Number of patients with stage IA cutaneous melanoma discussed at the MDT meeting.
	Denominator:	All patients with stage IA cutaneous melanoma.
	Exclusions:	• No exclusions.
Specification (ii)	**Numerator:**	Number of patients with stage IB and above cutaneous melanoma who are discussed at the MDT meeting before definitive treatment (wide local excision, chemotherapy/SACT, supportive care and radiotherapy).
	Denominator:	All patients with stage IB and above cutaneous melanoma.
	Exclusions:	• Patients who died before first treatment.
Target:	95% The tolerance within this target is designed to account for situations where patients require treatment urgently, or where patients may be upstaged e.g. from IA to IB (or above) following pathology review for MDT.	

QPI 4: Clinical Examination of Draining Lymph Node Basins

QPI Title:	Patients with cutaneous melanoma should undergo clinical examination of relevant draining lymph node basins as part of clinical staging.
Description:	Proportion of patients with cutaneous melanoma undergoing clinical examination of relevant draining lymph node basins as part of clinical staging.
Rationale and Evidence:	Scottish Intercollegiate Guidelines Network[7] reports the examination of the regional lymph node basin as an important aspect of the clinical evaluation of patients with cutaneous melanoma as the presence of nodal metastasis is an important predictor of outcome and prognosis[4, 7].
Specifications:	**Numerator:** Number of patients with cutaneous melanoma who undergo clinical examination of relevant draining lymph node basins as part of clinical staging. **Denominator:** All patients with cutaneous melanoma. **Exclusions:** • No exclusions.
Target:	95% The tolerance within this target is designed to account for factors of patient choice.

QPI 5: Sentinel Node Biopsy Pathology

QPI Title:	Sentinel node biopsy (SNB) reports for patients with cutaneous melanoma should contain full pathology information to inform treatment decision making.
Description:	Proportion of patients with cutaneous melanoma who undergo SNB where the SNB report contains a full set of data items (as defined by the current Royal College of Pathologists dataset).
Rationale and Evidence:	Evidence suggests SNB reports should be carried out in a standardised way so that findings between centres are comparable[10]. The importance of meticulous diagnosis and reporting has been outlined by Royal College of Pathologists; histological parameters play a major role in defining patient treatment[8]. The dataset is available from: Royal College of Pathologists - minimum dataset Cutaneous Melanoma
Specifications:	**Numerator:** Number of patients with cutaneous melanoma undergoing SNB, where the SNB report contains a full set of data items (as defined by the current Royal College of Pathologists dataset). **Denominator:** All patients with cutaneous melanoma undergoing SNB. **Exclusions:** • No exclusions.
Target:	90% The tolerance level within this target is designed to account for situations where there is insufficient tissue to perform additional testing.

QPI 6: Wide Local Excisions

QPI Title:	Patients with cutaneous melanoma should undergo a wide local excision of the initial diagnostic biopsy site to reduce the risk of local recurrence.
Description:	Proportion of patients with cutaneous melanoma who undergo a wide local excision, following diagnostic excision or partial biopsy.
Rationale and Evidence:	Surgical excision is an effective cure for primary cutaneous melanoma[11]. The lesion is initially removed for histological diagnosis and assessment of tumour depth. A further excision is carried out to minimise the risk of local recurrence[11,12]. Studies have shown the importance of removing the tumour and a margin of healthy skin[13]. The standard treatment for primary cutaneous melanoma is wide local excision of the skin and subcutaneous tissues around the melanoma[14, 15]. Treatment for melanoma aims to achieve histologically free margins with low likelihood of local recurrence or persistent disease[16]. The appropriate surgical margin is determined by the thickness of the lesion[4,12,13,15,16]. Various evidence exists determining the most clinically appropriate surgical margin[4,12,13,16]. The Cutaneous Melanoma QPI Group felt ensuring a wide local excision took place was a good indicator of quality, with the decision of appropriate wide local excision surgical margin being left to MDT/Clinical judgement.
Specification:	**Numerator:** Number of patients with cutaneous melanoma undergoing diagnostic excision or partial biopsy who undergo a wide local excision. **Denominator:** All patients with cutaneous melanoma undergoing diagnostic excision or partial biopsy. **Exclusions:** • Patients who require no wide local excision as agreed by MDT.
Target:	95% The tolerance within this target accounts for situations where it is not clinically possible to undertake a wide local excision due to the size and location of the tumour, and for factors of patient choice. In addition, it accounts for deteriorating patient fitness including those who have died prior to further treatment.

Please note:
The total number and percentage of patients who require no wide local excision as agreed by the MDT will be reported alongside this QPI to identify any variation between NHS Boards.

QPI 7: Time to Wide Local Excision

QPI Title:	Patients with cutaneous melanoma should have their wide local excision in a timely manner.	
Description:	Proportion of patients with cutaneous melanoma where reporting of diagnostic biopsy and wide local excision is within 84 days. **Please note:** Rather than an overall timeframe, this QPI measures two distinct elements of the pathway: (i) Diagnostic biopsy reported within 21 days; and (ii) Wide local excision undertaken within 63 days of diagnostic biopsy reporting.	
Rationale and Evidence:	Patients with melanoma will undergo their diagnostic biopsy and may continue to have a wide local excision. A wide local excision is undertaken to achieve histologically negative margins and decrease the risk of local recurrence[17]. It is important that patients with cutaneous melanoma undergo surgical excision as soon as possible. There is no clear consensus from clinical literature on the most appropriate timeframe for wide local excision however studies have found that delays in receiving definitive treatment can have an unfavourable impact within a number of cancer types[18-20]. They have also documented that these delays could cause the patient and relatives psychological distress[20]. The Cutaneous Melanoma QPI review group has agreed that 21 days is the most appropriate timeframe in which to report diagnostic biopsy with a further 63 days to undertake wide local excision. This is based on clinical consensus and current best practice.	
Specification (i):	**Numerator:**	Number of patients with cutaneous melanoma undergoing diagnostic biopsy where this is reported within 21 days.
	Denominator:	All patients with cutaneous melanoma undergoing diagnostic excision or partial biopsy.
	Exclusions:	• No exclusions.
Specification (ii):	**Numerator:**	Number of patients with cutaneous melanoma undergoing diagnostic biopsy where wide local excision is undertaken within 63 days of diagnostic biopsy reporting.
	Denominator:	All patients with cutaneous melanoma undergoing diagnostic excision or partial biopsy who proceed to wide local excision.
	Exclusions:	• No exclusions.
Target:	90% The tolerance within this target accounts for factors of patient choice.	

QPI 8: BRAF Status

QPI Title:	Patients with stage III or IV cutaneous melanoma should have their BRAF status checked.
Description:	Proportion of patients with stage III or IV cutaneous melanoma who have their BRAF status checked.
Rationale and Evidence:	BRAF status is an important tumour characteristic which influences treatment decision making. Patients with stage III and IV melanoma should undergo a B-RAF status check to assess suitability for BRAF inhibitors and Mek inhibitors[21]. BRAF inhibitors, and Mek inhibitors, are used for the treatment of patients with BRAF V600 mutation positive unresectable or metastatic melanoma[22,23]. Combination therapy with the BRAF inhibitor dabrafenib plus the MEK inhibitor trametinib has been shown to improve survival in patients with advanced melanoma with BRAF V600 mutations[22,23]. In resected patients with stage III and IV melanoma with BRAF V600E or V600K mutations, adjuvant use of combination therapy with dabrafenib plus trametinib demonstrates a significantly lower risk of recurrence[22].
Specifications:	**Numerator:** Number of patients with stage III or IV cutaneous melanoma who have their BRAF status checked. **Denominator:** All patients with stage III or IV cutaneous melanoma **Exclusions:** • No exclusions.
Target:	90% The tolerance level within this target is designed to account for situations where there is insufficient tissue to assess the BRAF status. In addition, the tolerance accounts for situations where patients may have significant co-morbidities or may not be fit for investigation and/or treatment and for patient choice.

QPI 9: Imaging for Patients with Advanced Melanoma

QPI Title:	Patients with stage IIC and above cutaneous melanoma should be evaluated with appropriate imaging to guide treatment decision making.
Description:	Proportion of patients with pathologically confirmed stage IIC and above cutaneous melanoma who undergo computed tomography (CT) or positron emission tomography (PET) CT within 35 days of pathology report being issued.
Rationale and Evidence:	Guidelines recommend that patients with stage IIC and above should be offered initial staging imaging[7]. Guidelines report that patients with high grade cutaneous melanoma should undergo imaging of the head, chest, abdomen and pelvis to exclude metastases[4]. It has been reported that low grade cutaneous melanoma do not benefit from imaging due to the high incident rate of false positives[4,7]. To ensure alignment with current clinical practice stage has been utilised to stratify patients for inclusion within this QPI over grading.
Specifications:	**Numerator:** Number of patients with pathologically confirmed stage IIC and above cutaneous melanoma who undergo CT or PET CT within 35 days of pathology report being issued. **Denominator:** All patients with pathologically confirmed stage IIC and above cutaneous melanoma. **Exclusions:** • No exclusions.
Target:	95% The tolerance within this target accounts for situations where patients are not fit enough to undergo investigation and for factors of patient choice.

QPI 10: Systemic Therapy

QPI Title:	Patients with stage III or IV cutaneous melanoma should receive Systemic Anti-Cancer Therapy (SACT).
Description:	Proportion of patients with stage III or IV cutaneous melanoma undergoing SACT. **Please note:** The specifications of this QPI are separated to ensure clear measurement of both: (i) Patients with unresectable stage III or IV cutaneous melanoma who undergo SACT; and (ii) Patients with resected stage III or IV cutaneous melanoma who undergo adjuvant SACT.
Rationale and Evidence:	As the majority of metastatic melanomas are not amenable to surgery, it is often found that systemic therapy is the best option[21]. SACT should be available for the management of patients with cutaneous melanoma where appropriate[6]. Studies have found that SACT is beneficial for patients who have a high risk of recurrence[24].
Specification (i):	**Numerator:** Number of patients with unresectable stage III or IV cutaneous melanoma who undergo SACT. **Denominator:** All patients with unresectable stage III or IV cutaneous melanoma. **Exclusions:** • Patients who died before first treatment.
Specification (ii):	**Numerator:** Number of patients with resected stage III or IV cutaneous melanoma who undergo adjuvant SACT. **Denominator:** All patients with resected stage III or IV cutaneous melanoma. **Exclusions:** • Patients who died before SACT treatment.
Target:	Specification (i) and (ii) 60% The tolerance accounts for situations where due to co-morbidities and fitness patients may not be suitable for SACT, and for factors of patient choice.

QPI 13: Clinical Trials and Research Study Access

QPI Title:	All patients should be considered for participation in available clinical trials / research studies, wherever eligible.
Description:	Proportion of patients diagnosed with cutaneous melanoma who are consented† for a clinical trial / research study.
Rationale and Evidence:	Clinical trials are necessary to demonstrate the efficacy of new therapies and other interventions. Evidence suggests improved patient outcomes when hospitals are actively recruiting patients into clinical trials[25]. Clinicians are therefore encouraged to enter patients into well-designed trials and to collect longer-term follow-up data. High accrual activity into clinical trials is used as a goal of an exemplary clinical research site. The measurement of this QPI focuses on those patients who have consented in order to reflect the intent to join a clinical trial and demonstrate the commitment to recruit patients. Often patients can be prevented from enrolling within a trial due to stratification of studies and precise inclusion criteria identified during the screening process.
Specifications:	**Numerator:** Number of patients diagnosed with cutaneous melanoma consented for a clinical trial / research study. **Denominator:** All patients diagnosed with cutaneous melanoma. **Exclusions:** • No exclusions.
Target:	15%

Please note:

The Clinical Trials and Research Study Access QPI is 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.

Utilising SCRN data allows for comparison with CSO published data and ensures capture of all eligible clinical trials and research studies, not solely first line treatment trials, as contained in the clinical audit data. Given that a significant proportion of clinical trials and research studies 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 further details of definitions, inclusion criteria and methodology used, please see the full Clinical Trials and Research Study Access QPI. This can be found at:

Healthcare Improvement Scotland - Cancer Quality Performance Indicators

† Consented is defined as patients who have given consent to participate in a clinical trial / research study subject to study specific screening for eligibility.

QPI 14: Sentinel Lymph Node Biopsy

QPI Title:	Patients with cutaneous melanoma should undergo a sentinel lymph node biopsy (SLNB) where eligible.
Description:	Proportion of patients with stage pT1b (with either a mitotic rate of ≥2/mm^2 or lymphovascular invasion) and stage pT2 and above cutaneous melanoma that undergo SLNB.
Rationale and Evidence:	Undergoing SLNB may provide more accurate staging and a better indication of survival and the potential of recurrent disease[7]. The sentinel lymph node is the node at greatest risk for the development of metastasis therefore biopsy of this node can assist in staging patients at risk of metastatic disease. It can determine whether metastasis are present within the regional lymph node basin and is a useful for staging in melanomas which are AJCC stage IB or above[7,25]. Patients with a pT1b melanoma should be considered if they display lymphovascular invasion or a mitotic rate of ≥2/mm^2 [26]. In addition to a prognostic indicator, sentinel node biopsy influences treatment decision making in terms of access to adjuvant therapy[26].
Specifications:	**Numerator:** Number of patients with stage pT1b (with either a mitotic rate of ≥2/mm^2 or lymphovascular invasion) and stage pT2 and above cutaneous melanoma who undergo SLNB. **Denominator:** All patients with stage pT1b (with either a mitotic rate of ≥2/mm^2 or lymphovascular invasion) and stage pT2 and above cutaneous melanoma. **Exclusions:** • No exclusions
Target:	45% The tolerance accounts for those patients where fitness, co-morbidities and patient choice preclude sentinel lymph node biopsy.

QPI 15: 30 Day Mortality following Systemic Anti-Cancer Therapy (SACT)

QPI Title:	30 day mortality following Systemic Anti-Cancer Therapy (SACT) treatment for cutaneous melanoma.	
Description:	Proportion of patients with cutaneous melanoma who die within 30 days of SACT treatment.	
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)[9]. 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. This QPI is intended to ensure treatment is given appropriately, and the outcome reported on and reviewed.	
Specifications:	**Numerator:**	Number of patients with cutaneous melanoma who undergo SACT that die within 30 days of treatment.
	Denominator:	All patients with cutaneous melanoma who undergo SACT.
	Exclusions:	• No exclusions
Target:	<5%	

Please note:
Data from Chemocare (electronic chemotherapy prescribing system) 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 provide a more accurate report of all patients with melanoma undergoing chemotherapy. Standard reports will be specified to ensure nationally consistent analysis and reporting.

7. Survival

Improving survival forms an integral part of the national cancer quality improvement programme. Cutaneous Melanoma survival analysis will be reported and analysed on a 3 yearly basis by Public Health Scotland (PHS). The specific issues which 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 Cutaneous Melanoma QPI Group has identified; during the QPI development process, the following issues for survival analysis.

- 1, 2 and 5 year overall 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 Cutaneous Melanoma QPI Groups have not able to identify sufficient evidence, or determine appropriate measurability specifications to address all areas felt to be of key importance in the treatment of Cutaneous Melanoma, and therefore in improving the quality of care for patients affected by Cutaneous Melanoma.

The following area for future consideration has been raised across the lifetime of the Cutaneous Melanoma QPIs.

- Genotyping of a patient's melanoma.

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.

- 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.

- Public Health Scotland (previously Information Services Division (ISD))
    - Publish national comparative report on tumour specific QPIs and survival for 3 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.
- Identification of regional and local actions required and development of an action plan to address regional issues identified.
- Performance 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. References

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11. 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 Cutaneous Melanoma QPIs and a search narrative were defined and agreed by the Cutaneous Melanoma QPI Development Group. The table below shows the final search criteria used in the literature search.

Inclusion	Exclusion
Melanoma types: • Primary cutaneous melanoma: *Interventions*: • Diagnosis • Staging and prognostic indicators • Surgical management • Non-surgical management *Age range:* Adults only *Date:* 2005 to present day *Language:* English only *Document type:* Clinical guidelines	*Related melanoma types:* • Secondary malignant melanoma • Cutaneous squamous cell carcinoma • Basal cell carcinoma • Primary cutaneous lymphoma • Non-cutaneous melanoma (including ocular) *Interventions*: • Clinical trials recruitment and protocols • Communication, information sharing and support • Follow-up • Palliative/end-of-life care (pain management, end-of-life counselling, hospice management) • Pre-cancerous conditions including: in situ and lentigo maligna • Prevention • Primary care/referral • Recurrent disease/relapsed disease management • Screening • Symptom management (e.g. nausea and vomiting, neutropenic sepsis)

Table 1 – Cutaneous Melanoma 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 one guidelines were appraised for quality using the AGREE II instrument[27]. This instrument assesses the methodological rigour used when developing a guideline. Seven of the guidelines were not recommended for use. The remaining 14 were recommended for use with consideration of their applicability or currency.

Indicator Development

The melanoma 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 February 2014 where the Cutaneous Melanoma 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 Cutaneous Melanoma and the wider public were given the opportunity to influence the development of Cutaneous Melanoma 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 Cutaneous Melanoma QPI Development Group and used to produce and refine the final indicators.

Appendix 2: Cutaneous Melanoma QPI Development Group Membership (2013)

Name	Designation	Cancer Network/Base
Jim Docherty (Chair)	Consultant Surgeon	NOSCAN / NHS Highland
Asok Biswas	Consultant Dermatopathologist	SCAN / NHS Lothian
Lorna Bruce	SCAN Audit Manager	SCAN
Sandy Burnham	Patient Representative	
Hazel Carnegie	Patient Representative	
Tim Crooks	Medical Oncologist	NOSCAN / NHS Tayside
Michaela Davies	Consultant Plastic Surgeon	NOSCAN / NHS Grampian
Amanda Degabrielle	Macmillan Skin Cancer Clinical Nurse Specialist	NOSCAN / NHS Tayside
Sheena Dryden	Clinical Nurse Specialist	SCAN / NHS Lothian
Alan Evans	Consultant Pathologist	NOSCAN / NHS Tayside
Colin Fleming	Consultant Dermatologist	NOSCAN / NHS Tayside
Girish Gupta	Consultant Dermatologist	WoSCAN / NHS Lanarkshire
Michelle Hilton Boon	Programme Manager	Healthcare Improvement Scotland
Alex Holme	Consultant Dermatologist	SCAN / NHS Lothian
Matt Hough	Consultant Plastic Surgeon	NOSCAN / NHS Tayside
Ehab Husain	Consultant Pathologist	NOSCAN / NHS Grampian
Daniel Kemmett	Consultant Dermatologist	WoSCAN / NHS Greater Glasgow and Clyde
Kelly Macdonald	Project Manager	National Cancer QPI Development Programme
Melanie McColgan	General Manager, Emergency Care & Medical Services	WoSCAN / NHS Greater Glasgow and Clyde
Claire McKenzie	Clinical Quality Service Coordinator	WoSCAN / NHS Lanarkshire
Neil McLachlan	MCN Manager	NOSCAN / NHS Grampian
Frank Muller	Consultant Dermatologist	NOSCAN / NHS Grampian
Brian Murray	Principle Information Development Manager	Information Services Division
Taimur Shoaib	Consultant Plastic Surgeon	WoSCAN / NHS Greater Glasgow and Clyde
Leigh Smith	Patient Representative	

Name	Designation	Cancer Network/Base
Amir Tadros	Consultant Plastic Surgeon	NOSCAN / NHS Grampian
Evelyn Thomson	Regional Manager (Cancer)	WoSCAN
James Vestey	Consultant Dermatologist and Melanoma coordinator	NOSCAN / NHS Highland
Ashita Waterston	Consultant Oncologist	WoSCAN / NHS Greater Glasgow and Clyde

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

Appendix 3: Cutaneous Melanoma QPI Formal Review Group Membership (2018)

Name	Designation	Cancer Network/Base
Carrie Featherstone (Chair)	Consultant Clinical Oncologist	WoSCAN / NHS Greater Glasgow and Clyde
Andrew Affleck	Consultant Dermatologist / MCN Clinical Lead	NOSCAN / NHS Tayside
Lorna Bruce	Audit Manager	SCAN
Roger Currie	Consultant Maxillofacial Surgeon / MCN Clinical Lead	WoSCAN / NHS Ayrshire and Arran
Jen Doherty	Project Co-ordinator	National Cancer Quality Programme
Megan Mowbray	Consultant Dermatologist / MCN Clinical Lead	SCAN / NHS Lothian
Lorraine Stirling	Project Officer	National Cancer Quality Programme

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

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

Appendix 4: Cutaneous Melanoma QPI Formal Review Group Membership (2021)

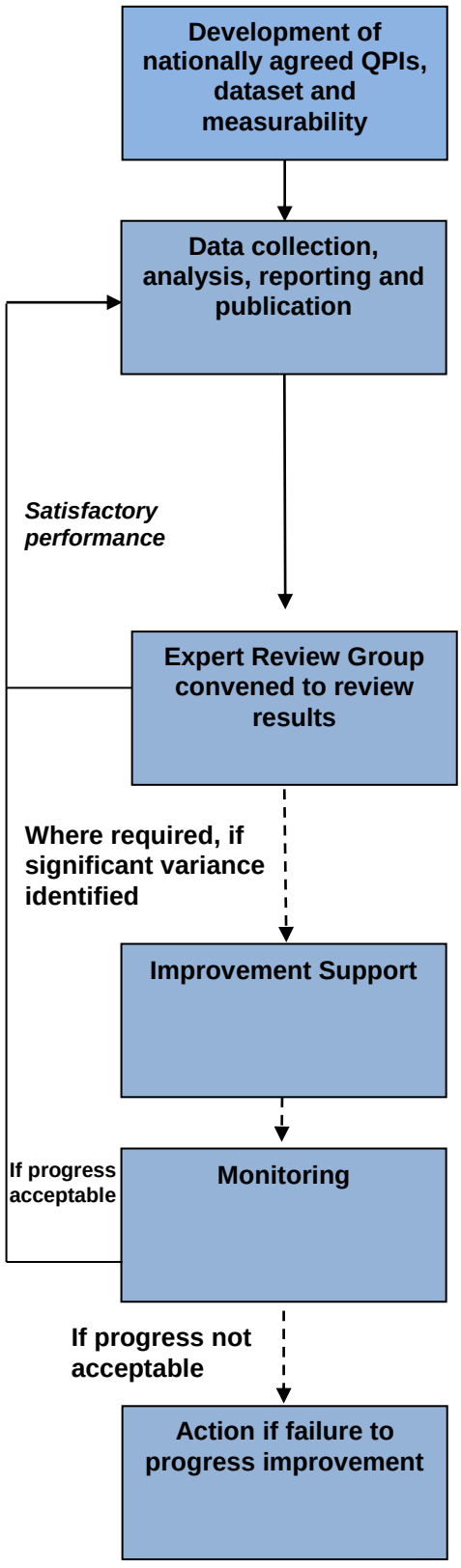
Name	Designation	Cancer Network/Base
Carrie Featherstone (Chair)	Consultant Clinical Oncologist	WoSCAN
Ewan Brown	Consultant Medical Oncologist / MCN Clinical Lead	SCAN
Lorna Bruce	Audit Manager	SCAN
Roger Currie	Consultant Oral and Maxillofacial Surgeon	WoSCAN
Sarah Digby	Consultant Pathologist	WoSCAN
Jen Doherty	Project Co-ordinator	National Cancer Quality Programme
Andy Malyon	Consultant Plastic Surgeon / MCN Clinical Lead	WoSCAN
Fiona Macdonald	Consultant Dermatologist	WoSCAN
Bryan McKellar	Programme Co-ordinator	NCA
Megan Mowbray	Consultant Dermatologist	SCAN
Kaz Rahman	Consultant Plastic Surgeon / MCN Clinical Lead	NCA
Shantini Rice	Consultant Dermatologist	SCAN
Lorraine Stirling	Project Officer	National Cancer Quality Programme
Christine Urquhart	Information Analyst	WoSCAN
Heather Wotherspoon	MCN Manager	WoSCAN

Formal review of the Cutaneous Melanoma QPIs has been undertaken in consultation with all relevant clinical specialties.

NCA - North Cancer Alliance
SCAN - South East Scotland Cancer Network
WoSCAN - West of Scotland Cancer Network

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:

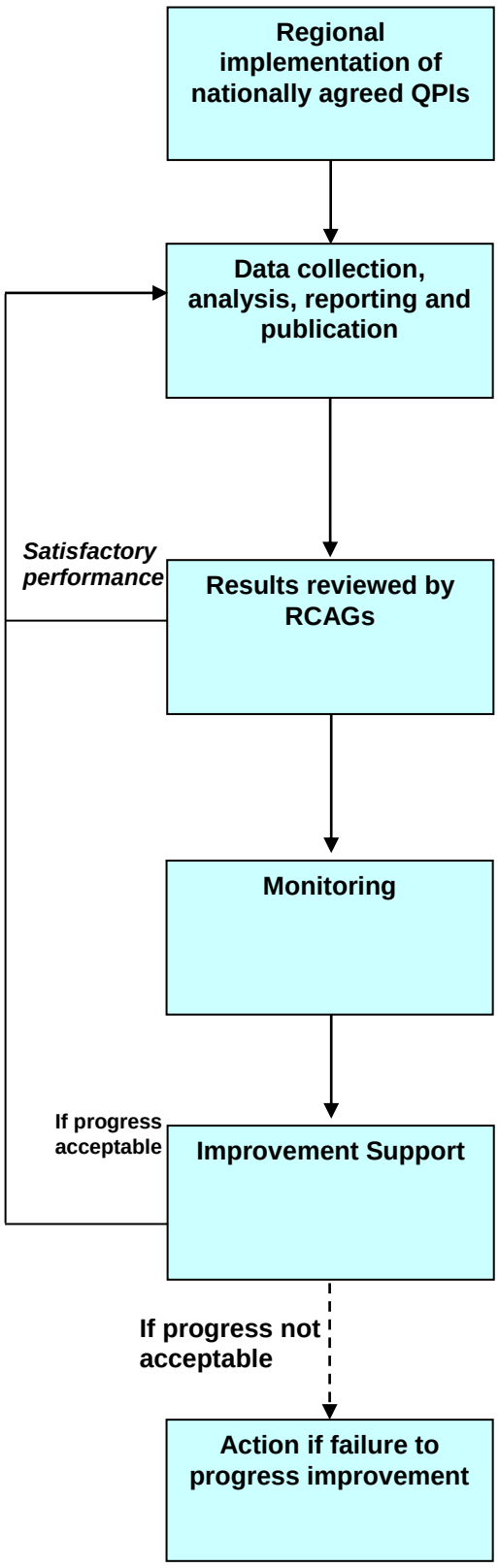
- RCAGs work with Boards to progress outstanding actions, monitor improvement plans and submit progress report to Healthcare Improvement Scotland.
- Healthcare Improvement Scotland report to Scottish Cancer Taskforce as to whether progress is acceptable**.**

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.

*The Regional Cancer Planning Group (South and East of Scotland) and the North Cancer Clinical Leadership Group (North Cancer Alliance) are equivalent to the Regional Cancer Advisory Group (RCAG) in the West of Scotland.

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 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.

*The Regional Cancer Planning Group (South and East of Scotland) and the North Cancer Clinical Leadership Group (North Cancer Alliance) are equivalent to the Regional Cancer Advisory Group (RCAG) in the West of Scotland.

Appendix 7: Glossary of Terms

Adjuvant Treatment	Treatment such as chemotherapy, or radiotherapy that is given after a surgical procedure to reduce the risk of the cancer coming back.
Biopsy	Removal of a sample of tissue from the body to assist in diagnosis of a disease.
BRAF	Specific genetic marker that when mutated allows tumour cells to be killed off with a specific class of anticancer drugs
Chemotherapy	The use of drugs used to kill cancer cells, to prevent or slow their growth.
Clinical 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. *See TNM Classification*
Co-morbidity/ Comorbidities	Other conditions and symptoms prevelant other than the primary diagnosis.
Computed Tomography (CT)	An x-ray imaging technique, which allows detailed investigation of the internal organs of the body.
Curative Treatment	Treatment given to cure the illness.
Definitive Treatment	Treatment designed to potentially cure cancer using one or a combination of interventions.
Dermatologist	A clinician who works within a branch of medicine concerned with the study and treatment of disorders of the skin.
Diagnosis	The process of identifying a disease, such as cancer, from its signs and symptoms.
Grade	The degree of malignancy of a tumour, i.e. how closely the cancer cells look like normal cells.
Histological / Histopathogical	The study of the structure, composition and function of tissues under the microscope, and their abnormalities.
Immunotherapy	A treatment that uses the body's own immune system to help fight cancer.
Lymphoedema	A swelling that develops as a result of an impaired lymphatic system.
Metastatic	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.
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 a specific region, age group, disease or other classification, usually expressed as deaths per 1,000, 10,000 or 100,000.
Multidisciplinary Team	Team which consists of various specialities and may be different depending on disease. For example, pathologist, surgeon, etc.
Multidisciplinary 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 agreed.
Lymph nodes	Small bean shaped organs located along the lymphatic system. Nodes filter bacteria or cancer cells that might travel through the lymphatic system.
Pathological/Pathology	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 a post mortem.

Positron emission tomography / Computed Tomography (PET CT)	A specialised imaging technique which demonstrates uptake of tracer in areas of high cell metabolism and can help differentiate between benign and malignant masses.
Postoperative Complication	Postoperative complications are unexpected problems that arise following surgery; these can range from minor to major complications.
Prognosis	An assessment of the expected future course and outcome of a person's disease.
Radiotherapy	The use of radiation (such as x-rays) to diagnose or treat disease.
Sentinel Node Biopsy	The lymph node near a body organ or part of an organ which is thought to be the first reached by tissue fluid draining from that organ. This lymph node may be the one most likely to contain cancer cells if the cancer has begun to spread.
Surgery/ Surgical Resection	Surgical removal of the tumour/lesion.
Subcutaneous	Beneath the skin.
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.
Systematic Anti Cancer Therapy (SACT)	Treatment of cancer using drugs which prevent the replication or growth of cancer cells. This encompasses biological therapies and cytotoxic chemotherapy.
Toxicity	The extent to which something is poisonous or harmful.
Tumour Node Metastases (TNM)	'TNM' stands for Tumour, Node, Metastasis. This system can describe the size of a primary tumour, whether the cancer has spread to the lymph nodes and whether the cancer has spread to a different part of the body (metastasised). The system uses numbers to describe the cancer.
Wide Local Excision	The removal of the lump together with some surrounding normal tissue.