Scottish Cancer Taskforce
National Cancer Quality Steering Group

Acute Leukaemia
Clinical Quality Performance Indicators
Engagement Document

July 2018

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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 indicators are in place for 18 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 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 (QPI) 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 Acute Leukaemia QPI Development Group was convened in January 2013, chaired by Mr Khaver Qureshi (Consultant Urological 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 Acute Leukaemia QPIs were undertaken in April 2018.

A Formal Review Group was convened, chaired by Mr Khaver Qureshi, Consultant Urological Surgeon. 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 NHS Scotland.

- 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 reporting of Acute Leukaemia QPIs. The updated document will be implemented for patients diagnosed with Acute Leukaemia on, or after, 1st July 2018.

6. Quality Performance Indicators for Acute Leukaemia

QPI 1 – Complete Diagnostic Panel

QPI Title:	Patients with acute leukaemia should have complete diagnostic panel undertaken to inform appropriate management.
Description:	Proportion of patients with acute leukaemia undergoing treatment with curative intent who have complete diagnostic panel undertaken, defined as: (i) Morphology; (ii) Immunophenotyping; (iii) Cytogenetics; and (iv) Storage of genetic material for routine diagnostic testing.
Rationale and Evidence:	Prior to patients undergoing intensive treatment for acute leukaemia the diagnosis must be established and prognostic markers obtained where relevant. Diagnosis and classification is as per World Health Organisation (WHO) 2008, and thus requires morphological, flow-cytometric, cytogenetic and (in selected cases) molecular analysis. Diagnostic material must be obtained and analysed or stored prior to treatment. By incorporating these different testing modalities into the diagnostic pathway, accurate diagnosis and sub classification is possible. A complete panel is required as findings from one test may alter the testing strategy for other techniques[2]. Current guidelines state that morphology, immunophenotyping, and cytogenetic/ molecular testing of the bone marrow aspirate and / or blood / bone marrow trephine are required in the diagnostic evaluation of all patients with suspected acute leukaemia[2,3,4]. Together, these studies allow determination of the WHO Acute Myeloid Leukaemia (AML) or Acute Lymphoblastic Leukaemia (ALL) subtype and cytogenetic risk group. In terms of prognosis, molecular testing has important treatment implications and should be routinely tested for in normal karyotype patients. Unless material is archived at diagnosis testing later will be impossible[5]. While such testing may occur within the context of a clinical trial, it may not be available to the treating clinician and not all patients enter into such a trial. As a minimum it is suggested that nucleic acid is stored on each patient.
Specifications:	**Numerator:** Number of patients with acute leukaemia undergoing treatment with curative intent where complete diagnostic panel undertaken. **Denominator:** All patients with acute leukaemia undergoing treatment with curative intent. **Exclusions** • No exclusions.
Target:	90% The tolerance within this target level is designed to account for situations where marrow aspirates fail to yield adequate material.

Revisions:	***Amendment to rationale statement only – no changes to QPI.***

QPI 2 – Diagnostic Classification

Revisions:	***This QPI has been archived – all Boards are achieving 100% target in Years 1-3 for patients having a WHO classification assigned and recorded.***

QPI 3 – MDT Discussion

QPI Title:	Patients with acute leukaemia should be discussed by a multidisciplinary team (MDT) at diagnosis.
Description:	Proportion of patients with acute leukaemia who are discussed at MDT meeting within 8 weeks of diagnosis.
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[6]. Given the lack of evidence regarding exact timeframe for discussion at MDT the Acute Leukaemia QPI Development Group consensus was agreed as 8 weeks, given time to completion of induction therapy. Discussion at MDT prior to consolidation treatment decisions being made provides reassurance that patients are being managed appropriately[7].
Specifications:	**Numerator:** Number of patients with acute leukaemia discussed at the MDT within 8 weeks of diagnosis. **Denominator:** All patients with acute leukaemia. **Exclusions:** • No exclusions.
Target:	95% The tolerance within this target is designed to account for situations where a patient's response to induction therapy is not assessable within the specified timeframe.

Revisions:	***QPI timescale changed for patients who are discussed at MDT from 6 weeks to 8 weeks of diagnosis to provide a more appropriate time to complete induction therapy.***

QPI 4 – Minimal Residual Disease Marker

Revisions:	***This QPI has been archived – numbers are too small to provide meaningful data and currently not enough evidence to expand the age group. This has been added as an area for future consideration.***

QPI 5 – Early Deaths

QPI Title:	Mortality rate following diagnosis of acute leukaemia.
Description:	Proportion of patients with acute leukaemia being treated with curative intent who die within 30/35 days of treatment. **Please note:** This QPI measures 2 distinct elements: i. Patients with Acute Myeloid Leukaemia (AML) treated with curative intent who die within 30 days of treatment[a]; and ii. Patients with Acute Lymphoblastic Leukaemia (ALL) treated with curative intent who die within 35 days of treatment.
Rationale and Evidence:	Early death can be defined using the time point of 30/35 days following treatment as response status is normally evaluated within this timeframe[5]. Differing timepoints are utilised for AML and ALL given different treatment regimens. Treatment related mortality is a marker of the quality and safety of the whole service provided by the Multi Disciplinary Team (MDT). Outcomes of treatment, including treatment related morbidity and mortality should be regularly assessed. Target levels reflect published evidence from clinical trials which suggest that risk of complication increases with age, this is primarily due to the intensity of curative treatment regimens. Despite this, evidence suggests that age alone is not a valid reason to withhold intensive therapy and can increase quality of life. Risk of complication is assessed on an individual basis[8,9,10,11].
Specification (i):	**Numerator:** Number of patients with AML being treated with curative intent who die within 30 days of treatment. **Denominator:** All patients with AML being treated with curative intent. **Exclusions** • No exclusions.
Target:	Patients under 16 years of age < 2% Patients aged between 16 and 60 years < 8% Patients over 60 years of age < 18%
Specification (ii):	**Numerator:** Number of patients with ALL being treated with curative intent who die within 35 days of treatment. **Denominator:** All patients with ALL being treated with curative intent. **Exclusions:** • No exclusions.
Target:	Patients under 16 years of age <2% Patients aged between 16 and to 60 years <8% Patients over 60 years of age < 20%

Revisions:	***Change to footnote only – measurement changed from the last dose of the final cycle to the first dose of the first cycle of chemotherapy.***

[a] This QPI will be measured from the start of chemotherapy, i.e. the first dose of the first cycle of chemotherapy. [b] Within the measurement of this QPI complete remission as confirmed by morphology will be utilised.

QPI 6 – Access to ATRA for Patients with Acute Promyelocytic Leukaemia

Revisions:	***This QPI has been archived – the QPI accounts for a small group of patients and it is difficult to obtain useful measurement for this particular aspect of quality. A more appropriate quality measure for APL patients (early deaths) has been included.***

QPI 7 – Deaths in Remission

QPI Title:	Remission deaths for patients with acute leukaemia receiving treatment with curative intent.
Description:	Proportion of patients with acute leukaemia undergoing treatment with curative intent who die in first complete remission (CR)[b], within 1 year of diagnosis.
Rationale and Evidence:	Outcomes of treatment, including treatment related mortality should be regularly assessed. This QPI measures the quality of supportive care provision and management of complications in patients treated with curative intent who achieve morphological remission following consolidation therapy. Target level is stratified by age as due to intensity of treatment risk of complication increases with age.
Specifications:	**Numerator:** Number of patients with acute leukaemia undergoing treatment with curative intent who achieve first CR and die within 1 year of diagnosis, whilst in CR. **Denominator:** All patients with acute leukaemia undergoing treatment with curative intent who achieve first CR. **Exclusions** • Patients undergoing bone marrow / stem cell transplant.
Target:	Patients under 16 years of age <4% Patients 16 years of age and over <10% **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.

Please Note: In order to ensure that a full 12 month period has elapsed since diagnosis, enabling accurate measurement, this QPI will be reported 1 year in arrears. This will ensure accurate and appropriate reporting against this QPI.

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

[b] Within the measurement of this QPI complete remission as confirmed by morphology will be utilised.

QPI 8 – Clinical Trials with Curative Intent

QPI Title:	Patients with acute leukaemia under 60 years of age[c] who are suitable for treatment with curative intent should be considered for participation in available clinical trials, wherever eligible.
Description:	Proportion of patients with acute leukaemia being treated with curative intent who are enrolled in a clinical trial.
Rationale and Evidence:	Clinical trials are necessary to demonstrate the efficacy of new therapies and other interventions. Furthermore evidence suggests improved patient outcomes from participation in clinical trials. Non-participation in clinical trials does not affect quality of care. Patients with Acute Myeloid Leukaemia (AML) and Acute Lymphoblastic Leukaemia (ALL) should be treated on a clinical trial wherever possible[3,6,12,13].
Specification:	**Numerator:** Number of patients with acute leukaemia who are treated with curative intent enrolled in a clinical trial. **Denominator:** All patients with acute leukaemia who are treated with curative intent. **Exclusions** • Patients who refuse entry into a clinical trial. • Patients over 60 years of age[c].
Target:	Patients under 16 years of age 80% Patients aged between 16 and 60 years of age over 60% The tolerance within this target is designed to account for situations where an appropriate clinical trial is not available, patients are ineligible for open clinical trial for example due to fitness levels and/or co-morbidities.

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

[c] Patients over 60 years of age are specifically included in QPI 10

QPI 9 – Tissue Typing for Transplant

QPI Title:	Patients with acute leukaemia treated with curative intent should have a specimen sent to the lab for tissue typing at diagnosis.
Description:	Proportion of patients with acute leukaemia eligible for transplant (i.e. over 16 years of age and under 65 years of age) being treated with curative intent should have a specimen sent to the lab for tissue typing at diagnosis.
Rationale and Evidence:	Human Leukocyte Antigen (HLA) typing (high-resolution molecular typing of classes I and II) of the patient and, when available, of his/her siblings should be performed at diagnosis for patients free of severe co morbidities[14]. HLA typing should be performed in all patients with newly diagnosed acute leukaemia for whom allogeneic Haematopoietic Stem Cell Transplantation would be considered[15]. Treatment is not restricted by age and is considered on an individual patient basis. Treatment may be restricted by co-morbidities, which are more common in the older patient group. To ensure focussed measurement and a QPI examining expected outcomes the age range of 16-65 years has been selected. This represents the majority of patients who would be eligible for transplant and therefore provides a good proxy for the whole patient population. This does not affect clinical practice, as patients are considered for treatment on an individual basis.
Specification (i):	**Numerator:** Number of patients with acute leukaemia between 16 and 65 treated with curative intent with a specimen sent to the lab for tissue typing at diagnosis. **Denominator:** All patients with acute leukaemia between 16 and 65 being treated with curative intent. **Exclusions** • No exclusions.
Target:	90% The tolerance within the target is designed to account for situations where patients have co-morbidities or fitness levels which preclude transplant.

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

QPI 10 – Intensive Chemotherapy in Older Adults

QPI Title:	Patients with acute leukaemia over 60 years of age should be offered intensive chemotherapy, within the context of a clinical trial wherever possible, as this provides quality of life and survival benefit.
Description:	Proportion of patients with acute leukaemia over 60 years of age with performance status (PS) 0-1 who receive intensive chemotherapy. **Please note:** This QPI measures 2 distinct elements: i. Patients with acute leukaemia 60 years of age and over who receive intensive chemotherapy; and ii. Patients with acute leukaemia 60 years of age and over receiving intensive chemotherapy who are treated within a clinical trial.
Rationale and Evidence:	Older age should not be a reason to withhold intensive therapy. Evidence suggests that intensive chemotherapy provides better quality of life and longer survival than supportive care only Regardless of chronologic age[3,12,15]. Performance status, adverse features (e.g. unfavourable cytogenetics) and co-morbidities should be utilised to select treatment options rather than relying on chronological age alone[15,16]. Patients with acute leukaemia should be treated on a clinical trials wherever possible[3,12,13].
Specification (i):	**Numerator:** Number of patients with acute leukaemia 60 years of age and over with PS 0-1 who receive intensive chemotherapy. **Denominator:** All patients with acute leukaemia 60 years of age and over with PS 0-1. **Exclusions** • No exclusions.
Target:	30% The tolerance within the target is designed to account for situations where patient's co-morbidities preclude treatment with intensive chemotherapy and for factors of patient choice.
Specification (ii):	**Numerator:** Number of patients with acute leukaemia 60 years of age and over who receive intensive chemotherapy enrolled in a clinical trial. **Denominator:** All patients with acute leukaemia 60 years of age and over who receive intensive chemotherapy. **Exclusions:** • Patients who refuse entry into a clinical trial.
Target:	70% The tolerance within the target is designed to account for situations where an appropriate clinical trial is not available, patients are ineligible for open clinical trial due to fitness levels or 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.

Revisions:	***Target increased for specification (i) from 20% to 30%*** ***Target decreased for specification (ii) from 80% to 70%***

QPI 11 – Clinical Trials with Non Curative Intent

QPI Title:	Patients with acute leukaemia who are suitable only for treatment with non-curative intent should be considered for participation in available clinical trials, wherever eligible.	
Description:	Proportion of patients with acute leukaemia being treated with non curative intent who are enrolled in a clinical trial.	
Rationale and Evidence:	Clinical trials are necessary to demonstrate the efficacy of new therapies and other interventions. Furthermore evidence suggests improved patient outcomes from participation in clinical trials. Non-participation in clinical trials does not affect quality of care[6].	
Specifications:	**Numerator:**	Number of patients with acute leukaemia who are treated with non-curative intent enrolled in a clinical trial.
	Denominator:	All patients with acute leukaemia who are treated with non-curative intent.
	Exclusions	• Patients who refuse entry into a clinical trial.
Target:	10% The tolerance within this target is designed to account for situations where an appropriate clinical trial is not available, patients are ineligible for open clinical trial for example due to fitness levels and/or co-morbidities.	

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

QPI 12 – Palliative Treatment

QPI Title:	Patients with acute myeloid leukaemia (AML) who are suitable only for treatment with non-curative intent should be considered for treatment with an appropriate systemic anti-cancer therapy (SACT) regimen.
Description:	Proportion of patients with AML who are suitable only for treatment with non-curative intent who receive an appropriate SACT regimen[d].
Rationale and Evidence:	For patients with acute leukaemia who are deemed ineligible for treatment with curative intent by the multi-disciplinary team treatment with palliative chemotherapy is recommended to optimise disease control while avoiding serious treatment-related toxicities[18]. Evidence suggests palliative chemotherapy in this indication has an associated quality of life benefit for patients. Unless patients with AML opting for palliative chemotherapy are entered into clinical trials, treatment should be offered with either low-dose cytarabine[3] or azacytidine, according to Scottish Medicines Consortium (SMC) recommendations. Azacitidine is accepted for use within NHSScotland by the SMC for treatment of adult patients with AML, with 20-30% blasts and multilineage dysplasia, who are not eligible for haematopoietic stem cell transplantation[17].
Specifications:	**Numerator:** Number of patients with acute myeloid leukaemia who are suitable only for treatment with non-curative intent who receive an appropriate palliative SACT regimen. **Denominator:** All patients with acute myeloid leukaemia who are suitable only for treatment with non-curative intent. **Exclusions** • Patients who refuse chemotherapy treatment. • Patients with adverse cytogenetics.
Target:	70% The tolerance within this target is designed to account for situations where co-morbidities and/or patients fitness levels preclude consideration of palliative chemotherapy.

Revisions:	***QPI wording updated to remove reference to palliative chemotherapy and replace with systemic anti-cancer therapy. Other palliative treatments to be included within the QPI e.g. hydroxycarbamide.***

[d]Appropriate SACT regimen will include any drug which is licensed in this indication, for example cytarabine, azacitidine or hydroxycarbamide.

QPI 13 – Early death for patients with Acute Promyelocytic Leukaemia (APL)

QPI Title:	Mortality rate following diagnosis of Acute Promyelocytic Leukaemia (APL).
Description:	Proportion of patients with APL who die within 30 days of diagnosis.
Rationale and Evidence:	Early death is defined as death within 30 days of diagnosis. Preventing early death in patients with APL is an important factor as there is a high probability of cure for these patients following initial the management phase[18]. This QPI measures the outcome of all patients with APL within 30 days of diagnosis. This will include those patients who may die before any treatment has commenced as well as treatment related mortality. Treatment related mortality is a marker of the quality and safety of the whole service provided by the Multi Disciplinary Team (MDT). Target levels reflect published evidence which suggests higher early death rates than those reflected within clinical trials as these may exclude elderly patients and those with co-morbidities and / or poor performance status[18].
Specification:	**Numerator:** Number of patients with APL who die within 30 days of diagnosis. **Denominator:** All patients with APL. **Exclusions** • No exclusions.
Target:	<25%

Revisions:	***New QPI.***

QPI 14 – Clinical Trials and Research Study Access

Revision(s):	***The revised Clinical Trial Access QPI which is applicable to all tumour sites will be included with the final Acute Leukaemia QPI document.***

7. Survival

Improving survival forms an integral part of the national cancer quality improvement programme. Acute Leukaemia 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 Acute Leukaemia 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 Acute Leukaemia 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 treatment of Acute Leukaemia, and therefore in improving the quality of care for patients affected by Acute Leukaemia.

The following areas for future consideration have been raised across the lifetime of the Acute Leukaemia QPIs.

- Quality of life following treatment with curative intent.
- The role of nutrition and diet in improving patient outcomes.
- Minimal Residual Disease (MRD) testing for all patients with Acute Lymphoblastic Leukaemia (ALL).

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 4 and 5 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 Acute Leukaemia 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 Acute Leukaemia QPIs via the Scottish Government Consultation Hub (website link below):

https://consult.scotland.gov.uk/west-of-scotland-cancer-network/acuteleukaemia-qpi

All responses should be submitted by **Friday 7th September 2018.**

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

Email: AcuteleukaemiaQPIPublicEngagement@gov.scot

10.2 Engagement feedback

At the end of the engagement period, all comments and responses will be collated for review by the Acute Leukaemia 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 Acute Leukaemia 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 Acute Leukaemia QPIs and a search narrative were defined and agreed by the Acute Leukaemia QPI Development Group. The table below shows the final search criteria.

Inclusion	Exclusion
Primary acute myeloid leukaemia (AML), including acute promyelocytic leukaemia • Primary acute lymphoblastic leukaemia (ALL) • Diagnosis and prognostic indicators • Non-surgical management of disease (chemotherapy, stem cell transplant, autologous stem cell rescue) *Age Range*: All (adults, children and infants) *Date:* 2005 to present day *Language:* English only *Document Type:* Clinical guidelines	• Recurrent disease/relapsed disease management • Follow up • Primary care/referral • Pre cancerous conditions including: Myelodysplastic Syndromes and Myeloproliferative Neoplasms. • Prevention • Screening • Clinical trials recruitment & protocols • Symptom management (e.g. nausea & vomiting, neutropenic sepsis) • Communication, information sharing and support • Palliative/end of life care (pain management, end of life counselling, hospice management)

Table 1: Acute Leukaemia Literature Search Criteria

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

Ten guidelines were appraised for quality using the AGREE II instrument[19]. This instrument assesses the methodological rigour used when developing a guideline. Two of the guidelines were not recommended for use. The remaining eight guidelines were recommended for use.

Indicator Development

The Acute Leukaemia 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 December 2013, where the Acute Leukaemia 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 Acute Leukaemia and the wider public were given the opportunity to influence the development of Acute Leukaemia 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 Acute Leukaemia QPI Development Group and used to produce and refine the final indicators.

Appendix 2: Acute Leukaemia QPI Development Group Membership (2013)

Name	Designation	Cancer Network/Base
Khaver Qureshi	Consultant Urological Surgeon	WoSCAN / NHS Greater Glasgow and Clyde
Jane Belmore	Paediatric Oncology Outreach Nurse Specialist	WoSCAN / NHS Greater Glasgow and Clyde
Shelagh Bonner-Shand	Regional Manager (Acting)	NOSCAN
Mark Drummond	Consultant Haematologist	WoSCAN / NHS Greater Glasgow and Clyde
Val Findlay	Audit Facilitator	SCAN
Brenda Gibson	Consultant Haematologist	WoSCAN / NHS Greater Glasgow and Clyde
William Gordon	Consultant Haematologist	WoSCAN / NHS Ayrshire and Arran
Nick Heaney	Consultant Haematologist	WoSCAN / NHS Greater Glasgow and Clyde
Michele Hilton Boon	Programme Manager	Healthcare Improvement Scotland
Jeff Horn	Clinical Nurse Specialist	NOSCAN/ NHS Grampian
Derek King	Consultant Paediatric Haematologist	NOSCAN / NHS Grampian
Kathryn Love	Principle Clinical Scientist	WoSCAN / NHS Greater Glasgow and Clyde
Avril Morris	Principle Clinical Scientist	WoSCAN / NHS Greater Glasgow and Clyde
Brian Murray *(from September 2013)*	Principle Information Development Manager	ISD
Frances Murray	Clinical Quality Service Coordinator	WoSCAN / NHS Lanarkshire
Anne Parker	Consultant Haematologist	WoSCAN / NHS Greater Glasgow and Clyde
Margaret Quinn *(until September 2013)*	Principle Information Development Manager	ISD
Nan Ramsey	Senior Charge Nurse	WoSCAN / NHS Greater Glasgow and Clyde
Huw Roddie	Consultant Haematologist	SCAN / NHS Lothian
Iona Scott	Project Manager	
Deborah Shanks	Consultant Paediatrician	NOSCAN / NHS Highland
Anne Sproul	Principle Clinical Scientist	SCAN / NHS Lothian
Sudhir Tauro	Consultant Haematologist	NOSCAN / NHS Tayside
Evelyn Thomson	Regional Manager (Cancer)	WoSCAN

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

Appendix 3: Acute Leukaemia QPI Formal Review Group Membership (2018)

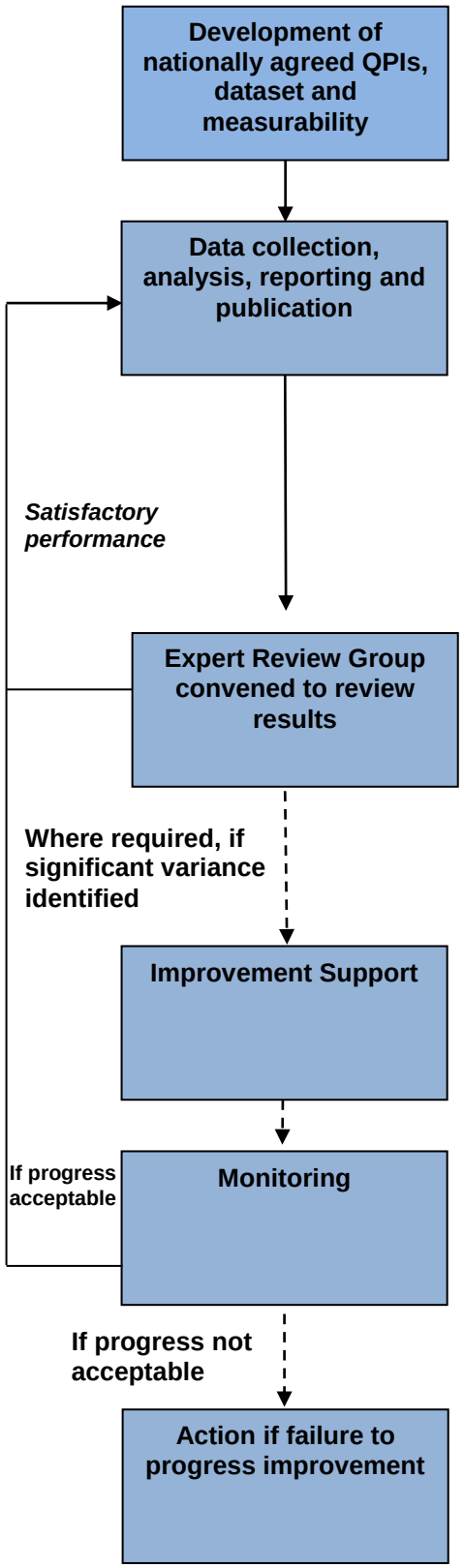
Name	Designation	Cancer Network/Base
Khaver Qureshi	Consultant Urological Surgeon	WoSCAN / NHS Greater Glasgow and Clyde
Dominic Culligan	Consultant Haematologist	NOSCAN / NHS Grampian
Jen Doherty	Project Co-ordinator	National Cancer Quality Programme
Mark Drummond	Consultant Haematologist	WoSCAN / NHS Greater Glasgow & Clyde
Carol Marshall	Audit Manager	WoSCAN
Grant McQuaker	Bone Marrow Transplant Consultant	WoSCAN / NHS Greater Glasgow & Clyde
Anne Parker	Consultant Haematologist	WoSCAN / NHS Greater Glasgow and Clyde
Huw Roddie	Consultant Haematologist	SCAN / NHS Lothian
Lorraine Stirling	Project Officer	National Cancer Quality Programme
Sudhir Tauro	Consultant Haematologist	NOSCAN / NHS Tayside
Heather Wotherspoon	MCN Manager	WoSCAN

Formal review of the Acute Leukaemia QPIs have 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: 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).



6. 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:

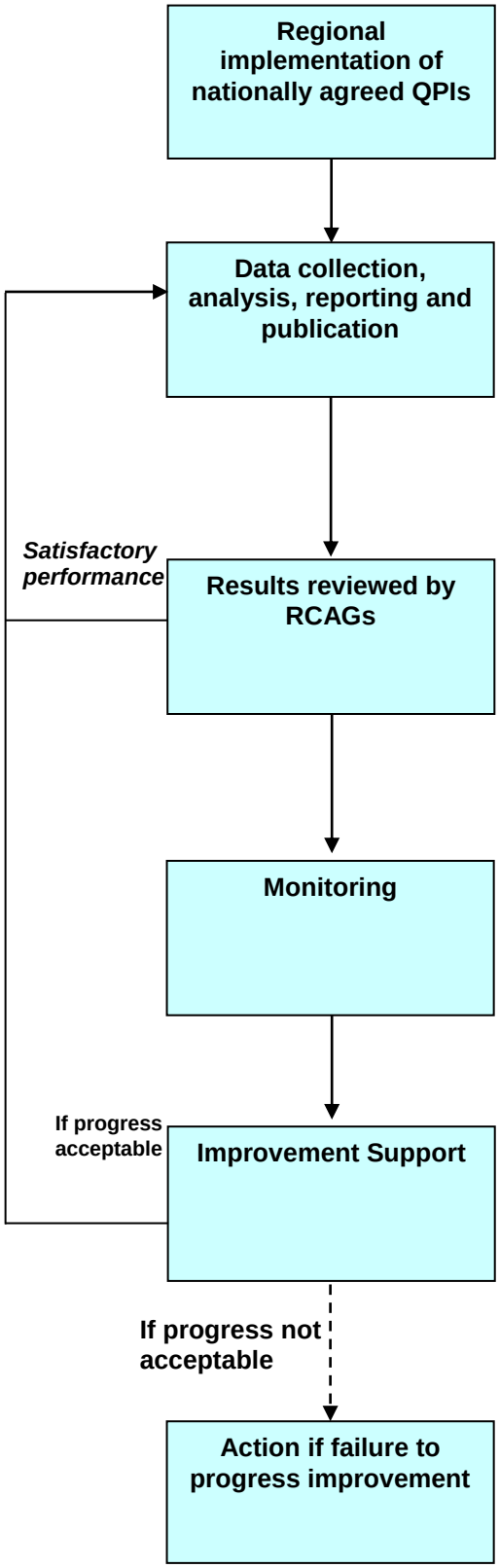
- RCAGs work with Boards to progress outstanding actions, monitor improvement plans and submit progress report to Healthcare Improvement Scotland.
- Healthcare Improvement Scotland report to Scottish Cancer Taskforce as to whether progress is acceptable**.**

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



6. 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.

Appendix 6: Glossary of Terms

Acute Leukaemia	Leukaemia is cancer of the white blood cells. Acute leukaemia means the condition progresses rapidly and aggressively and requires immediate treatment.
Acute Lymphoblastic leukaemia (ALL)	ALL is a rare type of cancer affecting the white blood cells, occurring most frequently in children under 15; in adults it is most common between the ages of 15-25 and in people over 75.
Acute Myeloid Leukaemia (AML)	AML is a rare type of cancer. It can affect people at any age but is more common in people over 65. AML is a cancer of blood-forming cells in the bone marrow. Abnormal immature white blood cells (blasts) fill the bone marrow and spill into the bloodstream. Production of normal blood cells is affected, causing anaemia.
Acute Promyelocytic Leukaemia (APL)	An aggressive (fast-growing) type of acute myeloid leukaemia in which there are too many immature blood-forming cells in the blood and bone marrow. It is usually marked by an exchange of parts of chromosomes 15 and 17.
Adjuvant therapy / treatment	Additional cancer treatment given after the primary treatment to lower the risk that the cancer will come back. Adjuvant therapy may include chemotherapy, radiation therapy, hormone therapy, targeted therapy, or biological therapy.
All Trans Retinoic Acid (ATRA)	A nutrient that the body needs in small amounts to function and stay healthy. ATRA is made in the body from vitamin A and helps cells to grow and develop, especially in the embryo. A form of ATRA made in the laboratory is taken by mouth to treat acute promyelocytic leukaemia.
Azacytidine	A chemotherapy drug which may be used to treat acute myeloid leukaemia (AML).
Bone marrow aspirate	A procedure in which a small sample of bone marrow is removed, usually from the hip bone, breastbone, or thigh bone.
CEBPA mutation	A potential marker for monitoring minimal residual disease
Chemotherapy	The use of drugs used to kill cancer cells, to prevent or slow their growth.
Clinical trial(s)	A type of research study that tests how well new medical approaches or medicines work. These studies test new methods of screening, prevention, diagnosis, or treatment of a disease.
Complete Remission	When the blood and bone marrow return to normal after treatment.
Complication	A medical problem which occurs during disease, or after a procedure or treatment. The complication may be caused by the disease, procedure or treatment or may be unrelated.
Consolidation treatment/ therapy	Treatment that is given after cancer has disappeared following the initial therapy. Consolidation therapy is used to kill any cancer cells that may be left in the body.
Curative intent	Refers to treatment provided for the purpose of treating and curing disease.
Cytarabine	A chemotherapy agent used mainly in the treatment of cancers of white blood cells such as acute myeloid leukemia (AML)
Cytogenetics	The study of chromosomes and chromosomal abnormalities.

Flow Cytometry	Routinely used in the diagnosis of blood cancers. It is a laser-based, biophysical technology employed in cell counting, cell sorting, biomarker detection and protein engineering,
Haematologist	A doctor who specialises in diseases of the blood, blood-forming tissues or organs.
Haematopoietic stem cell transplantation	Transplantation of stem cells collected from bone marrow or peripheral blood can be from the patient themselves (autologous transplant) or another donor (allogneic transplant)
Haemoglobin	The oxygen carrying component of red blood cells which gives them their red colour and serves to convey oxygen to tissues.
Immunophenotyping	A technique used to study the protein expressed by cells, frequently used in laboratory tests for diagnostic purposes.
Induction therapy	The first stage of cancer treatment.
Intensive chemotherapy	High dose treatment to kill the cancer cells, but also destroys the bone marrow.
International Classification of Diseases (ICD) 10	The International Classification of Diseases is the standard diagnostic tool for epidemiology, health management and clinical purposes. It is used to monitor the incidence and prevalence of diseases and other health problems.
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.
Palliative chemotherapy regimen	Treatment where the impact of intervention is insufficient to result in major survival advantage, but does provide an improvement in symptoms.
Prognostic markers	Also referred to as biomarkers, are characteristics that help to identify or categorise people with different risks of specific future outcomes.
Progression	The process of cancer spreading or becoming more severe.
Remission deaths	When a patient dies whilst there is no evidence of active disease, i.e. or no evidence of disease in the blood cells and/or bone marrow.
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.
Tissue Typing	A series of diagnostic texts before an organ transplant to determine whether the tissues of a donor and recipient are compatible.
Toxicity	The extent to which something is poisonous or harmful.
World Health Organisation (WHO) 2008	World Health Statistics 2008 presents the most recent health statistics for WHO's 193 Member States.