

Scottish Cancer Strategic Board National Cancer Quality Improvement Board

Acute Leukaemia Clinical Quality Performance Indicators

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Revision History

Version	Date	Summary of Changes
V1.0	April 2014	Initial publication
V2.0	June 2016	Baseline review changes
V3.0	September 2018	Formal review changes (1st Cycle)
V4.0	November 2021	Formal review changes (2nd Cycle)
V5.0	July 2025	Formal review changes (3rd Cycle)

Contents Update Record

July 2025 (v5.0)

This document was updated following formal review (3rd cycle) of the Acute Leukaemia Quality Performance Indicators (QPIs) which took place following analysis of year 9 of the acute leukaemia QPI data.

The following QPIs have been updated:

- QPI 1: Complete Diagnostic Panel
- QPI 5: Early Deaths
- QPI 9: Tissue Typing for Transplant
- QPI 10: Remission Inducing SACT in Older Adults
- QPI 13: Early Deaths in Patients with Acute Promyelocytic Leukaemia

The following QPIs have been archived:

- QPI 7: Deaths in Remission
- QPI 8: Clinical Trials with Curative Intent
- QPI 12: Palliative Treatment
- QPI 14: Clinical Trials Research Study Access*

The following new QPIs have been added:

- QPI 15: Next Generation Sequencing in Acute Myeloid Leukaemia
- QPI 16: NPM1 MRD Assessment in Patients with Normal Karyotype Acute Myeloid Leukaemia

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

Please note that this version of the Acute Leukaemia QPI document applies to cases diagnosed from 1st July 2024. Where amended or new QPIs require new data items for measurement, this will apply for patients diagnosed from 1st July 2025.

Previous Updates:

November 2021 (v4.0)

This document was updated following formal review (2nd cycle) of the Acute Leukaemia Quality Performance Indicators (QPIs) which took place following analysis of year 6 of the acute leukaemia QPI data.

^{*} This important indicator will continue to be monitored via other national reporting systems rather than through the QPI process.

The following QPIs have been updated:

- QPI 1 Complete Diagnostic Panel
- *QPI 5 Early Deaths
- *QPI 7 Deaths in Remission
- *QPI 8 Clinical Trials with Curative Intent
- QPI 9 Tissue Typing for Transplant
- QPI 10 Intensive Chemotherapy in Older Adults
- QPI 12 Palliative Treatment

The following QPI has been archived:

QPI 11 – Clinical Trials with Non Curative Intent

*QPI target change only – the target has been removed for patients under 16 years of age. This data is now being collected through the Managed Service Network (MSN) for Children and Young People with Cancer.

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

Please note that this version of the Acute Leukaemia QPI Document applies to cases diagnosed from 1st July 2020. Where amended QPIs require new data items for measurement, this will apply for patients diagnosed from 1st July 2021.

September 2018 (v3.0)

This document was updated following formal review of the Acute Leukaemia Quality Performance Indicators (QPIs) which took place following analysis of year 3 of the Acute Leukaemia QPI data.

The following QPIs have been updated:

- QPI 1 Complete Diagnostic Panel
- QPI 3 MDT Discussion
- QPI 5 Early Deaths
- QPI 10 Intensive Chemotherapy in Older Adults
- QPI 12 Palliative Treatment

The following QPIs have been archived:

- QPI 2 Diagnostic Classification
- QPI 4 Minimal Residual Disease Marker
- QPI 6 Access to ATRA for Patients with Acute Promyelocytic Leukaemia

The following new QPI has been added:

• QPI 13 - Early Deaths in Patients with Acute Promyelocytic Leukaemia

Please note the Clinical Trial and Research Study Access has now been added into each tumour specific QPI document (see QPI 14: Clinical Trials).

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

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

June 2016 (v2.0)

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

- QPI 5 Early Deaths
- QPI 6 Access to ATRA for Patients with Acute Promyelocytic Leukaemia
- QPI 7 Deaths in Remission
- QPI 9 Tissue Typing for Transplant
- QPI 10 Intensive Chemotherapy in Older Adults

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

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1. National Cancer Quality Programme

Beating 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 QPIs ensure that activity is focused on those areas that are most important in terms of improving survival and individual care experience whilst reducing variation and supporting the most effective and efficient delivery of care for people with cancer. QPIs are kept under regular review and are responsive to changes in clinical practice and emerging evidence.

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

1.1 Quality Assurance and Continuous Quality Improvement

The ultimate aim of the programme is to develop a framework, and foster a culture of continuous quality improvement, whereby real time data is reviewed regularly at an individual Multidisciplinary Team (MDT)/Unit level and findings actioned to deliver continual improvements in the quality of cancer care. This 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 summary reports published annually. These reports highlight the publication of performance data in the Cancer QPI Dashboard held within the Scottish Cancer Registry and Intelligence Service (SCRIS). The dashboard 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) for inclusion in the Cancer QPI Dashboard and subsequent national summary reports. This 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 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, Information Services Division (ISD) and patient/carer representatives. The development process and membership of the development group can be found in appendix 1.

3. QPI Formal Review Process

As part of the National Cancer Quality Programme, a systematic rolling programme of national review process has been developed. This ensures all tumour specific QPIs are subject to formal review following every 3rd year of comparative QPI data analysis.

The formal review process is clinically driven with proposals for change sought from specialty specific representatives in each of the Regional Cancer Networks. It is designed to be flexible in terms of the extent of review required with tumour specific Regional Clinical Leads undertaking a key role in this decision making. Formal review meetings to further discuss proposals are 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 archived 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, associated data items will continue to be collected where these are utilised for other indicators, or measures such as survival analysis.

Any new QPIs are 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?

Three formal reviews of the Acute Leukaemia QPIs have been undertaken to date. Further information can be found in appendix 2.

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 have been developed in parallel with the indicators to support the monitoring and reporting of the Acute Leukaemia QPIs. The latest version of these documents can be found at:

Public Health Scotland Cancer Audit

6. Quality Performance Indicators for Acute Leukaemia

QPI 1: Complete Diagnostic Panel

QPI Title:	Patients with acute leukaemia should have a complete diagnostic panel undertaken to inform appropriate management.	
Description:	Proportion of patients with acute leukaemia undergoing intensive chemotherapy treatment who have a complete diagnostic panel undertaken, defined as: (i) Morphology; (ii) Immunophenotyping; (iii) Cytogenetics (iv) Molecular marker analysis; and (v) 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 techniques². 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 leukaemia².³.⁴. Together, these studies allow determination of the WHO Acute Myeloid Leukaemia (AML)⁵.6.7 or Acute Lymphoblastic Leukaemia (ALL)³ 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 impossible³. 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.	

(Continued overleaf)

QPI 1: Complete Diagnostic Panel (continued.....)

Specifications:	Numerator:	Number of patients with acute leukaemia undergoing intensive chemotherapy treatment where a complete diagnostic panel is undertaken.
	Denominator:	All patients with acute leukaemia undergoing intensive chemotherapy treatment.
	Exclusions	No exclusions.
Target:		thin this target level is designed to account for marrow aspirates fail to yield adequate

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 ¹⁰ .		
	Given the lack of evidence regarding an exact timeframe for discussion at MDT, the Acute Leukaemia QPI Development Group consensus agreed this as 8 weeks, giving time to completion of induction therapy.		
	Discussion at MDT prior to consolidation treatment decisions being made provides reassurance that patients are being managed appropriately ¹¹ .		
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.		

QPI 5: Early Deaths

QPI Title:	Mortality rate following diagnosis of acute leukaemia.		
Description:	Proportion of patients with acute leukaemia being treated with intensive chemotherapy who die within 30/35 days of treatment ^a . Please note: This QPI measures 2 distinct elements: i. Patients with Acute Myeloid Leukaemia (AML) treated with intensive chemotherapy who die within 30 days of treatment; and ii. Patients with Acute Lymphoblastic Leukaemia (ALL) treated with intensive chemotherapy 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 ⁹ . Differing time-points 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 12,13,14,15.		
Specification (i):	Numerator: Number of patients with AML being treated with intensive chemotherapy who die within 30 days of treatment. Denominator: All patients with AML being treated with intensive chemotherapy. Exclusions No exclusions.		
Target:	Patients aged between 16 and 60 years < 8% Patients over 60 years of age < 18%		

(Continued overleaf)

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^a This QPI will be measured from the start of chemotherapy, i.e. the first dose of the first cycle of chemotherapy.

QPI 5: Early Deaths (continued.....)

Specification (ii):	Numerator:	Number of patients with ALL being treated with intensive chemotherapy who die within 35 days of treatment.
	Denominator:	All patients with ALL being treated with intensive chemotherapy.
	Exclusions:	No exclusions.
Target:	Patients aged between 16 and to 60 years <8%	
	Patients over 60 years of age < 20%	

QPI 9: Tissue Typing for Transplant

QPI Title:	Patients with acute leukaemia treated with intensive chemotherapy should have a specimen sent to the lab for tissue typing following 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 intensive chemotherapy should have a specimen sent to the lab for tissue typing within 28 days of 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 ¹⁶ .	
	HLA typing should be performed in all patients with newly diagnosed acute leukaemia for whom allogeneic Haematopoietic Stem Cell Transplantation would be considered ¹⁷ .	
	Until relatively recently, only patients fit for intensive chemotherapy as remission inducing SACT have been considered suitable for consolidation with allogeneic stem cell transplantation. Lower intensity treatments (with less toxicity) may have comparable efficacy as intensive chemotherapy in some situations therefore some recipients of lower-intensity, remission inducing SACT may receive allogeneic stem cell transplantation as consolidation. This practice is relatively uncommon in the United Kingdom and there is insufficient evidence at present to set a QPI measuring the benefits of tissue-typing to all patients receiving remission-inducing SACT.	
	Treatment is not restricted by age and is considered on an individual patient basis. Treatment may be restricted by comorbidities, 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.	

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QPI 9: Tissue Typing for Transplant (continued....)

Specifications:	Numerator:	Number of patients with acute leukaemia between 16 and 65 years of age undergoing intensive chemotherapy treatment that have a specimen sent to the lab for tissue typing within 28 days of diagnosis.
	Denominator:	All patients with acute leukaemia between 16 and 65 years of age undergoing intensive chemotherapy treatment.
	Exclusions	 Patients with Acute Promyelocytic Leukaemia (APML) Patients who decline tissue typing.
Target:		ithin the target is designed to account for patients have co-morbidities or fitness levels ransplant.

QPI 10: Remission Inducing Systemic Anti-Cancer Therapy (SACT) in Older Adults

QPI Title:	Patients with acute leukaemia over 60 years of age should be offered remission inducing Systemic Anti-Cancer Therapy (SACT) as this provides quality of life and survival benefit.		
Description:	Proportion of patients with acute leukaemia over 60 years of age who receive remission inducing SACT.		
Rationale and Evidence:	Older age should not be a reason to withhold SACT, including intensive therapy. Evidence suggests that treatment with a remission inducing SACT regimen provides better quality of life and longer survival than supportive care only regardless of chronologic age ^{3,17,18} .		
	A number of remission inducing treatments are accepted for use within NHSScotland including newer drug combinations approved by the Scottish Medicines Consortium (SMC). These include intensive and less-intensive options that demonstrate a significant improvement in survival ¹⁹ .		
	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 17,20.		
Specifications:	Numerator: Number of patients with acute leukaemia 60 years of age and over who receive remission inducing SACT.		
	Denominator: All patients with acute leukaemia 60 years of age and over.		
	Exclusions • No exclusions.		
Target:	40%		
	The tolerance within the target is designed to account for situations where patient's co-morbidities preclude treatment with remission inducing SACT and for factors of patient choice.		

QPI 13: Early Deaths in Patients with Acute Promyelocytic Leukaemia (APL)

QPI Title:	Mortality rate following diagnosis of Acute Promyelocytic Leukaemia (APL).		
Description:	Proportion of patients with Acute Promyelocytic Leukaemia (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 the initial management phase ²¹ . 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 ²¹ .		
Specifications:	Numerator: Number of patients with APL who die within 30 days of diagnosis.		
	Denominator: All patients with APL.		
	Exclusions • No exclusions.		
Target:	<20%		

QPI 15: Next Generation Sequencing in Acute Myeloid Leukaemia (AML)

QPI Title:	Next Generation Sequencing (NGS) should be performed in patients with Acute Myeloid Leukaemia (AML) to inform treatment decision making.		
Description:	Proportion of patients with Acute Myeloid Leukaemia (AML) undergoing intensive chemotherapy treatment who have Next Generation Sequencing (NGS) performed within 6 weeks (42 days) of diagnosis.		
	Please note: This QPI measures 2 distinct elements: i. Patients with AML undergoing intensive chemotherapy treatment who have NGS performed; and ii. Patients with AML undergoing intensive chemotherapy treatment who have NGS performed within 6 weeks of diagnosis		
Rationale and Evidence:	Molecular analysis has a significant role in diagnosis, prognosis and treatment decision making, as well as long term follow up in patients with Acute Myeloid Leukaemia (AML) ^{22,} .		
	Evidence has highlighted the importance of Next Generation Sequencing (NGS) testing for disease classification and defining prognosis, as well as the selection of appropriate treatments including allogeneic stem cell transplantation to optimise disease control. In addition, testing may identify patients for further investigation for germline predisposition to AML ²² .		
Specification (i):	Numerator:	Number of patients with AML undergoing intensive chemotherapy treatment who have NGS performed.	
	Denominator:	All patients with AML undergoing intensive chemotherapy treatment.	
	Exclusions	No exclusions.	
Specifications (ii):	Numerator:	Number of patients with AML undergoing intensive chemotherapy treatment who have NGS performed within 6 weeks (42 days) of diagnosis.	
	Denominator:	All patients with AML undergoing intensive chemotherapy treatment who have NGS performed.	
	Exclusions	No exclusions.	
Target:	90%		
		thin this target level is designed to account for there is failure to yield adequate material for	
	l		

QPI 16: NPM1 MRD Assessment in Patients with Non-Adverse Risk Karyotype Acute Myeloid Leukaemia (AML)

QPI Title:	be undertaken ii risk karyotype A	ole Residual Disease (MRD) assessment should in intensively treated patients with non-adverse cute Myeloid Leukaemia (AML) to inform reatment decisions.
Description:	Proportion of patients with NPM1 mutated non-adverse risk karyotype Acute Myeloid Leukaemia (AML) undergoing intensive chemotherapy who have NPM1 MRD assessment undertaken after 2 cycles of treatment ^b .	
Rationale and Evidence:	measurable resi reverse transcrip based on their fileukaemia, lack reduction with transt patients, where the most patients, where the matter of NPM1 mutater marker 23,24. In addition, by ic cycle 2 who will	s are an ideal and validated target for dual disease (MRD) monitoring by quantitative oftion polymerase chain reaction (RT-qPCR), requency in normal karyotype acute myeloid of association with clonal haemopoiesis, eatment and re-appearance prior to relapse in with established thresholds predictive of relapse. In blood after 2 treatment cycles is the major reminant of outcomes, making MRD monitoring and transcripts in blood a powerful prognostic dentifying patients with detectable disease post benefit from allogeneic stem cell transplantation of MRD monitoring is a practice defining arker ²⁵ .
Specifications:	Numerator:	Number of patients with NPM1 mutated non- adverse risk karyotype Acute Myeloid Leukaemia (AML) undergoing intensive chemotherapy who have NPM1 MRD assessment undertaken after 2 cycles of treatment. ^b
	Denominator:	All patients with NPM1 mutated non-adverse risk karyotype Acute Myeloid Leukaemia (AML) who complete 2 cycles of intensive chemotherapy treatment.
	Exclusions	 Patients who have not achieved complete remission.
Target:	90%	
		ithin this target accounts for situations where nay result in assay failure.

Please note: It is acknowledged there may be challenges in implementing this QPI due to the small numbers involved. The feasibility of reporting reliable data for NPM1 MRD Assessment across all NHS Boards has not yet been tested in practice and data will be reviewed after the initial reporting period to determine if meaningful results can be achieved.

^b NPM1 MRD Assessment should be undertaken after 2 cycles of intensive chemotherapy treatment and before cycle 3 commences.

Analysis will also be undertaken on the remission status of patients following treatment with intensive / non intensive chemotherapy treatment.

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 Public Health Scotland (PHS). 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 PHS 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 Improvement Board and Scottish Cancer Strategic Board. 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.
- Testing for disease genetics at relapse.
- Nucleic acid testing in patients for non-curative treatment.
- Psychological wellbeing following treatment for acute leukaemia.
- Screening for appropriate MRD markers.

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 3 and 4 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 Strategic Board
 - 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 (PHS)
 - 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 Strategic Board 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 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)	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)
Age Range: All (adults, children and infants) Date: 2005 to present day Language: English only Document Type: Clinical guidelines	. 3 ,

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 ²⁶. 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.

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	WoSCAN / NHS Greater
	Nurse Specialist	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
Ratiliyii Love	Findiple Clinical Scientist	Glasgow and Clyde
Avril Morris	Principle Clinical Scientist	WoSCAN / NHS Greater
Aviii Moilis		Glasgow and Clyde
Brian Murray (from	Principle Information	ISD
September 2013)	Development Manager	
Gepterriser 2013)	Development Manager	

Name	Designation	Cancer Network/Base
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 2: Acute Leukaemia QPI Formal Reviews

Formal review of the Acute Leukaemia QPIs were undertaken for the first time in April 2018. A Formal Review Group was convened, chaired by Mr Khaver Qureshi, Consultant Urological Surgeon, NHS Greater Glasgow and Clyde. Membership of this group is outlined below.

Acute Leukaemia QPI Formal Review Group Membership (2018)

Name	Designation	Cancer Network/Base
Khaver Qureshi (Chair)	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

2nd Cycle Formal Review

The 2nd cycle of formal review commenced in May 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 Megan Mowbray, Consultant Dermatologist, SCAN appointed as Clinical Advisor/Chair to the group. Membership of this group is outlined below.

Acute Leukaemia QPI Formal Review Group Membership (2021)

Name	Designation	Cancer Network/Base
Megan Mowbray (Chair)	Consultant Dermatologist	SCAN
Bobby Alikhani	Regional Manager (Cancer)	SCAN
Jen Doherty	Project Co-ordinator	National Cancer Quality Programme

Name	Designation	Cancer Network/Base
Alastair Lawrie	Clinical Lead	NCA
Grant McQuaker	Clinical Lead	WoSCAN
Huw Roddie	Clinical Lead	SCAN
Lorraine Stirling	Project Officer	National Cancer Quality Programme
Christine Urquhart	Information Analyst	WoSCAN
Heather Wotherspoon	MCN Manager	WoSCAN

Formal review of the Acute Leukaemia QPIs have been undertaken in consultation with various other clinical specialties.

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

3rd Cycle Formal Review

The 3rd cycle of formal review commenced in March 2024. Dr Megan Mowbray, Consultant Dermatologist, SCAN appointed as Clinical Advisor/Chair to the group. Membership of this group is outlined below:

Acute Leukaemia QPI Formal Review Group Membership (2024)

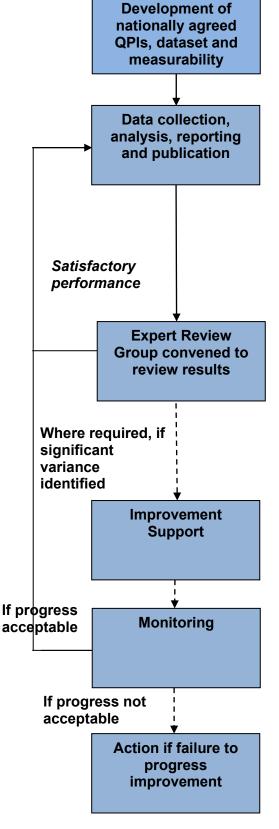
Name	Designation	Cancer Network/Base
Megan Mowbray (Chair)	Consultant Dermatologist	SCAN
Victoria Campbell	Clinical Lead	SCAN
Jen Doherty	Project Co-ordinator	National Cancer Quality Programme
Caroline Duncan	Consultant Haematologist	NCA
Katrina Farrell	Clinical Lead	WoSCAN
Claire McKeeve	Prinicipal Clinical Scientist	WoSCAN
Sudhir Tauro	Clinical Lead	NCA
Lorraine Stirling	Project Officer	National Cancer Quality Programme
Christine Urquhart	Information Analyst	WoSCAN
Heather Wotherspoon	MCN & Improvement Manager	WoSCAN

Formal review of the Acute Leukaemia QPIs has been undertaken in consultation with various other clinical specialties e.g. pathology.

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

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

This process is underpinned by the annual regional reporting and governance framework (see appendix 4).



6. National QPI Development Stage

 QPIs developed by QPI development groups, which include representation from Regional Cancer Networks, Healthcare Improvement Scotland, PHS, 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 4.
- Submit yearly reports to PHS for collation and publication every 3 years.
- National comparative report approved by NHS Boards and RCAGs.
- PHS 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 Strategic Board.

4. Improvement Support Stage:

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

5. Monitoring Stage:

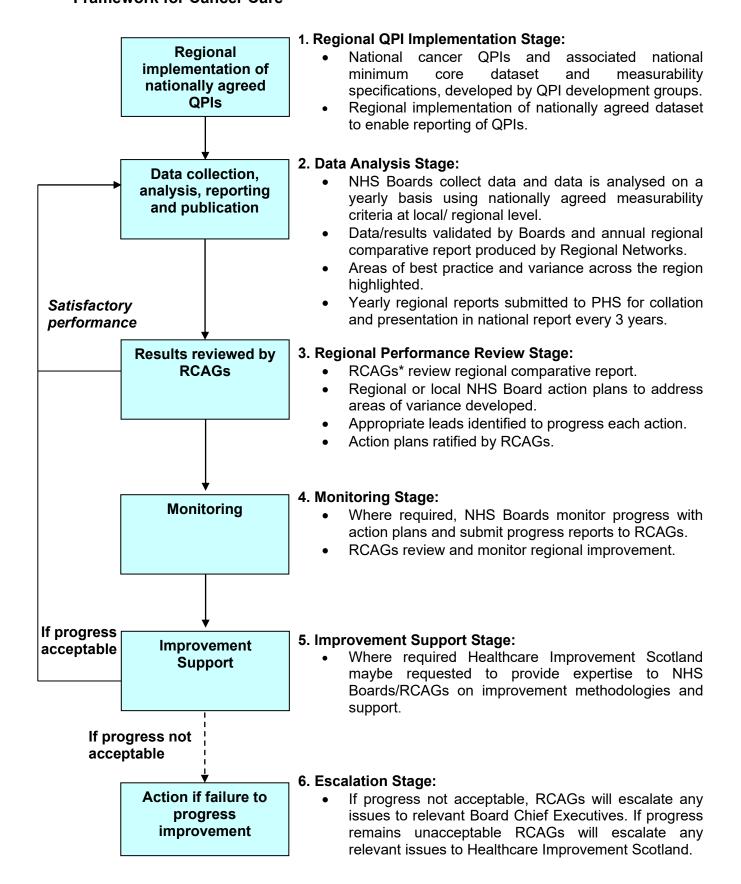
- RCAGs work with Boards to progress outstanding actions, monitor improvement plans and submit progress report to Healthcare Improvement Scotland.
- Healthcare Improvement Scotland report to Scottish Cancer Strategic Board as to whether progress is acceptable.

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 Strategic Board 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 4: Regional Annual Governance Process and Improvement Framework for Cancer Care



^{*}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 5: 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 of stem cells collected from bone marrow or
transplantation	peripheral blood can be from the patient themselves (autologous transplant) or another donor (allogneic
	(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,
Induction therapy	frequently used in laboratory tests for diagnostic purposes. The first stage of cancer treatment.
Intensive chemotherapy	High dose treatment to kill the cancer cells, but also
	destroys the bone marrow.
International Classification	The International Classification of Diseases is the standard
of Diseases (ICD) 10	diagnostic tool for epidemiology, health management and
	clinical purposes. It is used to monitor the incidence and
Multidiacialinamataana	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
meeting (MD1)	disease area, where diagnosis, management and
	appropriate treatment of patients is discussed and agreed.
Next Generation	Next Generation Sequencing (NGS) is a technique used to
Sequencing (NGS)	detect variants and mutations in a cancer. This increases
	the precision of disease classification, prognosis and
	treatment stratification which can then be used to help patients receive personalised treatment.
Palliative chemotherapy	Treatment where the impact of intervention is insufficient to
regimen	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
Progression	future outcomes. The process of capper spreading or becoming more severe
Remission deaths	The process of cancer spreading or becoming more severe. When a patient dies whilst there is no evidence of active
Remission deaths	disease, i.e. or no evidence of disease in the blood cells
	and/or bone marrow.
Systematic Anti Cancer	Treatment of cancer using drugs which prevent the
Therapy (SACT)	replication or growth of cancer cells. This encompasses
Tienes Temines	biological therapies and cytotoxic chemotherapy.
Tissue Typing	A series of diagnostic tests 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	World Health Statistics 2008 presents the most recent health
(WHO) 2008	statistics for WHO's 193 Member States.