

NOSCAN

North of Scotland
Cancer Network



**NORTH OF SCOTLAND
PLANNING GROUP**

Haematology Managed Clinical Network

Audit Report

Acute Leukaemia Quality Performance Indicators

Patients diagnosed July 2015 – June 2016

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The North of Scotland Cancer Network (or NOSCAN), is one of the 3 regional Scottish Cancer Networks, which report to their respective regional NHS Board Planning Groups and for specific workstreams, to the Scottish Cancer Taskforce Group.

The principle role of NOSCAN is to support the organization, planning and delivery of regional and national cancer services, and thereby to ensure consistent and high quality cancer care is being provided equitably across the North of Scotland.

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EXECUTIVE SUMMARY

This publication reports the performance of acute leukaemia services in the six NHS Boards in the North of Scotland (NoS) against the Acute Leukaemia Quality Performance Indicators (QPIs) for patients diagnosed between July 2015 and June 2016. This is the second year in which QPIs results for acute leukaemia have been collected and results are compared with those from 2014-2015.

In the North of Scotland during the 2015-2016 period audited:

- 79 patients diagnosed with acute leukaemia were audited.
- Overall case ascertainment was high at 130%; this indicates excellent capture of patients through cancer audit.
- The results reported were considered to be representative of acute leukaemia services in the region.

Summary of QPI Results for patients aged 16 and over

QPI	QPI Target	NOS
QPI 1: Complete Diagnostic Panel - Proportion of patients with acute leukaemia undergoing treatment with curative intent who have complete diagnostic panel undertaken.	90%	97% n=35
QPI 2: Diagnostic Classification - Proportion of patients with acute leukaemia who have World Health Organisation (WHO) classification assigned and recorded (either by multi-disciplinary team (MDT) or reporting haematologist/haematopathologist).	100%	100% n=53
QPI 3: MDT Discussion - Proportion of patients with acute leukaemia who are discussed at MDT meeting within 6 weeks of diagnosis.	95%	90% n=72
QPI 4: Minimal Residual Disease Marker - Proportion of patients with ALL, <25 years of age, undergoing treatment with curative intent who are assessed for the presence of MRD marker.	90%	-
QPI 5: Early Deaths - Proportion of patients with acute leukaemia being treated with curative intent who die within 30/35 days of treatment.		
Specification (i) Patients with Acute Myeloid Leukaemia (AML) treated with curative intent who die within 30 days of treatment.		
Patients aged between 16 and 60 years	< 8%	6% n=16
Patients over 60 years of age	< 18%	0% n=16
Specification (ii) Patients with Acute Lymphoblastic Leukaemia (ALL) treated with curative intent who die within 35 days of treatment.		
Patients aged between 16 and 60 years	< 8%	-
Patients over 60 years of age	< 20%	-

QPI 6: Access to ATRA for Patients with Acute Promyelocytic Leukaemia - Proportion of patients with APL who receive ATRA within 1 day of diagnosis.	95%	83% n=6
QPI 7: Deaths in Remission - Proportion of patients with acute leukaemia undergoing treatment with curative intent who die in first complete remission (CR), within 1 year of diagnosis.	< 10%	4% n=23
QPI 8: Clinical Trials with Curative Intent - Proportion of patients with acute leukaemia being treated with curative intent who are enrolled in a clinical trial.	60%	50% n=16
QPI 9: Tissue Typing for Transplant - 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.	90%	77% n=26
QPI 10: Intensive Chemotherapy in Older Adults - Proportion of patients with acute leukaemia over 60 years of age with performance status (PS) 0-1 who receive intensive chemotherapy.		
(i) Patients with acute leukaemia 60 years of age and over who receive intensive chemotherapy.	20%	38% n=29
(ii) Patients with acute leukaemia 60 years of age and over receiving intensive chemotherapy who are treated within a clinical trial.	80%	60% n=15
QPI 11: Clinical Trials with Non Curative Intent - Proportion of patients with acute leukaemia being treated with non curative intent who are enrolled in a clinical trial.	10%	17% n=29
QPI 12: Palliative Treatment Proportion of patients with AML who are suitable only for treatment with non-curative intent who receive an appropriate palliative chemotherapy regimen.	70%	52% n=21
Clinical Trials Access - Proportion of patients with acute leukaemia who are enrolled in an interventional clinical trial or translational research.		
Interventional clinical trials	7.5%	52% n=61
Translational research	15%	0% n=61

Performance shaded pink where QPI target has not been met.

^b Excluding results for QPIs based on less than 5 patients.

Within NOSCAN 5 out of 12 QPIs were achieved during this audit cycle, the same as in 2014-15. Performance against the Acute Leukaemia QPIs was considered to be good in the North of Scotland for patients diagnosed in 2015-16, although a number of areas where further work is required were highlighted, specifically work around the functioning and recording of information at MDT meetings in NHS Highland (QPI 3), ensuring adequate access to clinical trials in NHS Tayside (QPI 8). In addition clinicians should be mindful of the need to for tissue typing for all relevant (QPI 9). Specific actions to address the issues highlighted above have already been identified and work by NHS Boards on these is

ongoing. In addition to these, the following specific actions have been identified to improve on the quality of clinical services particular to the care and management of patients with acute leukaemia diagnosis in the North of Scotland include:

- **All NHS Boards to check that all patients meeting the denominator for QPI 4 are appropriately audited and reported.**
- **All NHS boards to continue to support appropriate clinical trials when available and continue to ensure no delay in the opening of new clinical trials.**

A number of other areas have also been identified where further work might be required with national partners to ensure that the Acute Leukaemia QPIs are as clinically relevant as possible in the future, and able to better evaluate patient and service outcomes. As such this report also suggests a number of suggested amendments to the QPIs for consideration at the Formal Review of Acute Leukaemia QPIs, which will take place in early 2018.

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1. Introduction

In 2010, the [Scottish Cancer Taskforce](#) established the [National Cancer Quality Steering Group](#) (NCQSG) to take forward the development of national [Quality Performance Indicators](#) (QPIs) for all cancer types to enable national comparative reporting and drive continuous improvement for patients. In collaboration with the three Regional Cancer Networks ([NOSCAN](#), [SCAN](#) & [WoSCAN](#)) and [Information Services Division](#) (ISD), the first QPIs were published by [Healthcare Improvement Scotland](#) (HIS) in January 2012. [CEL 06 \(2012\)](#) mandates all NHS Boards in Scotland to report on specified QPIs on an annual basis. Data definitions and measurability criteria to accompany the Acute Leukaemia QPIs are available from the ISD website¹.

The need for regular reporting of activity and performance (to assure the quality of care delivered) was first nationally set out as a fundamental requirement of a Managed Clinical Network (MCN) in [NHS MEL\(1999\)10](#)². This has since been further restated and reinforced in [HDL\(2002\)69](#)³, [HDL \(2007\) 21](#)⁴, and most recently in [CEL 29 \(2012\)](#)⁵.

This report assesses the performance of specialist cancer services for patients diagnosed with Acute Leukaemia in the North of Scotland Cancer Network during the twelve months from 1st July 2015 to 30th June 2016. Results are measured against the Acute Leukaemia Quality Performance Indicators (QPIs)⁶ which were implemented for patients diagnosed on or after 1st July 2014. Regular reporting of activity and performance is a fundamental requirement of a Managed Clinical Network (MCN) to assure the quality of care delivered across the region.

This report presents performance against 12 Acute Leukaemia QPIs using clinical audit data. The generic Clinical Trials QPI is also reported for lymphoma patients.

2. Background

Six NHS Boards across the North of Scotland serve the 1.40 million population⁷. There were 79 patients diagnosed with acute leukaemia in the North of Scotland between 1st July 2015 and 30th June 2016. The configuration of the Multidisciplinary Teams (MDTs) in the North of Scotland for the management of haematological cancer, which includes acute leukaemia, is set out below.

MDT	Constituent Hospitals
Grampian	Aberdeen Royal Infirmary, Balfour Hospital, Kirkwall, Gilbert Bain Hospital, Lerwick
Highland	Raigmore Hospital, Inverness
Tayside	Ninewells Hospital, Dundee, Perth Royal Infirmary

2.1 National Context

With 600 new cases diagnosed in Scotland during 2014; leukaemia was the 15th most common cancer, with incidence declining by 31% in the last 10 years⁸.

Relative survival from all leukaemias in Scotland is similar to the average for all cancer types and has increased considerably since 1987-1991⁹. The table below details the percentage change in 1 and 5 year relative survival for patients diagnosed 1987-1991 to 2007-2011.

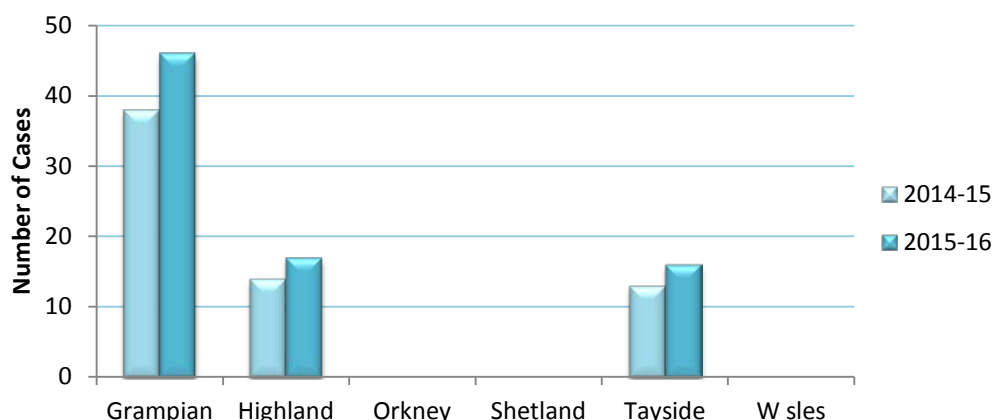
Relative age-standardised survival for leukaemia in Scotland at 1 year and 5 years showing percentage change from 1987-1991 to 2007-2011⁹.

Relative survival at 1 year (%)		Relative survival at 5 years (%)	
2007-2011	% change	2007-2011	% change
73.3%	+ 17.3%	53.6%	+ 17.2%

2.2 North of Scotland Context

Between 1st July 2015 and 30th June 2016, a total of 79 cases of acute leukaemia were diagnosed in the North of Scotland and recorded through audit. The number of patients diagnosed within each Board is presented below.

	Grampian	Highland	Orkney	Shetland	Tayside	W Isles	NoS
Number of Patients	46	17	0	0	16	0	79
% of NoS total	58.2%	21.5%	0.0%	0.0%	20.3%	0.0%	100.0%



Number of patients diagnosed with acute leukaemia by Board of diagnosis, 2014-15 and 2015-16.

3. Methodology

The clinical audit data presented in this report was collected in accordance with an agreed dataset and definitions¹. The data was entered into the electronic Cancer Audit Support Environment (eCASE): a secure centralised web-based database.

Data for patients diagnosed between 1st July 2015 and 30th June 2016 were locally collated by cancer audit staff within individual NHS Boards. These data and any comments on QPI results were then signed-off at NHS Board level to ensure that the data was an accurate representation of service in each area prior to submission to NOSCAN for collation at a regional level. The reporting timetable was developed to take into account the patient pathway (i.e. time taken from first cancer diagnosis until the point at which all information required to measure the QPIs is available) and thereby ensure that a complete treatment record was available for the vast majority of cases.

Where the number of cases meeting the denominator criteria for any indicator is between one and four, the results have not been shown in any associated charts or tables. This is to avoid any unwarranted variation associated with small numbers and to minimise the risk of disclosure. Any charts or tables impacted by this are denoted with an asterisk (*). However,

any commentary provided by NHS Boards relating to the impacted indicators will be included as a record of continuous improvement.

4. Results

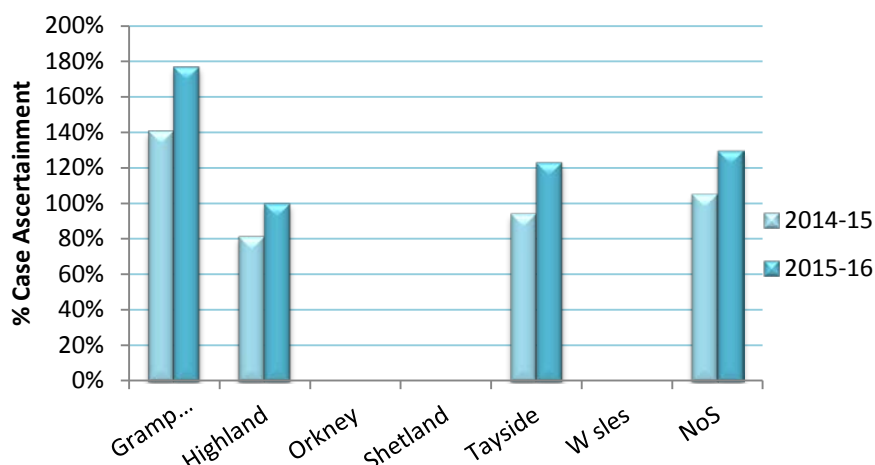
4.1 Case Ascertainment

Audit data completeness can be assessed from case ascertainment, which is the proportion of expected patients that have been identified through audit within the time period measured. Case ascertainment is calculated by comparing the number of new cases identified by the cancer audit with a five year average of the total numbers having a similar diagnosis, as recorded by the National Cancer Registry (provided by Information Services Division (ISD)).

Cancer Registry figures were extracted from the ISD published figures. Due to timescale of data collection and verification processes, National Cancer Registry data are not available for 2015. Consequently an average of the previous five years' figures (i.e. 2010 to 2014) has been used to take account of annual fluctuations in incidence within NHS Boards. It should be noted that case ascertainment figures are provided for guidance only: as it is not possible to compare the same cohort of patients, these are not an exact measurement of audit completeness.

Overall case ascertainment for the period reported in the North of Scotland was high at 129.5%, indicating high levels of capture of patients in the cancer audit.

Case ascertainment for each Board across the North of Scotland is illustrated below.



Case ascertainment by NHS Board for patients diagnosed with acute leukaemia in 2014-15 and 2015-16.

	Grampian	Highland	Orkney	Shetland	Tayside	W Isles	NoS
Cases from audit 2015-16	46	17	0	0	16	0	79
ISD Cases (2010-2014)ⁱ	26	17	2	1	13	2	61
% Case ascertainment 2015-16	176.9%	100.0%	0.0%	0.0%	123.1%	0.0%	129.5%
% Case ascertainment 2014-15	140.7%	81.4%	0%	0%	94.2%	0%	105.2%

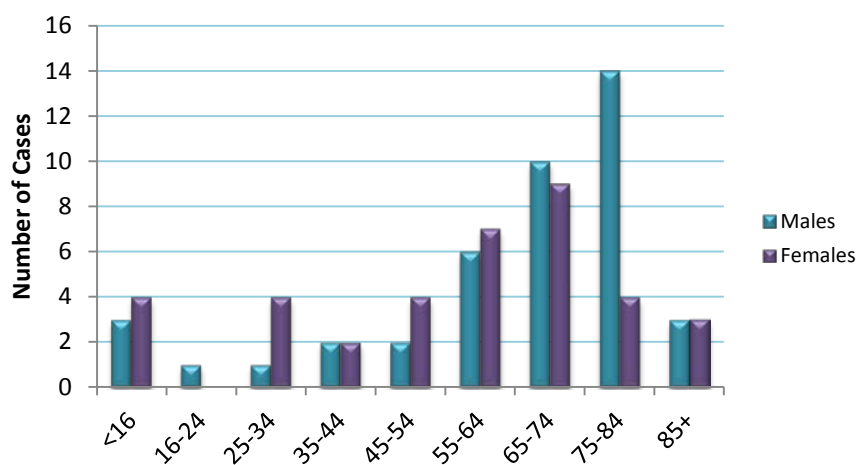
ⁱ Data by NHS Board of residence.

The capture of patients diagnosed with acute leukaemia by cancer audit was high and therefore QPI calculations based on data captured are considered to be representative of all patients diagnosed with acute leukaemia during the audit period.

For patients included within the audit, data collection was near complete with the exception of information on performance status, which was missing for a small number of patients in NHS Highland and NHS Tayside, affecting results for QPI 10(i).

4.2 Age and Gender Distribution

The figure below shows the age and gender distribution of patients diagnosed with acute leukaemia in the North of Scotland in 2015-2016 with incidence peaking in the 65-74 age group in women and in the 75-84 age group in men.



Age distribution of patients diagnosed with acute leukaemia in NOSCAN 2015-16.

4.3 Performance against Quality Performance Indicators (QPIs)

Results of the analysis of the Acute Leukaemia Quality Performance Indicators are set out in the following sections. Where appropriate, numbers have also been included to provide context.

Due to the small numbers of patients diagnosed with Acute Leukaemia annually, it was agreed by the QPI development group that annual results for the Acute Leukaemia QPIs would be presented at a regional level rather than for individual NHS Boards. However, three yearly cumulative national reports will include information presented by NHS Board.

QPI results presented include only patients aged 16 years and over. It has been agreed at a national level that analysis of patients under the age of 16 years will not be included in published QPI reports, due to the very small numbers of patients involved. However, these data have been analysed and results supplied to clinical staff for consideration when identifying areas for improvement in the service.

Where performance is shown to fall below the target, commentary is often included to provide context to the variation. Specific actions have been identified to address issues highlighted through the data analysis where appropriate.

QPI 1: Complete Diagnostic Panel

QPI 1: Complete Diagnostic Panel: Patients with acute leukaemia should have complete diagnostic panel undertaken to inform appropriate management.

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, flowcytometric, 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.

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%

QPI 1 Performance against target

Of the 35 patients diagnosed with acute leukaemia in North of Scotland in 2015-16 and undergoing treatment with curative intent, 34 had complete diagnostic panel undertaken. This equates to a rate of 97.1%, which exceeds the target rate of 90% set and is an increase compared to the 2014-15 figure of 92.6%.

	Performance (%)	Numerator	Denominator	Not recorded - Numerator	% not recorded - Numerator	Not recorded - Exclusions	% not recorded - Exclusions	Not recorded - Denominator	Change since 2014-15
NoS	97.1%	34	35	0	0%	0	0%	0	+4.5%

Actions Required:

No action required.

QPI 2: Diagnostic Classification

QPI 2: Diagnostic Classification: Patients with acute leukaemia should have a World Health Organisation classification recorded to facilitate appropriate management.

Management of patients with acute leukaemia is determined in part by diagnostic classification therefore it is essential that this is assigned and recorded to ensure most appropriate management, inform treatment decision making and determine clinical trial availability.

Numerator: Number of patients with acute leukaemia who have a WHO classification assigned and recorded (either by MDT or reporting haematologist/haematopathologist).

Denominator: All patients with acute leukaemia.

Exclusions: Patients receiving supportive care / palliation only.

Target: 100%

QPI 2 Performance against target

Across the North of Scotland, all of the 53 patients diagnosed with acute leukaemia in 2015-16 (100%) had a WHO classification assigned and recorded, meeting the target rate of 100% and matching the 2014-15 performance.

	Performance (%)	Numerator	Denominator	Not recorded - Numerator	% not recorded - Numerator	Not recorded - Exclusions	% not recorded - Exclusions	Not recorded - Denominator	Change since 2014-15
NoS	100%	53	53	0	0%	0	0%	0	0%

Actions Required:

No action required.

QPI 3: MDT Discussion

QPI3: MDT Discussion: Patients with acute leukaemia should be discussed by a multidisciplinary team (MDT) at diagnosis.

Evidence suggests that patients with cancer managed by a multidisciplinary team have a better outcome. There is also evidence that the multidisciplinary management of patients increases their overall satisfaction with their care.

Numerator: Number of patients with acute leukaemia discussed at the MDT within 6 weeks of diagnosis.

Denominator: All patients with acute leukaemia.

Exclusions: No Exclusions

Target: 95%

QPI 3 Performance against target

In the North of Scotland, 90.3% of patients diagnosed with acute leukaemia in 2015-16 were discussed at MDT within 6 weeks of diagnosis; this means that at a regional level, the target of 95% was not met although results are an increase compared with the 2014-15 figure of 78.3%.

	Performance (%)	Numerator	Denominator	Not recorded - Numerator	% not recorded - Numerator	Not recorded - Exclusions	% not recorded - Exclusions	Not recorded - Denominator	Change since 2014-15
NoS	90.3%	65	72	0	0%	0	0%	0	+12.0%

Results for this indicator improved between 2014-15 and 2015-16, especially in NHS Highland, however performance is still suboptimal. Changes to MDT procedure implemented following the 2014-15 results will not be fully reflected in the 2015-16 data and therefore no new actions have been identified at this time, however the results for this QPI should continue to be monitored carefully in future years.

Actions Required:

- **MCN to suggest to Formal Review of Acute Leukaemia QPIs that the definition of QPI 3 is amended to exclude patients that died within 24/48 hours of presentation.**

QPI 4: Minimal Residual Disease Marker

QPI 4: Minimal Residual Disease Marker: Patients with Acute Lymphoblastic Leukaemia (ALL) under the age of 25 receiving curative treatment should be assessed for the presence of Minimal Residual Disease (MRD) marker.

Treatment stratification based upon MRD analyses at particular time points has become standard of care in the treatment of patients within paediatric and young adult protocols (currently not clinically indicated in patients over 25 years of age).

Identification of an MRD marker must be done at diagnosis, to allow later measurement of disease levels. In this way more intensive treatments can be directed at patients who continue to harbour significant levels of leukaemic cells, while treatment intensity may be reduced for patients in whom no disease is detected.

Numerator: Number of patients with ALL, <25 years of age, undergoing treatment with curative intent who are assessed for the presence of MRD marker.

Denominator: All patients with ALL, <25 years of age, undergoing treatment with curative intent.

Exclusions: No exclusions.

Target: 90%

QPI 4 Performance against target

There were no patients with ALL between 16 and 25 years of age undergoing treatment with curative intent in the North of Scotland in 2015-16 and therefore no result to report for this QPI.

There is concern that some patients should have been reported in this QPI but may not have been adequately captured by data audit.

Actions Required:

- **All NHS Boards to check that all patients meeting the denominator for QPI 4 are appropriately audited and reported.**

QPI 5: Early Deaths

QPI 5: Early Deaths: Mortality rate following diagnosis of acute leukaemia.

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.

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 aged between 16 and 60 years < 8%
Patients over 60 years of age < 18%

QPI 5 (i) Performance against target

Of the 16 patients between the ages of 16 and 60 years diagnosed with AML in the North of Scotland in 2015-16 and treated with curative intent, one (6.3%) died within 30 days of treatment. These figures show that the QPI target of less than 8% was met in the North of Scotland and results are lower than the 2014-15 figure of 9.1%. However it should be noted that:

- Figures are based on very small numbers *and*
- results for both years were the result of the death of a single patient

On that basis, it is not appropriate to draw conclusions on trends in performance over time.

None of the 16 patients over 60 years of age meeting this QPI (0%) died within 30 days of treatment, meeting the target of less than 18% for this age-group. This result was the same as that in 2014-15.

	Performance (%)	Numerator	Denominator	Not recorded - Numerator	% not recorded - Numerator	Not recorded - Exclusions	% not recorded - Exclusions	Not recorded - Denominator	Change since 2014-15
16-60 years	6.3%	1	16	0	0%	0	0%	0	-2.8%
Over 60 years	0%	0	16	0	0%	0	0%	0	0%

QPI 5: Early Deaths: Mortality rate following diagnosis of acute leukaemia.

Specification (ii)

Numerator: Number of patients with ALL being treated with curative intent who die within 35 days treatment.

Denominator: All patients with ALL being treated with curative intent.

Exclusions: No exclusions.

Target: Patients aged between 16 and 60 years < 8%
Patients over 60 years of age < 20%

QPI 5 (ii) Performance against target

Numbers of patients between the age of 16 and 60 years diagnosed with ALL in the North of Scotland in 2015-16 and treated with curative intent were very small (less than 5), none (0%) died within 35 days of treatment. These figures show that the target of less than 8% was met in the North of Scotland with the result mirroring that in 2014-15.

Numbers of patients over 60 years of age that was diagnosed with ALL during 2015-16 that was treated with curative intent were also very small, however none (0%) died within 35 days of treatment, indicating that the target has been met. There were no results for this QPI in 2014-15.

Data are not provided in tabular form due to the very small numbers of patients on which these QPI results.

Actions Required:

- **MCN to suggest to Formal Review of Acute Leukaemia QPIs that that the definition of QPI 5(i) is amended to include all patients with AML rather than only those treated with curative intent.**

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

QPI 6: Access to ATRA for Patients with Acute Promyelocytic Leukaemia: Patients with suspected Acute Promyelocytic Leukaemia (APL) should undergo treatment with All Trans-Retinoic Acid (ATRA) within 1 day of diagnosis.

Treatment with ATRA should be started immediately after a diagnosis of APL is suspected. In doubtful cases, ATRA should be commenced until a definitive result is available.

Numerator: Number of patients with APL who receive ATRA within 1 day of diagnosis.

Denominator: All patients with APL.

Exclusions: No exclusions.

Target: 95%

QPI 6 Performance against target

In 2015-16, six patients were diagnosed acute promyelocytic leukaemia in the North of Scotland. Five of these (83.3%) received ATRA within one day of diagnosis, missing the target rate of 95%. Although figures were lower in 2015-16 than in 2014-15 (100%), results are based on small numbers and the failure to meet the target was due to the results for a single patient, who was not fit enough to receive ATRA within 1 day of diagnosis.

	Performance (%)	Numerator	Denominator	Not recorded - Numerator	% not recorded - Numerator	Not recorded - Exclusions	% not recorded - Exclusions	Not recorded - Denominator	Change since 2014-15
NoS	83.3%	5	6	0	0%	0	0%	0	-16.7%

Actions Required:

No actions identified.

QPI 7: Deaths in Remission

QPI 7: Deaths in Remission: Remission deaths for patients with acute leukaemia receiving treatment with curative intent.

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.

Numerator: Number of patients with acute leukaemia undergoing treatment with curative intent who achieve first complete remission (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: < 10%

NOTE: to ensure that one year has elapsed since diagnosis before reporting, this particular QPI is reported one year in arrears.

QPI 7 Performance against target

In 2014-15, 23 patients diagnosed with acute leukaemia and undergoing treatment with curative intent achieved first complete remission (CR). Of these one patient (4.3%) died within 1 year of diagnosis whilst in CR, meeting the target rate of less than 10%. This being the first year for this data being reported, there are no previous data with which to compare results.

	Performance (%)	Numerator	Denominator	Not recorded - Numerator	% not recorded - Numerator	Not recorded - Exclusions	% not recorded - Exclusions	Not recorded - Denominator	Change since 2014-15
NoS	4.3%	1	23	0	0%	0	0%	0	-

Actions Required:

No actions identified

QPI 8: Clinical Trials with Curative Intent

QPI 8: Clinical Trials with Curative Intent: Patients with acute leukaemia under 60 years of age who are suitable for treatment with curative intent should be considered for participation in available clinical trials, wherever eligible.

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.

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.

Target: 60%

QPI 8 Performance against target

In 2015-16, 16 patients below the age of 60 and diagnosed with acute leukaemia were treated with curative intent in the North of Scotland. Of these eight (50.0%) were enrolled in a clinical trial which is a slight increase from the 2014-15 figure of 46.7%, but is still below the target of 60% set for this QPI.

	Performance (%)	Numerator	Denominator	Not recorded - Numerator	% not recorded - Numerator	Not recorded - Exclusions	% not recorded - Exclusions	Not recorded - Denominator	Change since 2014-15
NoS	50.0%	8	16	0	0%	0	0%	0	+3.3%

Performance against this QPI is dependent on the availability of suitable trials. Clinical trials are now available for all AML patients and should result in improved performance in the next reporting cycle. It is noted that it is not appropriate for patients to be recruited into clinical trials in another NHS Board for AML due to the duration of treatment for this disease.

Actions Required:

- **All NHS boards to continue to support appropriate clinical trials when available and continue to ensure no delay in the opening of new clinical trials.**

QPI 9: Tissue Typing for Transplant

QPI 9: Tissue Typing for Transplant: Patients with acute leukaemia treated with curative intent should have a specimen sent to the lab for tissue typing at diagnosis.

Human Leukocyte Antigen (HLA) typing should be performed in all patients with newly diagnosed acute leukaemia for whom allogeneic Haematopoietic Stem Cell Transplantation would be considered.

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.

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%

QPI 9 Performance against target

In 2015-16 in the North of Scotland, 76.9% of patients between the ages of 16 and 65 years diagnosed with acute leukaemia and being treated with curative intent had a specimen sent to the lab for tissue typing at diagnosis. This falls short of the target of 90% but is an increase from the 2014-15 figure of 70%.

	Performance (%)	Numerator	Denominator	Not recorded - Numerator	% not recorded - Numerator	Not recorded - Exclusions	% not recorded - Exclusions	Not recorded - Denominator	Change since 2014-15
NoS	76.9%	20	26	0	0%	0	0%	0	+6.9%

All clinicians should continue to be mindful of the need to tissue type patients as soon as possible where appropriate, as outlined in the NOSCAN Clinical Management Guidelines for AML and ALL.

Actions Required:

No Actions identified.

QPI 10: Intensive Chemotherapy in Older Adults

QPI 10 (i): Intensive Chemotherapy in Older Adults: 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.

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.

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. Patients with acute leukaemia should be treated on a clinical trial wherever possible.

Specification (i) Patients with acute leukaemia 60 years of age and over who receive intensive chemotherapy

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: 20%

QPI 10 (i) Performance against target

In 2015-16 in the North of Scotland, 37.9% of patients included within the denominator for this QPI received intensive chemotherapy. This meets the target of 20%, although is less than the 2014-15 figure of 50%. It should be noted that Performance Status was not recorded for 9 patients; these patients were therefore not included in the calculations for this indicator.

	Performance (%)	Numerator	Denominator	Not recorded - Numerator	% not recorded - Numerator	Not recorded - Exclusions	% not recorded - Exclusions	Not recorded - Denominator	Change since 2014-15
NoS	37.9%	11	29	0	0%	0	0%	9	-12.1%

QPI 10 (ii): Intensive Chemotherapy in Older Adults: 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.

Specification (ii) Patients with acute leukaemia 60 years of age and receiving intensive chemotherapy who are treated within a clinical trial.

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: 80%

QPI 10 (ii) Performance against target

In 2015-16 in the North of Scotland, 60.0% of patients over the age 60 that were diagnosed with acute leukaemia and who received intensive chemotherapy were treated within a clinical trial. This falls short of the target of 80% and is lower than the 2014-15 figure of 77.8%.

	Performance (%)	Numerator	Denominator	Not recorded - Numerator	% not recorded - Numerator	Not recorded - Exclusions	% not recorded - Exclusions	Not recorded - Denominator	Change since 2014-15
NoS	60.0%	9	15	0	0%	0	0%	0	-17.8%

There are no concerns about the NOSCAN performance against this QPI and it was noted that the target for Specification (ii) is particularly challenging given the cohort of patients (those aged 60 years and over).

Actions Required:

- MCN to suggest to Formal Review of Acute Leukaemia QPIs that the target for QPI 10(ii) should be reviewed as it is considered to be too high.

QPI 11: Clinical Trials with Non Curative Intent

QPI 11: Clinical Trials with Non Curative Intent: 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.

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.

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%

QPI 11 Performance against target

Of the 29 patients diagnosed with acute leukaemia in North of Scotland in 2015-16 who were treated with non-curative intent, 5 were enrolled into a clinical trial. This equates to a rate of 17.2%, which is above the target rate of 10% and an increase from the 2014-15 result of 11.1%.

	Performance (%)	Numerator	Denominator	Not recorded - Numerator	% not recorded - Numerator	Not recorded - Exclusions	% not recorded - Exclusions	Not recorded - Denominator	Change since 2014-15
NoS	17.2%	5	29	0	0%	0	0%	0	+6.0%

Actions Required:

No actions required.

QPI 12: Palliative Treatment

QPI2: Palliative Treatment: Patients with acute myeloid leukaemia (AML) who are suitable only for treatment with non-curative intent should receive treatment with an appropriate palliative chemotherapy regimen.

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. 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 or azacytidine, according to Scottish Medicines Consortium (SMC) recommendations.

Numerator: Number of patients with acute myeloid leukaemia who are suitable only for treatment with non-curative intent who receive palliative chemotherapy with either low dose cytarabine or azacytidine.

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%

QPI 12 Performance against target

Across the North of Scotland, 21 patients diagnosed with acute myeloid leukaemia were suitable for treatment with non-curative intent only. Of these, 52.4% received palliative chemotherapy with either low dose cytarabine or azacytidine, therefore the target rate of 70% was not met although results are higher than those from 2014-15 where 44.4% of patients met this target.

	Performance (%)	Numerator	Denominator	Not recorded - Numerator	% not recorded - Numerator	Not recorded - Exclusions	% not recorded - Exclusions	Not recorded - Denominator	Change since 2014-15
NoS	52.4%	11	21	0	0%	0	0%	0	+8.0%

Some patients entered into clinical trials (e.g. the LI-1 trial) may receive different chemotherapy treatment to that required by QPI 12 and therefore not meet the QPI target despite being appropriately treated.

Actions Required:

- **MCN to suggest to Formal Review of Acute Leukaemia QPIs that patients being treated with an alternative regimen as part of a clinical trial are excluded from this QPI or the definition of the numerator is broadened to include other appropriate palliative regimen.**

Clinical Trials Access QPI

The ability of patients to readily access a Clinical Trial is a common issue for all cancer types, and in order to further support recruitment through more active comparison and measurement of Board and network performance across the country, a generic QPI was developed as part of the National Programme of cancer quality improvement. Further details on the development and definition of this QPI can be found [here](#).

The QPI is defined as follows.

Clinical Trials Access QPI	
All patients should be considered for participation in available clinical trials, wherever eligible.	
Numerator:	Number of patients with acute leukaemia enrolled in an interventional clinical trial of translational research.
Denominator:	All patients with acute leukaemia
Exclusions:	No exclusions
Target:	Interventional clinical trials – 7.5% Translational research - 15%

Key points during the period audited:

- 52.5% of patients diagnosed with acute leukaemia in the North of Scotland in 2016 were recruited into interventional clinical trials in one of the three cancer centres in the region; this significantly exceeds the required target of 7.5% and is an increase in figures from 2014 (37.1%) and 2015 (42.6%).
- Recruitment into translational research was lower with no patients (0%) being enrolled in 2015 or 2016 in the North of Scotland: this is clearly below the target of 15%. However, it should be noted that while most of the interventional clinical trials do have a translational element within them, patients entered into these trials are not included within the figures for translational research. Consequently the percentage of patients contributing to such work is significantly underestimated.

	Number of patients recruited 2016	ISD Cases annual average (2010-2014)	% patients recruited 2016	% patients recruited 2015	% patients recruited 2014
Interventional Clinical Trials	32	61	52.5%	42.6%	37.1%
Translational Research	0	61	0%	0%	6.5%

The QPI targets for clinical trials are:

- 7.5% for interventional trials
- 15% for translational trials

It should be noted that these targets are ambitious, particularly with the move towards more targeted trials.

All cancer patients that pass through each of the three cancer centres in NOSCAN are considered for potential participation in the open trials currently available. When appropriate trials are available, most clinicians aim to treat the majority of patients receiving intensive chemotherapy within a clinical trial. However, acute leukaemia is more common in the elderly and in this patient group co-morbidities and performance status can limit trial entry.

During 2016 in NOSCAN, there were 6 interventional trials and no translational trials open and recruiting patients with an acute leukaemia diagnosis, thereby offering patients the opportunity to participate in a range of different acute leukaemia trials. Furthermore, all patients with an acute leukaemia diagnosis passing through the cancer centres in NOSCAN will have been assessed for eligibility for clinical trials. The number of patients screened for clinical trials can often be higher than the number recruited as not all patients will pass the screening stage, however the screening phase can be a involve a considerable amount of time and resource.

Due to the increasing complexity of trials and time burden needed to run them effectively, and a lack of clinical and research support to run such further trials, it is not currently possible to open a greater number (and thereby to have a greater scope) of available trials in the North of Scotland. Constraints imposed by the commercial trial sponsors also limit the number of trials it is possible to open in smaller cancer centres such as those in the NOSCAN region. However a large number of feasibility requests for trials are continually being reviewed by all consultants and if an expression of interest is submitted, the chances that the site will be selected for running the trial are high.

5. Conclusions

The Quality Performance Indicators programme was first introduced in order to launch and thereafter drive forward a programme of continuous service improvement and to ensure the quality and equity of access to care for cancer patients across Scotland.

This is the second time that the results of performance against the Acute Leukaemia QPIs have been reported in the North of Scotland, and results are starting provide a clear picture of overall performance across the region, and a more formal structure around which any improvements will be made.

Case ascertainment was high at 130% and measures of performance against the Acute Leukaemia Cancer QPI's for patients diagnosed between 1st July 2015 and 30th June 2016 were considered to be representative of cancer services specific to the management of acute leukaemia in the North of Scotland.

For 5 of the 12 QPIs measured, the audit report indicated that the required QPI targets were met. Performance against the Acute Leukaemia QPIs was considered to be good in the North of Scotland for patients diagnosed in 2015-16, although a number of areas where further work is required were highlighted, specifically work around the functioning and recording of information at MDT meetings in NHS Highland (QPI 3), ensuring adequate access to clinical trials in NHS Tayside (QPI 8). In addition clinicians should be mindful of the need to for tissue typing for all relevant (QPI 9). Specific actions to address the issues highlighted above have already been identified and work by NHS Boards on these is ongoing. In addition to these, the following actions have been identified to improve on the quality of clinical services particular to the care and management of patients with acute leukaemia diagnosis in the North of Scotland:

- All NHS Boards to check that all patients meeting the denominator for QPI 4 are appropriately audited and reported.
- All NHS boards to continue to support appropriate clinical trials when available and continue to ensure no delay in the opening of new clinical trials.

A number of other areas have also been identified where further work might be required with national partners to ensure that the Acute Leukaemia QPIs are as clinically relevant as possible in the future, and able to better evaluate patient and service outcomes. As such the MCN has an action to suggest the following QPI amendments at the Formal Review of Acute Leukaemia QPIs, which will take place in early 2018.

- MCN to suggest to Formal Review of Acute Leukaemia QPIs that the definition of QPI 3 is amended to exclude patients that died within 24/48 hours of presentation.
- MCN to suggest to Formal Review of Acute Leukaemia QPIs that that the definition of QPI 5(i) is amended to include all patients with AML rather than only those treated with curative intent.
- MCN to suggest to Formal Review of Acute Leukaemia QPIs that the target for QPI 10(ii) should be reviewed as it is considered to be too high.

- MCN to suggest to Formal Review of Acute Leukaemia QPIs that patients being treated with an alternative regimen as part of a clinical trial are excluded from this QPI or the definition of the numerator is broadened to include other appropriate palliative regimen.

The North of Scotland Haematology MCN will actively take forward regional actions identified and NHS Boards are asked to develop local Action / Improvement Plans in response to the findings presented in the report. A blank Action Plan template can be found in the Appendix to this report.

Completed Action Plans should be returned to NOSCANA within two months of publication of this report.

Progress against these plans will be monitored by the North of Scotland Haematology MCN and any service or clinical issue which the Advisory Board considers not to have been adequately addressed will be escalated to the NHS Board Lead Cancer Clinician and Regional Lead Cancer Clinician.

Additionally, progress will be reported to the Regional Cancer Advisory Forum (RCAF) annually by the NOSCANA Acute Leukaemia Clinical Lead as part of the regional audit governance process to enable RCAF to review and monitor regional improvement.

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Appendix 1: List of clinical trials for patients with acute leukaemia into which patients were recruited in 2016.

Trial	Principle Investigator	Trial Type
AML 18	Dominic Culligan (Grampian) Sudhir Tauro (Tayside)	Interventional
AML 19	Dominic Culligan (Grampian) Catherine Ogilvie (Highland) Sudhir Tauro (Tayside)	Interventional
FIGARO	Dominic Culligan (Grampian)	Interventional
LI-1	Dominic Culligan (Grampian)	Interventional
UKALL 2011	Dominic Culligan (Grampian) Gordon Taylor (Grampian) Sudhir Tauro (Tayside)	Interventional
UKALL14	Dominic Culligan (Grampian) Sudhir Tauro (Tayside)	Interventional
UKALL60+ (recruitment suspended)	Catherine Ogilvie (Highland) Sudhir Tauro (Tayside)	Interventional

Appendix 2: NHS Board Action Plans

A blank Action Plan template can be found attached. Completed Action Plans should be returned to NOSCAN within two months of publication of this report.



North of Scotland
Cancer Network

Action Plan: Acute Leukaemia Cancer

Based on QPI results for patients diagnosed 2015-2016

Board:	
Action Plan Lead:	
Date:	

Status key	
1	Action Fully Implemented
2	Action agreed but not yet implemented
3	No action taken (please state reason)

QPI	Action Required	NHS Board Action Taken	Date		Lead	Progress	Status
			Start	End			
	<i>Ensure actions mirror those detailed in Audit Report</i>	<i>Detail specific actions that will be taken by the NHS Board</i>	<i>Insert date</i>	<i>Insert date</i>	<i>Insert name of responsible lead for each action.</i>	<i>Detail actions in progress, changes in practice, problems encountered or reasons why no action has been taken.</i>	<i>Insert no. from key</i>