NOSCAN
North of Scotland Cancer Network

NHS SCOTLAND

NORTH OF SCOTLAND PLANNING GROUP

Haematology Managed Clinical Network

Audit Report

Acute Leukaemia
Quality Performance Indicators

Patients diagnosed July 2014 – June 2015

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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 cancer services in the six NHS Boards in the North of Scotland (NoS) for patients diagnosed with acute leukaemia between July 2014 and June 2015. The quality of Board and regional performance are measured and reported against a set of nationally agreed standards (the Acute Leukaemia Quality Performance Indicators, or 'QPIs') that were clinically identified and thereafter service implemented across Scotland.

2014-2015 is the first year in which Acute Leukaemia QPI data have been collected in Scotland, during which time in the North of Scotland:

- 65 patients diagnosed with acute leukaemia were audited.
- Overall case ascertainment was high at 105%: this indicates good 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, defined as: (i) Morphology; (ii) Immunophenotyping; (iii) Cytogenetics; and (iv) Storage of genetic material for routine diagnostic testing.	90%	93% n=27
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=38
QPI 3: MDT Discussion - Proportion of patients with acute leukaemia who are discussed at MDT meeting within 6 weeks of diagnosis.	95%	78% n=60
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.		
(i) Proportion of patients with AML being treated with curative intent who die within 30 days of treatment.		
Patients aged between 16 and 60 years	< 8%	9% n=11
Patients over 60 years of age	< 18%	0% n=8
(ii) Proportion of patients with ALL being treated with curative intent who die within 35 days treatment.		

Patients aged between 16 and 60 years	< 8%	0% n=6
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 24 hours (1 day) of diagnosis.	95%	100% n=5
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%	To be reported in 2017
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%	47% n=15
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%	70% n=20
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%	50% n=18
(ii) Patients with acute leukaemia 60 years of age and over receiving intensive chemotherapy who are treated within a clinical trial.	80%	78% n=9
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%	11% n=27
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%	44% n=9
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%	37% n=62
Translational research	15%	6% n=62

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.

Standards in diagnostics (QPIs 1 and 2) were high and it is important to maintain these high standards in completing a diagnostic panel and assigning WHO classification. MDT discussion (QPI 3) was not met but should be achievable with simple adjustments to current

practice. Likewise, the proportion of patients with samples sent for tissue typing (QPI 9) was not met but following amendment to CMGs and increased awareness should be easily achieved. QPI 4, examining assessment for an MRD marker was met.

QPI 5(i) looking at early death in adults with AML treated with curative intent was not met in patients aged 16-60 years but was achieved in those aged over 60 years. In the younger patient group numbers were small. One patient died having been very unwell at initial presentation; due to small patient numbers this 1 death meant the QPI could not be met. QPI 5 (ii) looking at early death in patients with ALL was met.

Access to ATRA (QPI 6) was excellent with 100% of patients receiving this treatment within 24 hours of presentation.

Participation in clinical trials with curative intent was assessed in QPI 8. This was not met. Despite the tolerance for this QPI being set to account for lack of trial availability and poor performance status, it was these factors which meant the QPI was not met. It is noted that the audit period included several months when there was no trial available for patients with AML treated with curative intent (a 'gap' between the UK wide study AML17 closing to recruitment and study AML19 opening). It will be important to ensure this QPI is met during the next audit period when trial availability should be improved.

QPI 10 looked at the proportion of older patients receiving intensive chemotherapy. Specification (i), the number of older patients receiving intensive chemotherapy, was met but the number of those being treated within a clinical trial (ii) was not met. Lack of trial availability contributed to this target not being achieved and it was noted that the QPI target was fairly high (80%).

The number of patients treated within a clinical trial with non-curative intent (QPI 11) was achieved though the target is fairly low (10%).

QPI 12 examined patients treated with palliative chemotherapy. This QPI was not met but it was felt that rather than patients refusing treatment (an exclusion criterion) there was often a decision made jointly by clinicians and patients not to treat based on performance status and co-morbidities.

To date, areas identified requiring further work 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:

- NHS Highland to ensure that MDT discussions are appropriately recorded.
- All NHS boards to be more thorough in ensuring all patients discussed at MDT.
- All NHS boards to ensure that tissue typing for transplant is included as a baseline investigation as outlined in the NOSCAN Clinical Management Guidelines for AML and ALL.
- All NHS boards to continue to ensure appropriate clinical trials are promoted and opened locally as soon as available.

- NHS Highland and NHS Tayside to explore opening the LI-1 study or other suitable clinical trial for older patients with AML.

- All NHS boards to continue to offer palliative chemotherapy to those patients likely to benefit from this treatment.

Contents

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 website[1].

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 2014 to 30th June 2015.

Using clinical audit data, which has been collected at individual Board level for all patients diagnosed with acute leukaemia during the period indicated, performance is reported against the Acute Leukaemia Quality Performance Indicators (QPIs)[6] which were implemented for patients diagnosed on or after 1st July 2014. Results are reported both by Board, and collectively as a network, with supporting narrative to enhance understanding of performance outcomes.

2. Background

Six NHS Boards across the North of Scotland serve the 1.39 million population[7]. There were 65 patients diagnosed with acute leukaemia in the NoS between 1st July 2014 and 30th June 2015. 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

Latest available cancer registration figures for all leukaemia show approximately 550 cases recorded in Scotland during 2013; leukaemia is the 16th most common cancer, with incidence declining by one third in the last 10 years[8].

Relative survival from all leukaemias in Scotland is similar to the average for all cancer types and has increased considerably since 1987-1991[9]. The table below details the percentage change in 1 and 5 year relative survival for patients diagnosed 1987-1991 to 2007-2011.

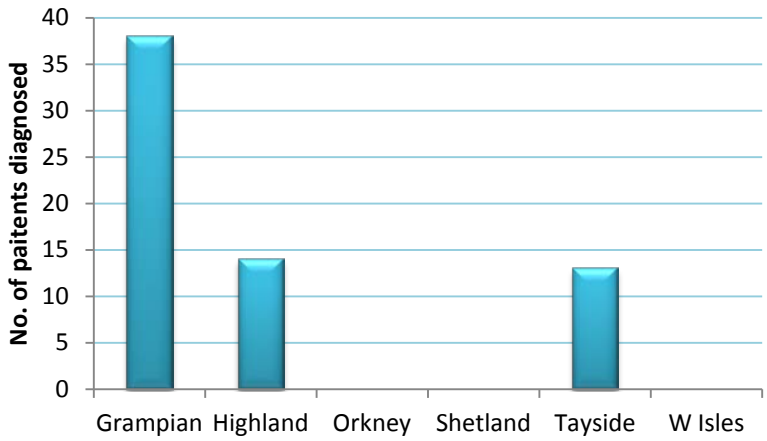
Relative age-standardised survival for leukaemia in Scotland at 1 year and 5 years showing percentage change from 1987-1991 to 2007-2011[9].

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 2014 and 30th June 2015, a total of 65 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	**38**	**14**	**0**	**0**	**13**	**0**	**65**
% of NoS total	**58%**	**22%**	**0%**	**0%**	**20%**	**0%**	**100%**



Number of patients diagnosed with acute leukaemia by Board of diagnosis, July 2014 – June 2015.

3. Methodology

The clinical audit data presented in this report was collected in accordance with an agreed dataset and definitions[1]. The data was entered locally into the electronic Cancer Audit Support Environment (eCASE): a secure centralised web-based database.

Data for patients diagnosed between 1st July 2014 and 30th June 2015 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

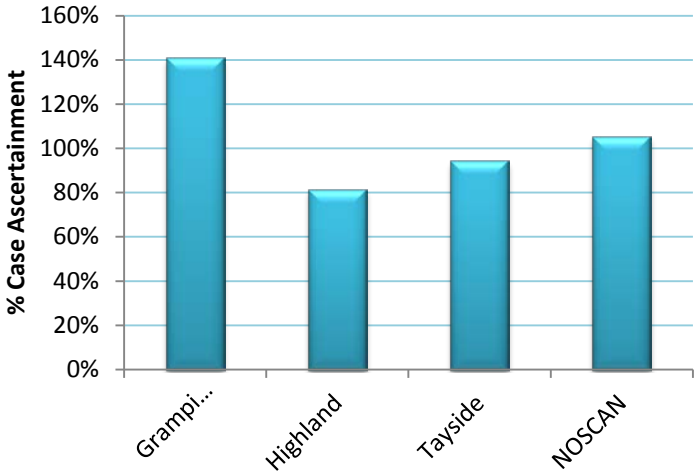
4.1 Case Ascertainment

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 105%, 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 2014-2015.

	Grampian	Highland	Orkney	Shetland	Tayside	W Isles	NoS
Cases from audit	38	14	0	0	13	0	**65**
ISD Cases (2009-2013)[i]	27.0	17.2	1.4	0.4	13.8	2.0	**61.8**
% Case ascertainment	140.7%	81.4%	0%	0%	94.2%	0%	**105.2%**

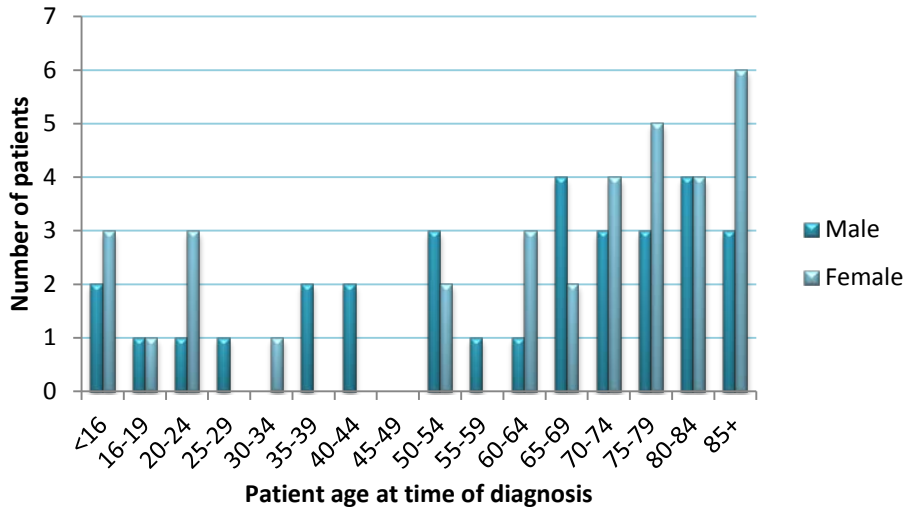
[i] Data by NHS Board of residence.

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 the MDT date (which was missing for a number of patients in NHS Highland), performance status and final diagnosis (which were missing for a small number of patients in NHS Tayside).

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 2014-2015.



Age distribution of patients diagnosed with acute leukaemia in NOSCAN 2014-2015.

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 27 patients diagnosed with acute leukaemia in North of Scotland in 2014-2015 and undergoing treatment with curative intent, 25 had complete diagnostic panel undertaken. This equates to a rate of 92.6%, meeting the target rate of 90%.

	Performance (%)	Numerator	Denominator	Not recorded - Numerator	% not recorded - Numerator	Not recorded - Exclusions	% not recorded - Exclusions	Not recorded - Denominator
NoS	**92.6%**	**25**	**27**	**0**	**0%**	**0**	**0%**	**0**

While this QPI was met at a regional level, at an individual NHS board level this QPI was met by NHS Tayside and NHS Highland: NHS Grampian just failed to meet this target (achieved 86.7%) when two patients did not have immunophenotyping performed but the other 13 patients had a complete diagnostic panel performed.

It should be noted that in some situations it can be clinically difficult to perform the flow cytometric testing required (e.g. ‘dry tap’ at diagnostic marrow biopsy and no circulating blasts). In this situation it is usually possible to perform immunocytochemistry on the trephine sample. There may be a good explanation for some patients not completing a diagnostic panel and therefore a risk that the target will not be met despite good clinical practice when results are based on a small numbers of patients.

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, 38 patients with acute leukaemia (100%) had a WHO classification assigned and recorded, meeting the target rate of 100%.

	Performance (%)	Numerator	Denominator	Not recorded - Numerator	% not recorded - Numerator	Not recorded - Exclusions	% not recorded - Exclusions	Not recorded - Denominator
NoS	**100%**	38	38	0	0%	0	0%	0

This QPI target was achieved by all NHS boards (100%).

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, 78.3% of patients diagnosed with acute leukaemia in 2014-2015 were discussed at MDT within 6 weeks of diagnosis; this means that at a regional level, the target of 95% was not met.

It should be noted that for 9 of the 13 patients not meeting this QPI, information on the MDT date was not recorded; it is therefore unclear whether they were discussed at the MDT within 6 weeks of diagnosis.

	Performance (%)	Numerator	Denominator	Not recorded - Numerator	% not recorded - Numerator	Not recorded - Exclusions	% not recorded - Exclusions	Not recorded - Denominator
NoS	78.3%	47	60	9	15.0%	0	0%	0

There was significant variation between NHS boards; NHS Grampian 90.9%, NHS Highland 28.6%, NHS Tayside 100%. In NHS Highland it was unclear if patients had ever been discussed at MDT or if there was a separate data management problem relating to lack of electronic recording of MDT discussion. However, in NHS Highland MDT discussions are now electronically recorded with documents uploaded to 'SC I Store' rather than simply being filed in patient case notes. In addition, there are plans for the Haematology MDT to start using new fully electronic MDT software that has recently been introduced in Highland at the colorectal cancer MDT.

Actions Required:

- **NHS Highland to ensure that MDT discussions are appropriately recorded.**
- **All NHS boards to be more thorough in ensuring all patients discussed at MDT.**

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

Of the four patients with ALL under the age of 25 years and undergoing treatment with curative intent in the North of Scotland all (100%) were assessed for the presence of MRD marker. Consequently the North of Scotland met the target rate of 90%, as did both NHS Boards with patients included within this QPI.

Actions Required:

- No action required, continue to maintain high standard.

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 11 patients between the ages of 16 and 60 years diagnosed with AML in the North of Scotland in 2014-2015 and treated with curative intent, one (9.1%) died within 30 days of treatment. These figures show that the QPI target of less than 8% was not met in the North of Scotland.

None of the eight patients over 60 years of age meeting this QPI died within 30 days of treatment, meeting the target of less than 18% for this age-group.

	Performance (%)	Numerator	Denominator	Not recorded - Numerator	% not recorded - Numerator	Not recorded - Exclusions	% not recorded - Exclusions	Not recorded - Denominator
Age 16-60	9.1%	1	11	0	0%	0	0%	0
Age 60+	0%	0	8	0	0%	0	0%	0

Patient numbers are small, particularly in NHS Grampian and NHS Tayside. In NHS Highland, one patient was significantly unwell at presentation (ECOG 4) and unfortunately died within 48 hours of starting chemotherapy. The decision to treat this patient with curative intent has been reviewed and was found to be clinically appropriate.

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

Of the six patients between the age of 16 and 60 years diagnosed with ALL in the North of Scotland in 2014-2015 and treated with curative intent, 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.

There were no patients over 60 years of age that were diagnosed with ALL during 2014-2015 that were treated with curative intent.

	Performance (%)	Numerator	Denominator	Not recorded - Numerator	% not recorded - Numerator	Not recorded - Exclusions	% not recorded - Exclusions	Not recorded - Denominator
Age 16-60	0%	0	6	0	0%	0	0%	0

Actions Required:

- No action required.

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 24 hours (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 24 hours (1 day) of diagnosis.

Denominator: All patients with APL.

Exclusions: No exclusions.

Target: 95%

QPI 6 Performance against target

In 2014 - 2015, five patients were diagnosed acute promyelocytic leukaemia. All of these (100%) received ATRA within one day of diagnosis, meeting the target rate of 95%.

	Performance (%)	Numerator	Denominator	Not recorded - Numerator	% not recorded - Numerator	Not recorded - Exclusions	% not recorded - Exclusions	Not recorded - Denominator
NoS	100%	5	5	0	0%	0	0%	2

Actions Required:

- No action required, continue to maintain high standard.

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%

QPI 7 Performance against target

For patients diagnosed in 2014-2015 this QPI will be reported in 2017 to ensure that one year has elapsed since diagnosis.

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 2014 – 2015, 15 patients below the age of 60 and diagnosed with acute leukaemia were treated with curative intent in the North of Scotland. Of these seven were enrolled in a clinical trial, this equates to 46.7% below the target for this QPI of 60%.

	Performance (%)	Numerator	Denominator	Not recorded - Numerator	% not recorded - Numerator	Not recorded - Exclusions	% not recorded - Exclusions	Not recorded - Denominator
NoS	46.7%	7	15	0	0%	0	0%	0

This QPI was met by NHS Grampian (66.7%) and NHS Tayside (66.7%). In NHS Highland only 16.7% of patients treated with curative intent were enrolled in a clinical trial.

Looking at the NHS Highland patient group in more detail, there were 6 patients treated with curative intent, 1 within a clinical trial. Two patients were not fit to consent to trial entry (both ECOG 4, requiring intensive care admission at presentation). The 3 remaining patients presented in March and April 2015 during the period between the closure of the AML17 study and opening of the AML19 study. This was outwith control of NHS Highland. There was no delay in opening AML19; this study was opened in February 2016 in line with the rest of the UK.

NHS Grampian noted that only 2 patients were not enrolled in a clinical trial; there was no suitable trial at the time these patients were diagnosed. AML studies tend to run for approximately 5 years so it is likely that when there is a 'gap' between studies it will be more difficult to meet this QPI.

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.

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 acute leukaemia 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 2014 – 2015 in the North of Scotland, 70.0% 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%.

	Performance (%)	Numerator	Denominator	Not recorded - Numerator	% not recorded - Numerator	Not recorded - Exclusions	% not recorded - Exclusions	Not recorded - Denominator
NoS	**70.0%**	**14**	**20**	0	0%	0	0%	0

Not all patients with acute leukaemia will be considered for allogeneic stem cell transplant. It is likely there is variation in practice with some clinicians waiting for prognostic information before determining the need to send samples for tissue typing.

It should be straight forward to address failure to meet this QPI. Tissue typing for transplant has now been included as a baseline investigation in the NOSCAN CMG for AML and ALL for this patient group.

Actions Required:

- **All NHS boards to ensure that tissue typing for transplant is included as a baseline investigation as outlined in the NOSCAN Clinical Management Guideline for AML and ALL.**

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 2014 – 2015 in the North of Scotland, 50.0% of patients included within the denominator for this QPI received intensive chemotherapy. This meets the target of 20%.

	Performance (%)	Numerator	Denominator	Not recorded - Numerator	% not recorded - Numerator	Not recorded - Exclusions	% not recorded - Exclusions	Not recorded - Denominator
NoS	**50.0%**	**9**	**18**	0	0%	0	0%	3

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: No Exclusions

Target: 80%

QPI 10 (ii) Performance against target

In 2014 – 2015 in the North of Scotland, 77.8% of patients over the age 60 that were diagnosed with acute leukaemia and received intensive chemotherapy were treated within a clinical trial. This falls short of the target of 80%.

	Performance (%)	Numerator	Denominator	Not recorded - Numerator	% not recorded - Numerator	Not recorded - Exclusions	% not recorded - Exclusions	Not recorded - Denominator
NoS	**77.8%**	**7**	**9**	0	0%	0	0%	0

Patient numbers are small (9 patients in total) and the QPI target is fairly high at 80%; the North of Scotland just missed this target achieving 77.8%. As in the younger patient group there was a gap in clinical trial availability with no trial being available from July – Nov 2014.

Actions Required:

- **All NHS Boards to continue to ensure appropriate clinical trials are promoted and opened locally as soon as available.**

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 27 patients diagnosed with acute leukaemia in North of Scotland in 2014-2015 who were treated with non-curative intent, 3 were enrolled into a clinical trial. This equates to a rate of 11.1%, which is above the target rate of 10%.

	Performance (%)	Numerator	Denominator	Not recorded - Numerator	% not recorded - Numerator	Not recorded - Exclusions	% not recorded - Exclusions	Not recorded - Denominator
NoS	**11.1%**	**3**	**27**	**0**	**0%**	**0**	**0%**	**0**

This QPI was met but with variation across NHS boards. No patients were recruited to clinical trials in NHS Highland or NHS Tayside. There was no clinical trial available in NHS Highland for older patients with AML. UKALL 60+ is now available for older patients with ALL but was not available during the audit period in NHS Highland.

Actions Required:

- **NHS Highland and NHS Tayside to explore opening the LI-1 study or other suitable clinical trial for older patients with AML.**

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, nine patients were diagnosed with acute myeloid leukaemia and were suitable only for treatment with non-curative intent. Of these, 44.4% received palliative chemotherapy with either low dose cytarabine or azacytidine, therefore the target rate of 70% was not met.

	Performance (%)	Numerator	Denominator	Not recorded - Numerator	% not recorded - Numerator	Not recorded - Exclusions	% not recorded - Exclusions	Not recorded - Denominator
NoS	44.4%	4	9	0	0%	0	0%	2

It was commented that reasons for patients not receiving palliative chemotherapy included poor performance status and co-morbidities; rather than patients refusing chemotherapy a decision not to treat is often made jointly by clinicians and patients. Poor performance status is not an exclusion in this QPI which may make it difficult to achieve especially with such small patient numbers.

Actions Required:

- **All NHS Boards to continue to offer palliative chemotherapy to those patients likely to benefit from this treatment.**

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:

- 37.1% of patients diagnosed with acute leukaemia in the North of Scotland in 2014 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%.
- Recruitment into translational research was lower at 6.5%, falling short of 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 significantly underestimating the percentage of patients contributing to such work.

	Number of patients recruited	ISD Cases annual average (2009-2013)	Percentage of patients recruited
Interventional Clinical Trials	23	62	**37.1%**
Translational Research	4	62	**6.5%**

The QPI targets for clinical trials are 7.5% for interventional trials and for translational trials are 15%.

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. In this audit period this has been limited by trial availability and patient co-morbidities. Acute leukaemia is more common in the elderly and in this patient group co-morbidities and performance status limits trial entry.

During 2014 in NOSCAN, there were 4 interventional trials and 2 translational trials open and recruiting patients, thereby offering patients with an acute leukaemia diagnosis the opportunity to participate in a range of different acute leukaemia trials. Furthermore, all the acute leukaemia patients passing through the cancer centres in NOSCAN will have been assessed for eligibility for clinical trials: further enquiry indicates that of patients diagnosed with acute leukaemia in the NoS during 2014, 21 (33.9%) patients were screened for interventional trials and 4 (6.5%) were screened for translational trials during the reporting period.

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 NoS. 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.

As part of this programme, the North of Scotland has also recently launched a programme of annual reporting of regional performance against QPIs. This is the first time that the results of performance against the Acute Leukaemia QPIs have been reported in the North of Scotland, providing a clearer measure of overall performance across the region, and a more formal structure around which any improvements will be made.

Case ascertainment was high at 105% and measures of performance against the Acute Leukaemia Cancer QPI's for patients diagnosed between 1st July 2014 and 30th June 2015 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.

Standards in diagnostics (QPIs 1 and 2) were high and it is important to maintain these high standards in completing a diagnostic panel and assigning WHO classification. MDT discussion (QPI 3) was not met but should be achievable with simple adjustments to current practice. Likewise, the proportion of patients with samples sent for tissue typing (QPI 9) was not met but following amendment to CMGs and increased awareness should be easily achieved. QPI 4, examining assessment for an MRD marker was met.

QPI 5(i) looking at early death in adults with AML treated with curative intent was not met in patients aged 16-60 years but was achieved in those aged over 60 years. In the younger patient group numbers were small. One patient died having been very unwell at initial presentation; due to small patient numbers this 1 death meant the QPI could not be met. QPI 5 (ii) looking at early death in patients with ALL was met.

Access to ATRA (QPI 6) was excellent with 100% of patients receiving this treatment within 24 hours of presentation.

Participation in clinical trials with curative intent was assessed in QPI 8. This was not met; despite the tolerance for this QPI being set to account for lack of trial availability and poor performance status, it was these factors which meant the QPI was not met. It is noted that the audit period included several months when there was no trial available for patients with AML treated with curative intent (a 'gap' between the UK wide study AML17 closing to recruitment and study AML19 opening). It will be important to ensure this QPI is met during the next audit period when trial availability should be improved.

QPI 10 looked at the proportion of older patients receiving intensive chemotherapy. Specification (i) – the number of older patients receiving intensive chemotherapy was met but the number of those being treated within a clinical trial (ii) was not met. Lack of trial availability contributed to this target not being achieved and it was noted that the QPI target was fairly high (80%).

The number of patients treated within a clinical trial with non-curative intent (QPI 11) was achieved though the target fairly low (10%).

QPI 12 examined patients treated with palliative chemotherapy. This QPI was not met but it was felt that rather than patients refusing treatment (an exclusion criterion) there was often a decision made jointly by clinicians and patients not to treat based on performance status and co-morbidities.

To date, areas identified requiring further work 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:

- NHS Highland to ensure that MDT discussions are appropriately recorded.
- All NHS boards to be more thorough in ensuring all patients discussed at MDT.
- All NHS boards to ensure that tissue typing for transplant is included as a baseline investigation as outlined in the NOSCAN Clinical Management Guideline for AML and ALL.
- All NHS boards to continue to ensure appropriate clinical trials are promoted and opened locally as soon as available.
- NHS Highland and NHS Tayside to explore opening the LI-1 study or other suitable clinical trial for older patients with AML.
- All NHS boards to continue to offer palliative chemotherapy to those patients likely to benefit from this treatment.

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 NOSCAN 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 NOSCAN 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 2014.

Trial	Principle Investigator	Trial Type
AML 17	Dominic Culligan (Grampian) Chris Lush / Catherine Ogilvie (Highland) Sudhir Tauro (Tayside)	Interventional
UKALL2011	Dominic Culligan (Grampian) Sudhir Tauro (Tayside)	Interventional
UKALL 14	Dominic Culligan (Grampian) Sudhir Tauro (Tayside)	Interventional
RavVA	Dominic Culligan (Grampian)	Interventional
LI-1	Dominic Culligan (Grampian)	Interventional
INCiTE	Joanne Craig (Highland) Sudhir Tauro (Tayside)	Translational
Understanding and managing the coagulopathy of APL (Pilot Study)	Joanne Craig (Highland)	Translational

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.

NOSCAN
North of Scotland Cancer Network

Action Plan: Acute Leukaemia Cancer

Based on QPI results for patients diagnosed 2014-2015

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			
	Ensure actions mirror those detailed in Audit Report	*Detail specific actions that will be taken by the NHS Board*	*Insert date*	*Insert date*	*Insert name of responsible lead for each action.*	*Detail actions in progress, changes in practice, problems encountered of reasons why no action has been taken.*	*Insert no. from key*