NHS
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Scottish Cancer Taskforce
National Cancer Quality Steering Group

Clinical Trial Access Quality Performance Indicators

Engagement Document

June 2017 (v2.0)

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Contents Update Record

June 2017 (v2.0)
This document has been updated following formal review of the Clinical Trial Access Quality Performance Indicator (QPI) which took place following analysis of year 3 of the clinical trial access QPI data.

The QPI has been updated along with sections 1 – 12 and the appendices. As a result of these changes, the contents page and page numbering differ from the earlier version of this document.

Please note that this version of the Clinical Trial Access QPI document applies to cases consented for clinical trials from 1st January 2017 onwards.

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1. National Cancer Quality Programme

Better Cancer: Ambition and Action (2016)[1] details a commitment to delivering the national cancer quality programme across NHSScotland, with a recognised need for national cancer QPIs to support a culture of continuous quality improvement. Addressing variation in the quality of cancer services is pivotal to delivering improvements in quality of care. This is best achieved if there is consensus and clear indicators for what good cancer care looks like.

Small sets of cancer specific outcome focussed, evidence based indicators are in place for 18 different tumour types. These are underpinned by patient experience QPIs that are applicable to all, irrespective of tumour type. These QPIs ensure that activity is focused on those areas that are most important in terms of improving survival and individual care experience whilst reducing variation and supporting the most effective and efficient delivery of care for people with cancer. QPIs are kept under regular review and are responsive to changes in clinical practice and emerging evidence.

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

1.1 Quality Assurance and Continuous Quality Improvement

The ultimate aim of the programme is to develop a framework, and foster a culture of, continuous quality improvement, whereby real time data is reviewed regularly at an individual Multi Disciplinary Team (MDT)/Unit level and findings actioned to deliver continual improvements in the quality of cancer care. This will be underpinned and supported by a programme of regional and national comparative reporting and review.

NHS Boards will be required to report against QPIs as part of a mandatory, publicly reported, programme at a national level. A rolling programme of reporting is in place, with approximately three national tumour specific reports published annually. National reports include comparative reporting of performance against QPIs at MDT/Unit level across NHSScotland, trend analysis and survival. This approach helps to overcome existing issues relating to the reporting of small volumes in any one year.

In the intervening years tumour specific QPIs are monitored on an annual basis through established Regional Cancer Networks and local governance processes, with analysed data submitted to Information Services Division (ISD) for inclusion in subsequent national reports. This approach ensures that timely action is taken in response to any issues that may be identified through comparative reporting and systematic review.

2. Quality Performance Indicator Development Process

The QPI development process was designed to ensure that indicators are developed in an open, transparent and timely way. The development process can be found in appendix 1.

A short life working group (SLWG) established by the National Cancer Quality Steering Group (NCQSG) was convened in June 2013, chaired by Dr Hilary Dobson (Chair – National Cancer Quality Steering Group). Membership of this group included representatives from all four Scottish Cancer Research Networks (SCRN) and can be found in appendix 2.

3. QPI Formal Review Process

As part of the National Cancer Quality Programme a systematic national review process has been developed, whereby all tumour specific QPIs published are subject to formal review following 3 years analysis of comparative QPI data.

Formal review of the Clinical Trial Access QPI was undertaken in April 2017. A Formal Review Group was convened, chaired by Mr Gren Oades (Regional Clinical Lead, Urological Cancers MCN, West of Scotland Cancer Network). Membership of this group included Clinical Leads and Network Mangers from the regional Scottish Cancer Research Networks (SCRN). Membership of this group can be found in appendix 3.

The formal review process is clinically driven with comments sought from specialty specific representatives in each of the Regional Cancer Networks for discussion at the initial meeting. This review builds on existing evidence using expert clinical opinion to identify where new evidence is available.

During formal review QPIs may be removed and replaced with new QPIs. Triggers for doing so include significant change to clinical practice, targets being consistently met by all Boards, and publication of new evidence.

Any new QPIs have been developed in line with the following criteria:

- **Overall importance** – does the indicator address an area of clinical importance that would significantly impact on the quality and outcome of care delivered?
- **Evidence based** – is the indicator based on high quality clinical evidence?
- **Measurability** – is the indicator measurable i.e. are there explicit requirements for data measurement and are the required data items accessible and available for collection?

4. Format of the Quality Performance Indicators

QPIs are designed to be clear and measurable, based on sound clinical evidence whilst also taking into account other recognised standards and guidelines.

- Each QPI has a **short title** which will be utilised in reports as well as a fuller **description** which explains exactly what the indicator is measuring.
- This is followed by a brief overview of the **evidence base and rationale** which explains why the development of this indicator was important.
- The measurability **specifications** are then detailed; these highlight how the indicator will actually be measured in practice to allow for comparison across NHS Scotland.
- Finally a **target** is indicated, this dictates the level which each unit should be aiming to achieve against each indicator.

In order to ensure that the chosen target level is the most appropriate and drives continuous quality improvement as intended it will be kept under review and revised as necessary, when baseline data or further evidence becomes available.

Rather than utilising multiple exclusions, a tolerance level has been built into the QPI. It is very difficult to accurately measure patient choice, as well as eligibility for trials due to co-morbidities and patient fitness levels, therefore the target level has been set to account for these factors. In addition, there may be a lack of available trials recruiting during the

specific period of reporting, or studies may be available that do not meet the approval criteria for inclusion noted in Section 5.

5. Inclusion Criteria

In order to ensure the most complete and accurate data is available for national comparative reporting, the Clinical Trials QPI Formal Review Group have agreed specific inclusion criteria for the measurement of this QPI:

- The clinical trials access QPI will be measured for patients with a confirmed cancer diagnosis that aligns to those tumour types with nationally agreed QPIs.
- Clinical trials must be approved by the National Institute for Health Research (NIHR) or the Chief Scientist Office (CSO) as eligible for addition to the UKCRN portfolio. This will incorporate interventional trials, translational research and observational studies. The definition of eligibility for addition to the UKCRN Portfolio[2] is detailed in appendix 4.

Revision(s):	***Updated sections 1-4 in line with all formal review QPI documents.*** ***Removed the section on Clinical Trials Definitions.*** ***Added section 5: Inclusion Criteria*** ***Added appendix 4: CSO eligibility for addition to the UKCRN Portfolio***

6. Quality Performance Indicator for Clinical Trial Access

QPI Title:	All patients should be considered for participation in available clinical trials, wherever eligible.
Description:	Proportion of patients with **[insert tumour type]** cancer who are consented* for a clinical trial.
Rationale and Evidence:	Clinical trials are necessary to demonstrate the efficacy of new therapies and other interventions. Furthermore evidence suggests improved patient outcomes from participation in clinical trials[3]. Clinicians are therefore encouraged to enter patients into well-designed trials and to collect longer-term follow-up data. High accrual activity into clinical trials is used as a goal of an exemplary clinical research site.
Specifications:	**Numerator:** Number of patients with **[insert tumour type]** cancer consented for a clinical trial. **Denominator:** All patients with **[insert tumour type]** cancer. **Exclusions:** • No exclusions.
Target:	15% The target level has been agreed based on National Cancer Research Institute (NCRI) data (see appendix 5).

*consented is defined as patients who have given consent to participate in a clinical trial subject to study specific screening for eligibility.

Revision(s):	***Updated to measure patients consented rather than enrolled*** ***Combined target of 15% (for all types of trials)***

7. Methodology

The clinical trials QPI will be measured utilising SCRN data and ISD incidence data, as is the methodology currently utilised by the Chief Scientist Office (CSO) and NCRI. The principal benefit of this approach is that this data is already collected utilising a robust mechanism. At present a 'clinical trial' data item is contained within all tumour specific datasets, however in order to avoid any duplication of effort, and focus resources appropriately, SCRN data is the preferred option.

Utilising SCRN data allows for comparison with CSO published data and ensures capture of all clinical trials activity, not solely first line treatment trials, as contained in the clinical audit data. Given that a significant proportion of clinical trials are for relapsed disease this is felt to be particularly important in driving quality improvement. This methodology utilises incidence as a proxy for all patients with cancer. This may slightly over, or underestimate, performance levels, however this is an established approach currently utilised by NHSScotland.

8. Reporting

The Clinical Trial Access QPI will be reported alongside tumour specific QPIs for the most recent calendar year. The patient cohort used to measure the Clinical Trial Access QPI is different to that of the tumour specific QPIs due to the methodology utilised and it is therefore not necessary to use an identical timeframe for reporting. In order to avoid multiple data requests to SCRN for different tumour groups it is considered most appropriate to align the tumour sites to one calendar year for reporting purposes.

Additional information will be reported alongside the QPI in order to provide further context for each tumour site. This will include the following:

- Details of all clinical trials open to recruitment in each cancer centre during the audit period.
- Percentage of patients enrolled in clinical trials.

Revision(s):	***Added section 7: Methodology (previously text within the QPI)*** ***Updated section 8: Reporting***

9. Governance and Scrutiny

A national and regional governance framework to assure the quality of cancer services in NHSScotland has been developed; key roles and responsibilities within this are set out below. Appendices 6 and 7 provide an overview of these governance arrangements diagrammatically. The importance of ensuring robust local governance processes are in place is recognised and it is essential that NHS Boards ensure that cancer clinical audit is fully embedded within established processes.

9.1 National

- Scottish Cancer Taskforce
  - Accountable for overall national cancer quality programme and overseeing the quality of cancer care across NHSScotland.
  - Advising Scottish Government Health and Social Care Directorate (SGHSCD) if escalation required.

- Healthcare Improvement Scotland
  - Proportionate scrutiny of performance.
  - Support performance improvement.
  - Quality assurance: ensure robust action plans are in place and being progressed via regions/Boards to address any issues identified.

- Information Services Division (ISD)
  - Publish national comparative report on tumour specific QPIs and survival for 3 tumour types per annum and specified generic QPIs as part of the rolling programme of reporting.

9.2 Regional – Regional Cancer Networks

- Annual regional comparative analysis and reporting against tumour specific QPIs.
- Support national comparative reporting of specified generic QPIs.
- Identify and share good practice.
- In conjunction with constituent NHS Boards identify regional and local actions required to develop an action plan to address regional issues identified.
- Review and monitoring of progress against agreed actions.
- Provide assurance to NHS Board Chief Executive Officers and Scottish Cancer Taskforce that any issues identified have been adequately and timeously progressed.

9.3 Local – NHS Boards

- Collect and submit data for regional comparative analysis and reporting in line with agreed measurability and reporting schedule (generic and tumour specific QPIs).
- Utilise local governance structures to review performance, develop local action plans and monitor delivery.
- Demonstrate continual improvements in quality of care through on-going review, analysis and feedback of clinical audit data at an individual multidisciplinary team (MDT) or unit level.

10. How to participate in the engagement process

In order to ensure wide inclusiveness of clinical and management colleagues from across NHSScotland, patients and the wider public, several different methods of engagement are being pursued:

Professional groups, health service staff, voluntary organisations and individuals:

- Wide circulation of the draft documentation for comment and feedback.

Patient representative groups:

- Organised patient focus group sessions to be held.

10.1 Submitting your comments

You can submit your comments on the Revised Clinical Trial Access QPIs via the Scottish Government Consultation Hub (website link below):

https://consult.scotland.gov.uk/nhs/review-of-clinical-trial-access-qpi/

All responses should be submitted by 18 August 2017.

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

Email: ClinicaltrialsQPIPublicEngagement@gov.scot

10.2 Engagement feedback

At the end of the engagement period, all comments and responses will be collated for review by the Clinical Trials QPI Formal Review Group. Those who have participated in the engagement process will receive an overview of the changes made and a copy of the final Clinical Trial Access QPI document.

11. References

1. Scottish Government (2016). Beating Cancer: Ambition and Action. Available from: http://www.scotland.gov.uk/Resource/Doc/242498/0067458.pdf

2. Chief Scientist Office (2013). Scottish Studies and the UK CRN Portfolio. Available from: http://www.cso.scot.nhs.uk/wp-content/uploads/Scottish-studies-and-the-UKCRN-Portfolio.pdf

3. NHS Quality Improvement Scotland (2008) Management of Core Cancer Services Standards. Available from: http://www.healthcareimprovementscotland.org/our_work/cancer_care_improvement/cancer_resources/standards_for_cancer_services.aspx

4. National Cancer Research Institute (2013) NCRI Clinical Studies Groups: A prospectus. Available from: https://www.ncri.org.uk/wp-content/uploads/2013/11/2013-NCRI-CSG-prospectus.pdf

12. Abbreviations

CSO	Chief Scientist Office
ISD	Information Services Division
MDT	Multi - Disciplinary Team
NCQSG	National Cancer Quality Steering Group
NCRI	National Cancer Research Institute
QPIs	Quality Performance Indicators
RCAGs	Regional Cancer Advisory Groups
SCRN	Scottish Cancer Research Network
SGHSCD	Scottish Government Health and Social Care Directorate
SLWG	Short Life Working Group

13. Appendices

Appendix 1 – Clinical Trial Access QPI Development Process

Preparatory Work and Scoping

The National Cancer QPI Development Programme commenced in May 2010. At the outset, it was apparent that various issues were common to all cancer types. These areas were agreed by the National Cancer Quality Steering Group (NCQSG) to be: Multi-Disciplinary Team Meeting; Clinical Trial Access; and Patient Experience.

A generic QPI regarding Clinical Trial Access was developed by the NCQSG, based upon the NHS Quality Improvement Scotland Standards for the Management of Core Cancer Services[3], published in 2008. Following discussion at the NCQSG, further development and consultation was undertaken, principally with the Scottish Cancer Research Networks.

Indicator Development

The Clinical Trials short life working group (SLWG) defined an evidence based, measurable indicator with a clear focus on improving the quality and outcome of care provided.

The following criteria was utilised when developing the QPI:

- **Overall importance** – does the indicator address an area of clinical importance that would significantly impact on the quality and outcome of care delivered?

- **Evidence based** – is the indicator based on high quality clinical evidence?

- **Measurability** – is the indicator measurable, that is, are there explicit requirements for data measurement and are the required data items accessible and available for collection?

Engagement Process

The Clinical Trial Access QPI was included as part of the Clinical Trial Quality Performance Indicator Engagement Document which was made available on the Scottish Government website in January 2014, as part of a wide clinical and public engagement exercise.

During the engagement period clinical and management colleagues from across NHSScotland, patients and the wider public were given the opportunity to influence the development of the Clinical Trial Access QPI. Several different methods of engagement were utilised:

Professional groups, health service staff, voluntary organisations and individuals:

- Wide circulation of the draft documentation for comment and feedback.

Patient representative groups:

- Organised patient focus group sessions were held.

Following the engagement period all comments and responses received were reviewed by the SLWG and used to produce and refine the final indicator.

Appendix 2 – Membership of the Clinical Trial Short Life Working Group (2014)

Name	Designation	Organisation
Shelagh Bonner-Shand	Manager	SCRN North
Dorothy Boyle	Manager	SCRN South East
Chloe Cowan	Manager	SCRN West
Hilary Dobson (CHAIR)	Chair - National Cancer Quality Steering Group	
David Dunlop	Clinical Lead	SCRN West
Charlie Gourlay	Clinical Lead	SCRN South East
Kelly Macdonald	Project Manager	National Cancer QPI Development Programme
Marianne Nicolson	Clinical Lead	SCRN North
Iona Scott	Project Manager	National Cancer QPI Development Programme
Alistair Thompson	Clinical Lead	SCRN East
Charles Weller	Manager	SCRN East

Appendix 3 – Clinical Trial QPI Formal Review Group Membership (2017)

Name	Designation	Organisation
Gren Oades (Chair)	Regional Clinical Lead, Urological Cancers MCN	WoSCAN
Karen Bell	Acting Network Manager	SCRN West
Dorothy Boyle	Network Manager	SCRN East
Ewan Brown	Clinical Lead	SCRN East
Lorna Bruce	Audit Manager	SCAN
David Cameron	Scottish Cancer Research Champion	SCAN
Louise Devlin	Lead Cancer Trials Nurse	WoSCAN
Jen Doherty	National Cancer Quality Programme Co-ordinator	WoSCAN
Iain MacPherson	Clinical Lead	SCRN West
Marianne Nicolson	Clinical Lead	SCRN North
Kirsty Shearer	Network Manager	SCRN North
Lorraine Stirling	Project Officer	WoSCAN
Christine Urquhart	Audit Manager	NOSCAN

Appendix 4 - Definition of eligibility for addition to the UKCRN Portfolio

Research taking place in NHSScotland can be added to the UKCRN Portfolio if it falls into one of the following categories:

(a) Studies supported by a funder which appears on the CSO Eligible Funders list can be added automatically.

http://www.cso.scot.nhs.uk/wp-content/uploads/2013/05/NRS-Funding-Guidance-Annex-2-Eligible-funders-v4.pdf

(b) Studies which are supported by a funder which is not on the list may apply for adoption to the Portfolio if funding is provided by:

- an overseas government *or*
- an ineligible national charity *or*
- a commercial concern, but are non-commercially sponsored

The process varies depending on lead site and participating sites:

- Studies led from England with Scottish sites can be considered for adoption by the NIHR CRN
- Scottish-led studies which intend to also recruit in England can be considered for adoption via the NIHR CRN process
- Studies only taking place in Scotland can apply for adoption through the defined process (link below)

http://www.cso.scot.nhs.uk/wp-content/uploads/2013/05/NRS-Funding-Guidance-Annex-3-SOP-for-Adoption-v2.1.pdf

(c) All industry-led studies (where the study has been initiated, funded and sponsored by the company) are eligible for addition to the Scottish Portfolio. Where a study is led from England, this may be carried out by NIHR, however due to concerns over confidentiality, not all industry-led studies active in Scotland will be added to the Portfolio. Activity on all Scottish-led studies is tracked by NRS Commercial Managers. If a study does not fall into any of the above categories, it should not be added to the UKCRN Portfolio.

Addition of Scottish studies to the UKCRN Portfolio
NHS Boards are responsible for addition of eligible research projects led from Scotland to the UKCRN Portfolio.

The primary contact for addition should be the R&D office of the NHS Board which hosts the study Chief Investigator.

Boards may delegate the actual addition and maintenance of the Portfolio entry to another party, such as a Research Network, but are ultimately responsible if the study has not been added or maintained.

Further information on Scottish Studies and the UKCRN Portfolio can be found at:

http://www.cso.scot.nhs.uk/wp-content/uploads/Scottish-studies-and-the-UKCRN-Portfolio.pdf

Appendix 5 – National Cancer Research Institute Data

NCRI Clinical Studies Group Recruitment Data 2012/13

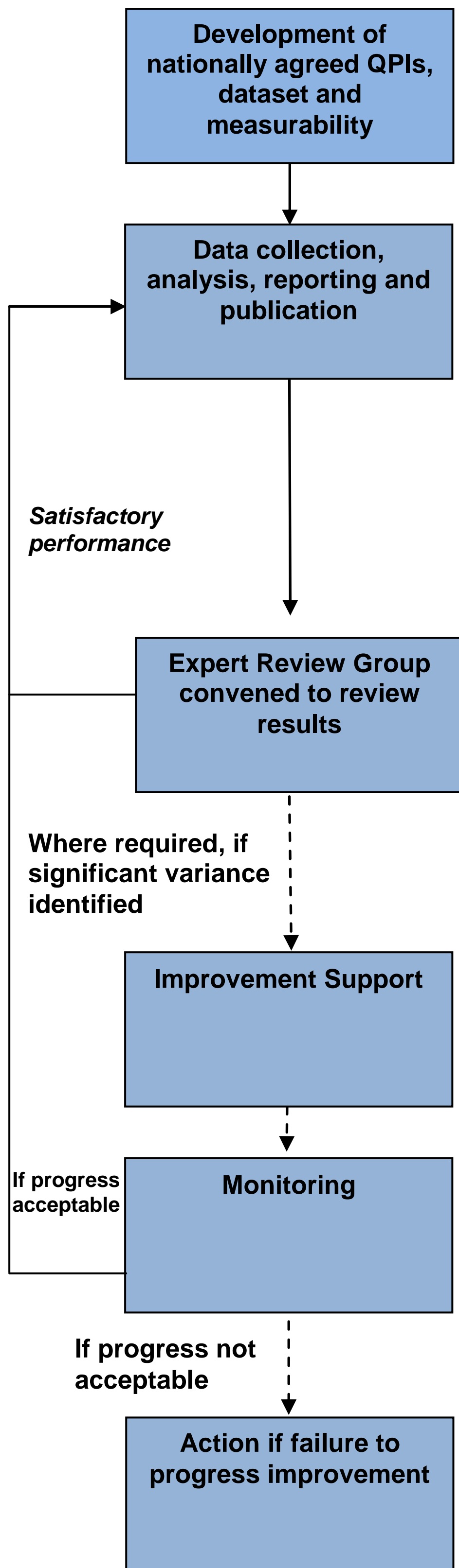
Cancer Type	% of cancer patients recruited into clinical studies relative to incidence (2012/13)
Bladder	3.1
Brain	23
Breast	28.1
Colorectal	16.3
Gynaecological	5.3
Haematological Oncology	43
Head and Neck	32.1
Lung	7.6
Lymphoma	28.9
Melanoma	5.4
Prostate	11.4
Renal	12.6
Sarcoma	7.8
Testis	72.2
Upper GI	15.4

Table 1: % of UK cancer patients recruited into clinical studies relative to incidence (2012/13)

Source: NCRI (2013) NCRI Clinical Studies Groups: A prospectus[4]

Appendix 6 – Yearly National Governance Process & Improvement Framework for Cancer Care

This process is underpinned by the annual regional reporting and governance framework (see appendix 6).



1. National QPI Development Stage

- QPIs developed by QPI development groups, which include representation from Regional Cancer Networks, Healthcare Improvement Scotland, ISD, patient representatives and the Cancer Coalition.

2. Data Analysis Stage:

- NHS Boards and Regional Cancer Advisory Groups (RCAGs)* collect data and analyse on yearly basis using nationally agreed measurability criteria and produce action plans to address areas of variance, see appendix 6.
- Submit yearly reports to ISD for collation and publication every 3 years.
- National comparative report approved by NHS Boards and RCAGs.
- ISD produce comparative, publicly available, national report consisting of trend analysis of 3 years data and survival analysis.

3. Expert Review Group Stage (for 3 tumour types per year):

- Expert group, hosted by Healthcare Improvement Scotland, review comparative national results.
- Write to RCAGs highlighting areas of good practice and variances.
- Where required NHS Boards requested to submit improvement plans for any outstanding unresolved issues with timescales for improvement to expert group.
- Improvement plans ratified by expert group and Scottish Cancer Taskforce.

4. Improvement Support Stage:

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

5. Monitoring Stage:

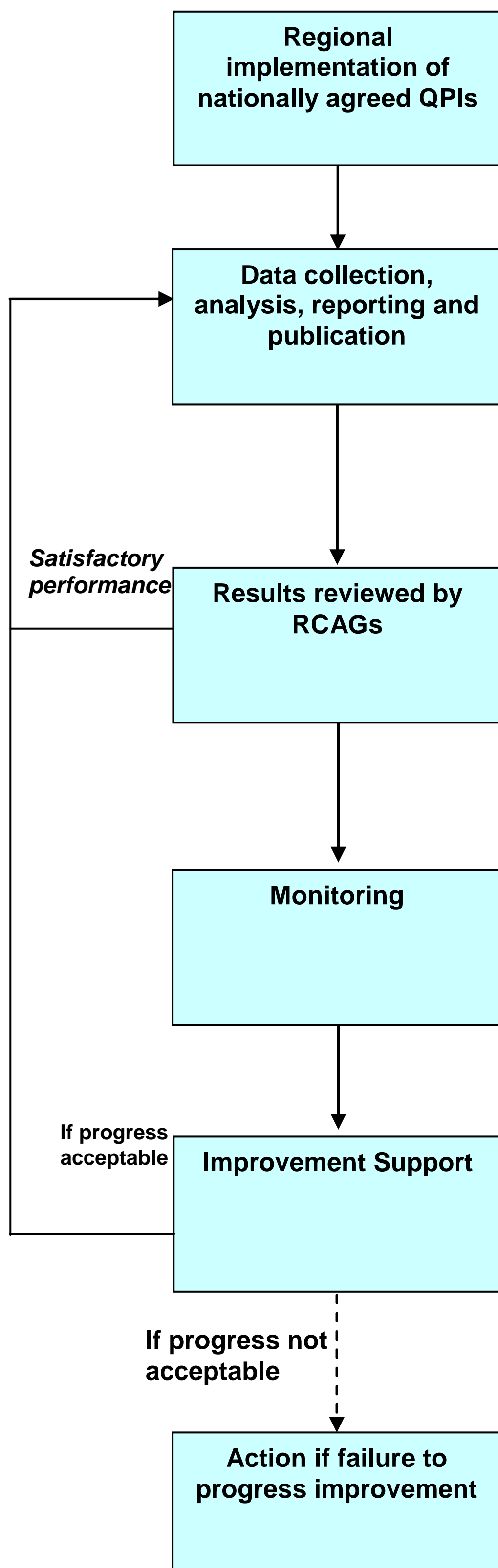
- RCAGs work with Boards to progress outstanding actions, monitor improvement plans and submit progress report to Healthcare Improvement Scotland.
- Healthcare Improvement Scotland report to Scottish Cancer Taskforce as to whether progress is acceptable.

6. Escalation Stage:

- If progress not acceptable, Healthcare Improvement Scotland will visit the service concerned and work with the RCAG and Board to address issues.
- Report submitted to Scottish Cancer Taskforce and escalation with a proposal to take forward to Scottish Government Health Department.

*In the South and East of Scotland Cancer Network (SCAN) the Regional Cancer Planning Group is the equivalent group to Regional Cancer Advisory Group (RCAG).

Appendix 7 – Regional Annual Governance Process and Improvement Framework for Cancer Care



1. Regional QPI Implementation Stage:

- National cancer QPIs and associated national minimum core dataset and measurability specifications, developed by QPI development groups.
- Regional implementation of nationally agreed dataset to enable reporting of QPIs.

2. Data Analysis Stage:

- NHS Boards collect data and data is analysed on a yearly basis using nationally agreed measurability criteria at local/ regional level.
- Data/results validated by Boards and annual regional comparative report produced by Regional Networks.
- Areas of best practice and variance across the region highlighted.
- Yearly regional reports submitted to ISD for collation and presentation in national report every 3 years.

3. Regional Performance Review Stage:

- RCAGs* review regional comparative report.
- Regional or local NHS Board action plans to address areas of variance developed.
- Appropriate leads identified to progress each action.
- Action plans ratified by RCAGs.

4. Monitoring Stage:

- Where required, NHS Boards monitor progress with action plans and submit progress reports to RCAGs.
- RCAGs review and monitor regional improvement.

5. Improvement Support Stage:

- Where required Healthcare Improvement Scotland maybe requested to provide expertise to NHS Boards/RCAGs on improvement methodologies and support.

6. Escalation Stage:

- If progress not acceptable, RCAGs will escalate any issues to relevant Board Chief Executives. If progress remains unacceptable RCAGs will escalate any relevant issues to Healthcare Improvement Scotland.

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