

NATIONAL EXTERNAL QUALITY ASSESSMENT SCHEME IN CLINICAL CYTOGENETICS

ANNUAL REPORT

2008

UK NEQAS for Clinical Cytogenetics

Room 2809, Women's Centre, John Radcliffe Hospital, Headington, Oxford OX3 9DU. UK.
(Tel: +44 1865 857644; Fax: +44 1865 857632 and email: ros.hastings@orh.nhs.uk)

Personnel

Scheme Organiser (S.O):
Deputy Scheme Organiser:
Quality Manager

Dr Ros Hastings (Oxford)
Mr Eddy Maher (Edinburgh)
Mrs Bettina Quellhorst-Pawley (Oxford)

Assessors

Constitutional Scheme

Dr Heleen Schuring (Utrecht, Netherlands)
Dr Ron Hochstenbach (Utrecht, Netherlands)
Mrs Kath Smith (Sheffield)
Dr Lorraine Gaunt (Manchester)
Mr Richard Ellis (London)

Dr Carol English (Newcastle)
Mr Eddy Maher (Edinburgh)
Mrs Carolyn Campbell (Oxford)
Mr Graham Fewes (Birmingham)

Haemato-Oncology Scheme

Mrs Helen Dickinson (Leeds)
Mrs Sarah Ryley (KGC, Harrow)
Mr David Betts, (Dublin, Ireland)
Mr Paul Roberts (Leeds)
Dr Fiona Ross (Salisbury)
Mrs Sandra Birdsall (Cardiff)

Mr Mike Griffiths (Birmingham)
Mrs Polly Talley (Sheffield)
Mr Nick Bown (Newcastle)
Dr Manual Teixeira (Oporto, Portugal)
Dr Sheila O'Connor (HMDS, Leeds)
Ms Nicola Foot (London)

Molecular Rapid Aneuploidy (MRA) Joint EQA with Molecular Genetics (MG)

Mrs Kathy Mann (London)
Dr Ros Hastings (S.O, Oxford)

Mrs Cathy McConnell (Glasgow)
Dr Sandi Deans (MG S.O, Newcastle)

Microarray Pilot EQA

Mrs Nicole de Leeuw (Nijmegen, The Netherlands)
Mr Dom McMullan (Birmingham)

Mr Eddy Maher (Edinburgh)
Mr Björn Menten (Ghent, Belgium)

Steering Committee

Dr Tony Parkin (Chair, Nottingham)
Mr Eddy Maher (Deputy S.O, Edinburgh)
Mrs Sandra Birdsall (Cardiff, since Feb 2009)
Mrs Carolyn Campbell (Oxford)
Dr Sheila O'Connor (Leeds, since Dec 2008)
Dr Steven Richards (Leeds, until Sept 2008)
Mr Roger Mountford (NQAAP, Liverpool) or
Dr Fiona MacDonald (Birmingham) or

Dr Ros Hastings (S.O, Oxford)
Mr Paul Roberts (Secretary, Leeds)
Mrs Helen Dickinson (Leeds)
Mrs Sarah Ryley (London)
Dr Lorraine Gaunt (Manchester)
Prof Andrew Green (Dublin)
Mrs Val Davison (NQAAP, Birmingham)
Dr Sandi Deans (MG S.O, Newcastle)

CONTENTS

| Scheme report | Page No: |
|--|-----------------|
| 1. Introduction to the Scheme | 4 |
| 2. External Quality Assessment (EQA) distributions in 2008 | 4 |
| 3. Scheme participation | 4 |
| 4. Scheme submissions | 5 |
| 5. Performance scoring | 5 |
| 6. Scheme personnel | 6 |
| 7. Changes to the Scheme for 2009 | 6 |
| 8. Scheme finances | 7 |
| 9. CPD | 7 |
| 10. Scheme presentations | 7 |
| 11. Participants' meeting | 8 |
| | |
| Appendix A | |
| Final summary reports scores | 9 |
| • Blood | |
| • Amniotic Fluid | |
| • CVS | |
| • Urgent Bloods | |
| • MRA(constitutional) | |
| • CML | |
| • MDS | |
| • ALL | |
| • Solid Tumours | |
| • Lymphoma and LPD | |
| | |
| Appendix B | |
| Appeals by year, EQA and outcome | 11 |

1. Introduction to the Scheme

The National External Quality Assessment Scheme (NEQAS) for Clinical Cytogenetics is a member of the UK NEQAS Consortium. The Scheme had an accreditation inspection under the new CPA guidelines (ILAC 43) in November 2006. The Scheme has been accredited with CPA (UK) Ltd since July 2007. The Scheme received a further full accreditation inspection in November 2008.

The annual management review for the 2008 EQA seasons was completed in April 2009 and a summary report sent to the CPA office. The annual management review will be reviewed by the Steering Committee in July. Quality objectives for 2009 have been set and are available on request.

For further information about the Clinical Cytogenetics Scheme please contact the Scheme Organiser (ros.hastings@orh.nhs.uk) or visit the Scheme web site at www.cneqas.org.uk or via the UK NEQAS web site, www.ukneqas.org.uk

2. External Quality Assessment (EQA) distributions in 2008

The EQA assessments consider **technical, analytical and interpretive performance**

- Technical proficiency tested via submitted slides and DNA samples;
- Analytical proficiency tested via validated slides and online EQA;
- Interpretive proficiency tested via case scenarios and retrospective external audit of reports on work undertaken in diagnostic laboratories.

2.1 Constitutional Scheme

In 2008 there was a single distribution for the following EQAs –

- Amniotic fluid (retrospective reports)
- CVS (online)
- Blood (online)
- Urgent Bloods (slide distribution)
- Molecular Rapid Aneuploidy (MRA) (DNA distribution)

2.2 Haematological Scheme

In 2008 there was a single distribution for the following EQAs -

- CML (slide distribution)
- AML (retrospective reports)
- ALL (online)
- Tumour (case scenario)
- Lymphoma & LPD EQA (online)

2.3 Pilot EQA Schemes

- Microarray EQA
The online Microarray pilot involved the analysis of data from one case. 26 laboratories participated in this pilot.

3. Scheme participation

In 2008, 96 laboratories participated in the scheme; 36 UK cytogenetic laboratories, 4 UK haematology or histopathology laboratories and 56 non-UK cytogenetic laboratories. The haematology and histopathology laboratories participate in either the Lymphoma and LPD EQA or the Solid Tumour EQA. A total of 443 EQA distributions were sent out by the scheme office and more than 900 cases were assessed. UK cytogenetic laboratories participated in an average of 7 EQAs while non-UK laboratories participated in an average of 3 EQAs.

4. Scheme submissions

- Fewer laboratories failed to remove their laboratory identification on the reports or referral cards this year.
- For non-UK labs:- Interpretation of a cytogenetic result is an essential part of the diagnostic report. In this EQA scheme, laboratories must submit an interpretation with the report. If the interpretation is routinely done by a clinician or Clinical Geneticist in your department, please (a) involve them when completing the case online and (b) submit a copy of the clinician's or Clinical Geneticist's letter with the retrospective reports.
- UK NEQAS for Clinical Cytogenetics does not determine the Professional Guidelines. The ACC Professional Standards Committee (UK), CPA UK Ltd and other European or International bodies (e.g. ECA, ISO standards, ISCN, leukaemia trial studies) produce the guidelines and standards. UK NEQAS for Clinical Cytogenetics has referred issues arising out of the EQA rounds to the ACC Professional Standards Committee and the ISCN Committee in the past and will continue to approach the professional organisations if additional guidance/clarification is required
- UK NEQAS marks the laboratory submissions against its interpretation of these guidelines/standards. If you have issues in the way the guidelines/standards have been interpreted by UK NEQAS please submit them to the Scheme Office through the appeals process.

4.1 ISCN 2009

- Laboratories will be expected to use ISCN 2009 in all their reports from April 2010. Prior to this date laboratories will be marked against ISCN 2005 and only against ISCN 2009 if this nomenclature was submitted by the laboratory.

5. Performance scoring

In accordance with the performance criteria, the standard for all laboratories to reach is satisfactory (CPA (EQA) Standards E5 and F5). The laboratories' performance scores (after completion of the appeals process) for the 2008 constitutional and haemato-oncology EQA schemes are given in Appendix A.

5.1 Consistency across the Scheme

The Scheme tries to be consistent between EQA schemes and across both constitutional and haemato-oncology areas but inconsistencies sometimes occur (see slight differences in the marking in the constitutional and haemato-oncology cytogenetics performance criteria). The complexity of haemato-oncology karyotypes and presence of small side-lines is taken into account when marking the Haemato-Oncology Scheme.

In addition, joint EQAs may sometimes identify inconsistencies in reporting, for example Molecular Rapid Aneuploidy results between Cytogenetic depts and Molecular Genetic depts.

5.2 Appeals

The performance criteria (v3.1) were used to assess all the EQA rounds and pilots this year. There were 35 appeals to the Scheme, of which 12 were upheld, 2 were partially upheld and 18 were not upheld. The remaining three appeals were due to clerical errors that were rectified. A review of the outcome of appeals for the last three years was undertaken for the Steering Committee. CVS and MRA are the tissue types with the highest number of appeals. MRA and the online EQAs have a disproportionate number of appeals not upheld. Over the last 3 years there have been a total of 82 appeals, 35% of appeals were not upheld; 33% were upheld; 15%

were partially upheld and 17% were clerical errors. The breakdown of some of these data is given in Appendix B.

5.3 Poor performance

A zero mark in the analytical or interpretative score will automatically result in poor performance (see Performance Criteria). Poor performance can also occur if the laboratory accumulates four or more penalty points. Since Autumn 2007, non-UK laboratories with a poor performance are requested to review their reporting policy and no obligatory additional EQA rounds are sent.

Solid Tumours was the only EQA where there were no instances of poor performance this year. A total of 18 different laboratories received a poor performance in the 2008 EQAs. In addition, six non-UK laboratories failed to participate in the EQAs for which they had registered for and were therefore automatically given a poor performance (see Appendix A and Performance Criteria).

5.4 Persistent poor performance

One non-UK laboratory received a persistent poor performance designation; two non-UK laboratories with continued persistent poor performance were referred to the Steering Committee.

6. Scheme personnel

- **Scheme Organiser:** Dr Ros Hastings was appointed in June 2003.
- **Deputy Scheme Organiser:** Mr Eddy Maher was appointed in November 2003.
- **Quality Manager:** Bettina Quellhorst-Pawley was appointed in October 2005. Bettina is also the CEQA (European Cytogenetics EQA) QM/administrator.
- **Steering Committee:** Sheila O'Connor replaced Steve Richards as the BSH representative in December 2008. Sandra Birdsall joined the Steering Committee in February 2009, replacing Mike Griffiths.
- **Steering Committee Executive:** Consists of the Chair, Scheme Organiser, Deputy Scheme Organiser, Secretary and a senior cytogeneticist specialising in haemato-oncology (Helen Dickinson) from the Steering Committee.

6.1 Assessors –

The Scheme is keen to recruit new assessors for 2009/10, as some assessors are completing their term of office. UK assessors normally have part 1 of the FRCPath and non-UK assessors are normally recognised experts with 10 years experience in their specialist area. Potential assessors need to send a brief curriculum vitae to the Scheme Office (ros.hastings@orh.nhs.uk) in the first instance. All assessor appointments will be ratified by the Steering Committee.

7. Changes to the Scheme for 2009

7.1 Constitutional Scheme –

Solid Tissues will replace the Urgent Blood EQA.

Molecular Rapid Aneuploidy (MRA) will run in the AUTUMN EQA season in collaboration with UK NEQAS for Molecular Genetics (it has previously run in the Spring season). There will be a single distribution of 3 cases.

7.2 Haemato-Oncology Scheme –

MDS will replace the AML EQA.

7.3 Microarray

The pilot will involve a questionnaire and one DNA sample to analyse and report.

7.4 Laboratory codes

Please use your unique laboratory code in all communications with the Scheme (including emails).

7.5 Future Developments to Management System (QA Manager)

The static website has been updated with the 2009 timetable and participants' manual for 2009.

For assessors the 'print all' facility for laboratory submissions (saving all documents to the assessor's computer as zip files) should be available by May 2009.

7.6 EQA structure and format

- Details of all EQAs are available online (download document under diary).
- All EQAs involve submission of documentation or analysis online. In addition, the slide distribution EQAs will require laboratories to submit slides via the post; MRA will involve analysis of DNA samples; the Lymphoma & LPD EQA will involve an online case plus FISH analysis of a cell suspension sample.
- All EQA summary letters will include the range of actual scores, so laboratories can see how their performance compares with other laboratories. The standard that should be obtained is 'satisfactory'.
- UK laboratories receiving additional EQA rounds following a poor performance will be charged an additional fee of £100 to cover the increased administration costs. Non-UK laboratories will be notified by letter of any poor performance.
- Laboratories have 15 working days to appeal against any penalties/comments in their individual laboratory reports.
- Three new UK Assessors will be involved in the MDS, CML and CVS EQAs this year. They are Sian Morgan (Cardiff), Amy Logan (Belfast) and Markella Mikkelsen (Manchester). There are now 7 non-UK and 20 UK assessors (including the MRA assessors), excluding the Scheme Organiser.

8. Scheme finances

The financial position of the Scheme is a standing item on the agenda at the annual participants' meeting. The fees were increased for 2009. Laboratories who provide assessors for the Scheme receive a credit of £100 per assessor on their invoice for 2009.

9. CPD recognition for activities within the Scheme

Scheme-based activities performed by the Assessors are accredited by the Royal College of Pathologists for CPD (minimum 6 CPD credits).

10. Scheme presentations

The Scheme Organiser or Quality Manager for UK NEQAS for Clinical Cytogenetics have given presentations on quality issues at the following meetings:-

- ACC Spring Meeting, London, April 2008 (RJH)
- Reference Materials Symposium, Geel, April 2008 (RJH)
- Eurogentest Steering Meeting, Rome, May 2008 (RJH)
- ESHG Conference, Barcelona, June 2008 (RJH)
- Participants' Meeting, London, June 2008 (BQP & RJH)
- Eurogentest (Unit 1) Board Meeting, Leuven, September 2008 (RJH/BQP)

- Microarray workshop, Leuven, September 2008 (RJH)
- Italian Cytogenetic Laboratories Meeting, Florence, October 2008 (RJH)
- UKNEQAS Scheme Organisers Annual Meeting, Birmingham, October, 2008 (RJH, BQP)
- 5th Forum Meeting of national EQA providers, Madrid, October 2008 (RJH/BQP)
- Eurogentest General Assembly and Steering Meeting, Leuven, November 2008 (RJH/BQP)

In addition, there was a UK NEQAS stand at the BSHG Conference in September 2008.

The ACC Spring meeting, participants' meeting and the microarray workshop expenses as well as travel expenses for the BSHG conference were met from UK NEQAS income. Conference fees and travel expenses for the other meetings were met from other income sources.

11. Annual Participants' Meeting

The next participants' meeting will be held on **Tuesday 28th April 2009 during the ACC Spring Conference**. This meeting is open to all staff.

In response to feedback from participating laboratories, the whole day meeting will be held biennially.

Appendix A
CONSTITUTIONAL SCHEME
PERFORMANCE SCORES

BLOODS

| | |
|----------------|----|
| Satisfactory | 51 |
| Poor | 3 |
| Non submission | 3 |
| Total | 57 |

AMNIOTIC FLUID (AF)

| | |
|----------------|----|
| Satisfactory | 49 |
| Poor | 1 |
| Non submission | 3 |
| Total | 53 |

CHORIONIC VILLUS (CVS)

| | |
|----------------|----|
| Satisfactory | 32 |
| Poor | 5 |
| Non submission | 1 |
| Total | 38 |

URGENT BLOOD

| | |
|-----------------------|----|
| Satisfactory (>16/20) | 32 |
| Poor (\leq 16/20) | 1 |
| Total | 33 |

MRA

| | |
|----------------|-------------------------------------|
| Satisfactory | 22 |
| Poor | 3 |
| Non submission | 1 |
| Total | 26 (excludes the 15 molecular labs) |

HAEMATO-ONCOLOGY SCHEME
PERFORMANCE SCORES

CML

| | |
|----------------|----|
| Satisfactory | 45 |
| Poor | 1 |
| Non submission | 1 |
| Total | 47 |

AML

| | |
|----------------|----|
| Satisfactory | 42 |
| Poor | 2 |
| Non submission | 1 |
| Total | 45 |

ALL

| | |
|--------------|----|
| Satisfactory | 42 |
| Poor | 5 |
| Total | 47 |

SOLID TUMOUR

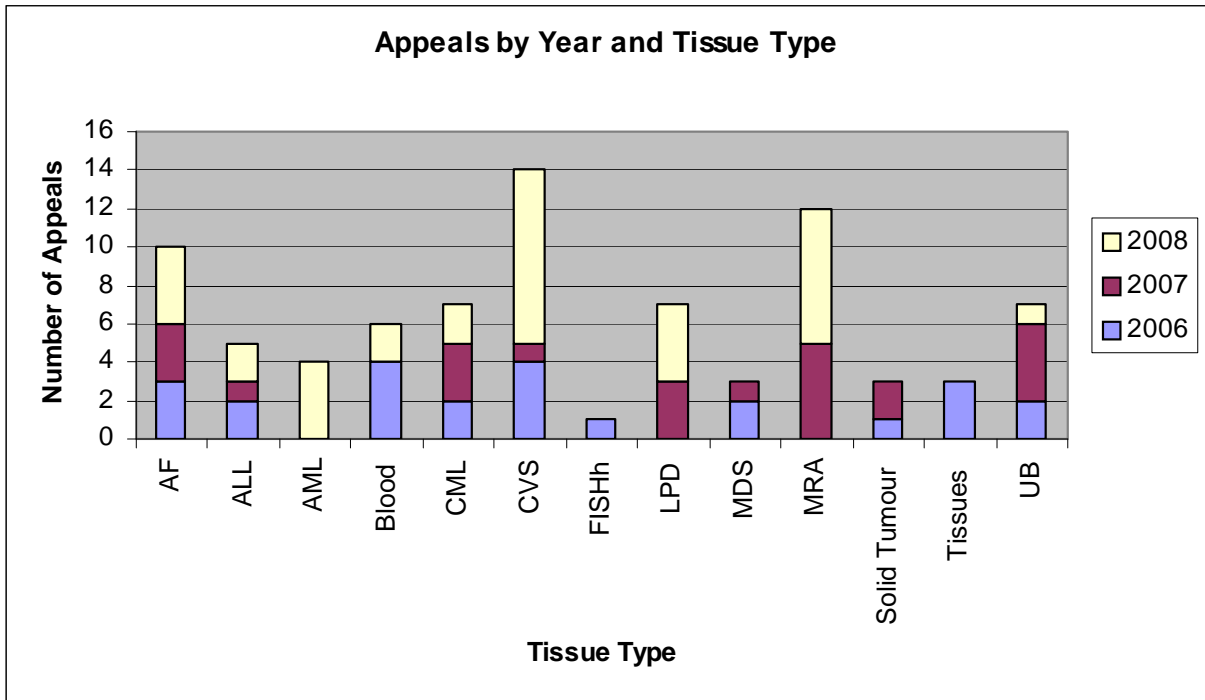
| | |
|----------------|----|
| Satisfactory | 22 |
| Poor | 0 |
| Non submission | 0 |
| Total | 22 |

LYMPHOMA and LPD

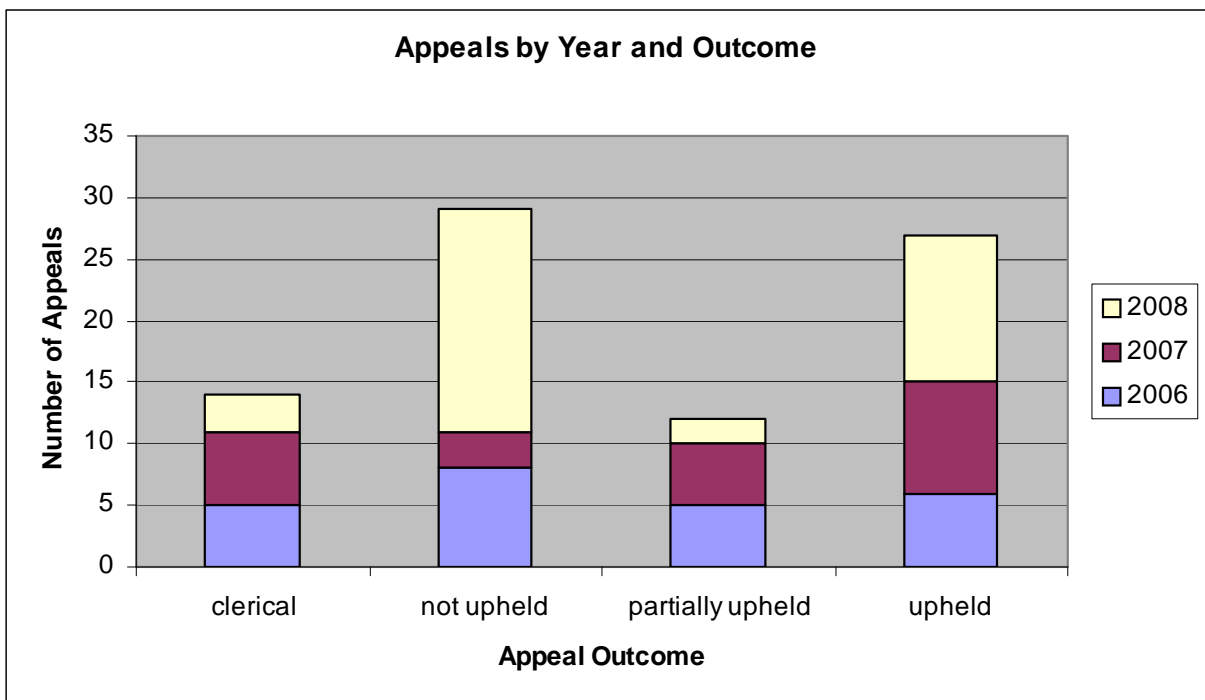
| | |
|-----------------------|-----------|
| Satisfactory | 39 |
| Poor | 2 |
| Non submission | 0 |
| Total | 41 |

Appendix B

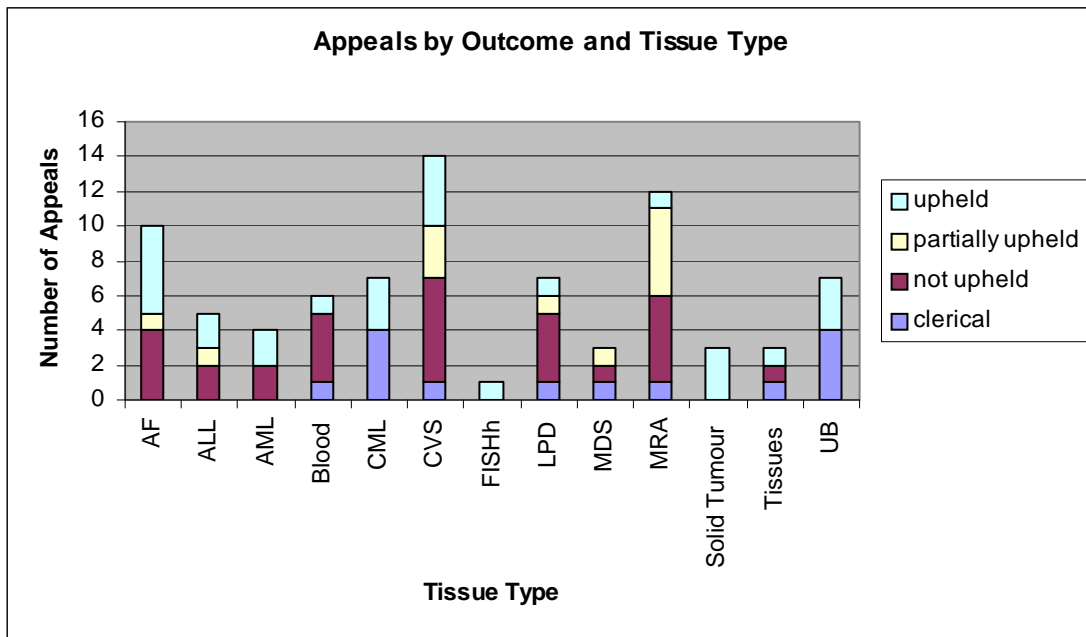
Appeals by Year and Tissue Type



Appeals by Year and Outcome



Appeals by Outcome and Tissue Type



Appeals by Outcome and EQA type

