ANDROLOGY EQA SCHEMES

Department of Reproductive Medicine
Andrology Laboratories
Central Manchester University Hospitals NHS Foundation Trust
Department of Reproductive Medicine
Old St Mary’s Hospital
Oxford Road
Manchester
M13 9WL

ANNUAL REPORT

2010-2011

Tel No: 0161-276-6437  Non UK: +44-161-276-6437
Fax No: 0161-276-6609  Non UK: +44-161-276-6609

Scheme Organiser: Mr. Greg Horne
Scheme Manager: Mrs. Kathy Cumming
Scheme Administrator Mrs. Diane Shearden
Quality Manager Miss. Justine Hartley
Training Officer Mrs. Anne McEwen
Health and Safety Officer Mr. Peter Goddard

Email: gregory.horne@cmft.nhs.uk
       kathy.cumming@cmft.nhs.uk
       andrology@ukneqas.org.uk
Progress Report 2011

Dear Colleague

The Andrology external quality assessment (EQA) schemes are now in their eighteenth year of operation under the umbrella of the UK National Quality Assessment Schemes (UK NEQAS).

The Andrology Steering Committee (ASC) meets twice a year to discuss the operation of the schemes and advise the Scheme Organiser on future developments.

The National Quality Assurance Advisory Panel for Andrology (NQAAP) meets twice a year, actively working to promote quality in Andrology both within the scheme and at a national level.

The Scheme retained its CPA accreditation this year.

The scheme was represented at Fertility 2011 in Dublin and the Association of Biomedical Andrologists’ Annual General Meeting on the 22nd of April 2010 in Nottingham.

We are continuing to contact distributors outside the UK to see if we can expand the Scheme throughout Europe and further. Laboratories in South Africa, Spain, Italy and United Arab Emirates have now enrolled and information has been requested by Lebanon, and Belgium.

Participants of the scheme are welcome to make comments and suggestions at any time and, in fact, many people do contact us. Any feedback is always welcome and is reported to the ASC to help us to continually develop and, hopefully, improve the schemes.

Following the success of the one-day practical sessions started in 2000 these have been repeated this year. Again they were all fully booked and feedback from those who attended was very good. These sessions will continue whilst there is demand.

Ongoing changes include:

- The introduction of the online pilot sperm morphology as part of the Scheme.
- Working towards online registration for meetings, training days etc.

We are all very excited about the future running of the scheme – watch this space!
Please can I draw your attention to the Conditions of Participation (COP) (Appendix 1). As a member of the Andrology scheme it is assumed that you have read and accepted the COP in full.

Finally, I would like to remind participants that it is not within the NEQAS scheme remit to endorse or discredit any method used to perform sperm concentration, motility and morphology. It is the responsibility of the individual laboratory to validate any changes within their own methodology.

With best wishes

Mr. Gregory Horne B.SC., M.Sc. F.R.C.Path
Scheme Organiser - Andrology EQA
Andrology Steering Committee (ASC)

Function

All established UK NEQAS’s are supported by advice from an appropriate UK NEQAS Steering Committee, accountable to the UK NEQAS Board. The Chairman is normally independent of UK NEQAS operational interests, and membership will include appropriate experts, participants and advisors. Chairmen and members are appointed by the UK NEQAS Board, on the advice of appropriate professionals, and sit in their own right and normally not as representatives of any professional or other group, though some may fulfil an invaluable liaison function with such groups. Steering Committees do not consider the performance of individual participating laboratories, except in advising on performance criteria or where this may indicate a failure in the operation of the Scheme (and even in such cases the laboratories will not be identifiable).

Remit

1. To advise the Scheme Organiser(s) on the overall design and operation of the Scheme(s), including aspects such as:
   - appropriateness of the investigations surveyed;
   - nature of the specimens distributed;
   - number and frequency of specimen distribution;
   - source of target values;
   - data analysis and performance assessment;
   - data presentation;
   - communication with participants, including meetings, newsletters, educational activities;
   - communication with the diagnostics industry;
   - research and development for the Scheme(s);

2. In consultation with the Scheme Organiser, to liaise with the relevant National Quality Assurance Advisory Panel in setting performance criteria.
3. To promote harmonisation, in scheme design and practice, with other UK NEQAS’s as appropriate.
4. To consider, and advise the Scheme Organiser(s) on, the need for initiation or termination of EQA services for investigations in the area covered.
5. To review Schemes’ annual reports.
6. To receive any representations, to Chairman, members or Organiser, from participants concerning the Schemes.
7. To advise the UK NEQAS Board, and where appropriate other relevant organisations (e.g. Department of Health, Joint Working Group on Quality Assurance, CPA (UK) Ltd, Medical Devices Agency, Royal College of
Pathologists), on any aspect of EQA or quality assurance in the area covered.

The Organiser ensures that notes and reports from the ASC are reported directly to the UK NEQAS office. The ASC meets formally at least twice a year and the Scheme Organiser and Manager keep in touch with members when the occasion demands this, particularly the Chair.

Membership of the ASC 2010/2011

1. Chair: Dr. Allan Pacey  
   Senior Lecturer in Andrology, University of Sheffield.

2. Deputy Chair: Mr. Alan Webster  
   Chief Biomedical Scientist, Wythenshawe Hospital, Manchester.

3. Mrs. Beverley Duffy  
   Senior Biomedical Scientist, Whiston Hospital, Merseyside.

4. Mrs. Trudy Johnson  
   Departmental Manager, Queen Elizabeth Hospital, Gateshead.

5. Dr. D. Iwan Lewis-Jones  
   Senior Lecturer and Consultant Clinical Andrologist, Reproductive Medicine Unit, Liverpool Women’s Hospital.

6. Dr. Kevin Lindsay  
   Principal Clinical Scientist in Andrology, Hammersmith Hospital, London.

7. Dr. Diane Critchlow  
   Principal Embryologist, St Mary’s Hospital, Manchester.

8. Dr. Debbie Falconer  
   Principal Clinical Embryologist, Manchester Fertility Services Ltd, Bridgewater Hospital, Manchester.

9. Mr. Paul Hancock  
   Head of Andrology, Somerset Pathology Services, Yeovil District Hospital.

Organisations represented by members of the Steering Committee.

- Association of Biomedical Andrologists (ABA)
- Association of Clinical Embryologists (ACE)
- British Andrology Society (BAS)
- European Society for Human Reproduction & Embryology (ESHRE)
- Institute of Biomedical Science (IBMS)
National Quality Assurance Advisory Panel for Andrology (NQAAP)

Function

The NQAAPs are professional groups which have executive responsibility for maintaining satisfactory standards of analytical and interpretative work in laboratories in the UK, whether in the private or in the public sector, in which investigations are performed for the detection, diagnosis or management of disease in humans. The Royal College of Pathologists, the Institute of Biomedical Science and two or three other appropriate professional bodies each nominate one member, who normally serve for four years. The Chairperson of each of the Panels reports to the Joint Working Group on Quality Assurance.

The Panels work closely with the Organisers of the relevant UK NEQAS and other approved EQA schemes, who bring to their attention laboratories whose performance and/or frequency of returns are judged unsatisfactory by criteria agreed by the Panels with the appropriate Steering Committee. At this stage the Panels identify the laboratory only by code. A Panel reviews information provided by the Organiser and if it decides to intervene in the case of a particular laboratory, the Chairman writes a 'Dear Colleague' letter, which is forwarded to the laboratory by the Organiser. This asks about problems which have been identified and remedial action taken and offers to provide help and advice. Recipients are assured of the professional relationship which exists between the Panel and participants and are invited to disclose their identity when they reply. If a participant remains anonymous, choosing not to disclose their identity to the Panel Chairman, and the poor performance continues, the Panel Chairman will then ask the Organiser for the address of the laboratory. The Panel Chairman will then communicate directly with the Head of Department.

Terms of reference and membership

1. NQAAP are responsible to the pathology professions and the Health Departments for monitoring the maintenance of satisfactory standards of laboratory performance in the United Kingdom, whether in the private or public sector.
2. Their members are nominated by the Royal College of Pathologists, the Association of Clinical Pathologists and the Institute of Biomedical Science, as well as by specialist professional bodies, with the approval of the Joint Working Group. Members may be co-opted subject to approval by the Joint Working Group.
3. Panel Members' relationship with scheme participants is professional, and information obtained regarding performance in EQA schemes is strictly confidential within the JWG/Panel/Scheme Organiser's network.
4. Panel Members are accountable to the professions through the Joint Working Group.
Remit

1. To be responsible for monitoring the maintenance of satisfactory standards of laboratory performance in the United Kingdom, whether in the private or public sector.

2. For Histopathology, Cytopathology, Cytogenetics, and Molecular Genetics, to consider appropriate EQA Schemes for approval for the time being, until alternative arrangements acceptable to the professions and DH have been agreed.

3. To relate to approved EQA Schemes. This will involve appointing a designated Panel member to act as a 'link person' on the Steering Committee of the Scheme or group of Schemes. Scheme Organisers must report to the Panel on performance matters and may be invited to attend when appropriate.

4. To approve the criteria for satisfactory and unsatisfactory performance in relevant EQA Schemes and to review these criteria from time to time, to ensure that the Schemes achieve their aims and reflect good laboratory practice.

5. Where regional schemes exist, to promote co-ordination among such schemes.

6. To inform participating laboratories when their performance persistently falls below that considered to be acceptable and to offer advice, appropriate assistance and support. The Panel's relationship with the participants in a Scheme is strictly professional and is governed by the guidelines drawn up by the Joint Working Group.

7. To ensure that, where there is clear evidence of a problem with a 'product' in general use (kit, instrument, reagent etc), the Medical Devices Agency of the department of health is informed in the first instance by the Scheme Organiser.

8. To report annually (or more often if necessary) to the professions directly and to the Joint Working Group on Quality Assurance, on the effectiveness of the advisory machinery and on problems arising out of the operation of EQA Schemes.

The Joint Working Group (JWG) on EQA set up a NQAAP for Andrology in 2003. The panel meets every 6 months. Membership is usually granted for 4 years.
Membership of the NQAAP for Andrology

Chair Dr. Kevin Lindsay  
Association of Clinical Biochemists  
Dr. D. Iwan Lewis-Jones  
British Andrology Society  
Mr. Alan Webster  
Institute of Biomedical Sciences  
Dr. Paul Bishop  
Royal College of Pathologists  
Mrs. Joanne Adams  
Association of Biomedical Andrologists  
Dr. Rachel Gregoire  
Association of Clinical Embryologists

Unsatisfactory Performance

We continue to alert laboratories as soon as a distribution falls outside the accepted criteria or they fail to return any results. In the last 3 distributions we have sent out 139 emails to first and second time ‘offenders’. Although it increases our workload most laboratory managers tell us it is helpful to be alerted to any problems at an early stage.

Persistent Unsatisfactory Performance

A laboratory is considered to be a persistent unsatisfactory performer for a given technique if:

- The cumulative performance is outside the prescribed limit on three distributions within the last 8 distributions;
  or
- It fails to return results for two distributions within the last 8 distributions, without notifying the UK NEQAS Centre of a change in participation;
  or
- A combination of both.

For UK laboratories this is followed up in accordance with the Conditions of Participation (Appendix 2).

During this year there have been 63 letters sent to laboratories advising them that they are persistent unsatisfactory performers and also 24 letters sent referring laboratories to the NQAAP, some of which will have then been contacted by the Chair of the panel.
Participation

UK NEQAS services are designed principally for UK NHS or Private Clinical Laboratories. Participation is however open to Research, Industrial and non-UK Laboratories. Enrolment can take place at any time. Current charges are available on request.

January 2011 Membership by Discipline:

<table>
<thead>
<tr>
<th>Discipline</th>
<th>Participants</th>
</tr>
</thead>
<tbody>
<tr>
<td>Andrology</td>
<td>22 participants</td>
</tr>
<tr>
<td>Haematology</td>
<td>21 participants</td>
</tr>
<tr>
<td>Histology/Cytology</td>
<td>52 participants</td>
</tr>
<tr>
<td>Microbiology</td>
<td>45 participants</td>
</tr>
<tr>
<td>Other Pathology</td>
<td>39 participants</td>
</tr>
<tr>
<td>Reproductive Medicine/Assisted Conception</td>
<td>89 participants</td>
</tr>
<tr>
<td>Unspecified</td>
<td>26 participants</td>
</tr>
</tbody>
</table>

Distributions

The Andrology Scheme has a quarterly distribution frequency. The dates for all distributions are set each year in advance and if samples are not received by the due date, the responsibility has to lie with each laboratory to let us know.

Distribution Dates for 2010/11

- 17th of May 2010,
- 16th of August 2010,
- 15th of November 2010,
- 14th of February 2011.

Sperm Concentration

January 2011 counting chamber use:

- Improved Neubauer 205 participants
- Makler 58 participants
- Microcell 6 participants
- Horwell 4 participants
- Leja 6 participants
- Various others 18 participants
Morphology Assessment

January 2011 Morphology criteria used:

- WHO Manual (1999) 209 participants
- WHO Manual (1992) 2 participants
- Strict 39 participants
- In house 8 participants
- Enrolled for information only 35 participants

Reports are presented as histograms and each unit’s result is shown as a figure and also indicated by an arrow on the graph. Different methodologies are listed and the shaded area on the graph indicates all the units using the same as the one to whom the report relates. There are a number of statistical values quoted on reports. These relate to individual specimen reports. There are also graphs that relate to performance over 6 distributions. Explanations for the derivation of values and examples of format are available in the Participants’ Handbook.

Sperm Motility Assessment

External quality assessment of this important aspect of semen analysis is difficult to organise. Live gametes are likely to deteriorate during distribution of samples. In 2005 we introduced the option of DVD instead of videotape and this has proved very popular. Although this does not allow motility assessment to be performed under routine conditions, we have not yet devised an alternative arrangement.

Furthermore, we proposed that participants used the WHO assessment methods in order to make analysis and presentation of the results possible. Obviously this is not ideal, since EQA should reflect the routine methods used in a participating laboratory. Nevertheless, one of the primary aims of the EQA scheme is to promote standardisation in laboratories by recommending use of methods proposed by the WHO 1999\(^1\). The motile sperm are graded as rapid, sluggish, non-progressive or immotile. Examples of the report format can be found in the Current Participants’ Handbook.

At present designated values are calculated from the mean of each motility category, rather than results from reference laboratories, but, as with the other schemes, setting of designated values remains a permanent agenda item for the ASC. In the report format running graphs, the progressively motile sperm (i.e. rapid and sluggish) form one graph and the non-progressive and immotile form the other. Explanations for the derivation of values and examples of format are available in the Participants’ Handbook.

Annual Participants' Meeting 9th March 2011

The Annual Participants’ meeting was again held at the Hulme Hall Conference Centre, Manchester University. The meeting was well attended and a full analysis of the feedback sheets will be described in next year’s Annual Report. The meeting was in the usual format of formal lectures in the morning followed by seminar type discussion groups in the afternoon. The programme was as follows:

**PROGRAMME**

09-00  Registration and Coffee

09-30  Introduction - Overview and Progress Report
       Greg Horne

09-45  ‘The Assessment and Treatment of the Infertile Male in 2011’
       Kevin McEleny

10-30  ‘The Male Pill: nearly there or never never land?’
       Professor Richard Anderson

11-15  Coffee / Tea

11-45  Does Sex Matter
       Angela Gregory

12-30  Lunch

13-30  New Reports Format
       Finlay Mackenzie

14-00  ‘What’s unusual about azoospermia? Interesting case studies.’
       Sue Kenworthy

14-15  Hypersensitivity in Human Semen
       Dr Michael Carroll

14-30  WHO update
       Dr Allan Pacey, Dr Kevin Lindsay & Dr Con Mallidis

Open Forum - Chair: Dr Allan Pacey

16-00  Close
Introduction - Overview and Progress Report

Mr. Greg Horne  
NEQAS Scheme Organiser

Membership of the Andrology scheme has now leveled off in the UK. Semen Analysis (concentration and morphology) and Sperm Motility were combined into one Scheme on the 1st of April 2009. The total number of units in the Scheme stands at 296 (approximately 20-30% of participants are from abroad - Argentina, Germany, Iran, Israel, Italy, Nigeria, Portugal, South Africa, Southern Ireland, Switzerland, United Arab Emirates). At present we use distributors in Israel, Switzerland, Portugal and South Africa.

Please note if there is a part of the merged scheme that is not routinely performed in your laboratory (e.g. morphology) you must inform the Scheme Manager who will record the information.

Accuracy and comparability between and within laboratories are the prime objectives of Quality Assurance and Quality Control and it is gratifying to see that a large majority of participants are able to produce results consistent with designated values on a regular basis. Where there are problems scheme staff are available to offer support and advice and generally this is well received by participants. In cases of persistent poor performance a referral to the NQAAP is made.

A further 6 practical one-day training sessions were offered in 2009/10. They were again fully booked and feedback from those attending was excellent. We will continue to offer these courses as long as there is demand.

The response to the questionnaires from last year’s Participants’ Meeting was 76%, which is great as this feedback can alter the make up of the next meeting. It was requested that this year should include presentations on WHO changes to the ‘Gold Book’ and environmental impact on sperm counts. 95% of participants who returned the questionnaires were happy with the content of the day.

After 14 years of being the Manager of the NEQAS Andrology Scheme, Kathy is stepping down. Without her, my life as Organiser would have been impossible. I and all the staff involved with the scheme would like to thank her for all the time, patience and knowledge passed on from her to the scheme participants. Pete Goddard has got the unenviable task of trying to fill her shoes. Not an immediate problem as Kathy has size 4 shoes and Pete has size 11!

For administration purposes please refer/contact andrology@ukneqas.org.uk. For any urgent matters please refer/contact kathy.cumming@cmft.nhs.uk or gregory.horne@cmft.nhs.uk
‘The Assessment and Treatment of the Infertile Male in 2011’
Kevin McEleny
The Newcastle-upon-Tyne Hospitals NHS Trust

IVF/ICSI has revolutionised the care of infertile couples, but much remains unknown about the specific causes of male infertility and it remains to a large degree a taboo subject in society. This presentation will discuss contemporary practice in the management of male infertility, with an emphasis on the investigation and treatment of azoospermia/severe OAT.

‘The Male Pill: nearly there or never never land?’
Professor Richard Anderson
University of Edinburgh

Male contraception is enormously widely used but there have been no significant advances for decades. The absence of reversible effective hormonal methods contrasts sharply with the pharmacological and technical developments that have made a wide range of hormonal methods so beneficial to women. A hormonal male method has, however, been investigated for some 40 years with early studies showing that sperm counts could be suppressed to zero in many men rapidly and reversibly by the administration of supraphysiological doses of testosterone. Subsequent refinements demonstrated that progestins are also very potent gonadotrophin suppressors in men as in women and, over the last 20 years many studies have been carried out refining this approach. Landmark studies were carried out by WHO 20 years ago which demonstrated that a prototype hormonal male method could achieve good contraceptive efficacy. The data available, however, indicated that some men are more resistant to suppression than others, the basis for which is as yet unclear. Differences in 5-alpha-reductase activity and androgen receptor CAG repeats have been postulated. Recent studies have used the newer long acting testosterone preparations in combination with a long acting progestogen. WHO has a contraceptive efficacy study underway using this approach with norethisterone enanthate combined with testosterone undecanoate, both given by injection at eight week intervals. The field has markedly suffered from minimal input from industry and, although, there was some industrial input a few years ago this has now been withdrawn. It remains in the balance, therefore, whether a hormonal method will become available in the foreseeable future despite the willingness of a significant proportion of men and their partners to use such methods and the clear contraceptive efficacy that can be achieved.
‘Does Sex Matter’
An overview of Male and Female Sexual Dysfunction

Angela Gregory
Chandos Clinic
Nottingham University Hospital Trust

For some men and women Sexual Dysfunction can be the primary cause for their difficulty in starting a family and some will be referred to their local fertility clinic for medical intervention to help them have a child. An understanding of what these sexual problems are will be the focus of this presentation. It will also highlight the fact that sexual dysfunction in men and women can also result due to the stress some couples experience as they attempt to get pregnant and also as a consequence of the impact of childbirth itself.

New Reports Format

Finlay Mackenzie
Birmingham Quality
Scheme Organiser for the UK NEQAS for Thyroid Hormones

The UK NEQAS Birmingham Centre has a long-standing reputation as an innovator in the way that EQA schemes are designed, how statistical techniques are used to help describe performance and how this data can be displayed graphically.

The UK NEQAS Andrology Centre in Manchester has been using the ‘Wolfson Birmingham’ software for over 15 years. This was based around Birmingham’s ‘MRVIS’ approach to scoring, pioneered by Whitehead and Bullock in the 1980s. Birmingham now uses the ‘ABC of EQA’ system, which superseded this, and since 2008 has added coloured symbols and a traffic light system to give Participants an easy to understand approach to their EQA performance.

Given the applicability of the ‘ABC of EQA’ approach for any EQA scheme, the UK NEQAS for Andrology wishes to take advantage of the progress that has been made over recent years and I present today the type of approach that might best suit the specialist areas of Sperm Motility and Semen Analysis.
‘What's unusual about azoospermia?
Interesting case studies.’

Sue Kenworthy
Portsmouth Hospitals NHS Trust

Sue Kenworthy joined Portsmouth Hospitals NHS Trust as the Lead Andrologist in 2006 following a long customer-focussed career in the private sector. At that time, as in most hospitals with an Andrology service, the majority of patients dropped off their samples and quickly hurried away.

A non-compliance in the 2007 CPA inspection stated that insufficient information was being gathered about aspects that could profoundly affect sperm quality. In addition, diagnosing the causes of infertility was less well handled by GPs; referrals to secondary care were often inappropriate and patients misinformed. Sue realised that patients were not receiving the best care and decided to become the patients’ advocate.

Since 2007, Sue has developed and refined a patient-centred, Biomedical Andrologist-led service that is considered by peers, GPs, Fertility Consultants and HFEA inspectors as current best practice. The service includes a patient/couple interview to collect not only information about the sample but a relevant clinical history. This enables a much more comprehensive interpretation of results and sperm characteristics and gives helpful advice, helping the clinician to follow up and refer the couple more appropriately. The service has formed the basis of Sue’s Professional Doctorate research project through the University of Portsmouth.

Sue will present several different case studies of azoospermic patients where the interview with the Andrologist helped a speedier and appropriate resolution of the situation for the patient (although sadly not always in the way that they’d hoped).

Hypersensitivity in Human Semen

Dr Michael Carroll
Central Manchester University Hospitals NHS Foundation Trust

Hypersensitivity to Human Semen (HSS) is a rare condition, which can be life threatening if misdiagnosed and untreated. Reports of HSS have been documented since the late 1950s and it is believed to be an IgE-mediated allergic (type I) reaction to specific components of the seminal plasma. Possible allergens are glycoproteins produced by the prostate. Women aged 20-30 years are most affected, displaying symptoms immediately or within 1 hour after contact with semen. Local reactions include itching, erythema and edema in the vulvar region, or other areas where semen has been in contact. Systemic reactions are experienced as dyspnea, dysphagia, rhinoconjunctival complaints,
generalized urticaria, angioedema, gastrointestinal symptoms, and exacerbation of existing atopic eczema and in severe reactions can cause anaphylactic shock.

The diagnosis of human seminal plasma allergy is based on history, demonstration of specific IgE antibodies in the serum and skin prick allergy tests. Therapeutic options include allergen avoidance by use of condoms, prescription of antihistamines and attempts at desensitization.

Three cases of HHS in women aged 19, 25 and 28 (referred to patient A, B and C respectively) were presented to the Dept of Reproductive medicine within an 18 month period. All three patients complained of symptoms such as itching, angioedema and a burning sensation in the vulvar / vaginal region.

Each patient attended the Regional IVF Unit at St. Mary’s Hospital, providing a semen sample from their respective partners. This semen sample was then prepared for an allergy skin prick test. The semen was fractionated into seminal fluid, a sperm pellet, clinical grade washed sperm; samples of the wash media and the density gradient used in the preparation was also supplied for the skin prick test. All three patients elicited an immune response to the semen samples, but were negative to the washed sperm.

W.H.O.Update
Dr Allan Pacey, Dr Kevin Lindsay & Dr Con Mallidis

Open Forum
Chair: Dr Allan Pacey

Thank you to all our speakers, workshop leaders and Steering Committee for making this day a success.
Training Days

Six semen analysis training days were held between April 2010 and March 2011. A total of 87 people attended and the feedback from those participating was positive.

Practical sessions covered sperm concentration, motility and morphology. Course manuals were supplied and staff were on hand to answer questions throughout the day. The training days were eligible for CPD points.

Requirements from people wishing to attend future courses are that they are:

1. Able to operate a microscope
2. Able to perform dilutions using automatic pipette.
3. Able to use a counting chamber.

Quality Report for NEQAS Steering Committee

Miss Justine Hartley
Quality Manager

Summary for NEQAS Andrology Annual Review 2010-2011

The Annual Quality Review includes: Summaries from the 2010 Annual Participants Meeting; 2009-2010 Annual Scheme Questionnaire; and Training Days during 2010. There is also information on participant comments and complaints to the scheme and Audits conducted.

The report is available online through the NEQAS Andrology webpage http://www.cmft.nhs.uk/directorates/ivf/neqas.asp. From this year the website also includes a Feedback Summary with NEQAS management responses to issues raised by participants’ from the previous years Scheme Questionnaire.

In 2010 Quality Control Charts relating to participant complaints in semen analysis and motility schemes have been implemented.
Another year; meandering thoughts of ABA chair by K S Lindsay

Kevin Lindsay – Chair.

It hardly seems possible that the 5th edition of the WHO manual recommending methods for semen analysis is over a year old. In addition to the changes in methodology new reference ranges are no doubt still causing some consternation. I am certainly aware that the introduction of these values can cause differences of opinion in users of laboratory services and result in uncertainty that can create patient complaints. I should of course be rather careful in the use of the word uncertainty. It is increasingly used in laboratory medicine in the sense of confidence in a measurement and in this regard we all need to be mindful. Establishing uncertainty of measurement is a CPA standard and as such a requirement for accreditation. Semen analysis is not different from other tests in pathology in this regard. In principle, all factors contributing to uncertainty need to be taken into consideration to give a degree of confidence in any result. On this basis although still controversial, weight rather than volume is recommended by WHO as a better method for semen analysis as the simplest way of minimising the uncertainty within semen profile. Even if your laboratory has a high degree of technical competence for counting sperm when multiplied by the an unreliable volume the resultant value will be of less merit when using reference values based on the total number of sperm in the ejaculate as recommended by WHO with an unreliable volume. The total number of sperm in the ejaculate must have greater relevance than sperm concentration alone. Measuring by weight is doable with a little thought and brings the potential of greater control over procurement yet does not seem to be wholeheartedly welcome. With the recent increase in the number of specialist Andrology CPA inspectors we should see improved standardisation in terms of laboratory assessment so now is the time to be looking at your methods in this regard, if you have not done so already, but we as a profession also need consensus.

On an entirely different topic, that is Modernisation of scientific careers. Like it or not MSC is with us but in two related but separate guises. Early ‘implementation’ of MSC is the introduction of the new training models. Curricula have been developed and Reproductive Healthcare Scientist information can be found within training for Cellular Science. For all disciplines, the new centrally funded scientists, sometimes know as ‘A’ grade trainees, are being recruited for this training through a DOH delegated single PCT as of January this year. Unfortunately there are, as yet, no accredited training programmes to match the curricula, which remains something of a challenge; however the existing training is considered the default position according to sources at the Department of Health. Practitioner training seems somewhat less developed and along with registration and the mechanism of ‘equivalence’ in terms of alternative training, it seems likely that critical details will be unclear for some time. Therefore, the time scale for this implementation and overlap with existing training is likely to be considerable. Not so, I fear for early adoption of MSC by the NHS. Some 20
NHS trusts have agreed to adopt MSC which will result in the scientific staff migrating to the new career structure at some point. The educationalists see this migration as theoretical and not affecting staff currently in post but only new appointments; however the accountants undoubtedly see the opportunity to bring forward a workforce configuration with the intent of cost savings at a faster pace. The futures is seen as fewer Chiefs and more Indians, but beware as the changes are not supposed to be another Agenda for Change although there is anecdotal evidence that some NHS managers may think that it is.

Lastly, but by no means least is training. The portfolio based semen analysis training is now well established. Due to the sterling work of the ABA Education group and others, it has recently been joined by other programmes covering sample preparation, sperm cryopreservation, donor banks and aspects of handling clients and patients. The new programmes have been recently been piloted and will soon join semen analysis with on-line logbooks available after registration. Anyone interested should contact the ABA via website or one of the executive.

As a final note, both as individuals and via the ABA if you prefer please take part in the current HFEA consultation about the use of donors.
Appendix 1:

**Joint Working Group for Quality Assurance : Conditions of EQA Scheme Participation**

The Joint Working Group for Quality Assurance (JWG) is a multidisciplinary group accountable to the Royal College of Pathologists for the oversight of performance in external quality assurance schemes (EQA) in the UK. Membership consists of the Chairmen of the National Quality Assurance Advisory Panels (NQAAPs), and representatives from the Institute of Biomedical Sciences, the Independent Healthcare Sector, the Department of Health and CPA (UK) Ltd.

1. The Head of a laboratory is responsible for registering the laboratory with an appropriate accredited EQA scheme.

2. The laboratory should be registered with available EQA schemes to cover all the tests that the laboratory performs as a clinical service.

3. EQA samples must be treated in exactly the same way as clinical samples. If this is not possible because of the use of non-routine material for the EQA (such as photographs) they should still be given as near to routine treatment as possible.

4. Changes in the test methodology of the laboratory should be notified in writing to the appropriate scheme organiser and should be reflected in the EQA schemes with which the laboratory is registered.

5. Samples, reports and routine correspondence may be addressed to a named deputy, but correspondence from Organisers and NQAAPs concerning persistent poor performance (red – see below) will be sent directly to the Head of the laboratory or, in the case of the independent healthcare sector, the Hospital Executive Director.

6. The EQA code number and name of the laboratory and the assessment of individual laboratory performance are confidential to the participant and will not be released by Scheme Organisers without the written permission of the Head of the laboratory to any third party other than the Chairman and members of the appropriate NQAAP and the Chairman and members of the JWG. The identity of a participant (name of laboratory and Head of Department) and the tests and EQA schemes for which that laboratory is registered (but not details of performance) may also be released by the Scheme Organiser on request to the Health Authority, Hospital Trust/Private Company in which the laboratory is situated after a written request has been received.

7. A NQAAP may, with the written permission of the Head of a laboratory, correspond with the Authority responsible for the laboratory, about deficiencies in staff or equipment which, in the opinion of the NQAAP members, prevent the laboratory from maintaining a satisfactory standard.
8. Laboratories’ EQA performance will be graded using a traffic light system; green will indicate no concerns, amber poor performance, red persistent poor performance, with black being reserved for the tiny number of cases that cannot be managed by the Organiser or NQAAP and that have to be referred to the JWG. The criteria for poor performance (amber) and persistent poor performance (red) are proposed by the EQA scheme Steering Committee in consultation with the EQA Provider/Scheme Organiser and approved by the relevant NQAAP.

9. When a laboratory shows poor (amber) performance the Organiser will generally make contact with the participant in accordance with the Scheme Standard Operating Procedure for poor performance. Within 2 weeks of a laboratory being identified as a persistent poor performer (red), the Organiser will notify the Chairman of the appropriate NQAAP together with a resume of remedial action taken or proposed. The identity of a persistently poor performing laboratory (red) will be made available to members of the NQAAP and JWG. The NQAAP Chairman should agree in writing any remedial action to be taken and the timescale and responsibility for carrying this out; if appropriate, this letter will be copied to accreditation/regulatory bodies such as CPA (UK) Ltd, UKAS and HFEA who may arrange an urgent visit to the laboratory. Advice is offered to the Head of the Laboratory in writing or, if appropriate, a visit to the Laboratory from a NQAAP member or appropriate agreed expert may be arranged.

10. If persistent poor performance remains unresolved (black), the NQAAP Chairman will submit a report to the Chairman of the JWG giving details of the problem, its causes and the reasons for failure to achieve improvement. The Chairman of the JWG will consider the report and, if appropriate, seek specialist advice from a panel of experts from the appropriate professional bodies to advise him/her on this matter. The Chairman of the JWG will be empowered to arrange a site meeting of this panel of experts with the Head of the Department concerned. If such supportive action fails to resolve the problems and, with the agreement of the panel of experts, the Chairman of the JWG will inform the Chief Executive Officer, or nearest equivalent within the organisation of the Trust or Institution, of the problem, the steps which have been taken to rectify it and, if it has been identified, the cause of the problem. The Chairman of the JWG also has direct access and responsibility to the Professional Standards Unit of the Royal College of Pathologists. Should these measures fail to resolve the issues, the laboratory will be referred to the Care Quality Commission for further action.

11. Problems relating to EQA Schemes, including complaints from participating laboratories, which cannot be resolved by the appropriate Organiser, Steering Committee or NQAAP, will be referred to the Chairman of the JWG.

Joint Working Group for Quality Assurance in Pathology, August 2010.