THE CLINICAL ADVISORY COMMITTEE ON DIAGNOSTIC IMAGING (CACODI)

SECOND MEETING, PORTCULLIS HOUSE, WESTMINSTER

7TH March 2007

Present:

- Professor Marshall, Acting Chair
- Dr John Giles
- Jim Thurston
- Dr Burling
- Dr Ian Gibson, MP
- Dr Sneh Khemka, BUPA (representing Peter Mace)

Apologies:

- Professor John Martin
- Dr Rodney Foales
- Dr Chris Steed
- Dr Jeremy George
- Dr Stuart Taylor
- Dr Peter Mace
- Dr Richard Evans
- Charlotte Atkins, MP

Correction to previous minutes (30.1.007)

Page 5.

Jim Thurston asked for the minutes to show the following change: His comment about poacher turned gamekeeper was with reference to the Radiation Protection Division of Health Protection Agency (previously known as the MRPB) which acts as both regulator and arbiter when bringing people to count.

Professor Marshall

Putting CACODI into context

CACODI is not in competition with COMARE or any other regulatory agency. It's purpose is to gather practical information and insights into the current issues effecting the private sector from individuals working in the private sector and feeding this into the current framework which is under review.

CACODI's remit in terms of regulations

- Inform the current regulatory agencies;
- Offer input into the existing framework that is currently under review;
- Gather individual opinion from specialists in the private sector about the current apparatus for policing this sector and the effectiveness of the HCC;
- Discuss problems, real and imagined, and gain a consensus of opinion about issues that need addressing, and the best method for doing so;
- Look at the whole area of screening, but in particular, regulations and compliance;
- Be proactive ahead of COMARE: ensue private specialists have a voice and guide implementation of changes by COMARE through appropriate discussion;
- Collaborate with COMARE to ensure a smooth transition to workable practises.

CACODI's remit in terms of training and accreditation

- CACODi is not seeking to set itself up as a training and accreditation body but bring a reality check to the review process
- Working in the laser eye arena for The All Party Parliamentary Committee on the safety of laser eye surgery in the UK, the advisory committee was able to help the Royal College of Ophthalmologists (RCO) avoid setting up an untenable position.
- The RCO had proposed that only ophthalmogists on the specialist registrar should be allowed to practice laser eye surgery.
- But the specialist registrar training programme had no module for laser eye training since it was conducted only in private practice.

- The Committee recommended that the College insert a specific training programme for laser eye surgery into its current training module, which didn't upset the 'grandfather's' and would be acceptable to a wider audience of ophthalmologists.

A question for CACODI to discuss:

Is there a case to set up a loose federation of independent screening centres, and individual radiologists within that sector, a 'collective voice' that would ensure it has a voice within the Royal College of Radiologists and the world at large.

Standards and Regulations

Dr John Giles

- In the private sector, CT has generated a bad reputation with the perception that is not regulated or controlled.
- Many of the concerns being aired in the UK today have been generated by what happened in the US.
- There have been many technological advances and it is gathering huge evidence based benefits, but the science must be used in the right situation and setting.
- CACODI needs to expose false perceptions and appropriately educate and inform people

The group were broadly happy with the safety standards and current UK regulations.

Training and Accreditation

David Burling

- There is a strong need for reviewing the training and quality controls within the area of CT colongraphy.
- Within the College of Radiologists there is little communication and understanding of the new technology and the benefits it can bring.
- CACODI needs to bring leadership to the debate, and help set and guide the agenda.
- Currently there is no regulatory audit system whether in the NHS or private sector.

Jim Thurston

- In Germany every patient undergoing an exposure to radiation has an individual diary, which assesses his or her radiation load over a period of time.
- Currently in the UK there is no model for this.

David Burling

- There is a compelling case for screening for colon cancer, and later this year, a National Screening Programme (NSP) will be introduced to the UK.
- It will use faecal testing only. It represents a good start but it still has a long way to go. It will show a significant mortality benefit which will be a strong rationale for Lifescan and other private providers to underpin the need and effectiveness of colon screening.
- The screening programme reinforces the proven evidence based case for screening. What remains to be proven is the case of one technology over another.
- The criticism against private screening is blanket screening where you scan from head to toe. The NSP is specific to a disease and part of the body.
- The real issue is that in the NHS the majority of cases for screening will be in symptomatic patients where there is bleeding, weight loss, and changes of bowel habits.
- With these symptoms the radiologist is looking for a cancer.
- In the case of asymptomatic patients, the low prevalence of abnormality and the form that abnormality will take – i.e. polyps - are much more difficult to detect.
- A radiologist working with asymptomatic patients has a different job to do, and training needs to reflect this, which it doesn't at the moment.
- In the US Virtual Endoscopy (VE) has exceeded all expectation in finding these polyps. Since its introduction 12 years ago, VE has brought in more sophisticated software which requires only a thin tube, no sedation and is able to see beyond the colon,
- The benefits of VE were brought to bear only last week when I saw a patient with symptoms of colon cancer but we were able to see that in fact it was the kidney.
- In the future, it is expected that they will be able to omit the laxative that many patients dislike.

- VE was seen like a Holy Grail. It was introduced widely with intense tracking and research. Marked variability and little consistency in outcomes followed, and there were pockets where outcomes did not stand up to scrutiny, both in US and Europe.
- Virtual Colonoscopy depends on individual aptitude. Training is needed to bring everyone up to the same standard. Training and accreditation are critical,
- Efforts were made to upgrade Training and Accreditation (T&A) but it was not based on evidence and there was little rationalisation.
- Now that T&A has become more sophisticated there is a need for better standards.
- Survey of UK radiologists about T&A showed that of those using VC 70% want accreditation beyond the current process.
- An internal audit process needs to be set up under the aegis of a National Society or College, not HCC where audit responsibility currently lies.

<u>Points raised about Technology</u>

- Need to bring in changes in a stepped approach like in the US
- As new technologies are introduced the T&A programme needs to respond and address them. For instance radio-controlled robots going round the colon. T&A needs to build in a framework to allow for it.
- New technology has built in specificity and markers. How will this fit into training?
- Computer Aided Diagnosis (CAD) software can't act alone without interaction and input of radiologists.
- FDA in the US is looking at CAD but wants radiologist interaction.
- Mass screening using CAD could be possible within 5 – 10 years.
- This will move realm of screening firmly into the arena of VC.
- For now screening effectiveness is dependent on the effectiveness and skill of interpretation. Human error is the key concern.
- David Burling: At St Marks where a VC shows a polyp, they can immediately call on endoscopy to tell them how easy the disease is to access. It can all be done in one day.
- Automated diagnosis is evolving but there is some professional resistance.
- In breast cancer screening its been shown that the automatic system is better than having two readers.
- CAD diagnosis combined with radiologist input is the most effective method.

Key question is which body/bodies should be responsible:

- Professional bodies such, as the College of Radiologists is the preferred option. Most individuals feel the Society has a vested interest in their case and is the best agency.

- Manufacturers usually implement industry training. Should the College validate their training courses?

- Burling and Stuart run a training programme for VC, which is approved by the College but run by Burling and Stuart. This programme earns the radiologist CME points.

- Burling and Stuart have not been invited to feed their opinions or findings to COMARE. COMARE has ignored primary patient input

- ESGAR: helps to coordinate many training courses in collaboration with the College.

- Training module must have element for asymptomatic patients. This requires very different training requirements between the private sector and an NHS district hospital.

Regulatory Compliance

This is problematic: there are a complex and multiple ranges of bodies and organisation that oversee different areas

- Regulations and Standards Compliance relies on effective auditing of private centres for different aspects and elements of its equipment, its procedures and protocol, and the reliability of screening outcomes.
- The Committee noted that auditing of outcomes across a vast range of medical procedures – x-rays for instance – are not mandatory.

Auditing

- BUPA suggests that the protocols it uses for MRI could provide a framework to the HCC
- David Burling: Issue of double-reporting needs to be addressed

The agencies currently overseeing the radiology sector are:

1. NRPB

2. Health Protection Agency

3. IRMER

- Government agency
- Check for equipment safety and that they meet standards
- Proactive – check equipment
- Proactive – in the event of issues/problems
- But no in-house expertise in radiation.
- Have Associate inspectors who then bring in expertise (Stan)
- Only the experts are skilled enough to know whether further investigation is necessary where excessive/abnormal exposure has occurred.

4. HCC

- Register and approve clinics
- Also have authority to close down a clinic that fails checklist
- But no specialists in HCC re radiation and exposure
- Who polices the HCC? HCC
- Dr Ian Gibson says the HCC reports to Parliament and therefore any problems should be directed towards MPs.

5. Health and Safety Executive

Dr John Giles summarised the audit procedures and protocols used by Lifescan:

- Random checks are made across all centres and all radiologists for technical quality of the scan and the interpretation/type of reporting
- Dr Giles reviews the data and identifies if there are any gaps or discrepancies. If the fault lies with the radiologist they are retrained and their performance closely monitored.
- Where something is found, Lifescan go back to the patient but there is no resource to follow-through and get feedback further down the line.
- Lifescan has good audit procedures but can we do more?
- VC is particularly good for audit purposes. BUPA: checking they have a separate code to differentiate them

Summary points about auditing:

- College buy-in is essential
- The Report should consider and recommend a framework that would help
- This should include follow-up in relation to IRMER
- Following inspections there is no feedback but it was noted that this is the same for X-rays and many other procedures

Need for a Collective Voice

Dr Ian Gibson

- The NHS screening lobby need to consider a move to fund patients through the independent sector

- As and when Dr Gibson raises issues in the House from the Report, he requires an umbrella voice representing the private sector.

Prof Marshall

Issues that CACODI need to consider are:

- Should this Federation represent experts in general across the whole range of body screening, or be specific to one area?

- There is already an NHS National Screening Committee

- Should this suggested 'private' Federation use the term 'screening' since it is associated by custom and tradition as an NHS term

- In private sector, 'screening' is about preventative medicine. BUPA categorise it as a Wellness Product.

Next Action

ALL: Professor Marshall asked all present and participants not present today to contribute to the template that was handed out as hard copy to all present. Lisa ter Haar will forward the template electronically with the Minutes.

David Burling: to provide more information on the current training course he runs and provide as a discussion document.

Jim Thurston: to provide more information about current standards, regulations and compliance. It was suggested these minutes to be forwarded to Stan Batchelor, the RPA inspector.

Next Meeting: will be on Wednesday May 23rd. All comments and input to be forwarded to Lisa ter Haar (lisa@onlyconnectsolutions.com) at least a week before the next meeting.