This response was submitted to the consultation held by the Nuffield Council on Bioethics on *Medical profiling and online medicine: the ethics of 'personalised' medicine in a consumer age* between April 2009 and July 2009. The views expressed are solely those of the respondent(s) and not those of the Council.

The Royal College of Radiologists

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From the Chief Executive
Andrew Hall

Ref/AAH/cf/017

23 April 2009

Professor Christopher Hood
Nuffield Council on Bioethics
28 Bedford Square
London
WC1B 3JS

Dear Professor Hood

Re: Medical profiling and online medicine: The ethics of "personalised" healthcare in a consumer age

We were very interested to see the announcement that the Nuffield Council on Bioethics has set up a Working Party to examine further the issues on medical profiling. We thought it would be helpful to let you know as Chair of the Working Party of the concerns this College has had as regards scanning for health assessment of asymptomatic individuals.

In the past we have done some work with the NHS Director of Screening Programmes who was at the time Sir Muir Gray. The statement we issued in 2004 is attached for your information.

More recently, we have been following with interest the recommendations made by the Committee on the Medical Aspects of Radiation in the Environment (COMARE). We responded to a consultation by the Department of Health on the recommendations from the COMARE report on this topic and you may be interested in seeing a copy of those comments.

We would be very pleased indeed to offer input or support to the work you are undertaking and if you feel it would be helpful to arrange a meeting or seek further views from us, either now or later in the work you are doing, then please let us know.

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We will of course respond to the consultation but thought it would be appropriate to write in this way to draw your attention to the work we have done and the concerns we have raised.

Yours sincerely

Andrew Hall
Chief Executive
andrew_hall@rcr.ac.uk

enc.

cc: Dr Tony Nicholson, Dean, Faculty of Clinical Radiology
Dr Giles Maskell, Register, Faculty of Clinical Radiology
Vicky Preston, Policy and Project Support Manager

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APRIL 2004

To all CR Members and Fellows:

Dear Colleague

Re: **Whole body screening with computed tomography**

I enclose a copy of a document which was prepared by the UK National Screening Committee under the direction of J A Muir Gray. The College is aware that there is a growing body of evidence which examines the role of electron beam computed tomography and formal multi-slice CT in the assessment of a number of conditions. The evidence for certain applications for whole body CT is more robust than for other applications but at the present time, the National Screening Committee has not seen fit to support this mode of screening in the public sector.

Furthermore, the College is conscious of the fact that if such screening methodology is adopted within the private sector, this could have considerable impact on further investigation and treatment within the NHS. The National Screening Committee and the Royal College of Radiologists would therefore believe that if such whole body screening is offered within the private sector, such screening should also include the costs of subsequent follow-up procedures that might be suggested as a consequence of the screening process. There is very significant potential for any screening methodology to reveal a pathology that has no prognostic import but which would require very significant further investigation in order to satisfy the clinician and the patient that the pathology was not of significance. If this cost were to be borne by the NHS then it would have very significant impact on the delivery of other services.

Neither the College nor the National Screening Committee is making a judgement on the efficacy of screening programmes at present but simply recommending that such screening programmes in the private sector need to be introduced in a way that all marginal costs are identified as well as a robust evidence base established.

Dr Paul Dubbins
Vice-President and
Dean, Faculty of Radiology

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NATIONAL SCREENING COMMITTEE

WHOLE BODY SCREENING WITH COMPUTED TOMOGRAPHY

BACKGROUND

Considerable publicity is being given to the work of an American company that has developed techniques for whole body screening. The company is offering screening privately but an article in the Observer on 4 May indicated that it was in discussion with some primary care trusts. Steps are being taken to try to identify these trusts.

The issues

There are two issues for the National Screening Committee to consider. The first is the appropriateness of recommending computed tomography as a screening interventuion; the second is to consider the contribution that computed tomography can make, in isolation or in addition to other technologies in screening for specific conditions, notably coronary artery disease, lung cancer and colorectal cancer.

The recommendation of computed tomography as a screening tool

In previous attempts to review the contribution that a technology or single intervention can make to screening for a number of diseases, the National Screening Committee has encountered difficulties. For example, in reviewing ultrasound screening in pregnancy or the newborn examination the approach of the National Screening Committee has been to identify the health problems for which screening is claimed to be beneficial and then to review each of those health problems against the criteria.

Having made decisions about a number of different conditions which may or may not benefit from screening, consideration can then be given to managerial issues and the amalgamation of such tests for the convenience of the person being screened or the efficiency of the service.

It is therefore, not appropriate to consider whether or not computer tomography should be offered as a screening test.

Screening for lung cancer

The National Cancer Institute in the United States has launched the National Lung Cancer Screening Trial which will be comparing screening with computed tomography and screening with x-ray, using mortality as the end point. It has been decided that this type of trial should not be mounted in the UK. The current policy of the National Screening Committee is that we should not recommend screening for lung cancer for the whole population or sub groups of the population until the results of this trial area

available, and because computed tomography is included within this trial this can be considered an intervention currently being evaluated.

Screening for coronary artery disease

Computed tomography can undoubtedly demonstrate lesions in coronary arteries but the evidence that the identification of these lesions reduces mortality is not strong. This issue will be raised with NICE and with the Health Technology Assessment Programme but at present there is insufficient evidence to support the claim that computed tomography screening of coronary arteries would reduce mortality or NHS costs.

Screening for Bowel Cancer

As part of the review of evidence for the Colorectal Cancer Screening Programme, the effectiveness and feasibility of screening using computed tomography was considered. CT screening of the colon was never considered as an initial screening test but as a possible alternative to colonoscopy in people who required follow up. At present it is not seen that CT screening of the colon is suitable for the large numbers of people likely to be referred for colorectal screening. The views of the team evaluating the pilot will be sought on this issue.

Recommendations

At present it is recommended to the National Screening Committee that:

1. computed tomography should not be supported by the NHS as a generalised screening test;
2. computed tomography should not be used to screen for lung cancer until the results of the trial in the US become available and demonstrate more good than harm;
3. screening by computed tomography for coronary artery disease should not be offered through the NHS;
4. the part that computed tomography can play in screening for bowel cancer or the follow-up of those found positive on screening should be considered when the report of the pilot is received with further evidence being sought if necessary;
5. private sector providers making such services available should make clear to people being offered screening the lack of evidence about benefit and the possibility of harm, and furthermore should take steps to ensure that all the costs and follow-up of people identified as positive should be met either by the individual themselves or the insurance policy supporting the cost of any CT screening that is offered.

JA Muir Gray, CBE, DSc, MD, FRCP, FRCPSGlas
Programme Director – UK National Screening Committee

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THE ROYAL COLLEGE OF RADIOLOGISTS

Response to consultation on:

The impact of personally initiated X-ray computed tomography (CT) scanning for health assessment of asymptomatic individuals. Recommendations made by the Committee on Medical Aspects of Radiation in the Environment (COMARE).

The Royal College of Radiologists (RCR) fully supports and endorses the recommendations in COMARE's report. Radiologists will always consider the risks inherent in any radiological investigation and balance them against potential benefit to the individual. However, the RCR approves the conclusion of COMARE's report regarding 'whole body scanning' services which states that the potential risks outweigh the benefits.

We also have some specific comments as follows:

1. Whilst this consultation rightly focuses on the potential harm caused by the radiation associated with whole body scanning, this is by no means the only potential source of harm associated with this practice. The COMARE report itself puts great emphasis on the negative effects of the findings of unknown clinical significance which will inevitably be detected. These may be both physical, such as harm caused by further unnecessary diagnostic procedures, and psychological.

2. These services are currently unregulated. We consider it very important they should be regulated by an appropriate body such as the Healthcare Commission (or Care Quality Commission as it will become).

3. We attach paramount importance to the issue of providing accurate and appropriate information to individuals considering undergoing such a procedure. All related advertising materials as well as information given to the individual on attendance must be scrupulously accurate and should include information about false positive and false negative rates *specific to the unit providing the service* as well as in general terms. It is important that the information is presented in a way that is easily understood by patients and the public.

4. CT scanning is a fast evolving modality. The evidence base for CT scanning of asymptomatic individuals is likely to change substantially in the future. In particular, there are ongoing research studies evaluating the role of CT in the early diagnosis of lung cancer and in heart disease. The results of these studies, when published, may necessitate revision of the COMARE recommendations. Whatever regulatory mechanism is employed must be able to respond rapidly to such changes.

5. It is important to make clear that CT scanning in the context of illness is an invaluable technique, essential to the practice of modern medicine.

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The RCR would welcome the opportunity to work with the Department of Health, the Healthcare Commission and the companies involved in CT scanning of asymptomatic individuals, to develop rigorous standards of practice and a regulatory framework.

August 2008

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From the Office of the President

Professor Andy Adam FRCP FRCS PRCR

15 July 2009

Hugh Whittall

Director

Nuffield Council on Bioethics

28 Bedford Square

London WC1B 3JS

Dear Mr Whittall

Re: Consultation Paper on *Medical profiling and online medicine: the ethics of 'personalised' healthcare in a consumer age*

The Royal College of Radiologists (RCR) is pleased to respond to this consultation. We also welcomed the opportunity to meet with representatives from the Council on 1 July 2009 and hope they found the meeting helpful.

The two main areas of interest to the RCR within the consultation paper are: whole body scanning and teleradiology.

Whole Body Scanning

As in our previous letter to Professor Hood of 23 April we would like to reiterate the concerns the College has raised in the past through our 2004 statement and our response to the consultation by the Department of Health on the recommendations from the COMARE 12th report (all enclosed).

Dr Tony Nicholson, Dean of the Faculty of Clinical Radiology at the RCR, has also sent to you by separate email a number of anonymised cases which have been referred to College Officers by concerned patients and colleagues.

The following is a brief summary of our comments and concerns regarding the scanning for health assessment of asymptomatic individuals:

- CT scanning in the context of an illness is an invaluable technique, essential to the practice of modern medicine. Radiologists will always consider the risks inherent in any radiological investigation and balance them against potential benefits to the individual.
- The RCR believes the benefits of 'whole body scanning' of asymptomatic individuals by private imaging companies are outweighed by the risks, which include potential harm caused by radiation and the negative effects of findings of unknown clinical significance which will inevitably be detected. These effects may be both physical, such as harm caused by further unnecessary diagnostic procedures, and psychological.
- We attach paramount importance to the issue of providing accurate and appropriate information to individuals considering undergoing such a procedure. All related advertising materials as well as information given to the individual on attendance must be scrupulously accurate and should include information about false positive and false negative rates specific to the unit providing the services as well as in general terms. It is important that the information is presented in a way that is easily understood by patients and the public and that fear is not used as a marketing tool by the scanning companies.
- All imaging services including private companies should be regulated by an appropriate body such as the Care Quality Commission. They could also be subject to an accreditation scheme.

<u>Teleradiology</u>

The RCR considers teleradiology to be useful in ensuring that patients receive the best possible care in a timely fashion and access to the appropriate levels of expertise. It has many advantages in the emergency context and its introduction does help to reduce delays in the production of reports.

However:

- The distinction must be made between teleradiology which involves non-UK reporting and that which is wholly properly used in the UK (such as for remote and rural areas).
- The RCR believes that patients care about who provides the report on their imaging and this should not be forgotten.
- Patient confidentiality, including the security of all data, information and images, must be maintained.
- The teleradiologist must have access to full clinical information, previous images and the results of other investigations such as blood tests.
- The teleradiologist must be available for electronic consultation with the referring clinician.
- Teleradiologists must be subject to the same UK medical regulation as all other medical disciplines.

I hope these comments are useful. We would be happy to discuss any of these points with you or provide any further assistance.

With kind regards,

Yours sincerely

Professor Andy Adam FRCP FRCS PRCR

President

andy_adam@rcr.ac.uk

Enc.