

# Electron beam computed tomography (EBCT) — funding protocol

A J Dalby, V B Andrijich, E Q Klug, E P Manga, T J Nel, V J Pinkney-Atkinson, for the EBCT Funding Protocol Working Group

## 1. Objectives of the protocol

To outline the clinical indications for electron beam computed tomography (EBCT) scans and the indications for which funding is appropriate in the following areas:

- use as a CT scanner
- use as a diagnostic aid in cardiology for coronary artery calcium scoring
- other uses as a diagnostic aid in cardiology.

## 2. Introduction

In 1997 an EBCT scanner was introduced into South Africa. Controversy surrounded the introduction of the technology and positions rapidly became polarised. This culminated in the Representative Association of Medical Schemes (RAMS) recommending non-payment for third-party funding claims, and legal action against a number of groups was advocated. In the interests of conciliation and fairness the Medical Association of South Africa (MASA) as represented by Dr E M Barker (Chairperson, Committee for Science and Education) facilitated the discussions.

When making a decision to introduce an expensive and new technology, it would be ideal if the introduction and usage were based on a clinical guideline linked to a technology assessment and systematic review of the literature. Clearly this process was not followed in this instance, resulting in the current conflict. The acknowledgment of this problem is not to apportion blame or be divisive, but rather to clarify for the future. It is very easy to be wise after one has been confronted with a difficult situation.

MASA is very keen to facilitate resolution of the above difficulties without resorting to litigation and further very costly negotiations, and for this reason became involved in the current controversy.

A **funding protocol** simply states the clinical indications for a particular procedure or treatment so that funders of health care may make an informed decision on reimbursement. It is only developed as an interim document until a full technology assessment and/or clinical guideline is available. Neither the development of a new systematic review nor the development of a national clinical guideline is

a short-term solution. The methodology used to develop a funding protocol is much shorter and simpler than that for a clinical guideline. It represents a very abbreviated but audited process that has allowed the South African medical profession to study the matter by:

- having access to selected literature
- discussing with international and local content experts
- attending international symposia
- providing a neutral facilitation process
- engaging national specialist groups in a dialogue.

This **funding protocol** represents the best possible solution to a difficult situation and MASA recognises that the process is not ideal (see comments in Annexure A). However, every care has been taken in the past 8 months to ensure that the protocol is as unbiased, non-prescriptive and clear as possible.

The funding protocol is **not prescriptive** and each funder will have to make its own decision about whether to include EBCT scans as a benefit.

It is recommended that a strategy/policy for the introduction of expensive technology is agreed in partnership with all stakeholders including the Department of Health, RAMS, other funders, and medical professional groups.

Comment(s) for noting should be directed to the corresponding author.

## 3. EBCT scanner used as conventional CT scanner

- An EBCT scanner may be used as a conventional CT scanner in conditions where CT scanning is usually indicated.
- The motivation procedure and tariff codes and reimbursements are the same as for conventional CT scans.

## 4. Coronary artery calcium assessment by EBCT — indications

The presence of coronary artery calcification is associated with the presence of coronary atheroma. EBCT is a sensitive method for detecting coronary artery calcification. EBCT is not a functional test (nuclear medicine study or dobutamine echo), and therefore a positive test does not imply that the calcified lesion is causing ischaemia.

### 4.1 In symptomatic patients

A coronary artery calcium score exceeding that predicted for the age and gender of the patient can provide supportive evidence of the presence of coronary artery disease in patients who:

4.1.1 have presented with a chest pain syndrome suggesting cardiac ischaemia

**AND**

4.1.2.1 in whom alternative non-invasive testing has yielded an unexpected negative result

**OR**

4.1.2.2 in whom alternative non-invasive testing would be unhelpful in arriving at the diagnosis due to:

- physical disability (e.g. dyspnoea at rest, lower limb amputation or orthopaedic disability), when an alternative functional study is not available

**OR**

- abnormalities in the resting electrocardiogram which prohibit the interpretation of an ischaemic change (e.g. left bundle-branch block, Wolff-Parkinson-White syndrome, left ventricular hypertrophy or concomitant digitalis administration) or the interpretation of an alternative functional test.

These studies are helpful only in men under 60 years of age and women under 70 years of age.

This investigation is **inappropriate** in any patient in whom coronary artery disease has been identified previously.

A positive coronary artery calcium score is not an indication for coronary angiography and/or a coronary revascularisation procedure.

**It is appropriate to reimburse coronary artery calcium assessment performed for the above indications under code 3598.**

To qualify for reimbursement the patient must have been referred by a cardiologist or a specialist physician who is knowledgeable regarding the management of patients with coronary artery disease.

Requests to third-party payers for reimbursement must be accompanied by a written motivation from the referring doctor, who shall indicate the reason/s for the investigation.

The third-party payers shall establish a data base to collect and collate information about the performance of coronary artery calcium assessment which will be available to the profession to enable peer review.

## 4.2 In asymptomatic subjects

Coronary artery calcium assessment cannot be recommended for screening of asymptomatic subjects at this time as the implication of a positive score with regard to subsequent management and outcome is unknown.

It is **inappropriate** for third-party payers to reimburse coronary artery calcium assessment performed in the asymptomatic subject.

## 5. Potential uses of EBCT in cardiology (excluding coronary artery calcium assessment)

Because EBCT has the advantage of ultrafast image acquisition, its capabilities exceed those of standard CT investigations in the evaluation of the cardiac patient. It is able to freeze cardiac motion and, with its higher resolution, detect smaller structures.

The potential applications of EBCT in cardiology already described in the literature are the assessment of:

- ventricular function
  - (a) at rest
  - (b) after exercise
- chamber volume
- myocardial mass

- improved resolution imaging of
  - (a) cardiac structures (especially in relation to congenital cardiac anomalies in infants and small children)
  - (b) intracavitary tumour/thrombus
  - (c) paravalvular abscess
  - (d) peri-cardiac vasculature
  - (e) coronary arteries
    - (i) coronary artery bypass graft patency
    - (ii) stent patency
- myocardial perfusion
- visualisation of great vessels
  - (a) centrally located pulmonary emboli
  - (b) aortic coarctation
  - (c) dissecting haematoma of the aorta.

Most of the above investigations can also be performed with alternative modalities, e.g. echocardiography, stress echocardiography, radio-isotope ventriculography, radio-isotope myocardial perfusion imaging, pulmonary perfusion-ventilation scanning, angiography, standard CT and magnetic resonance imaging. The cost-effectiveness ranking of EBCT compared with these other diagnostic methods has not yet been established. These alternative uses of EBCT make up a very small percentage of the total cardiac caseload in established units.

Certain of these EBCT investigations require the use of X-ray contrast media.

Reimbursement of such EBCT investigations by third-party payers is warranted provided motivation has been provided by the referring cardiologist, paediatric cardiologist or physician with a special interest in cardiology which specifically indicates why in the particular instance EBCT was preferred to an alternative technology.

## 6. Endorsements

This final funding protocol is endorsed by the following national professional groups:

- South African Society of Cardiac Practitioners (SASCP)
- Southern African Cardiac Society (SACS)
- Radiological Society of South Africa (RSSA).

Neither the Department of Health nor RAMS wished to endorse the draft funding protocol, and their full statements are enclosed (annexures A and B respectively).

Endorsements by individuals were noted. The revisions to the document were again circulated to the professional groups and Pretoria HeartScan before publication. All have endorsed the document.

## 7. List of EBCT Working Group

### Attended meeting on 22 February 1998:

- Dr E M Barker, Chairperson, MASA
- Dr V B Andrijich, RSSA
- Dr C J Botha, Aerospace Medical Society of South Africa
- Prof. P Corr, RSSA
- Dr A J Dalby, SASCP
- Dr A Dasoo, RAMS
- Dr F de Beer, Medical Advisors Group
- Dr C Hugo-Hamman, Department of Health
- Dr I Illes, Pretoria HeartScan\*

Dr D G King, Imatron, USA\*  
 Dr P Mavengere, Medical Advisors Group  
 Dr T J Nel, Pretoria HeartScan\*  
 Ms V J Pinkney-Atkinson, Centre for Quality Care, MASA  
 Ms E Prins, Health Policy, Economics and Private Practice, MASA  
 Dr Rumberger, international content expert†  
 Dr J Swartzberg, Pretoria HeartScan\*  
 Dr R Tuft, RSSA  
 Dr M Versache, Pretoria Heart Hospital\*  
 Dr C van Wyk, Pretoria Heart Hospital\*

\*Financial interest in the EBCT machine or in the manufacturing company.  
 †Financial interest or fee for presentation not clarified despite request for such information.

### Did not attend meeting:

Dr E Klug, MASA Committee for Science and Education nominee  
 Prof. P Manga, SACS  
 Mr B Pharasi, Department of Health  
 Prof. A D Rothberg, Guideline Committee, MASA  
 Dr A J Snyman, Guideline Committee, MASA  
 Dr L Steingo, SACS

## 8. Financing of meeting

- HeartScan
- RSSA
- MASA
- Imatron.

The Department of Health funded the participation of its delegate.

## 9. Methodology

During the course of meetings and discussion about the funding of EBCT it was agreed that a funding protocol should be developed for use by third-party funders specifically in relation to coronary artery calcium assessments. The funding protocol development methodology is shorter than that of a national clinical guideline. There are numerous differences in the methodology, but in essence it is less rigorous, takes less time and involves a smaller segment of the profession. However, it serves the purpose of outlining indications for EBCT scanning other than coronary artery calcium scoring using a combination of consensus and evidence-based strategies.

A list of working group participants was developed including those with financial interest and representatives of professional disciplines who may use the output of EBCT scanners and funders who would be requested to pay for EBCT scanner usage. All participants were supplied with the relevant documentation. Each participant completed a declaration about their own financial interest in the technology, and these are noted in the participant list.

After the meeting a draft document was written up by Dr T J Nel and this was circulated to all participants for comment and endorsement. The comment and endorsement process continued from November 1997 to the end of April 1998. The collation of the comments and this

final draft has been facilitated by the MASA Centre for Quality Care. The final funding protocol is substantially different from that developed by Dr Nel and has been endorsed by the major professional groups and Pretoria HeartScan.

This report will be available on the Internet at the Health Channel site ([www.hc.co.za/quality](http://www.hc.co.za/quality)) and will be available to the funders of health care on request.

The Executives of the SACP and SACS have produced statements on EBCT. Much of these has been incorporated into the funding protocol, but they are also available on request.

## 10. Disclaimer

This funding protocol is for reference and education only and is not intended to be a substitute for the advice of the appropriate health care professional or for independent research and judgement. The MASA relies on the source of the funding protocol to provide updates and to notify us if the protocol becomes outdated. The MASA assumes no responsibility or liability arising from any outdated information or from any error in or omission from the protocol or from the use of any information contained in it.

## Annexure A. Submission from the Department of Health

The controversy over electron beam computed tomography (EBCT) has raised concerns which have gone beyond the utility to be derived from the use of the technology in any given set of clinical circumstances. Some concerns are generic to all sophisticated health care technologies, while others are particular to EBCT. These issues are of such fundamental concern to the practice of medicine and to the health system in general, that it is our view that any discussion of clinical application cannot take place without due consideration of them.

### 1. Ownership

The Department of Health opposes the practice whereby referring physicians have a financial interest in the equipment and/or services which they requisition for their patients. The objections are based on the belief that this creates a potential moral hazard where the likely financial return becomes an important factor that may obscure any genuine, scientifically based, biomedical criteria for the procedure or intervention. This would not be in the best interests of the patient or of society at large. Such self-ownership also contributes to over-utilisation of these services and therefore to the overall costs of care.

This is true of many technologically based diagnostic or therapeutic interventions. Today the debate concerns EBCT. Tomorrow it may be elsewhere, for example orthopaedic surgeons with shareholdings in magnetic resonance imaging facilities.

### 2. Self-referral

EBCT has been marketed directly to the public by the provider as a useful screening procedure for asymptomatic patients at risk of coronary artery

disease. The veracity of this particular claim has been challenged by the representative societies of specialist cardiologists in South Africa and abroad.

The Department of Health is in general opposed to self-referral for expensive, sophisticated, technology-based procedures (such as EBCT). The public may not be adequately informed about the procedure and their interests are of paramount concern. We believe that only adequately and appropriately qualified professionals who are familiar with and understand the complex issues relating to the usage of these procedures and interpretation of the results should be requesting these investigations. They can then be held professionally responsible for the decision to recommend the procedure and they are best placed to provide appropriate counselling in the presence of both positive and negative results.

From a concern for overall costs of care, we believe that self-referral lends itself to inappropriate utilisation and overutilisation of these diagnostic modalities.

### 3. **Need**

Health care technology assessment should guide the acquisition, distribution and utilisation of health care technologies so that issues of need, equity in access, cost-benefit and cost efficacy can be addressed. These concerns apply equally to publicly and privately funded health care. We are acutely aware that any 'agreement' on the utilisation of this particular machine will be used by other parties to justify further investments in EBCT at other facilities. Therefore the desire to ensure that the final opinion on the protocols is well considered.

### 4. **Indications for EBCT**

There are fundamentally opposing views on the application of EBCT in coronary artery disease. Whereas advocates argue strongly for its use even in asymptomatic patients, in their submission of 27 February 1998 the South African Society of Cardiac Practitioners wrote, 'It [EBCT] does not presently merit a position in the investigative armamentarium of practising cardiologists.' For their part, the South African Cardiac Society wrote, 'There is insufficient data to recommend coronary artery calcium scoring in lieu of stress testing . . . in patients with chest pain.' These views are supported by the Representative Association of Medical Schemes in their independent assessment of the technology in 1997.

The Department of Health believes that clinical care should be based upon an analysis of the best available evidence. In the *absence of a systematic review* of the evidence for EBCT (which we regard as being the key component of health care technology assessment), the Department of Health will be guided by international practice and the appropriate expert, professional, cardiological and radiological societies of South Africa.

Consensus has now been reached between these groups on indications for EBCT for use as:

- a conventional CT scanner
- for coronary artery calcium assessment in symptomatic patients, and
- for other cardiological indications.

The protocol has excluded the use of EBCT for coronary artery assessment in the large groups of asymptomatic but at-risk patients.

The protocol has also effectively ruled out self-referral and has recommended to third-party payers that referral by an appropriately qualified and experienced medical specialist should be a precondition to requests for reimbursement. This is a welcome development with significant implications for the reimbursement of other diagnostic and therapeutic procedures.

**Conclusion.** The protocol has not by definition addressed concerns of ownership, or of equity, need and cost-effectiveness. The Department of Health aims to address issues of ownership of facilities and equipment through other mechanisms. It reserves its judgement on the benefits of EBCT until such time as a proper systematic review and health care technology assessment has been performed.

**D O Shisana**

*Director-General: Health*

22 May 1998

## **Annexure B. Comments from RAMS**

The funding proposal on EBCT sent to RAMS and other interested parties refers, and I wish to respond as follows:

1. The clinical relevance of EBCT is still the subject of much debate, both locally and abroad, and until such time as there is sufficient consensus on the technology and the conditions for which its use is indicated, our position remains as we have stated before.
2. RAMS therefore, even in the light of further extensive lobbying by interested parties, holds that no recommendation for reimbursement will be made to member schemes referable to the use of this machine, except where it is used as a conventional CT scanner in conditions where CT scanning is usually indicated. In this instance, existing CT codes and reimbursement levels in the Scale of Benefits will suffice.
3. RAMS will only reconsider its position in the light of substantial clinical consensus on this technology within the medical fraternity, but will predicate any shift in position on the financial impact on medical schemes and in keeping with the emergent technology regulatory policy of the State.

**Aslam Dasoo**

*Director: Policy*

16 April 1998