SOUTH AFRICAN PET USERS ASSOCIATION

Predicted demand for PET services in South Africa

Introduction
At the founding meeting of SAPUA held on the premises of Tygerberg Hospital on 4 December 2004 the newly appointed management committee of SAPUA was given the task of appointing a task group to make recommendations regarding the initial requirements for PET facilities in South Africa. This is stated under goal 6.2:

6.2 Propose initial PET needs for the country as a whole and use and share this for the purposes of strategic planning and advocacy.

The task group, known as the "National Strategy Task Group" was appointed and consists of the following members:

M Sathekge (chairman)
F Peer
W Flowers
A van Aswegen
J van Zyl
J Warwick (ex-officio)

New applications of imaging have been among the most dramatic developments in medicine in the last three decades. With PET-CT being hailed as an imaging device of the century, in introducing this device we should be aware of the situation set out in the March 2003 report to the US Congress by the Medicare Payment Advisory Commission (MedPAC) indicating that imaging was the fastest-growing of all physician services in the Medicare program. A subsequent report by the Blue Cross Blue Shield Association projected that the (USA) nationwide costs of imaging would increase by 33% between 2000 and 2005 and would reach $100 billion in 2005.

Since diagnostic imaging is the fastest growing medical expenditure in the United States with no signs of a slowdown, the growing number of imaging centers and their utilization has given imaging a high priority with Certificate of Need (CON) policy. With similar legislation due to be implemented in South Africa, much potential conflict can be avoided through self-regulation by the profession.

A number of considerations support the performance of a needs analysis for PET in South Africa. Firstly, there is presently (June 2005) no legislative mechanism in place whereby the government or any other regulatory authority can place a restriction on the number of PET facilities opening in South Africa. The possibility therefore exists that if the technology is introduced in a piecemeal fashion that there could be an oversupply and/or a maldistribution of facilities.

Secondly, the financial implications of opening a PET facility are significant and

therefore expenditure on PET facilities within the country should be done in a way that achieves optimal benefit for patients in both the state and the private sectors.

Thirdly, the provision of PET facilities in state hospitals, as proposed for Nuclear Medicine as part of the Modernisation of Tertiary Services programme of the Department of Health requires an assessment of the need for these facilities nationally.

In this document proposals are made regarding regulatory issues for future South African PET facilities, and an approach to determinine initial PET requirements for the country is put forward.

Regulation of PET in South Africa

Government regulation can affect PET and PET-CT facilities in three main ways: (a) PET quality standard regulations, (b) certificate of need regulations (CON). (c) Resources, reimbursement policy and the Council for Medical Schemes

A. Quality Standard Regulation

The purpose of these proposed regulations is to institute new rigorous quality standards, thus ensuring the quality, safety and appropriateness of PET services.

A PET Centre must demonstrate that it has suitably trained staff, workload and facilities to provide a PET service. There are six general standards proposed that have been modified from the proposals of the Intercollegiate Standing Committee on Nuclear Medicine of the Royal College of Physicians in 2003.

STANDARD 1

The PET Centre shall provide appropriate supervision for the examination being carried out.

Criteria:

1.1 The provision of a full-time PET service is expected to require at least one whole time equivalent PET Specialist (Nuclear Medicine specialist with PET training).

1.2 The PET Specialist shall be based within the PET Centre 60% or greater of the time that the PET facility is operating.

1.3 The PET Specialist should ensure that the requests for PET imaging are vetted according to set criteria (see Protocols Document from Protocol Task Group of SAPUA) and that scans are reviewed following their acquisition. During holiday

and professional leave of the PET Specialist there must be a named appropriate PET Specialist to provide cover.

1.4 There should be written guidelines of the areas of responsibility of each clinician involved in the department

STANDARD 2

The PET Centre shall have a sufficient workload of patients to maintain the expertise of clinicians involved in reporting.

Criteria:

2.1 The target workload of a PET Centre, in the start up period, should aim at ±1000 patients per annum. Individual clinicians should be actively involved in reporting at least 300 cases annually to maintain their level of skill. The Centre will perform oncology examinations encompassing a variety of cancer types and sites.

2.2 A system of audit is required for every PET Centre. This is particularly important in South Africa since all centres will be new; from its inception a system should be in place for audit. Local and national meetings need to be arranged to discuss difficult cases.

STANDARD 3

Every PET centre should have a teaching and training programme.

3.1 The centre must comply with the Standards set by the College of Nuclear Physicians (CMSA) and be inspected by the HPSCA.

3.2 The PET Centre should have a training programme for all health care professionals involved.

STANDARD 4

The Centre shall have access to the necessary scientific staff and equipment to ensure the optimum use of equipment and the highest quality of examinations and patient safety.

Criteria:

4.1 The Centre shall employ, or demonstrate ready access to, the services of a Medical Physicist who must also be registered with the HPCSA. This Medical Physicist must be experienced in the application of physics to the diagnostic uses of ionizing radiation and specifically have expertise in nuclear medicine.

4.2 Quality control (QC) and quality assurance (QA) procedures must be carried out regularly and the results recorded. QC and QA procedures must be appropriate to the studies being performed and be approved by the PET Medical Physicist and Nuclear Physician. Results of QC and QA procedures must be checked regularly by the Medical Physicist, to ensure the maintenance of image quality

4.3 All routine preventative maintenance must be performed to a prearranged schedule, and all faults must be investigated and resolved in a timely manner.

4.4 The Centre shall have a Radiation Protection Officer.

4.5 The Centre will only use radiopharmaceuticals from a supplier which is registered with the Medicines Control Council and has regular quality control procedures of radiolabelling techniques and related issues.

4.6 When more than one group is involved in the operation of a centre (e.g. a nuclear physician and a radiologist partner) the responsibilities and reporting structures for these staff must be formally agreed upon.

STANDARD 5

The PET Centre will have suitably trained radiographers and nursing staff operating the facility.

Criteria:

5.1 The Centre should only employ staff trained in use of the PET or PET-CT equipment or be able to offer supervised training of new radiographers. This training should not be merely on-site application training provided by the supplier of the equipment addressing the equipment only, but a comprehensive programme, accredited either internationally or in South Africa.

5.2 Depending on the case mix and numbers of patients, suitably trained nursing staff should be employed to carry out relevant nursing procedures and monitoring of patients undergoing PET.

STANDARD 6

The Centre shall have a mechanism for communicating results and providing advice to Multidisciplinary Team Meetings.

Criteria:

6.1 The Centre should have a specialist Nuclear Physician who consults with Oncologists, Radiologists, Surgeons and Endocrinologists within a multi disciplinary team (MDT) which meets regularly. This commitment has to be included in consultant job plans and adequately resourced.

6.2 Where MDT attendance of the referring clinician is not possible routinely, a detailed report and relevant images should be provided for a local expert clinician to attend the MDT.

6.3 This will enable training and education for local clinicians and ensure that the local expert is available to advise on appropriate referrals and discuss further queries and problems

B. Certificate of Need

A meeting of representatives of SAPUA and SAMA in Pretoria on 8 April 2005, recommended that the introduction of PET Technology in South Africa should take place taking into account Health Technology Assessment legislation because it is a new, costly, high profile technology. It is also likely that in the near future, the introduction of PET will be affected by Certificate of Need (CON) regulation as proposed in the National Health Act. SAMA intends to host an information session of stakeholder representatives on the objectives of the CON shortly. The Department of Health has been invited to participate in this process and SAMA plans to convene this information session by July 2005. This will be followed by research on similar initiatives elsewhere in the world with a view to providing broader access to health care services in South Africa. (SL Vol 2 No5[1])

C. Resources and Council for Medical Schemes

PET studies are not presently reimbursed by Medical Aids in South Africa. A coding structure is currently at an advanced stage of development. A tariff structure, based on the rules set down is currently being developed for presentation to the CMS.

Cost of PET Facilities:

The cost of setting up a PET facility in South Africa needs to be estimated in order to assess the financial impact of these services on the funding industry and the national health budget. For the purposes of this exercise two types of hypothetical PET facilities are envisaged. Firstly the costs of a variable number of private facilities is calculated based on a variety of estimated tariffs for PET scanning, FDG costs, number of centres, and scanner utilisation. This is not an exhaustive process but rather serves as an exercise to give an indication of the costs involved.

A: Private Facilities:

Final tariffs for PET procedures are not yet available, but for the purposes of this exercise the following estimates are used:

FDG: R3000-R4000 per dose

PET scanning R7000-R10000 per scan

The following 3 scenarios are given, using variations in the number of PET facilities in the country (??), number of patients undergoing scanning in each facility, PET tariff, and FDG price. The PET tariff and FDG price have been decreased with increasing utilisation of cameras and FDG.

Scenario 1

No. PET	No.of patient/d	Total patients/d	Estimated Scan Cost	Estimated FDG Cost	National Cost/annum
2	5	10	10k	4k	14k x 10 = 140k/d 140k x 250d = **R35 m pa**

Scenario 2

No. PET	No.of patient/d	Total patients/d	Estimated Scan Cost	Estimated FDG Cost	National Cost/annum
2	10	20	8k	4k	12k x 20 = 240k/d 240k x 250d = **R60 m pa**

Scenario 3

No. PET	No.of patient/d	Total patients/d	Estimated Scan Cost	Estimated FDG Cost	National Cost/annum
5	8	40	7k	3k	10k x 40 = 400k/d 400k x 250d = **R100m pa**

For each PET scanner there is conservatively an additional 5 patients/day x 10k x 250 days = R12.5 million per annum, which must be added to the budget for medically funded patients. These scenarios need to be considered in the light of current benefits paid out by the funding industry.

Benefits paid to Nuclear Medicine, Radiology, and Medical Oncology during 2003, based on the Council for Medical Schemes Annual Report 2003-2004:

Medical Oncologists	R83.6 m
Nuclear Medicine	R43.5 m
Radiologists	R1459.0 m

B. State Facilities:

Resources for health in South Africa are very limited in the public sector. Clinical indications for PET are probably similar in different populations, however the need for this technology may vary in different provinces/communities, depending on the incidence of various diseases. For instance, the potential influence on public health that PET may represent is likely to differ in for relatively more developed provinces and or communities (e.g Gauteng and Western Cape) with longer life expectancy and higher prevalence of cancer compared to others whose main health problems are infant mortality, malnutrition and infectious diseases. Optimal allocation of PET resources needs to acknowledge that both realities coexist in South Africa.

According to the CMS annual report of 2002, about 18% of the population (7 million members) is covered by medical aid at present. These figures highlight the need for PET facilities in the state as well as the private sectors to enable access to this powerful modality to enhance health care for the majority of South Africans.

Current available and soon to be available state facilities are:

1 Gamma-PET in Inkosi Albert Luthuli Hospital
1 Gamma-PET at Wits DGMC
1 Gamma-PET at Medunsa (installed needs updating)
1 Gamma-PET at Pretoria Academic (installed needs updating)
1 Gamma-PET at Red Cross Children's Hospital (currently being installed)

It must however be pointed out that these are not dedicated PET or PET-CT facilities, but instead are all gamma-PET facilities with its inherent limitations in terms of tumour detection, patient throughput, and indications. Despite these limitations these facilities are likely to be extremely important initially by providing a platform for teaching and clinical work, and research. They are however no substitute for strategically placed dedicated PET facilities in the public sector.

The cost to the state of running a PET facility is based on using an existing Nuclear Medicine department in a tertiary hospital (using a distant source of FDG):

Estimated Initial Capital for PET and PET-CT

	PET-CT
Scanner	12.5-15m
Building (depending on alterations per site)	1m
Furniture and Fixtures	100k
Hot lab equipment	120k
Total	**16.2m**

Estimated Operating Costs for PET and PET-CT

	PET	PET-CT
Nuclear Medicine Physician x2	200k-567k/annum x 2	200k-567k/annum x 2
PET Radiographer x 2	87k-186k/annum x2	87k-186k/annum x2
FDG (special public price)	1.5-2.5k	1.5-2.5k
Radiological supplies	90	90k
Maintenance contract	1m	1.5m
Miscellaneous expenses	90k	90k
Total	**2-3m**	**2.1-3.1m**

Predicted demand for PET services

In much of the developed world PET technology has been in place for decades in specialised research centres. Over the last decade facilities have expanded in these countries with mounting evidence for its efficacy as a clinical tool. South Africa currently has no dedicated PET facilities and due to the costly nature of the technology it is necessary to estimate an initial total and regional demand for PET facilities in South Africa.

In the UK due to a relative backlog in PET facilities, proposals exist that were put forward in 2003 by the Intercollegiate Standing Committee on Nuclear Medicine (ICSCNM) for the roll out of PET technology in that country. In this document the proposals of the ICSCNM are extrapolated using the reported cancer incidence in South Africa.

In the ICSCNM report estimates of the need for PET facilities are based on cancer incidence in that country. Taking a conservative approach this was first limited to cases of lung cancer, colon cancer, and lymphoma where the value for PET was seen as clearly demonstrated by meta-analysis or robust clinical data. Based on this it is estimated that at least 730 new cases per annum per million members of the population would benefit from PET scanning. In what is described as a “more realistic” approach a figure of 1600 new cases per annum per million members of the population is proposed based on about 20% of all cancers. The report recommends the roll out of 40-60 PET facilities in the UK.

Based on the figures given in the report, this translates into 1 PET facility per 13035-8690 (??) newly diagnosed cancer cases per annum respectively.

In this document a determination of total and regional PET needs is made using the same number of new cancer cases per PET facility, using the most recent data available from the National Cancer Registry of South Africa (1998-1999). These figures are based on histologically proven cases obtained from pathology laboratories in the public and private sectors. These data undoubtedly under estimate the true cancer incidence in the country due to a large number of South Africans with cancer not ever having a histiological diagnosis. These figures also largely reflect regional provision of services rather than disease burden. The NCR figures are however a good reflection of cases that are histologically proven. It can be argued that the role for PET is limited in patients lacking access to a histiological diagnosis. On this basis the NCR data can be useful as a determinant of initial demand for PET in South Africa. The NCR data however provides no indication of the relative distribution between the public and private sectors.

The results of this extrapolation are shown in Appendix 1. Based on this approach it is predicted that initially there will be a demand for a total of 5-7 PET facilities in South Africa. Due to the fact that the regional distribution of NCR data is a reflection of service provision rather than disease burden, this is also reflected in the predicted regional distribution of PET facilities. This may however be addressed to some extent by the grouping of poorly serviced provinces with better serviced provinces to make up 4 regions.

Predicted demand for PET centres

Based on the numbers of PET facilities shown in Appendix 1, the following proposals are made for the provision of PET facilities in the country.

Free State, North West

- Academic Nuclear Medicine at Free State

Prediction:
1 x centre

Gauteng, Limpopo, Mpumalanga

- Academic Nuclear Medicine at Medunsa, Pretoria, Wits

Prediction:
3 x centres (including 1 x state national referral centre)

KZN

- Currently no Nuclear Medicine physician in the public sector in KZN!

Prediction:
1 x centre

Western Cape, Eastern Cape, Northern Province

- Academic Nuclear Medicine at UCT, Stellenbosch

Prediction:
2 x centres (including 1 x state national referral centre)

Conclusions:

1. An initial demand for up to 7 PET centres is predicted for the entire country. This is for an initial period after which the service provision should be reviewed to determine if additional facilities are required.
2. These predictions should be discussed within SAPUA at a national meeting, before being are submitted to the Government and the DOH.
3. The Department of Health should be encouraged to publish this report as soon as possible, and to consult with SAPUA on a regular basis to facilitate access to PET by the majority of South Africans.

SAPUA National Strategy Task Group, July 2005

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References

Intercollegiate Standing Committee on Nuclear Medicine. *Nuclear medicine and radionuclide imaging: a strategy for provision in the UK*. London: Royal College of Physicians, 2003.

Interim Steering Committee on Health Technology. Health Technology Assessment: Discussion Document on a Strategy for the Future, 2004.

CANSA. World Health Report. 2003

Council for Medical Schemes Annual Report 2003-2004

Incidence of Histologically Diagnosed Cancer in South Africa, 1998-1999. National Cancer Registry of South Africa, National Health Laboratory Service, 2004

Appendix 1:

A. Total number of facilities

	incidence (/annum)	
reported cancer	60258	(National Cancer Registry 1998-1999)

number of facilities

min	max
4.6	**6.9**

B. Regional distribution

	reported cancer	**number of facilities**	
		min	max
1. Free State, and North West Province	6216	**0.5**	**0.7**
2. Gauteng, Limpopo, and Mpumalanga	25697	**2.0**	**3.0**
3. Kwazulu-Natal	11226	**0.9**	**1.3**
4. Western Cape, Eastern Cape, and Northern Cape	17120	**1.3**	**2.0**
TOTAL	60258	**4.6**	**6.9**