COLLEGE OF RADIOLOGY
Academy of Medicine of Malaysia

College of Radiology, Academy of Medicine of Malaysia Position on Whole Body Screening CT scans in Healthy Asymptomatic Individuals

July 2008

Whole Body Screening in the Healthy Asymptomatic Individual

To date, the College of Radiology (CoR) does not see any clear benefit from whole body screening CT scans in healthy individuals. Therefore, after reviewing all available current data, the CoR does not recommend whole body screening CT scan in healthy asymptomatic individuals

College of Radiology CT Working Group

Dr Evelyn Ho Lai Ming (Chair)
Prof Dr Basri JJ Abdullah
Dr Alex Tang Ah Lak
Dr Asokan Raman Nair
Dr Gerard Lim Chin Chye
Prof Dr Humairah Samad-Cheung
Prof Dr Ng Kwan Hoong
Dr P. Sathyamoorthy
Dr Siti Fathimah Abbas
Assoc Prof Dr Shaikh Ismail Bux
Assoc Prof Dr Yang Faridah Abdul Aziz
Dr V. Subramani
Dr Zaharah Musa
Dr Zaleha Abdul Manaf

Preamble

This recommendation is made based on available evidence. It does not replace case to case or individual clinical assessment where the need arises. It is also not meant to be used for legal purposes.

It provides guidance to medical and healthcare professionals for appropriate radiologic care that is as effective as possible and safe for the patient. It is recognized that many factors are in play in the delivery of health care. This includes patient condition, available resources and new information, results from studies and new equipment after the date of this recommendation.

Both parties, the radiologist agreeing to perform this examination and interpreting it, as well as the patient must fully understand the limitations and implications of the findings, as well as the risks entailed (from the radiation and contrast media). All must be cognizant of the fact that there may be ensuing investigations for

abnormalities found on the CT scan and these may have potentially profound financial, psychological and physical effects.

Introduction

Sectional imaging such as Computed Tomography (CT) or Magnetic Resonance Imaging (MRI) have revolutionized the capabilities for imaging, image guided therapeutic intervention and improved targeted radiation therapy. Unlike the non-ionising ultrasound examinations, it is not limited by gas and body habitus and takes the guessing game out of areas in the body previously not well visualized except by open surgery. The CT scan is much more widely available than the MRI and has benefitted many patients, clinching the diagnosis, guiding surgery, providing a road map, staging a disease so much more accurately and allowing radiation therapy to proceed ever more precisely.

The varieties of CT scanners available range from single slice, to spiral to multislice, dual source technology as well as electron beam CT. Scans can now proceed more rapidly by acquiring each sectional image of the body in millisecond or sub second duration. The multislice, dual source and EBCT allows elegant multiplanar and 3D reconstructions as well. Virtual colonoscopy is one good example where post processing has been invaluable.

Therefore, it is not surprising that the CT scan has now been explored and employed in whole body screening for disease. In fact, CT screening centres have sprouted up based on the premise of wellness screening – to detect diseases before they become more advanced. In fact as whole body CT is being marketed directly to consumers, the consumers (patients) are now beginning to demand the test.

Yet, the following are questions that have not been answered adequately for whole body CT screening and all of them focus on whether whole body CT screening meets the standards of a good screening test for the diseases (disease generally being marketed for are cancer and coronary artery disease) it is supposed to screen for [1,2,3]?

1. Large scale randomized clinical trials (RCT) for evaluation of whole body screening in apparently healthy individual has not been published to date. Studies such as these may be difficult to perform as ethical issues arise from the radiation dose, being very significant in whole body CT as well as the costs of the scan and the risks from contrast media, if administered in routine whole body CT Screening. In addition, RCTs tend to be disease specific and interpreting results of trials where an individual is being screened for multiple diseases at the same time may not be straight forward. In addition, CT technology is rapidly advancing and therefore by the time an RCT is concluded, can the results be applicable?

2. Should intravenous contrast media be used for all whole body screening CT scans? Non enhanced CT of the abdomen is generally inadequate for lesion characterization. Malpractice issues have to be considered in screening CT, particularly if the use of contrast media results in severe contrast reaction or if the lack of use resulted in a missed diagnosis [4]

3. Guidelines that exist for follow up or further evaluation for overall whole body CT screening when abnormalities are detected, e.g. callback rate. Currently there are some guidelines or consensus for CT lung findings but this is because there is a basis for these, size or other pretest probabilities. Guidelines for CT lungs (relatively organ specific) are easier to establish than CT abdomen (multiple organs).

4. Cost effectiveness of whole body screening CT

5. Indices for whole body CT such as negative predictive rate, sensitivity, specificity, false negative, false positive and others are unknown.

It is noted that whole body CT screening may include the head, neck, thorax, abdomen and pelvis or in some centres or countries, this may only include the neck, thorax, abdomen and pelvis or just the thorax, abdomen and pelvis.

Principles in Screening

Screening involves a test, procedure or investigation that is used to look for disease before it manifests with signs and symptoms. It is based on the premise that detecting a disease at its earliest affords the best chance of cure.

A screening test is considered effective if it reduces deaths from the disease being screened for. Screening tests can be applied to the whole population or to a subset of the population, for example, that is based on the risk profile of the person for a specific disease.

Main considerations for screening are as follows [3]:

1. Does the disease merit screening? (For example, is the disease very common in the population in question and is proving to be a major healthcare burden to treat and care for?)

2. Is there a reliable screening test for the disease in question? The false positive and false negative rates, positive and negative predictive values as well as accuracy are important parameters.

3. Is there available and effective intervention/treatment for the disease in question, if detected early? There is no point in screening for a disease if there is no cure or effective treatment for the disease. Another point would be a disease that is so slowly progressing that treating it early may not make a difference to the lifespan.

Therefore, screening should not be taken lightly and requires careful cost-benefit analysis. For individuals opting for any screening test/procedure/investigation, they should be counseled as to the pros and cons, benefits and risks (if any) entailed in the process.

Radiation Issues in CT

The effective doses from diagnostic CT procedures are typically estimated to be in the range of 1 to 10 milliSieverts (mSv)[5]. A CT examination with an effective dose of 10 mSv may be associated with an increase in the possibility of fatal cancer of approximately 1 chance in 2000. Therefore a CT scan must only be performed when the benefits outweigh the risks and information from the CT scan will alter the management of the patient's condition.

The amount of radiation dose received by the patient is variable by a factor of 10 [6, 7], depending on the size of the patient, make and type of CT scanner, scanning parameters and body part being scanned. It is also an established fact that CT studies account for the largest population radiation dose from medical diagnostic studies and this is increasing rapidly over the years [8,9,10]. The contribution of the different types of examinations to the average effective dose per capita from diagnostic exposures in 1998 in the Netherlands [8] was as follows:

Conventional Radiology	8%
Advanced Radiology (Interventional, Angiography etc)	37%
Nuclear Medicine	11%
Mammography Screening	2%
Extramural Dentistry	0.2%
Computed Tomography	**42%**

According to the UNSCEAR 2000 Report on Sources And Effects of Ionising Radiation, the percentage contribution by CT scans to global collective dose from medical x-ray examinations have increased from about 14% in the period 1955-1990 to about 33% in the period 1991-1996 [9]. The growth is phenomenal and therefore the cumulative dose to the population is significant.

The College of Radiology, Academy of Medicine Position on Whole Body Screening CT

In all medical procedures, there must be indications and justification for its use. Consideration of the available resources versus clinically useful information that alters management inclusive of financial and safety issues cannot be compromised. This is even more imperative with medical procedures requiring ionizing radiation.

Justification, Optimisation and Dose Limitation remains the main tenets for radiology practitioners. In clinical scenarios where benefit exceeds risks and further management of the patient is dependent on information gleaned from the CT scan, then the examination is deemed justified. The radiologist and the radiographer or radiologic

technologist operating the CT scanner must optimize the examination to get the most information by using scan parameters that do not use excessive radiation (dose limitation). CT scans should be performed keeping in mind the principle of ALARA (As Low As Reasonably Achievable).

All CT scans must be conducted by a trained medical practitioner who is a qualified radiologist with a valid practising licence from the Malaysian Medical Council (MMC) and is preferably listed in the National Specialist Register (currently a voluntary registration process). The equipment must be operated by trained and qualified radiographers. The facility providing the CT service must have in place radiation protection and quality assurance programmes.

Where CT may be considered appropriate for screening:

CT	Purpose	Appropriate Indications	Other Comments
Cardiac (Unenhanced)	Calcium Scoring (calcifications in the coronary arteries)	Most appropriate for asymptomatic patients at medium-risk for cardiovascular events	Those with Agatston score greater than 400 may be restratified to high risk and may require more vigorous risk modification. More recently seen to be independently predictive of cardiovascular risk and adds incremental prognostic information to the conventional risk factor scoring methods.
Cardiac CT Angiogram (CCTA)	To detect significant coronary artery stenosis	Asymptomatic High risk patients; Asymptomatic low-to-moderate Risk but with positive Stress ECG	Stenosis of more than 50% is considered haemodynamically significant
Colon	To detect polyps and early cancers in the colon	Can be considered if part of a programme for colorectal cancer screening; for average-risk individuals 50	Good for detecting polyps or lesions 6mm and larger

		years or older	
Lung	To detect early lung cancer	Still controversial even if applied in high risk individuals (eg smokers)	A number of large trials are in progress in the world for eg National Lung Screening Trial, USA
Whole Body (head to symphysis pubis or chest, abdomen & pelvis)	Early detection of disease & peace of mind	**No** appropriate indication for asymptomatic individual **Definitely Not** to be used for body fat composition and osteoporosis	High rate of false negatives potentially leading to additional tests, some of which may be high risk; uncertainty from findings of unknown clinical significance leading to unnecessary investigations

Source: Consensus Statement for Utilisation of Cardiac CT [11]; 12th COMARE Report [14]

Special Circumstances for targeted CT screening procedures

A. For calcium scoring in Cardiac CT, this is most useful for patients with a medium risk level for coronary artery disease for whom a total calcium score greater than 400 HU (by Agatston method) may render the patient as high risk requiring more intensive risk modification. For cardiac CT angiogram, only asymptomatic and low to moderate cardiovascular risk patients with positive stress ECG presents an appropriate indication [11].

B. CT Colonography (Other names are Virtual Colonoscopy and Virtual colonography)
This is a CT examination of the colon, after distending the colon with carbon dioxide or air, and then, performing a CT scan of the abdomen and pelvis usually in both prone and supine positions. The data is reconstructed and can provide both axial images, 3-D, MPR as well as a colon fly-through.

The radiation dose in CT Colonography ranges from 1.8mSv to 15 mSv with an average of 8 mSv. The barium enema (barium study using xray fluoroscopy) radiation dose averages 7 mSv.

Recently, CT colonography has been included in the Joint Guideline of the American Cancer Society, the US Multi-Society Task Force on Colorectal Cancer and the American College of Radiology on Screening and Surveillance for the Early Detection of Colorectal Cancer and Adenomatous Polyps, 2008 [12, 13]. Screening average-risk individuals over 50 years old may reduce mortality from colorectal cancer. Screening should proceed in a proper programme that begins with risk stratification, and results from an initial test followed through appropriately based on findings. For this screening to be effective, one must adhere to the programme and undergo good quality tests. The use of CT colonography must be used judiciously and existing recommendations for screening in low, medium and high risk individuals should factor into the decision to proceed with CT Colonography.

C. Screening CT Lung is still controversial [14, 15, 16, 17, 18]. Although CT is probably best at detecting early lung cancer, the evidence to suggest that treatment/intervention at this stage reduces mortality or improves life span is not clear cut [19]. In addition, CT lungs detects many small benign nodules, and the cost-safety-benefit analysis is not straight forward, as lung biopsy carries with it significant risks. There are ongoing trials in screening lung CT in the at risk population for example the National Lung Screening Trial in the USA [20]. However, even trials are surrounded by controversy as the International Early Lung Cancer Action Programme was reported on 26 March 2008 to have received some funding from a tobacco company [21]. The latter adds to the other questions on lead time bias, length time and overdiagnosis bias.

Whole Body Screening in the Healthy/Asymptomatic Individual

To date, the College of Radiology (CoR) does not see any clear benefit from whole body screening CT scans in healthy individuals. Therefore, after reviewing all available current data, the CoR does not recommend whole body screening CT scan including routine CT lung in healthy asymptomatic individuals in the absence of risk factors as the risks outweigh the potential benefits. The appropriateness of CT screening examinations may change with new evidence, improvements

or changes in CT technology, disease pattern, type, treatment and various other factors. [12-28]

References

1. Furtado CT, Aguirre DA, Sirlin CB, et al. Whole-Body CT Screening: Spectrum of Findings and Recommendations in 1192 Patients. Radiology 2005; 237:385-394.

2. Hall FM. Callback and Follow-up Guidelines for Whole-Body CT Screening. Radiology 2006; 241:627-629 (Letters to Editor)

3. Modic MT & Obuchowski N. Whole-body CT screening for cancer and coronary disease: Does it pass the test? Cleveland Clin J of Med 2004; 71(1):47-56

4. Berlin, L. Should Whole-Body CT Screening Be Performed with Contrast Media? Am J Roentgenol 2003; 180: 323-325

5. Patient Dose Information, Health Protection Agency, UK: http://www.hpa.org.uk/webw/HPAweb&HPAwebStandard/HPAweb_C/1195733826941?p=1158934607708 (Date of access: 7 April 2008)

6. **US Food and Drug Administration on Radiation Risks:** http://www.fda.gov/cdrh/ct/risks.html (Date of access: 7 April 2008)

7. American Association of Physicists in Medicine Report No.96, 2008. The Measurement, Reporting and Management of Radiation Dose in CT.

8. Meeuwsen E & Brugmans M. Radiation exposure of the Dutch population from medical examinations. National Institute for Public Health and the Environment, Laboratory for Radiation Research, Bilthoven, The Netherlands. http://www.srp-uk.org/utrecht/utr43.pdf (Date of access: 7 April 2008)

9. UNSCEAR Report 2000: Sources and Effects of Ionizing Radiation. Vol 1. http://www.iop.org/EJ/abstract/0952-4746/21/1/609 (Date of access: 7 April 2008)

10. Brenner DJ & Hall EJ. Computed Tomography – An Increasing Course of Radiation Exposure. New Eng J Med 2007; 357 (22): 2277-2284

11. National Heart Association of Malaysia & College of Radiology, Academy of Medicine of Malaysia, 2008. Consensus Statement on the Utilisation of Cardiac CT

12. CT Colonography. International Atomic Energy Agency Resources on Radiological Protection of Patients. http://rpop.iaea.org/RPoP/RPoP/Content/InformationFor/HealthProfessionals/1_Radiology/CTColonography.htm (Date of access: 7 April 2008)

13. Screening and Surveillance for the Early Detection of Colorectal Cancer and Adenomatous Polyps, 2008: A Joint Guideline from the American Cancer

Society, the US Multi-Society Task Force on Colorectal Cancer, and the American College of Radiology. CA Cancer J Clin 2008 (online Mar 5, 2008; Print: May/June 2008). http://caonline.amcancersoc.org/cgi/content/full/CA.2007.0018v1

14. 12th Report of the Committee on Medical Aspects of Radiation in the Environment: The Impact of Personally Initiated X-Ray Computed Tomography Scanning for the Health Assessment of Asymptomatic Individuals. http://www.comare.org.uk/documents/COMARE12thReport.pdf (Date of access: 7 April 2008)

15. MacMahon H, Austin JHM, Gamsu G et al. Guidelines for Management of Small Pulmonary Nodules Detected on CT Scans: A Statement from the Fleischner Society. Radiology 2005; 237: 395-400

16. Brenner DJ. Radiation Risks Potentially Associated with Low-Dose CT Screening of Adult Smokers for Lung Cancer. Radiology 2004; 231: 440-445

17. New York Early Lung Cancer Action Project Investigators. CT Screening for Lung Cancer: Diagnoses Resulting from the New York Early Lung Cancer Action Project. Radiology 2007; 243: 239-249.

18. The International Early Lung Cancer Action Program Investigators. Survival of Patients with Stage 1 Lung Cancer Detected on CT Screening. N Engl J Med 2006; 355:1763-1771 http://content.nejm.org/cgi/reprint/355/17/1763.pdf

19. Swensen SJ, Jett JR, Hartman TE et al. CT Screening for Lung Cancer: Five-year Prospective Experience. Radiology 2005; 235: 259-265

20. National Lung Screening Trial. http://www.cancer.gov/nlst/what-is-nlst (Date of access: 7 April 2008)

21. Tobacco Money Financed CT lung Cancer Screening Trial. Diagnostic Imaging Online, 26 March 2008. http://www.dimag.com/showNews.jhtml?articleID=206905969

22. Beinfield Mt, Wittenberg E & Gazelle GS. Cost Effectiveness of Whole-body CT Screening. Radiology 2005; 234:415-522

23. US Food and Drug Administration on Whole Body CT: www.fda.gov/cdrh/ct (Date of access: 7 April 2008)

24. Health Physics Society Position Statement on Whole Body CT Screening http://hps.org/documents/ctscreening_ps018-0.pdf (Date of access: 7 April 2008)

25. Royal Australian and New Zealand College of Radiologists Media Statement on Whole Body CT http://www.ranzcr.edu.au/newsandevents/mediareleases/index.cfm (Date of access: 7 April 2008)

26. Radiation Health and Safety Advisory Council (Australia)
www.arpansa.gov.au/pubs/rhsac/st1_aug02.pdf (Date of access: 7 April 2008)

27. NSW Department of Environment and Climate Change
Information on Whole Body Scanning
http://www.environment.nsw.gov.au/radiation/ctbodyscans.htm (Date of access: 7 April 2008)

28. New South Wales Health: New Penalties to Control Whole Body CT Scan
www.health.nsw.gov.au/news/2003/June/08-06-03ct.htm (Date of access: 7 April 2008)

About the College of Radiology, Academy of Medicine of Malaysia

The College of Radiology is a chapter under the Academy of Medicine and its members comprises clinical radiologists, clinical oncologists, medical physicists and allied professionals.

It is a non-profit professional body and aims to serve patients and society by maximizing the value of radiology, clinical oncology, interventional radiology, nuclear medicine, medical physics and other allied health sciences by:

- Improving the quality of patient care with better outcomes, cost-effectiveness and safety
- Advancing the science of radiology/biomedical imaging/clinical oncology/nuclear medicine through adoption of newer proven technologies and treatment modalities
- Positively influencing the socio-economics of the practice of radiology/biomedical imaging/clinical oncology/nuclear medicine
- Facilitating continuing education for radiology/biomedical imaging/clinical oncology/nuclear medicine and allied health professions
- Supporting, facilitating and promoting the conduct of research for the future of radiology/biomedical imaging, nuclear medicine and clinical oncology
- Forging closer relationships with other colleges to form partnerships in post graduate training and research activities
- Advising and assisting the relevant regulatory authorities
- Participating in educational community projects
- Establishing standards and practice guidelines in the use of Information Technology in the related disciplines.
- Improving the quality of patient care with better outcomes, cost-effectiveness and safety
- Advancing the science of radiology/biomedical imaging/clinical oncology/nuclear medicine through adoption of newer proven technologies and treatment modalities
- Positively influencing the socio-economics of the practice of radiology/biomedical imaging/clinical oncology/nuclear medicine
- Facilitating continuing education for radiology/biomedical imaging/clinical oncology/nuclear medicine and allied health professions
- Supporting, facilitating and promoting the conduct of research for the future of radiology/biomedical imaging, nuclear medicine and clinical oncology
- Forging closer relationships with other colleges to form partnerships in post graduate training and research activities
- Advising and assisting the relevant regulatory authorities
- Participating in educational community projects
- Establishing standards and practice guidelines in the use of Information Technology in the related disciplines.

College of Radiology Website: www.radiologymalaysia.org