



**Consultation response to the
COMARE 12 Report
recommendations on CT
scanning of asymptomatic self-
referred individuals**

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Consultation response to the COMARE 12 Report recommendations on asymptomatic CT scanning of self- referred individuals

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Executive summary

Introduction

1. The Department of Health asked the independent expert committee, the Committee on the Medical Aspects of Radiation in the Environment (COMARE) for advice on the use of computed tomography (CT) scanning of the asymptomatic individual. The Committee offers independent advice to all Department of Health Departments and Devolved Authorities on the health effects of natural and man-made radiation. It is also asked to assess the adequacy of the available data and advise on the need for further research. www.comare.org.uk
2. COMARE established a Medical Practices Subcommittee which incorporated representatives from COMARE, the Royal College of Radiologists (RCR), the Royal College of Physicians (RCP), the Independent sector and a Patient Representative selected from a number of applicants from the Commission for Patient & Public Involvement in Health (CPPIH). The subcommittee's deliberations were passed to the full committee for consideration.
3. On 19 December 2007 the Committee's report entitled "The impact of personally initiated X-ray computed tomography scanning for the health assessment of asymptomatic individuals" was published. COMARE made nine recommendations including recommendations that certain types of CT scans for individual members of the public who have no symptoms should not be allowed and that strict criteria should be applied for other specific assessments. This CT scanning service for asymptomatic individuals is only offered in the private sector, so these recommendations do not affect the CT services offered by the NHS.

The Consultation process and responses received

4. In order to get a wider impact on the issues raised by the COMARE report, on 17 June 2008 a consultation document was placed on the Department of Health website, inviting comments on the Committee's recommendations from members of the public, interested parties and stakeholders. Individual notification of the start of the consultation process was sent to private companies offering CT scanning services; to the relevant Royal Colleges; and groups representing professionals in this field. Those responding to the consultation were asked to confirm whether they supported each of the nine recommendations, and if they had any comments to make on a particular recommendation, to provide evidence to support those comments.
5. When the consultation closed on 9 September 2008, 86 responses had been received. These responses included 24 from members of the public, 40 professionals, 10 professional groups and Royal Colleges, 3 private companies offering CT scans, 1 charity, 1 healthcare inspectorate, 1 group representing patients, 1 patient representative. 5 individuals responded but were unable to be assigned to a category. 14 individuals related their own experiences of private scanning services but made no comments on the recommendations. A list of respondents is included at Annex A.
6. 62 of the respondents were content for their responses to be made treated as freely available.

7. The Department is grateful to everyone who took the time to respond to the consultation

Key findings and future actions

8. It should be noted that the COMARE Report and the recommendations it contains, only address the CT scanning of self-referred asymptomatic individuals and not asymptomatic individuals in population health screening programmes or those referred for diagnosis. COMARE specifically referred to this practice as assessments because the clients were asymptomatic.
9. The Royal Colleges and bodies representing professionals in this field responded positively to the recommendations in the COMARE 12th Report.
10. The responses from CT scanning companies ranged from opposition to the recommendations, to the provision of evidence to support small changes to certain recommendations.
11. It was clear from the consultation that appropriate regulation of this field is required.

Key points made by respondents were as follows:

12. That information on the benefits of the investigation and the risks associated with the radiation exposure should be made clear to any individual undergoing a CT scan.
13. Private CT scanning services should be integrated into healthcare pathways.
14. Many clients of these private CT services were positive about their experiences and believed that they should be allowed to choose private health services and to spend money how they see fit, particularly when the Department of Health is encouraging people to take steps to look after their health.
15. It was suggested that whole body CT scans were not undertaken in the UK and should not be undertaken unless they are done as an adjunct to PET-CT.
16. The advertising of CT examinations of the heart, lungs, abdomen and pelvis, and bone density as one package (thus providing CT images from the collar bone to pelvis) to asymptomatic individuals was noted.
17. Specific issues were raised and evidence presented about aspects of the recommendations on CT scanning for osteoporosis, lung, cardiac and colon disorders. This included evidence that the current risk scoring for cardiac CT is flawed and that a lower age limit of 45 years for virtual colonoscopy should be set rather than the 50 years recommended by COMARE.

Expert review of Evidence

18. The issues raised by respondents have also been discussed with the Royal Colleges, the Health Protection Agency, the Healthcare Commission, relevant Department of Health policy leads, other Department of Health departments, the devolved administrations and particularly the National Screening Programmes Committee and the National Imaging Board.
19. Independent experts were asked to review the additional scientific evidence presented by respondents on the use of CT scanning for the detection of :-

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- Osteoporosis – Currently, DEXA scanning of the spine and hip is the gold standard test for Bone Mineral Densitometry. If bone density is found to be low, it is just one of the many risk factors that aid the diagnosis and treatment of osteoporosis and not necessarily the final diagnosis.
- Lung disease - Large randomized controlled studies are currently in progress but the evidence will not be available for some time. There appears to be some evidence presented to support the use of CT for those individuals at high risk such as those with significant smoking history or previous exposure to asbestos.
- Coronary Artery Calcium Scoring - There seemed to be some debate as to the accuracy of the traditional Framingham risk assessments and some suggest that Framingham factors do not account for all patients at risk of heart attacks. The evidence provided needs to be considered and a more appropriate clinical scoring system needs to be established and accepted.
- Virtual colonoscopy - Best practice is recognised such that patients at high risk should be assessed in specialist multi-disciplinary oncology services with an appropriate clinical support infrastructure. However, the facts presented by correspondents about asymptomatic virtual colonoscopy and suggested age limits are noted.

Department of Health Conclusions

20. It can be concluded from the consultation that there are two distinct views. There are the views from the scanning companies and their former customers and the views from professional bodies.
21. Department of Health can conclude from the responses to the consultation, when compared to COMARE's recommendations, that the practice of scanning self-referred asymptomatic individuals needs to be clearly brought within UK regulations, whilst ensuring that the practice is not confused with diagnostic procedures or population health screening programmes.
22. Department of Health therefore intends to make appropriate changes to the Ionising Radiation (Medical Exposure) Regulations 2000 (IRMER2000) which will assist all of the UK IRMER2000 enforcement authorities. The change will mean that Individual Health Assessments (IHA) are clearly brought within the regulatory regime. For the purposes of this document and future references, we shall refer to such CT scans as IHA CT.
23. Department of Health has formed the view that up to date guidance needs to be available to practitioners and regulators that is acceptable to professional bodies such as the Royal College of Radiologists and the Royal College of Physicians. Thus for example, if research brings new evidence that IHA lung CT was justified, then any guidance that stated IHA lung CT was not justified would have to be quickly changed.
24. The evidence on the justification of x-ray exposures drawn from the COMARE report and from the consultation confirm that whole-body (neck to pubic symphysis), non targeted, spinal, osteoporosis, and body fat IHA CT scans are very unlikely to be justified. The UK IR(ME)R enforcement authorities need to be aware of this evidence and guidance needs to be agreed by relevant stakeholders about when an IHA CT scan is justified for lung, coronary artery calcification scoring for intermediate risk individuals and virtual colonoscopy.
25. In consequence, Department of Health intends to review the Justification of Practices Involving Ionising Radiation Regulations 2004 to see if any changes are necessary to achieve these objectives

SUMMARY OF RESPONSES AND THE DEPARTMENT OF HEALTH'S RESPONSE TO EACH RECOMMENDATION.

Recommendation One

26. *Medical exposures using ionising radiation and the equipment used to undertake these exposures are controlled by a number of regulations, including the Ionising Radiation (Medical Exposure) Regulations 2000 and Ionising Radiations Regulations 1999. These regulations apply to exposures undertaken both in the NHS and in the commercial sector. Commercial CT services themselves, however, are not subject to additional regulation as they do not involve interventions or treatment. COMARE recommend that the Department of Health should review this situation and consider regulating these services against agreed standards. Any regulation should address and provide guidelines on appropriate referral processes, justification and optimisation of CT scans.*

27. *It should also require that providers of CT services should submit agreed datasets to the regulator regarding the rate of reported findings.*

28. 62% of those commenting fully agreed with this recommendation. All of the professional groups, UKNSC, BUPA and the European Scanning Centre agreed that there should be a common standard of regulation for both independent and NHS CT scanning services including any requirement to submit datasets.

29. The Society and College of Radiographers (SCoR) suggested that:

“the set of service accreditation standards, part of the radiology accreditation programme being developed currently through a partnership between the Society & College of Radiographers and the Royal College of Radiologists, will be useful as a way of helping to provide standards for measurement.

“The following is an example that supports the recommendation. SCoR received a query from a member of the public who had undergone CT scanning within a commercial CT service, including cardiac calcium scoring. Subsequently, this person received a letter asking her to attend her GP urgently as there was a problem with her coronary arteries. She was given no advice by this particular commercial CT provider, and they had no mechanism of referring her on. Her GP was surprised by the report but, as she was concerned, he referred her privately to a cardiologist. The cardiologist felt that the only way to assess her coronary arteries was by cardiac catheterisation which was done, again privately. The cardiologist concluded that her coronaries were in perfect shape. The person was not privately insured.

This healthy person, but from the ‘worried well’ community, underwent significant additional worry, unnecessary visits to her GP, an invasive procedure with both morbidity and mortality risks, and spent a sizeable sum of her own money – all directly attributable to the ‘opportunity’ offered to such individuals to undergo a commercially available scanning procedure, itself not without risk.

Our view is that the above is not an atypical experience. While it receives calls from members of the public, it is by no means their first port of call. Doubtably, therefore, other members of the public will have had similar experiences that have not come to the Society's attention."

30. The Healthcare Commission, as IR(ME)R enforcement authority in England, made the following comments.

"We would, propose that the Commission is in a good position to assess and inspect against these standards. We would propose that the standards themselves should be laid down by another authority, such as DH in consultation with professional bodies and HPA who are well placed to review and assess additional evidence for CT scanning as it becomes available. We note the intention of DH to consider amending existing legislation to make provision for the use of radiological examination, and in particular look forward to the provision of referral and justification guidelines of individual client scans."

Department of Health response to recommendation one

31. Department of Health agrees that the practice of Individual Health Assessment CT scanning needs to be appropriately regulated in accordance with the globally-accepted radiation protection ethos of balancing the radiation detriment against the benefits of the CT scans.

Recommendation Two

32. *The information supplied to asymptomatic clients attending commercial CT services is inconsistent and incomplete. COMARE recommend that all such services should provide comprehensive information regarding eligibility criteria and the dose and risk of the initial CT scan. The rates of false negative and false positive findings associated with CT scanning of asymptomatic individuals should be independently audited and explained. In particular, the range of further investigations that may be required to confirm initial findings and the risks associated with subsequent scans if recommended, should be discussed. The provision of these investigations will need to be clarified. An outline of this information should be made available to individuals before they present for scanning, as part of websites, advertising literature, etc*

33. 68% of those commenting agreed with this recommendation. Professional groups, professionals and the scanning companies all agreed that the issues involved in the benefit versus risk discussion around a particular exposure to radiation are extremely complicated. They agreed that written guidance that is clear and simple is essential in enabling an asymptomatic individual to make an informed decision.

34. The Clinical Radiology Patients' Liaison Group of the Royal College of Radiologists suggested that:

“Guidelines should be available on the presentation of information to individuals in a form comprehensible to people unused to dealing with statistics and the discussion of risks.”

35. The British Institute of Radiology said that:

“Statements such as the one saying that false positives and false negative rates must be quoted make good sense but are often much more complicated than they appear. For example, the risk of a false positive in finding an incidental lung nodule will be dependent upon where the patient has lived in the past - benign lung nodules being much more commonly found in the cotton growing belt of the USA due to their particular pattern of infectious disease exposure.”

36. The Healthcare Commission commented that:

“Concerning the auditing and explanation of audit (false positive and false negative rates) we would support that the outcomes and findings of CT scans of asymptomatic clients are independently assessed in the way described. We are not sure we are the right organisation which should do so as our current role does not involve the independent audit of clinical services.
Concerning the completeness of the information (evidence, risks and benefits) provided to asymptomatic clients prior to their scan must be included in the regulatory (assessment and inspection) process carried out by the IR(ME)R enforcement authority. We would recommend that guidance and information issued to clients by service providers is as specific as possible to allow more straightforward assessment. Consideration should be

given to a formalised consenting process before the scan takes place to ensure that the clients have been fully informed of the risks and benefits and that the information passed to the client is documented.”

37. The Institute of Physics and Engineering in Medicine

“believes that, in addition to the radiation risks associated with CT scans there are potentially damaging psychological effects for patients receiving false results and potential risks from receiving additional investigations.”

38. The Royal College of Physicians considered that

“Since the scans are performed on asymptomatic individuals it is important that they appreciate the risk associated with the examination and understand the procedure that must be followed if there are any positive findings. Many clients probably simply look on this as an easy high-tech check-up and do not have a clear idea of the consequences and the potential costs that might ensue if a finding were positive. They almost certainly will not be aware of the risks of false-negative or false-positive findings. They are thus embarking blindly on a course, which they might not choose if they were better informed.

We also support its application to the NHS organisations providing CT services. We would like to think we are consistent and comprehensive but the ad-hoc queries from members of the public can sometimes suggest otherwise.”

39. The Society of Radiological Protection stated that

“We support these recommendations. Since the scans are performed on asymptomatic individuals it is important that they appreciate the risk associated with the examination and understand the procedure that must be followed if there are any positive findings. The same would presumably apply to any use by the NHS of CT particularly for screening applications. We support a consistent and comprehensive approach.

Many clients probably simply look on this as an easy high-tech check-up and do not have a clear idea of the consequences and the potential costs that might ensue if a finding were positive. They almost certainly will not be aware of the risks of false-negative or false-positive findings. They are thus embarking blindly on a course which they might not choose if they were better informed.”

40. The UK National Screening Programmes Committee advises Ministers, the devolved national assemblies and the Scottish Parliament on:

- the case for implementing new population screening programmes not presently provided by the NHS within each of the countries in the UK;
- screening technologies of proven effectiveness but which require controlled and well-managed introduction
- the case for continuing, modifying or withdrawing existing population screening programmes. In particular, programmes inadequately evaluated or of doubtful effectiveness, quality, or value.

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- As such it has formal interest in any schemes that propose to assess or test the whole population for risk or early disease. The definition of screening it uses is set out below.

“Screening is a public health service in which members of a defined population, who do not necessarily perceive they are at risk of, or are already affected by a disease or its complications, are asked a question or offered a test, to identify those individuals who are more likely to be helped than harmed by further tests or treatment to reduce the risk of a disease or its complications

The COMARE report gives an excellent description of the risks and benefits that accrue to testing people with no reason to think that they have a problem. There are particular issues that relate to the areas explored in terms of excess radiation but the concerns about false reassurance and the potential for unnecessary investigations and anxiety occur in every screening programme and need to be weighed carefully.

With respect to the particular issues of personally initiated CT scanning in asymptomatic individuals, the UK NSC expressed concern that the high profile marketing of self-initiated CT scans is founded on commercial motivation seeking to maximise profits and that, regrettably, the potential benefits are highlighted while the risks and potential disbenefits are not made explicit.

A 2004 *Which?* report examined five different private screening clinics, and concluded that essential safeguards in relation to quality assurance and information provision were lacking. The scale of the harmful effects, in terms of induced cancers and economic impact are quantified in the DH Impact Assessment and, as a minimum, providers of these scans should be required to provide all potential users of the service with full and frank detail of these disbenefits. The UK NSC has explicitly adopted a policy of “informed choice” whereby effort and resource is expended by the NHS and the individual practitioner in ensuring that the screenee has all the information they need to make a choice appropriate to them and their circumstance.”

41. BUPA agrees that

“for people to give proper informed consent for any investigation they must be appraised of all relevant facts before undertaking that investigation. It is thus important that all this information is available for customers seeking a scan in any arena. This is no less true in the area of scanning asymptomatic people for disease.”

42. The European Scanning Centre maintained that

“It is not possible to gather the false positive data because individuals do not attend for follow-ups.”

43. Lifescan believes it

“is essential is that patients should have access to comparable information about the risks of different procedures, and that patients should have access to this information whether they are considering diagnosis on the NHS or in the private sector. In short, any new rules on information provision should:

- apply to all diagnostic treatments equally (including breast and cervical cancer screening, optical colonoscopy, barium enema, and FOBT);
- apply to the NHS and the private sector equally.”

Department of Health response to recommendation Two

44. We will recommend to the Care Quality Commission and Devolved Administrations that they review how they may collate assessments of the quality of information provided to clients, by means of CQC’s and the Devolved IRMER Enforcement Authorities routine IRMER inspections; and that they seek guidance on appropriate literature from professional bodies.

Recommendation Three

45. *Any medical intervention will be most effective when part of a locally agreed and coordinated clinical care pathway that is under the supervision of a multidisciplinary team. COMARE recommend that commercial CT services should have well-developed, robust and confidential mechanisms for integrating the results of their examinations into an established care pathway, including the availability of scans and data relating to any individual scanned in formats consistent with NHS information technology programmes. This intended transfer of medical data must be discussed with and agreed by patients prior to medical exposures taking place.*

46. 65% of those commenting supported this recommendation and some of the additional comments that were made are set out below.

47. Cancer Research UK

“strongly supports recommendations 3 and 4. Protocols for the prompt reporting of diagnostic tests and the onward referral of patients to specialist doctors within agreed timescales already exist for the public sector. It is essential that, where cancer is suspected, commercial providers refer back to the individual’s GPs within agreed timescales and standards so that the patient’s care can be referred to the relevant specialist multidisciplinary team for immediate assessment and treatment.”

48. The Healthcare Commission states

“We believe that CT scanning should always be part of an established care pathway and that a CT scan is an additional diagnostic jigsaw piece in addition to other pieces forming a more complete picture of the clients condition, and one which is normally and rightly based on results from those other tests (the diagnostic work-up). This observation applies to other recommendation responses

The approach to require outcomes of the CT scan to be made known to the patient’s General Practitioner appears to be sensible and achievable. They will then become known on the patient’s electronic patient record and become available to the patient’s specialist healthcare providers within the public system. No involvement of the Commission is expected from this recommendation.

In the circumstance that these services become registered with the Care Quality Commission, we would be in the position to assess whether they transfer information about scans to the other elements of the healthcare pathway, in order that the care provided is safe.”

49. IPEM

“agrees the patient care pathways are very important and need to be maintained. The availability of data to the NHS should be supported in order to reduce unnecessary investigations.”

50. The Clinical Radiology Patients’ Liaison Group of the Royal College of Radiologists commented that

“the COMARE report draws attention to the significance of psychological outcomes of scanning, particularly where false positives or negatives are reported or the outcome of a scan is unclear. We are also concerned about the possibilities of self-diagnosis following a scan and of individuals seeking further medical opinion involving additional scans. We suggest that robust mechanisms for informed post-report discussion are essential. We further suggest that mechanisms should be established to ensure that a complete record is maintained of all scans on an individual and is accessible to those responsible for justifying a scan, to ensure that any cumulative radiation effects are is monitored.”

51. The Royal College of Physicians support this recommendation and commented that

“If such systems are not in place, then the person may find themselves with a potentially serious diagnosis which they do not know how to follow-up. NHS scanners and those in private hospitals will always be part of a carefully established care pathway.

Appropriate investigative technology will be available somewhere within the NHS to ensure the patient is managed appropriately. If CT scans are performed in isolation, this in many ways fulfils the easy part of the process. The follow-up care and treatment and the organisation involved in this are both more important and more complex to organise. Placing the onus on the CT scanning service for this would seem to be appropriate. In order to avoid additional unnecessary CT scans being performed, it is also reasonable to recommend that such companies should be able to provide the medical data in a format which can be transferred to NHS or other hospital facilities in order to contribute to future management of the patient.”

52. The Society and College of Radiographers

“The Society definitely supports this recommendation.

Commercial CT services should follow all national clinical guidelines (e.g. those from the National Institute for Health and Clinical Excellence (NICE)) and report appropriate incidental findings in a timely fashion to a multidisciplinary clinical team or general practitioner able to provide the necessary continuing support and care.

We have anecdotal evidence of patients with a transient ischaemic attacks (TIAs) being scanned using CT at a commercial site but, according to NICE guidelines and the Stroke Strategy, these patients should be referred for MRI and not CT. These patients should also have carotid artery assessment and, if appropriate, urgent carotid stenting or endarterectomy – there needs to be a mechanism to get these patients onto an appropriate care pathway.

It is essential that findings and patient data be integrated into NHS IT systems in the same format as NHS technology, with the opportunity to integrate with the electronic patient record when this becomes available nationally. If this is not achievable then patient safety may well be jeopardised. Integration with the electronic patient record will be particularly important to monitor the frequency of scans being undertaken on an individual over a time period.”

53. The UK National Screening Programmes Committee said

“We support this recommendation. It should be made clear to users of these services that integration of their CT scan results into an agreed and explicit care pathway involving an appropriate multi-disciplinary team is in their best interest. Information sharing between the commercial sector and NHS, subject to confidentiality and prior patient consent, represents good practice and should be the norm. The UK NSC is very clear that screening is not a test but the whole pathway, and regards offering an assessment of health without any recourse to proper diagnosis or treatment if required as unethical.”

54. BUPA agrees that

“any investigation should be part of a care pathway that may be initiated either at the point of delivery, or through the patients GP if he/she prefers this. Additionally we feel that new imaging tests should be subject to the same type of evaluation as is being called for lab tests by the Royal College of Pathologists and the PHG Foundation whereby the analytic validity, the clinical validity and the clinical utility of the imaging of each anatomic region with a view to discovering signs of pre-specified diseases are examined.”

55. European Scanning Centres state that

“they have no right to inform the individual’s GP, however all self-referred patients with significant findings have consented to have their GP informed. They go on to say that “We agree that all scans performed in the independent sector should be made fully available in a CD format that is compatible with the workstations of NHS CT scanners and has the appropriate measuring device on them to allow subsequent follow-up measures to be performed for comparison”

56. Lifescan stated

“Lifescan does not scan everyone who requests a CT scan. Indeed, we estimate that around 20%-30% of approaches by individuals are turned down, following assessment against protocols provided by a specialist Consultant Radiologist, because a CT scan is deemed to be an inappropriate course of action. In these cases, we provide information on more appropriate diagnostic tools and refer individuals back to their GP – in other words, back into their primary care pathway. In the case of patients who have been scanned, we do not support any transfer of medical data without the written consent of the patient. It is for the patient to decide whether they would like their medical data to be transferred, and if so, to whom. The patient may legitimately withhold their consent. There remain a wide variety of NHS information technology programmes, about which commercial providers

could not reasonably be expected to have knowledge. So a requirement to supply data to the NHS in specific formats would simply add unreasonably to the cost of commercial providers.”

Department of Health response to recommendation Three

57. Ensuring that only justified exposures take place will minimise any risk to individuals and ensure no unnecessary exposure occurs. Registration of IHA service providers could constitute a means by which referral into an appropriate pathway could be monitored. We will recommend to the Care Quality Commission and Devolved Administrations that they consider monitoring care pathway referrals and the adequacy of data exchange as part of any registration requirements.

Recommendation Four

58. *Any individual with symptoms relevant to conditions likely to be identifiable by CT scanning, should be entered into an appropriate care pathway as soon as possible. The customary process is for this to be initiated by a referral from a general practitioner (GP). Therefore commercial CT services, which may not be able to provide a full range of diagnostic capabilities, should in most circumstances refer personally initiating symptomatic individuals back to their GP without delay. This will, of course, not apply where a patient has been referred for a CT scan by their GP or a relevant NHS hospital-based medical specialist who is responsible for the individual's care.*

59. 65% of those commenting agreed with this recommendation and the following additional comments are noted.

60. IPEM agrees that

“integrated patient care pathways are very important and need to be maintained. There needs to be follow up systems for individuals where symptoms are identified.”

61. The Royal College of Physicians added the comment that

“The commercial CT scanning services should not take on the role of diagnosis from the GP. Therefore this would seem to be a reasonable general rule. We are not sure how a situation in which an individual has referred themselves for a CT scan because they have not been satisfied with actions taken by their GP should be dealt with. There should perhaps be some degree of flexibility to take this into account.”

62. The Society and College of Radiographers supports this recommendation

“agree that GPs are the appropriate gatekeeper for symptomatic individuals and are the group that should be responsible for referrals. The use of the words “*in most circumstances*” within this recommendation may allow too much flexibility and so ‘allow’ commercial CT providers license to scan before referring their symptomatic clients back to their GP. Some form of audit is required to measure the frequency of these referrals.”

63. The Healthcare Commission said

“This recommendation requires that individuals with symptoms requiring a CT scan do not receive a scan from the independent scanning centre, but become integrated within the public system, perhaps resulting in the patient receiving their scan at a later date. We understand that, at this stage, the individual will have initiated a scan personally and begun a consultation with the staff at the centre, and perhaps, payment for the consultation alone. A motivated individual (or scanning centre) is likely not to be dissuaded from their initial enquiries and will not want their efforts to stall the scan. However we agree that clients with symptoms are patients, and the appropriate referral pathway should be via their GP. Again this is something the enforcement authority could assess.”

64. The UK National Screening Programmes Committee supported the recommendation and stated that:

“Referral to the patient’s General Practitioner should be the norm except in the circumstances identified.”

65. BUPA believes that

“an abnormal investigation should be the beginning of any care pathway. In the case of a normal investigation if the patient has continuing symptoms and worries, then it is appropriate for the CT provider to refer back to the GP. If there are significant findings on the scan, then the patient may be referred to a specialist unit, either by the CT provider directly or via their GP dependent on the patient’s wishes.”

66. European Scanning Centre commented that

“We believe that one of the biggest strengths and advantages of independent scanning centres is that individuals who have not received adequate investigation by their GP can obtain a specialised investigation for their symptoms.”

67. Lifescan

“believe it should be for the patient to decide which care pathway they choose to follow. So we do not support this recommendation if it implies that it should take place without the consent of the patient. In many cases, the patient may wish to be transferred into the NHS care pathway, in which case we agree that this is what should happen. However, if the patient prefers to continue with private sector healthcare, then that choice should be respected.”

Department of Health response to recommendation Four

68. Department of Health agrees that symptomatic individuals should be swiftly referred into an appropriate (and comprehensive) care pathway, in cases where the CT scanning provider is not itself able to provide such care. We will recommend to the CQC and Devolved Administrations that they consider monitoring the adequacy and appropriateness of such referrals as part of any registration requirements.

Recommendation Five

69. *There is a regulatory requirement that all medical exposures using ionising radiation should be referred, justified and optimised. Referral and justification must be carried out by registered healthcare professionals. Justification of any medical exposure should be based on the scientific evidence available. There is little evidence that demonstrates, for whole body CT scanning, the benefit outweighs the detriment. COMARE recommend therefore that services offering whole body CT scanning of asymptomatic individuals should stop doing so immediately. Where scans are offered for a number of discrete anatomical regions within a single scanning procedure, the advertising should clearly*

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state which regions are examined and for which conditions the scan is optimised. In CT scanning it is not possible to optimise exposure parameters for scans of the whole of the body.

70. 64% of those commenting agreed with this recommendation. Many respondents stated that whole body CT scanning is not performed in the UK except as an adjunct to PET-CT scans. Further information was provided and is summarised below.

71. The Healthcare Commission stated that

“This recommendation concerns the justification of the scan being based on conventional evidence of risk and benefit. Clearly the risk and benefit ratios in such scanning centres will not be comparable with those where there are clearer medical criteria such as strong suspicion of underlying disease following the evaluation of other medical evidence. The criteria are more likely to be based on more arbitrary data or personal concerns. We accept that the scientific and medical evidence for the different categories of scans (whole body, lung, colorectal, cardiac and ‘other’) will vary, though the rationale for the motivation and personal concerns of the individual may in most cases be similar. We are absolutely agreed that justification of exposures should be based on the latest available medical evidence to support the risk/benefit analysis. We accept the scientific basis for the justification of CT scanning of the asymptomatic individual as presented in the report, in particular that for the whole body and ‘other’ scans where alternative assessment technologies are readily available and impart a far reduced dose. We wonder whether controls might be required for individuals who self-present for (say) a cardiac scan on one occasion and colorectal elsewhere on another occasion. This raises questions about dose monitoring and whether additional thought should be given to accumulated dose.”

72. The Clinical Radiology Patients’ Liaison Group of the Royal College of Radiologists suggests

“that information provided to individuals in connection with scanning for discrete anatomical regions should explicitly state the qualification of the final sentence of this recommendation.”

73. The Royal College of Radiologists

“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. 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.”

74. The Society and College of Radiographers supports this recommendation.

“Whole body CT scanning is not appropriate for asymptomatic individuals. Self-referral for any radiological examination should not be condoned as it may reveal conditions that have no clinical significance but may lead to further unnecessary follow up investigations which may well increase the radiation burden for the individual for no benefit. We do not agree that the completion of a questionnaire by an asymptomatic individual within the commercial CT provider premises is enough clinical indication to support the justification of a CT examination. Justification under IR(ME)R cannot be done legitimately if there are no clinical concerns beforehand. We are not suggesting that the staff (including radiographers) working in some commercial CT premises are acting unprofessionally and we do accept that strict protocols exist for the booking and assessment of asymptomatic clients. It must be recognised, however, that CT may not be the first route for certain asymptomatic clients and that other modalities with less radiation risk may be more appropriate. The RCR publication “Making the best use of a Department of Clinical Radiology”, 6th Edition (2007), and the Royal College of General Practitioners and the RCR joint publication “Right Test, Right Time, Right Place”, (2006) both detail (for GPs and others) the particular radiology procedures that should be requested for symptomatic patients. Neither publication proposes CT examination as a first option for detecting heart abnormalities or colon cancers in asymptomatic clients.

Commercial CT providers should ensure that asymptomatic clients who ‘self refer’ are appraised of the risks of any x-ray procedure including information about cumulative doses. One particular commercial CT provider presently advertises CT examinations of the heart, the lungs and bone density and in addition includes a scan of the abdomen and pelvis – thus capturing CT images from the collar bone to the pelvis (all within one package) – we consider this to be whole body CT scanning and do not support this procedure, yet this could be argued as including “targeted” CT examinations to specific anatomical sites.”

75. The UK National Screening Programmes Committee

“support this recommendation and action to stop self-initiated whole body CT scanning of asymptomatic individuals should be taken as a matter of urgency. For scanning of specified anatomical regions the advertising material should state for which conditions the scan is optimised and offer to provide the evidence on request.”

76. The Royal College of Physicians

“agree with this recommendation. Indiscriminate whole body scanning of asymptomatic individuals is not justified. This is a matter which is raised with NHS radiation protection practitioners as members of the public as well as NHS staff cannot understand why such scans are allowed to go ahead, when there are very strict criteria against which any scan must be justified in NHS and private hospitals. Moreover, if these justification criteria are not followed correctly, then NHS staff would consider themselves to be liable for prosecution under IRMER 2000.”

77. BUPA believe

“there is no place for “whole-body scanning” either by CT or MRI. Again any test should be subject to analysis of analytic validity, clinical validity and clinical utility. These concepts

cannot be evaluated in this context except by linking the imaging of a particular region to a search for signs of a specified disease. This cannot be true of whole body scanning.”

78. The European Scanning Centre states that

“The exposure to an individual undergoing a heart scan and virtual colonoscopy (abdomen and pelvis) covers the majority of the area covered in a whole body scan and therefore the so called whole body scan involves little additional radiation exposure. However, we accept that the indications to screen the remaining chest are often not required.”

79. Lifescan maintains that

“In summary, Lifescan only undertakes scans for patients with appropriate risk factors. Individuals under the age of 40 will only be scanned if they have been referred by a GP and the scan can be justified by a Consultant Radiologist. For CT colonoscopies, patients under the age of 45 will be refused a scan, unless they are symptomatic or have a strong family history and are referred on these grounds by their GP.”

Department of Health response to recommendation Five

80. The evidence shows that it is very unlikely that whole body or non-targeted scans will be justifiable in the individual case, as required under the principles of the Ionising Radiation (Medical Exposure) Regulations 2000, as the detriment far outweighs the benefits. Department of Health will work with the Care Quality Commission, the Devolved Administrations, the Royal College of Radiologists, the Royal College of Physicians and other relevant stakeholders to produce suitable clinical referral guidance reflecting these principles.

Recommendation Six

81. *Investigation of a number of clinical conditions can be better undertaken using modalities other than CT. COMARE recommend that where there is evidence that CT is not the modality of choice for diagnostic purposes, then it should not be made available for the assessment of asymptomatic individuals. In particular, CT scanning primarily for spinal conditions, osteoporosis and body fat assessment should cease, since there are more appropriate methods available and which have lower radiological risk consequences. If analysis of data available from a scan intended for other purposes provides clinically useful and reliable information on, for example, osteoporosis, it would be permissible to include these data in the results.*

82. 62% of those commenting fully agreed with this recommendation. The following comments are being considered

83. The British Institute of Radiology recommended

“that CT scanning for spinal conditions, osteoporosis and body fat assessment should cease. However, there may be circumstances in which these investigations are justified as part of carefully controlled and ethically approved clinical trials.”

84. The Royal College of Physicians said

“We agree with this recommendation. CT is an easy catch all screening procedure, but is not the most appropriate for many conditions. Moreover, there is more risk associated with a CT scan than with many other investigations. Therefore, CT scanning should not be used as a screening methodology for diseases such as spinal conditions, osteoporosis and body fat assessment for which it is not the diagnostic technique of choice.”

85. The Society and College of Radiographers said

“This area requires strict regulation as there is some danger that, if other modalities are not easily available, CT will be done regardless. CT diagnosis of osteoporosis is a commercial and research tool and should not be used clinically due to the radiation risks to individuals. NICE and the National Osteoporosis Society (NOS) both quote the World Health Organisation (WHO) who state that Dual Energy X-Ray Absorptiometry (DEXA) scanning of the spine and hip is the Gold Standard test for Bone Mineral Density (BMD) which, if low, is one of the many risk factors that aid the diagnosis and treatment of osteoporosis. We support the use of DEXA in screening for BMD. The use of DEXA scanning meets the necessary screening criteria of clinical effectiveness, proven evidence base and an appropriate risk benefit analysis, and could be undertaken in both NHS and commercial centres provided the scan is undertaken by a suitably qualified radiographer.

The 3-Dimensional volumetric BMD assessment of Quantitative CT (QCT) has no large population based reference data to make it a useful tool. The difference in radiation dose to

the patient (2.5 μ Sv for DEXA) as compared to up to 1 mSv for QCT makes it a very poor choice in longitudinal follow up of disease. QCT is not useful in categorising the results in accordance with WHO thresholds as the QCT measures different components of the Bone Profile (ie trabecular alone not trabecular and cortical combined), and these thresholds have not been ratified and cannot be cross calibrated with DEXA. There is no population screening programme (and no plans to provide one) for the routine measurement of BMD. This has been evaluated and found not to be cost effective (NICE TA 87) and treatment for osteoporosis is not permitted on low BMD alone. There is no correlation for body fat values between DEXA and QCT and DEXA is again the modality of choice for this.”

86. The Healthcare Commission

“acknowledge that it is a requirement under IR(ME)R regulation 6 to ensure that alternative modalities are considered. The use, in research, of CT scanning for the diagnosis, assessment and monitoring of osteoporosis has been established in the UK with centres providing this service to patients. It may be more a matter of degree, but it is one possible interpretation that the authors suggesting that individuals may self-initiate bone mineral density scanning and this (very small) dose is justifiable (because it is so much smaller than that from a CT scanner). Of course, in principle, we would support the use of alternative radiological examinations, which provide equivalent information at a reduced dose. We are comfortable with the use of hip and spine BMD scans in the diagnosis and assessment of potentially osteoporotic patients for which there is a well established evidence base.”

87. BUPA agrees that

“where there are more suitable tests for assessment of a condition, as judged by analytic validity, clinical validity and clinical utility, then it is appropriate to use these tests. If, however, useful information such as that above can be gleaned as an incidental finding, then this may be reported to the patient.”

88. The European Scanning Centre stated that

“We fully agree that it is good clinical practice that the most appropriate modality should be used to investigate specific conditions. However, there is considerable evidence that CT densitometry is preferable to DEXA scans for assessing bone density for several reasons. CT densitometry measures both cortical and cancellous bone and gives a more accurate assessment of the whole bone density, whereas DEXA only measures cortical bone density. Furthermore, DEXA scans are influenced by calcium within the aorta as well as osteophytes - not the case with CT measurement. It is for these reasons why several NHS Trusts now offer CT densitometry including St Mary's Hospital, Paddington.”
The Centre suggested the following amendments to COMARE 12 recommendation six

CT densitometry should be reserved for patients who:-

- Are at risk of osteoporosis
- are post-menopausal women
- are Hypogonadrenal
- Have previous history of breast cancer/ prostate cancer requiring anti-estrogen therapy
- Have a previous history of eating disorder
- Have a strong family history”

89. Lifescan made a number of comments *and this is a summary of those comments*

“agrees that CT scanning is not appropriate for the investigation of spinal conditions or body fat assessment, unless there are specific symptoms, which may justify the use of a CT scan. The clinical value of body fat assessment is debatable and MRI is a more appropriate tool for investigating symptomatic spinal conditions. However, Quantitative Computed Tomography (QCT) is a well-established and proven accurate method of measuring bone mineral density and diagnosing osteoporosis. Although there are no randomized clinical trials demonstrating that CT reduces the risk of fracture, it is accepted that early detection and treatment reduces the risk of fracture. QCT is a well established tool for the diagnosis of osteoporosis and is more sensitive and precise than DEXA and USS”

and Lifescan provided the following supporting evidence

QCT is recognised by the National Osteoporosis Foundation as useful and safe in the evaluation of osteoporosis.

Both QCT and DEXA are more sensitive measures of bone density than USS because they measure spinal bone mass whereas USS measures bone in the peripheral skeleton where change in density is slower.

QCT is more sensitive to changes in skeletal density than DEXA because of its unique ability to provide separate bone mineral density estimations of high-turnover trabecular (spongy) and cortical (compact) bone, in both the axial and appendicular skeleton. Trabecular bone is eight times more metabolically active than cortical bone.

Only QCT provides a true (actual volumetric) assessment of bone density. Other methods, including SXA, DEXA and radiographic absorptionmetry, only provide *estimates* of true bone density, which cannot be truly calibrated against a bone mineral standard.

QCT has been shown to be more precise than DEXA. A study which compared QCT scans of hip and/or spine with DEXA measurements found that 3D QCT was more precise than DEXA and was a better predictor of vertebral fracture.

QCT has been shown to be better at fracture discrimination. For example, it has been proven to be better at distinguishing between healthy women with vertebral deformities and those with fractures caused by osteoporosis.

QCT is more accurate at detecting osteoporosis in obese patients. QCT is not affected by differences in height or weight which has been shown to confound DEXA measurements. For example, a number of studies have found that DEXA scanning in obese patients can have substantial errors, leading to misdiagnosis of the patient.

QCT is not vulnerable to inaccuracies that occur with DEXA caused by extra-osseous calcification and hyperostosis.”

Department of Health response to recommendation six

90. The consultation review has confirmed that DEXA scanning is still, in general, more appropriate than CT scanning to assess for osteoporosis. It therefore shows that it is very unlikely that IHA CT scans will be justifiable in the individual case, as required under principles of the Ionising Radiation (Medical Exposure) Regulations 2000, since the detriment far outweighs the benefits. The evidence shows that it is very unlikely that IHA spinal or body fat CT scans will be justifiable in the individual case, as required under the principles of the Ionising Radiation (Medical Exposure) Regulations 2000, as the detriment far outweighs the benefits. Department of Health will work with the Care Quality Commission, the Devolved Administrations, the Royal College of Radiologists, the Royal College of Physicians and other relevant stakeholders to produce suitable clinical referral guidance reflecting these principles.

Recommendation Seven

91. *Current evidence suggests that there is no benefit to be derived from CT scanning of the lung in asymptomatic individuals. Further research is required in this area but, until this is available, CT scanning of the asymptomatic individual cannot be justified for the lung and should not be made available.*

92. While this recommendation was supported by Cancer Research UK and others, it was noted that the scientific evidence supplied by the three scanning companies that responded to the consultation and CACODI warranted careful consideration. Their evidence alongside other comments are summarised below. 55% of those commenting fully agreed with this recommendation.

93. Cancer Research UK stated that

“In the UK, screening is the means of testing asymptomatic individuals for the early signs of cancer. Strong evidence supports the introduction of national screening programmes as set out in a European Council recommendation¹. The World Health Organisation² states that ‘only organised programmes are likely to be fully successful as a means of reaching a high proportion of the at-risk population’. And in its first report into cancer screening in the EU, the Council found that the benefits of screening asymptomatic individuals relies on a comprehensive quality assurance system at all levels. This entails the co-ordination of complex communications skills, systematic monitoring and evaluation, the integration of cancer registration into monitoring and the availability of subsequent diagnosis, treatment and follow up care. We believe that your recommendations go a long way to achieving these principles.

Commission of the European Communities: Council recommendation on cancer screening. COM(2003) 230 final.

WHO: Screening for various cancers:

www.who.int/cancer/detection/variouscancer/en/index/html”

94. The British Institute of Radiology felt it was

“Important for Department of Health policies and statements to be fully consistent. NIHR have recently put out a call for proposals on protocol development for CT lung cancer screening. Also in other countries, treatment techniques are developing rapidly. One example would be the development in Japan of carbon ion radiotherapy and the use of a single fraction of Carbon ions to treat small, early stage lung tumours. This is a developing treatment which is an alternative to surgery which may become quite widely available in Europe (though not in UK) in the next 5 years. We must be careful that these recommendations will stand the test of time.”

95. The Healthcare Commission was surprised at

“the lack of evidence of the change in outcomes in lung scanning, given the number of international studies which have taken place. Although the outcomes may not change following a scan, one benefit of a true outcome may allow the individual to buy time and put affairs in order. This alone, although not a conventional basis for justification, may be sufficient to allay concerns of a long-term heavy smoker without symptoms. We would also look forward to a mechanism being established to review the changing evidence base for CT scanning.”

96. The Royal College of Radiologists noted that

“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.”

97. The Clinical Advisory Committee on Diagnostic Imaging (CACODI)

“does not support COMARE’s recommendation that CT scanning of the asymptomatic individual cannot be justified for lungs and should not be made available.” CACODI states that “CT screening is the only diagnostic intervention from the past 30-40 years that has had any impact on lung cancer mortality.” It sets out its analysis of the current situation and makes the following recommendations: Issues with CT lung screening for cancer include the problem that the vast majority of screen-detected nodules are not cancerous. It is therefore important that suggested protocols (IELCAP) on further management are followed to avoid unnecessary intervention and associated risks. Additionally it is important to understand the risk of treatment. In the USA the risk of dying from surgery is approx 5% while the risk suffering a non-fatal complication is in the region of 20%. Provide patients with balanced information on the perceived value of CT screening, making it clear that, although screening may result in the detection of an early treatable cancer, this approach will not necessarily avoid the development of an aggressive fatal cancer. Patients should be informed fully about the potential benefits and risks when considering being screened. Provide consultants and GPs with relevant research.

98. The Society of Radiographers states that

“High-Resolution Computed Tomography (HRCT) and or chest screening was popular in the USA but there are now worries about radiation induced cancers, and medical insurers in the USA are not funding them without risk assessments. We agree that further research is required in this area and should be targeted for research resources (if this is not already the case).”

99. A radiographer in the private sector makes the following points

“My initial letter, in response to reading this report, contains some accounts of personal views and experiences as a highly qualified long-time CT practitioner. I have had to change my views on lung scanning in the asymptomatic person, and urge the committee to look very carefully into patients whose lives have been saved by it. I am not advocating a national lung screening programme, however I know that for patients who wish to give themselves the best chance they can of surviving lung cancer, there is no better way than by having regular lung screening by CT, and to deny them that personal choice would be criminal. Patients decide to have lung screening with full access to all the research. The possible range of consequences and outcomes are discussed with them prior to proceeding.

I would also like to state that to limit those attending for a scan to those deemed by the NHS to be “at risk” would mean that many of the clients whose lives we have saved would now no longer be with us. For example at least half of the lung cancers that I have scanned have been found in people that have never smoked a cigarette!”

100. BUPA wellness believes that

“this is a moving field and that while there is no definite evidence of benefit yet, there is enough evidence to suggest that those who feel themselves to be at high risk of disease, through a personal history of heavy smoking and a family history of cancer, then there is justification in performing this “screening test”. This subject to the patient being gives sufficient information to give informed consent to that investigation.

There is evidence from large observational studies, such as IELCAP (1), that such a program can diagnose a majority of lung cancers at early stages when curative treatment is feasible. In routine clinical practice, less than 20% of non-small cell lung cancers would be expected to be stage 1, whereas the IELCAP study reported that 85% of lung cancers were detected at this early stage. The estimated 10 year survival of patients diagnosed with lung cancer in the IELCAP study was very high at 80%. The authors concluded that deaths from lung cancer could be reduced by 80% if people at a suitable level of risk enrolled in a screening program.

It has been suggested that CT screening may preferentially diagnose indolent lung cancers, which are unlikely to become significant during the patient’s natural life. Moreover, it has been suggested that the risks associated with diagnosing and treating

Indolent screen-detected cancers may not be justified if these cancers are unlikely to shorten the patient’s life.

A separate study (2) used a mathematical model based on retrospective data in a non-screened cohort to predict lung cancer deaths, and compared this with three small CT screening studies.(1) The study again demonstrated that the majority of screen-detected

Lung cancers were early stage but found that there were significantly more cancers than predicted. The study also found that the numbers of advanced lung cancers and the mortality from lung cancer in the screened population was very similar to that predicted. The authors concluded that, although screening led to the detection of indolent cancers at early stages, it failed to diagnose aggressive lung cancers at stages when survival would be improved.

The controversy surrounding CT screening for lung cancer is unlikely to be resolved until large randomized controlled studies have been completed, which compare the disease specific mortality in a screened population with that observed in a control group. Such studies are now in progress but the results will not be available for several years. Until the results of such studies are known, it is reasonable to conclude that CT screening has the capability to detect lung cancers at early stages when curative treatment is feasible but that this approach may not necessarily prevent death from more aggressive tumours.

Until such time as this is resolved through research, BUPA believes that it is appropriate for those patients who, by virtue of lifestyle or a family history are at risk of lung cancer, should be given the opportunity to have along scan of this sr ort, so long as they are aware of the

implications of having a scan of this sort, and that there is, under current evidence, no proven certainty of benefit.

There are a number of other potentially promising tests for lung cancer on the horizon. It may be that these will prove more sensitive than CT scanning or not. Each of these must be evaluated against the criteria of analytic validity, the clinical validity and the clinical utility and the best test used.

Henschke C et al. Survival of Patients with Stage I Lung Cancer Detected on CT Screening. NEJM Volume 355:1763-1771

(2) Bach PB, et al. Computed Tomography Screening and Lung Cancer Outcomes. JAMA. 2007;297:953-961.”

101. The European Scanning Centre accept that

“the CT screening of individuals for lung cancer is controversial but believe that the ELCAP study has demonstrated that some might gain benefit. We believe that CT screening is justified in certain high-risk individuals ie those with significant smoking history or previous exposure to asbestos, as well as those with a strong family history of lung cancer.” They suggest the following amendments:-

Lung Cancer Screening is limited to high-risk individuals.

Screening should be repeated at a maximum of 3 yearly intervals and not annually.

The scans should be reported by a specialist radiologist with an interest in chest imaging who has experience in detecting early pre-malignant lesions as well as being aware of all the current recommendations of the Fleischner Society regarding follow-up of nodules. Computer assisted measurement of nodules should not be used as the first line tool in reporting lung scans, as it is our experience that this frequently overestimates the size of the nodules by including adjacent vascular structures and scarring (atelectasis).

There should be the facility for close liaison with specialist chest physicians for expert follow-up of any suspicious lesion.

Any scans given to a patient on their CD must be of diagnostic use which can be read by NHS hospitals and include accurate measurements of any lesion, to avoid the need for repeat baseline scanning.

Patients should be fully informed of the likelihood of false positive and the possible need for further follow-up scans, as well as the potential need for surgery”.

102. Lifescan states that

“A significant body of good quality observational studies published in reputable, high impact journals (such as the study undertaken by the International Early Lung Cancer Action Program or ELCAP, which represents 48 world class lung cancer institutions in nine countries), strongly suggests that CT scanning for the early signs of lung cancer in high risk groups is effective on both clinical and cost grounds.

CT scanning has a proven capacity to detect lung cancers in individuals before they develop symptoms and, with early detection the only hope of survival for the majority of patients, can significantly improve survival rates. This view has been endorsed by ELCAP, the largest, long-term study of CT lung scanning: “annual screening with CT scans can find lung cancers in their earliest stage, when up to 92% can be cured.” The ELCAP findings, which are based on nonrandomized trials, have since been confirmed in randomized trials.

For example, a large Italian multicentre screening trial concluded that CT scanning of smokers is effective in finding lung cancer in time to cure it

Lifescan acknowledges the absence of prospective randomized controlled trials demonstrating the impact of CT scanning on survival rates for lung cancer. However we believe this should not prevent those at risk from the right to access what is a potentially life-saving intervention. The lack of similar trials has not prevented the widespread use of diagnostic tests in other areas of medicine, such as screening for prostate cancer.

Lifescan does not have access to comprehensive follow-up data because clients are under no obligation to inform us of the outcome of their CT scan. However, our experience and patient feedback supports the available academic literature. Many of the individuals who have written to us have done so because they have had cancerous lung nodules successfully removed as a result of their CT scan. If these patients – the vast majority of which were asymptomatic - had not had been given the opportunity to have a CT lung scan, their lung nodules may not have been detected early enough to be treated successfully.

Since October 2006, Lifescan has detected lung nodules in around 13% of patients scanned. This is in line with the ELCAP programme whose rate of detection is 12%. While the vast majority of detected lung nodules are recognised as benign, a significant number of patients have been subsequently diagnosed with early stage lung cancer. These individuals are unlikely to have been picked up by their GP because the vast majority of them were not showing symptoms other than what would be expected of those with a history of smoking. In addition, had these individuals undertaken a conventional chest X-ray, instead of a CT scan, studies strongly suggest that a large proportion of the nodules could have been missed.

The fact that CT scanning for lung cancer is becoming increasingly available in the US, Pacific Rim countries and Europe is testimony to growing international confidence in its ability to save lives, in spite of the absence of prospective randomized controlled trials. No authority has yet to advise either against CT scanning for lung cancer in asymptomatic individuals or in favour of it. If COMARE's recommendation is accepted, the UK would become the first country in the world to restrict asymptomatic individuals' access to a CT lung scan. If accepted, the recommendation would also be at odds with the national Cancer Reform Strategy which included a commitment to commission research on the feasibility of a UK trial of CT screening for lung cancer.”

“Finally, the risk of false positives resulting in unnecessary invasive procedures or surgery is very low. If the ELCAP protocols are followed then it is improbable that an invasive procedure or surgery would be performed on benign non-growing nodule.

In summary, we believe that because of the comparatively low risks associated with CT scanning, a growing and compelling evidence-base, increasing international recognition of CT scans as a valid diagnostic tool for lung cancer, the dramatically increased chances of a successful outcome from early treatment and the absence of any other life-saving intervention for lung cancer, asymptomatic individuals at risk must be given the right to a low-dose CT lung scan.”

The headings used for the extensive supporting evidence provided by Lifescan are set out below:

Detecting the early signs of lung cancer before symptoms develop can dramatically reduce mortality
CT lung scans are better than conventional chest X-ray (CXR) at detecting the early signs of cancer in asymptomatic individuals
CT lung scanning is highly cost effective for high-risk individuals
The use of protocols to determine the significance of findings dramatically reduces the risk of false positives and unnecessary biopsy or thoractomy
A CT scan is a quick, safe and non-invasive diagnostic tool

Department of Health response on recommendation Seven

103. The evidence shows that it is very unlikely that IHA Lung CT scans will be justifiable in the individual case as required under principals of Ionising Radiation (Medical Exposure) Regulations 2000 since the detriment far outweighs the benefits. Department of Health will work with the Care Quality Commission, the Devolved Administrations, the Royal College of Radiologists, the Royal College of Physicians and other relevant stakeholders to produce suitable clinical referral guidance reflecting these principles.

Recommendation Eight

104. *CT scanning to determine coronary artery calcification is valuable for predicting cardiovascular risk in asymptomatic individuals. Further studies with multi-detector CT are expected to have similar results. COMARE recommend that CT scanning should only be undertaken on individuals with intermediate risk identified by a comprehensive cardiovascular Framingham risk score assessment, unless the referral is by a cardiac specialist. Research will be required to determine the feasibility and efficacy of a combined coronary artery calcification score/conventional risk score approach in reducing coronary heart disease events in this population. It is recommended that scans should not be performed routinely more frequently than once every three years.*

105. 55% of those commenting fully agreed with this recommendation. The following comments (amongst others) were carefully considered.

106. The Healthcare Commission stated that

“IR(ME)R is clear in its approach to referral and justification from individuals who have been entitled to do so by their employer. The referral and justification of cardiac CT scans by consultant clinical cardiologists, and trained and entitled cardiac radiographers or cardiac nurse specialists is allowable within existing regulatory frameworks. We would look forward to guidance on whether such approaches are sufficient in the example of referring and justifying high-dose procedures such as cardiac CT. We note the use of Framingham risk scores and look forward to more guidance on what additional diagnostic tests would be required specifically in advance of the justification of a cardiac CT scan. In addition, more information may be required concerning optimisation, and whether retrospective gating techniques are allowable in the assessment of asymptomatic persons. We support the clear recommendations concerning the frequency of examination.”

107. The Institute of Physics and Engineering in Medicine agrees that

“CT scanning to determine coronary artery calcification should only be undertaken on individuals in those cases where there are associated risk factors.”

108. The Society of Radiographers said that

“Risk assessments, such as the Framingham risk score assessment or other recognised assessment for cardiac disease must be undertaken by a person competent to undertake this assessment (i.e. a cardiac specialist). Only those individuals at risk should be accepted for CT examination.

We believe that dual energy CT may have a place in cardiac screening.

We also agree that scans should not be performed routinely more frequently than once every three years but there must be some mechanism put in place to regulate this type of screening to ensure that this limit is not abused, and the frequency is not increased.”

109. **BUPA** believes that

“where there is the potential for an individual to gain information about his/her health, and where the test provides useful information that will enable that individual to better understand their health and health risks, and where there is a chance that through undertaking a change, that health risk may be modified, then that individual may make a choice to have that test. This subject to appropriate information and informed consent. This should be an individual choice.

BUPA considers calcium scoring a useful tool for the presence of coronary artery disease and should be available to people who are interested in their health who are in an at risk group, either by virtue of their age, gender, family history or lifestyle. We recognise that the place of scanning of this sort should be further evaluated through follow up data for subjects undertaking this test, and understanding health outcomes and causes of mortality in this group.

Frequency of evaluation should be dependent on initial result. Thus those with a moderate score – and a moderate degree of atheroma, who undertake medical and lifestyle changes designed to reduce risk of symptomatic disease should have a repeat test more frequently than those with a zero score to monitor the progress of the disease. This should again be evaluated formally in research.”

110. The European Scanning Centre said

“We are pleased that the beneficial role of EBCT coronary artery scoring is recognised. However, we do not agree with the restriction to only those with an intermediate Framingham risk. We have performed EBCT heart scans on more than 13,000 individuals and have enormous numbers of individuals who have either had a significantly elevated calcium score despite having few traditional Framingham risk factors, or conversely were classified as being at a high Framingham risk but had a zero calcium score. Framingham risk profiling maybe useful for population based screening and intervention but is generally recognised by cardiologists as being a crude surrogate and does not take genetic predisposition into account. Indeed, the report states that traditional Framingham factors account for only 60% of patients who suffer a heart attack (p32). The calcium score on the other hand distils all risk factors, known and unknown, into an objective measure of an individual's risk of future cardiac event. We agree that calcium scoring is of no benefit in individuals with known coronary heart disease.

Our data indicates that 60% of women and 40% of men under the age of 55 years who have been prescribed a statin by their GP according to current guidelines have a zero calcium score, and therefore have no objective evidence of heart disease. Given that the American Heart Association has stated that a zero calcium score is associated with a 0.05% risk of cardiac event, these patients are taking their statins unnecessarily and can discontinue them, with consequent significant savings to the NHS.

We propose that calcium scoring should be available to any male over 35 years old and women over 40 years old.”

111. Lifescan welcomes

“the recognition by COMARE that coronary calcium scoring is valuable for predicting cardiovascular risk in asymptomatic patients. Between May 2007 and July 2008, Lifescan has identified 6,137 individuals (around 16% of those who undertook heart CT scan during this period) with calcium scores that put them at above average risk of CVD. The vast majority of these individuals were asymptomatic. Following the CT scan, these individuals were given the opportunity to take action to reduce the risk of an adverse cardiovascular event, as illustrated by the excerpts from the sample of patient letters. Around seventeen per cent of those scanned are in the top 25% of the population most at risk of CVD and for whom treatment is most cost-effective

COMARE recognises the value of electron beam CT (EBCT) (whose availability is limited in the UK) for predicting cardiovascular risk, but not that of modern multidetector CT (MDCT), which is mainstream practice in the NHS. Although most of the available evidence relates to EBCT, there are a growing number of studies showing that MDCT has now been shown to be comparable in performance to EBCT. The reason why MDCT for coronary calcium scoring has not been used more widely in the UK is because of the wide variation in the availability of the necessary cardiac software in the NHS. However, this situation is starting to improve. Increasing numbers of NHS cardiologists now recognise coronary calcium scoring as the gold standard in scanning for cardiovascular disease (CVD) and are acquiring the supporting software.

Lifescan also agrees that coronary calcium scoring is likely to have the most impact on asymptomatic patients at intermediate risk of cardiovascular disease (10% chance of CVD within ten years). However, Lifescan does not agree that the determination of who is at risk should be restricted to Framingham Risk Score (FRS) assessment or to primary care referral, both of which are flawed predictors of risk.

FRS has been shown to predict only 60-65% of CVD risk. Studies have repeatedly validated coronary calcium scoring not only as a complement to FRS but increasingly as a replacement for it. In line with the guidelines issued by the SHAPE Task Force, an international panel of prominent cardiologists, Lifescan advocates the use of MDCT screening as a stand alone test in all men and women in age groups associated with above average risk of CVD.

Since FRS has been shown to miss up to 40% of those at risk of CVD and statistics show that the risk of a cardiovascular event starts to increase dramatically for both men and women between 35-44 years of age, Lifescan advocates MDCT heart scans for all men and women over 40 years of age. Over the age of 40, the number of individuals with a calcium score of over 100 increases and studies show that a calcium score of over 100 equates to a 20% risk of an adverse CVD event within five years. According to European guidelines this level of risk and above justifies treatment with statins on the NHS.

Lifescan agrees that the benefits of CT coronary calcium scoring should be weighed against the risks. However, there is no evidence of any health risks associated with coronary calcium scoring. A coronary calcium score with a low-dose CT scan typically uses 2.5 mSv. As has already been stated in our answer to question 5, there is no evidence of any risks to health from such low levels of radiation.

Finally, coronary calcium scoring does not generate false positives. This is because any level of coronary artery calcification equates to CVD. Any detected material that could lead to over-score is too insignificant to have any impact on the patient's risk assessment. False negatives are also rare: under 0.5% experience coronary artery disease without the

presence of calcium.” The extensive evidence provided by Lifescan was presented under the following headings:

Detection of the early signs of cardiovascular disease (CVD) and subsequent intervention, could significantly reduce mortality from what is the UK’s most common cause of death.

The Framingham Risk Score assessment, and the traditional risk factors on which it is based, are flawed predictors of CVD

Coronary artery calcium scoring by CT scan has been proven to be the most accurate independent method of predicting CVD

A significant proportion of those undertaking coronary calcium scoring at Lifescan centres have been found to be those at risk of CVD and for whom treatment is most effective MDCT is as effective as EBCT at detecting coronary artery calcification and more reproducible

MDCT is non-invasive, safer and more cost effective method of screening for CVD

Coronary calcium scoring generates no false positives and minimal false negatives”

112. The Clinical Advisory Committee on Diagnostic Imaging states that

“Cardiovascular disease remains Britain’s most common cause of death and in a significant proportion of patients (40%) the first symptom is sudden death. Despite recent improvements, coronary artery disease remains the leading cause of death in the western world. In the UK in 2004 just over 216,000 deaths occurred due to cardiovascular disease. Coronary artery calcium scoring (CACS) has been used for cardiovascular risk assessment for over 20 years.

The use of CACS for enhanced risk stratification has now been endorsed by both the American College of Cardiology and American Heart Association as well as the SHAPE task force. The Royal College of Radiologists publication “Making the best use of clinical radiology service” is due for publication later this year, and will offer some guidance on this procedure.

Though there are currently no trials demonstrating an increased survival in those who are aware of their (high) coronary calcium score, the correlation between the presence of coronary calcium and coronary atheroma is proven.

At present, there is no evidence that finding a high coronary calcium level and starting conventional treatment to lower coronary risk (as used in secondary prevention of heart disease, such as statins, blood pressure lowering, weight loss etc) either does or does not have a positive impact on mortality. Absence of evidence does not constitute evidence of absence of benefit. More importantly, recent research showed that 30-40% of people, when told that their calcium score was high and they were at high risk, would make a significant lifestyle change. This information provided on an individual basis clearly therefore helps to inform individual life choices and may reinforce verbal advice to alter behaviour. It is intuitive that drugs such as statins, which have already been proven to reduce cardiovascular risk in a primary care setting but whose prescription is currently limited by cost to Department of Health targets of 15% 10-year cardiovascular risk, are likely to provide proportionately more benefit in those with higher risk. CT Coronary Artery Calcium

Scoring can identify risk with significantly greater accuracy than standard clinical parameters.”

The Committee recommends:

“That a trial be undertaken to seek to demonstrate the cost effectiveness of coronary calcium scoring and subsequent intervention in those with high scores.”

Department of Health response to recommendation Eight

113. NICE currently recommend adherence to the adjusted Framingham risk tool for predicting cardiovascular risk in asymptomatic individuals. Many PCTs, particularly those in more deprived parts of the country, have elected to use QRISK2 as this tool takes into account important risk factors such as relative deprivation and ethnicity. It remains Department of Health policy to use simple risk predictors that can be applied to the large numbers of the adult population that require risk assessment. This is the basis of the National Healthchecks Programme which began rolling out in April 2009 with the intention of providing it to 3 million people each aged 40 to 74 over the next few years. This has been shown to be clinically and cost-effective. It is not intended to extend this programme to include routine calcium scoring on the present evidence, where data on cost-effectiveness in an NHS setting are lacking.
114. Within the vascular risk assessment programme, those found to be at high risk will be offered a full range of interventions and additional information regarding arterial calcification will not give added value. For those found to be at low risk in the programme, scanning with CT would not be beneficial or alter clinical advice.
115. CT scanning may, on the advice of a health professional, be suggested if the individual is at intermediate risk (i.e. facing an estimated 10 year risk of a cardiovascular event of 10 to 20%). This investigation is available on the National Health Service for carefully selected patients who should not necessarily be expected to pay for it
116. Department of Health will work with the Care Quality Commission, the Devolved Administrations, the Royal College of Radiologists, the Royal College of Physicians and other relevant stakeholders to produce suitable clinical referral guidance reflecting these principles.

Recommendation Nine

117. *CT colonography has the potential to detect small lesions in asymptomatic individuals, although the finding of a suspicious lesion on CT colonography would require a conventional colonoscopy for histological diagnosis or treatment. Despite this, CT colonography may find a place in routine diagnostic and screening practice. COMARE recommend that screening for colorectal cancer outside of the NHS screening programmes should only be undertaken in individuals in the appropriate age group, and not, therefore, under the age of 50 years, unless they have been referred by an appropriate medical specialist. In keeping with the NHS screening programmes, scans should not be performed routinely more frequently than once every two or three years. Individuals at high risk of developing colorectal cancer (eg with familial adenomatous polyposis, or those with a family history of colorectal cancer) should be assessed in a specialist unit that includes access to medical genetics, and specialist services in surgery, histopathology, and oncology. Screening of high-risk individuals by CT colonography should only be performed as part of a multidisciplinary care package with input from an appropriate specialist unit.*

118. 54% of those commenting were in full agreement with this recommendation. A sample of the additional evidence and comments made on this recommendation are included below.

119. The Healthcare Commission said

“Concerning CT of the colon, we note the reference to an ‘appropriate medical specialist’ which suggests that the flexibility of referral and justification not being based on professional groups may no longer apply. It suggests that a nurse specialist in colorectal disease, employed by the scanning company would not be able to refer or justify such scans, and would welcome additional guidance. As above we welcome the clear guidance on frequency of examination being not greater than 2-3 years. We would also welcome further guidance and clarification of whether, for example, a family history of colorectal disease in itself would justify a CT scan as ‘part of a multidisciplinary care package.’”

The Society and College of Radiographers supports this recommendation “but with some reservation. Fundamentally, we believe that CT Colonography should not be a stand alone procedure but should be included within a care package under a multidisciplinary team. We believe that asymptomatic clients require a full and thorough assessment by an MDT before CT colonography is justified and undertaken and we do not support this examination being undertaken in commercial CT premises.

Should screening CT colonography be permitted to continue in the commercial context, then these procedures should only be undertaken at the same time intervals as those in the NHS screening service, and some mechanism will need to be put in place to regulate this and to ensure that frequency is not increased. There should also be mechanisms in place for referral into multidisciplinary teams for all patients with 'non normal' results.”

120. European Scanning Centre stated that

“The advantage of CT colonography is that it can visualise structures outside of the bowel wall as well as intracolonic pathology. If a cancer is seen, it also provides an immediate staging scan to determine the extent of any spread.

As the majority of sporadic polyps/ cancers occur in the sigmoid colon or rectum, they can be reached by a sigmoidoscopy rather than requiring a conventional colonoscopy.

We do not agree with the recommendation that virtual colonography should only be available for individuals over 50 years. In the last 6 months, we have had 4 patients aged 31- 40 years who had been complaining of abdominal symptoms and whom were told by their GP that they did not require any investigation as they would not have colon cancer. Our CT screening demonstrated a colon cancer in all cases.

We agree with the recommendation that CT screening is not suitable for individuals with known familial polyposis but do not agree that it should also not be used for patients with a family history of colon cancer. These patients are not routinely offered screening in a specialist NHS unit.”

The Centre suggested the following amendments:

CT screening should be available to asymptomatic individuals over the age of 40 years, including those with a family history, and younger if symptomatic.

CT screening is not suitable for patients with known Crohn's disease or ulcerative colitis, All CT colon scans must be reported by a specialist radiologist with experience in virtual colonography (more than 100 scans).

All CT colon scans should routinely use intravenous contrast or fecal tagging to maximise the sensitivity and specificity of the scans and reduce false positives. The reports should state whether either of these were used.”

121. BUPA said that

“10% of cancers are diagnosed under the age of 50 years. The main purpose of this test is not to detect cancer, which is more common in the over 50's, but to detect potentially precancerous lesions, such as polyps, which may occur up to 10 years in advance of a symptomatic cancer. BUPA believe therefore that this test should be available to people from age 45, when polyps - which may become malignant – may arise.

BUPA further recommends that those people identified as being at high risk through genetic syndromes associated with an increased risk of colon cancer. e.g.

Hereditary nonpolyposis colorectal cancer (HNPCC, also known as Lynch Syndrome)

Familial adenomatous polyposis (FAP)

Attenuated Familial adenomatous polyposis (AFAP)

MYH associated adenomatous polyposis (MAP)

Peutz-Jeghers syndrome (PJS)

Familial juvenile polyposis coli (FJP)

should be evaluated in a clinic able to perform diagnostic and therapeutic procedures such as conventional colonoscopy, and not through a non invasive test of this sort.

Other patients may be assessed with CT colonography.”

122. Lifescan made the point that

“CT colonography (CTC) has been proven to be more sensitive and accurate than optical colonoscopy, Faecal Occult Blood Testing (FOBT), barium enema and flexible sigmoidoscopy as a scanning tool for the early signs of colorectal cancer in asymptomatic individuals. It is widely recognised to be safer, more cost-effective and, because it is less invasive than optical colonoscopy, flexible sigmoidoscopy and barium enema, is preferred by patients. In the US its cost-efficacy has now been endorsed - CTC has recently been included as one of several options for colorectal cancer screening and prevention in average-risk adults aged 50 years and older, and recommended once every five years.

Unlike FOBT, CTC is designed to detect adenomatous polyps – the precursor to colorectal cancer – as well as cancers. Between October 2006 and July 2008, Lifescan detected adenomatous polyps in over 2000 individuals (around 8% of patients scanned), the vast majority of whom were asymptomatic. We estimate that around half of the polyps detected by Lifescan are ‘positive’ and require removal. A finding is positive when a polyp of 8mm or larger or multiple smaller polyps have been detected, as defined by the widely used CT colonography reporting and data system known as CRADS. This detection rate fits in with national statistics which indicate that 5% of the population will develop colorectal cancer.

Since the majority of the individuals undertaking CT colonoscopies with Lifescan are asymptomatic, they are unlikely to be picked up by their GP. Studies also suggest that if these individuals had undertaken FOBT instead of a CT colon scan, over 80% of these polyps could have been missed. Those with positive findings (large polyps over 8mm or multiple smaller polyps) were advised to have them removed (depending on the location of the polyp and the age of the patient) before they developed into invasive cancer, when it is much harder to treat.

Lifescan does not agree with the recommendation that screening for colon cancer outside of NHS screening programmes should be restricted to those over the age of fifty, unless referred by a medical specialist. Ten per cent of colon cancer occurs in people under the age of 50 and two to six per cent occurs in people under the age of 40. It takes ten years for polyps to develop into invasive colon cancer so this significant proportion of people will have had been carrying polyps in their forties and possibly their thirties which could have been detected by CT before they developed into cancer. It therefore makes sense to continue to offer CT scans to a younger age group than is applicable for FOBT, which aims to detect cancers rather than polyps.

There has been concern that because CTC is more sensitive it may increase the risk of false positives leading to unnecessary testing and treatment. This is not the case. As has already been indicated, Lifescan detects polyps in less than 10% of patients scanned, approximately half of which are positive. The proportion of these that turn out to be *false* positives resulting in unnecessary further testing and treatment is very low. This is because Radiologists at Lifescan follow the evidence-based interpretative guidelines provided by CRADS which designed to prevent this.

Only patients with positive polyps, which are associated with the highest risk of colorectal cancer and whose removal studies have proved to be highly cost effective, are referred for targeted optical colonoscopy or flexible sigmoidoscopy with the purpose of biopsy. For patients with smaller polyps (unless they are multiple), no immediate further action is advised other than a follow-up CT scan in three years. This is usually undertaken by

Lifescan and paid for by private insurance or the individual, thereby incurring no further costs to the NHS.

Asymptomatic patients with a negative CT colonography do not need to have any type of colon cancer test (FOBT or otherwise) for five years, again incurring no costs to the NHS.

For a small number of patients, where there is uncertainty over a finding, referral for optical colonoscopy may be needed to confirm whether it is significant. In these cases, optical colonoscopies can be targeted and therefore less invasive. If the finding is significant, a biopsy can be performed at the same time, justifying the referral. If the finding is negative, no further action is needed.

There has also been concern about the incidence of extra-colonic findings resulting from a CT scan. About 10%-15% of CT scans detect clinically significant findings outside the colon, such as Gall stones or kidney stones, but the majority of these require no immediate further action. The incidence of aortic aneurysms and other tumours is low but clinically important.

Lifescan agrees that the benefits of CT colonoscopy need to be weighed against the risks. The principal alleged risk to health from CT colonoscopy is from exposure to radiation. However, as with other CT scans, the dose used by a typical CT colonoscopy – 5 mSv – is far too low to be associated with any health risks. As stated in our response to question 5, studies have repeatedly failed to find any risks to health from exposure to 100 mSv. These estimated theoretical risks are less than the recognised and proven risks for optical colonoscopy. These proven risks show that you are more likely to die from complications resulting from an optical colonoscopy (such as perforation of the colon), than you are from a CT colonoscopy. It stands to reason therefore that proposals to restrict access to colorectal diagnostic techniques on risk grounds should first begin with optical colonoscopy, which is widely practiced in the UK.

Finally, Lifescan does not agree with COMARE's view that it is inappropriate for patients at risk of developing colorectal cancer to be investigated in private scanning centres such as those operated by Lifescan. Lifescan centres are staffed by specialist Consultant Radiologists who do not recommend scans without undertaking clinical assessments using internationally recognised risk factors. Patients for whom a CT scan is deemed inappropriate, are advised of an alternative screening tool, if appropriate, or are referred back to their GP.

In sum, the incidence of colon cancer under 50 years of age, the proven superior diagnostic capabilities of CT colonoscopy, the opportunity to treat the precursor to colon cancer rather than the cancer itself which is harder to treat, the lack of proven risks to health associated with CT scanning, the comparatively low rates of false positives provide sufficient grounds to allow individuals aged over 45 and of average risk access to CT scanning. This access should not be dependent on a GP referral, since, as has already been stated, GPs can fail to detect individuals at risk of colon cancer if those individuals fail to articulate their history and symptoms well enough."

123. Lifescan provided supporting evidence under the following headings:

Consultation response to the COMARE 12 Report recommendations on asymptomatic CT scanning of self-referred individuals

- The early detection and removal of adenomatous polyps saves lives
- CT is as effective, or more effective, at detecting the early signs of colon cancer in asymptomatic individuals than other screening tools currently in use Although there are not trials demonstrating outcomes,
- experts generally agree that CTC could significantly reduce mortality
- CTC is potentially more cost-effective than other screening tools
- CTC is safer, less intrusive and more acceptable to patients than other screening tools
- The incidence of false positives leading to unnecessary further testing or treatment is comparatively low and certainly lower than FOBT, the Department of Health's chosen screening system
- The incidence of extra-colonic findings resulting in unnecessary invasive testing and treatment is low

Department of Health response to recommendation Nine

124. We note the CT scanning provider's suggestions to restrict patients to 45 years and above. Following the consultation, the Department of Health discussed this issue with the National Screening Programmes Committee, who were keen for us to ensure that individuals should be informed that a faecal occult test is available on the NHS as part of the national health screening programme. Department of Health will pass on both of these suggestions to the Care Quality Commission and the Devolved Administrations. Department of Health will work with the Care Quality Commission, the Devolved Administrations, the Royal College of Radiologists, the Royal College of Physicians and other relevant stakeholders to produce suitable clinical referral guidance reflecting these principles.

TABLE AND LIST OF RESPONDENTS

Group	Description	Number of responses
Professional groups	BIR, CACODI, DRGNWP, IPEM, NIB, RCR, RCR, SCoR, SRP, UKNSC	10
Health Professionals	General Practitioners, Medical Physicists, Nuclear Medicine Physicians, Radiation Protection Advisers, Radiographers, Radiologists, Surgeons	40
Private companies providing CT services	BUPA, European Scanning Centre, Lifescan	3
Individuals	22 individuals using Lifescan CT facilities 2 individuals using other non specified private CT facilities	24
Charity	Cancer Research UK	1
Patient Representative		1
Patient group	Patient' Liaison Group RCR	1
Healthcare Inspectorate	Healthcare Commission (now the Care Quality Commission)	1
Unknown affiliation		5

Professional Groups

British Institute of Radiology
 Clinical Advisory Committee on Diagnostic Imaging
 Diagnostic Radiology Group, North Western Physics
 Institute of Physics and Engineering in Medicine
 National Imaging Board
 Royal College of Physicians
 Royal College of Radiologists
 Society and College of Radiographers
 Society of Radiological Protection
 UK National Screening Committee

Health professionals

Dr H Anderson
 Dr M Bradnam
 Dr H Burnett
 Dr C Charlesworth
 Dr R Connor
 Mr R Corrigan

Consultation response to the COMARE 12 Report recommendations on asymptomatic CT scanning of self-referred individuals

Mr M Dunn
Dr M Hughes
Ms V Isaksen
Mr M Jones
Prof R Lawson
Dr A Longstaff
Dr E Loveday
Dr A Mackie
Dr C Martin
Dr D J Matthews
Dr M McCartney
Dr P McCoubrie
Dr K Osborne
Dr M Prescott
Dr J Shirley
Dr D Sinclair
Dr K Singh
Dr G Stewart
Ms S Stopforth
Mr N Timperley
Dr G Urquhart
Mrs P Wade
Mr S Yates

11 individuals who have requested that their names be treated as confidential

Individuals

Mr R Atkins
W A Birch
M C Bristow
Mrs D Cook
Mr D Gardner
Mr A J Goddard
Ms J Lockhart
Mr E Parker
Ms M Sharp
Mrs V Stewart
Mr P Thomas
Mr E Wallner

13 individuals, who have used Lifescan facilities and have requested that their names be treated as confidential

Unknown affiliations

Mr K Armoogum
Dr P Duffy
Mr J Hyslop
Mr S Kelly
Dr F W Poon