HERCA
Heads of the European Radiological protection Competent Authorities

June 2013

Title:	**HERCA WG Medical Applications / WP justification** **Survey about the situation in Europe regarding the use of CT on asymptomatic individuals outside screening programs**

Summary:	Results of a survey carried out in July 2012 within HERCA WG on Medical Applications about the situation in Europe regarding the use of CT on asymptomatic individuals outside screening programs

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Survey about the situation in Europe regarding the use of CT on asymptomatic individuals outside screening programs

Introduction

The issues with unjustified exposures in medicine have been accentuated by recent developments in imaging procedures, especially in preventive health care or procedures claiming to belong to it. Normally, imaging procedures are performed on patients presenting with symptoms of some sort in a typical setting of curative medicine. This is not the case in preventive health care, where the persons examined are not characterized as patients (literally: persons who "suffer") nor do they present any symptoms. These persons are often referred to as "asymptomatic individuals".
There is a European and international focus on this group of individuals and both the European Commission (EC) and the International Atomic Energy Agency (IAEA) have proposed requirements to get regulatory control of medical exposure of asymptomatic individuals. Lack of regulatory control of this group, especially with CT-examinations, may result in a significant contribution to the collective dose to the population.

Article 54 (2) (h), related to justification, of the proposal for a Council Directive laying down basic safety standards for protection against the dangers arising from exposure to ionising radiation (24 May 2013 version), requires that "*any medical radiological procedure on an asymptomatic individual, to be performed for the early detection of disease, is part of a health screening programme, or requires specific documented justification for that individual by the practitioner, in consultation with the referrer, following guidelines from relevant medical scientific societies and the competent authority. Special attention shall be given to the provision of information to the individual subject to medical exposure, as required by Article 56(1)(d).*"

The IAEA Safety Requirements "Radiation Protection and Safety of Radiation Sources: International Basic Safety Standards" was published as General Safety Requirements Part 3 (Interim Edition, November 2011).
Requirement 36, "*Responsibilities of registrants and licensees specific to medical exposure",* requires that *"Registrants and licensees shall ensure that no person incurs a medical exposure unless there has been an appropriate referral, responsibility has been assumed for*

ensuring protection and safety, and the person subject to exposure has been informed as appropriate of the expected benefits and risks."
Paragraph 3.150 requires that *"Registrants and licensees shall ensure that no patient, whether symptomatic or asymptomatic,undergoes a medical exposure unless:*
(a) The radiological procedure has been requested by a referring medical practitioner and information on the clinical context has been provided, or it is part of an approved health screening programme;
(b) The medical exposure has been justified through consultation between the radiological medical practitioner and the referring medical practitioner, as appropriate, or it is part of an approved health screening programme;
(c) A radiological medical practitioner has assumed responsibility for protection and safety in the planning and delivery of the medical exposure as specified in para. 3.153(a);
(d) The patient or the patient's legal authorized representative has been informed, as appropriate, of the expected diagnostic or therapeutic benefits of the radiological procedure as well as the radiation risks."

Examinations of asymptomatic individuals can be grouped in two main categories with associated sub-groups (see part A for definitions):

1. Well-established screening programs
2. Individual health assessment (IHA)
    a. Individual examinations in an occupational or medico-legal framework;
    b. Medical imaging examinations, for instance full body CT, offered by employers to their managerial staff members, as part of their periodical "medical check-up";
    c. "On request" exams for individual with no clinical indication (no symptoms/clinical signs) and thus often occurring as a result of an individual request.

It is important to differentiate formal screening programmes from more informal arrangements usually denoted as individual health assessment (see annex 1). In the case of IHA there is no, or insufficient medical evidence with regard to the potential "net benefit" of the procedure, and thus questions related to justification arise. As opposed to official screening programs, the application of quality assurance is not guaranteed. This implies that the examinees may not be adequately informed, image quality may be insufficient for reliable diagnosis (false negatives and false positives), and the persons with positive findings may not get an adequate diagnostic/therapeutic follow-up. While health authorities systematically invite well defined groups of the population to attend established screening programs, IHA is based on individual initiatives often based on advertisements from private X-ray institutes. It has to be emphasised that company policies and publicity claims may have significant influence on individual's decision to request IHA examinations.

In recent years, commercial services offering CT scans to individuals for the detection of lung, cardiac and colorectal disease has been reported in the USA and in some parts of Europe (e.g. Germany and the UK). Some of these private services are associated with aggressive advertisement and are in conflict with the general principle of justification. Faced with this situation, in July 2012, HERCA WG Medical Applications launched a survey about the situation in Europe regarding the use of CT on asymptomatic individuals outside screening programs for group 2.c. described above).

A. Content of the survey

To get an overview of the use of CT on asymptomatic individuals in Europe for group 2.c. described above), the 8 following questions were asked to the members of the HERCA WG on Medical Applications:

1. To your knowledge, in your country, are CT examinations on asymptomatic individuals outside screening program being performed?
2. Do(es) your Authority(ties) actively search for the existence of these practices?
3. Is it or would it be allowed from a legal point of view / tolerated in your country? Why?
4. Does your current regulation mention exposure to asymptomatic individuals? If yes, please provide details.
5. How do (did) you react on these practices? (What would you do?)
6. Are CT examinations on asymptomatic individuals outside screening program reimbursed by the national health and pensions organization or by private insurance companies?
7. Are you aware of some kind of advertisement on this service in your country? If yes, does it seem to you that it is a small or large scale phenomenon?
8. How would you suggest to create awareness to this focus-group?

B. Results of the survey

21 countries answered the survey:

Austria (Federal Ministry of Health)
Belgium (Federal Agency for Nuclear Control)
Bulgaria (National Center for Radiobiology and Radiation Protection)
Denmark (National Board of Health - National Institute of Radiation Protection)
Estonia (Environmental Board, Radiation Safety Department)
Finland (Radiation and Nuclear Safety Authority)
France (French nuclear safety authority)
Germany (Federal Ministry for the Environment, Nature Conservation and Nuclear Safety)
Greece (Greak Atomic Energy Commission)
Ireland (Health Service Executive)
Iceland (Icelandic Radiation Safety Authority)
Lithuania (Radiation Protection Centre)
Luxembourg (Ministry of Health of Luxembourg)
Norway (Norwegian Radiation Protection Authority)
Poland (Cancer Center and Institute of Oncology)
Romania (National Commission for Nuclear Activities Control)
Spain (Spanish Nuclear Safety Council)
Sweden (Swedish Radiation Safety Authority)
Switzerland (Federal Office of Public Health)
The Netherlands (Ministry of Health, Welfare and Sport)
United Kingdom (Department of Health)

Question 1 : To your knowledge, in your country, are CT examinations on asymptomatic individuals outside screening program being performed?

13 countries answered that CT examinations on asymptomatic individuals outside screening program are not performed in their country (see figure 1).

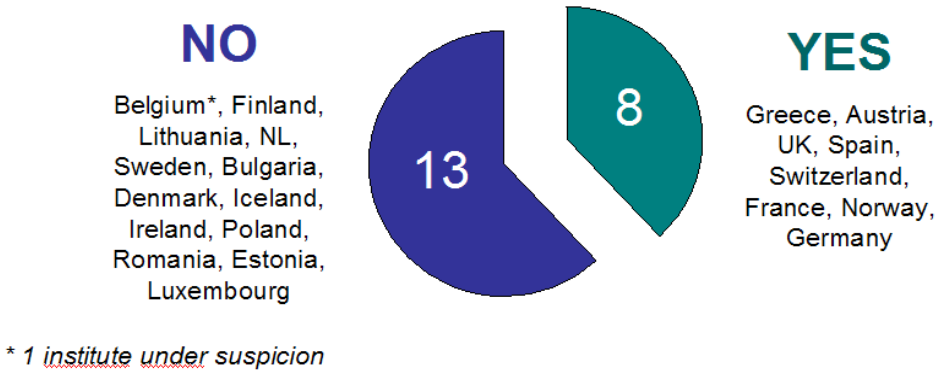

Figure 1. Answers to question 1

Question 2 : Do(es) your Authority(ties) actively search for the existence of these practices?

16 countries answered that their Authority(ties) do not actively search for the existence of these practices (see figure 2).

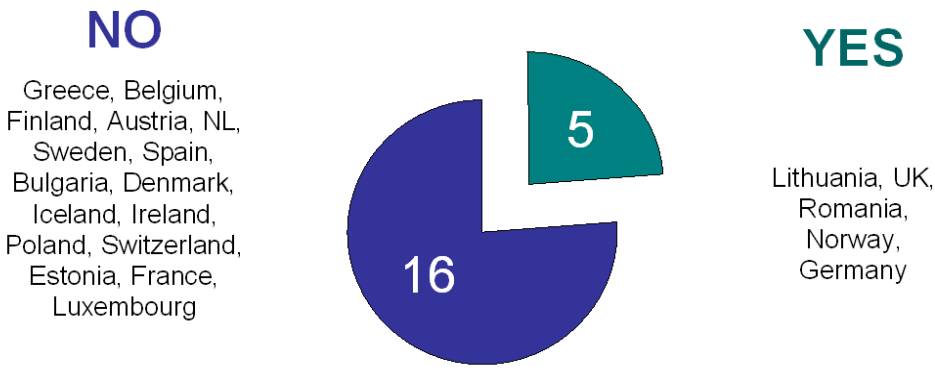

Figure 2. Answers to question 2

Question 3 : Is it or would it be allowed from a legal point of view / tolerated in your country?

17 countries answered that this practice would not be allowed from a legal point of view or tolerated in their country (see figure 3).

In Ireland the current legislation does not prohibit it.

In Sweden, an examination could be judged as justified when other factors than clinical symptoms are weighed into the judgment. For example, if a patient is extremely worried about lung cancer, an x-ray of the lungs could be justified to calm the patient
In Switzerland, this topic is not thoroughly regulated yet and will be reviewed in the oncoming revision.
In UK, certain procedures such as virtual colonoscopy and coronary artery calcification scoring are justified in certain circumstances.

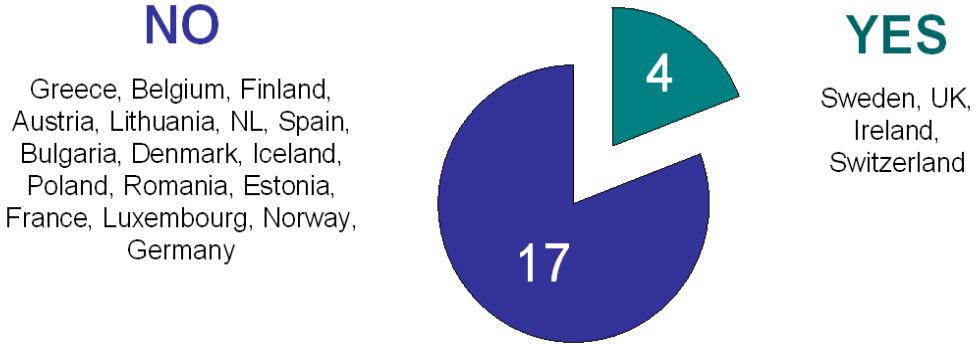

Figure 3. Answers to question 3

Question 4 : Does your current regulation mention exposure to asymptomatic individuals?

16 countries indicated that their current regulation does not mention exposure to asymptomatic individuals (see figure 4).

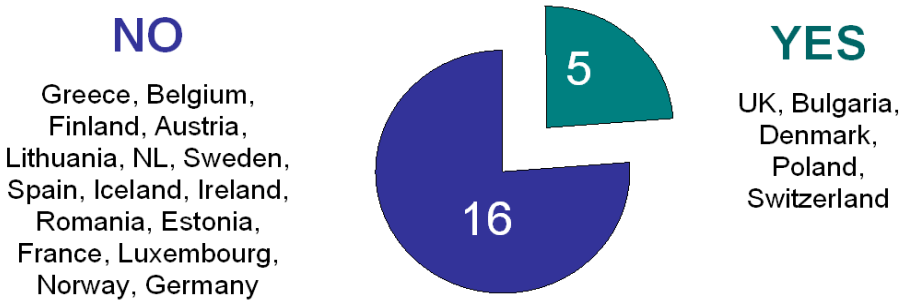

Figure 4. Answers to question 4

Question 5 : How do (did) you react on these practices? (What would you do?)

Several actions were proposed to be undertaken in case practices of IHA using CT come to the knowledge of Authorities:

- The attention of the organisations proposing this service should be drawn on the fact that these practices are not justified and therefore not allowed.
- A letter with a demand to stop the practice could be sent to the organisations and a withdrawal of the license could be considered if needed.
- This practice would be referred to the competent Health authorities.
- Inspections should be conducted by the auditing medical agencies.

Greece will introduce, during on-site inspections, investigations on the existence of referrals for every patient exposure
Norway started off a national project to map the occurrence of these practices.
UK has commissioned a working party to provide government with up to date guidance following a previous study by the government advisory body (COMARE).

Question 6 : Are CT examinations on asymptomatic individuals outside screening program reimbursed by the national health and pensions organization or by private insurance companies?

CT examinations on asymptomatic individuals outside screening program are not reimbursed in 15 countries. Spain clarified that this kind of examinations are not reimbursed by the National Health System but only by some private insurance companies. There is an uncertainty in 6 countries : private companies may possibly contribute to the reimbursement of this kind of examinations (see figure 5).

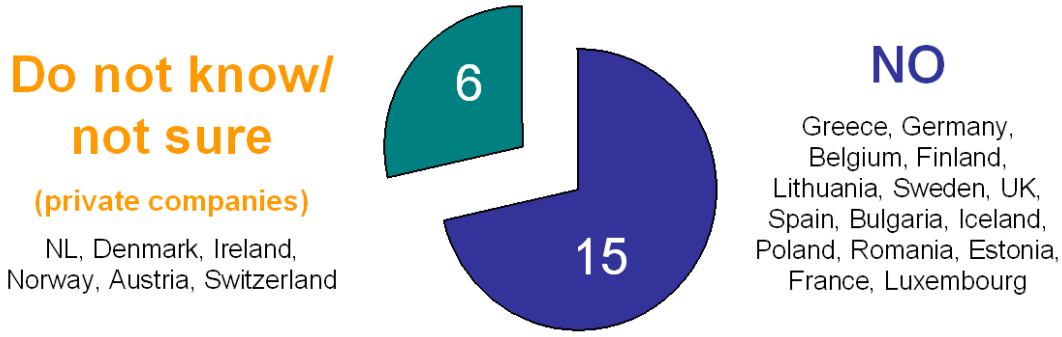

Figure 5. Answers to question 6

Question 7 : Are you aware of some kind of advertisement on this service in your country? If yes, does it seem to you that it is a small or large scale phenomenon?

9 countries are aware of some kind of advertisement of companies or hospitals proposing IHA exams using CT (see examples in Annex 2).
The countries mentioned that it is a small case phenomenon except for 3 of them:

- UK, where a significant budget is spent on national campaigns and TV commercials.

- Norway, where the advertisement is mainly on CT calcium scoring, and in some implicit cases on CT colonography as a substitute to optical colonoscopy. CT calcium scoring has been heavily advertised.
- Germany, where it is an increasing problem.

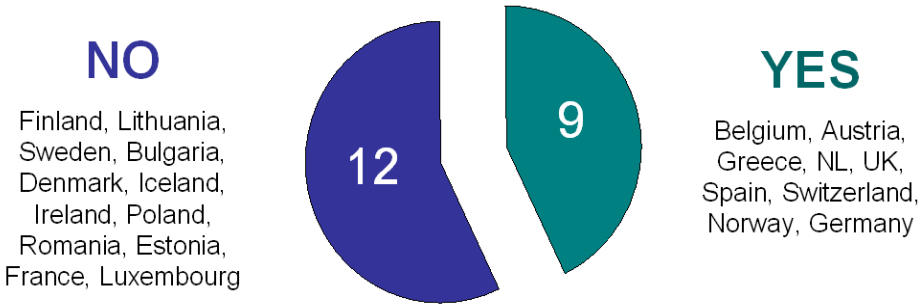

Figure 6. Answers to question 7

Question 8 : How would you suggest to create awareness to this focus-group?

To create awareness on this issue, it was suggested to:
- develop national awareness campaigns on appropriateness in medical imaging, directed at both health care providers and public at large. An example of awareness initiative can be found here: http://www.zuinigmetstraling.be/fr (Belgium);
- organize practical workshops regarding justification, proper use of medical imaging for the professionals in the working field like physicians, referrers, nurses, … ;
- provide information to patients on benefits and risks regarding CT examinations;
- implement an independent clinical audit system;
- explicitly stipulate in the regulation that, outside approved screening programs, IHA examinations are not generally justified;
- develop common actions with health authorities, social security providers and private insurances not to reimburse these kind of CT examinations.

C. Discussion and conclusion

This survey has revealed that CT examinations on asymptomatic individuals are performed in at least eight European countries. The number is assumed to be higher, since only five countries actively search for the existence of these practices. Most countries indicate that examinations on asymptomatic individuals are not allowed from a legal point of view even though the fact that asymptomatic individuals are not directly mentioned in most countries legislation. Most national radiation protection regulations can regulate this practice by means of their general justification paragraph, since exposure of asymptomatic individuals is generally found not justified. Despite of the general unjustified practice, companies and hospitals in at least nine countries advertise for IHA by use of CT examinations. Only few countries have some kind of reimbursement of CT examinations on asymptomatic individuals and, in most cases, only if some sort of individual justification is observed. This is positive, since reimbursement may act as a driving force for performing these examinations from an economical point of view.

Even though CT examinations on asymptomatic individuals are not common practice in the majority of the European countries, it is important with increased focus on this practice to reduce its implementation. The survey collected several proposals on how to increase awareness among the public and the performing institutions, in order to reduce the level of IHA. In addition to an increased level of awareness, there is a need for a more active involvement from the authorities from a legal point of view. This can be done by reacting on unjustified examinations and by strengthening the regulation in future revisions.

HERCA WGMA has identified a need for further work with respect to IHA to reduce the already current practice and prevent it to get established in more countries.

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Annex 1. Definition of relevant terms with respect to screening

In June 2012, HERCA released a position paper on screening[1] on its website. The following definitions are taken from this position paper.

1. Healthcare:

Traditionally, health strategies focus on a patient with recognized symptoms or at least with a high likelihood of disease, presenting to a medical doctor in a hospital or private practice.
If the medical doctor needs further diagnostic information, he refers the patient to a radiologist for performing the appropriate medical imaging examination. This scenario is usually considered as an exposure with diagnostic benefit, taking place as part of the patient's healthcare and it is expected that such a healthcare episode takes place within a defined clinical pathway.

2. Screening:

Screening is a significant departure from the clinical model of healthcare, because apparently healthy individuals are offered a test. An effective screening intervention detects either pathology demonstrating risk factors for developing a disease or the disease itself at an early stage, where treatment can improve clinical outcome. The aim is to identify those individuals who are more likely to be helped than harmed by further diagnostic tests or treatment.

Concerning screening, two scenarios have tended to be considered together but in fact should be clearly distinguished:

2.1 Screening as part of a programme

Screening programmes systematically invite all members of a certain population to take a screening test. Examples of this are the breast screening programmes in Europe where all women between 50 and 69 routinely receive invitations to have an X-ray mammography. Screening programmes have to:

- be evidence based;
- meet stringent quality requirements, taking into account the need to include all parts of the program (i.e. invitation, X-ray devices, performance and reading of X-ray procedure, diagnostic workup, training and education, documentation, evaluation, etc);
- be approved by competent health authorities.

It is also worth mentioning that WHO have defined a set of criteria that should be met by a screening program[2].

2.2 Opportunistic "screening" or individual health assessment

It is important to differentiate more informal arrangements from formal screening programmes. This scenario, often occurring as a result of the patient's choice, is usually

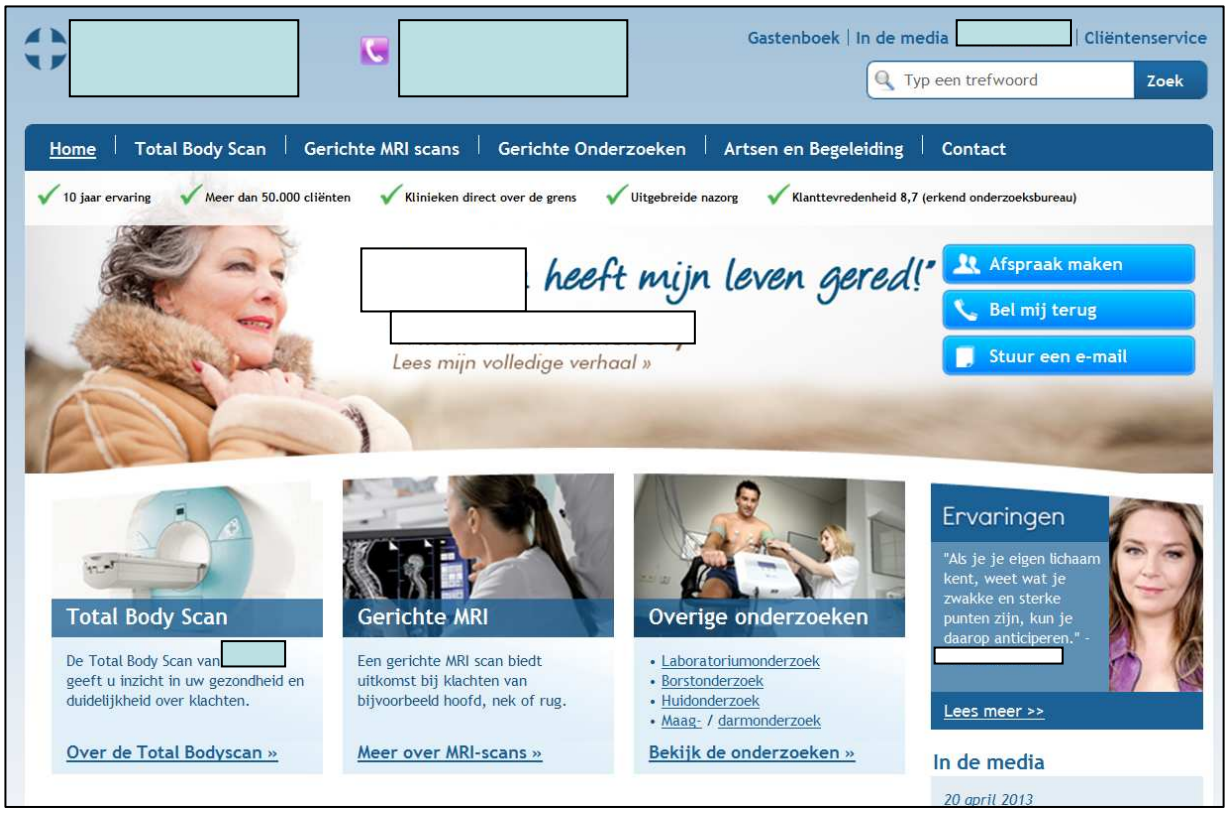
[1] http://www.herca.org/herca_news.asp?newsID=22
[2] http://www.who.int/bulletin/volumes/86/4/07-050112/en/index.html

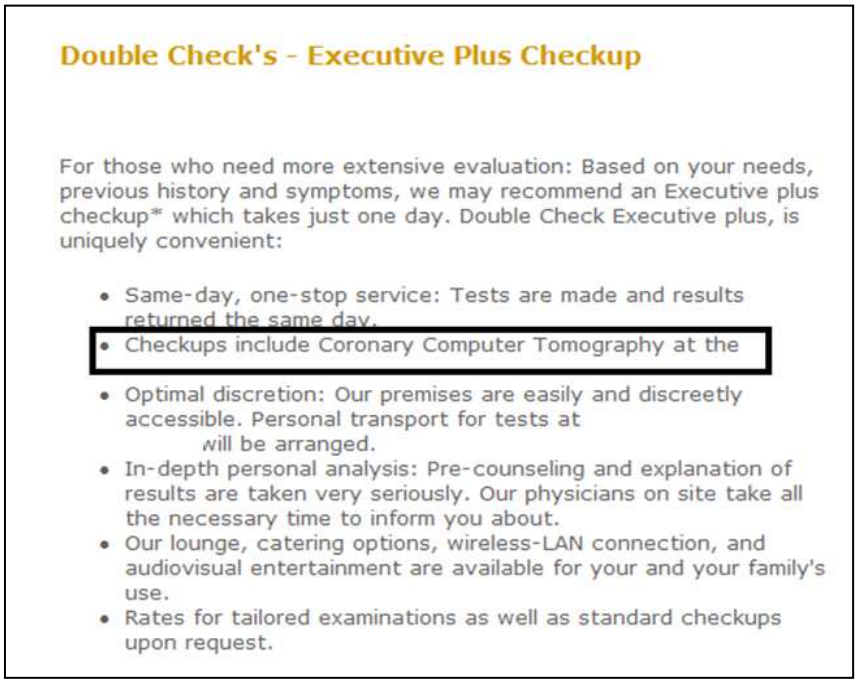
denoted as “opportunistic screening” or “individual health assessment” (IHA). The latter of these terms is preferred, as it offers a clearer differentiation.
By definition they apply to individuals and not large populations.
With the evolving new technology of multi-slice spiral CT, predominantly CT procedures are discussed in the context of individual health assessment:

- lung CT for early detection of lung cancer, particular in smokers;
- CT colonography – also denoted as virtual CT colonoscopy – for early detection of intestinal polyps (which might be pre-cancerous lesions) and colorectal cancer;
- CT quantification of coronary artery calcification (which is considered a sensitive marker of arteriosclerosis), also denoted as CT-calcium score;
- whole-body CT, particularly for early detection of cancer.

It should be noted that individual health assessment is not restricted to CT alone. CT however is of particular interest as it has been seen to be profitable and commercially viable in a number of countries and this has resulted in aggressive marketing. CT examinations are also associated with relatively high doses. As a result, an uncontrolled increase in the number of IHA performed by CT may result in a significant contribution to the population dose from medical exposure.

Annex 2.
Examples of advertisement / website of companies or hospitals which propose CT examinations on asymptomatic individuals outside screening programs





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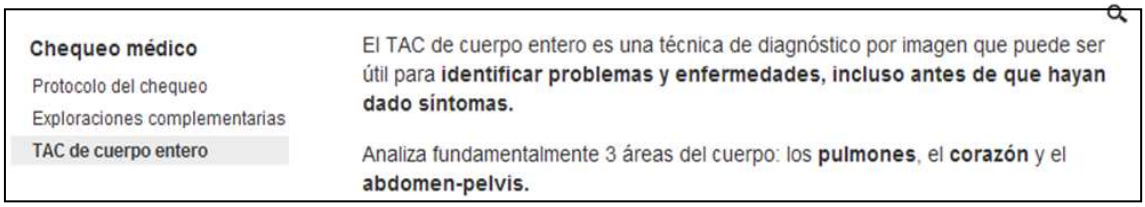
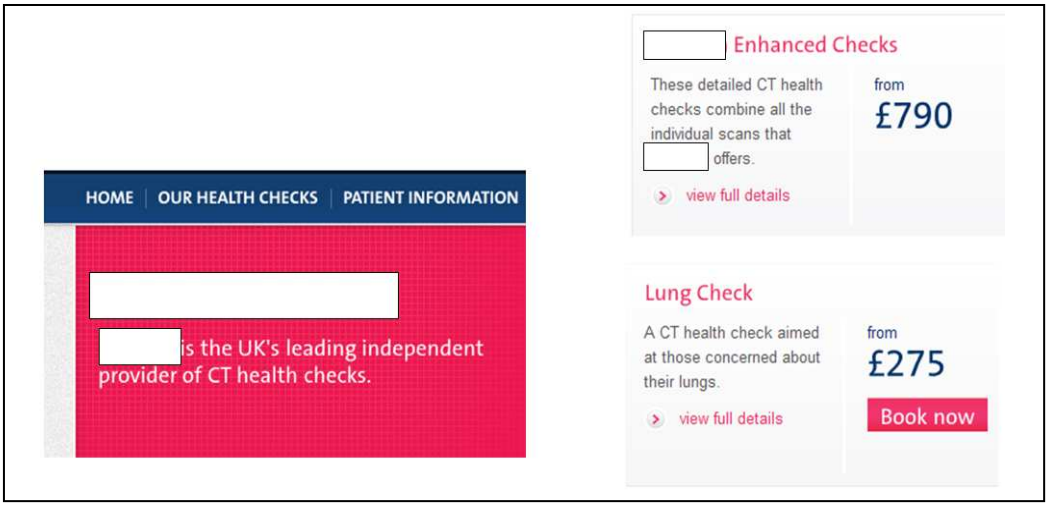

Chequeo médico
Protocolo del chequeo
Exploraciones complementarias
TAC de cuerpo entero
El TAC de cuerpo entero es una técnica de diagnóstico por imagen que puede ser útil para identificar problemas y enfermedades, incluso antes de que hayan dado síntomas.
Analiza fundamentalmente 3 áreas del cuerpo: los pulmones, el corazón y el abdomen-pelvis.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