

# Justification of the Use of CT in Asymptomatic People for Individual Health Assessment (IHA)

26-28 September 2016, Seoul, Korea

Workshop organized by the World Health Organization (WHO), in cooperation with the Korean Society of Radiology (KSR) and the Korean National Evidence-based Healthcare Collaborating Agency (NECA)

## MEETING REPORT

### 1. Introduction

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Constant innovation of health technology has expanded the applications of radiation in medical imaging and improved patient care. The justification of such exposures is based on the judgment that the clinical benefit of the medical imaging procedure will outweigh the radiation detriment. The established scenario for medical imaging in many parts of the world involves a patient with signs and/or symptoms being referred to a radiological procedure. In this scenario, the healthcare service is provided to people with a clinical condition to determine the presence or absence of disease, as a basis for making further treatment decisions. In this scenario, evidence-based imaging referral guidelines developed for a number of clinical conditions can support the justification process and enhance appropriateness of referrals by informing referrers and radiologists of the most appropriate examination. The scenario is different when medical imaging is performed on apparently healthy people (i.e. asymptomatic people) to detect early disease or risk factors for disease. In this context, medical imaging may take place within a formal population screening program (e.g. national mammography screening programs) or as an individual health assessment (IHA). The present workshop was built upon the outcomes of an expert consultation kindly hosted by Bundesamt für Strahlenschutz (BfS) in Munich, Germany, in October 2014<sup>1</sup>**Error! Reference source not found.** The present workshop was focused

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<sup>1</sup> The conclusions of this expert consultation are summarized in the paper of J. Malone et al. "Justification of Computed Tomography for Individual Health Assessment (IHA) of asymptomatic persons: a WHO consultation", in press Journal of the American College of Radiology (2016)

on the key elements to enhance justification of the use of CT for IHA, with the ultimate goal of producing a policy guidance document proposing a framework for good clinical governance of these practices.

## 2. Opening Session

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### Welcome addresses

Seung Hyup Kim, President of the Korean Society of Radiology (KSR), welcomed all participants and thanked the core IHA expert group and the co-organizers: WHO, NECA, and KSR. Korea as a host country considers that justification is an important issue in CT for IHA, which requires persistent efforts. Currently there are no guidelines in Korea for CT for IHA. KSR is dedicating efforts to resolve issues in justification of diagnostic radiology, including reviewing evidence-based literature and developing guidelines.

Tae Hwan Lim, President of the National Evidence-based Healthcare Collaboration Agency (NECA), thanked the organizers, referenced the "*groundbreaking meeting*" held 2 years ago in Munich, Germany, hosted by BfS, and this workshop as a follow-up. NECA is a Governmental agency which conducts HTA based on scientific evidence. It was founded 8 years ago. This workshop subject is deeply related to NECA's core values. CT is overused in many countries, including South Korea, a country with a unique healthcare system. The outcomes of this global expert discussion will lead to an agreement based upon which experts in South Korea will create policies. The Ministry of Health and Welfare is aware of and interested in this meeting.

Dr. Ki Bae Seung, President of the Seoul St. Mary's Hospital, welcomed participants<sup>2</sup> and echoed that CT for IHA should be performed in the context of tangible evidence, and after necessary information is furnished to examiners and examinees. He is himself an interventional cardiologist and therefore the topic of this workshop is relevant for him not just as the hospital President but also as a specialist.

Maria del Rosario Perez, WHO Radiation Programme, expressed her appreciation expressed to all, particularly to St. Mary's Hospital for hosting the meeting, NECA and KSR as co-organizers, the South Korea Ministry of Health and Welfare for its support, the Core IHA expert group for the technical support for the preparation of the workshop, the participation of the IAEA (represented by Jenia Vassileva), the contribution of 3 WHO Collaborating Centres: BfS, Germany; Center of Bioethics National University of Singapore; and Public Health England (PHE), U.K; and the representation of 4 NGO's in official relations with WHO: ISR (Dr. Lawrence Lau), ICRP (Sandor Demeter and Dr. Park), RAD-AID (Dr Miriam Mikhail) and WONCA (Dr Ernesto Mola). It was noted that medical imaging is an essential component of healthcare, that new technologies and medical devices provide new applications to handle burden of disease but the incorrect use can cause harm and unnecessary exposures. The topic of this workshop is relevant for WHO's objective ("attainment of the highest possible level of health by all peoples") and consistent with the

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<sup>2</sup> He delivered his welcome speech just before Plenary Session 2

WHO definition of health as a "state of complete physical, mental, and social well-being and not merely the absence of disease or infirmity". All 6 WHO 6 core functions relate to this workshop and follow-up actions<sup>3</sup>. Universal Health Coverage (UHC) includes full access to health services of high-quality, and this encompasses radiation safety.

## Scope and purpose of this workshop

The purpose of this workshop is consistent with the objectives of the WHO Global Initiative on Radiation Safety in Healthcare Settings, will contribute to the implementation of the BSS and the Bonn Call for Action which identifies 10 priority actions to improve radiation protection in medicine: priority action #1 is JUSTIFICATION, of asymptomatic people. The scope of this workshop extends beyond radiation protection and covers other aspects as shown in the agenda. Even if this this project 2 years ago because of radiation safety concerns, we realized that the scope is much more multifactorial than initially anticipated: e.g. it has implications on research, ethics, financing, governance...A multidisciplinary approach is needed to devise a framework for policy guidance to improve clinical governance of this practice. The expected result this workshop is to identify a conceptual framework for good governance and to outline a roadmap to move forward for producing a policy guidance document proposing such a framework.

## 3. Setting the Scene and goal

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Steve Ebdon-Jackson, Centre for Radiation, Chemical & Environmental Hazards, Public Health England, Chilton, Oxon, UK starting this session by noting that global input is necessary for this evolving IHA framework and he described history of the RP regulatory processes from mid-90's through the 2014 IHA workshop in Munich, BfS. In the mid-90's there were Directives and Standards- European Council Directive 96/29/Euratom, European Council Directive 97/43/Euratom, and International BSS (Safety Series No. 115, 1996)- which did not contain specific reference to asymptomatic individuals - only to those involved in population screening programs. IHA was not a specifically identified existing practice and it was therefore a gap between diagnostic imaging and IHA. At the time, there was no way to think that CT would be used for IHA and it was thought MRI would replace CT. Then, the multidetector CT arrived and a landmark document was published: Hillman BJ (2003). *CT Screening: who benefits and who pays*. Radiology 22, pages 26-28. That paper addresses many of the critical issues: funding, consumerism, marketing, and it differentiates between IHA and population screening, false/true negatives and positives, individual organ assessment vs. broad body region. After that, the Committee on Medical Aspects of RP in the Environment (COMARE) was created, the Department of Health (England) requested advice on IHA and expert opinions were published. This included the COMARE report 2007 which identified 5 key findings and 9 recommendations, considered IHA rationale, justification, and anatomical regions:

1. Services should be regulated

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<sup>3</sup> Norms and standards, ethical and evidence-based policies, research agenda, technical support; catalyzing change, sustainable institutional capacity, leadership on matters critical to health and partnerships where relevant, monitoring/assessment of the health situation and trends.

2. Patients require accurate data and information.
3. IHA results should be integrated into established healthcare pathways
4. Symptomatic individuals should be referred to normal healthcare systems
5. Whole body CT for IHA of asymptomatic individuals should cease
6. Alternative imaging modalities should be considered as relevant
7. Lung IHA is not justified
8. Coronary calcium scoring may have value in some groups
9. Routine colorectal investigations should be restricted to > 50 y/o

Subsequent revised COMARE recommendations (12th COMARE report 2014) included some key changes such as: IHA should be offered by and involve expert clinicians, and CT thorax for IHA in asymptomatic would be inappropriate for non-smokers or < 55 years old.

The Working Group on Medical Applications (WGMA) of the Heads of the European Radiation protection Competent Authorities (HERCA) published a position paper in May 2012 with an RP focus which defines screening programs, opportunistic screening/IHA, and special requirements for IHA – consensus guidelines, defines risk profiles, information to users, QA programs, education/training, documentation and evaluation. This position paper had an Impact upon European RP authorities – e.g. legal approaches in some countries such as case studies UK and Germany, Europe did not have a consistent approach in 75% of the EU states. The HERCA WGMA conducted a survey in June 2013 to assess the status of the IHA practice in Europe. This survey, which included 8 questions and 21 respondent countries indicated that 38% countries in Europe are aware that IHA is being performed, 19% believe it is legally allowable, 70% think reimbursement isn't possible through state or insurance systems and 43% aware of current IHA advertising.

Then, the Department of Health (England) produced an Expert Working Party Report: “Justification of CT for IHA”, published July 2014. The new International BSS includes IHA as does the new Euratom BSS- the new legal directive requires to develop a framework of guidance for IHA, although the term is not explicitly used in both, it is implicit that such a framework is needed in both the European BSS and the international one, and not only in screening programs as it was in the past. This is a legal platform we didn't have in the 90's. The Article 4 2013/59/Euratom has a medical exposure definition - "exposure incurred by patients or asymptomatic individuals as part of their own medical diagnosis, intended to benefit their health". The Article 55(h) on Justification requires: (i) specific documented justification for a radiological procedure on an asymptomatic individual following guidelines from relevant medical scientific societies and the competent authority and (ii) provision of information to the individual subject regarding the exposure (benefits/risks --- see article 57.1(d). With respect to the International BSS (GSR Part 3) 2014, there is a Paragraph 3 160: “any radiological procedure on an asymptomatic individual that is intended to be performed for the early detection of disease but not as part of a health screening program shall require specific justification for that individual...in accordance with the guidelines of relevant professional bodies or the health authority”. “The individual shall be informed in advance of expected benefits, risks and limitations of the radiological procedure”

Jim Malone, Trinity College, Dublin presented the outcomes of the expert consultation held in Munich, Germany in October 2014, which were summarized in a in press for JACR<sup>4</sup>. CT is widely deployed but its success is accompanied by increasing doses and risks. Often there's no evidence that CT for IHA is worthwhile as with (e.g.) the whole-body CT - not justified in Radiation Protection (RP) terms. The radiation benefit-risk tradeoff is progressively being assessed by policy makers, in general with an unfavorable balance who aim to include all imaging modalities (e.g. ultrasound) in ultimate RP framework. The WHO expert consultation in 2014 had a broad canvas – several key elements were reviewed e.g. state of art, new consensus positions arose during the meeting, the practice of IHA exists globally in all countries, mainly in the private sector; it is not embedded in care pathways; there is an inadequate follow-up, QA, records, and information transfer. There is a WHO web link where all 20 presentations can be consulted.

The International Conference on RP in Medicine held in Bonn in 2012, organized by the IAEA and co-sponsored by WHO, identified 10 actions to improve RP in medicine in the next decade, with Justification as the action #1 (using evidence base). There will be a 5-year follow-up conference in Vienna in December 2017.

Several challenges were identified around IHA justification: terminology/culture (use of "Practitioners", use of "Presenters" rather than "Patients"? - Is the person presenting a patient when presents for IHA? Or he/she is a consumer since is entering into an economic relationship?). IHA raises ethics concerns under public health umbrella. It also has health economics issues and need for optimal allocation of resources.

There was consensus at the Munich 2014 consultation on those new positions described in the JACR paper about terminology; risk communication; guidelines/clinical audit; social, ethics, public health and resources considerations; education and training including health professionals and public; need to devise a framework including regulatory concerns. The final decision regarding the terminology was to use "presenters" rather than patients. The IHA in asymptomatic individuals was differentiated from population screening programs. IHA was divided into: IHA A (some developing evidence or risk profile warranting, some reason to do it) vs. IHA B: no evidence or risk profile to warrant exam. Approved screening vs. IHA A and IHA B — may develop better set of definitions at end of the meeting.

Other new consensus positions referred to need for honesty/openness/transparency, need to manage expectations, need to deal with uncertainty and not create greater uncertainties. Regarding the costs, they are not just related with the IHA scans but also with the consequent interventions: between 1 or 2 additional scans arise from each IHA event. Who pays? The presenter? The public health service? The bond or insurance system?. Ethics concerns were defer to be discussed later in the workshop.

In summary, IHA poses challenges to justification, ethics, public health and resources/financial issues (IHA B is the most challenging practice). A robust regulatory/operational/and good governance frameworks is essential. Currently the RP regulators are empowered by International and Euratom BSS and by the Bonn Call for Action and would be a good momentum to move forward. We talk about right image, right

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<sup>4</sup> This paper was electronically distributed before International Workshop held in Seoul, and then was also included in the printed materials provided to all participants, to be used as a basis for the work during the meeting.

dose, for right patient: the right image may be no image at all when there is no foreseeable benefit. The international organizations, alike, will play a great role, working together towards framework for CT for IHA.

## 4. Plenary Session 1: Individual Health Assessment (IHA) – a spectrum of views

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### Keynote Lecture (video-recorded)

John Brodersen, clinical researcher, University of Copenhagen said that overdiagnosis occurs when individuals are diagnosed with conditions that will never cause symptoms or death and that the ultimate criterion for overdiagnosis comes at the end of life (if the person never developed a problem from her condition, he/she has been overdiagnosed"). From the perspective of the patient what makes the difference is "Feels well vs. feels sick", while for the physician is "No disease vs. has disease". He presented the concepts of primary, secondary, tertiary and quaternary prevention using a chart. Quaternary prevention is the action taken to protect individuals from medical interventions that are likely to cause more harm than good. He explained that he would focus on the intended benefits and unintended harms of CT for IHA. He shows the three forms of practice involving radiological imaging of asymptomatic individuals presented in the *JACR* paper in press: formal screening program vs. IHA A vs. IHA B; populations vs. Individual presenters, who pays? Who provides the service? Who refers? Evidence?

He then developed further the concept:

1. *Mass screening* e.g. mammography
2. *High risk screening* e.g. heavy smokers and CT chest
3. *Cascade screening*: hereditary disease --> family of patients with snowball effect of relatives found with disease
4. *Opportunistic screening*: healthcare professional initiates process, e.g. patient presents with headache but physician seizes opportunity to screen for breast ca.
5. *Screening on demand*

Evidence is lacking for aforementioned 3, 4, and 5. Regarding prevention among healthy people: when considering early diagnosis, there may be pros and cons and overdiagnosis/overdiagnosis. The pros include reassurance from normal results. There may be psychosocial consequences of IHA that have not been studied. For instance in the case of lung cancer CT screening, the impact on a smoker who continues smoking because the CT is negative.

He presented and discussed images of 2 particular cases: a very slow-growing breast cancer and a very slow-growing lung cancer. There is an article "Reassurance After Diagnostic Testing With a Low Pretest Probability of Serious Disease" that shows that diagnostic tests for symptoms with a low risk of serious illness do little to decrease anxiety, or resolve their symptoms, although the tests may reduce further primary care visits.

Further research is needed to maximize reassurance from medically necessary tests and to develop safe strategies for managing patients without testing when an abnormal result is unlikely. What happens at lung cancer screening? He discussed overdiagnosis in DLCST at 5-year follow-up (must stratify by pack years to obtain benefit for a few and presented data about the ACRIN trial: COPD and under-vs. overdiagnosis

For any medical intervention, there should be a consideration of the balance between benefits and harms e.g. threshold of abdominal aortic aneurysm diagnosis discussed: 85% overdiagnosis if 2.5cm is chosen as parameter. He then discussed the “Inverse Care Law” and the “Inverse Benefit Law”. In IHA, both of these laws are worsened and this was illustrated with a figure showing harms vs benefits of IHA when risk is low vs when risk is high. The survivor stories increase the demand for more screening, more IHA, more secondary care, more overdiagnosis and downward spiral.

There was an annual conference on Preventing Overdiagnosis in Barcelona, Spain in September 2016 (overlapping with this IHA Workshop in Seoul). The next conference will take place in August 2017 in Quebec, Canada and the following one will be hosted by Denmark (September 2018). He encourage the groups to participate and report of the progress of this project

He concluded that overdiagnosis is or may be a substantial harm — there is a need for high quality evidence for IHA in setting of diseases other than lung cancer

## Panel debate

Composition of the Panel:

Narayan Pendse (radiologist, India)

Stephanie Newell (patient advocate, Australia)

Rachael Moorin (health systems and economics, Australia)

Sang-Ho Yoo (Korean Society of Medical Ethics)

Moderator: Steve Ebdon-Jackson (PHE, UK)

*Do patients really need to be protected?*

People don't know what they don't know. If we expect people to look after themselves, there's a responsibility to assist people to do that. Society has more access to information and information seeking, not just in healthcare. This has increased people's need to be involved and has provided people with information open to misinterpretation (e.g. internet). Must look at multiple steps and avenues of decisions.

Health literacy is important, not just about the person taking control and giving them access to information; also about the system creating the proactive environment to enable them to do that. The onus is too frequently on the patient. As well, just because we have access to medications or devices, people don't identify them as harmful since they are indeed available. People have free access and think they should be entitled to something if they think they need it. They identify the benefits but not

necessarily the harms.

*Is the society's understanding that service availability means no harm?*

The concept that "Best ethics is best evidence" is not necessarily true. There are 3 main ethical principles:

1. promotion of common good
2. respect justice
3. respect autonomy

The harm to any individual patient or population can be assessed in terms of 1 to 3 above. Overdiagnosis does not promote common good, justice, or beneficial autonomy. There is uncertainty of "over" term in terms of diagnosis and screening as well as in terms of overtreatment". The individual's decision (especially in Korea) in non-governmentally driven or subsidized centers, it is wholly based upon individual choice. There has to be some good justifying ground for them *not* to do this kind of thing because it's common currently in Korea and they would like (e.g.) early detection of cancer. Would there be harm to the people if this right were removed? "Overdiagnosis" is not enough reason to remove this right from the people. People feel that they want to have a cancer detected/diagnosed.

*If we think patients need protection, from whom do they need protecting and why? Should the radiologists be protecting people or do the people need protection from radiologists?*

We should think about quality and safety, patient records work currently. We still need to define the problem (e.g. IHA A and IHA B) and quantify it (not just use qualitative studies), this is warranting greater discussion. Protection from harm and from whom? It all depends upon model. What is the motive? Different countries have different models. In a private sector model, there is a financial disincentive to scan less, an incentive to scan more (If I scan more, I earn more) . Is there any motive to scan less? We should define individual risk. What is the harm? How much is the harm? It is very complex. In a private setup, there is not much motive. In a public setup, there is not much implementation.

*Self-regulation is a difficult thing to expect to work. What role do health systems have in protecting patients?*

There is no simple answer. Patients need protection from themselves and from unscrupulous marketing of ever-expanding health technologies with the capacity for early diagnosis. Health technology is an industry. Self-perpetuating incremental increase in image quality; the incremental benefits are now very small as dose goes up but concurrent increases in capacity for diagnosis go up marginally. We should keep the public health perspective. For example, if a heavy smoker gets negative CTs, which reinforces his/her negative behavior. For clinicians, what do they tell patients? There is a massive market failure. Patients don't have full information. The referrer and radiologist are not being given opportunities *not* to do the service. They may lose a client, reduce their revenue stream. They work in silos rather than in a health system and don't see the downstream effects. You have a unique opportunity to use RP to regulate because of the new BSS (even if radiation



exposure is not the biggest risk in IHA). How the health care systems have an impact on what we do? What we should expect ethically about advertisements from providers?

*What about the "soft issues" like cultural differences, availability of information, financial motives, other/s??.*

Regarding the public/patients they also need to be protected from themselves, by increasing approach of patients being involved in their own care and respecting their needs. It's the patients' final decision on how to proceed. A new paradigm is that patients have rights to access but they may not understand what they're demanding and the potential impact (before: "doctors have the knowledge and doctors make the decision on my behalf"). If a service is available, they may think that perhaps equates to it being good. Even medical professionals don't always understand well enough to convey the information to patients. Patients have an expectation that the information will be provided. They don't realize when lacking information has not been provided.

*We are working in an information vacuum. Do patients present because they want to know they're well or not well?*

The culture of a physician - huge bias to do something. Since lung cancer is the #1 cancer killer with 75% diagnosed at advanced stages, you want to help the patients. Nobody wants to give up. The bias to cure and save is misguided. Huge bias against doing nothing. There is a medico-legal aspect. If you don't do anything because a study said not to, that may not be good enough as a defense. The prudent doctor vs. the prudent patient: who decides for whom? Are we as doctors trained not to do anything? No. But an elevated PSA can represent an innocuous lesion.

In many countries with alternative medicine they, too, are sometimes advocating the use of CT scans. Pharmacists may sell, for example, antibiotics. Radiologists' biggest driver is money, especially in the private sector. You must have an inner private conviction as to what to do. Teaching ethics is good but someone has to check upon the radiologist, in terms of justification and optimization, not just justification. How can we regulate justification? Patients must be empowered to make a decision. What are the risks? Patients must be presented with a very simple concrete debate.

In some countries (e.g. Uganda) having a kickback makes things worse. The referrer gets some of the money back for having ordered a CT.

If a patient has something, he wants to do something. Is it ethically justifiable to prohibit it, if both patient and doctor want something? If the harm to population is greater than the benefit... If the evidence shows that the technology causes greater harm, then it should be stopped, not just increasing awareness of patients and doctors but to increase the regulators, and which regulators?

Granted that an IHA plan does not have a strong evidence base of efficacy, should advertisements be banned or have a warning box as for cigarettes, or is that too strong?

Why do we have regulation at all? To promote greatest benefit. Private or

public, we're soaking up resources. Opportunity cost: once you use resources for one thing, you can't use them for something else. If you do something that's unwarranted, you're doing harm not only to the individual but to the society. But the marketplace has to be sustainable, so perhaps only the wealthiest can afford the resource, but we know that the lowest socioeconomic levels bear the heaviest burden of disease. Insurance premiums will go up if IHA becomes more common i.e. many repercussions. RP regulators regulate for population health and individual health. Should medical advertising on IHA be banned altogether? Or we can use other approaches e.g. Choosing wisely- it's about educating the patients in a way that they can be informed.

*Somebody's IHA means my car insurance may go up. I would prefer a watch and wait oncologist for a prostate cancer. One approach may be licensing. There is no incentive for radiologist or referrer to self-police. Go back to standards on IHA: can they be set by professional bodies? Or government? Other regulators?*

For patients, having medical professionals involved give the reassurance that a medical intervention is OK. People assume that standard setting has been done. People derive comfort from standards of a radiologist college. But with IHA, individual patients have variable expectations of an outcome. The demonstration of justification should be made explicit to the public. That speaks to the heart of the BSS. This could be a starting point for justification.

If radiologists are the gatekeeper, then clinical standards are the way forward. In the absence of quantification of the problem, what quantum of harm — to whom and by whom, then we should at least do controlling advertising and promoting awareness.

Ethical experts feel that clinical standards better to be set by professional bodies than regulators. Lobby groups sometimes do harm and overturn decisions based upon evidence, as with breast cancer in Australia. Professional bodies must be involved, they know the evidence and are best to set standards for IHA but not definitely best to implement them. Need multi-stakeholder collaboration and involvement of HTA, RP regulators, health authorities and professional bodies.

There are 3 areas in which to find solutions

- *Radiation safety: what can the RP regulators do to improve the situation?*
- Culture of the family doctors to try to detect disease although the ultimate goal is to decrease morbidity and mortality? We are increasing disease but not saving lives. *How can we promote the culture of reducing mortality?*
- Conflict of interest: *can we change this, to be paid for quality performance?*

*Ultimate goal of this project is some type of policy statement or policy guidance document. It's no coincidence that we're in South Korea because we would like something applicable to the world. How do we approach this granted the variation?*

Our problems are diverse and it will be very difficult to conceive of a singular approach. U.K. is very different from India, but the greatest problem currently is in the highest resource countries.

The science can be universal but the social aspects and expectations will vary across the world, therefore it's pivotal to engage with the stakeholders including the patients and what matters to them. Financial drivers, employers, insurers should be around the table — all stakeholders. IHA may even be a pre-requisite for employment, but the employers may not realize that they're exposing their employees to potential harm. In some countries (e.g. U.K) it's mandatory to declare you have undergone IHA to the insurance company. It is very difficult to have one regulation.

## 5. Plenary 2: Stakeholder's concerns

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### Co-chairs

Kyun Hyun Do, Korean Soc. of Radiology RP

Jurgen Griebel, Federal Office of Radiation Protection in Germany

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Presentation by Eva Godske-Friberg, Norwegian Radiation Protection Authority, regarding the concerns from regulators. It started reminding the characteristics for IHA of asymptomatic individuals

- Examinations performed on healthy individuals, often without an identified risk-profile
- Examinations often based on self-presentation or self-referral and not a justified referral
- IHA often available as a commercial service, outside healthcare service
- Examinations often paid by the presenter
- IHA is not normally a part of the healthcare system

More recent European BSS (Article 55) and International BSS provide a platform for regulatory activities for justification of IHA. In the EU-BSS: Article 55 (h) – Member States must ensure 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 point (d) of Article 57(1): "...patient is provided with adequate information relating to the benefit and risks associated with the radiation dose from the medical exposure.....". The transposition and implementation of this directive raises challenges and concerns when it comes to IHA. The establishment of guidelines for CT IHA is required by the EU-BSS, which says that:

- Justification of IHA should follow national guidelines
- National guidelines should be developed by professional societies in conjunction with national competent authorities

These guidelines must be risk-based instead of symptom-based (as for patients) and need to define the risk profile for individuals expected to benefit from the examination. How to establish such guidelines? There is no system established that systematically collects relevant data at a national level and facilitate a continuous review and evaluation to establish the evidence base needed. Results from IHA should be included in healthcare records. Where there is lack of evidence base, guidelines should be based on expert

consensus. The EU BSS also refer to balanced information and informed consent. Ensure that honest information is given to the presenter to obtain informed consent (especially when not clinically justified) and to manage expectations. Information must be balanced in the benefit/risk-dialogue. Information needs to mention risks like stress arising from false-positive or false-negative findings, follow-up examination, morbidity and significant harm arising from over-diagnosis and overtreatment, equivocal/incidental findings, radiation dose, etc.. Advertisements are often aggressive and play on people's fear of sickness, often not balanced to give information about its risks and limitations, often a major driving force: need to be regulated. EU BSS also refer to QA system requiring:

- Technical equipment and QC
- Performance and interpretation of the examination
- Management of findings and follow-ups
- Proper education and training for staff
- Systems for documentation and evaluation of the benefit from IHA

Achieving good quality in all steps is challenging, since they often are performed isolated and fail to be fed back to the patient record and healthcare system. Clinical audit must be part of the QA-system to monitor the outcomes and follow-ups and support the establishment of evidence based knowledge

There are finance and resource issues. CT IHA is associated with a high rate of follow-up examinations, with a tremendous effect on health finance. Follow-up examinations often feed into the public healthcare system. Who shall pay these examinations? The presenter, the provider or the public healthcare system? If paid by healthcare system it diverts resources from more needy patients and adds to inequality, often with little gain in real health outcomes: Is this ethically acceptable?, Should providers of IHA also commit to cover follow-up expenses? When does a presenter turn in to be a patient with right to be included in healthcare system?. The justification of IHA should not depend on who's the payer. The same principles to be valid also for examinations paid by the presenter. If IHA is reimbursed, it should not be in conflict with the justification principle. Who reimburses IHA? Reimbursed by insurance companies or public healthcare system?

RP takes into account radiation-induced cancers, but good governance of healthcare is - broader than just RP. Need for close cooperation with other health authorities, professional societies...best use of resources; robust coordinated framework of good governance warranted

Q&As, comments: tendency for people to contemplate IHA programs to become like screening programs. Does the evidence base need to be equivalent to population-based screening evidence? We should question the evolution of IHA to screening-type programs. We need to think about dose as variable since a monophasic liver CT, for example, confers a lesser dose than a multiphasic exam. Regulate in different ways for different exams — must discuss.

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Presentation by Rosmini Omar, Patient champion, WHO patients for patient safety, Malaysia.

Stakeholders' concerns, based upon interviews with "presenters" for IHA in Malaysia. 5 groups of responses:

1. A group which doesn't understand CT and opts for alternative medicine. Resistant.

(\*this group was mentioned verbally but not included on slides)

2. A group (growing) “Health is my first wealth”, 5-10% who find IHA is crucial, go once or twice/yr. on advice of their doctors. (Most medicine is private sector.)
3. A group where IHA is taken as a *currency for security/getting ahead in life* (university/job/loan offers)
4. A group with *Societal expectations: “follow the flow...”* Follow their peers through social media, etc.
5. A group *Engaged, informed, empowered*

Factors discussed of those Aware vs. Unaware. Advertising: is not heavy in her country. Either word of mouth (electronic and face-to-face) and/vs. push-strategy - phone calls by private practices with “health and wellness packages”. Most Malaysians pay out of pocket for IHA, unless diagnosed and then they can get health insurance out of it.

The right image, right dose, right follow-up: the Malaysians trust doctors. The doctor needs to explain the results and evidence that the scan should lead to a certain outcome, but patients also feel they are responsible to inform themselves (e.g. from internet). What about potential adverse effects? We want to understand the need for a scan, the impact, what the scan involves?. Equality is an issue e.g. use of CT in public and private sectors must be equally beneficial for presenters. Responses such as “sometimes I am afraid they do a whole check of my body for the sake of charging my insurance, when it’s not relevant” Need for explanation of risks and benefits, potential outcomes before decision-making, upon getting results so don’t overdo. IHA should be done by experts who can ethically guide decisions, JUSTIFICATION: ethical, efficiency in cost, care coordination, quality consequences/follow-up, empowerment to make informed decision

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Presentation by Yoon-Ho Choi, M.D. Director, Center for Health Promotion, Samsung Medical Center, Professor, Department of Internal Medicine, Sungkyunkwan University School of Medicine, President, The Korean Society of Health Screening and Promotion. He referred to clinical CT uses in medical checkup programs. Samsung Medical Center is a top-ranked health screening center in Korea. It conducts a *comprehensive medical checkup (IHA): about 50,000 presenters/year* \$ 600 ~ \$ 10,000 (average \$1,500) including blood, endoscopy, sonography, CT, MRI, PET, genetics. Their staff (full time) includes 320 p (67 board certified specialist- 21 radiologist, 120 RN). All presenters receive enough explanation about programs from RN before checkup: radiation hazard for CT (LDCT, coronary Ca CT), informed consents for CT or MRI, abdomen CT: pre-visit doctors (IM, FM). They follow CT recommendations/guidelines

#### Chest LDCT

Initial CT            20 pack years smoker: age > 35~40  
                             otherwise: age > 40~45

Follow-up CT    Male: age > 45            q 1 year  
                             Female: age > 50        q 2 years

#### Coronary Calcium CT

Initial CT            Male: smoker            age > 40  
                             non-smoker        age > 45  
                             Female: age > 55

Follow-up CT    q 2~5 years by calcium scores

#### Abdomen-Pelvis Area CT (or MRI)

Male: age > 50 q 5 years

Follow-up CT Recommendations for Lung nodules  
(LDCT in IHA)

Solid nodule

- =< 5mm: Follow-up CT at 6 months  
(benign looking nodule: Follow-up CT at 12 months)
- 6 ~ 8mm: Follow-up CT at 3 or 6 months
- >= 8mm: pulmonology consultation for further evaluation

Pure ground glass nodule: Follow-up CT at 6 months

Part solid nodule

- =< 10mm: F/U Follow-up CT at 6 months
- >10mm: pulmonology consultation

IHA Presenters and CT scans

| 2014                  | age | ~19 | 20~29 | 30~39 | 40~49 | 50~59  | 60~69 | 70~   | subtotal      | Total         |
|-----------------------|-----|-----|-------|-------|-------|--------|-------|-------|---------------|---------------|
| <b>Presenter</b>      | M   | 94  | 712   | 2,519 | 6,551 | 11,973 | 5,105 | 1,771 | <b>28,725</b> | <b>50,772</b> |
|                       | F   | 44  | 698   | 2,131 | 6,254 | 8,724  | 3,230 | 966   | <b>22,047</b> |               |
| <b>LDCT, Chest</b>    | M   | 2   | 55    | 774   | 3,482 | 7,821  | 3,264 | 1,090 | <b>16,488</b> | <b>24,304</b> |
|                       | F   | 0   | 8     | 98    | 1,844 | 3,900  | 1,516 | 450   | <b>7,816</b>  |               |
| <b>Coronary Ca CT</b> | M   | 0   | 3     | 257   | 1,631 | 3,865  | 1,775 | 614   | <b>8,145</b>  | <b>9,818</b>  |
|                       | F   | 0   | 0     | 8     | 138   | 696    | 606   | 225   | <b>1,673</b>  |               |
| <b>Abd-Pelvis CT</b>  | M   |     | 2     | 17    | 60    | 200    | 129   | 54    | <b>462</b>    | <b>656</b>    |
|                       | F   |     |       | 11    | 43    | 83     | 41    | 16    | <b>194</b>    |               |

|                                   |      |
|-----------------------------------|------|
| Follow-up LDCT                    | 2725 |
| Abd-Pelvis CT as additional order | 2029 |

Effectiveness of medical checkup in cancer detection

women 40-59 natl incidence breast ca 135/100,000 and detection by checkup 396/100,000 in their center

men lung ca age 50-59 natl incidence 60/100,000 detection by checkup (LDCT) 120/100,000 in their center

Cancers detected at checkup, and cancers missed at checkup but diagnosed in one year, among 615,886 checkups (about 300,000 individuals) (1995 ~ 2014)

| Cancers               | All          | Detected     | %           | Missed     | %           |
|-----------------------|--------------|--------------|-------------|------------|-------------|
|                       | <b>7,582</b> | <b>6,768</b> | <b>89.3</b> | <b>814</b> | <b>10.7</b> |
| Thyroid               | 1,750        | 1,657        | 94.7        | 93         | 5.3         |
| Stomach               | 1,252        | 1,183        | 94.5        | 69         | 5.5         |
| Colon                 | 867          | 785          | 90.5        | 82         | 9.5         |
| Prostate              | 692          | 669          | 96.7        | 23         | 3.3         |
| Breast                | 669          | 607          | 90.7        | 62         | 9.3         |
| <b>Lung</b>           | <b>532</b>   | <b>487</b>   | <b>91.5</b> | <b>45</b>  | <b>8.5</b>  |
| Uterine cervix        | 326          | 309          | 94.8        | 17         | 5.2         |
| Brain                 | 298          | 201          | 67.4        | 97         | 32.6        |
| Liver                 | 229          | 185          | 80.8        | 44         | 19.2        |
| Renal cell carcinoma  | 214          | 208          | 97.2        | 6          | 2.8         |
| Pancreatic or Biliary | 146          | 102          | 69.9        | 44         | 30.1        |
| Bladder (TCC)         | 104          | 78           | 75.0        | 26         | 25.0        |
| Blood                 | 96           | 77           | 80.2        | 19         | 19.8        |
| Skin                  | 91           | 26           | 28.6        | 65         | 71.4        |
| Head and Neck         | 84           | 29           | 34.5        | 55         | 65.5        |
| Esophagus             | 46           | 45           | 97.8        | 1          | 2.2         |
| Ovary                 | 44           | 35           | 79.5        | 9          | 20.5        |
| Other Urologic cancer | 39           | 24           | 61.5        | 15         | 38.5        |
| Lymphoma              | 33           | 17           | 51.5        | 16         | 48.5        |
| Others                | 70           | 44           | 62.9        | 26         | 37.1        |

The radiation doses vary by study and CT scanner. He noted that the lifetime increased risk of cancer from CT is low: 1% additional lifetime cancer risk (incidence) from 100 mSv. LDCT rarely leads to surgery for non-lung cancers (articles discussed). Enthusiasm exists for cancer screening in U.S. (article): likely even > enthusiasm in Korea —over-testing but not necessarily overtreatment. The CT coronary calcium scoring discussed as case in point. There are already many CT scanners in Korea —inappropriate allocation of resources is not an issue since nobody in need is being deprived of a CT because of CT for IHA. He thinks that the presenter can be seen as patient vs. consumer

- Presenter is willing to pay
- Self-presentation
- Presenters free will vs. guidelines or regulations

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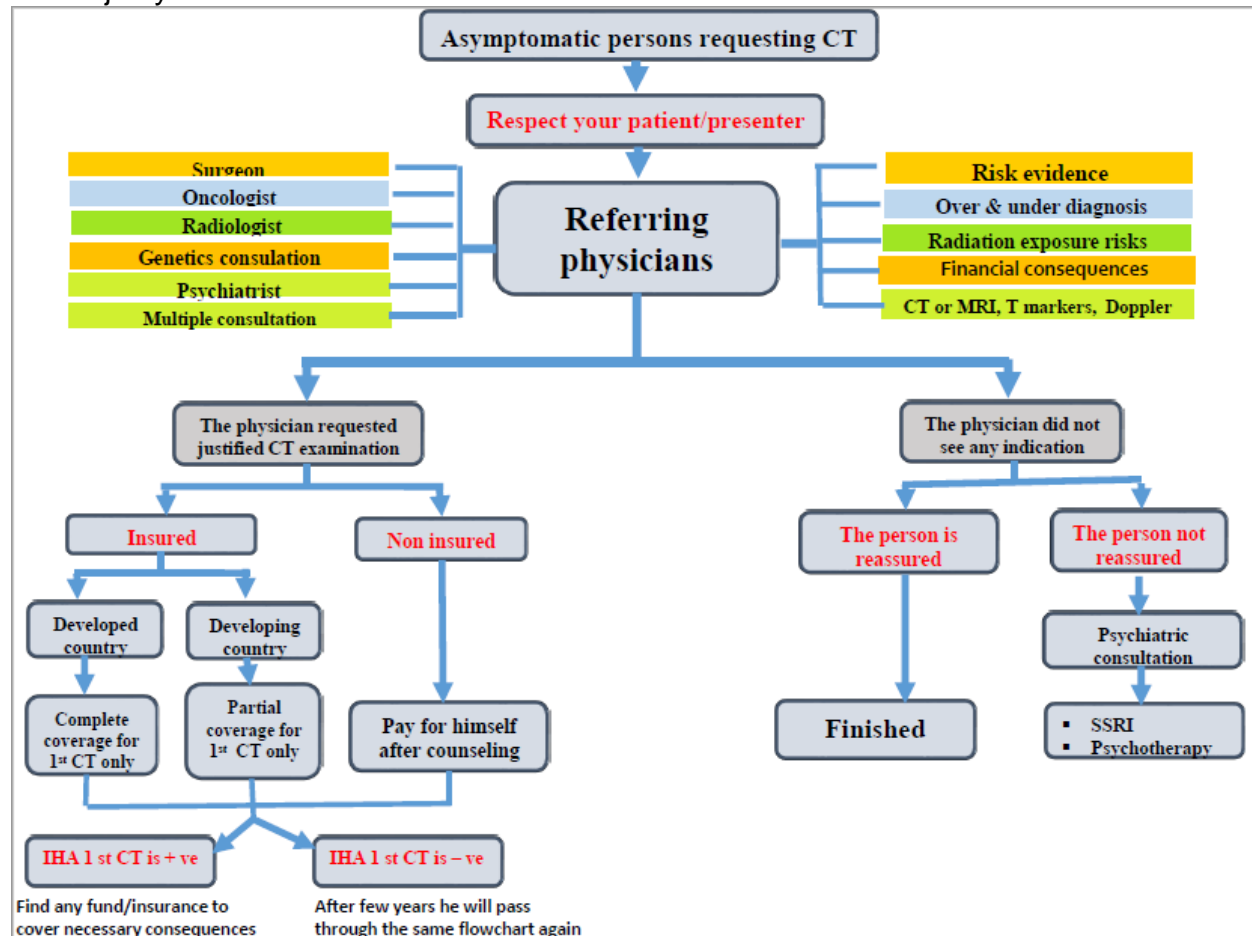
Presentation by Professor Dina Hussein, Head of radiology and RP at facility in Egypt. She highlighted that there are many IHA stakeholders and that the motives for asymptomatic IHA are several

- fear of inherited diseases
- abnormal psychosis or hypochondriasis
- unnecessary requests by referring physicians
- atypical presentation leads to atypical requests
- no/improper audit in private practice

She expressed 3 concerns: ethical, medical, and financial issues. Ethically we should respect the patient/presenter for CT for IHA, refer to proper physician. Who? Or multiple consultations? do not reassure without evidence, and differentiate between

normal and psychotic persons (exaggerated fear) and to inform/counsel. The medical aspect relates to early diagnosis (screening =easy programs), very early diagnosis (IHA difficult task) and prediction (the future =epigenetics & metabolomics). We should take it seriously, in a multidisciplinary approach. Sometimes multiple consultations warranted, keeping records and tracking patient dose(s).

Financially, insurance should only cover indicated CT exams after proper health assessment. Self-presentation for CT is very rare in Egypt and prohibitively expensive for the majority.



IHA is not common in Africa. Very few countries in Africa can cover it. The health assessment is the most difficult step. Basically it is an ethical concern in 80% then medical and financial issues come later. We do not have a lot of media advertisement about IHA. No medical litigation if use flow-chart (see above). Don't forget need for a *justified referral form*.

Presentation by Clara Carpeggiani, CNR Institute of Clinical Physiology, cardiologist from Pisa. The Italian Health System has a budget constrained environment: where do cuts in spending take place? Health ministers change and no change happens... In U.S., 85% of radiation attributable to nuclear medicine and 28% of radiation attributable to radiology are from *cardiovascular* tests. Large doses from interventional cardiology. 2010 ACCF/AHA Guideline for Assessment of Cardiovascular Risk in Asymptomatic Adults: first global risk score (Framingham) - class I simple and inexpensive recommendations, determine



strategy: low risk - no further testing & intermediate and high risk – greater options and modalities. There is little evidence of outcome benefit for cardiac CT (article reviewed). Does screening for disease save lives in asymptomatic adults? Very rarely. Among currently available screening tests for diseases where death is a common outcome, reductions in disease-specific mortality are uncommon and reductions in all-cause mortality are very rare or non-existent. Doses in invasive radiology are high. Bad for the patients and the operators. Regarding cardiac catheterization risks, there is a lack of awareness on side of both operators and patients.

# Cardiac Catheterization

## Occupational Health Risks in Cardiac Catheterization Laboratory Workers

Maria Grazia Andreassi, MSc, PhD; Emanuela Piccaluga, MD; Giulio Guagliumi, MD; Maurizio Del Greco, MD; Fiorenzo Gaita, MD, PhD; Eugenio Picano, MD, PhD; on behalf of the Healthy Cath Lab Study Group\*

*Circ Cardiovasc Interv.* 2016

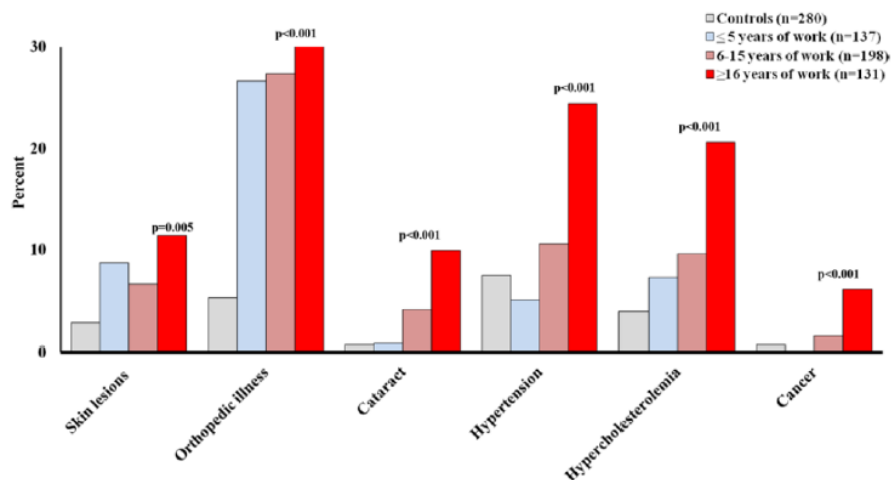


Figure 3. Rate of health problems by years of occupational work.

Informed consent strategies: the current policy in Italy is not to say a word before cardio CT, stent, etc... culturally. The dose corresponds to a common radiography — understatement. Full disclosure is needed. Her take home messages:

- Screening does not necessarily save lives (no or weak evidence base)
- If no guideline, shouldn't use ionizing radiation
- Ethical issues including questions on resource allocation
- We have to make it easier for everyone to be healthy
- In the last twenty years the per capita dose from medical imaging has increased by a factor of 6 (Mettler F et al, Radiology 2008)
- Low to moderate (<100 mSv) radiation doses from diagnostic and therapeutic imaging procedures in cardiological patients may increase cancer frequency after

decades (Eisenberg MJ. CA Cancer J Clin 2012; Hung MC, Asian Pacific J Cancer Prev 2013; Carpeggiani C Int J Cardiol 2015)

- The communication of doses and risks is often based on a highly specialized technical language, often difficult to understand even for practitioners and prescribers

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Presentation by **Ernesto Mola, M.D.**, WONCA.

The World Organization of Family Doctors (WONCA) has 118 member organizations from all over the world, and many members. Regarding IHA: what boundaries?: demand of health and family doctors, quaternary prevention and overdiagnosis, patients ask for health - health services answer about diseases, a few suggestions to improve appropriateness in the IHA. The General Practice:

- is normally the first point of medical contact..
- makes efficient use of health care resources through coordinating care ....
- develops a person-centred approach.....
- is responsible for the provision of longitudinal continuity of care as determined by needs of the patient
- has a specific decision making process determined by the prevalence and incidence of illness in the community
- promotes health and well-being both by appropriate and effective intervention
- manages comprehensive care....

Quaternary prevention is an “*an action taken to identify a patient at risk of over-medicalization, to protect him/her from new medical invasion, and to suggest interventions which are ethically acceptable*” (WONCA Dictionary of General Practice). “Prevention, in a narrow sense, means averting the development of a pathological state. In a broader sense, it includes all measures—definitive therapy among them—that limit the progression of disease at any stage of its course” (Clark-MacMahon 1967).

The patient-doctor encounter needs a discussion of the concept of prevention. “A renewed (and possibly renamed) conceptualization of “prevention” would consider:

1. Population orientation (even for clinical medicine)
2. Population-attributable risk rather than individual (relative) risk
3. Morbidity burden rather than disease burden
4. Tandem estimation of the benefits and costs of strategies to improve both population health and the distribution of health within populations
5. Improving overall health rather than disease prevention as a major goal. There may never be agreement on priorities for prevention or what “prevention” is, but there can be agreement on what should be achieved, in the context of equity and maximisation of population health.” (B. Starfield 2007)

Which are the reasons to request IHA? :

- Fear of disease
- Fear of doctor to underestimate disease or defensive medicine
- Financial/industry incentives

Not to do - difficult to explain to patient. It's easiest to comply with the patient. The art of doing nothing (Iona Heath quote). In Italy, muddled information: requested biennial mammography, PSA screening, blood tests, car or CT scan for smokers —but if you're a big smoker, what are you doing for your health? There is a cultural pressure: industry, financial ties with patient groups, consumer advertisements...What can we do?

- Promote awareness concerning overdiagnosis
  - Promote doing nothing culture
  - Influence defensive medicine legislation
  - Promote doctor education —to educate healthcare professionals, to share info. With patients
- 

## 6. Plenary 3 Public Health Issues

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Co-chairs:

Maria del Rosario Perez, WHO Radiation Program

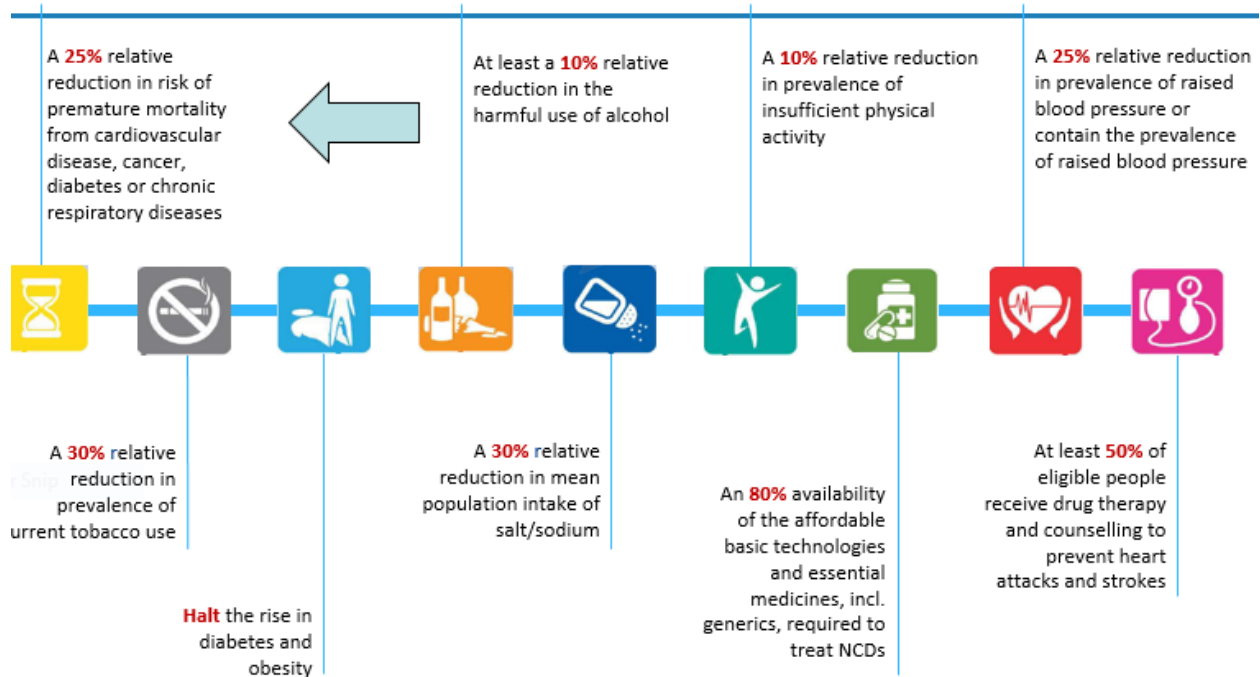
Dukhyoung Lee, Director of National Cancer Control Institute, NCC Korea

Presentation by Oyere K. Onuma, WHO medical officer, cardiovascular diseases Management of Non-Communicable Diseases (NCDs), Violence and Injury Prevention.

Regarding screening of asymptomatic individuals we need to have a view as to screening and public health approach. The NCD mortality in 2012 was 38 million out of 56 million deaths. NCDs are increasing, particularly in LMIC. The 2013 Global Monitoring Framework: includes 25 indicators and 9 voluntary targets,

- Overarching target: a 25% reduction of premature mortality from the 4 major NCDs (cardiovascular diseases, cancer, chronic respiratory diseases, diabetes) by 2025.

## World Health Assembly, May 2013: 9 global NCD targets to be attained by 2025 (against a 2010 baseline)



Need for a comprehensive disease control program along spectrum from prevention—> early diagnosis & screening, diagnosis —>treatment—>palliative and supportive care—> survivorship care. There are 2 strategies: screening (organized or unorganized) vs. early diagnosis. The goal = early identification —> improve survival?

Early identification = less morbid treatment (tx) at less cost to individual and health system secondary prevention (i.e. precancerous lesions)

Screening vs. early diagnosis (dx)- screening is the testing of persons in a target population who do not have symptoms– with referral for diagnosis of those found to have an abnormality suspicious for disease. Screening should be high quality, accurate, accessible —>confirmatory diagnosis, path, staging—>referral for treatment—>accessible, affordable, high quality treatment. The early diagnosis is more than symptom awareness; link to health system, the awareness of symptoms is linked to accurate diagnosis.

Which are the screening pre-requisites? need strong health system, high quality delivery, high participation rates, screening has potential to cause significant harm — to individuals and to health system by diverting essential resources.

Formal national screening programs advocated by WHO are those organized (see below):

Screening approaches:

- Organized
  - greatest impact, fewest harms, equitable, >70% participation
  - e.g. breast cancer screening, colorectal cancer screening
- Organized screening of CVD:-evidence mixed. WHO recommends above age 40 screening using CVD risk charts unless specific risk factors < -age 40 (ongoing work at WHO to clarify WHO guidance).
- Opportunistic screening (IHA)

- unorganized, also known as opportunistic screening or IHA, < cost effective, has potential for > harm, low quality screening, overdiagnosis

One issue is the unequal accessibility. In CT for coronary calcium, the costs and public health benefits are not well-defined, well suited to research/clinical registry until better defined cost-benefit analysis

When not to screen?

| <b>Conditions when Cancer Screening Should not be Introduced</b>                     |
|--|
| Inadequate infrastructure or funding   |
| Weak health system   |
| Early diagnosis capacity limited or absent   |
| Shortage in health workforce or inadequate trained personnel                         |
| Lack of available, accessible, high quality treatment                                |
| When disease incidence is not high enough in an identifiable target population       |
| No mechanism to ensure high participation or coordination                            |
| Inadequate commitment from responsible authorities to provide oversight & management |

- Public health case is weak (IHA A) to non-existent (IHA B)

|                              | <b>Formal Screening Programme</b>  | <b>IHA(A)</b>   | <b>IHA(B)</b>   |
|------------------------------|--|---|---|
| <b>Participants</b>          | Populations  | Presenters /Patients  | Presenters  |
| <b>Who pays?</b>             | Public healthcare services   | Presenter, Insurer, or Employer   | Presenter or Employer   |
| <b>Service Provider</b>      | Healthcare System  | Usually Practice or Hospital  | Usually Private Practice or Private Hospital  |
| <b>Referral by</b>           | Healthcare System  | Presenter's Employer, Physician or other Healthcare Professional, Self-Referral, Self-Presentation  | Presenter, Self-Referral (conflicts of interest may exist), Self-Presentation, Other Referrers or Practitioners |
| <b>Recognisable Features</b> | National approval and/or approval by professional bodies; population-based rather than individual justification; demanding governance framework, and quality assurance programme along the whole screening chain | At least partial evidence base; risk profile considerations; evolving research findings; individual justification; additional requirements concerning justification and quality assurance; possibly a register. | No Framework <sup>o</sup>   |

Potential for significant danger exists, particularly in some low- and middle- income countries where a weak regulatory climate as well as weak, poorly functioning health systems, can leave patients exposed

Key messages:

1. Organized screening programmes can reduce mortality only when key criteria are met: high quality services, high participation rates, and process is linked to accessible, affordable treatment with robust quality assurance at each step.
2. Poorly performed screening can cause harm, misappropriate resources, and worsen inequities in care.
3. Significant pre-planning is required before initiating a demonstration project and also essential to appropriate capacity building after a successful demonstration.
4. Population-based organized screening is the goal and can take decades to accomplish. In settings unable to meet or sustain the key criteria of programme organization, population-level screening should not be introduced.

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Presentation by Jim Malone, Trinity College, Dublin. He referred to ethics and RP of the presenter/patient. The systems of RP in most countries are based upon ICRP recommendations. Medical ethics has explicit values agreed upon, unlike in RP community where values aren't well defined. The ethics approach proposed for RP community will be soon be available to all stakeholders. What is ethics?

Personal moral is not sufficient for professional context – it warrants agreement across the profession Ethics refers to how ought practice of medical IHA be conducted by individual A with problem B? Ethics has practical implementation issues, obligatory vs. ordinary, and very numerous. He discussed ethics for RP in medicine and IHA. The system of RP developed by the ICRP consists of science, value judgments and experience. ICRP is now working on ethics (TG-94, report/consultations). The RP values still have low recognition and are isolated in medicine. Medical ethics and society has a strong scholarship and research. IHA must be consistent with medical ethics<sup>5</sup>.

1. Dignity and autonomy
2. Non-maleficence & beneficence
3. Justice
4. Prudence (including precautionary principle<sup>6</sup>)
5. Honesty (social expectation — transparency)

We are dealing with uncertainty: in the philosophy, uncertainty in communication, uncertainty about risk (e.g. “6 months to live”, “5% mortality during a procedure” does it mean no operation?), the LNT Uncertainty, fraudulent science or irreproducible science Scenarios: self-referral (e.g. cardiology) how to manage it? We will have to use a pragmatic value set consistent with new ethics in RP, based on 5 intuitive values (as applied to the specific scenario). It is necessary for consistency of IHA with medical ethics and social expectations.

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Presentation by Sandor Demeter, Faculty of Health Sciences, College of Medicine University of Manitoba, September, 2016

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<sup>5</sup>(from Beauchamp & Childress, 1979/2012) Medical Ethics

<sup>6</sup>“Potential for irreversible harm - lack of full scientific knowledge”

He referred to IHA from a public health perspective, and reminded the WHO definition of health: physical, mental, social wellbeing. Determinants of health are diverse: biology, health care system, social environment, and physical environment including working conditions and epigenetics. He mentions the definition of screening as the application of tests to asymptomatic individuals to risk stratify them into high or low risk with an aim to inform further definitive testing. The goal is to detect the pathology early and provide an opportunity for radical intervention. Screening can be applied en masse or to targeted “at risk” groups. Need to look at harm vs. benefit: lead time bias, length time bias, overdiagnosis. IHA for lung cancer is an example:

- Lung cancer morbidity and mortality burden
- Early detection of lung cancer
- High risk based on age and smoking history
- NEJM Results of Initial Low-Dose Computed Tomographic Screening for Lung Cancer<sup>7</sup>
- Including smoking cessation and managing psychological issues related to false positives

\*

WHO provided criteria for screening:

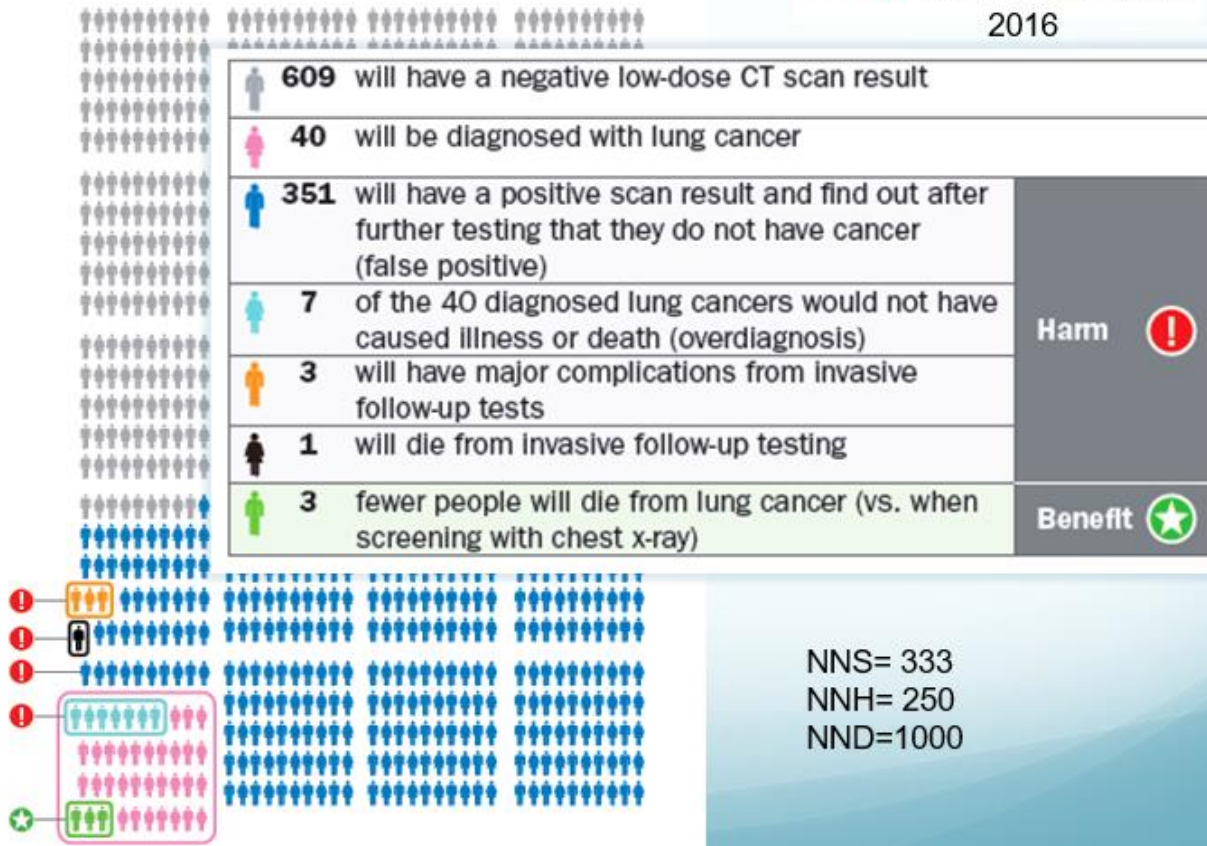
1. The screening programme should respond to a recognized need.
2. The objectives of screening should be defined at the outset.
3. There should be a defined target population.
4. There should be scientific evidence of screening programme effectiveness.
5. The programme should integrate education, testing, clinical services, and programme management.

The ACR guideline says that if it is self-referred must have a follow-up!

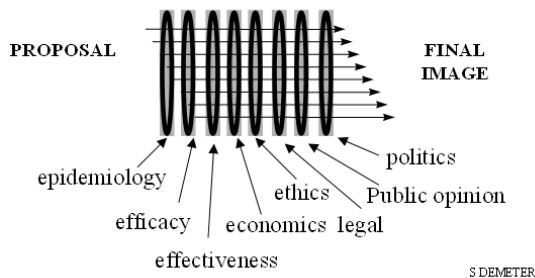
Lung Cancer Risk: smoking must be dealt with! They may see screening as an alternative to smoking cessation (as discussed before- the psychological impact). We need to consider harm vs. benefit of IHA screening, considering the principles of RP (ICRP 103)- Justification, Optimization/DRLs. The Canadian Task Force LDCT study concluded that for 1000 screened, you will prolong the lives of 3, 3 will have major complications, 1 will die from testing, 351 will have false positives

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<sup>7</sup> Reduced Lung-Cancer Mortality with Low-Dose Computed Tomographic Screening The National Lung Screening Trial Research Team N Engl J Med 2011; 365:395-409



ASSESSMENT LENSES



Conclusions:

- Lung cancer constitutes a major incidence and mortality burden
- A majority of cases are diagnosed at later stages with poor prognosis.
- Previous screening interventions have not been successful (sputum cytology and chest x-ray)
- Low dose CT screening of high risk populations results in a mix of benefits and harms – societal values and ethical considerations, as well as a well-designed screening program, are needed prior to implementation
- IHA driven Low dose CT imaging of asymptomatic individuals, whether at high risk or not, is not recommended



- The role of primary prevention cannot be understated!

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Presentation by Prof. Rachael Moorin School of Public Health, Curtin Univ., Western Australia. How do we make decisions for public health? social efficiency is the objective of any health system, and getting greatest improvements in wellbeing from resources  
 Opportunity cost: value of best alternative forgone where given limited resources, a choice needs to be made between mutually exclusive alternatives, maximize benefits and minimize costs, deploy resources efficiently. Resources are limited so what interventions should be available? How? By whom? For whom? What before and after intervention?  
 Decision-makers need information about available options and their consequences so this requires emergence of evidence-based medicine, HTA, multidisciplinary activity which seeks to assess the technical performance, safety, effectiveness and cost-effectiveness of health technologies. We need systematic reviews about relative safety, effectiveness, and cost-effectiveness, and to compare IHA to not having test at all. Causal pathway and determinants simplified: “the presumptive identification of unrecognized disease or defects by means of tests, examinations, or other procedures” (modified from WHO 1968). We need to differentiate between population-based vs. opportunistic vs. screening on demand. In Australia:

- population screening framework based upon strong evidence base, safety,
- effective, accessible and acceptable
- reproducibility, accuracy, efficacy, > benefit than harm, info. about condition,
- follow-up available (regardless of ethnicity, socioeconomic status...)
- treatment effective available
- benefit vs. harm

Opportunity cost should address allocative efficiency, technical efficiency (below)  
 IHA vs. problem based screening: How do we determine clinical pathway?, how to ensure going to be followed?, how to ensure access? How to ensure quality of test and follow-up?  
 There is a need for an economic evaluation to assess the opportunity cost of the screening program or activity. We should address the questions of allocative efficiency:

1. Is screening worthwhile?
  - Do the benefits exceed the costs?
  - Are the cost appropriate within the costs of the wider health care program?
2. Technical efficiency
3. What are the most cost effective options for achieving the objective?
  - Evaluate the other options , emerging improvements in treatment methods, funding more resources to increase interventions already in place.
  - What is the next best use of the resources?
  - Is the proposed screening a better use of those resources?

The results of the economic evaluation should demonstrate that screening is the most cost effective intervention to reduce the burden of disease. There is a market failure in the health system, asymmetry of information between principal patient and agent-physician, how much inconsequential disease is detected? insignificant lesions? overtreatment? false positives? How large is benefit on true positives? Change in management? Survival and/or quality of life? How accurate is the imaging service? False positives vs. negatives?

Accuracy variability? Unintended consequences of true negatives? e.g. smoker continues smoking if negative chest CT, Safety concerns: small radiation risk, contrast agent risk, risk from follow-up testing (including false positives), which is the aseline risk of disease? How many people? Sustainable use of resources? Equitable across population? Accessible to all? Screening intervals? What standards apply to facilities and systems for follow-up and treatment?

Summary:






The provision of health services needs to be:

- Effective, Equitable, Sustainable, Acceptable & Socially Efficient
- Choices need to be made about what health services are provided
- Based on evidence
- Health technology assessment can aid decisions
- Chance of market failure is high in Healthcare
- Asymmetry of information
- Supplier induced demand
- Individual health assessments (IHA) should not be exempt from the decision making process
- Evaluation should be undertaken using a health systems approach
- Ensures finite resources are used efficiently taking into account ALL consequences

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Presentation by Jae Kwan Jun, epidemiologist, Korean National Cancer Centre. He referred to Public Health Issues in Korea about IHA. In recent years, investigations for asymptomatic individuals have been made available to those who may consider they are at risk of a disease. To differentiate these from screening programmes, this practice has been termed individual health assessment (IHA). Although the principles of early detection and more successful outcome remain the driver behind such investigations, the fact that they are targeted at individuals rather than populations, and performed in independent institutions, has meant that evidence base, quality assurance, arrangements for information transfer into established care pathways and assessment regarding the net benefit have not been conducted to the same standard as is applied to screening programmes. The Wilson criteria for screening test were discussed, with emphasis on last criterion: cost-benefit balance

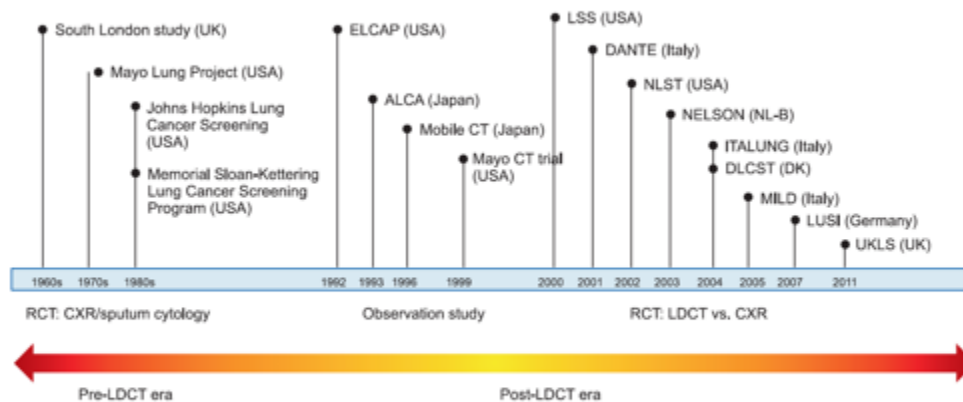
## Protocol of the National Cancer Screening Program (NCSP) in Korea (2002~present)

| Cancer   | Age                     | Interval | Methods   |
|--|-------------------------|----------|---|
|  Stomach    | ≥40                     | 2 years  | Upper endoscopy or <b>UGI series</b>              |
|  Liver      | ≥40<br>high risk group* | 6 months | Liver <u>sonography</u> & AFP                     |
|  Colorectum | ≥50                     | 1 year   | FOBT, if positive<br>→ colonoscopy or <b>DCBE</b> |
|  Breast     | ≥40, women              | 2 years  | <b>Mammography</b>                                |
|  Cervical   | ≥20, women              | 2 years  | Conventional Pap smear                            |

\* 40 & over with HBsAg positive or anti-HCV positive or liver cirrhosis

Extensive review of various lung cancer imaging trials:

## History of Lung Cancer Screening



CT: computed tomography; CXR: chest X-ray; DANTE: Detection and Screening of Early Lung Cancer; LDCT: low-dose chest CT; LSS: Lung Screening Study; NLST: National Lung Screening Trial; RCT: randomized controlled trials; UKLS: UK Lung Screen.

Source: Park YS. Tuberc Respir Dis 2014;77:55-9.

Korean lung ca screening pilot program will start next year (article reviewed). It is difficult to balance benefits vs. harms of cancer screening.

## Target Population of Lung Cancer Screening (2012)

|  | Male             | Female        |
|--|------------------|---------------|
| Mid-year population aged 55-74 (N) <sup>1)</sup> | 4,552,107        | 4,936,874     |
| Prevalence of high-risk group (%) <sup>2)</sup>  | 28.7             | 0.28          |
| Estimated target population (N)                  | <b>1,304,721</b> | <b>13,992</b> |

1) Statistics Korea

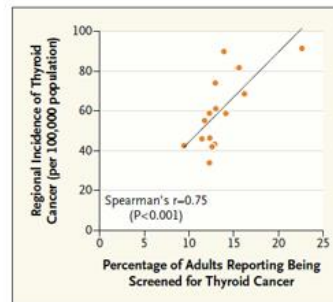
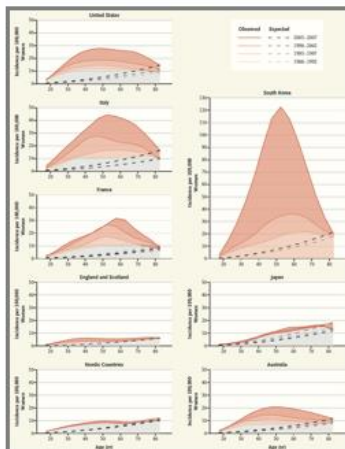
2) Proportion of current and ex-smokers (less than 15 years) with 30 P-Y and over among Korean men and women aged 55-74 based on the Korean National Health Examination and Nutrition Survey, 2012

| National Cancer Screening Program (2012) |                       |                 |                      |
|--|-----------------------|-----------------|----------------------|
| Type of Cancer                           | Target population (N) | Participant (N) | Participant rate (%) |
| Gastric cancer                           | 12,655,315            | 5,988,631       | 47.3                 |
| <b>Liver cancer</b>                      | <b>1,127,877</b>      | <b>445,360</b>  | <b>39.5</b>          |
| Colorectal cancer                        | 15,535,690            | 3,884,839       | 25.0                 |
| Breast cancer                            | 6,459,450             | 3,351,641       | 51.9                 |
| Cervical cancer                          | 8,412,689             | 3,436,724       | 40.9                 |



The screening rates of lung ca screening with LDCT by smoking status (many nonsmokers and/or those who don't meet criteria – chart presented). Many false positives and incidental findings. Breast cancer and prostate cancer overdiagnosis (charts and articles).

## Worldwide Thyroid-Cancer Epidemic: the Increasing Impact of Over-diagnosis



Penetration of Thyroid-Cancer Screening (2008–2009) and Incidence of Thyroid Cancer (2009) in the 16 Administrative Regions of South Korea.

Source: Ahn HS, et al. N Eng J Med 2014;371:1765-7  
 Vaccarella S, et al. N Eng J Med 2016;375:614-7



Benefits and Harms:

- *In conclusion, the current evidence is insufficient to assess the balance of benefits and harm of thyroid cancer screening by ultrasonography and the recommendation is that thyroid sonography is **NOT** routinely recommended for **heathy subjects**.*
- No longer recommended in Korea routine thyroid sonography, but people still want it and it's still done

Survey: Most Korean physicians are not concerned with overdiagnosis, radiation protection, false positives. Patient decision support tools are available but not broadly implemented > discussion with patients warranted as to benefit-risk

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Audience comments:

HTA can have an important role esp. insofar as downstream role of economic effects, to be considered in framework.

Justification important focus but also optimization — is it really optimized? is it really low-dose CT? Actions 1 and 2 of the Bonn Call for Action must be considered *together*.

There may be reasons to permit a lower evidence base for IHA but there should be some evidence base.

Is it cost-effective on an HTA basis?

If you are going to do an intervention, must demonstrate more good than harm as priority. Worries about individual patients go to individual practitioners, and loss of follow-up. What measures need to be in place to assess greater benefit than harm in an IHA program? As soon as you screen positive, you shift to a public system in Canada. No clear direction as to when you stop screening.

We defined IHA A, IHA B, and we might need a 3rd category in countries with no screening programs (LMIC and MIC)...could be IHA C (when you have the evidence but not the resources to do an organized population screening programme but only IHA.)

We must stick to separate categories of screening as opposed to IHA

Is there an ethics question concerning 5 points, first do no harm (doing nothing) may get in the way of beneficence as we develop a framework for good governance. How not to undermine potential beneficence?

Someone commented that we should have a lawyer in the room. As a medical and radiation community, physical and psychological harm can be taken into account as the framework is being developed. Courts will always favor physical harm over psychological harm. Must be careful about defining harm, which can be defined different ways for different people.

We are dealing with diagnostic procedures, there isn't a history of significant harm from diagnostic radiology procedures. In one area it's clear — if there is no chance of benefit from the procedure, one doesn't need to look at a benefit-risk ratio. In contrast endoscopy can cause harm, as an example. Ethical thinking may be better developed in other areas such as endoscopy where thinking is more mature.

Follow the patient wish and follow the flowchart to see if beneficial.

The discussed Korean lung cancer screening program to start next year.

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## 7. Plenary session 4 current status of practice in the world

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Co-chairs:

Eva Friberg (Norwegian RP)

Lawrence Lau, M.D. (International Society of Radiology)

### WHO IHA survey

Presentation by Eva Friberg of the WHO Global Survey on Use of CT for IHA

Rationale: current status of practices, global overview, identify key elements to justify practice and create a regulatory framework.

Purpose: to identify means to encourage more appropriate use of medical exposure and to improve population health and well-being.

From 2014 consultation in Munich we knew that IHA was nearly universal in developing and developed countries, mainly private sector, not embedded in healthcare pathways, inadequate QA processes. The composition, limitations, and results of the survey were discussed. WHO plans to prolong and improve this survey. For example, get data from more countries, needs to be translated into multiple languages —> towards a regulatory framework for good governance for health

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Presentation by **Lawrence Lau**, about the findings of the WHO survey on IHA Practice - preliminary results. He discussed WHO Global Initiative on Radiation Safety in Healthcare settings, how it works with stakeholders: countries, groups, individual experts. Preliminary data were collated after 8 weeks. It was a small sample size, there were some overlapping responses about practice, procedures, reimbursement, guidelines; regulation, advertisement, health tourism

AFRO5

AMRO SE 5

SEARO 3

EURO 26

EMRO 2

WPRO 5

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46 total countries participated

Discussed breakdown of participants:

55 organization, society, or body participants

21 institution, assoc., or co.

42 individual participants

Current IHA practice:

- 22/46 countries have CT for IHA
- CT commonly used for IHA

- agree vs. disagree roughly 50/50

Most typical CT for IHA exams: N=118\*

- lung 39
- Coronary Ca 34
- CT a/p 24
- angio 23
- colonography 23
- whole body 21

N=22 for countries: CT IHA providers

- mainly private

CT IHA reimbursement

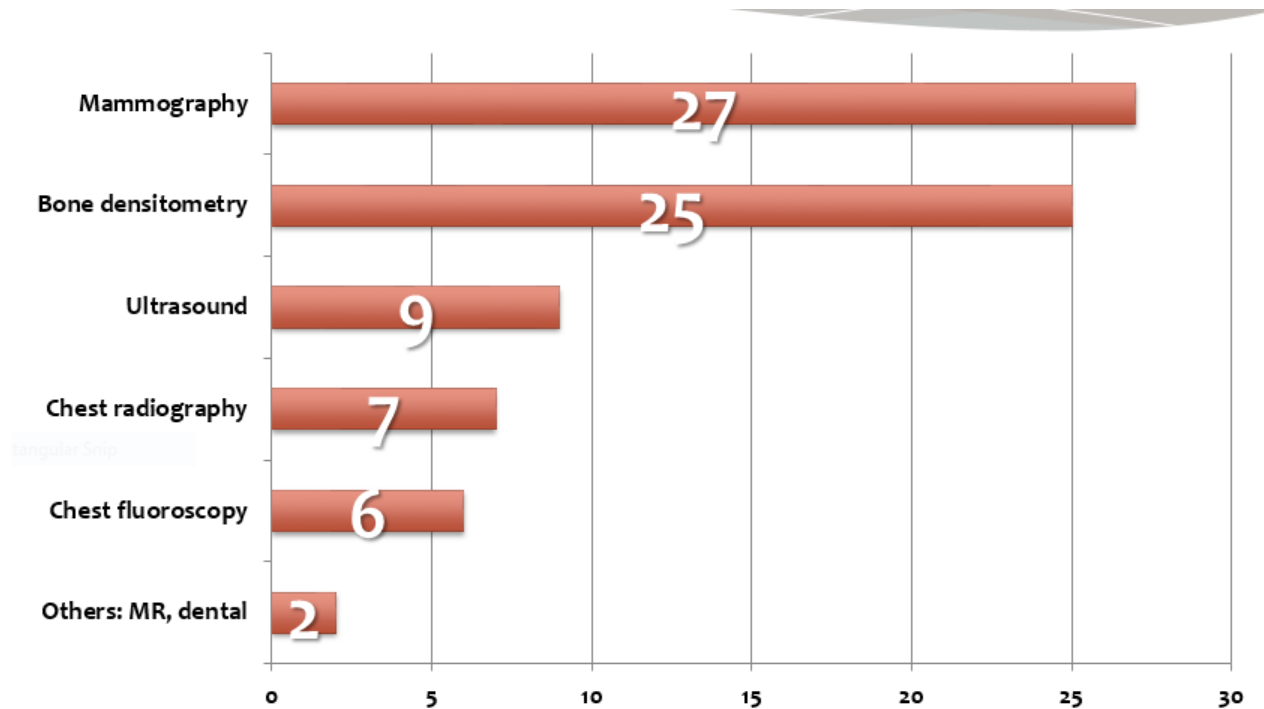
- 1/3 are reimbursed

CT IHA Payers N=8

- 4/8 by public health system

IHA imaging procedures other than CT available in your country?

34/46 countries – yes



Please specify the types of other IHA examinations performed on asymptomatic individuals in your country.

22

WHO International Workshop on Justification of the Use of CT for IHA of Asymptomatic People | Seoul | 26-28 September 2016

Availability of CT IHA guidelines: yes, available in 1/5 countries

- 9/46 countries have guidelines

- Of these 9, what are the guidelines:

## Examples of Guidelines N = 9

|                          |   |
|--------------------------|---|
| Australia                | <a href="http://www.safetyandquality.gov.au/">www.safetyandquality.gov.au/</a> ;<br><a href="http://www.arpana.gov.au/RadiationProtection/Factsheets/Is_CTScansReferrers.cfm">www.arpana.gov.au/RadiationProtection/Factsheets/Is_CTScansReferrers.cfm</a>  |
| Japan                    | Japanese Guideline for Lung Cancer Screening<br><a href="http://www.Canscreen.ncc.go.jp/guigeline/haigan.htm">www.Canscreen.ncc.go.jp/guigeline/haigan.htm</a>  |
| Malaysia                 | Consensus Statement on Utilisation of Cardiac CT<br>College of Radiology Statement on Whole Body CT<br>Many other guidelines and circulars listed in College of Radiology website: <a href="http://www.radiologymalaysia.org">www.radiologymalaysia.org</a> |
| Norway                   | Norwegian Directorate of Health   |
| Republic of Moldova      | Government Decree Nr.451 from 24/7/2015 of the Republic of Moldova on the safe rules for providing X-Ray examinations to the patients Fundamental Radiation protection Norms and Rules - NFRP-2000  |
| Romania                  | The Guidelines for using Imaging, made by the Romanian Radiological Society (French and UK inspiration) and adopted by the health ministry. Presently under revision.   |
| Macedonia                | <a href="http://zdravstvo.gov.mk/upatstva_update/">http://zdravstvo.gov.mk/upatstva_update/</a>   |
| United Kingdom           | Committee on Medical Aspects of Radiation in the Environment Report<br>iRefer: Making the best use of clinical radiology<br>Ionizing Radiation (Medical Exposure) Regulations amendment 2012  |
| United States of America | ACR Appropriateness Criteria<br>US Preventive Services Task Force (USPSTF) recommendations  |

- Please specify the name of the guideline and provide the web-link if possible.

Are these guidelines being used: yes in 4/9 countries

CT IHA follow-up: in less than 1/2 of countries

Is the use of CT to perform IHA regulated by either health authorities or RP?

- Yes, in <1/2; more in countries w/o CT IHA

Advertising:

- Yes in 1/3 overall, in 1/2 of countries with CT for IHA
- No, most ads are not balanced
- Regulation of advertisement: in 1/4 overall and less in countries with CT for IHA

CT IHA Health tourism:

Is health tourism providing IHA with CT available in your country (i.e. citizens from other countries crossing international borders to get IHA with CT)? Yes in 1/4

Top driver is patient demand

- Societal influence: no
- 2/3 of countries do not have awareness campaigns
- 84 of 97 answered yes as to need for policy guidance

Steps:



- *Research to inform good practice framework & guidelines*
  - *Update survey findings*
- *Raise awareness & advocate more appropriate practice*
- *Draft & facilitate use of good practice guidance tools*
- *Develop & implement regulatory framework*
- *Monitor progress & apply on-going improvement actions*

## Talks by Panelists from WHO regions

AFRO: presentation by Michael Kawooya (Uganda)

10 African countries (of 15 countries invited)

Survey mailed to radiologists

Uganda, Kenya, Tanzania, Rwanda, Ethiopia, N Sudan, Nigeria, Togo, Zimbabwe, South Africa

### Availability of RG and infrastructure (survey 2014)

|                                  | UG      | KEN  | TZ          | RNDA        | N.SUD       | ETHI    | TG          | SA           | ZIM         | NIG |
|----------------------------------|---------|------|-------------|-------------|-------------|---------|-------------|--------------|-------------|-----|
| #CT machines                     | 13      | 30   | 12          | 4           | 12          | 15      | 10          | 262          | 8           | 150 |
| CT in busiest facility           | 30      | 50   | 20          | 40          | -           | 30      | 20          | 30           | 13          | 10  |
| Is CT used for IHA in yr country | YES     | YES  | YES         | YES         | YES         | YES     | YES         | YES          | YES         | NO  |
| IHA in PUB or PRIV               | PRIV    | PRIV | PRIV        |             | PRIV        | PRIV    | PRIV        | PRIV         | PRIV        | -   |
| % CT for IHA                     | < 2     | < 2  | < 2         | < 2         | < 2         | < 2     | < 2         | < 2          | < 2         | -   |
| Body part for IHA                | CH, ABD | ABD  | BRAIN       | BRAIN       | BRAIN       | CH, ABD | BRAIN       | HEART        | BRAIN       | -   |
| Why IHA                          | COMB    | COMB | PT PRESSURE | PT PRESSURE | PT.PRESSURE | COMB    | PT.PRESSURE | WORRIED-WELL | PT.PRESSURE | -   |
| Guidelines on IHA                | NO      | NO   | NO          | NO          | NO          | NO      |             | NO           | NO          | -   |
| Enforcement on guidelines        | -       | -    | -           | -           | -           | -       |             | -            | -           | -   |
| Reimbursement for IHA            | NO      | NO   | NO          | NO          |             | NO      |             | NO           | NO          | -   |

IHA present <2%

CT chest, abdomen, brain, heart

No regulatory framework or public reimbursement, no health tourism, no IHA in Nigeria

Summary of responses:

- CT # (4-150)
- Numbers in busiest facility(10-50)
- IHA practiced ( 9/10 countries)
- Private vs public ( in all 9 countries)
- % of IHA in all CT individuals (<2% for all)
- Commonest body parts: chest, abdomen, brain.
- Commonest indication –presenter pressure
- Presence of IHA guidelines –none
- Legislation/enforcement –none
- Re-imburement –none
- Ads for IHA 2/10 countries

All stakeholders must be involved in framework development

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[AMRO: presentation by Ella Kazerooni \(Univ. of Michigan; ISR, ACR, and RSNA\)](#)

CT for IHA:

- For lung CA, colon CA, and to a lesser degree CAD
- Demand peaked a decade ago then fell
- Continued self-referral
- Continued requests for executive physicals, scale difficult to quantify
- Professional society statements against whole-body CT

IHA and lung ca screening: USPSTF guidelines

Issues:

- Research
- Natl. guideline
- Insurance Coverage
- Shared decision making is for the first time required in the Medicare system for lung
- ca screening\* web-based publicly available shared decision making aid

From research to practice: efficacy to effectiveness

ACR lung ca screening registry Sept 2015, and ACR designated lung ca screening Centers

LungRADS structured reporting and management tool

Practice parameter for performance and interpretation

AMRO: Pablo Sofia and Gloria Soto-Giordani<sup>8</sup>

CT for IHA in 11/18 countries surveyed

- Very low scale, only in private sector — not in public sector, mainly for lung CA or CAD, < for colorectal CA
- Only in Mexico were there regulations: lack of legislation
- In no countries are authorities actively searching for these practices
- General opinion that CT for IHA would be considered legal
- Most frequently not reimbursed: may be reimbursed if justification for referral
- 6/11 countries have advertisements of CT for IHA but not much
- Among radiologists, opinion that it should be legally allowed
- This emphasizes importance of justification and education; benefit-risk awareness

EMRO: presentation by Dina Hussein

- LMIC and MIC
- Usual monthly income for ordinary person covers 2 CT exams
- Very rare to see IHA in Egypt/N Africa
- High to middle social classes are aware of high doses, and middle to low social classes can't afford them

Egypt is a referral country for Gulf Countries and Africa; already long lines for CT among symptomatic individuals, so CT for IHA is only in private sector

CT chest most common exam for IHA

Patient demand as most common driver

No existing campaign to raise awareness

Breast US and mammo — successful national screening campaign  
abd us

No national guidelines or regulatory framework in Egypt or Africa

EURO: presentation by Jurgen Griebel focus on Germany

IHA in gray zone: not addressed in legal perspective/regulations

In reality, IHA occurs in practices and hospitals, ads (unbalanced w/ respect to RP)

Symptoms are fabricated as excuse for performing IHA

Patient demand, ads. marketing, financial incentives

Most common: CT colon, lung, coronary; X-ray mammography in addition to screening

If positives, switched to health care system and then reimbursed

Process of transposition to Euratom directives

Will be 3 key elements to regulation:

1. justification

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<sup>8</sup> Presented by M. Perez on their behalf

2. guidelines with much legal involvement
3. info. to patient

[SEARO: Presentation by Narayan Pendse, India](#)

Medicine: science/art

WHO defines health, but did not define what disease is

Disease: subjective, objective, cultural, idealized norm, statistical elements

India: 18% of world population

- Mostly private sector healthcare

Informal ads, proxy ads, editorials, fear-mongering (e.g. headache might be brain tumor)

Current practice:

- CT for IHA performed: head, ab, lung

Stand-alone private centers

Fed back into public healthcare system

Profit as motive, reimbursed mostly out of pocket

No regulation or guidelines

Not known: degree of health tourism

There is a need for guidelines

[SEARO: Liang Wang, China, Chinese Society of Radiology](#)

IHA: Mostly CT chest, also CTA (coronary), CT head (including nasopharynx Ca), CT bone (disc herniations)— multiple publications reviewed

Law of People's Republic of China

- CT cannot be used for the physical checkup unless patient has symptoms

Awareness posters exist as to dose

In private sector, there are ads for CT for IHA and PET/CT

Several publications (w/ Eric Stern and Michael Bettman "summit" ..., in Quality News "Chinese Experience")

[WPRO: Tsuneo Ishiguchi, interventional radiologist, Japan](#)

Japanese Radiological Society (WPRO)

IHA most commonly for lung ca screening

- Patient demand
- No regulatory framework

- Not reimbursed by public insurance
  - Ads common online
  - Risks and benefits are explained
  - Japanese Imaging Guideline available for free\* including for LDCT for lung ca
  - Japanese DRLs including for lung cancer screening LDCT
  - Pulmonary nodule follow-up schedule flowchart
  - Health tourism not common in Japan because of language difference
  - Imaging guideline of a target organ
  - High-risk groups to be defined
  - CT for IHA may not be suited for regulation by law; will remain a personal option; scientific evidence and effectiveness of Ct in IHA is not sufficient in Asian countries
- 

## 8. Plenary session 5 Framework elements/requirements:

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Co-chairs: Steve Ebdon-Jackson (U.K) and Min Jeong Kim from NECA (Korea)

Framework elements and requirements

Health Authority: Shantini Arasaratnam (Malaysia)

2 most common:

CT coronary calcium — not routine

CT colonoscopy — indicated as last resort

Guideline for utilization of cardiac CT in Malaysia: looks at contrast media, scanner, software, radiation dose reduction parameters

- No benefit of whole-body scans: position paper
- CT laser mammography: College of Radiology does not support its use in screening
- Colorectal consensus guideline: colonoscopy recommended
- Lung cancer screening using LDCT: high-risk cases only, study in progress –

Education: awareness programme (public and healthcare professionals), website MoH, website Malaysian College of Radiology, posters at hospitals

IHA only done in private sector

Malaysian Radiological Society referral guidelines (adopted and adapted from RCR iRefer)

National radiology request form/requisition; the lower part includes the doses of the major examinations, piloted in 3 hospitals, to be implemented nationwide in all MoH hospitals

- For every exam, radiographer fills in dose record book — must bring this book to any government hospitals
- Awareness campaigns (clinicians and public)

Issues: any radiation issues are discussed at radiation advisory committee (RAC)

- chaired by DG of health, held twice/yr.

Also an HTA unit

Most insurance schemes do not cover for CT for IHA

Question from Steve: Was it difficult to get the professional societies and MoH together?

No. Are the guidelines going to include IHA? No

### Regulators' Perspective: Jurgen Griebel Germany)

Justification principle: justify exposure by weighing benefit(s) vs. risks. Net benefit.

Available non-ionizing alternatives.

Scenarios

#1 symptomatic individual, high-prevalence disease (dz)

#2 asymptomatic target population (mammo screening), low prevalence dz

#3 asymptomatic individuals — IHA low prevalence dz

Medical and radiological practitioners both involved in justification

What level of scientific evidence is to be claimed for appropriate justification?

Progress: both new BSS and new Euratom address IHA, as well as HERCA position

Paper:

3 key topics to be addressed in framework:

1. Evidence base: mechanism, guidelines by professional bodies and competent authorities, risk profile defined, screening and follow-up algorithm, QA, training, documentation, info. or benefit vs. risk
  2. Governance: legal framework, context of RP; if not justified, mechanism to make sure it's not performed; promote honest advertising; discourage self-referral
  3. Finance: should be independent of willingness to pay out of pocket or not
- In Germany: Ministry of Environment: responsible for RP and MoH: responsible for health

### Perspective of referrers: Ernesto Mola, WONCA

Framework elements/requirements: evidence base, governance, finance

Physicians should avoid ordering tests for asymptomatic individuals outside of

screening programs. Guidelines and Clinical Decision Support as useful tools

...but individual case justification can fall outside of aforementioned contexts,

warranting cooperation between patient, referrer, and radiology. There is a fear of cancer, recent negative experiences, online information.

- Advertising should be pre-approved by health authorities
- Main responsibility is upon the practitioner
- Does a patient have the right to buy a CT scan and does the radiologist have a duty to conduct the exam?
- Report must be sent to family doctor or primary physician(s) to ensure continuity of care
- If positives, patient is switched to NHS

*What we can do?* the referring physician is the one who will decide the pathway of this patient. How can we reach them with the IHA framework to be developed?

'Referring physician must share with patient why an exam is not justified, or why another exam is justified. Italy does not broadly use referral guidelines. We must set CDS tools; this is a problem. In Korea, it's difficult to say, "No," to the patients. In Europe, it's easier to rationalize, engage in dialogue, and *not* comply with the request.

Patients' perspective: Stephanie Newell and Rosmini Omar (WHO PFPS):

Framework needed. Referrer must engage in benefit-risk dialogue:

- informed consent including cost
- will it be part of medical record
- will I receive report
- dose record
- pathways/follow-up?

Will health tourism grow? In lower-resource countries, those with less money receive lower quality care and have less access to services such as IHA:

- Question of governance and ethics.
- Little package vs. big package, poor vs. wealthy.
- Do I receive quality care, is my history correlated/checked?
- Tell me the truth, expert diagnosis, transparent on risks/benefits, evidence base, will this contribute to my quality of life, assurance that I'm fine, no abuse of funds/health insurance, will my treatment be delayed because I don't have money— trust?

Radiologists views: Seung Eun Jung (KSR):

- evidence — little; need for more research (big data using central repository & connection with other health data resources) on risks and harms of IHA, towards development of IHA guidelines.
- However, poor implementation of current clinical guidelines so would need to focus on IMPLEMENTATION and user groups, not just development of guidelines.
- Integrate into clinical pathway and quality management.
- Governance
- Finance

Role of radiologists: gatekeeper, producer of guidelines, political, public health

Provider, ..., many roles

IHA accreditation as opposed to regulated justification?

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## Breakout Sessions

- A. Methods of improving evidence base
- B. Governance around how IHA should be practiced.
- C. Financial models

## Reports from Breakout sessions:

### Group A: Methods of improving evidence base

- Governance/Implementation/Operations
  - communication and education strategies to referrers [stakeholders] with a Knowledge - Attitude - Behavior model suggested
  - optimization and quality assurance through the entire cycle from IHA to various end points
  - reduce variability in protocols and doses between and within centers
  - specific DRLs for IHA?
  - how far do physicians push refusing a patient of unnecessary IHA
- Contextualized guidelines for IHA by nation/health care system
- How do we regulate advertisement of IHA?
- a continuum of education to all stakeholders based on research
- accreditation as a means of regulation
- Fold IHA into existing clinical imaging guidelines (symptomatic or asymptomatic still requires justification and separating them may be artificial)
- decision support for advanced imaging for the referring physician to the radiologist
- How do we collect IHA scan data?
  - ACR National registry for IHA – administrative quality assurance database (not research), includes: patient demographics, patient dose, indications, structured report findings and 12 month follow up with link by SSN and sequential follow up for each subsequent screen
  - No other national registry amongst the group A participants
- **there is a need for a comprehensive registry for IHA procedures**
- Systematic review for IHA/screening – very little data available to synthesize and summarize (best single study for lung cancer screening - NLST –USA)
- Need more primary research on IHA- evidence is lacking and there is a need to collect practical data in medical fields
  - Need a mechanism to systematically collect IHA data
  - Feasibility of large RCTs?
  - HTA approach - use of best evidence available - surrogates (e.g. use data from other trials - e.g. COPD) or lower levels of evidence (e.g. observational studies) may be a pragmatic choice
- Need to be able to link and follow IHA participants
  - E.g. National health insurance data identifier (patient information security and privacy issues acknowledged) – perhaps use radiation protection levers to get around privacy issues
- Solution - construct a registry – USA example – if you want to include Medicare patients you need to be in the registry
- Need to be mindful on research of psychological, lifestyle and incidental finding impacts of IHA



- Example - Japan – lung cancer screening accreditation, via education of Radiologists, Rad Technologists
- Example – UK COMARE recommendations that patients consent to their data being forwarded to their family docs and this may lead to opportunities for further sharing/data link. Also benefit of appropriate risk assessment low (stop), intermediate (IHA like test), high ( diagnostic like test)
- Need government (e.g. MOH) sign off to be able to collect appropriate data
- accreditation as a means of shaping data collection and research
- Need for institutes who provide IHA to have access to follow up data, perhaps from other centers, perhaps a link would be an accreditation criteria
- Education of health care learners

Comment: (Australian MoH) May de-identify the data base for RCT to avoid privacy issues

Comment: already have that capacity in Manitoba

Comment: increasing push to have > controls, even over de-identification of data (U.S.) - still requiring broad levels of consent. Pending approval. You should be getting IHA consent and potential research, who would be governing it.

Comment: how do you convince someone to sign over their data?

Comment: people are typically willing. An option is to not allow them to opt out of databases.

Comment: should IHA be kept within the system? National registry - who exactly has access?

Comment: massive distrust of centrally held data in U.K. If you are opting into IHA, a condition of opting in is that you will let your data be used.

Comment: perhaps opt in only if test is positive?

Comment: No.

Comment: general consensus data in Australia, happy that someone was doing something for public good as long as privacy was being upheld. People are happy to have their data collected. Electronic medical record with option of opting in but people didn't understand; people will now opt in by default with option of not being a part of electronic medical record.

Comment: necessity of outcome evaluation is good. Is IHA without outcome evaluation (registry, etc.) acceptable?

Comment: must have infrastructure, may not be possible in some regions, countries, etc. and perhaps IHA B should be discouraged or outlawed in those settings whereas IHA A could be used. Beware of informed consent: minors, prisoners.

Comment: for big data, organizations needed to manage.

Comment: In RP, justification — if no benefit but we know there's a potential detriment, then no. But there's a psychological component and, for an individual patient, there may be value in a particular scan. But patient must be informed in the first place. Give them good information before they even arrive at the healthcare institution, then further information if/when they do present.

Comment: not just a question of "justification". How can we consider outcome assessment in the absence of evidence?

Comment: if a country will allow IHA A to go forward, one must start developing and

evaluating so as not to perpetuate an information vacuum. Data collection and ongoing evaluation should be part of the contract both provider and presenter buy into.

Comment: in the U.S. before guidelines for lung imaging, their statements included that such imaging but was not advised but if you do choose to undergo the exam, it should be performed at a facility involved in data collection. Then over time enough of a body of evidence grew to produce recommendations.

Comment: evidence as one lens, other lenses : political, public lobbying... Must make enrollment in data collection attractive in the particular setting so they'll see it's of benefit, from a policy point of view.

Comment: how do we create a framework in absence of evidence.

Comment: the value of the dignity of the individual will trump the requirement of justification, though it does not fit well with an RP regulatory point of view. It is reasonable in the interest of the individual's autonomy to enable people to manage their own health.

Comment: but this leads to undue public health expense

Comment: so do people who smoke, but it's a question of autonomy

Comment: in some countries, another patient may have to forgo undergoing an indicated CT because someone used the resource for an optional IHA CT.

Comment: many would rather see money spent on other health initiatives (e.g. vaccination)

Comment: Nat'l. registry. is overwhelmingly in public sector as opposed to private sector (e.g. in India). Diversity of healthcare systems. How big is IHA a vs. B? For example, little IHA in Africa.

Comment: In a country such as India, how might one collect evidence?

Comment: involve professional bodies - much more in touch with private sector than Regulators

## Group B. Governance around how IHA should be practiced

### Points for Final Discussion on IHA

- Examinations conducted for Insurance purpose and for occupation/employment purpose do not come under medical exposure for IHA as per ICRP (should be specifically mentioned in inclusion/exclusion criteria)
- Clear definition of IHA-A and IHA-B needed especially distinction between IHA-A and Screening.
- If a country does not have a *structured* (national) screening program, where do such investigations be grouped? If included in IHA A same to be specified in definition of IHA-A.
- Should the term Individual Health Assessment be extended to include other modalities beyond CT

## Mechanisms for IHA Governance:

- Regulatory Framework
- Self-regulation by Professional bodies
- Guidelines
- Health Literacy
- Delivery Standards
- Compliance Monitoring
- Financing (link to Insurance System, Group C)

## Regulation

- Must be based on International Consensus
- Must include Justification
- Must describe individual responsibilities for IHA (Radiologist, Referrer, Presenter)
- Must define standards of and monitoring mechanism of dissemination of health information to presenter (especially radiation risk, over-diagnosis, false positives)
- Must mandate Informed Consent process
- Must include all aspects of Equipment use (equipment type, commissioning, QA)
- Should define reporting of IHA including dose levels
- Should guide self-regulation by professional bodies

## Self-regulation

- Should be done by professional bodies (Radiologists, Referrers)
- Should address the 'ethics' part of IHA
- Develop a 'code of conduct' [e.g. Do's and Don'ts, guidance on gatekeeping role, when and when not to perform IHA]

## Guidelines

- Must be developed jointly by involvement of all stakeholders [Radiologists, Referrers, Regulators, Patient Groups, Authority, etc]
- Must cover entire process of IHA
- Should include education & training aspects
- Should include Dose Optimization concepts [e.g. adopting low dose protocols]

#### Health Literacy

- Effective awareness raising and dissemination of health information related to IHA jointly by Health and Radiation authority (e.g. advocacy campaigns)
- Information on Risks and Benefits of IHA provided in ways that presenters understand to enable them to ask questions and consent
- Awareness on importance of capturing radiation dose

#### Standards

- Definition of Service Standards and Quality Management
- Presenter Feedback to be included as a standard
- Accreditation of Service providers

#### Compliance Monitoring

- System for Clinical Audits
- Periodic inspections by regulatory bodies
- Reporting of IHA and Dose levels
- Link to National Registry

Comment: regulation at a national level is important

Comment: advertising considerations important

Comment: good medical practice, system sustainability

Comment: Did you discuss the stakeholders involved in the regulation? Divorce between devices regulation and RP regulation.

Comment: we need to cover the entire spectrum of IHA. All stakeholders, international consensus must be at the table as regulation is formulated though the group did not specify and name stakeholders.

Comment: member states prioritize regulations but regulators vary by country

Comment: The regulator is the appropriate regulator for what you're regulating:

separate regulators for RP, advertising standards, quality of service provision. Difficult to coordinate their responsibility and get them to collaborate but it's essential. This is the power of having this meeting under the auspices of the WHO: strong international lever.

Comment: since we are making a regulatory framework beyond RP, the framework should include how to combine input from all the relevant regulators.

Comment: health literacy — person's experience of going through process of IHA. Patient feedback can be key in identifying system gaps, including quality improvement.

Comment: this needs to be published in a broad public health journal such as the *Lancet*, not just a radiology-related journal. The case needs to be made that imaging for IHA concerns some of the most prevalent maladies when burden of disease is taken into account. We should not just focus on CT, but should include focused exams in other modalities such as thyroid and/or prostate ultrasound (without including the whole modality of ultrasound).

Comment: informed consent process should include tailored information. Important relationship between physicians/radiologists and patients. Importance of continuity of care as well.

### Group C. Financial models

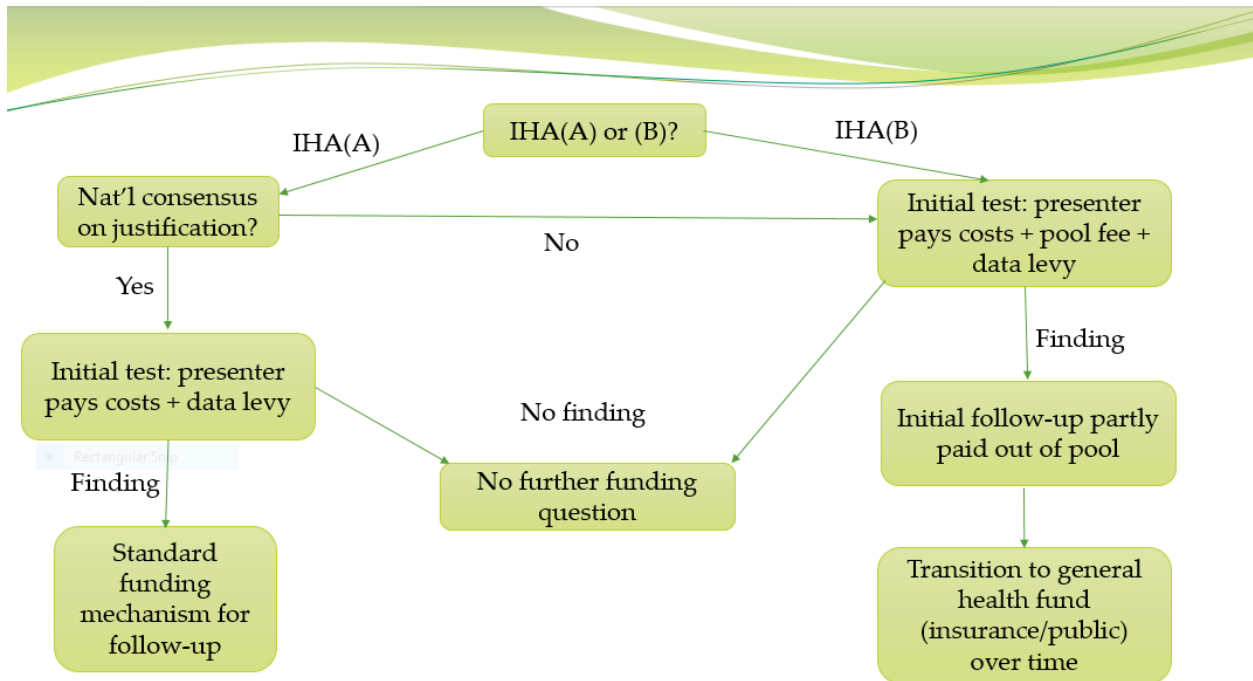
- IHAs need a higher consent standard than standard clinical procedures
  - Due to complexity + level of misunderstanding over IHA risk & benefit
- Health authorities, professional societies and other high-level groups should take the lead in promulgating societal awareness + understanding of IHA issues
- National Health Technology Assessment boards should assess CT IHA use
- Use of IHAs in minors and adults lacking capacity needs to be addressed
  
- IHAs need a higher consent standard than standard clinical procedures
  - Due to complexity + level of misunderstanding over IHA risk & benefit
- Health authorities, professional societies and other high-level groups should take the lead in promulgating societal awareness + understanding of IHA issues
- National Health Technology Assessment boards should assess CT IHA use
- Use of IHAs in minors and adults lacking capacity needs to be addressed
- Conflicts of Interest need to be curtailed
  - Referrer should be distinct from (personally and financially) the radiologist performing IHA
  - No true 'self-referral' – presenters seeking IHA should first go to referrer, not radiologist directly.

- Complication: may not be practicable in some contexts (e.g., dentistry; low-resource nations)
- Need for evidence → countries should establish national databases for all IHA activity
  - Presenters must be fully informed, but no opt-out
  - Int'l standard for minimum data & analytic tools
  - Data made available to researchers to assess IHA outcomes

#### Health Financing

- Two categories of IHA funding:
  - 1) Initial test itself
  - 2) Downstream costs if positive finding – follow up tests + treatments + counselling
- (1) is typically paid by presenter; this is acceptable
- (2) paid by insurer/public health system?
  - Public payment could be justified because gov't takes on responsibility for IHA outcomes by allowing the activity to occur
  - But it is deeply unfair to have population bear burden (resource usage/cost/premiums) of presenter and gov't irresponsibility
- Proposed financing of downstream tests: dedicated pool paid at point of test by presenter
  - All presenters pay surcharge
  - Upon positive finding, fund used to (partly) offset costs of follow-up tests + initial treatment
  - Over time, offset phased out and regular funding phased in
  - Flexible system: pool could be designed for reimbursement to public health system or unique insurance scheme
  - Further levy (likely minimal) should also be put on IHA fee, to fund national database
- But what about IHA(A) vs IHA(B)?
- IHA(B) completely lacks justification; preceding proposal applies easily
- IHA(A) may be exempt and funded through normal insurance/public health schemes...

- But ONLY IF there is consensus agreement by national health authorities, professional bodies (& others?) that the procedure is justified in a given population



- In some countries, IHAs may be mandated as condition of employment, loan or travel
  - This practice forces potentially harmful and wasteful procedure on population and should be prohibited
- Some companies may offer IHAs as fringe benefit (not forced, but heavily subsidised/encouraged)
  - Objectionably offers compensation in form of 'illusory' benefit
  - But perception of IHAs as benefit is a barrier to reform; education & cultural change needed? Regulation as driver of cultural change?

Medical tourism complicates funding model

- Medical tourists should be liable to same pool/levy funding scheme as citizens
- May pay higher fees without benefit, but this will hopefully discourage medical tourism for IHAs (undesirable anyway)

Comment: Costs of IHA should not drain funds of public health for programs which stand to benefit population more.

Comment: for coronary CT, what is the degree of stenosis which warrants intervention. Finding stenosis in and of itself is not pathologic since all of a certain age will exhibit some plaque formation. > education as to what's not pathologic.

Comment: lacking or absent infrastructure in low-resource countries. Capacity of private sector for more complex interventions (e.g. biopsies) is limited. Once positive, patient enters public system. Is there infrastructure within the private facility to handle false positives and false negatives?

Comment: funding will be required even to set up the architecture for IHA monitoring; is it worth it to set up this funding to benefit such a small number of people? Depends upon resources and wishes of individual nation?

Comment: should IHA B be banned vs. strongly discouraged? May be too strong when dealing with justification at an individual level. We are artificially separating asymptomatic vs. symptomatic individuals, but justification is ultimately the same.

Comment: Is it possible to justify in the lack of evidence (i.e. IHA B). The person wants it is the justification — not good enough. Must assess group harm: false positives and an overburdened system already. Autonomy concerns do not outweigh concerns for common good to population.

## 9. Highlights from plenary sessions 1-5

(prepared by Jim Malone and Dina Husseiny, presented by Jim Malone)

## 10. Plenary 6: Towards a Framework for Good Governance:

Co-chairs: Maria Perez (WHO) and Jenia Vassileva (IAEA)

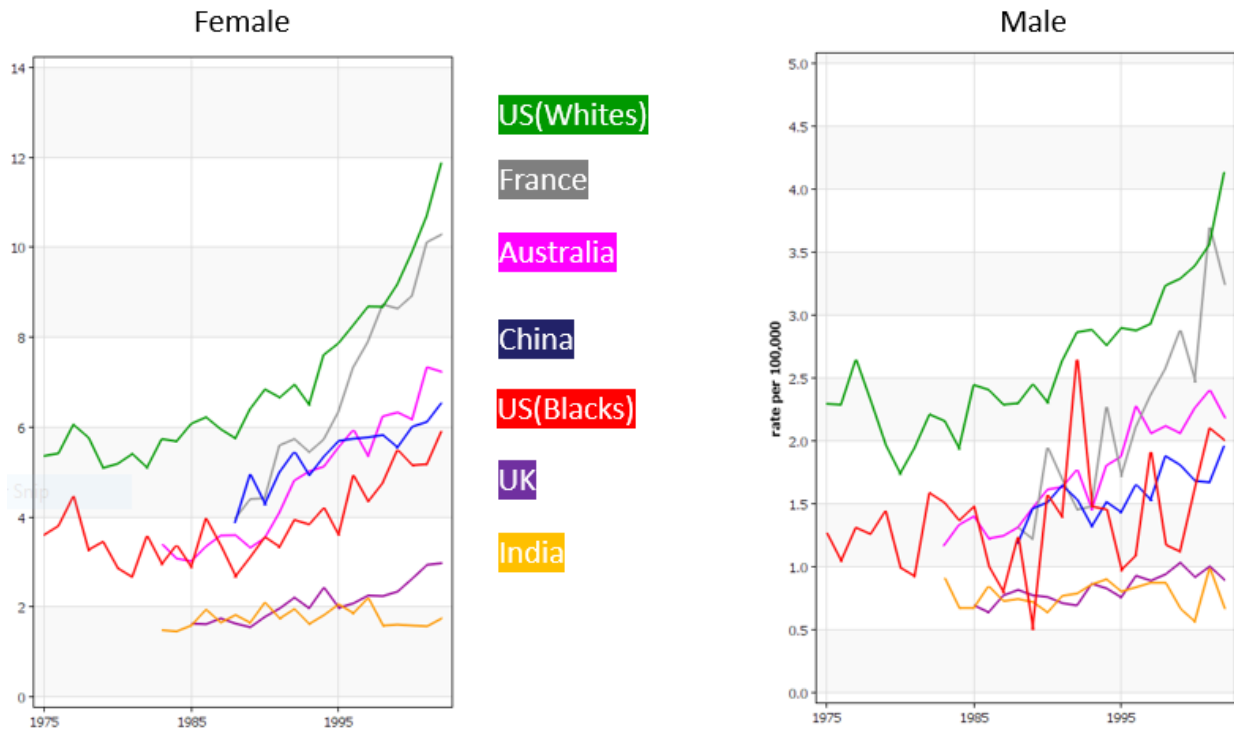
[Why we need good governance? A health service perspective](#)

Hyeong Sik Ahn, from South Korea University. School of Medicine Presented the Korea's Thyroid Cancer Epidemic and Afterwards

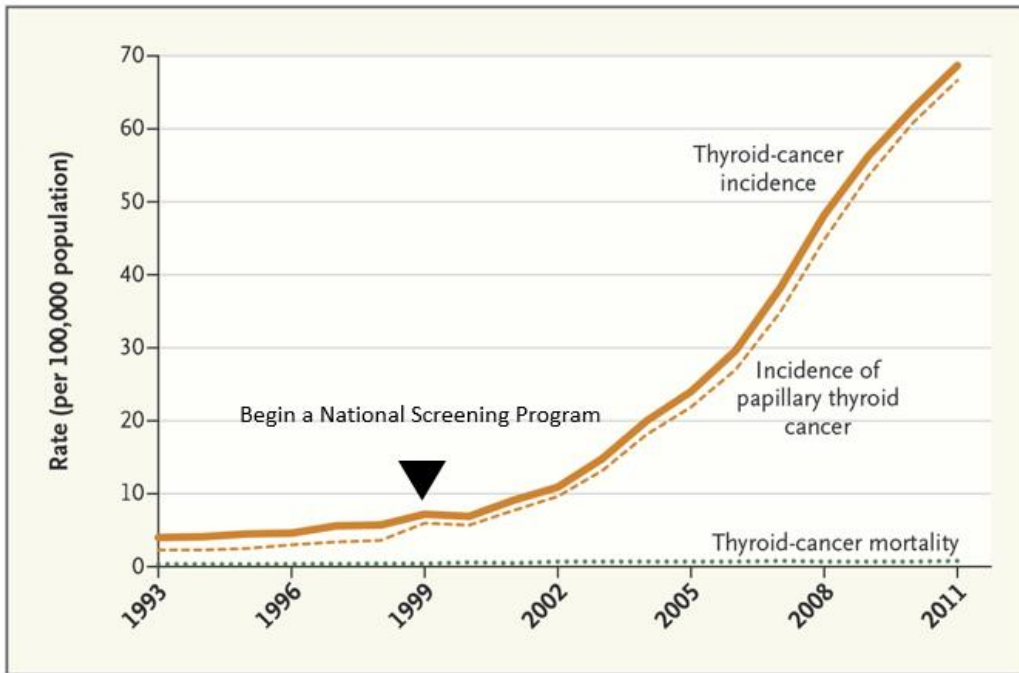


Worldwide incidence markedly increased due to increased ultrasound screening:

## Incidence of Thyroid Cancer ; Worldwide

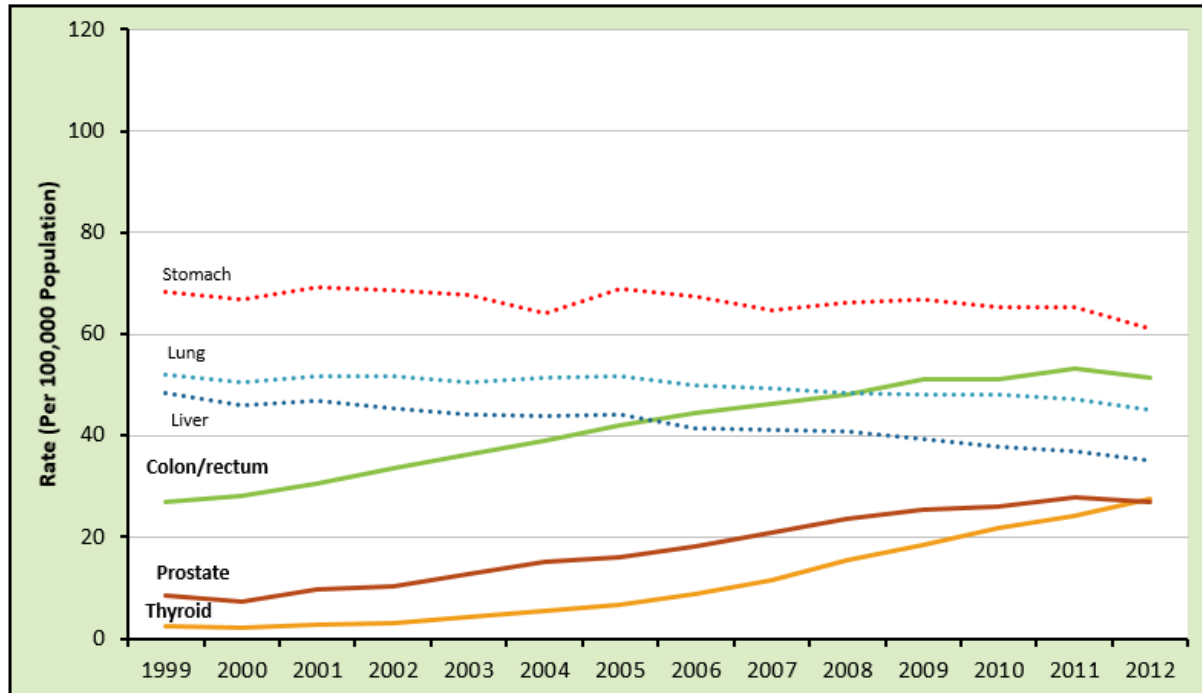


# Korea's Thyroid-Cancer "Epidemic"



Ahn HS et al. *N Engl J Med* 2014;371:1765-1767.

## Trend in Age-standardized Incidence Rates of Cancer (Male)

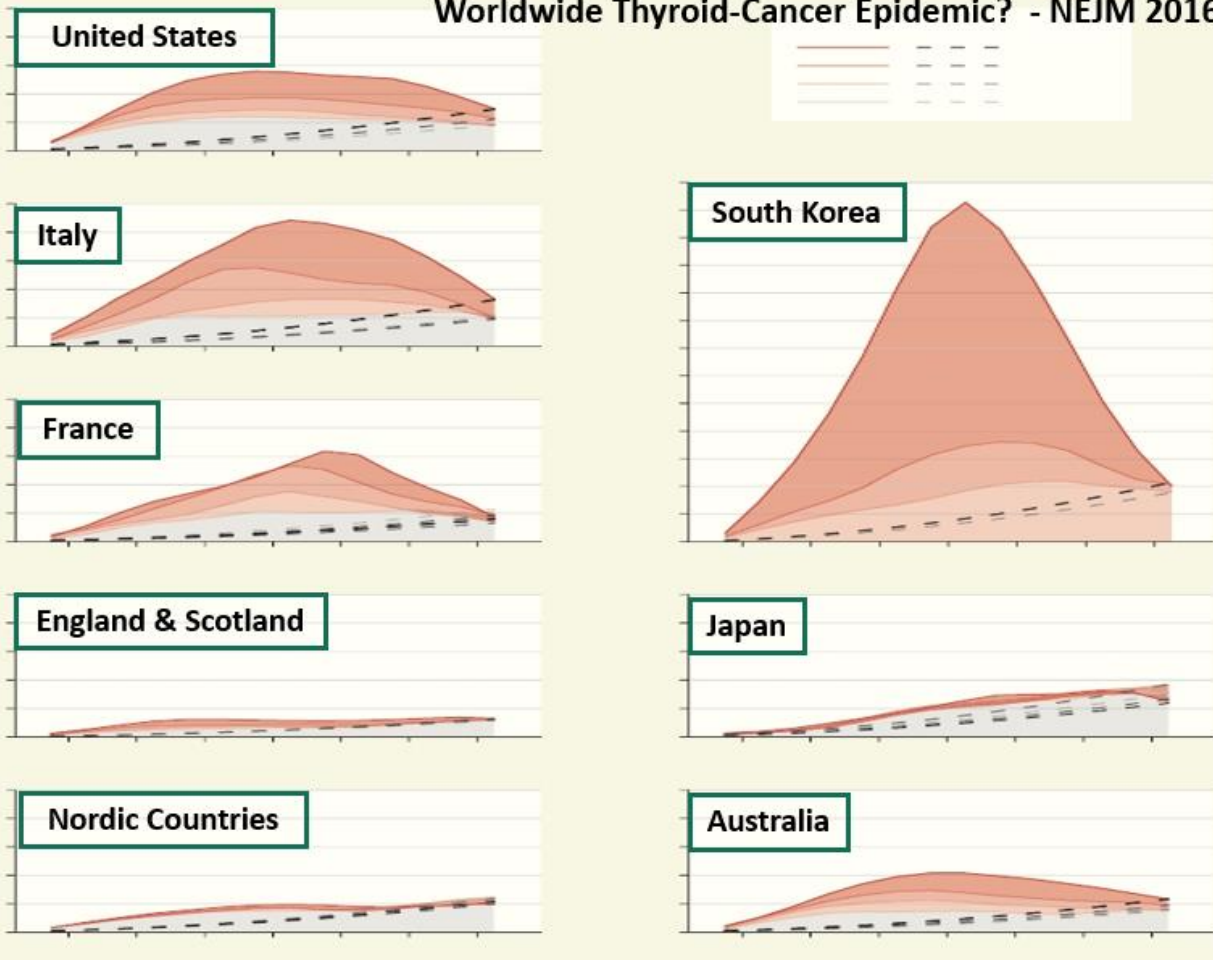


In Korea in 2014, a physician coalition called to stop thyroid screening because of its doubtful benefits, and fewer people now undergo screening:

Summary in Korea:

- Sharply increased cancer thyroid cancer incidence with screening
- No change in cancer related mortality  
-> overdiagnosis
- Thyroid cancer screening are not recommended to general public
- When studying on thyroid cancer epidemiology,  
'screening effect should be considered.'

## Worldwide Thyroid-Cancer Epidemic? - NEJM 2016



### Why we need good governance? An ethics perspective

Owen Schaefer (Centre for Biomedical Ethics, National University of Singapore) presented a biomedical ethics perspective. He discussed 4 major thoughts:

- An objection to de-medicalizing IHAs
- Justification: an extra ethical principle?
- Prudence: a problematic principle?
- Incidental findings: benefit or harm?

### Presenters vs. patients?

- We risk abandoning medical ethics framework and particular ethical richness of physician-patient relationship by de-medicalising IHAs
  - Medical exceptionalism: doctors have stronger duties than sales people
  - Medical ethics framework should be applied to IHAs, not business ethics framework (laxer, autonomy trumps)
- We should call presenters “patients”, and afford them all the protections that category merits

Justification is itself an ethical principle. If an act is known to cause harm or wrong, that act should not be conducted unless sufficient countervailing reason can be given to overcome the harm/wrong. CTs: radiation exposure + financial cost are known harms. Need good reason to offer CT; likely not met for IHAs. Also must consider uncertain harms (false positives/overdiagnosis). Stronger version: countervailing reasons need evidence. Hence, requirement for evidence of IHA efficacy. Precautionary principle: “where an action potentially causes a serious irreversible harm, measures to protect against it must be taken even if the causal relationships involved are not fully established scientifically.” (Malone and Zolzer 2016). Incidental findings not discussed at workshop. Should they be?

## Why we need good governance and how to move forward? WHO & IAEA views

WHO and IAEA perspectives respectively presented by Maria del Rosario Perez and Jenia Vassileva.

- Discussed their agency mandates, general principles of Radiation Protection, the International BSS, the Bonn Call for Action, and the Euratom directives; they reiterated the strong basis for why developing a guidance framework for IHA is indeed consistent with targets of the U.N., WHO, and IAEA.

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## 11. Next steps, way forward

Co-chairs: M. Perez (WHO) and Seung Hyup Kim (KSR)

Miriam Mikhail (RAD-AID, meeting Rapporteur) presented a summary of the meeting

The next steps were discussed

- *JACR* paper in press, to be published by December 2016 (based upon workshop in 2014)
- Slide presentations to be shared with all participants
- Meeting notes to be shared with participants by end of October
- Multinational IHA survey to continue until end 2016, including translation into multiple languages
- Need to expand the composition of the Core Expert Group in order to cover other relevant areas/disciplines addressed during this meeting

12. Primary deliverable: to produce a guidance document to include the aforementioned discussion of framework requirements, towards a roadmap outline for good governance (first draft outline by mid-2017, draft document by the end of 2017)

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## Appendixes

- A. Meeting agenda
- B. List of participants
- C. JACR paper
- D. References