Use of medical imaging in asymptomatic people for individual health assessment (IHA)

Expert Meeting

12-14 July 2017, Room L-18, WHO HQ, Geneva, Switzerland

Meeting Report

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Background

This expert meeting was held as part of an ongoing WHO project on justification of imaging asymptomatic people for individual health assessment (IHA[1]). It was convened as a follow-up of prior meetings: (i) IHA expert consultation in Munich, Germany, October 2014; (ii) IHA stakeholders' workshop in Seoul, South Korea, September 2016; (iii) IHA briefing to imaging experts in Vienna, Austria, March 2017. The main findings of this project have been summarized in a paper published in JACR in 20162. The aim of this meeting was to start working on the development of a document proposing a framework to enhance justification and clinical governance of IHA. The expert meeting was attended by representatives from Public Health England (PHE), Korean Society of Radiology (KSR), Alliance of Preventing Over-diagnosis, Trinity College Dublin, RAD-AID International, and WHO staff from various relevant departments/programmes. Representatives from the German Federal Office of Radiation Protection (BfS) and from the Korean National Evidence-based Healthcare Collaborating Agency (NECA) participated remotely on Day 2 sessions[3].

Opening session

The meeting was opened by Emilie van Deventer (EvD), WHO Department of Public Health, Environmental and Social Determinants of Health (PHE), Radiation Team Leader, who welcomed the participants on behalf of PHE/RAD. She mentioned that, as the UN with specific mandate on public health, WHO's objective is the attainment by all peoples of the highest possible level of health, which is defined as the physical, mental and social wellbeing and not just the absence of disease. As one of the eight co-sponsoring organizations of the international radiation Basic Safety Standards (BSS, 20144),WHO is committed to support its implementation, a task that requires a multi-sectoral approach and partnerships at global, regional and national levels. EvD identified PHE objectives aimed at promoting a healthier environment, intensifying primary prevention and influencing public policies in all sectors, to address the root causes of environmental and social threats to health. In this context, PHE is conducting a Radiation Programme to protect patients, workers and general public during planned, existing and emergency exposure situations, which includes the assessment, management and communication of radiation risks of medical exposures (i.e. WHO Global Initiative on Radiation Safety in Health Care Settings- GIRSHCS). The so-called Bonn Call for Action, jointly published by the IAEA and WHO, identified 10 priority actions to improve radiation safety in medicine that represent today the priority actions for the WHO GIRSHCS. The Action number 1 of the Bonn Call for Action is "Improving justification of radiological procedures". EvD explained that the purpose of the meeting was to start working on the development of a guidance document based upon evidence, to guide governance of the use of CT in asymptomatic people for IHA, a task which is in alignment with the new BSS and the Bonn Call for Action #1. She thanked the two WHO CCs represented at the meeting (i.e. PHE UK and BfS Germany) for their continued support to the WHO GIRSHCS, the Government of Germany

[1] For the purpose of this meeting report the term "IHA" will be used to refer to this practice

2 Malone J. et al. Justification of CT for Individual Health Assessment of Asymptomatic Persons: A World Health Organization Consultation. J Am Coll Radiol. 13(12Part A): 1447–1457, December 2016. Available at https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5357768/?report=printable

[3] For more details see "Appendix 3: List of participants" at the end of this report

[4] Radiation Protection and Safety of Radiation Sources: International Basic Safety Standards. Jointly sponsored by EC, FAO, IAEA, ILO, OECD/NEA, PAHO, UNEP, WHO http://www-pub.iaea.org/MTCD/Publications/PDF/Pub1578_web-57265295.pdf

through BMU/ BfS for having hosted the first expert consultation (Munich, Germany, 2015) and partially funding this project, the Korean Society of Radiology and NECA for having hosted the International Stakeholders' IHA Workshop (Seoul, Republic of South Korea, 2016), the technical support provided to this project by RAD-AID, an NGO in official relations with WHO, and the scientific contributions from the experts coming from the three academic institutions represented at the meeting i.e. University of Copenhagen (Denmark), Trinity College Dublin (Ireland) and Radboud University, Nijmegen (the Netherlands). Finally, she thanked her WHO from different relevant departments/programmes who attended the meeting to provide information about their respective areas of work and shared their views on this project.

After the introduction of participants[5], Maria del R Perez (MRP) provided a contextual overview of the project, highlighting that it is aligned with the GIRSHCS aimed at promoting the application of the international and mobilize the health sector to safer use of radiation in medicine. The new BSS include an overarching safety requirement on justification (i.e. Req. #37) and two specific safety requirements concerning imaging of asymptomatic people (i.e. Req # 3.158 & 3.159). As part of the BSS implementation, the International Conference on Radiation Protection (RP) in Medicine was held in December 2012 in Bonn, Germany, organized by the IAEA and co-sponsored by WHO (IAEA, 2015). It identified 10 priority actions for the coming decade to improve RP in medicine (i.e. the Bonn Call for Action[6]). The Action 1 of the Bonn Call for Action calls for improving justification of radiological medical procedures, with a specifically mentioned subset action concerning use of medical imaging in asymptomatic people. In the same period, new articles & reports/statements were published by medical journals and organizations (e.g. *BMJ*[7], COMARE[8], HERCA[9], *APMIS*[10], *Lancet*[11]) and IHA started appearing more often in advertisement as a commercial product, inciting action towards regulation. In this context WHO started this project- two kinds of IHA practice are addressed in the abovementioned article summarizing the finding of this WHO IHA project published in *JACR*: (i) IHA (A) participants may be "presenters" or patients, performed at public and private hospitals, and there is at least partial evidence base; and (ii) IHA (B) participants are "presenters", there is no framework, evidence weak/absent, often performed at private hospitals, sometimes without even a formal healthcare referral. Several issues associated with IHA (b) were brought to light e.g. prevention of overdiagnosis, ethics, financing, others.
The WHO Report on Principles and Practice of Screening for Disease (WHO,1968[12]) has been a major reference on this topic for almost 5 decades (now WHO is revisiting this document and

[5] *Declaration of interests had been sent to participants in advance- no conflict of interests were disclosed.*
[6] *The IAEA-WHO Brochure of the Bonn Call for Action brochure is available at http://www.who.int/ionizing_radiation/medical_exposure/bonncallforaction2014.pdf?ua=1.*
[7] *Moynihan R, Doust J and Henry D, Preventing overdiagnosis: how to stop harming the healthy, BMJ 2012;344:e3502;*
[8] *UK Department of Health, Committee on Medical Aspects of Radiation in the Environment (COMARE) 12th Report: Impact of CT scanning of asymptomatic individuals, , December 2007. Available at https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/304607/COMARE12thReport.pdf & UK Department of Health, Expert Working Party Report: Justification of Computed Tomography (CT) forIndividual Health Assessment, July 2014. Available at https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/326572/IHA_-_June_Report.pdf*
[9] *HERCA "Position Paper on Screening" in the framework of the exposure of asymptomatic individuals in healthcare, May 2012. Available at http://www.herca.org/uploaditems/documents/HERCA%20Position%20Paper%20on%20screening.pdf*
[10] *Brodersen J, Schwartz LM, Woloshin S. Overdiagnosis: how cancer screening can turn indolent pathology into illness. APMIS, 122(8):683-9, 2014.*
[11] *Lancet Right Care Series http://www.thelancet.com/series/right-care January 2017*
[12] *Wilson JMG, Jungner G.,Principles and Practice of Screening for Disease, WHO, Geneva, 1968. Available at http://apps.who.int/iris/bitstream/10665/37650/17/WHO_PHP_34.pdf*

updating some of those criteria). WHO just published a framework on integrated people-centered health services including infographics and a educational video (which was shown during the meeting). WHO is working to achieve Universal Health Coverage (UHC), which was adopted by WHO member states as a goal (IHA (A) challenges UHC). The topic of imaging asymptomatic people was addressed at two WHO meetings recently held in Geneva: Third WHO Global Forum on Medical Devices (May 2017), and 15th REMPAN meeting (July, 2017). The 70th World Health Assembly approved the resolution WHA 70.12 on integrated resolution. There is an open debate around criteria for screening asymptomatic population after nuclear accidents: this was addressed at the above-mentioned WHO REMPAN meeting, where a progress report of the SHAMISEN EC project including recommendations on population health screening was presented at this meeting. WHO is organizing a seminar entitled "Imaging asymptomatic people: are we doing more good than harm?" which will be held at the International Conference on "Preventing Overdiagnosis- winding back the harms of too much medicine" under the theme "Towards Responsible Global Solutions" (Quebec, Canada, August 2017). It is expected that this topic of IHA will be also a discussion issue at the forthcoming International Conference on RP in Medicine to be held in December 2017 in Vienna, Austria, organized by the IAEA and co-sponsored by WHO and PAHO. Building upon the previous meetings and the JACR paper, the goal of this meeting is to start working on the development of a policy brief/guidance document to inform dialogue about policy options, *not* providing specific recommendations on which is the best policy option but instead to propose a framework for good clinical governance and promote generation of useful data.

During the group discussion it was pointed out that it is not just the Action #1 of the Bonn Call for Action which is relevant for this meeting & project: e.g. also Action # 5 (research), Action #9 (communication) and Action#10 (BSS implementation) are relevant. It was also noticed that between IHA (A) and IHA (B) there may be another category: in some countries where national screening programs are not in place, IHA may be performed on an individual basis and might replace IHA (A) i.e. IHA A in one country is IHA B in another one. Ethical and communication issues raised at the Seoul workshop can also vary by country. The current RP legislation, such as the EC BSS, is benefit-risk ratio driven (i.e. the "net benefit"). Overdiagnosis is not just the benefit-risk ratio: need to integrate both perspectives in an integrative approach where risk-benefit isn't a sole driver (European countries- present funding based on risk-benefit).

Update on WHO activities relevant to the Project

Ethics and health

Ronald Johnson (RJ), chair of the WHO Public Health Ethics Consultative Group (PHECG), explained that WHO has a Research Ethics Review Committee (ERC) formally established and appointed by the DG, which has the role to ensure ethical standards in research projects involving human participants supported either financially or technically by WHO. Taking into account that public health interventions have similar ethical issues, WHO has created this

PHECG as a voluntary ethics resource to WHO staff. It can be consulted to provide advice at the development stage and/or other stages of WHO projects (i.e. as an ongoing dialogue for ethical assistance) with an advisory role rather than a binding role as the ERC. This PHECG was consulted by PHE/RAD in last December, to provide advice on ethical issues related with the IHA project. The PHECG focused on IHA subcategory B (i.e. no clear evidence of medical need for/benefit from the procedure) and agreed that good guidance is both lacking and needed. Some key ethical issues were identified for policymakers: must weigh risks with benefits, should consider rights to access health technologies, and consider the use of public resources. Need to answer some questions such as: Does the use of CT cause harms to the individual user or to others?, What is the magnitude of use IHAs? , What is the impact of incorrect diagnoses? Could restrictions on IHA violate one's rights to access health technologies?, Is access to CT technologies equitable?, What are the costs and how are they covered? (i.e. From the public purse, private insurance or out of pocket expenditures?: this is relevant for achieving Universal Health Coverage- UHC). IHA (B) has ethical issues related with:

1. Potential harms- insufficient evidence on CT radiation harms, incidental findings, false +/- diagnoses
2. Equity/autonomy- lack of guidance, right to access health technology, concerns about ethical access
3. Public resources- potential high cost to benefit ratio, cost of dealing w incidental findings

There is a need for guidance built on a participatory process including users, providers, media, community & patient advocacy groups, especially in low and medium income countries, addressing implementation as well as regulatory issues evidence-based guidance and a framework for action/implementation. Need to ensure ongoing monitoring of evidence base & of country implementation.

During the group discussion several issues were pointed out. John Brodersen (JB) noted that there are differences between research and public health interventions and asked why the PHECG did not discuss the issue of over-diagnosis- from harm/cost perspective (anxiety, unnecessary medical procedures). There are public health interventions that are not evidence based or have a low-quality evidence base, skip the grading process and skip ethical issues. The quality of the evidence is an issue- we need to generate more evidence through research to fill-up the gaps, and meanwhile consider reliance on expert opinion in case of lack of evidence, with incorporation of human rights in guidelines, qualitative as well as clinical trials. Laragh Gollogly (LG) noted that in IHA we see also the issue of inequities regarding access to health care services: do we see the evidence of inverse outcomes? – unmeasured harms due to better access – inverse care law, inverse outcome law (more harm to affluent group of society). JB provided examples of evidence- renal cancer (excess CT scanning), esophageal cancer, others. Andre Ilbawi (AI) noted that harm is a subjective perception and that overdiagnosis is a concept difficult to explain to patients/public. At individual level there is/may be an inadequate perception of over-diagnosis by patients/presenters: 70-90% were accepting false diagnosis and unnecessary screening – the problem is that these people control the narrative. JB said that those over-diagnosed present as "cancer survivors" (e.g. "I had a cancer and I survived because of/thanks to the screening")- There is a framing effect – showing patients risk and mortality rates. Dialogue is essential- we should try to use outcomes in radiology to explain these issues.

Steve Ebdon-Jackson (SEJ) raised the issues of access & equity: what about those people who really need care but cannot get it ? In UK there is a problem of outcome as an assessment for value of imaging with an ethical issue of people who start out asymptomatic and go into the national system because of false positives, and end up having something (e.g. incidental findings) blocking access to others who are symptomatic (screening vs. diagnosis). JB mentioned a study of men 90% over-diagnosed with prostate cancer, noting the importance of context & framework.

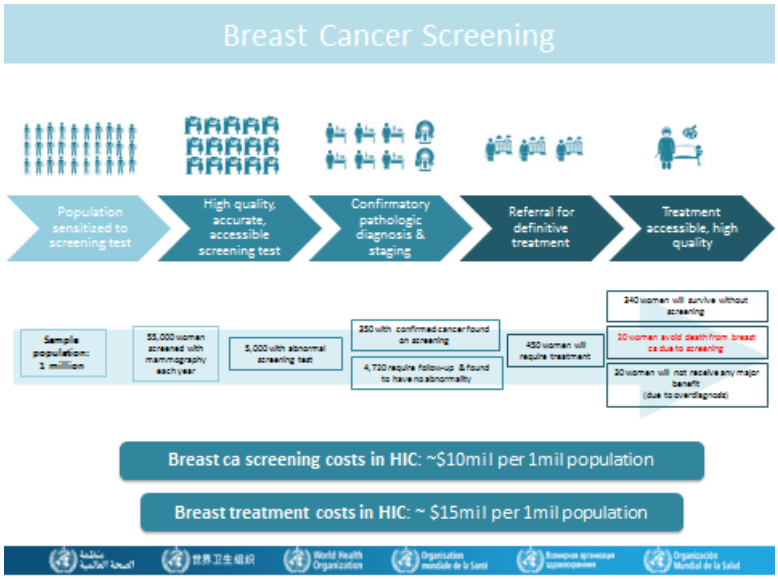
Cancer screening

Andre Ilbawi (AI, WHO Cancer Control Medical Officer) presented WHO's views on cancer screening.
He noted that dialogue about benefits and risks of screening should be different, policy makers need to change. The evidence from inform-consent trials is very tricky: prior briefing of risk/benefit slightly decreases screening participation rates – which is in contrast with informed consent in surgery due to lack of evidence base in case of screening asymptomatic people. But patients feel compelled/ that the test is necessary anyway e.g. citizen juries: they prefer to be screened if given benefit/harm ratio.
There is a perception gap and strong pre-assumptions. He mentioned the differences between individual intelligence vs. collective intelligence (i.e. thoughts of individuals can be biased and extreme, while collective intelligence, in contrast, aggregates the knowledge of many to form an unbiased and more accurate opinions). There is an incredible gap when dealing with policy-making on screening- it is not evidence-based, thus resulting in potential harms of screening & emotional epidemiology. It is based on "perception" of benefits rather than on evidence (i.e. screening is perceived as one of the strongest public health interventions). He provided the examples of breast and prostate cancer screening in the absence of infrastructure for diagnosis & treatment. This is reflected in the performance of screening in low income countries (LIC) without availability of diagnosis or where guidelines from high or middle income countries are being used. Opportunistic screening/screening on demand are not exactly the same as IHA, but it facilitates IHA in some ways. It is difficult to screen outside guidelines in Europe, but this is different in other countries e.g. USA < difference between screening & early diagnosis.
Early detection aims to identify cancer in early stages or pre-cancerous lesions in order to achieve (i) improved survival, (ii) reduced costs of care and (iii) less morbid treatment. It includes 2 strategies: screening & early diagnoses, which are not at all the same thing. Screening is based on a target population, it is more than a test (it's a system, it is a process), is the presumptive identification of unrecognized disease in general population and it has 2 key considerations: (i) what diseases should be screened and (ii) what type of programme should be implemented. Early diagnosis focuses on persons with disease, symptoms and also requires a robust, coordinated health system.
He then referred to Wilson & Junger criteria about "screenable" diseases[13] . and showed as an example a list of radiogenic cancers and how do they match with the "screenable" cancers but:

[13] *Wilson JMG, Junger G, Principles and Practice of Screening for Disease. WHO, 1968: condition is an important health problem, accepted treatment available, facilities for diagnosis and treatment available, recognizable latent or early symptomatic stage, suitable test or examination available, test acceptable to population, natural history adequately understood, agreed policy on whom to treat as patient, cost of*

there is a difference between what can screen and what should be screened. WHO has some screening targets:
Effective screening programs are those which are organized (vs. opportunistic), have greatest impact, fewest harms, are equitable, with over 70% participation as a benchmark. Which are the criteria for organized screening?: national program to make service available; coordination, centralized at national/regional level, protocol for screening frequency and target population; mechanism of inviting target population systematically; functioning health information system including registries; and monitoring & evaluation program. Out of 6 possible outcomes of screening- 4 are harmful. The potential harms include over-diagnosis, false results, & ineffectual service. He discussed the example of a costing exercise for breast cancer from Cochrane Review, Marmit Report, assuming 10-20 years of survival, the effects of breast cancer screening in a high income country (HIC) would be:

- Breast cancer screening costs about 10 mil USD per 1 mil population – higher for LICs – feasibility – relies on personnel, infrastructure
- Breast treatment costs- about 15 mil USD per 1 mil population
- For a sample population of 1 million, 20 women avoid death due to screening (see Fig. below)



However, there is a higher morbidity due to over-diagnosis (variation of costs between countries- report is from a HIC view) and this does not include immunotherapy. Why countries are not doing what WHO recommends? Countries are left to make decisions based on emotional epidemiology (e.g. a president gets a prostate cancer and next day the government puts in place a prostate cancer screening programme). This is due to lack of robust counterfactual evidence from WHO – development of cloud-based tool guiding health policymakers on what to prioritize – methodology for productions, costing, and health infrastructure- with IARC – health system requirements for early diagnosis and screening expected for winter 2017 (countries urged to

case finding should be economically balanced in relation to possible expenditure on medical care as a whole, and case finding should be a continuing process and not a "once and for all" project.

begin screening with a pilot site to test harm/benefit - change mentality that assumes it is beneficial) "If you will do opportunistic screening, first do a demonstration project".

Which are the potential harms from screening?

- Harm #1: Overdiagnosis consequences – with examples from prostate, breast, thyroid, melanoma. Overdiagnosis length-time bias: finding "extra" tumors that would never cause problem (i.e. detection of indolent tumors) produces an apparent increase in the number of cases of cancer and in survival, with no effect on mortality rate[14]. Overdiagnosis results unnecessary treatment, complications of treatment and inflates benefits of screening.
- Harm # 2: Consequences of False Positive Results. To the individual: psychological harm (can be equal to disease), distrust of health system. Women with false positve have psychological damage that range between those experienced by women with a normal mammogram and those with a diagnosis of breast cancer 3 years after[15]. To the system: increased costs of human resources and equipment, mammography (10-50% of program costs, about $500 each false). Further negative harms in the first year after the false positive- psychological effects- people do not trust their symptoms; go to health clinics more often. Low quality screening tests result in greater harm.
- Harm # 3 : Ineffectual Service – low quality services increase frequency of abnormal results, low follow-up rate. High participation, quality assurance and link to treatment are benchmarks of organized cancer screening. Where are we now? based on published studies: 10-30% participation rates, 50-60% sensitivity (quality) and 40-75% linked to treatment. Need to consider health system capacity when proposing screening programme.

Disease incidence has an impact on effectiveness: selecting the appropriate target population (high risk, high incidence) increases the effectiveness of an screening programme (see table below).

Situation	Women screened	Abnormal screening results	False positives	Women benefitting from screening	Program costs
Optimal conditions (Efficacy)	40,000	3,000	2,920	20	$ 300,000
Lower Incidence Participation 50% Poor quality Link to dx & rx 50%	30,000	3,600	3,580	<5	$ 300,000

Screening cannot succeed without basic cancer services and strong health system. Screening is a balance of benefits and harms, and the estimations of benefit/harms rate vary. For interpreting the results, assessing impact/value of screening is challenging e.g. impact modeling, effect of cultural vs. income factors? . Most non-European countries have very low participation rates – decision not to participate legitimate due to lack of incidence? There are several issues to

[14] *Patz EF Jr, Goodman PC, Bepler G. Screening for lung cancer. N Engl J Med. 2000;343(22):1629.*
[15] *Brodersen J, Siersma VD. Long-term psychosocial consequences of false-positive screening mammography. Ann Fam Med. 2013 Mar-Apr;11(2):106-15. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3601385/pdf/0110106.pdf*

consider in modeling the impact – target population, study methodology (biases), effectiveness of treatment, improving test quality. Alternatives? e.g. bladder cancer sniffing dog – extremely high incidence of false positives. Preparedness for screening and cancer control globally – lack of pathology and subsidized treatment in LICs
Regarding public health decision making – long term surveillance must ensure favorable benefit-harm ratio. Decision-making is limited data for evidence-based policies. It has to be context-specific with acceptable risks for population, and consider monitoring & evaluation programme. Screening requires balance of all medical ethics principles: autonomy, beneficence, non-maleficence, justice. Expert guidance tends to be biased toward intervention and its benefits, emotional epidemiology can be prevented by informed decision making, community education & empowerment – acceptance of harms ("are the harms/risks acceptable for the population/society?"). In summary:

- Just because it can be screened, doesn't mean it should: strict criteria should be applied when deciding whether to screen
- Screening can cause real harm to individuals and to health system: need to communicate balance of benefit/harm to all stakeholders and to ensure engagement in public sphere

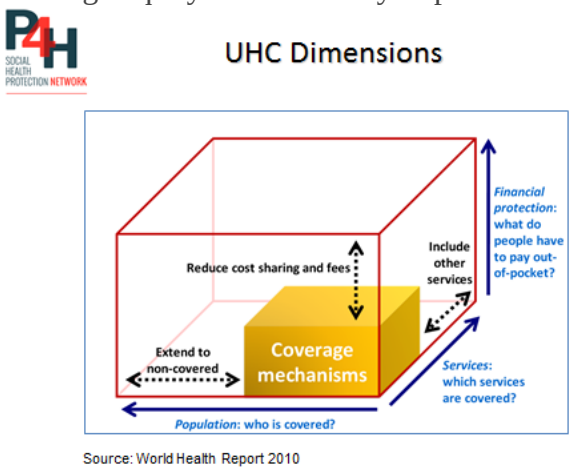
Health technology and medical devices

Adriana Velazquez (AV, WHO Senior Advisor on Medical Devices) summarized WHO activities in the area of health technologies and medical devices, highlighting that there are more than 10,000 types of medical devices, and it is there difficult to regulate their use. WHO is currently working together with other partners towards the achievement of the 17 sustainable development goals (SDG) adopted by the UN: the SDG#3 refers to ensuring healthy lives and promote wellbeing for all at all ages. So it is therefore the key goal for WHO, although all other SDGs are somehow related to human health. WHO has collected data about global density of CT – the information was provided by the Ministries of Health and we have now data available for some countries (need for more complete data). WHO has recently published new relevant documents on health technology assessment (HTA), health technology management, and lists of priority medical devices. The need to perform HTA increases where resources are limited – e.g. in LMICs. A WHO survey on national authorities conducted in 2015 (120 countries) including questions about which areas are being assessed for medical devices indicated that these are mostly related with clinical effectiveness and safety, very little on ethical issues. There are currently 9 global targets for non-communicable diseases (NCD) and WHO is working to identify priority medical devices through the continuum of care (prevention- screening-diagnosis-treatment-follow up/survivor care/palliative care-end of life care)

Health Systems Governance and Financing

Dorjsuren Bayarsaikhan (DB, WHO Health Systems Governance and Financing/ P4H-Social Health Protection Network) referred to P4H https://p4h.world/ , a global network established in 2007 to support countries to develop effective, efficient, equitable and sustainable Health Financing and Social Health Protection systems for Universal Health Coverage (UHC). He

provided an overview on UHC and its components/dimensions, aimed at all people in society getting comprehensive access & use of quality health services (promotive, preventive, curative, rehabilitative and palliative health services) without financial hardship (i.e. the costs of paying for services should not severely affect household income). UHC goal is the population health improvement (with equity, quality, and financial protection). In terms of dimensions, covering mechanisms should include everybody, all services, and reduced cost and sharing fees (see figure below). World Bank data indicate that 400 mil people lack access to essential services and 100 mil fall into poverty annually due to health payments. Health care services must be achievable by all countries regardless of income level. Health financing refers to arrangements that a country has to perform and govern the following 3 main functions: revenue collection, pooling, and purchasing (including defining and rationing health service benefits, allocating funds, and paying for providers).
The health financing reforms for UHC include raising "more money for health" domestically and externally, increasing share of prepaid and pooled funding (redistribution effect), and getting "more health for the money" through equity and efficiency improvement (i.e. value for money).



Source: World Health Report 2010

High levels of health spending do not necessarily translate in good health: 20%-40% of health expenditures is wasted (World Health Report 2010). Which are the main sources of inefficiency?: underuse of generic medicine, purchase of substandard and counterfeit medicines, over use of diagnostic tests, over supply of medical equipment, inappropriate hospital admission & length of stay, and fragmentation of health care. UHC is a set of policy goals and objectives which are relevant for all countries (not just LMIC but also HIC). Every country can make progress towards UHC at any given level of income, every health system can be changed, improved and transformed following their UHC related goals and objectives defined. Some major lessons/prerequisites were identified so far: need for clarity, high level commitment and support; predominant use of mandatory prepayment financing, taxation, social health insurances; focus on the main issues and obstacles, integrated and progressively expanding quality health service benefits provided by incentivized public and private providers (service integration, national comprehensive benefit package for all), increase effectiveness by eliminating resource waste, minimizing fragmentation and duplication. Some topics relevant for IHA were proposed for further discussions:

1. Coverage and equity in terms of access and use (e.g. patients, presenters and others left behind)
2. Affordability and financial protection: who pays, public and private, level of cost sharing, budget allocation, subsidy, out-of-pocket and protection against catastrophic health expenditure.
3. Efficiency and effectiveness: unjustified examination, evidence base, service integration and comprehensive benefit package for all.
4. Quality improvement: resource planning, private provider performance and financial incentives.

Fahdi Dkhimi (FD, WHO Health Systems Governance and Financing/ Health Economics and Financing)
highlighted that there is a need to approach this issue from a systemic perspective and to look into the purchasing function in the system. It is indeed important to identify who pays for health services, how these purchasers allocate resources to providers and how they define what resources should be allocated to what services. This is in order to get the most value for the money invested, but also to strategically manage resources in order to prevent from creating incentives that encourage over-diagnosis/overprescription. When it comes to introducing new technologies, this question of purchasing arrangements is fundamental because it may shape providers' behaviours in such a way that they go against your system's objectives e.g. without risk mitigation or strong regulation, when providers invest in a machine, they may be more inclined to overprescribe to yield return on investment (effect of financial incentives). Therefore, purchasing is one of the most powerful instruments to control prescription patterns (paying only against information that allows for monitoring) and to regulate providers' behaviours.
How can we align health financing with our objectives? How to use payment as a method to enforce justification/ shape behaviour of providers? One key pre-requirement is to put in place an information system that allows for tracking health service production costs in a detailed manner. This information should be the cornerstone of a tailored policy response.
To align payment modality with government priorities – which should emerge from a broad democratic process (which one? This will be always a bit contentious, but participatory arrangements like citizen jury have proved to be effective deliberative democratic methods when it comes to define priorities) – there is a need to rationalize use of health services and streamline expenditures. Efficiency is not self-contained goal but it is one of necessary condition to trigger the transformation of health systems towards greater equity. Last, but not least, putting such a system in place will require to take ethical issues into consideration as this would imply accessing individual patients' data – privacy is therefore at stake.

After these presentations, the group discussion raised further issues. Mathias Prokop (MP) gave the example of GPs who have bought with expensive ultrasound equipment – this is changing consumers' culture: when it is used on a pregnant woman she expects it to be used for every medical visit, when patients have specific symptoms they think they need technology e.g. viewing sore throat as an illness (public perspective – want a technological solution to a health problem: need to promote good clinical practice with appropriate use of ultrasound!). GPs in Germany with x-rays use them 7 times more frequently compared with those who refer patients to radiologists. Need to change the mindset to "performance-based incentives" – i.e. paying a

doctor based on performance (need way to assess quality and effectiveness of care). This has been used in LICs by external donors such as the World Bank e.g. sub-Saharan countries, Cambodia but the problem is what are quality & effectiveness? and how to measure them? (e.g. community surveys) . AV asked where funding of excessive use of medical technology comes from in thise LICs?. LG noted that there is a communication issue because individual health assessment (IHA) as a problematic term because it legitimizes it – "institutional bias" of WHO towards every intervention program that is promoted as well as a human bias towards care and attention, and there is also an "individual bias" – nobody will accept not to do anythingit is too late to change/introduce new policy for LICs -lack of honest debate about harms- the problem is not that public are not reading risk-benefit analysis but they don't have available rational information. People don't understand that many cancers are indolent, digressed, or misclassified – not unidirectional as presented. DB called for looking at mobilizing resources on a macro perspective – there maybe high social inequality even with public health care system e.g. Denmark – this can be solved with education, infrastructure, etc. (health problems are not only solved within health sector, also acting in the social and education sectors). Regarding financial incentive, it has to consider preventing from referring to others downstream, in the case of IHA taking place in the private sector, they don't have to pay for the downstream interventions and then it is the public sector which pays (e.g. a mistake made in private sector that is referred to public sector to be solved). Jim Malone (JM) noted that the medical sector could be accused of hiding harms because it is part of the culture not to worry the patient: this issue of "hiding the harm" has to be picked somehow in our document. In Belgium and Luxembourg – there is public education program- they put in hands on education rather than medical professionals. Steve Ebdon Jacson (SEJ) considers that doctors use equivocal language- communication approach and the way data is presented need to be improved. In LICs especially – symptomatic individuals must take precedence over asymptomatic. The financial incentive is really interesting: we need a body of resource in the public sector without hindering access to symptomatic individuals, outside of standard insurance process (it takes political will), but needs to be judged by standards, which are not available. DB highlighted that health financing is the mean to achieve UHC, financial incentives can be provided on side of consumer and provider, we need to incentivize outputs and outcomes e.g. public financing and private provision, private financing at public (mixed systems) – "IHA is outside the health care system": what does it mean? In UK they implemented pay-per-performance but the risk is that the high-risk patients may be left behind because they are more challenging for providers. This can be addressed by higher pay for caring for higher risk cases and vice versa e.g. Mongolia, paying more for practice in less educated areas, penalty for false referrals of "symptomatic" individuals to a health care facility. We should look for options suitable for different health care systems and different income levels. LG highlighted that some have too much access/coverage for things they don't need – need to bring a message to government to allocate services more effectively more those who really need it. MP noted that we need both: financial incentives and disincentives – e.g. to have disincentives for errors/ "stupid things". LG noted that there is a need for culture of malpractice legislation. DB noted that most healthy people are using most resources, and people in need bearing the highest burden and AV said that they are considering use of disinvestment[16]. It was raised again the issue of inverse care law and inverse benefit law, and it was debated whether the

[16] *Disinvestment is aimed at reducing the financial burden on the government and improves public finances. It introduces competition and market discipline and helps to depoliticize non-essential services*

use of health care without incentives maybe harmful. We have more evidence on IHA harms (eg. false positives) than benefits, with exception of lung cancer screening trials, SEJ agreed that we have evidence of detriment, no evidence of benefit, we need better data, patient record accessible to authorities but this may be difficult due to privacy issues.

Brainstorming on the policy brief/guidance document

A major concern is that the most rich and healthy people are getting most of the health care: the aspiration is to make that everybody receive the care they need and nobody takes the care they do not need. We need to support the clinicians to be able to achieve this goal: they need WHO to say "this is harmful". How could WHO help prevent the harms of misuse of imaging in IHA? EvD summarized the experience of the development of the WHO guidance document on artificial tanning beds- this might be a good example of a WHO guidance document targeted to policy makers. It has a compilation of different regulation that countries have implemented. We can use similar format/approach in our topic – e.g. disproving misinformation/ countering common beliefs /popular misconceptions. There was a debate around which typo of document WHO should produce to tackle this issues. LG said that we should not try to go around the guidelines review committee (GRC) and producing a report without recommendations. We need WHO guidelines on screening. Let's explore this further with GRC. JB said that there is probably not evidence about benefits but there is a lot of evidence about harms. We could start by th end i.e. answering the question "which is the most effective recommendation that WHO could provide?" and then go back and see which kind of evidence we do need IPICO questions). The discussion was then focused on whether to start with a guidance/framework document proposing policy options or to directly go for the WHO guidelines. As a preliminary conclusion of this first round of discussions, it was said that it would be more useful to write guidelines /recommendations first with concrete evidence (directed at policymakers and GPs), and then a pamphlet directed at public. It was agreed to revisit this discussion later, and JB volunteered to draft some possible PICO questions.

Building upon the outcomes of our previous work

Still was an open question which kind of document to start with and which medical imaging group to target (CT/MRI/Ultrasound). As a possible PICO question for a WHO guideline JB proposed "What are the benefits and harms of CT of asymptomatic individuals?"

Population: asymptomatic people
Intervention: CT, randomized control trial, qualitative studies, case control studies
Control: people who are not offered a CT
Outcome: all potential benefits and harms from the patient's perspective and/or from the health ministry's perspective (citizen v. societal point of view)

Measuring harms is different for measuring benefits, harms cannot be found in the randomized control trials (RCT), they can be found in observational and case-control studies.
There may be some targeting specific diseases (e.g. lung cancer? YES, there is some evidence , coronary calcifications? NO, colon? NO….) but the guidelines looking at CTs in general including unsystematic CT screening, screening on demand, opportunistic screening. Prejudice due to different standards for benefits than for harms? As CT scans are over-used on asymptomatic people, why not use those data?

We can use Russ Harris taxonomy[17] to categorize harms in 7 areas considering work-related costs, fault positives, overdiagnosist/overtreatment, increased morbidity and mortality…all the screening cascade. .
Benefits would be reduced mortality/morbidity and being re-assured. We need one PICO per main area of medical imaging:

- CT for lung cancer screening
- Coronary calcium scoring (cardiovascular disease down due to more aggressive treatment and smoking cessation)
- CT colonography

We need to consider the benefits and harms from the health system perspective & the patient/community perspective. There is a substantial cost which is not just what people have today: it is the half-a-day work lost, costs of travelling to reach the hospital, cost of parking, etc…this is not considered in the cost of the intervention, and it is part of the harm.

Our document has to say that if IHA it is going to be done, it has to fulfil certain conditions/requirements, in a way would be "If you are planning to do this in your country, these are the factors you have to consider…" e.g. facility structure, staffing, quality assurance, records …etc. Are you looking at this before you start? or you are looking at this when it is already in place?

Should ultrasound of the thyroid and/or prostate be included as examples? The consensus was in favour of including them, either within body of report or as an annex? - e.g. Korea thyroid cancer epidemic, Fukushima thyroid cancer.

It was suggested including the following interventions: CT for coronary calcium scoring, CT for lung cancer screening, CT for colon cancer screening, and to mention ultrasound for thyroid cancer screening and use of MRI for screening (not discussed the disease/s). The emphasis should not be in the ionizing radiation side (there are already RP regulations). It is important to disclose all the downstream data in order to get information about how many cancers were detected, false positives, incidental findings. The possible sources of evidence are (i) systematic reviews and (ii) clinical research.

[17] *Harris RP et al . The harms of screening: a proposed taxonomy and application to lung cancer screening.JAMA Intern Med. 2014 Feb 1;174(2):281-5.*

The WHO document/report would be aimed at clinicians – structuring the report around risk so that GPs/clinicians can present evidence to patients with recommendations.

Ethical issue – importance of randomized study rather than observational: not provide recommendations without RCT evidence. Only randomized studies can provide the evidence on the benefits of screening: we cannot accept screening studies based on observational studies-methodologically it would be unethical.
Present the framework elements: evidence-based mechanism to decide whether a specific type of IHA is to be considered as justified in general, to discuss the discrepancy between the seriousness of the disease and the seriousness of the treatment (how dangerous it is). Nordic countries used Scandinavian medical records to look at all procedures downstream of medical imaging on asymptomatic individual to create a
study www.dep.iarc.fr/NORDCAN/english/Graph

Aggressive vs non-aggressive cancers: what we want to do is to screen cancers that are aggressive.

1) SYSTEMATIC REVIEWS – benefits (RTC); harms (others: case-controls, observational)
2) CLINICAL RESEARCH – sources, patient records e.g. Korea
We can take best examples <5 to write a paper which would form basis of WHO document

Records of over two decades – early 2000s – need access to reason for referral – if it is IHA then look at downstream results. Take random samples of population (age matching) and view outcomes and costs
Or use South Korea example – Samsung Medical Center screening

We cannot use RCT to assess for harm, because the authors do not report on harms.
Observational data can serve as an indicator of an effect – incidence of early and late stages.

Options for way forward (both might be also considered as a series of different type of work):

1. Publication for 2018 needs current material – reframing the problem to support international BSS. It could be a paper or a WHO report/policy guidance about framework, writing down what we have now, describing existing framework and why it is inadequate, reframing the problem and thinking about systematic and non-systematic screening, including harm taxonomy[18].
2. Discrediting IHA as a bona fide modality vs. performing it then analyzing data prospectively. If IHA is going to happen, do it as bona fide medical practice, ready to be included in trials; we must identify what the most important types of studies are and what the conditions are that need to be imposed on the way an IHA is done. Need to be included in national databases.
3. Cochrane reviews (PICO) for clinical research: Cochrane systematic reviews making IHA available, identify research needs and priorities, preceding the research – or maybe outlining what research needs to be done: core priorities (e.g. research agenda). We will need one year per PICO question. Do research in existing data bases: Scandinavian and

[18] *Need to contact Russel Harris UNC Chapel Hill – taxonomy, harms of cancer screening and invite him to contribute*

Korean. What kind of research we need? We could do one case study on one disease and leave further research on other areas to them e.g. lung cancer screening systematic review all RCTs- but cannot be used to identify potential harms. US Service Preventive Task Force and Cochrane Review – reported benefits, not harms – need for research.

Justification of imaging in asymptomatic individuals will have to be addressed considering both: generic justification and individual justification. Need to revisit the terminology: IHA or opportunistic screening???This could be a piece of work in conjunction with the WHO guidelines on cancer screening presented by AI, as a series of WHO publications. However we need to differentiate between this report on individual screening and the population screening criteria for early detection of cancer presented by AI- common research work?

Are we going to conduct systematic review on each disease? It is a question of resources- time, facilities, and capacity. A full systematic review takes one year for a full time worker with experienced supervision (in the topic and in the methods): need to mobilize resources/ fundraising among potential donors to support the research. Worth the time- implementing a screening program takes much longer. We will need to research on existing databases – Scandinavian, South Korea
Criterion 10 of Wilson & Junger criteria 1968 is written in the wrong paradigm: "Overall benefits should outweigh the harm"- How to measure this? How to justify screening or not?

Update on WHO activities relevant to the Project (II)

Service delivery and safety

Nuria Toro Polanco (NTP, WHO Service Delivery and Safety Department/ Services Organization and Clinical Interventions) referred to the new WHO framework on integrated people-centred health services (IPCHS) The global context that health systems have to deal with has changed: ageing, migration, climate change, non-communicable diseases (NCD), urbanization, globalization, rising costs. This is challenging but at the same time it provides new opportunities e.g. growing tendency towards innovation. Citizens are more demanding, with increasing expectations on health systems, and more committed to play an active role in all aspects related to their health. Emerging demands are being posed to health systems e.g. unhealthy behaviours and lifestyle choices, double burden of disease and multi-morbidity, greater citizen expectations, increased need to self-manage care, need for cost-efficiency and accountability. On the other side, there are health system constraints: lack of community engagement, limited inter-sectorial action and engagement, inssuficient and misaligned financing, sub-optimal workforce, service fragmentation and innapropriate service delivery. Current health systems are not able to respond (obsolete systems). So patients and communities as well as providers and policy-makers are unhappy with the way in which health services are framed and delivered.

The WHO framework on IPCHS has a very ambitious vision, that "all people have equal access to quality health services that are co-produced in a way that meets their life course needs, are coordinated across the continuum of care and are comprehensive, safe, effective, timely, efficient and acceptable; and all carers are motivated, skilled and operate in a supportive environment". Integrated health services are managed and delivered so that people receive a continuum of health promotion, disease prevention, diagnosis, treatment, disease-management, rehabilitation and palliative care services, coordinated across the different levels and sites of care within and beyond the health sector, and according to their needs throughout the life course. An approach to care that consciously adopts individuals', carers', families' and communities' perspectives as participants in, and beneficiaries of, trusted health systems that are organized around the comprehensive needs of people rather than individual diseases.
People-centred care is broader than patient and person-centred care, encompassing not only clinical encounters, but also including attention to the health of people in their communities and their crucial role in shaping health policy and health services. People-centred health services adopt individuals', carers', families' and communities' perspectives that are organized around the comprehensive needs of people rather than individual diseases. People-centred care is broader than patient and person-centred care, encompassing not only clinical encounters, but also including attention to the health of people in their communities and their crucial role in shaping health policy and health services. The Framework provides a new way of thinking about how health services should be organised, managed and delivered and suggests 5 interdependent strategies for moving forward:

1. Engage and empower people and communities to take an active role in their health and health services
2. Strengthen governance and accountability to build legitimacy, transparency and trust
3. Reorient the model of care to ensure that care is provided in the most appropriate setting to maximise both health results and efficiency, based on a strong primary care
4. Strengthen the coordination of care across providers, organizations, care settings and beyond the health sector to include social services and others
5. Create an enabling environment to facilitate sustainable change through enhanced leadership and management, information systems, financial incentives and reorientation of the health workforce, among others

This framework was developed in 2016- agreed upon by 194 countries. The implementation strategy is under development ("how to …") and a set of services and technical products are being developed with specific steps to support implementation of IPCHS e.g. video on IPCHC, policy and practice briefs (11), knowledge web-based platforms, community of practice, research on indicators of level of implementation.

Katthyana Aparicio (KA, Service Delivery and Safety Dept/ Patient Safety and Quality Improvement) provided an overview on the WHO work on patient, family and community engagement. The current WHO Patient Safety agenda includes safety initiatives at global level, collaborations and partnerships, research activities, development of standards, guidelines and tools, provision of technical support and capacity building and technical support and monitoring of trends and progresses. As an example she referred to the recent publication of the WHO Safe Childbirth Checklist (SCC) and implementation toolkit in 3 languages, supported by a series of SCC technical webinars. Similarly, they have produced other patient safety resource materials in

different languages. A set of publications entitled 'Technical Series on Safer Primary Care' has been developed- technical webinars are organized to introduce and disseminate these on-line publications. Why is patient engagement so important? Because it is critical to reorienting healthcare, contributes to make more informed decisions resulting in better and more affordable care, improves recall of information, increase knowledge and confidence and promotes appropriate care path. It has proved to improve patient experience, leading to improved utilization patterns and adherence to treatment. There is a link between education and health. A recent survey showed that, while 99% of US citizens can read, only 12% are health literate, which indicates that health literacy cannot be taken for granted even in technologically advanced societies: in fact low health literacy is widespread. Patients with low health literacy are at greater risk of misunderstanding treatment recommendations, having problems in accurately taking prescription medications, and experiencing lower health status and poorer health outcomes. Health literacy enables people to have their own decision-making power and control of their own health. It can improve community welfare, communities have managerial capacity when health literacy is improved. Based on a survey conducted in 2015-2016, involving GPs, patients, and policymakers, the 4 main barriers for patient engagement are (i) low health literacy of patients, (ii) low/poor communication between providers and patients, (iii) low level of knowledge of benefits of engagement, and (iv) low patient confidence to advocate for safety. Patients for Patient Safety (PFPS) is a network of patient advocates- platform for collaboration between all health system actors. Patient champions around the world are change catalyzers. PFPS was created by WHO as an approach to empower and build capacity for patients and families as informed and knowledgeable health-care partners: it provides a platform to bring the patient voice to health care, serves as a mechanism to facilitate and foster collaborations. Under the theme "*Putting care back into health care*" WHO is promoting a Framework on Patient, Family & Community Engagement Advocate, to promote equity of access to people-centred health care and services; engage and empower people to work together in partnership for safe and quality care; promote people-centred policy through engaging and strengthening capacity of policy-makers; and empower people to be informed partners in their own health and health care. These 4 major framework blocks (i.e. access, policy, quality and safety and empowerment) are link to 4 major values: compassion, accountability, respect, and equity (see Fig XX). Three examples of patient engagement in the development of tools were presented: (1) Mother-baby 7day mCheck tool to help mothers recognize danger signs during the first 7 days after birth and encourage appropriate health care seeking behavior. Patients helped develop this mobile phone tool by identifying issues, proposing and testing messages, collaborating with health-care providers, and disseminating the tool; (2) Patient's Communication Tool for Surgical Safety, which was a collaboration between health-care providers and patients, the technical messages were drafted by health-care providers, patients helped review, comment and refine messages and patients helped disseminate the tool; (3) tool on Communicating Radiatin Risks in Paediatric Imaging, in collaboration with WHO PHE Radiation Programme. A working group of health care providers and radiation protection (RP) experts drafted the technical content, patients advocates participated in stakeholders' feedback workshops and provided comments, participated in the launching webinar and helped disseminate the communication tool for radiation safety.

The group raised additional issues during the discussion. JB made a comment about possible danger of people-centred approaches for screening ? People's expectations and pre-assumptions in getting secondary prevention are high. There is a consumer overestimation of benefits and underestimation of possible harms, there is a pressure on professionals to conform to patient perspective- lacking health literacy and they have to face the dilemma of who should bus health care. Policy makers do not have health background and doctors treat diseases rather than patients. The medical curricula are disease-oriented and not patient-oriented, there is lack of communication - fault with the system, not individual doctors. While primary health care is a continuous (Gps, family doctors), secondary health care is fragmented: several specialists acting in silos for multimorbidity e.g. one patient with diabetes & hypertension. We should aspire to deliver evidence-based health care at the extent possible, but sometimes we need to accept evidence-informed interventions.

Literature available at health services not strong enough, especially in LICs and MICs. There is a debate between patient needs, expectations, and social preferences e.g. avoiding vaccination. The problem is that it takes 10, 15+ years to acquire enough health literacy.

Regarding consumer needs, there is a difference between actual patient need vs perceived need, which are deeply engrained in the culture. IHA is seen as a societal need but the evidence base says that it is not a need. (social preferences vs. individual preferences, "what do you feel, you should do"). We need to educate but what about the time consumed for that purpose? Educating consumers is empowering them about what is good for them. Teaching health literacy in school, especially for medical students- education that prevention is not always the right thing to do, as well education campaign would take decades- (e.g. tobacco public education campaign has taken over 50 years) as well as risk-adverse human nature/ intuition clashing ethical perspectives: the dilemma between paternalism vs. autonomy - professional intuition (rejecting perceived need- however this can stop someone from seeking care in the future). GP-consumer consultation takes double the time - known from PSA testing - Oxford study shows consultation about benefits and doubts did not change anything —>takes away time from patients with serious issues, adds unnecessary cost in the health care system - follow up consultations etc.

e.g. campaigns in the Nordic countries against excess antibiotic use support GP - patients come seeking care rather than specific treatment. Building trust requires contact however, for example many young professionals only go to the doctor when they have an illness - once every few years.

Regulators' standpoint: at what point does cultural preference trump patient safety? - prosecution? legal binding? Is denying a patient from getting a CT a patient need? There are

differences between objective needs vs. subjective needs. How do you see WHO tackling the "perceived needs"? and What are WHO views on how tackling those "perceived needs" and prevent overdiagnosis? What is the way of denying practice?

Education can be a vehicle to support our work on needs vs expectations: WONCA education programme for family doctors / GPs, medical schools are the places for reaching the medical students, professional societies to reach radiologists and other radiological medical practitioners, education on RP and safety. The outcome of education will take time to show an impact in practice and we need to do something in between: here there is a place for regulations. One issue is that private clinics always offering screening when public facilities do not.
The US Preventive Services Task Force (USPSTF) recommends against screening for asymptomatic carotid artery stenosis in the general adult population (they concluded that the harms of this screening outweigh the benefits[19]). In May 2017 the USPSTF updated its recommendation on screening for thyroid cancer in asymptomatic adults- it is now is against for thyroid cancer screening in asymptomatic adults[20]. This is relevant for GPs and for the public to know. But there is a public misconception- e.g. from advertisements of sun beds, CT scanning, ultrasounds for baby photos – this cannot be banned by WHO but perceptions can be contested. There may be alternative solutions e.g. public database with pictures of moles to indicate whether melanoma is present, internet PSA tests.
The example of the Choosing Wisely campaigns in US & Canada - trying to empower the consumer to deny scans- causes lack of trust between GP & patient. Also the Nordic Federation of GP published a position paper on over diagnosis[21]. Pulmonary nodule testing- radiologists can deny the patient a follow-up if they are low-risk even if they are requested to do it. Talking about overdiagnosis may undermine patient-GP trust - but this is worth the risk. We should stop hiding the harm, even if it may undermine trust, to keep the patient happy. Benefits are easier to perceive than harms. We should communicate the diagnosis but also the uncertainty. But it is difficult to educate the public and explain the problem of uncertainty of low-quality evidence. It is usually perceived as benefit if a tumor is detected by a CT, then if a complication occurs during a surgery down the line, it is disconnected from the original detection and the surgeon is blamed. Then, the patient paradigm of diagnostics and its relation with the prevalence of the disease was discussed.

Education of stakeholders

The group focused the discussions of stakeholders education, trying to identify who should be educated and how. The discussion was not conclusive but allowed confirming that this is an important component of the framework that should be addressed in the future WHO framework document.

[19] https://www.uspreventiveservicestaskforce.org/Page/Document/RecommendationStatementFinal/carotid-artery-stenosis-screening
[20] JAMA Screening for Thyroid Cancer, US Preventive Services Task Force Recommendation Statement (2017) file:///C:/Users/perezm/Downloads/jama_BibbinsDomingo_2017_us_170007.pdf
[21] http://www.nfgp.org/files/8/position_paper_overdiagnosis.pdf

At least 3 major target audiences for education for improving IHA justification of preventing harms from overdiagnosis were identified:

1. Referring physicians (main target: GPs/ family doctors): WONCA as a key vehicle, other professional societies, other/s
2. Medical students: medical curricula implemented by medical schools
3. Consumers/patients: campaigns?

Some EU countries have radiation safety in core curriculum in European medical schools. This should include justification of screening, but this can be also in the curriculum of other subject/areas (e.g. in clinical medicine). The aspiration would be that clinical decision support systems were embedded into the referral process - bypassing the system for a certain clinical indication needs to be justified / audited. Referral system doesn't stop ordering the screening, but flags it

The curricula from trainees to GPs should include radiation safety, and this should include examining healthy (asymptomatic) people – it could part of their continued professional development (CPD) and also fit into a couple lectures before, during the undergraduate course, targeted at medical school deans. ICRP report on this topic demands displacement of several other lectures[22]. MEDRAPET EC project also made recommendations on RP education and training of health professionals[23].

The Bonn Call for Action No.4 is "strengthen RP education and training of health professionals" and it includes 5 sub-actions that are relevant to our purpose (i.e. the organizations and entities that are promoting the implementation of this Call for Action would potentially be partners):

I. Prioritize RP education and training for health professionals globally, targeting professionals using radiation in all medical and dental areas;
II. Further develop the use of newer platforms such as specific training applications on the Internet for reaching larger groups for training purposes;
III. Integrate RP into the curricula of medical and dental schools, ensuring the establishment of a core competency in these areas;
IV. Strengthen collaboration in relation to education and training among education providers in health care settings with limited infrastructure as well as among these providers and international organizations and professional societies;
V. Pay particular attention to the training of health professionals in situations of implementing new technology.

Medical schools would listen to the WHO regarding education of the health workforce (for them the ICRP, IAEA, EC documents are ineffective). Radiopharmacists, medical physicists, biomedical engineers more are needed in health workforce- medical physics is not recognized as a health profession in all European countries (nor beyond).

The European Society for Quality and Safety in Family Practice (EQuiP) is a WONCA Europe's network created in 1991 with the aim of developing tools and methods for quality improvement

[22] *ICRP, 2009. Education and Training in Radiological Protection for Diagnostic and Interventional Procedures. ICRP Publication 113. Ann. ICRP 39 (5) http://www.icrp.org/publication.asp?id=ICRP%20Publication%20113 and. http://www.icrp.org/page.asp?id=35*

[23] *European Commission, Radiation Protection 175, Guidelines on radiation protection education and training of medical professionals in the European Union, 2014, http://ec.europa.eu/energy/sites/ener/files/documents/175.pdf*

in general practice. The next EQuiP Assembly Meeting will take place in Bratislava, Slovakia in March 23-24, 2018 and JB is an invited speaker. This meeting will gather GPs and other medical practice specialists around Europe to address 3 main topics: (i) Quality of Medical Education (ii) eHealth (does it improve Quality and Safety in General Practice? and (iii) Preventing overdiagnosis and overtreatment. This meeting might provide an opportunity to put our topics in the agenda and raising the flag about education. JB will explore this further with the organizers, and MP will write a few lines on why/how WHO could help with this e.g. to integrated education on justification of medical procedures connected with the clinical training, to foster evidence-based medical practice and prevent overutilization / overdiagnosis (emphasis on this rather than on RP side, while linking it with RP as "one of many harms").
There is a gap on education and training on preventing overutilization / overdiagnosis and WHO has an important role to bridge that gap. The GP respond positively to training programs for continuous medical education (there are opportunities, particularly in Europe). The target audience for educational activities would be the health workforce and radiation medicine community, but also others eg. patients and community. We can consider producing a pamphlet for patients about dangers of overuse. Perhaps we can think about producing a toolkit through this IHA project? i.e. a set of inter-connected resources (i) a framework document, (ii) a research agenda and (iii) communication tools- leaflets, etc.

Drafting the document outline

JM presented a preliminary proposal of a document outline for the group discussion, picking a few themes which had been identified along this project to enhance IHA justification (benefit/harm rate) and improve the clinical governance of this practice. This would ultimately contribute to prevent overuse/overdiagnosis. The idea is to have a report/document with 4 or 5 achievable goals.
What can we do now?

1. Describe an overall harms' picture
2. Identify research gaps and priority needs (i.e. shaping a strategic research agenda - essential set of activities - fitting mandate of WHO as this is one of its core functions).
3. Promoting/implementing the research agenda, which can be done by 2 types or research (i) using big databases e.g. Scandinavia and South Korea and (ii) by systematic reviews – PICO questions
4. Put constraints put on IHA to generate medical records useful for future research
5. There are things we can say about GOVERNANCE. In particular about RP we could report from two extreme viewpoints if explored from the regulatory point of view
    a. IHA has to be a medical procedure and resulting conclusion.
    b. IHA cannot be a medical procedure and resulting conclusion.

6. We can refer to the topics discussed in the Munich meeting report (JACR paper 2016) and the minutes and set of PPT presentations from the Korea stakeholders' workshop 2016[24].
7. Public education- dilemma of consumer v. patient v. presenter, ethical issues, real needs vs. perceived needs, …
8. Detailed account of ethics involved (ethical principles, IHA ethical dilemmas)
9. Uncertainty — In dealing with the public and professionals, a certain degree of uncertainty should be explained as an unfortunate thing we would want to get rid of, but at the same time as a natural part of this, which we should be at ease with and accepting (discussing potential harms)
10. Finance and framework for good governance (health financing, health economics, etc)

After JM presentation of the abovementioned ideas, a group discussion took place- see below some of the issues raised/proposed.

- Mention new online databases which show possible outcomes and level of uncertainty?
- Explain how the health system is harming people
- Adding new risk factors increases uncertainty - widens disease definition, impacts on risk assessment
- Halfdan Petursson is an Icelandic GP, member of the Nordic network of GPs, who conducts research on cardiovascular (CV) screening. He published a study showing that combined assessment of 5 traditional risk factors helps identify high-risk individuals[25]. If we are going to screen people, we want to prevent overdiagnosis i.e. need to risk-stratify the population to have highly sensitive, specific screening (e.g. people with 0 risk factors, 1 risk factor, 2 risk factors and 3 or more risk factors, keeping in mind that CV risk increases with age).
- Assessment of individual risk profile has been increasingly addressed in the last years linking it with personalized medicine. The European Society of Radiology is currently advocating for the use of "-omics" technologies [i.e. detection of genes (genomics), mRNA (transcriptomics), proteins (proteomics) and metabolites (metabolomics) in different kinds of biological samples] as a way to move towards a personalized medicine. This might be used to assess individual risk profiles. There was debate in the group around this issue and the potential implications it may have on screening of asymptomatic people, overdiagnosis and overtreatment.
- There is a problem with statistical power/ amount of data/ precision increasing and bias decreasing, variance (uncertainty) increases therefore also total error increases i.e. uncertainty deserves a chapter to be discussed.

-We know that IHE is challenging the Basic Safety Standards (BSS) requirements but, if it is going to happen: how to make it happen in a way that is acceptable?.

- The issue of terminology came up again: emphasis that we started with IHA, but the other terms can apply to all asymptomatic individuals (presenters, patients, consumers?; IHA, individual screening, non-organized screening,opportunistic screening?).

Ethics ——>> Can you justify lack of evidence of benefits but presence of real harms?

Some proposals for the systematic reviews:

[24] *Note from MP: the minutes and set of PPT slides for this Geneva meeting 2017 will also be a relevant source of information that can be included in the framework document*

[25] *Petursson H, Getz L, Sigurdsson JA, Hetlevik I.Can individuals with a significant risk for cardiovascular disease be adequately identified by combination of several risk factors? Modelling study based on the Norwegian HUNT 2 population. J Eval Clin Pract. 2009 Feb;15(1):103-9*

- The Preferred Reporting Items for Systematic reviews and Meta-Analyses (PRISMA) statement was focused mainly on efficacy, therefore a PRISMA harms checklist has been developed to improve harms reporting in systematic reviews[26]
-Reporting guidelines for main study types www.equator-network.org for assessment of quality of data - one component of subsequent analysis by GRADE
-Strength of recommendation as determined by WHO guidelines review committee
-Harris 2014[27] - "The Harms of Screening, a Proposed Taxonomy and Application to Lung Cancer screening" and Harris 2015[28] - A value framework for cancer screening (i.e. increasing intensity beyond an optimal level leads to low-value screening and speculate about pressures that encourage overly intensive, low-value screening.

What to do next: working group and document outline

A) Working group:
   a. to determine core expert group to coordinate the work,
   b. once identify areas to be covered in chapters/sections, to propose a multidisciplinary development group (from inside & outside WHO) matching with those areas, including:
      i. leading authors & co-authors for each chapter/section,
      ii. leading writer to put together all the pieces of work,
      iii. corresponding members for reviewing and/or commenting

B) Topics proposed for the outline of the document (first preliminary group discussion)

1. Introduction/ background- Justification means that benefits substantially outweigh the harm/risks i.e. a net benefit.
   - IHA(B) challenges these principles - not justified at present as a medical procedure therefore public dose constraint is too low to perform it at all
   - Generic justification v. individual justification
2. Framing the harms of screening asymptomatic individuals incl. emotional e.g. anxiety
3. Research agenda (later changed to "research" to better fit with the scope, which would include the topics listed below under 3a and 3b)
4. Existing large data sources / registries — e.g. Scandinavia, South Korea
   a. Stratified systematic reviews, ideally with randomized control trials (RCT) with PICO for each of the following intervention & diseases:
      - CT for lung cancer screening
      - CT for coronary calcium scoring
      - CT colonography for colon cancer screening
      - for thyroid cancer screening

[26] *Zorzela L, Loke Y, Ioannidis J et al. PRISMA harms checklist: improving harms reporting in systematic reviews, BMJ 2016;352:i157 http://www.bmj.com/content/bmj/352/bmj.i157.full.pdf and Errata - April 19, 2016 http://www.bmj.com/content/353/bmj.i2229*
[27] *Harris RP et al . The harms of screening: a proposed taxonomy and application to lung cancer screening.JAMA Intern Med. 2014 Feb 1;174(2):281-5.*
[28] *Harris RP, Wilt TJ, Qaseem A; A value framework for cancer screening: advice for high-value care from the American College of Physicians. Ann Intern Med. 2015 ;162(10):712-7*

- ultrasound for prostate cancer screening
- *no intervention/disease proposed for MRI*

b. Constraints put on individual health assessments (IHA) to generate medical reports useful for future research (a linked registry to see downstream effects)
   - Properly consented volunteers who are asymptomatic individuals as quasi-research subjects, medical exposure defined as one that is beneficial for the patient[29]
   - Helsinki Declaration - informed consent for healthy volunteers much stricter than for patients, patients must be separated from healthy research participants
   - Elaborate on the example of the Korean Samsung clinic
   - Respecting the patient's autonomy while also promoting research

c. Gaps and needs

5. Control Systems/ Resources (capital and human)
   a. Regulation - if this phenomenon occurs, it should fit within the proposed guidelines.
   b. Evidence (or lack thereof) not reaching relevant stakeholders?
   c. Governance
   d. Finance
6. Stakeholder Education
   a. patient, presenter, consumer continuum
   b. health care providers
   c. medical students
7. Uncertainty- about benefits, risks/harms, effectiveness of communication, precision of estimates
8. Ethics - equality, , human resources

SEJ presented to the group some ideas about the element composing a framework for justification of IHA based on the outcomes of the stakeholders' workshop (Seoul, Korean, September 2016) and the discussions held so far during the current meeting in Geneva. He mentioned:

1. We will be shifting to talk about overall harm of IHA rather than focusing only on the radiation risks of the use of CT for IHA;
2. We will need to look at the ethical aspects of IHA in more detail (i.e. develop this further in our document);
3. When addressing uncertainty, we may start discussing general uncertainty about benefits and risks/harm and then pick up the additional challenges in terms of uncertainty when dealing with asymptomatic/healthy people;

[29] *There was a debate around whether or not the CTs done for IHA (B) sould be considered as non-medical human radiation exposure done by medical technology (because there is not a medical justification of these CTs), but if they were considered under public exposure, a dose limit would have to be applied and it would not be appropriate. The international BSS includes volunteers under research programme in the definition of medical exposures, no limits apply, eventually dose constraints might be applied and more recently it was suggested using Dose Reference Levels (DRLs) as tools for optimization of doses. If done as medical research it might not have to benefit the patient but lead to general societal and/or psychological benefits – It was concluded that IHA cannot be considered non-medical (ethically this was WHO's position when discussion this issue (e.g. legal, security, migrations, sports medicine) at an IAEA Technical Meeting on non-medical human exposures held in Vienna, Austria, in January 2017)*

4. We started with IHA but many of the issues identified go beyond IHA and are common to other form of screening: this can be discussed in our document;
5. Regarding governance, there are similarities and differences concerning governance of IHA and population screening that we may need to consider/highlight in the document; and
6. Concerning regulation, how we might see/address the RP components? This is unique for radiological tests such as CT (i.e. this component does not exist for other interventions where there is also a need to find ways for preventing overuse/ over-diagnosis, etc). IHA (A) challenges the BSS: we may spend some time talking about the BSS and the RP framework for regulation of medical imaging in asymptomatic people. This RP framework for IHA will have to be acceptable for the community.

The group did not debate these points, and it was in principle agreed that they would be considered for the development of the document,

Clinical research to generate evidence

We need to promote the generation of useful data to rebalance the evidence deficit regarding use of medical imaging for IHA. The group discussed how this could be done and how this might be reflected in the IHA project. Which kind of research? If we could get useful data to further explore potential harms, and also benefits (e.g. not just the individual benefits but societal benefits) we might be in a position to say whether IHA can be accepted/acceptable and under which circumstances. There are very few data about psychological benefits and harms of screening asymptomatic people[30], is "reassurance" an useful end-point to be studied as one of the benefits of the screening that is often mentioned in addition to reducing morbidity/mortality? It has been reported that diagnostic tests for symptoms with a low risk of serious illness do little to reassure patients, although the tests may reduce further primary care visits[31]. It has been shown that women have preconceptions about breast cancer screening that compromise the perception of balance between screening benefits and potential harms[32]. There are some issues related with human rights, which would be different if an individual wishes to undergo IHA (i.e. "screening on demand") or if it is the health care provider who decides to do it (i.e. "opportunistic screening"). Should we consider establishing dose constraints as it is the case for other medical exposures? (e.g. comforters, carers, and in some cases volunteers under research programs). IHA should be properly consented and it has to be an informed consent / informed decision making (what today is referred as to shared decision making about health care). This would require evidence/information about benefits and harms. How to generate this information? Which kind

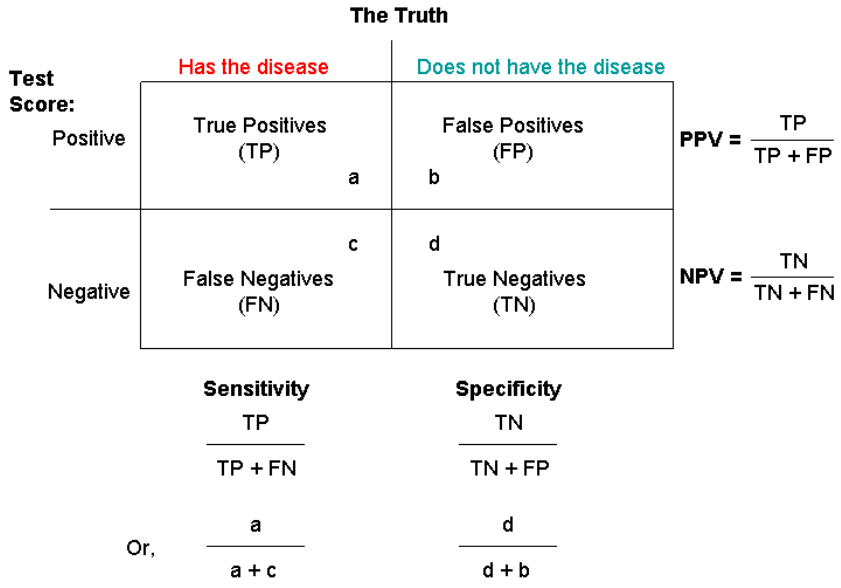
[30] *Rasmussena J, Siersmaa V, Pedersenb J and Brodersen J. Psychosocial consequences in the Danish randomised controlled lung cancer screening trial (DLCST) Lung Cancer 87 (2015) 65–72; Rolfe, A. and C. Burton (2013). "Reassurance after diagnostic testing with a low pretest probability of serious disease: systematic review and meta-analysis." JAMA Intern. Med 173(6): 407-416; Ostero, J., et al. (2014). "Breast cancer screening implementation and reassurance." Eur. J Public Health 24(2): 258-263.*

[31] *Rolfe A and Burton C. Reassurance After Diagnostic Testing With a Low Pretest Probability of Serious Disease- Systematic Review and Meta-analysis. JAMA Intern Med. 173(6):407-416 (2013). http://jamanetwork.com/journals/jamainternalmedicine/fullarticle/1656539*

[32] *Henriksen M, Guassora A and Brodersen J. Preconceptions influence women's perceptions of information on breast cancer screening: a qualitative study. BMC Res Notes (2015) 8:404*

of research? RCTs? Any research protocol would have to consider ethical principles (Helsinki Declaration) and the informed consent for healthy people is stricter than for sick people. Who should/could conduct such research? It could be done at local level e.g. collecting data at the hospital, and done by a researcher e.g. JD has a PhD student who is interested in conducting this kind of clinical research linked to public health. In any case, this part of the project would take much longer than the document itself so we will have to make a statement upfront in the document that there is no evidence about benefits and harms of IHA. This chapter on research should come before the chapter where governance and regulatory aspects are addressed. This chapter shouldn't be entitled "research agenda" because it will go beyond just listing the priorities, it will not be the agenda for research, although the research priorities will be identified. This chapter should refer not just about the data generated at the level of the "screening unit" but to the entire screening cascade: Harris addresses this in his abovementioned paper about taxonomy of harm.

JB mentioned the Bayesian paradigm[33] use by clinical investigators for medical data analysis and reporting the results of clinical research (i.e. statistical inference for the explanation of data and the extraction of information). JB used the example of the tables used for assessing sensitivity, specificity, positive predictive value (PPV) and negative predictive value (NPV) of a diagnostic test (see figure below): under which circumstance would you would accept false positives (e.g. serious infectious disease such as Ebola) vs. when you would really want to minimize the false positives? (e.g. lung cancer). The pre-test probability vs post-test probability have to be considered (i.e. the probabilities of the presence of a condition/ disease before and after the diagnostic test, respectively.



[33] *The Bayesian paradigm states that probability is the only measure of one's uncertainty about an unknown quantity. In a Bayesian clinical trial, uncertainty about a quantity of interest is described according to probabilities, which are updated as information is gathered from the trial. See https://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm071121.pdf*

Then the group discussed the sources of data. The Korean would be a valuable source of data for the use of CT in IHA as a case study. In other countries there maybe data about PET-CT (e.g. in China, Japan PET-CT is used for IHA). We should consider different scenarios. Are there differences between patients vs. presenters, consumers, citizens? Different terms are used but, what does it mean practically? They definitively become patients once a test is positive. The information should be rendered well ahead of the patient presenting for the exam, by which time they have already made a decision. We need to discuss these different scenarios/environments.

There is an opportunity for communication in the dialogue between:

- Patient <-------> doctor ----> diagnosis increases the prevalence of disease
- Consumer <----> provider ----> screening aims to early detection but diagnosis comes later

We should get a good narrative including the ethical and the human rights perspectives. For instance it was recently suggested that smokers who undergo a CT scan for lung cancer screening are more likely to quit smoking, which disputes the previous belief that a negative lung cancer screening screening would result in a sort of "licence to continue smoking"[34]. The possible effects of lung-cancer screening on smoking cessation should be considered and informed. To ensure that individuals are fully informed is an ethical requirement which is also in the BSS. If there is a booking system this can be requested in the informed consent form that has to be signed in advance. There are opportunities for advocacy during the process of dialogue/information, keeping in mind that there is always an emotional content in the relationship between the patient and the health care provider. There was a discussion around generic education/information (e.g. general public/ the community) vs. individual education/information (communication with the individual patient/consumer) ---who should educate? The provider? What about: the government, the health authorities, the professional societies?. Full information regarding benefits and harms of IHA has to be provided to the patient/consumer – this is already provided for broad-based population screening programs. The issue of IHA advertisement was raised and it was agreed that IHA is a very low priority for governments and they do not act against/ regulate IHA advertisement. Luxembourg and Belgium are case examples of advocacy campaigns coming from the government, in countries where imaging exams were highly used/advertised. Regarding regulation on advertisement: consider involving the advertising standards agencies (police inappropriate claims in some countries). e.g. a national advertising standards authority with a code of advertising practice, EASA as an example of advertising self-regulation in Europe[35]. Possible strategies for preventing overdiagnosis policy interventions were discussed, targeting the health system, the health authorities, the health care providers and the patients/ consumers/ community. Do we have numbers about % of over-used tests? Examples of communication strategies to explain

[34] *Ashraf H, Saghir Z, Dirksen A, et al. Smoking habits in the randomised Danish Lung Cancer Screening Trial with low-dose CT: final results after a 5-year screening programme, Thorax. 2014 Jun;69(6):574-9; Brain K. et al. Impact of low-dose CT screening on smoking cessation among high-risk participants in the UK Lung Cancer Screening Trial, Thorax (2017) http://thorax.bmj.com/content/thoraxjnl/early/2017/07/14/thoraxjnl-2016-209690.full.pdf ; and Lococo G, Cardillo G and Veronesi G. Does a lung cancer screening programme promote smoking cessation? Thorax on line http://thorax.bmj.com/content/thoraxjnl/early/2017/07/26/thoraxjnl-2017-210621.full.pdf (2017).*

[35] *The European Advertising Standards Alliance (EASA) is the single authoritative voice on advertising self-regulation issues to help ensure that ads are legal, decent, honest and truthful and to create consumer trust in advertising and in brands http://www.easa-alliance.org/ .*

overdiagnosis or overtreatment have been published such as the BMJ paper "Walking the tightrope: communicating overdiagnosis in modern healthcare"[36]. Other examples are:

1. Community back pain campaign (1997-99)
2. Patient decision aids
3. Changing disease terminology approaches
4. Citizen juries

Forthcoming conference on Preventing Overdiagnosis (POD2017)

An international conference on Preventing Overdiagnosis- Towards Responsible Global Solutions (POD2017) will be held in Quebec, Canada on 17-19 August 2017 www.preventingoverdiagnosis.net . WHO participated in the previous conference POD2016 held in Barcelona, Spain, in September 201737. WHO has submitted a proposal to POD2017 for a seminar entitled " Imaging asymptomatic people: are we doing more good than harm?", which has been accepted and will take place on 19th August 2017. We wish to share with the IHA working group the proposed structure, lectures, key messages and working procedures for this seminar, and get their opinions/suggestions. This seminar will provide an opportunity to present the WHO IHA project and collect feedback from some relevant stakeholders who will attend the Conference. JB summarized the history, scope and purpose of these international conferences POD, which started in 2013 as follows:

1. POD2013, Darmouth, USA, hosted by the Dartmouth Institute for Health Policy and Clinical Practice;
2. POD2014, Oxford, UK, hosted by the University of Oxford's Centre for Evidence Based Medicine
3. POD2015, Bethesda, USA, hosted by the National Institute of Health (NIH).
4. POD2016, Barcelona, Spain, hosted by the Agency for Health Quality and Assessment of Catalonia (AQuAS)
5. POD2017, Quebec, Canada, hosted by the Quebec Medical Association (QMA)

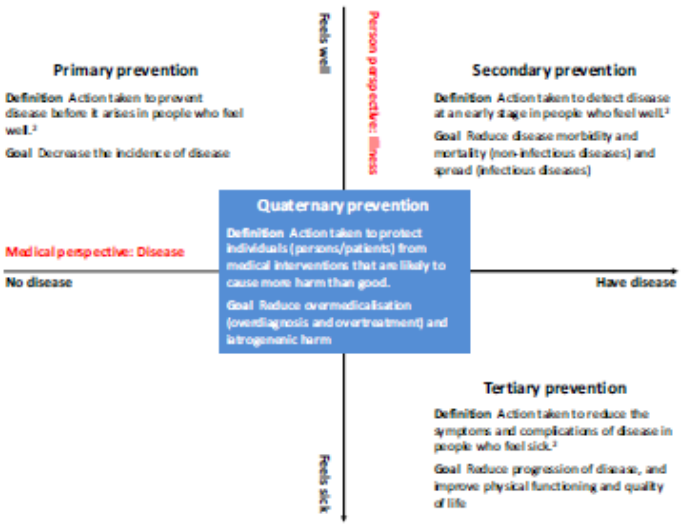
What does OVERDIAGNOSIS mean? JB reminded the concepts of "illness" and "disease" in the context of the 4 different kinds of prevention and the heterogeneity of cancer growth patterns which has an impact in overdiagnosis (see the 2 figures below[38]) explained the meaning of this term, the differences with other related terms and recommended some additional resources for further reading[39].

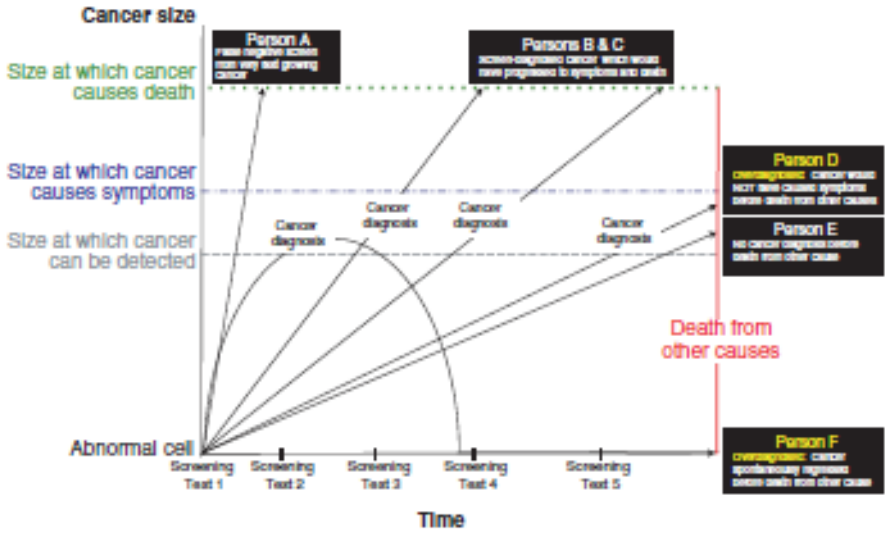
[36] *McCaffery K. et al "Walking the Tightrope: communicating overdiagnosis in modern healthcare" BMJ 2016;352:i348 http://www.bmj.com/content/bmj/352/bmj.i348.full.pdf*

[37] *Laragh Gollogly (WHO) participated as invited speaker in a debate on "Drawing the line between Health and Disease: who and how to define disease?"*

[38] *Brodersen J, Schwartz LM, Woloshin S. Overdiagnosis: how cancer screening can turn indolent pathology into illness. APMIS, 122(8):683-9, 2014.*

[39] *BMJ papers on "Too much medicine" e.g. Heath I. How medicine has exploited rationality at the expense of humanity. BMJ 2016;355:i5705 http://www.bmj.com/content/bmj/355/bmj.i5705.full.pdf; Book on "Overdiagnosed: Making People Sick in the Pursuit of Health" by Gilbert Welch ISBN-13: 978-0807021996 ISBN-10: 0807021997; Book "Selling Sickness: How the World's Biggest Pharmaceutical Companies Are Turning Us All Into Patients", by Alan Cassels and Ray Moynihan, 2006; Book "Seeking Sickness: Medical Screening and the Misguided Hunt for Disease" by Alan Cassels, 2012; "Users' Guide to the Medical Literature - A Manual for Evidence-Based Clinical Practice" by JAMA Evidence, 3rd Ed G.*





Guyatt, D. Rennie, M.O. Meade, and D.J. Cook. 2015, American Medical Association, ISBN 978-0-07-179071-0. Downloadable chapters and educational slides available at http://jamaevidence.mhmedical.com/book.aspx?bookId=847; "Show more spine" website for the campaign http://showmorespine.com/; Website "When evidence says no and doctors say yes" https://www.theatlantic.com/health/archive/2017/02/when-evidence-says-no-but-doctors-say-yes/517368/?utm_source=nl-atlantic-daily-022217; Melanda E and Brodersen J. Why several truths can be true. Scandinavian Journal of Primary Health Care, 2016 http://dx.doi.org/10.1080/02813432.2016.1207146 (2016); Harris, R. P., et al. (2015). "A value framework for cancer screening: advice for high-value care from the American College of Physicians." Ann Intern Med 162(10): 712-717; Brochure "What's in a Scan?" on how well are consumers informed about the benefits and harms related to screening technology (CT and PET scans) in Canada- by Alan Cassels, Wendy Armstrong, Jaclyn van Wiltenburg - Canadian Centre for Policy Alternatives (CCPA), 2009; Pathirana T, Clark J and Moynihan R. Mapping the drivers of overdiagnosis to potential solutions. BMJ 2017;358:j3879; Guidelines of the Canadian Task Force on Preventive Health Care https://canadiantaskforce.ca/; Recommendations of the US Preventive Services Task Force https://www.uspreventiveservicestaskforce.org/; series of papers around "To Screen or Not to Screen, That Is the Question" e.g. To Screen or Not to Screen, That is the Question: A Consumer's Guide to Health Screening (no link available); http://journals.sagepub.com/doi/pdf/10.1177/0003319717704324 , http://www.sciencedirect.com/science/article/pii/S0022522315002974?via%3Dihub , and http://cjasn.asnjournals.org/content/10/4/541.full.pdf+html .

- **Over-diagnosis** could be defined as the diagnosis of a disease that will never cause symptoms or death during a patient's ordinarily expected lifetime. However, there is no formal/agreed definition of overdiagnosis[40]. Overdiagnosis includes deviations, abnormalities, risk factors, and pathology, that never in themselves will cause symptoms, morbidity, or death, many plead separate definitions for each condition —> unclear definition —> e.g. overdiagnosis of mental conditions. It is not an incorrect assessment of the disease (i.e. this differentiates overdiagnosis from "misdiagnosis"- see below). Overdiagnosis occurs when a diagnosis is "correct" according to current professional standards but when the diagnosis or its associated treatment has a low probability of benefiting the person diagnosed. It can be caused by a range of factors such as use of increasingly sensitive tests that identify abnormalities that are indolent, non-progressive, or regressive (overdetection) and/or expanded definitions of "disease".
- **Misdiagnosis** is an incorrect diagnosis, which may lead to overdiagnosis
- **False Positive** refer to a test result which wrongly indicates an abnormality or suggests that a particular condition or disease is present. Patients may have to live with this knowledge/uncertainty for varying periods of time (i.e. from seconds to years).
- **Over-utilization** / **Over-use** – it refers to the unnecessary utilization of medical product of any kind (e.g. medicine, technology). This does not lead to overdiagnosis but it can be related with it.
- **Over-treatment** – (i) when the best available evidence shows no beneficial effect of a treatment, but it is not related to overdiagnosis, and (ii) when it is implemented as a consequence of overdiagnosis e.g. prostate cancer.

The focus of POD conferences is overdiagnosis, although often the submitted papers refer to the other forms of inappropriate health care mentioned above. The idea for the 90-minute WHO Seminar is to start setting the scene with 4 talks to present (i) MO to say why WHO is conducting this IHA project and which are the WHO's views about IHA, (ii) SEJ to explain radiation risks, radiation protection, existing RP regulatory frameworks, (iii) somebody TBC to provide an example/national experience and (iv) JB to provide an overview of IHA and overdiagnosis using the example of lung cancer screening. This first session would be followed by small group discussions around question we would propose (a kind of "focus groups"), to finalize with report to the plenary, general discussion and conclusions/ take home messages (see Appendix 4- seminar agenda). We could identify relevant questions that can help us in the development of our IHA framework document. We do not know how many people will attend the seminar since there will be several simultaneous parallel activities, but the expected audience of the whole Conference would be around 300 -400 participants. The profile of participants is usually GPs, clinical researchers, scientific journalists, experts from social sciences and patient's advocates. It is important to listen to them and see what do they think WHO can do to help prevent overdiagnosis in the context of the use of CT for IHA, and in general. CT is just a case for us, but the dilemmas we are addressing are present in other technologies too. Sandor Demeter would be a good candidate to be invited as speaker for the session I item (iii)--→ MP will contact him to explore willingness and availability. The working group agreed with the

[40] *Carter SM, Rogers W, Heath I, Degeling C, Doust J and Barratt A. The challenge of overdiagnosis begins with its definition, BMJ 2015;350:h869* *http://www.bmj.com/content/bmj/350/bmj.h869.full.pdf*

suggested approach for the Seminar in Quebec and made some comments/suggestions around the same proposed schedule. JB announced that the next POD Conference (POD2018) will take place in.Copenhague, Denmark, hosted by the University of Copenhagen where he works. This is an opportunity for the WHO European Regional Office (EURO) to be involved, since it has its premises in Copenhague. WHO could facilitate the dialogue and potential involvement of the Ministry of Health of Denmark. We could present our framework document/paper, we may consider organizing one or two seminars? WHO is collaborating with WONCA (NGO in official relations with WHO) in this IHA project, WHO was invited to a symposium on quaternary prevention organized by WONCA Europe to be held in September 2017 in Italy. These and other topics will be further discussed to define the level and scope of the WHO participation in this event POD2018.

WebEx session with the participation of NECA and BfS

During the second half of the morning the working group was expanded with the remote participation (through WebEx) of Juergen Griebel (JG) from the German Federal Office for Radiation Protection (BfS); Youngsung Lee (YL) President of Korean NECA, Miyoung Choi (MC) from the NECA Division of Health Technology Assessment Research; Insoon Choi (IC) from the NECA Division of Economic Evaluation Research; Jooyeon Park (JP) from NECA Office or Research Planning and Coordination and 5 more colleagues also from the NECA Office or Research Planning and Coordination (see Appendix 3: List of participants). MP provided a short summary overview of first day's and second day's discussions. A preliminary draft proposing an outline for the WHO framework document had been circulated to all the day before as a basis for the discussions during the WebEx session. The following agenda was suggested:

1. NECA's views on the project
2. JG's and BfS views on the project
3. Discussion of the preliminary draft document (feedback/ comments)

YL expressed his support to NECA international cooperation activities in general, and to this collaboration between NECA, KSR and WHO for this specific IHA Project. MC made a summary of the most recent activities of NECA relevant to the topic of IHA. As a follow-up of the WHO IHA Stakeholders' Workshop held in Seoul, South Korean in September 2016, which was jointly hosted by KSR and NECA, a NECA Round Table Conference ("NECA resonance") was held on 3rd November 2016. It was jointly organized by NECA and KSR and conceived as a consensus meeting on issues on healthcare services and policy and it included stakeholders such as scientists, radiologists, clinicians, policy makers, consumers (patients) and media representatives (total: 15 participants). During this round table 3 key questions were proposed for discussion:

- Q#1: When CT exam is used in individual health assessment, what information should we provide to the presenters, and are we providing accurate information before the exam?
- Q#2: Is there enough scientific evidence on the appropriate use of CT exams in individual health assessment?

- Q#3: What are the improvements to be made for the appropriate use of CT exams in individual health assessment in Korea?

As a result of this, a Consensus Statement on the Appropriate Use of CT Exam in Individual Health Assessment was produced (see full text of the statement in Appendix 5). The consensus statement emphasizes the need to provide accurate information to the presenters on the potential risks and benefits by the healthcare providers. It is therefore imperative that healthcare providers be equipped with adequate knowledge of the risks and benefits of CT use in IHA. NECA has disseminated this statement at national level, including a media release on 8th December 2016. Based on the NECA consensus statement, the KSR clinical imaging practice guidelines and their survey results, the Korea Consumer Agency (KCA http://english.kca.go.kr/brd/m_11/list.do) published in June 2017 a request about informing potential harm especially contrast media related adverse events in order to prevent/reduce adverse events due to contrast media related with CT screening. There was a discussion about revision and standardization informed consent format including routine explanation on contrast media by medical staff and about the rationale and feasibility of mandatory skin test for preventing adverse events of contrast media.

Regarding follow-up actions, NECA agrees on the importance of clinical data linkage and the need to strength evidence. Almost of hospitals and health assessment institutions in South Korea have electronic medical records (EMR) systems. NECA can link the healthcare "big data" for purpose of evidence research/retrieval. There are some limitations e.g. there is an Act in South Korea about personal information security. Autonomous involvement is needed from private health assessment institutions. Literature reviews have been conducted for assessing benefits and harms. Experts were involved during the process of development of the KSR imaging referral guidelines to consider also benefits and risk of imaging asymptomatic people. They could not find the evidence that was needed, evidence about harm is not available in RCTs, they are very interested also in looking at case-control studies and other observational studies. The reviews were not systematic and they also considered expert opinion. The group in Geneva asked NECA whether these reviews had been published anywhere: NECA responded that they are not yet published in peer reviewed English-speaking journals. This information was published in a NECA publication/journal but it is in Korean. There was a question about the literature search: was it done only in Korea are English? Or both? The search was done in English. There was an agreement on need for systematic reviews: —> NECA concluded that evidence is sparse on the issue, it is based on a literature search and expert opinion.

JG raised the question of how to achieve/gather some kind of evidence? and which are the steps to follow in order to get it? Formal systematic research guidelines on what are benefits and harms - must be transparent and done in a systematic way following specific rules —> it would be helpful for health ministries and policy makers. We should discuss this in one of the chapters of our framework document. He congratulated NECA for the very good- excellent work going on and the plans for improving documentation, clinical data and links. Are there any other plans to perform this kind of evaluation? In particular in the IHA area, the screening experience of the Samsung Medical Center is very rich including both thyroid cancer screening with ultrasound and other cancers screening using CT and PET. He acknowledged that this is a delicate issue which involves also citizen groups and confidentiality. But this is a very important source of data.

NECA colleagues agreed that they may consider having a meeting on this specific topic. Private clinics cannot easily open their "big data" and the process is going to be very slow. Thyroid cancer screening has decreased in Korea after the epidemics crisis which triggered an intensive work on advocacy and awareness raising about overdiagnosis in particular by the Physician Coalition for Prevention
of Overdiagnosis of Thyroid Cancer[41]. They have been collecting data on mortality and incidence of thyroid cancer, and also stages of disease. What kind of data could be provided for the IHA project, in case thyroid cancer screening is included? In the collaboration with US they could link the "big data" but there are some conditions: it has to be part of national research, they need to have registries of diseases and status of the diseases, health insurance data, national health care system data about incidence/mortality, etc. This is encouraging and suggests that similar activity in the other areas of IHA could also be successful- but we need evidence to communicate. The Korean health care system is very unique--→ in general doctors are keen to do too much medicine, and this might be promoted by financial incentives.

JG asked NECA colleagues whether they had considered how to assess downstream costs of detected lesions (identify the downstream interventions and estimate the associated costs for the health care system i.e. to assess the efficacy). They responded that indeed they have considered doing this; most of the institutions are inside the biggest hospitals and the problem is that large hospitals in Korea are autonomous - ongoing process of conglomeration/streamlining. It may be difficult but it's worth a try (e.g. to assess long-term survival, detection rates, other end points). This first non-systematic review was a small starting, but a great step to move forward.
The discussion moved next to the proposed draft outline of the framework document. There was a general consensus that the main target audience of this framework document will be policy makers, researchers, academics and practitioners. The section titles are not yet fixed and they need further refinement once the outline has been agreed- but they are a very good starting point.

In Chapter 1we will widen the concept of harm from radiation risk, and Chapter 3 will refer to existing regulations, it will review what has been done.

JG thinks that Chapter 2 must be a review of previous research, setting priorities for future research. This may require a future meeting on organization of collaboration/coordination for research, to discuss resources for systematic reviews and fundraising and how can WHO provide a platform for global collaboration. The title of Chapter 2 needs to be broadened- why proposing the term "research agenda" ? Whose research agenda? (i.e. whose agenda?). This chapter will not present results, it will rather talk about the needs for research that has to be done. It is good to have a separate section about the 'big data", which is probably more "attractive" at this time. It will be a kind of proposal for research (in fact based on this chapter such a proposal might be further developed as a stand-alone material to support fundraising and resource mobilization (e.g. focusing first on one single topic such as harms from colo-rectal cancer screening, with examples in more generic way). However, it was agreed that having a WHO approved/ published research

[41] *Ahn HS, Kim HJ, and Gilbert Welch H. Korea's Thyroid-Cancer "Epidemic" — Screening and Overdiagnosis; N Engl J Med 2014; 371:1765-1767 http://www.nejm.org/doi/full/10.1056/NEJMp1409841 & Ahn, HS and Gilbert Welch H. South Korea's Thyroid-Cancer "Epidemic" — Turning the Tide; N. Engl J Med 2015; 373;24 (correspondence to the editor) http://www.nejm.org/doi/pdf/10.1056/NEJMc1507622*

agenda would attract funding agencies (this has been the successful experience with the WHO research agenda on radiofrequency fields (RF research agenda[42]). This can be included in Chapter 2 as priorities for future research and then this can be a stand-alone derivative product that can be refined/ further developed and separately published. It would be an additional product in the "toolkit" that was proposed earlier this week. Is there an evaluation process of the retrieved evidence? , need for approval of the review process: what is the size of the evidence we need? (Probably this would be more linked to Chapter 5 on uncertainty?). International research collaboration is possible. JB supports this idea and JB could involve one of his PhD students, M Prokop could be involved from his University and NECA would be definitely pat of this. NECA volunteered to conduct literature reviews and try to seek some more funding ---> dividing the PICO questions in each area. JG is interested and willing to setting up a teleconference (TCon) specifically focused on this research topic and JB is keen to propose a meeting on this subject. Is the next step within WHO? How will this be funded? . WHO can provide a platform to facilitate global collaboration on IHA research.

Chapter 4 will refer to what the patient/consumer brings to the situation, when/where it is a relation between a patient and a doctor and where/when it refers to a consumer and a provider. We want to discuss these issues linking them to a professional consideration, with the implications in terms of education and training of stakeholders including both: public education and professional education.

Chapter 5 will be the uncertainty chapter. We all agree that we should stop hindering the notion of uncertainty is assessing benefits and harms. This is the chapter to talk about it in a transparent way. We can discuss here the Bayesian paradigm approach to statistical inference[43].

SEJ said that if we are going to consider IHA as medical exposures (which seems to be the case), then we have to consider these studies as "research studies" so we get the same standards we want for medical exposures under population screening or research. We should not only look at the point where the CT is prescribed and performed, we should look at the entire care pathway. Chapter 6 will address all the biomedical ethical considerations and how do they apply to the IHA scenarios.

Next steps

Regarding the composition of the developing group, basically the core group which has been working on this project from the beginning will continue and it will be expanded with a few more experts who contributed from different perspectives/disciplines to the Korea workshop and to this Geneva meeting. Need to identify potential gaps in terms of expertise/ profiles/disciplines to be covered, taking into account external experts as well as WHO staff from relevant departments/ programmes.

[42] *WHO, 2010. Research Agenda for Radiofrequency Fields* http://apps.who.int/iris/bitstream/10665/44396/1/9789241599948_eng.pdf .
[43] *Brodersen J, Schwartz LM, Woloshin S. Overdiagnosis: how cancer screening can turn indolent pathology into illness. APMIS, 122(8):683-9, 2014.*

WHO will involve technical officers from relevant WHO programs when/if necessary at any stage of the development of this document e.g. AI will be closely involved from the beginning as the responsible officer for WHO's work on criteria for cancer screening, and other colleagues from ethics & health, health financing & health economics, UHC, patient safety, people centered integrated health care, medical devices, IARC, etc will be invited to contribute to the drafting and /or review of relevant paragraphs/sections. The experts who participated in the Munich meeting and have expressing their interest in continuing being involved in the project could be invited to contribute as corresponding members (e.g. as peer reviewers), taking into account geographical and gender balanced representation).

We will need a leading writer for the document- based on the successful experience with the IHA JACR paper, we consider JM from Ireland to play this role of putting together the different pieces of work which will be produced by the leading authors and co-authors of each chapter. JM will work together with MRP who will provide the WHO Secretariat services.

As a general approach, shortly after the meeting it was discussed by email to produce a document with a text of overall length about 50 pages (based one page of A4, 1.5 spacing, approx = 350 - 400 words)[44].

A preliminary task distribution for drafting would be as follows (the proposed leading authors of each chapters have been underlined):

- Introduction: *MRP* 2 pages
1. Chapter 1: framing, scope *JB, MRP* 6 pages
2. Chapter 2: research *JB, MP*, *MC* (NECA), other researchers TBC[45] 8pages
3. Chapter 3: regulation, governance, financing *SEJ*, *JG*, *SEJ*, *EF*, other/s?[46] 8 pages
4. Chapter 4: stakeholders education *MRP*, *MM* *10* pages
5. Chapter 5: uncertainty *JB/JM, and MP* 8 pages
6. Chapter 6: ethics & screening *JM and MP/WHO* 8 pages

- Overall Editing (Leading writer Jim)

With regard to target dates, a proposed approach was discussed by email shortly after the meeting[47]:

1. Outline of topics (e.g. one page of bullet points for each chapter) by the end of September by the leading writer;

[44] *Although a 50-page document would allow relatively short contributions for each chapter, doubling the length of each chapter would result in a 100 page document which would probably be too long. However, since this was an exchange of ideas done by email shortly after the meeting, it still needs feedback in particular from the leading authors of the chapters regarding chapter lengths and task distribution.*
[45] *Eventually other researchers may be included e.g. Russell Harris has been later contacted and confirmed his willingness to contribute, other/s?*
[46] *Rachel Moorin, who attended the workshop in Seoul, expressed interested in contributing in the area of health financing*
[47] *Subject to revision and fine tuning based on feedback from the leading authors and co-authors of the chapters regarding timeline for deliverables.*

2. Review and contributions from the leading authors and other co-authors of each chapter by end of October;
3. First preliminary working draft (v00) put together by the end of November.
4. Review/comments on the draft v00 from all working group members by end of December

Most of the work will be done from home, with e-mail interaction, besides the TCons, WebEx sessions and face-to-face meeting/s. Which will be the next steps? Which one will be done by/at WHO?

It was agreed to continue interacting by email in the forthcoming weeks to share the meeting minutes, consolidated as a meeting report to help keep records of what was discussed during these 3 days. MRP will create a virtual space as a platform for share documents, maintain and update a library of references/relevant papers, and exchange ideas (e.g. EzeCollab or similar) in order to avoid overwhelming email account with attachments.

MRP thanked all participants for their instrumental contributions, and for their commitment to cooperate in this project and close the meeting looking forward to continuing this cooperation.

Appendix 1: Preliminary proposal for the structure of the document

Chapter 1: Define and introduce scope
a) Framing/emphasising the harms of the practice of imaging for IHA - ALL possible and probable harms
b) Terminology: "screening upon demand" ;. "opportunistic screening" vs. “organised screening” , screening vs early detection/diagnosis)

Chapter 2: What evidence exists and what evidence (empirical and systematic research) needs to be generated (shaping the research agenda)?
—> harnessing research and creating research agenda two of the WHO’s core functions - determining what research is relevant for public health (identifying methods, gaps, and needs), can help member states get funding to establish research programs
—> towards development of evidence-based policies and implementation
a.) existing sources of data - big data (already have data for Scandinavia and S. Korea)
b.) systematic reviews of literature -
— Korea/NECA offered to contribute using national health care insurance registry - can be matched with hospital registries, with data including incidence, mortality, and stages of the disease , Dr. Brodersen offered to contribute data on current colorectal screening study
— guidelines on this would be useful to member states - WHO provides a platform for global cooperation, and strives to avoid duplication.
—funding? - WHO has to find the funds if guidelines are being produced (contracting external research) but sometimes it is done independently
—low quality and little evidence hence prior studies and sources of data should be analysed - we’re planning to state what the gaps are but not perform the research
—Copenhagen systematic reviews of colorectal screening w/ Cochrane and US Preventive Task Force however these lack description of harms
— Need to broaden the problem of medical procedures on asymptomatic individuals
—> Not restricted to CT- also MRI, PET, ultrasound, self-testing (an expanding market, especially online)
— Thyroid cancer: incidence and mortality yield 1 kind of data, but data on stages of disease could improve quality of research
c.) establishing linked registries (able to demonstrate downstream effects)
d.) identify research gaps and need for greater data; if the practice is allowed, then record the exams
i. Example of PICO question “What are the benefits and harms of the use of CT in asymptomatic people for IHA?” Need to identify particular imaging modalities and pathologies? (e.g. chest CT for lung cancer screening?, abdominal CT for colon cancer screening?, heart CT for coronary calcifications? In some countries (e.g. China) PET CT is being used in IHA
e.) impact of harm from overdiagnosis and false positives
f.) limit to ionizing radiation?, or at least include case study of thyroid ultrasound? Prostate ultrasound? Synergies with IARC work. Carotid ultrasound/Doppler also affects a very large patient population.
i. for CT for IHA, perhaps the most complete data available are for lung CT

Chapter 3: regulation/governance and finance/resources (human and financial); equity-equality - special focus on documentation and evaluation of the process, need for appropriate review process (could also be in ch.5) - if this is viewed as medical procedures then we have to draw parallels, almost consider them as research studies as if being done on a population basis - Juergen (Germany), Steve (Public Health England), and Rachel Moori (Australia) as the authors with help of Seung Eun Jung (NECA Korea)

a.) Regulatory frameworks

i. Restricting and/or managing access

iii Discussion about Justification, (generic, individual) Background: Justification means that benefits substantially outweigh harms/risks (net benefit)

IHA(B) challenges the principles and, if the procedure isn't justified: it is not a "medical procedure"? (or medical exposure"?). This has to be discussed because the evidence-base is not there now but: what if it is not justified now but may be in future?

-generic justification vs. individual justification

-existing clinical imaging referral guidelines (Updated (8th edition) iRefer Clinical Imaging Referral Guidelines of the Royal College of Radiology now includes new section on imaging of asymptomatic individuals (e.g. CT for lung cancer screening; abdominal ultrasound in asymptomatic men > 65 to assess for abdominal aortic aneurysm)

b) Financial section

I health financing, issues related with resources (human and financial)

ii powerful financial interests mitigating against best practices

iii. financial models (examples/case studies e.g. presentation from Rachael Moorin (Health Systems & Economics/School of Public Health/Australia, Korean case study base on consensus statement & related actions)

Chapter 4: Education of all stakeholders

The information on evidence (or absence of evidence?) about benefits and harms is not reaching relevant stakeholders (general public as well as professionals, but also health authorities are not aware of this issue, other stakeholders…)

—> Ethical considerations that arise for each of the following stakeholders:

a.) patients/presenters/**consumers (biggest problem)**

b.) healthcare providers

d.) medical students

e) other/s

Chapter 5: Uncertainty --> about ---> benefits/effectiveness --> vs. risks/harm

--->precision in the estimates

In this chapter we will not be able to present numbers/percentages but at least identify sources of uncertainty and shortly describe/explain each of them

-To acknowledge that uncertainty is higher when dealing with diseases with low incidence and good prognosis (paper from... (John)

-Specific mortality will always be biased (over/underestimation in stated cause of death)

- Immediate impact on how information is presented to policymakers : level of uncertainty needs to be clearly stated upfront

Benefits (chart on no decrease in mortality with FOBT for colon cancer)
Harms; we are looking for "small" absolute effects (need to explain how this impacts uncertainty)
-What are the sources of uncertainty in attempting to quantify benefit vs. harm?

e.g. COCHRANE review on mammography screening. High-quality trials vs lower quality trials report very different numbers, ranging from a respective 7% decrease in mortality to 29%.

Chapter 6: Ethical considerations (including gender, human resources, equity)
This chapter will review/discuss the ethical issues identified (e.g. JACR paper, Seoul meeting report) plus others
- Including issues that arise in other 5 chapters - may/may not need this as a separate Ethics chapter?
- consideration of human rights
- collaboration of Jim Malone, John Brodersen, and WHO ethics experts

Appendix 2: Meeting agenda

PROPOSED MEETING AGENDA

Wednesday 12th July 2017

09:30h Opening

- Welcome address
- Introduction of participants
- Declaration of interests
- Project overview
- Scope and purpose of the meeting
- Working procedure and expected outcomes
- Q& As

09:45h Update on WHO activities relevant to the Project (i)

- Public Health Ethics Consultation Group
- New WHO guidelines on cancer screening
- Resolution WHA70.12 "Cancer prevention and control in the context of
- an integrated approach"
- WHO guidance on public health interventions to manage sunbeds
- Health financing for universal coverage
- 3rd WHO Global Forum on Medical Devices
- Quality Universal Health Coverage

11:00h Coffee break

11:30h Brainstorming on the policy brief/guidance document

- Purpose of the document
- Scope
- Target audience
- Type of publication (*e.g. format, length, general structure, other/s*)
- Key points to be considered for publication *(WHO policies and procedures, other/s)*

- Development group *(core expert group composition, leading writer, co-authors, other contributors/reviewers)*
- Working procedure *(roles & responsibilities, e-work, other/s?)*
- Expected time frame *(any "key" date/event to be considered for launching?)*
- General group discussion on the development process

12:30h Lunch break

13:45h Building upon the outcomes of our previous work

- Munich meeting 2014 *(overview of the outcomes as reflected in the IHA JACR paper)*
- Seoul workshop 2016 *(review of outcomes, conclusions and proposed actions based on the meeting report)*
- What is relevant for the policy brief/guidance *(what should be included/addressed, how)*
- Drafting a list of topics *(categorizing, prioritizing)*

14:45h Coffee break

15:15h Content of the IHA policy brief/guidance document

- Proposed outline for the document e.g.:
  - *title*
  - *executive summary*
  - *introduction*
  - *issues identified*
  - *policy options*
  - *research needs*
  - *discussion*
  - *conclusions*
  - *boxes and sidebars*
  - *tables, graphics*
  - *take home messages/ open questions*
  - *references*
  - *case studies and/or other annexes?*
- General group discussion on the technical content of the IHA paper

17.30h Wrap up and preparation of Day 2

17:45h Adjourn

Thursday 13th July 2017

09:00h Recap of first day's discussions

09:15h – Update on WHO activities relevant to the Project (ii)

- WHO framework on integrated people-centred health services
- Patient safety and quality- the global summit 2017 and the PFPS network

Working group drafting session
(start working in small sub-groups on specific sections of the document)

10:45 h Coffee break

11:15h Working group drafting session (cont.)
(continue working in small sub-groups on specific sections of the document)

12:30h Lunch break

13:45h Report back to the group on the outcomes of drafting session
– *Report from small sub-groups, general group discussion,*

14:45h Coffee break

15:15h Putting together a preliminary draft/outline of the document
(further editing work,putting together a preliminary draft/outline of the document)

17.15h Wrap up and preparation of Day 2

17:30h Adjourn

Friday 14th July 2017

09:00 Forthcoming seminar on " Imaging asymptomatic people: are we doing more good than harm?"
(International Conference on Preventing Overdiagnosis, August 2017, Quebec, Canada: working group feedback collection on key structure, lectures, key messages)

10:30h WebEx session with NECA
(recap of first and second day day's discussions, NECA's views on the project, discussion of the preliminary draft document, feedback/ comments)

11:30h Coffee break

11:50h Session 11: Working group drafting session
(working in small sub-groups to review/revise/further develop specific sections of the documentbased on the outcomes of sesión 10)

13:00h Lunch break

14:15h Session 12: Report back to the group and general group discussion,
(putting together a draft v00 of the document)

15:40h Coffee break

16:00h Session 9: Final discussion

Proposed roadmap for 2017-2018

- Actions, task distribution
- Deliverables, timeline, virtual/physical meetings
- Next steps until final publication

- AOB (free miscellaneous points)

- Closing remarks, wrap-up

16.30 Meeting ends

Appendix 3: List of participants

LIST OF PARTICIPANTS

John Brodersen
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Matthias Prokop
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Miriam Mikhail[48]
RAD-AID International
Geneva, Switzerland

Juergen Griebel[49]
Federal Office for Radiation Protection (BfS)
Neuherberg, Germany

[48] Rapporteur of this meeting, with the collaboration of Ms Roxana Lette
[49] Through WebEx

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[50] Through WebEx
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Ronald Johnson
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Dorjsuren Bayarsaikhan
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Fahdi Dkhimi
Department of Health Systems Governance and Financing
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Apologies:

Eva Godske-Friberg
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Østerås, Norway

Appendix 4: Consensus statement from NECA Resonance for the Appropriate Use of CT Exam in Individual Health Assessment approved in November 2016[59]

Question #1: When CT exam is used in individual health assessment, what information should we provide to the presenters, and are we providing accurate information before the exam?

- When CT exam is used in individual health assessment, there are **potential benefits** (such as early detection and treatment of disease) as well as **potential harms**:
  - ✓ potential benefits: early detection and treatment of disease, improvements in survival
  - ✓ potential harms: overdiagnosis, false positives, false negatives, radiation exposure, discomfort caused by exam itself, adverse reactions to contrast media, additional tests at additional costs to confirm a diagnosis, which may cause complications.
- Balanced information about the potential benefits and harms of CT exams is not provided to the presenters of individual health assessment, and this might violate the autonomy of the presenters in decision-making.
- Therefore, presenters of individual health assessment must be provided with adequate information about the potential benefits and harms of CT exams before making any decisions.

Question #2: Is there enough scientific evidence on the appropriate use of CT exams in individual health assessment?

Currently, there is only sparse scientific evidence on the potential harms and benefits of CT exams in individual health assessment, and therefore, accumulation of reliable scientific evidence is necessary.

Question #3: What are the improvements to be made for the appropriate use of CT exams in individual health assessment in Korea?

- When CT exams are done as a part of individual health assessment, the presenters must be provided with balanced and adequate information about the potential benefits and harms of CT exams through thorough explanation by medical personnel (medical doctor and nurse), after which the presenter must give informed consent. Steps must be taken to improve the current process so that the presenters can listen to the explanations by medical personnel, only after which the presenters may then decide whether or not to undergo CT exams. The presenters must also provide accurate information to the medical personnel so that they can get more personalized explanations and recommendations.
- We recommend developing materials and system for educating the healthcare providers including doctors about the potential benefits and risks of CT exams in individual health assessment.
- Support is needed for **data collection and research** in order to **accumulate reliable scientific evidence.** To this end, preexisting individual health assessment data should be openly available for review for public interest purposes, and further steps should be taken for linking the data with other healthcare data sources.

59 *Contents of this consensus statement may be different from the official standpoints of the participants' affiliated organizations, and extracted parts of the sentences cannot be used arbitrarily.*

Appendix 5: Agenda of the IHA seminar at POD2017

Imaging asymptomatic people: are we doing more good than harm?

Seminar at the International Conference Preventing Overdiagnosis (POD2017)
19 August 2017, Room 309B, Quebec City Convention Center, Canada

Chair: John Brodersen

Saturday 19th August 2017

11:00 to 11:50h Session 1: Setting the scene

11:00h Opening remarks (John Brodersen)
11:05h WHO views on individual health assessment- IHA (Maria Perez)
11:15h A radiation protection perspective of IHA practice (Steve Ebdon Jackson)
11:25h The Canadian Task Force findings (Sandor Demeter)
11:35h Benefits & harms when imaging asymptomatic people: lung cancer CT screening as the case (John Brodersen)
11:45h Q&As

11:50h to 12:15h Session 2: Breakout session

- Group discussions on the proposed questions
  - ✓ *What do you expect WHO to do to help minimize or prevent the harms of individual health assessment?*
  - ✓ *How does society, government and public health care system address the benefit versus harm of individual health assessment and of population based screening programmes?*
  - ✓ *What level of evidence is needed about the benefits and harms of individual health assessment?*
  - ✓ *How can health professionals and stakeholders be educated about benefits and harm of individual health assessment? Moreover, will such education minimise or prevent harms of individual health assessment?*
  - ✓ *Is the framework for justification of radiological procedures used in radio protection also applicable to other harms of individual health assessment?*

12:15 to 12:30 Plenary discussion

- Feedback from groups
- Final discussion, take home messages
- Closing remarks, meeting ends