



World Health
Organization



What do we need from ICRP in medicine?



Justification of medical exposures

Referral criteria and clinical decision support

Dr Maria del Rosario Pérez
Public Health and Environment

2nd International Symposium on the System of Radiological Protection, October 2013, Abu Dhabi, UAE

International days of medical physicists, radiologists, radiographers coming soon...

A word cloud graphic with 'Medical Physics' as the central theme. Other words include: healthcare, diagnostic, training, medicine, radiotherapy, CT, radiation, nuclear, devices, tomography, evidence, research, clinical, HDR, physics, imaging, research, medical, nuclear, devices, tomography, evidence, research, clinical, HDR, physics, imaging, research, medical. The background shows a faint image of a person's face.

**International Day of Medical Physics
November 7, 2013**

Radiation Exposure from Medical Procedures: Ask the Medical Physicist!

QR codes and social media links for Facebook and Twitter are present at the bottom.

ACR[®]
AMERICAN COLLEGE OF RADIOLOGY

ESRT
European Society of Radiology

RSNA[®]
Radiological Society of North America

INTERNATIONAL DAY OF RADIOLOGY

AN INITIATIVE OF THE ESR, ACR AND RSNA
Supported by the ISR

Radiographers Optimise Radiation Dose

**World Radiography Day
November 8, 2013**

ISRT
International Society of Radiographers and Radiological Technicians

<http://www.isrt.org/>

Designed for the ISRT by Kate Green, Canadian Association of Medical Radiation Technologists, 2013

A bit of history- some relevant dates

- **7th November 1867:** *Maria Skłodowska* was born in Poland. She and her husband were awarded the Nobel Prize for Physics in 1903, for their studies on radioactivity.
- **7th of November 1911:** *Marie Curie* was awarded the Nobel Prize for Chemistry in recognition of her discovery of the chemical elements radium and polonium.
- **8th November 1895:** *Wilhelm Conrad Röntgen* discovered a new kind of ray that he temporarily called "X-rays".



Use of radiation for medical imaging

- Following the discovery of X-rays, the use of radiation for diagnosis and treatment for human diseases expanded worldwide.
- Benefits gained recognition, and it represents today the major contributor to human exposure to artificial sources.
- Modern technology makes new applications safer. However, inappropriate or incorrect use can lead to **unnecessary or unintended radiation exposures and risks.**



International Conference on
RADIATION PROTECTION IN MEDICINE
Setting the Scene for the Next Decade

3–7 December 2012
Bonn, Germany



Organized by the



Co-sponsored by the
World Health
Organization

Hosted by the
Government of Germany

through the



www.iaea.org/meetings
CN-192

International Conference on RP in Medicine

Organized by the IAEA,
cosponsored by WHO, hosted by
the Government of Germany.

> 500 participants from around 80
countries and 16 organizations
reviewed advances, challenges
and opportunities.

Main outcome: **Bonn Call for
Action** to improve RP in health
care in the next decade.



Bonn Call for Action



1. Enhancing implementation of justification of procedures
2. Enhancing implementation of optimization of protection and safety
3. Strengthening manufacturers' contribution to radiation safety
4. Strengthening RP education and training of health professionals
5. Shaping & promoting a strategic research agenda for RP in medicine
6. Improving data collection on radiation exposures of patients and workers
7. Improving primary prevention of incidents and adverse events
8. Strengthening radiation safety culture in health care
9. Fostering an improved radiation benefit-risk-dialogue
10. Strengthening the implementation of safety requirements (BSS) globally

http://www.who.int/ionizing_radiation/about/med_exposure/en/index3.html

<https://rpop.iaea.org/RPOP/RPoP/Content/News/bonn-call-for-action-joint-position-statement.htm>





Bonn Call for Action



- 1. Enhancing implementation of justification of procedures**
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Action 1: Enhance the implementation of the principle of justification

- a) Introduce and apply the 3A ϕ (**awareness, appropriateness and audit**), which are seen as tools that are likely to facilitate and enhance justification in practice;
- b) Develop harmonized **evidence-based criteria** to strengthen the appropriateness of clinical imaging, including diagnostic nuclear medicine and non-ionizing radiation procedures, and involve all stakeholders in this development;
- c) Implement clinical imaging **referral guidelines** globally, keeping local and regional variations in mind, and ensure regular updating, sustainability and availability of these guidelines;
- d) Strengthen the application of clinical **audit in relation to justification**, ensuring that justification becomes an effective, transparent and accountable part of normal radiological practice;
- e) Introduce information technology solutions, such as **decision support tools** in clinical imaging, and ensure that these are available and freely accessible at the point-of-care;
- f) Further develop criteria for justification of health screening programmes for **asymptomatic populations** (e.g. mammography screening) and for medical imaging of **asymptomatic individuals** who are not participating in approved health screening programmes.





Appropriateness in imaging: "Best Test First !"

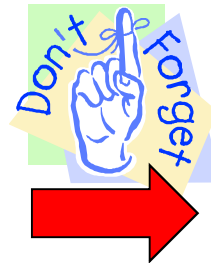
- When choosing a procedure utilizing ionizing radiation, the **benefit/risk balance** must be carefully considered.
- Even if benefits outweigh risks, there is **unnecessary** use of radiation when clinical evaluation or other imaging modalities could provide an accurate diagnosis (*e.g. US, MRI*).
- Cost, local expertise, available resources, accessibility and patient values have to be considered in addition to efficacy.



Reducing unnecessary radiation exposures

- The benefit outweighs the risk when the procedure is:
 - appropriately prescribed
 - properly performed.
- This is not the case if there is no clinical indication or the radiation dose is higher than necessary for the clinical purpose (e.g. adult protocols used for imaging children)

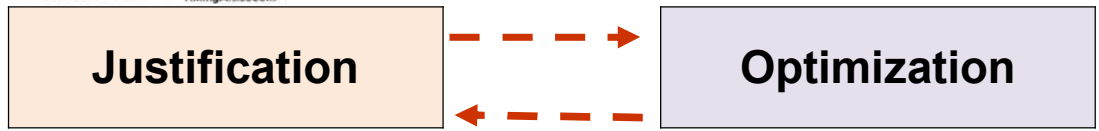
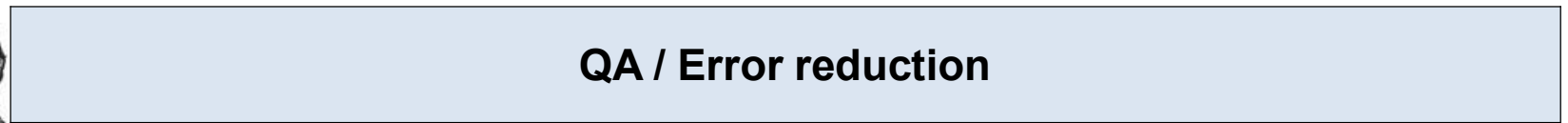
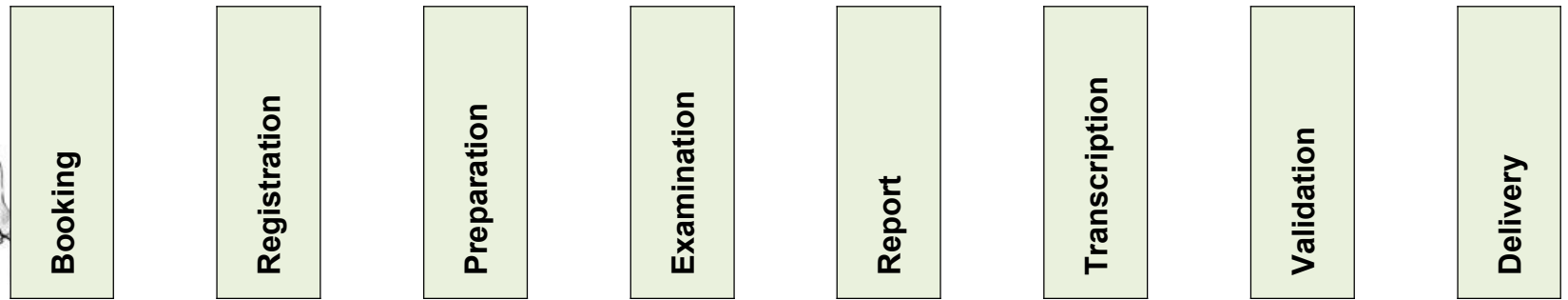
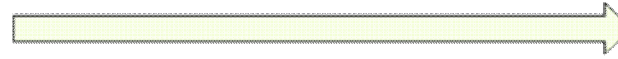
- ***Do the right procedure !***
- ***Do do the procedure right !***



JUSTIFICATION
OPTIMIZATION

Linking justification & optimization

Patient journey



↑
Gate keeper



(adapted from Dr. L. Lau IRQN/ISR)

Referral guidelines: what are we talking about?

- Evidence based medicine integrates the **best available clinical evidence** from systematic research with the **individual clinical expertise**, to consider what may be applicable to or appropriate for an individual patient.
- Referral guidelines (RGs) are **decision-support tools** systematically developed to assist practitioners on decision about appropriate healthcare for specific circumstances.



Referral Guidelines for Medical Imaging

- A medical imaging examination is useful if its outcome . either positive or negative . influences management of the patient or strengthens confidence in the diagnosis.
- **Referral guidelines for medical imaging** provide physicians with information on which procedure is most likely to yield the most informative results, and whether another modality is equally or more effective, and therefore more appropriate.
- These guidelines support the practice of evidence-based medicine and form a foundation to guide **appropriateness in prescribing diagnostic imaging services.**



ACR - Abdominal pain in children

Variant 4:



Fever, leukocytosis, possible appendicitis, atypical presentation in children (less than 14 years of age).





Radiologic Procedure	Rating	Comments	<u>RRL*</u>
US abdomen RLQ	8	With graded compression.	○
CT abdomen and pelvis with contrast	7	May be useful following negative or equivocal US. Use of oral or rectal contrast depends on institutional preference. Consider limited RLQ CT.	☼ ☼ ☼ ☼
X-ray abdomen	6	May be useful in excluding free air or obstruction.	☼ ☼
US pelvis	5		○
CT abdomen and pelvis without contrast	5	Use of oral or rectal contrast depends on institutional preference. Consider limited RLQ CT.	☼ ☼ ☼ ☼
MRI abdomen and pelvis without and with contrast	5	See statement regarding contrast in text under "Anticipated Exceptions."	○
CT abdomen and pelvis without and with contrast	4	Use of oral or rectal contrast depends on institutional preference. Consider limited RLQ CT.	☼ ☼ ☼ ☼
MRI abdomen and pelvis without contrast	4		○
X-ray contrast enema	3		☼ ☼ ☼ ☼
Tc-99m WBC scan abdomen and pelvis	2		☼ ☼ ☼ ☼
Rating Scale: 1,2,3 Usually not appropriate; 4,5,6 May be appropriate; 7,8,9 Usually appropriate			*Relative Radiation Level





- Chest & cardiovascular system ▶
- ENT/head & neck ▶
- Gastrointestinal system**
- Musculoskeletal system ▶
- Urogenital & adrenal ▶

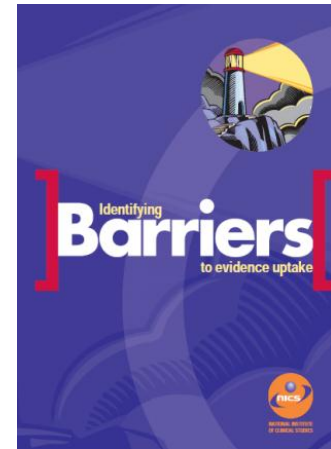
- P21: Intussusception in children
- P22: Ingested foreign body in children
- P23: Blunt abdominal trauma in children
- P24: Projectile vomiting in infants
- P25: Recurrent vomiting in children
- P26: Persistent neonatal jaundice
- P27: GI bleeding (per rectum) in children
- P28: Acute abdominal pain in children**
- P29: Constipation in children
- P30: Palpable abdominal/pelvic mass in children

Investigation	Dose	Recommendation [Grade]	Comment
US	None	Indicated [B]	There are many causes of acute abdominal pain. US is a useful first investigation but needs to be guided by clinical findings.
AXR		Specialised investigation [C]	AXR is rarely of value and is best performed under specialist guidance. Generally AXR is not undertaken before US.
CT	  	Specialised investigation [B]	Although CT is more sensitive than US for the diagnosis of appendicitis, specificities are similar and the strategy for imaging should take into account radiation dose and clinical features.
MRI	None	Indicated only in specific circumstances [B]	Following abdominal US, when TVUS is not feasible, MRI is occasionally helpful for evaluating pelvic masses in girls.

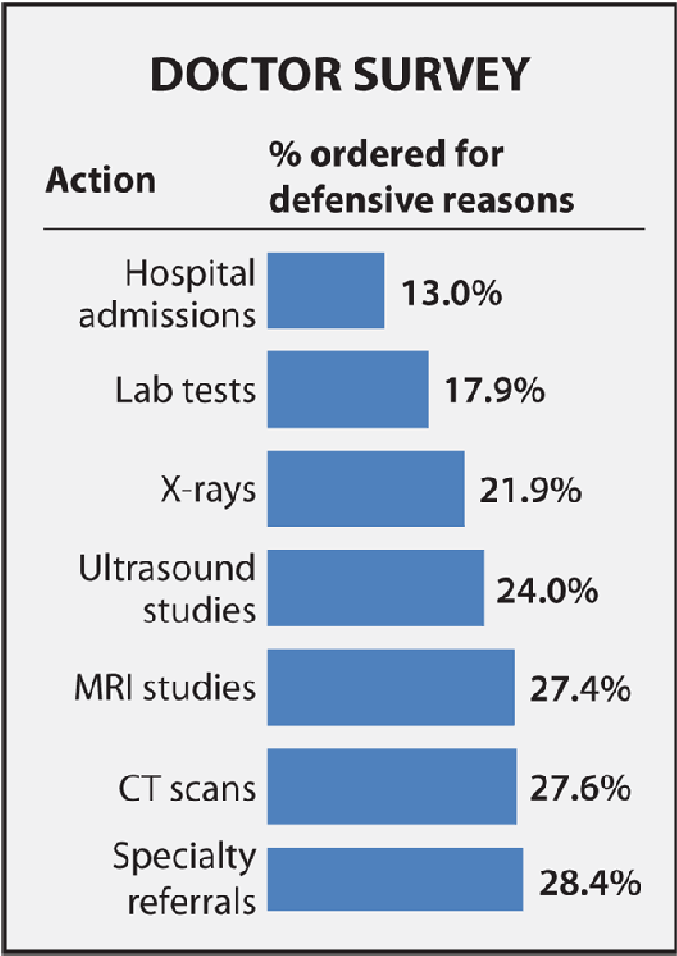
RCR:
Abdominal
pain in
children

Some reasons for unnecessary procedures

- *Lack of awareness about radiation doses & associated risks*
- *Insufficient access to referral guidelines at the point of care*
- *Low confidence in clinical diagnosis & over-reliance on imaging*
- *Consumer demand (patient's and/or family's expectations)*
- *Self-referral, opportunistic screening, defensive medicine*
- *Pressure from other specialists e.g. "What does the CT shows?"*
- *Pressure from promotion and marketing of sophisticated technology*
- *Lack of dialogue/consultation between referrers and radiologists*
- *Non-availability of other appropriate imaging modality (e.g. US, MRI)*
- *Fragmentation vs. continuity of health care: unnecessarily repeated examinations*



Defensive medicine is a strong driving force



Concerns about malpractice litigation

"...Physicians may respond to the perceived threat of litigation by ordering more referrals and more tests, some of which may be recommended by clinical guidelines and beneficial, but others might be wasteful and harmful"





Integration of decision support systems

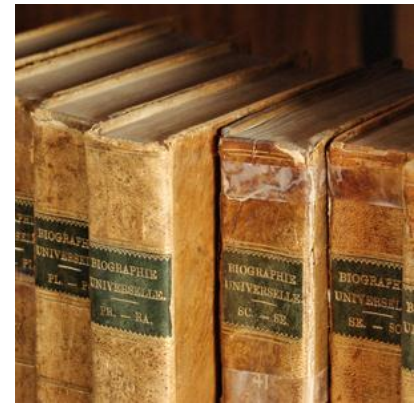
- Referral guidelines are decision support tools (i.e. advisory rather than compulsory). However, a physician should have good reasons to deviate from the recommendations.
- Linkage with voluntary use has limited success compared with integration of guidelines into electronic registries.
- Computerized Order ("*request*") Entry (COE) systems facilitate the integration of decision support systems into the daily workflow, with provision of interactive reminders.
- At the time of entry into the COE referring doctors receive feedback on the degree of appropriateness of their choices relative to the referral guidelines (it allows for warnings).



Clinical decision support: bringing the guidelines to the point of care



- Insufficient access at the point of care is a major cause of lack of adherence of physicians to referral guidelines (RGs).
- Bulky, paper manuals are likely to sit on a shelf and go unused. Physicians need timely and easy access to user-friendly evidence-based RGs that are relevant to their patients.
- Clinical decision support: implementation of referral guidelines depends not only on the content, but also on the format and media.

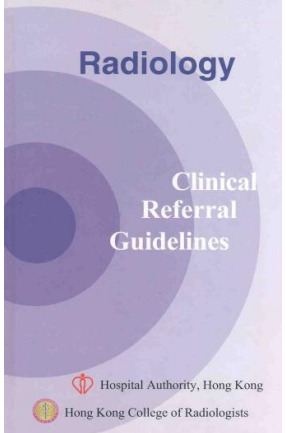


Criteria for media selection

- Ease of preparation/production
- User acceptance
- Cost
- Flexibility
- Convenience
- Durability
- Mode of distribution
- Local resources



Choice of media depends on users needs and setting conditions



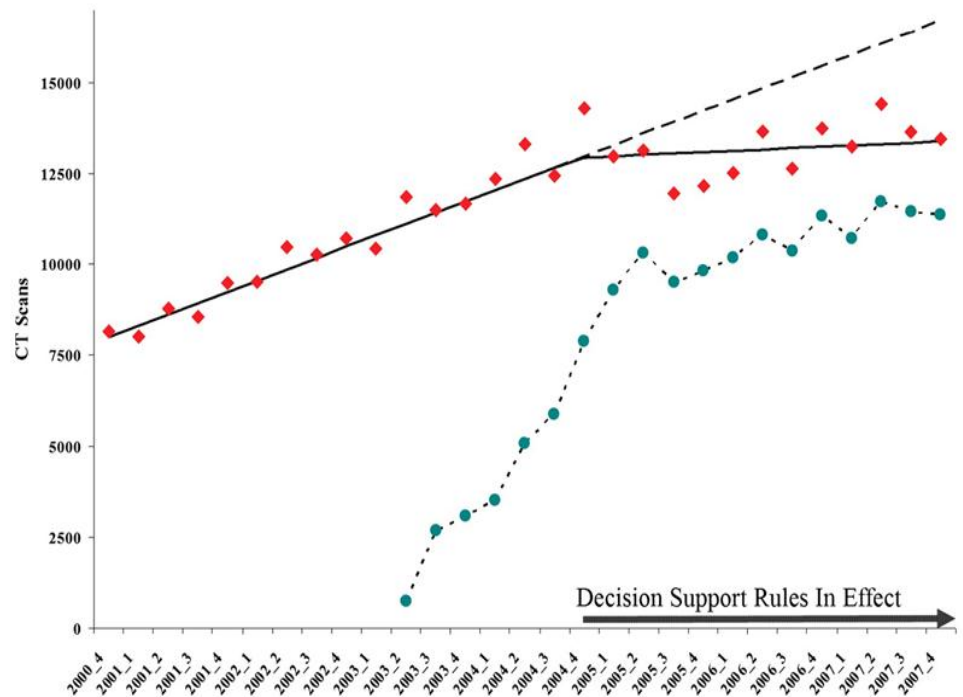
Effect of COE with integrated decision support: reduced the growth rate of CT procedures

Effect of Computerized Order Entry with Integrated Decision Support on the Growth of Outpatient Procedure Volumes: Seven-year Time Series Analysis¹

Christopher L. Siström, MD, MPH
Pragya A. Dang, MD
Jeffrey B. Weillburg, MD
Keith J. Dreyer, DO, PhD
Daniel I. Rosenthal, MD
James H. Thrall, MD

Purpose: To determine the effect of a computerized radiology order entry (ROE) and decision support (DS) system on growth rate of outpatient computed tomography (CT), magnetic resonance (MR) imaging, and ultrasonography (US) procedure volumes over time at a large metropolitan academic medical center.

Materials and Methods: Institutional review board approval was obtained for this study of deidentified aggregate administrative data. The research was compliant with HIPAA; informed consent was waived. This was a retrospective study of outpatient



Siström et al. Effect of Computerized Order Entry with Integrated Decision Support on the Growth of Outpatient Procedure Volumes: Seven-year Time Series Analysis. *Radiology*, 2009. 251, 147-155.

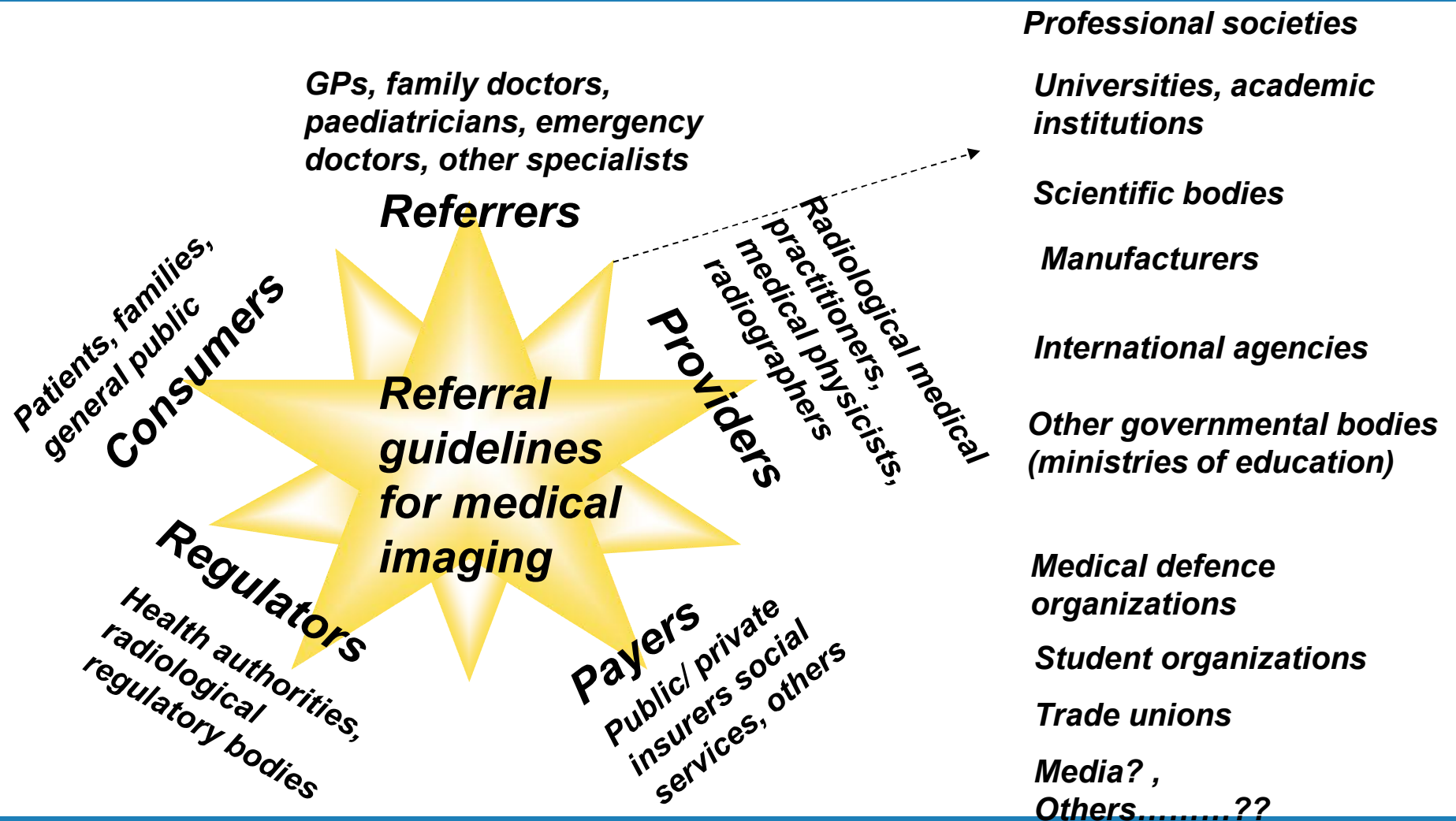
<http://radiology.rsna.org/content/251/1/147.long>

Involvement of stakeholders and end users

- By participation in the process they share **ownership** of solutions and outcomes and become **advocates**.
- This contributes to improve implementation of appropriateness criteria/referral guidelines.
- Need to identify suitable mechanisms for participation at different stages e.g. development/adaptation of guidelines; development of guidance/strategies for implementation, pilot testing, monitoring use, evaluation of the impact.
- The approaches need to be regionally/locally tailored.



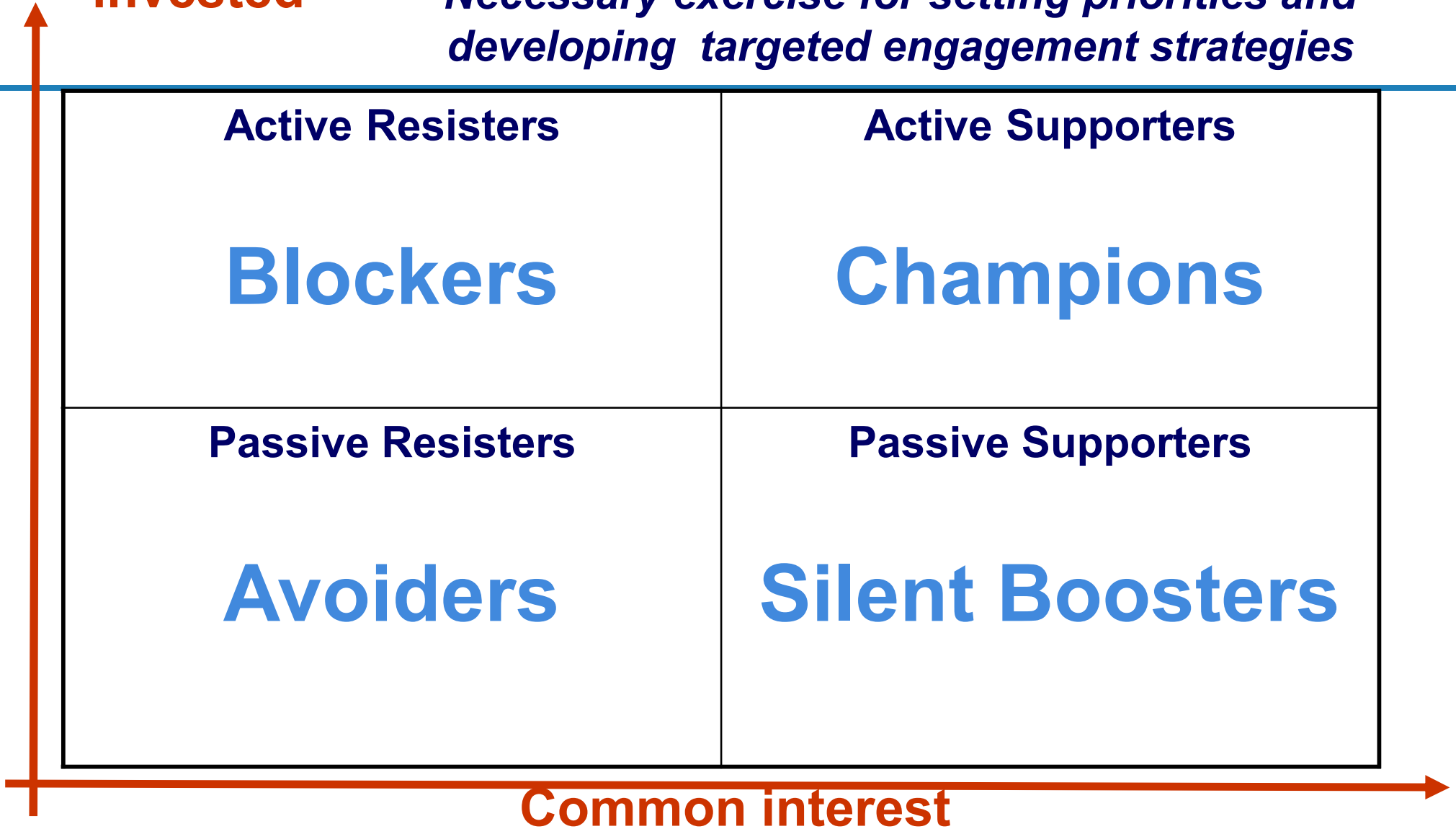
Potential stakeholders



**Energy
invested**

Stakeholders' mapping

Necessary exercise for setting priorities and developing targeted engagement strategies





Stakeholders engagement (I)

- Partnership as a key theme . healthcare professionals, patients, policy makers.
- Engagement of health care professionals in radiation protection should go beyond the radiological medical practitioners.

Referrers can significantly contribute to the implementation of radiation protection principles in health care: **GPs/family doctors, pediatricians, emergency doctors, dentists, medical and dental school students.**





Stakeholders engagement (II)

- Partnership as a key theme . healthcare professionals, patients, policy makers.
- The patient as the constant in the continuum of care . a repository of information and valuable resource for improving health care delivery.
- Safe healthcare is a goal of both patients and providers.
- Patient networks (e.g. Patients for Patient Safety /PFPS) . are collaborative partners and are therefore key partners to improve radiation safety culture in health care.

Stakeholders' engagement is crucial:

Patients' associations are "key" stakeholders



World Health Organization

Patients for Patient Safety News

February 2013

Welcome!

Margaret Murphy, Lead Advisor, Patients for Patient Safety (PFPS)



Happy New Year to all and welcome to the first edition of PFPS News for 2013. We have lots of good news to share with you.

The PFPS Steering Group held a meeting in January. It was a welcome opportunity for the Group to get to know Nittita Prasopa-Plaizier, the new PFPS Technical Lead. Nittita is truly passionate about the work and ethos of PFPS and she will be a wonderful asset presenting PFPS as an

Look inside:

- Infection Prevention Conference, Benin
- Patient Safety in Slovakia

Radiation Protection in Medicine

Nittita Prasopa-Plaizier, PFPS Technical Lead, Maria Perez, WHO Dept. of Public Health and the Environment, Margaret Murphy, PFPS Lead Advisor, and Stephanie Newell, PFPS Champion, Australia

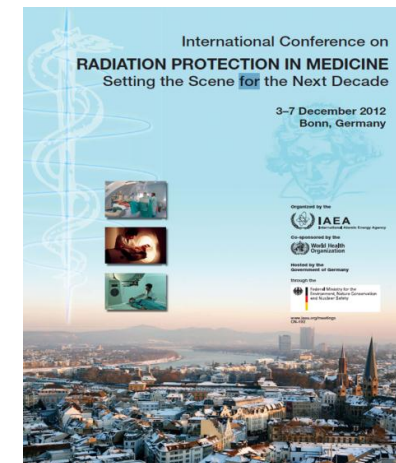


In December 2012, Nittita Prasopa-Plaizier, Margaret Murphy and Stephanie Newell represented the PFPS programme at a workshop "Radiation risk communication in paediatric imaging", at the

with the medical purpose". Radiation protection in medicine aims to ensure medical procedures relating to radiation are performed safely through correct indication, dosing and calibration of radiotherapy machines, and strict adherence to procedures.

Margaret presented the patients' perspective to about 60 experts at the workshop organized by WHO's Department of Public Health and the Environment. Nittita worked with Dr Maria Perez to collaborate on the planning and workshop organization. Margaret again presented at a "round table" session at the conference on patients' role in radiation safety.

"International Conference on Radiation Protection in Medicine", held in Bonn, Germany. The conference was organized by the International Atomic Energy Agency (IAEA), co-sponsored by WHO and hosted by the Government of Germany. It was attended by about



World Health Organization

Need to improve communication between doctors and patients, need to use other communication resources

- In the past doctors were trusted and respected as the source of medical advice (and patients followed their advice).
- Communication/dialogue between doctors and patients went downwards, internet is a major source of information and even advice (and many patients don't follow doctors' advice).



To improve risk/benefit dialogue



Communicating Radiation Risks in Paediatric Imaging



Communication tool for health care providers

Global Initiative on Radiation Safety in Health Care Settings

To support radiation risk communication (guidelines and tools for capacity building, information products, check-lists)



Communication toolkit



World Health Organization



Bonn Call for Action



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http://www.who.int/ionizing_radiation/about/med_exposure/en/index3.html

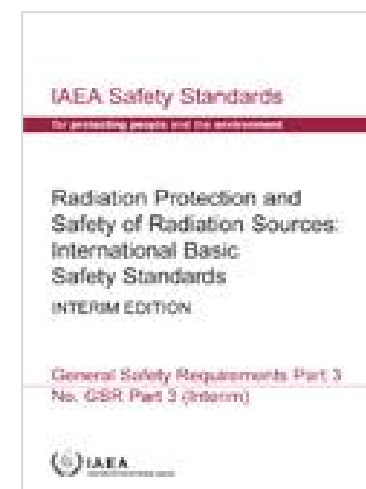
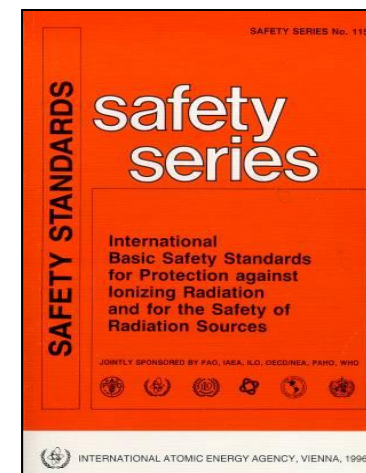
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International Radiation Basic Safety Standards (BSS)

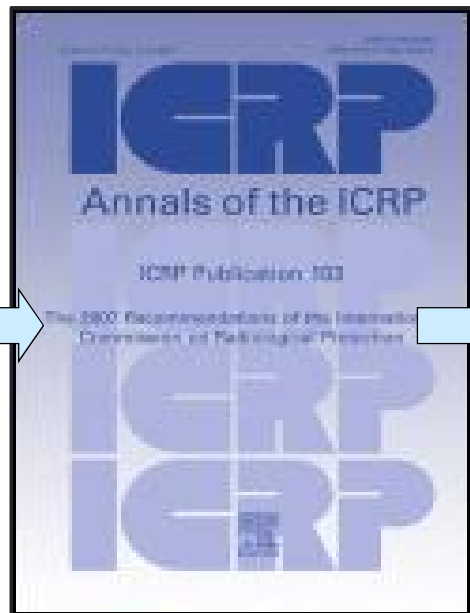
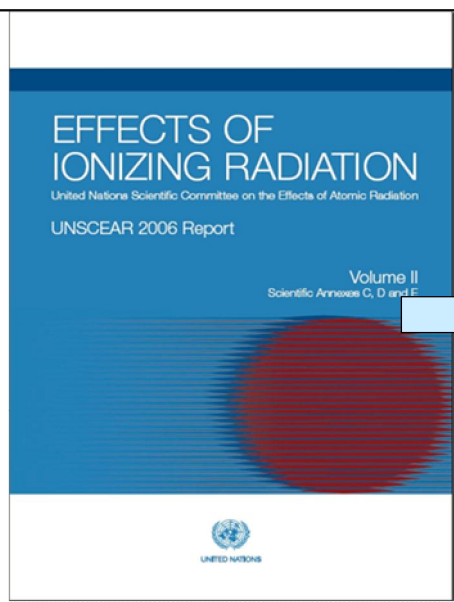


- The BSS are the benchmark^(*) for radiation safety requirements worldwide. *(*) not legally binding*
- Revision/update completed in 2011
- Adoption by cosponsoring organizations completed in 2012
- Current challenge: **BSS implementation.**





The paradigm: science, recommendations, standards



Medical settings

"What should I do to improve radiation safety in healthcare ?????"

Scientific basis
Effects, risks, sources, levels, trends, ...

Recommendations
System of RP (philosophy, principles, dose criteria, ...)

Standards
(safety requirements, regulatory language,...)



Need to bridge this gap

But... how?



Justification of medical exposures

Evolution of ICRP recommendations

1990 – ICRP 60 Should be dealt with in the same way as justification of any other practice

Adds that each procedure is subject to a separate decision, so that there is an opportunity to apply a further, case-by-case, justification for each procedure. Notes that this may be important for complex investigations and for therapy.

1996 – BSS 115

1996 – ICRP 73

A more complex approach - 3 levels

“Justification of a practice

“Generic justification of a defined procedure

“Justification for an individual patient

2007 – ICRP 103

– ICRP 105

ICRP 73 approach is maintained – medical exposure of patients calls for a different and more detailed approach to the process of justification

2011/2 – New BSS



Justification in the new BSS:

the "what" and the "who"

Consistent with ICRP 103, the new BSS note in *chapter 1* that **justification** needs a special approach when it applies for medical exposures.



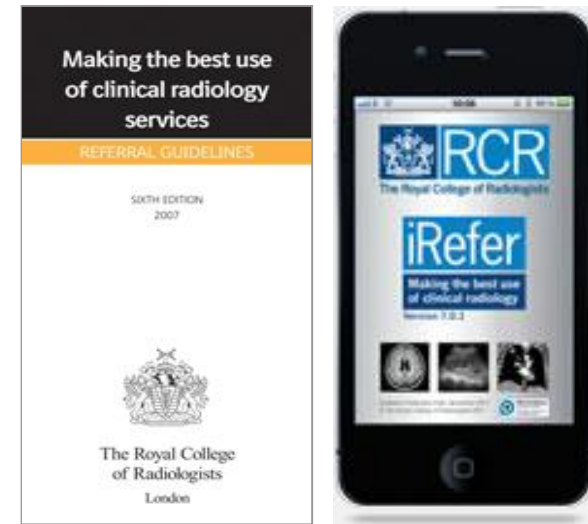
In *chapter 3*, the requirement 37 focuses on justification of medical exposures. Three levels:

- General/overarching justification of the use of ionizing radiation in medicine (**level 1**);
- Justification for a generic clinical condition (**level 2**);
- Justification of a radiological procedure for an individual patient (**level 3**).



What is the level 2 of justification?

- Second level -**generic justification**- refers to a particular radiological medical procedure for patients with a given clinical condition, or for a group of individuals at risk to a given condition that can be detected and treated.
- This generic justification is assigned to the *health authority* in conjunction with appropriate *professional bodies*. It shall be reviewed from time to time, with account taken of advances in knowledge and technology developments.
- *Referral guidelines/ appropriateness criteria* reflect this level of justification.



The level 3 : individual justification



- Third level- **individual justification** of a procedure judged to do more good than harm to given patient.
- It is assigned to health professionals involved in the patient's care ("*consultation between the radiological medical practitioner and the referring medical practitioner, as appropriate*").
- They have to integrate the best available scientific evidence with their own clinical expertise to decide what is appropriate for that particular patient.



Roles and responsibilities in justifying at level 3

- Two roles identified in the new BSS
 - Radiological medical practitioner
 - Referring medical practitioner
- Justification of medical exposure for an individual patient "shall be carried out through consultation between the radiological medical practitioner and the referring medical practitioner, as appropriate"



Relevant national or international referral guidelines shall be taken into account (evidence-based decision-support tools) considering, inter alia, patient values, local expertise, availability of resources & technology.

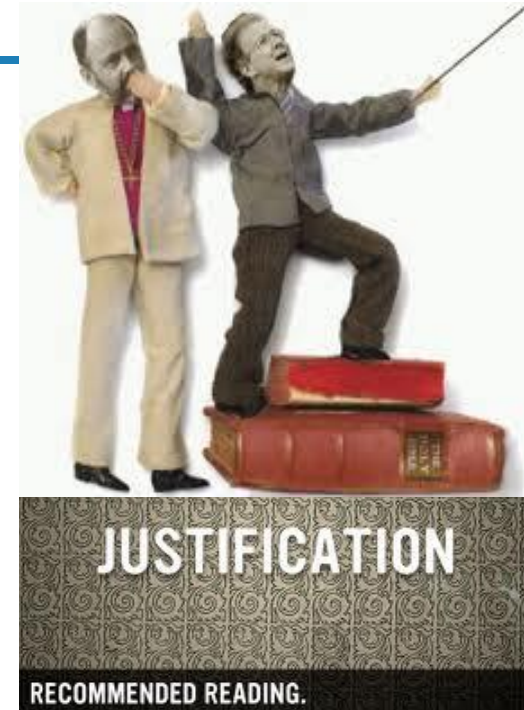
Individual Health Assessment (IHA)

- IHA is neither diagnosis nor population screening.
- Diagnosis is based on signs/symptoms; "assessment of possible disease" is based on individual risk profiles/factors.
- Evidence-based referral guidelines and appropriateness criteria for medical imaging do exist and can assist decision making about the best imaging procedure for a patient with a given clinical condition.
- Consensus about criteria for medical imaging of asymptomatic people for IHA does not exist yet.



BSS and asymptomatic individuals

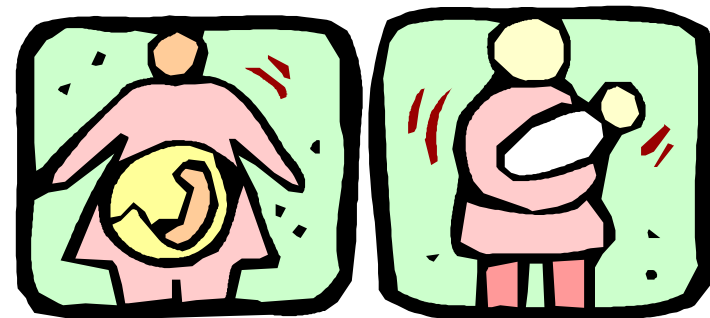
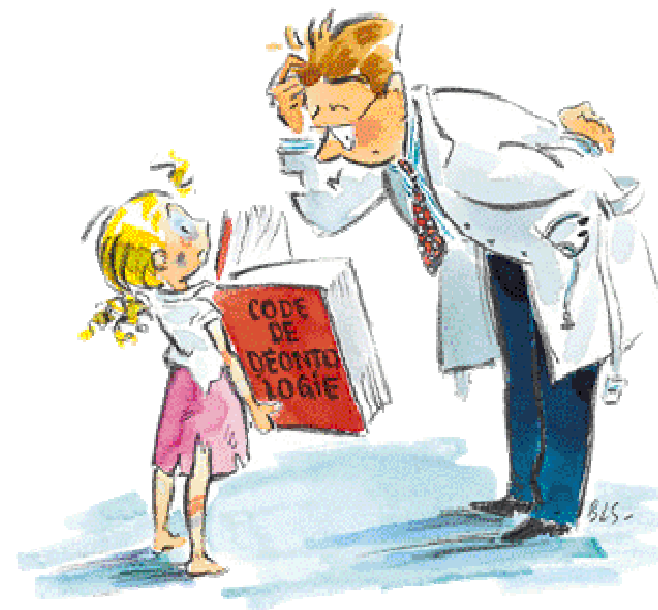
- Any radiological procedure on an ***asymptomatic individual*** that is intended to be performed for the early detection of disease, but not as part of an approved health screening programme, shall require specific justification by the ***radiological medical practitioner*** and the ***referring medical practitioner***.
- The individual shall be ***informed*** of the expected benefits, risks and limitations (e.g. heart CT, lung CT, colon CT, other/s ò)





Other specific justification requirements

- Volunteers as part of a research programme
- Female patients of reproductive capacity
- Breastfeeding and nuclear medicine
- Radiological audits and critical review of the implementation of the justification principle



What do we need from ICRP to improve justification of medical exposures?

- Input for a global **research agenda** on RP in medical exposures (quantities/units, dosimetry, radiation effects (cancer & non-cancer, children and pregnant women, individual radiosensitivity)
- **Framework for justification** of medical exposures- diagnostic imaging, IHA in asymptomatic people, ethical considerations (*ongoing*);
- **Materials/information products** to bridge the gap to target audiences in health care settings: plain language, key messages, key stakeholders e.g. referrers, patients (*to update/revise the existing GP guidance document and produce a companion educational PPT?*).
- Contribution/advice for the development of tools to support **radiation risk communication** and **risk-benefit dialogue** in medical settings.



Improving RP culture in medical settings



ICRP together with a number of actions from international organizations, professional societies, scientific institutions, regulators, others...





*Thank you very much
for your attention*

perezm@who.int





Thank you !

http://www.who.int/ionizing_radiation/about/med_exposure/en/index.html

perezm@who.int