

Bucarest June 2<sup>th</sup>, 2016

# RADIOLOGICAL INFORMED CONSENT FORM: A VIEW FROM THE PATIENT'S CORNER

No conflicts of  
interest to declare

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National Research Council of Italy

# Background

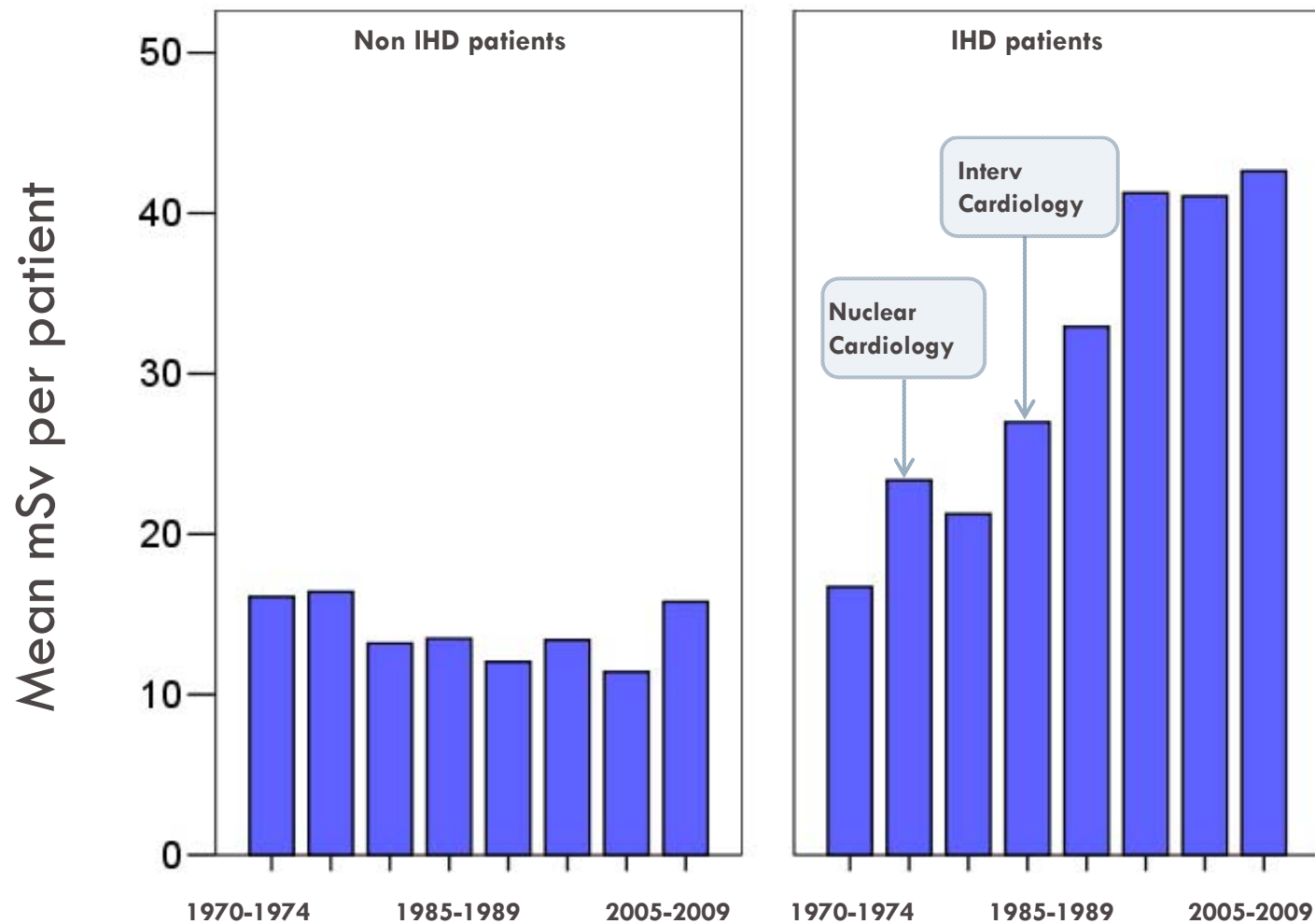
- In the last twenty years the per capita dose from medical imaging has increased by a factor of 6  
*(Mettler F et al, Radiology 2008)*
- Low to moderate(<100 mSv) radiation doses from diagnostic and therapeutic imaging procedures in cardiological patients may increase cancer frequency after decades  
*(Eisenberg MJ. CA Cancer J Clin 2012;Hung MC, Asian Pacific J Cancer Prev 2013, Carpeggiani C Int J Cardiol 2015)*
- The communication of doses and risks in medicine is often based on a highly specialized technical language, often difficult to understand even for practitioners and prescribers

# Radiation dose reference

EXAMINATION	Representative effective dose value (mSv)	Multiples of chest X-ray (PA projection)
Chest X-ray PA	0.02	1
CT chest	8	400
CT abdominal	10	500
64-Slice coronary CTA without tube current modulation	15	750
64-Slice coronary CTA with tube current modulation	9	450
Calcium score	3	150
Diagnostic invasive coronary angiogram	7	350
Abdominal angiography or aortography	12	600
Percutaneous coronary intervention	15	750
Radiofrequency ablation	15	750
Sestamibi (1-day) stress-test MPS	9	450
Thallium stress-rest MPS	41	2.050
F-18 FDG	8	00
Cardiac ventriculography (99mTc-labeled red blood cells)	7.8	780
Lung perfusion (99mTc-MAA)	2	100

*From E Picano et al. Eur Heart J 2014 Jan 8*

# Cumulative radiation exposure per patient



# Occupational Health Risks in Cardiac Catheterization Laboratory Workers (§)

- Health problems are more frequently observed in workers performing fluoroscopically guided cardiovascular procedures than in unexposed controls.
- The primary risks mostly related to work activity and radiation exposure include orthopedic illnesses, cataract, skin lesions, and *cancers*, particularly in workers with longer duration of occupational work.
- The secondary findings showed an increased prevalence of anxiety/depression, hypertension, and hypercholesterolemia, supporting the recent evidence of other radiogenic non-cancer effects.

(§) MG Andreassi, E Piccaluga, G Guagliumi, M Del Greco, F Gaita, E Picano,  
on behalf of the Healthy Cath Lab Study Group.  
*Circ Cardiovasc Interv.* 2016;9:e003273

# Background



- ❑ Physicians and patients are not aware of radiation doses and risks even in highly specialized centers
- ❑ Prescribers and practitioners do not include radiation dose and cancer risk in the risk-benefit assessment of their indications to testing
- ❑ Scientific societies have recently developed recommendations on how to prepare a clear and informative form
- ❑ We need best practices templates for validation, dissemination and standardization, also listening to the patient (final end-user) expectations and needs

# Informed Consent Strategies

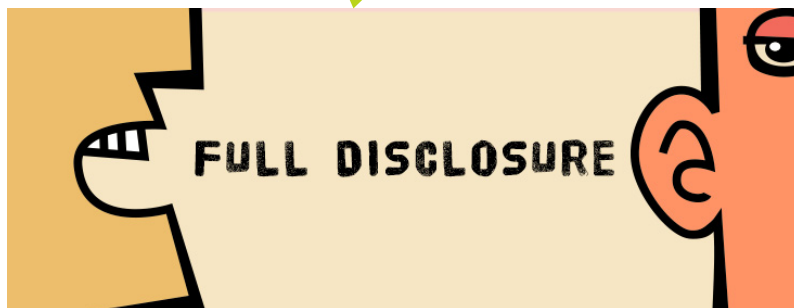


The current policy for cardio CT, stent, etc...:

**DON'T SAY A WORD**

“dose corresponding to a  
common radiography”

**UNDERSTATEMENT**



**NIH, ESC**

# The Information Imperative: Is It Time for Informed Consent Explaining the Risks of Medical Radiation? (§)

- The danger to the field of Radiology in not regulating itself and requiring informed consent for medical procedures using ionizing radiation is that we stand the very real chance of having regulations imposed upon us by government, as is already in process in Europe. The prospects of facing both poor public perception and imposed regulations is disturbing.

(§) Semelka RC, Armao DM, Elias J Jr, Picano E.  
*Radiology* - January 2012 Volume 262, Issue 1

Radiology

*Radiology* is a monthly journal devoted to clinical radiology and allied sciences, owned and published by the Radiological Society of North America, Inc.



# Be aware of the dose



For each clinical scenario, tests that impact ionizing radiation will be performed by labs that have adopted contemporary dose-radiation techniques.

*Wolk MJ, et al.. J Am Coll Cardiol. 2014;63:380-406*

*Education, justification, and optimization are the cornerstones to enhance the radiation safety of medical imaging. The continually expanding repertoire of techniques that allow high quality imaging with lower radiation exposure should be used when available to achieve safer imaging.*

*Fazel R et al, Circulation, 4 November 2014*

**A scientific Statement of American Heart Association**

The actual delivered dose should always be recorded and included in patients' records. Because of the numerous sources of variability, there is no threshold between acceptable and unacceptable exposure for any given examination, but the dose that is not even considered is certainly unacceptable .

*Picano E, et al. Eur Heart J. 2014;35:665-72*

# Aim



- To identify the features of a next generation radiological informed consent form based upon patients' demands and needs.
- To test an informative, transparent template of an informed consent form for radiological examinations, implemented with communications experts and patients' rights representatives.

# Informed Consent



- Instrument through which the patient is exercising the right to self-determination with regard to locating diagnostic and/or treatment that are proposed
  - containing description of the specific disease
  - detailed information about the proposed treatment/intervention for the specific disease/condition
  - alternative options
- It should report advantages and risks
  - mathematical probability that an event will occur, or that the potential level of damage could be reached
  - accuracy of the messages and attention to the used language
  - do not use terms incomprehensible or they can generate panic

# Ideal Informed Consent

- *Legibility*
  - short periods and sentences, clear design and characters
- *Comprehensibility*
  - plain language, free of jargon
- *Summary*
  - a guarantee that the card is actually read should not exceed two facades
- *Setup FAQ (Frequently Asked Questions)*
  - answer the questions most frequently asked by patients
- *Prerequisites*
  - the amount and type of information must be consistent with the purpose for which they are provided (to put the patient in terms of making an informed choice)
- *Truthfulness*
  - information must be updated and Evidence Based
- *Balance*
  - the more so the examination is diriment for the management of the case (and thus appropriate) the greater must be the care not evoke alarm responses

# Material and Methods

- A sample of 20 subjects (11 men, ages  $50 \pm 18$  years, educational level: 3 graduated participants) were tested with 2 different radiological informed consent forms for chest CT
  - ▣ *first generation form*: 3 pages detailed description of procedure/general risks
  - ▣ *second generation form*: a simplified text with tables and figures developed adopting the Federal Plain Language Guidelines
- At the end of the session a comprehension test with multiple choices (for each item, 1 correct answer out of 4) should be filled.
- And the subjects was asked to list the major comments and criticisms of the 2 forms.

# Type A - CONSENSO INFORMATO PER L'ESAME DI T.A.C. (TOMOGRAFIA ASSIALE COMPUTERIZZATA) CON MEZZI DI CONTRASTO IODATI

Gentile Signore/a,

l'indagine diagnostica prescritta prevede l'utilizzo di **MEZZI DI CONTRASTO ENDOVASCOLARI** che vanno somministrati per via venosa o arteriosa. Il mezzo di contrasto usato è stato scelto tenendo in considerazione i parametri di qualità, efficienza e tollerabilità, con l'obiettivo di utilizzare il prodotto migliore presente sul mercato. Questi preparati provocano la opacizzazione per via vascolare delle strutture anatomiche e ne rendono possibile una più certa identificazione e delimitazione, consentendo spesso una migliore definizione della patologia in causa sia ai fini diagnostici che terapeutici. Il loro utilizzo può avvenire, a seconda delle necessità diagnostiche, per infusione lenta o bolo rapido. Presso Radiologia Medica sono utilizzati mezzi di contrasto iodati non ionici notevolmente più sicuri ed affidabili che in passato.

Tuttavia, in una minima percentuale dei casi (1- 3%) sono possibili **reazioni avverse spesso di grado lieve (stravaso in sede di iniezione, sudorazione, nausea o vomito, secchezza delle fauci, orticaria) o medio (dispnea, broncospasmo, alterazioni pressorie e del ritmo cardiaco, angina, convulsioni, lipotimia); rare, ma possibili; sono le reazioni gravi (edema della glottide, shock anafilattico), di cui severe 0,04% e molto severe 0,004%.** La preghiamo, pertanto, di segnalare preventivamente al Medico Responsabile dell'esecuzione dell'esame tutte le patologie di cui è portatore.

Se le informazioni riportate in questo foglio, le risultassero poco comprensibili o avesse dubbi in proposito, si rivolga con fiducia al personale del servizio deputato all'esecuzione dell'indagine richiesta, che le fornirà ogni possibile ulteriore chiarimento e informazione

# Consent for CT Scan

## Type A



**NEW YORK  
RADIOLOGY  
PARTNERS**

**East Manhattan Diagnostic Imaging**  
P: 212.410.5100 F: 212.410.2500  
**Union Square Diagnostic Imaging**  
P: 212.473.2300 F: 212.473.4780

**Kingsway Diagnostic**  
P: 718.758.1500 F: 718.758.2400  
**Columbus Circle Imaging**  
P: 212.977.4100 F: 212.977.4271

Name: \_\_\_\_\_ Date: \_\_\_\_\_

Your doctor has asked that a CT scan be performed using intravenous contrast material. This is an iodine containing solution that aids in the visualization of your organs and blood vessels, which helps in the diagnosis of pathology in various parts of your body. In order for us to administer this "dye" you must be informed of the possible risks involved. I have read the above and understand it all.

After injection of the intravenous contrast, most patients feel a sensation of warmth, a funny metallic taste in their throat, transient nausea and a feeling of warmth in the groin. Some patients develop hives and itching, but this is self-limited and rarely needs to be treated with antihistamines. 1 in 500 patients may develop a severe reaction and 1 in 5,000 may have a life threatening reaction, all of which may have to be aggressively treated with medications. These reactions may involve; tightness in the throat; facial swelling; difficulty breathing; drop in blood pressure or even seizure. Generally speaking, intravenous contrast is extremely safe and well tolerated and these reactions are rare. I have read the above and understand it all.

This attached questionnaire will help us to decide other issues concerning the contrast material, including whether or not you should have it at all. If you have any questions, you will be able to speak to the supervising radiologist. When your questions have been answered or if you do not have any questions, please sign the form below. I have read the above and understand it all.

PATIENT SIGNATURE: \_\_\_\_\_ DATE: \_\_\_\_\_

WITNESS: \_\_\_\_\_

INTERPRETER: \_\_\_\_\_

RADIOLOGIST: \_\_\_\_\_

PHYSICIAN ASSISTANT: \_\_\_\_\_

# Informed consent for Coronary Computer Tomography Angiography(CTA) - Type B

Please read this document carefully. If you have any questions or concerns, talk to your doctor.

## 1) What is CORONARY COMPUTER TOMOGRAPHY ANGIOGRAPHY-CTA ?

CTA is an imaging exam for your heart. The exam shows the vessels that carry blood to the heart walls which are called coronary arteries.

## 2) What is the purpose of this exam ?

- To identify calcified plaques in the walls of the coronary arteries.
- Plaques can
  - reduce blood flow to the heart walls.
  - damage the heart walls.
- To obtain useful information in order to prescribe the right therapy.
- The benefit of this exam for you in a scale from zero to ten is ...

## 3) How is CTA performed?

- You will be asked to lie on an examination couch, relax and stay still.
- The couch slides into a tunnel in the scanning machine. The tunnel contains tools that rotate 360 degrees around the patient and produce the images
- During the exam you will hear a sound, not annoying.
- You will have to hold your breath for about 20 seconds.
- The exam takes about 20-30 minutes.
- A liquid called contrast medium will be injected into a vein. You may feel warmth spread throughout your body. Don't be afraid because this is normal.
- If you experience other symptoms such as shortness of breath, you must alert the staff immediately.

*In the machine there are microphones. The exam can be stopped at any time, if necessary.*

## 4) What are the risks?

- ⚠ Allergic reaction to contrast medium

**Attention!** In diabetics or patients with renal diseases contrast media can induce renal permanent impairment.

- ⚠ Ionizing radiation's risks

## Cancer risk

The greater the radiation dose, the greater the risk of cancer  
You must report all radiological and nuclear medicine exams you have already had to your physician

## Should avoid the exam:

- a pregnant woman.
- a man who would like to have children soon.

Women must report pregnancy, either certain or suspected. When in doubt, the procedure must be postponed.

## 5) Are there alternative tests ?.....

## 6) If I do not have this test, what are the risks?

## Risks

it may be difficult:

- to recognize or exclude a diagnosis of coronary disease.
- to recommend a proper care and therapy.

## 7) What are X-rays?

- X-rays/ionizing radiation is an energy delivered during certain procedures, that can go through the human body and can damage the cells.....

## 8) May I know more about the cancer risk for a coronary CTA scan?

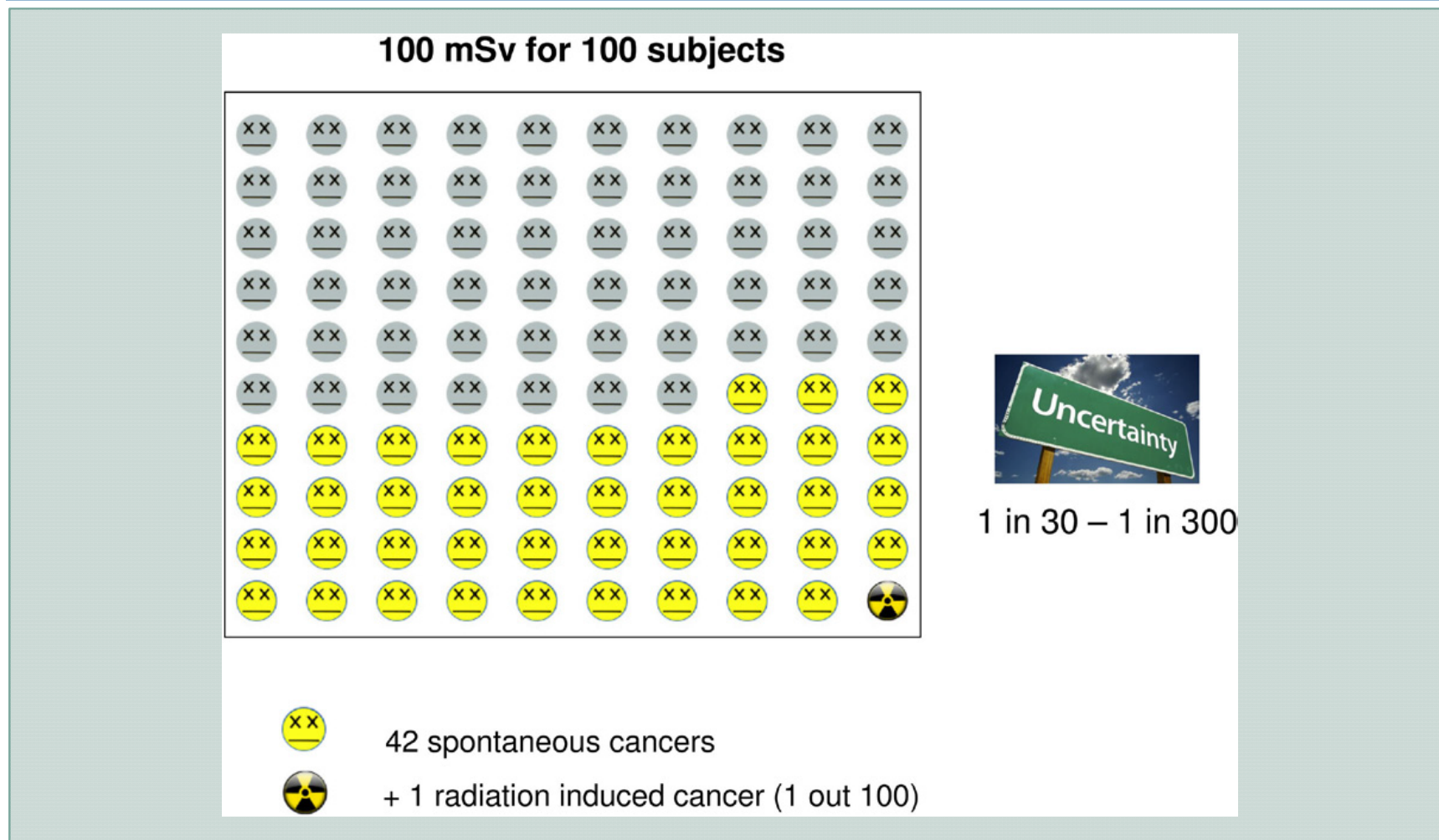
**Table 1. Radiation dose and cancer risk for CTA, expressed also as number of days in life lost and number of cigarettes smoked.**

Exam	Effective dose (mSv)	Cancer risk (fatal and non-fatal) for man, 40 ys	Equivalent number of cigarettes smoked	Number of days in life lost
CTA	12	1 / 1500	660	3

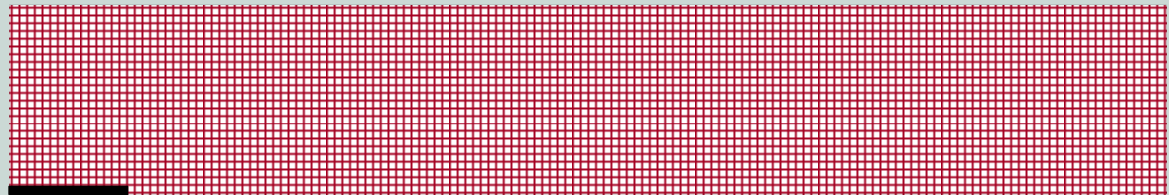
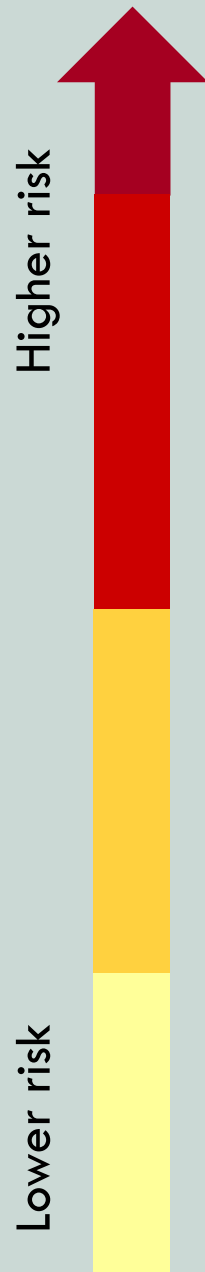
## 10) May cancer risk vary according to age and sex?.....



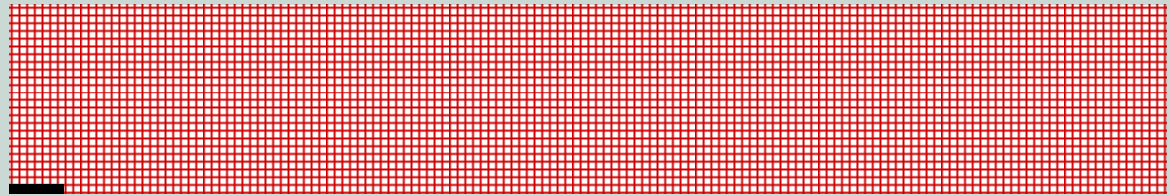
# The risk model of Biological Effects of Ionizing Radiation Committee VII for exposure to low-level radiation



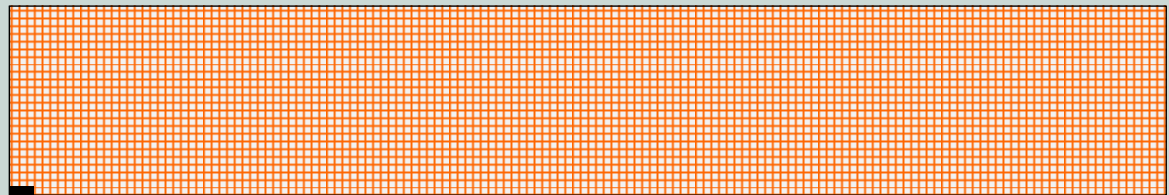
# Exposure to CCTA 64 slice



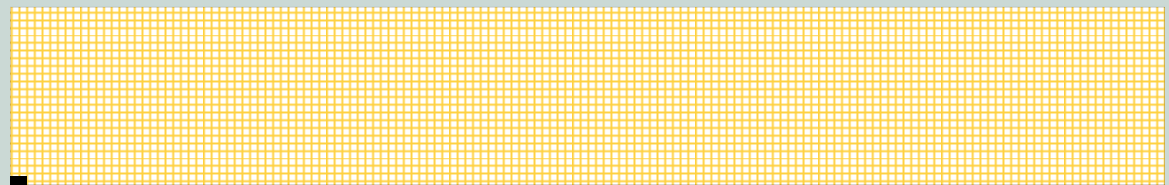
Female child <1yr, Cancer risk = 15 (black square) out of 1500



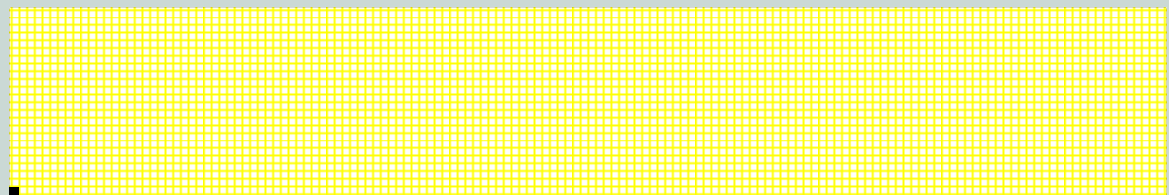
Male child <1yr, Cancer risk = 7 (black square) out of 1500



Adult woman, Cancer risk= 3 (black square) out of 1500



Adult man, Cancer risk= 2 (black square) out of 1500



Elderly, Cancer risk= 1 (black square) out of 1500

# Dose/Risk Communication following the Royal College of Radiologists approach

Investigation	Effective Dose (mSv)	Equivalent No. of Plain Chest Xrays	Approximate Equivalent Period of Natural Background Radiation	Additional Lifetime Risk of Fatal and Non-Fatal Cancer*
Chest radiograph	0.02	1	3 days	1:1.000.000
Lung perfusion scintigraphy (Tc99m)	1	50	6 months	1:10.000
Chest computer tomography (non contrast)	8	400	3.6 years	1:1.200 (M) 1:1.000 (F)
Perfusion cardiac Rest-stress Tc99m sestamibi scan	10	500	4 years	1:1.000 (M) 1: 750 (F)
Cardiac computer tomography (64-slice)	15	750	7 years	1:750 (M) 1: 500 (F)
Coronary stenting	15	750	7 years	1:750 (M) 1: 500 (F)
Thallium-201 scan	41	2000	16 years	1:250 (M) 1: 200 (F)

*Values are given for a 40 year old person (M, male; F, female). Multiply by 4 for children under 1 year, and by 0.5 in an 80-year-old male*

# Comprehension Test

## (Provided for CT scan)

- What is the radiology dose equivalent of your CT scan:
  - Zero x-rays; 10 x-rays; 750 chest x-rays; 100 chest x-rays
- What is the radiology risk corresponding to your CT scan:
  - Zero risk; 1 cancer out of 1 million exposed; 1 cancer out of 750 exposed; 1 cancer in 10 exposed
- Which type of long-term risk corresponds to your radiology examination:
  - Bronchitis; Myocardial infarction; Cancer; None
- When will the risk, if ever, show-up in your life:
  - In days; In weeks; In months; In years or decades
- Which organs will receive the greatest dose with your CT scan :
  - Kidney; brain; gonads; lungs.

# Results

- The patients found the radiological *Informed form B* (second generation) much more readable and informative, and scored significantly better than the original one

$1.2 \pm 0.6$  versus  $2.6 \pm 0.5$ ,  $p = 0.001$

- They listed the following limitations in their free comments (in descending order of frequency):
  - ▣ too much time consuming (on average  $> 10$  minutes);
  - ▣ still too difficult; and boring;
  - ▣ it should focus only on radiation risk and treat separately other risks.

# Results



- The suggestions were (in descending order of frequency):
  - ▣ To prepare a video format rather than a written text
  - ▣ To put it on smart phone or tablet platform with color 3-D graphics instead of percentages and absolute numbers;
  - ▣ To make it short (< 3 minutes)
  - ▣ To add an interactive section with frequently asked questions

# The future

- The “next-generation” informed form for each type of radiological procedure (e.g., CT, cardiac scintigraphy, coronary angiography, etc)
- A web and mobile-based technology platform
- Supported by audiovisual information materials, movie-clips, color graphics and 3 D tables, following the advice of communication experts and scientific society guidelines.
- Linked to other tools as Radio-Risk software, calculator of personal radiation exposure dose (cumulative effective dose in milliSievert, and equivalent number of chest X-rays) and the long-term risks related to ionizing radiation, with a graphic illustration of cancer risk and risk equivalent.

# Conclusions



- ❑ Current informed consent forms are unreadable for the average patient.
- ❑ Radiological informed consent should be transparent, clear, easy to understand and not misleading, and these mandatory requirements are best achieved with a simple and fast visual format on mobile platform. The time-consuming, wordy and boring paper-based informed consent forms are more likely to miss the point of transferring vital information for shared decision making and patient empowerment



# We Are Giving Ourselves Cancer

By RITA F. REDBERG and REBECCA SMITH-BINDMAN JAN. 30,  
2014

*The New York Times*

Neither doctors nor patients want to return to the days before CT scans. But we need to find ways to use them without killing people in the process.

