



Lubjana
June 17th, 2015

The Informed Consent

Clara Carpeggiani and
Eugenio Picano

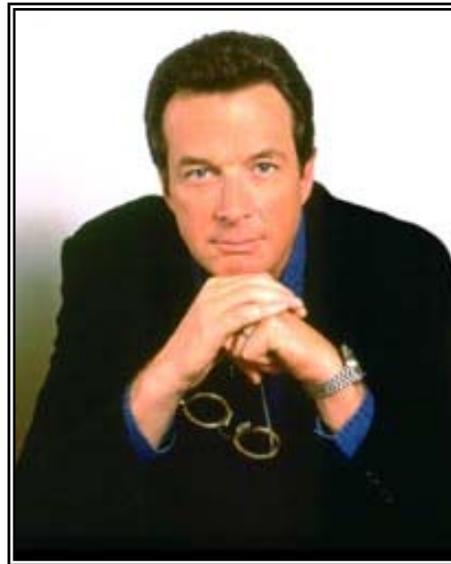
Istituto di Fisiologia Clinica, CNR, Pisa



The NEW ENGLAND
JOURNAL of MEDICINE

**“Medical writing is a highly skilled,
calculated attempt to confuse the
reader”**

(N Engl J Med 1975; 293:1257-9)



Michael Crichton

Magical Mystery Tour

Dose Length
Product

mAmp

KVolt



megaBecquerel

DAP and KAP

millicurie

BMJ

Education and debate

Informed consent and communication of risk from radiological and nuclear medicine examinations: how to escape from a communication inferno

Eugenio Picano (October 9, 2004)

“Mirate la dottrina che s'asconde sotto 'l velame de li versi strani”

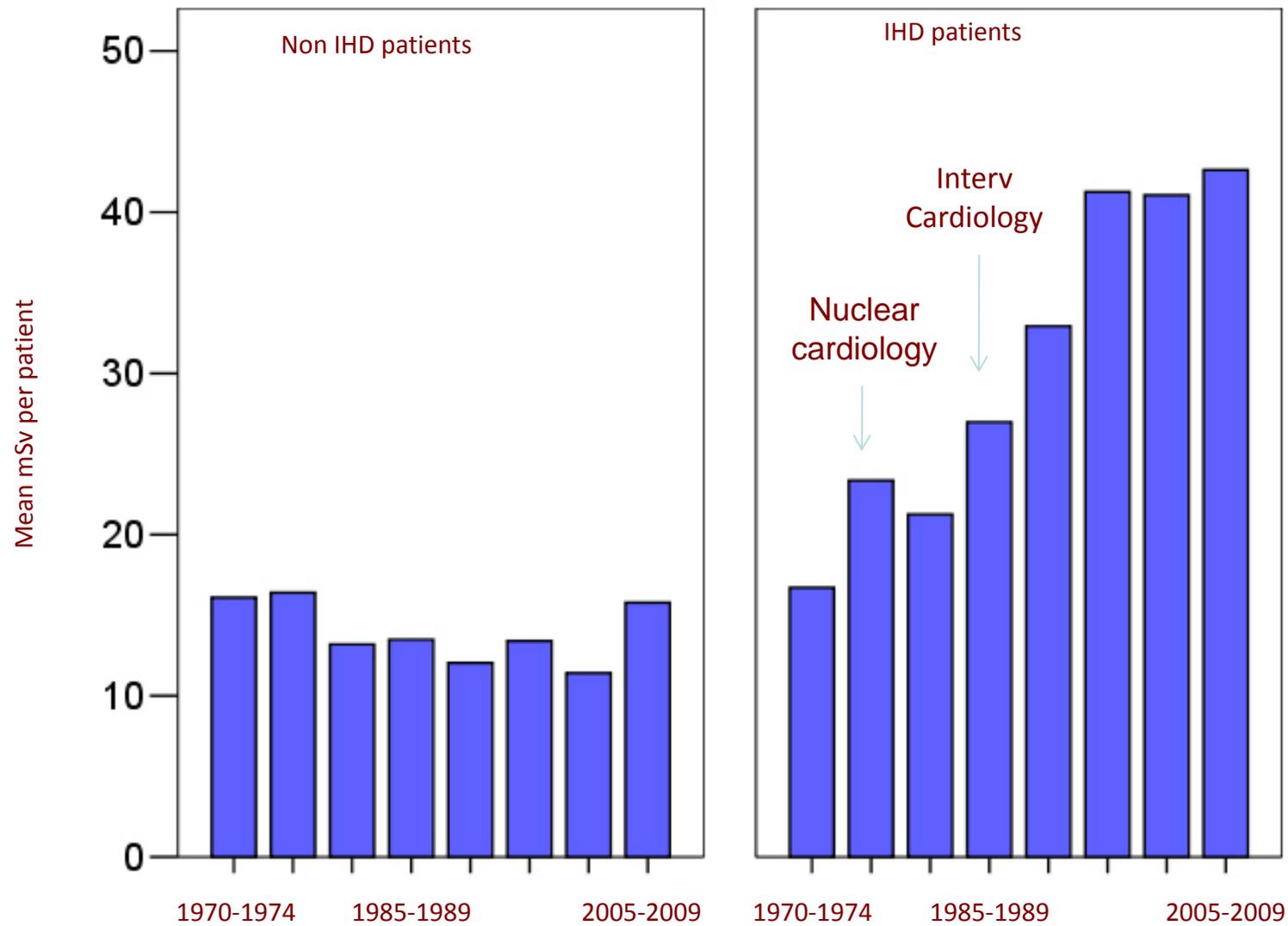
Dante. Inferno: Canto IX

...Beneath the veil of verses so obscure”

Standard average reference doses of common cardiological examination

Diagnostic procedures	Effective dose (mSv)	Equivalent CXRs	Background radiation (years)
Diagnostic coronary angiography	7 (2-16)	350	2.9
Percutaneous coronary Intervention	15 (7-57)	750	6.3
Dilation chronic coronary occlusion	81 (17-194)	4050	33.7
Aortic valvuloplasty	39	1950	16.2
Ablation procedure:	15.2 (1.6-59.6)	760	5.7
Regular PM or ICD implant	4 (1.4-17)	200	1.6
64-slice coronary CTA	15 (3-32)	750 (150-1,600)	6.25
PET F-18 FDG rest (400 MBq, viability)	8	400	3.3
^{99m} Tc -Sestamibi (1100 MBq, 1 day, stress-rest)	9.4	470	3.9
SPECT- ²⁰¹ Tl stress/redistr.(130 MBq, sing inj)	22	1100	91.6

Cumulative radiation exposure per patient





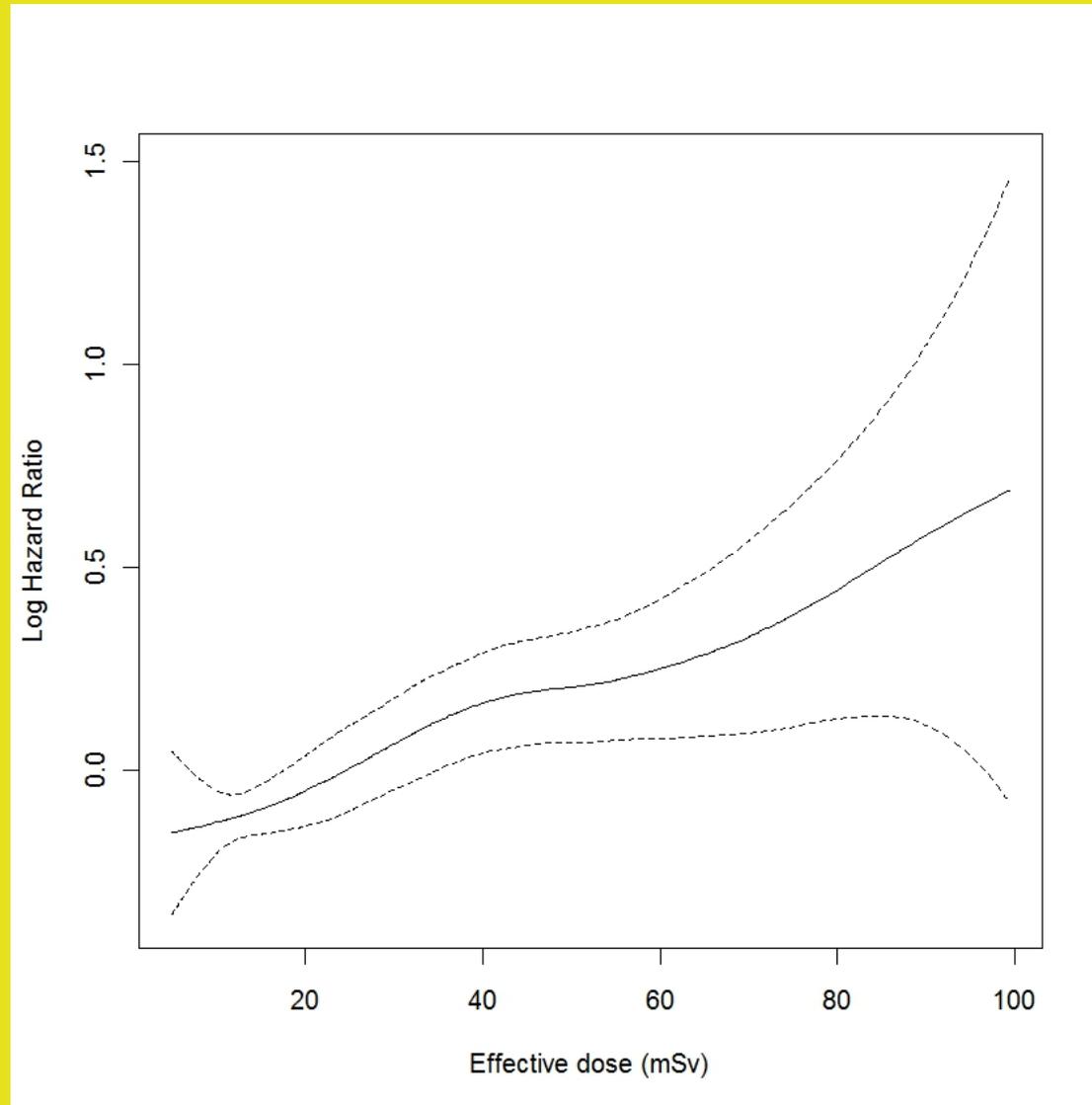
Long-term outcome and medical radiation exposure in patients hospitalized for cardiovascular disease.

C Carpeggiani, G Rossi, P Landi, C Michelassi, M Brambilla, L Cortigiani, E Picano. International Journal of Cardiology, 15 September 2015, Volume 195, Pages 30–36

Eisenberg MJ, Afilalo J, Lawler PR, Abrahamowicz M, Richard H, Pilote L. **Cancer risk related to low-dose ionizing radiation from cardiac imaging in patients after acute myocardial infarction.** CMAJ 183 (2011) 430–436.

Hung MC and Hwang JJ. **Cancer risk from medical radiation procedures for coronary artery disease: a nationwide population-based cohort study.** Asian Pacific J Cancer Prev 14 (2013) 2783-2787.

Log Hazard ratio for Cancer Onset plotted against effective dose below 100 mSv



The New York Times

[The Opinion Pages|Op-Ed Contributors](#)

We Are Giving Ourselves Cancer

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

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.



The perfect storm in risk communication



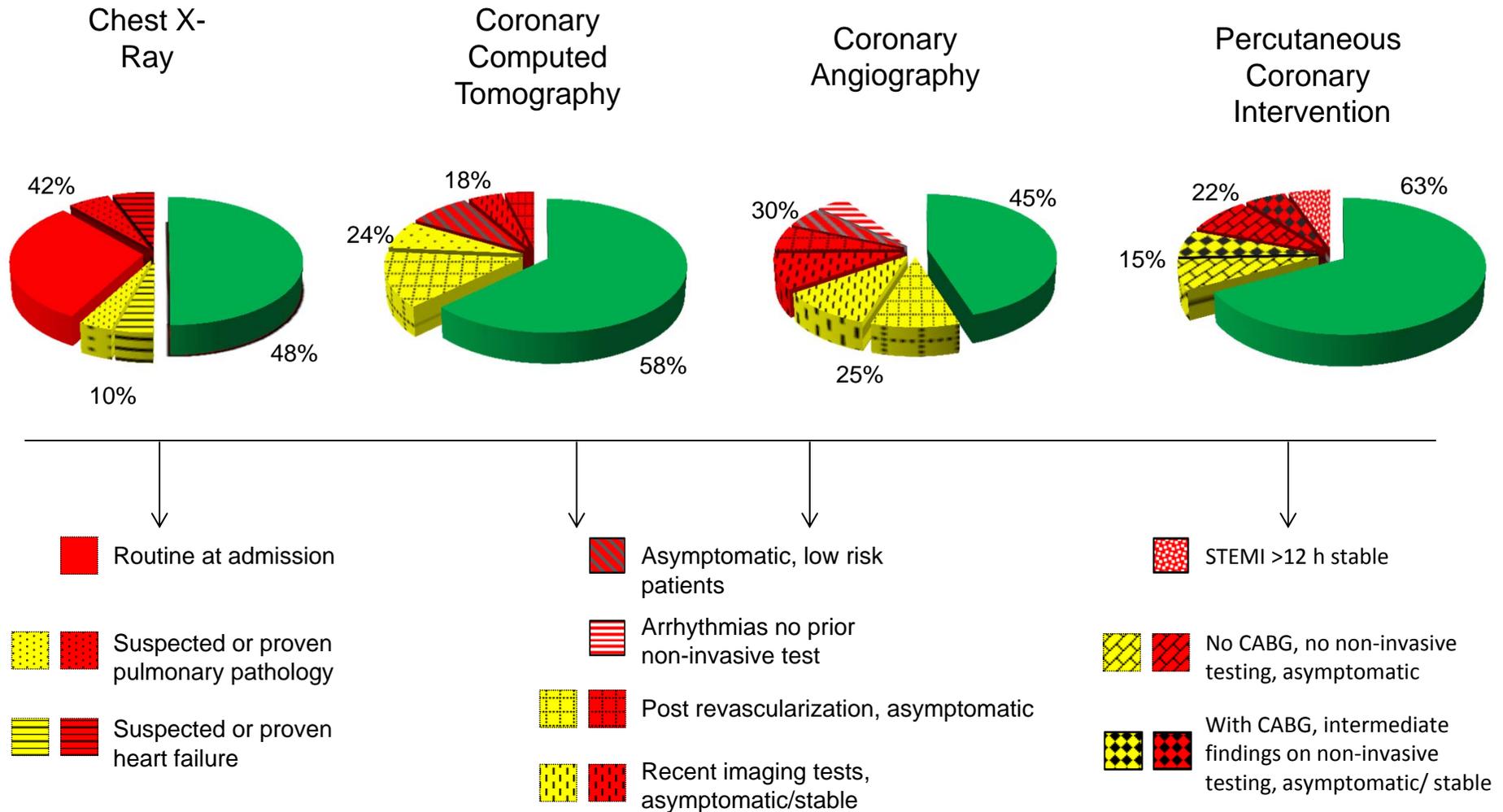
Inappropriateness

Doctors (un)awareness

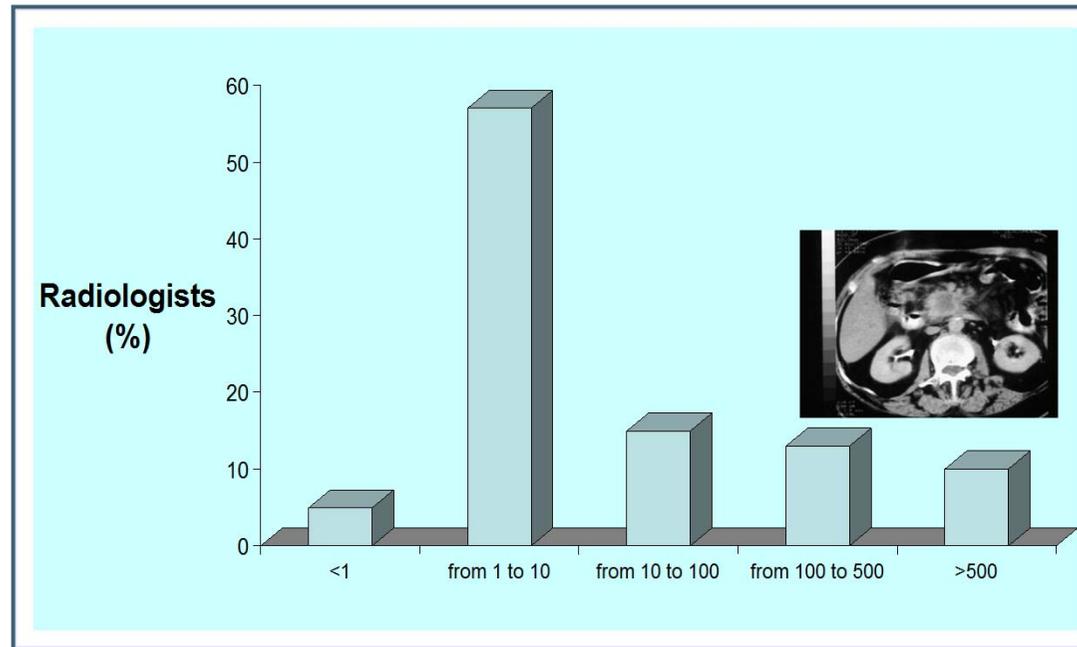
Patient (un)awareness

Carpeggiani C et al, PLOSOne, November 27, 2013

■ Appropriate
 ■ Partially inappropriate
 ■ Inappropriate



Trust me, I'm the expert!



Lee TH et al. Radiology. 2004;231:393-8

Dose abdomen CT =500 CXR's

- 20% of internists believe MRI is ionizing (Shiralkar. BMJ 2004)
- 12% of pediatricians think scintigraphy is non-ionizing (Thomas et al. Pediatr Radiol, 2006)
- 60% of cardiologists underestimate of 500 times the dose of a scintigraphy (Correia et al. Int J Cardiol, 2005)
- 22% of interventional radiologists do not wear dosimeter (Kottou et al. Radiat Prot Dosimetry, 2001)
- 81% of the interventional cardiology fellows did not know their radiation exposure (Kim C, Am J Cardiol 2010)
- Inverse relationship between experience and dose awareness, consistently poor (Brown N, J Med Im Rad Oncol, 2013)

Communication Strategy number one: DON'T SAY A WORD



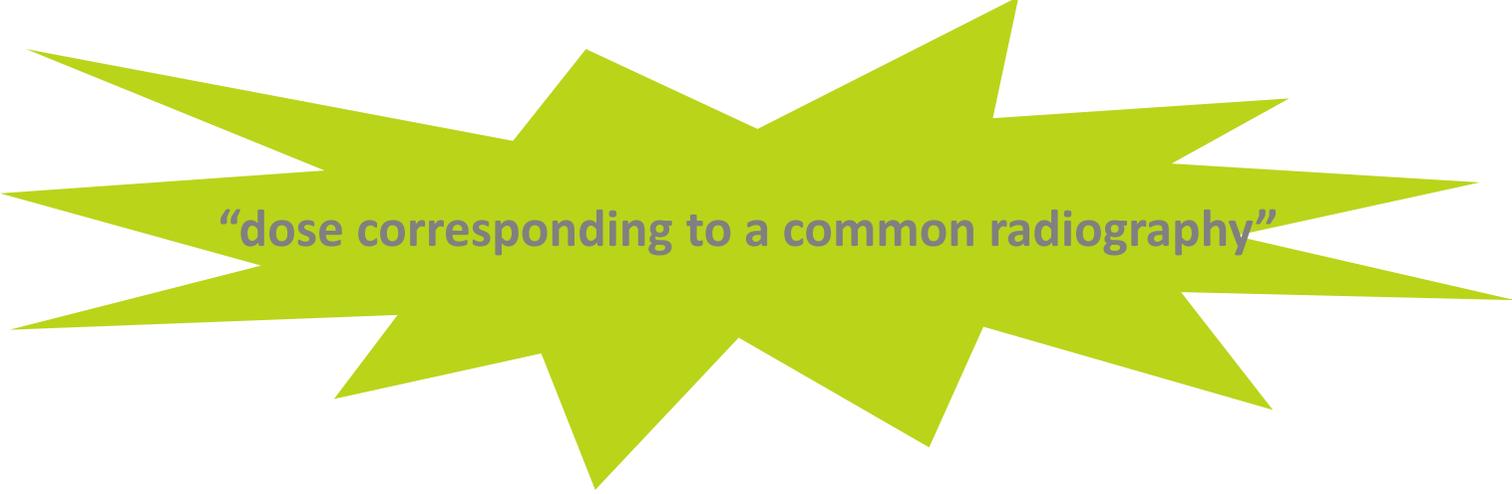
The current policy for cardio CT,
stent, etc...

“Il mio segreto è chiuso dentro me...

My mystery is closed within me”

Strategy n. 2: Understatement

MPI or PCI



“dose corresponding to a common radiography”

Strategy n. 3: Full disclosure

ESC position paper



European Heart Journal
doi:10.1093/eurheartj/ehz394

ESC REPORT

NIH.gov

Your scan in Nuclear Medicine involves exposure to radiation.your whole body radiation exposure during each scan will be about 15 milliSieverts, about five times the average annual radiation exposure a person in the United States receives from natural background radiation.

..... your long term risks of harm from this degree of radiation exposure might be as high as 1 in 1000. Harmful effects could include the development of cancer and genetic changes”

The appropriate and justified use of medical radiation in cardiovascular imaging: a position document of the ESC Associations of Cardiovascular Imaging, Percutaneous Cardiovascular Interventions and Electrophysiology

Eugenio Picano¹, Eliseo Vaño^{2,3}, Madan M. Rehani⁴, Alberto Cuocolo⁵, Lluís Mont⁶, Vicente Bodi⁷, Olivier Bar⁸, Carlo Maccia⁹, Luc Pierard¹⁰, Rosa Sicari¹, Sven Plein¹¹, Heiko Mahrholdt¹², Patrizio Lancellotti¹³, Juhani Knuuti¹⁴, Hein Heidbuchel¹⁵, Carlo Di Mario¹⁶, and Luigi P. Badano^{17*}

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Take-home message

- The informed consent form should spell out, possibly with a figure, the specific reference dose
- The jargon information should be translated into mSv, equivalent number of chest radiographs, and equivalent periods of natural background radiation.
- After the examination - the actually delivered dose should be stored in the patient's and laboratory's records; - the patient should be provided with dose information, a requirement enforced by law in many countries.
- Effective dose has the advantage that it is not modality-specific and can be cumulated between different imaging modalities over time
- A smart cardiologist cannot be afraid of the essential and often life-saving use of medical radiation, but must be very afraid of radiation unawareness.

Terminology that should be used

Table 6 Terminology that should be used

Investigation (example)	Effective dose range	Additional lifetime risk of fatal and non-fatal cancer	RCR symbolic representation	Proposed risk term
CXR	<0.1 mSv	1:1 million		Negligible
Abdominal X-ray	0.1–1 mSv	1 in 100 000 to 1 in 1 million		Minimal
Chest CT	1–10 mSv	1 in 10 000 to 1 in 1000		Very low
PCI	10–100 mSv	1 in 1000 to 1 in 100		Low

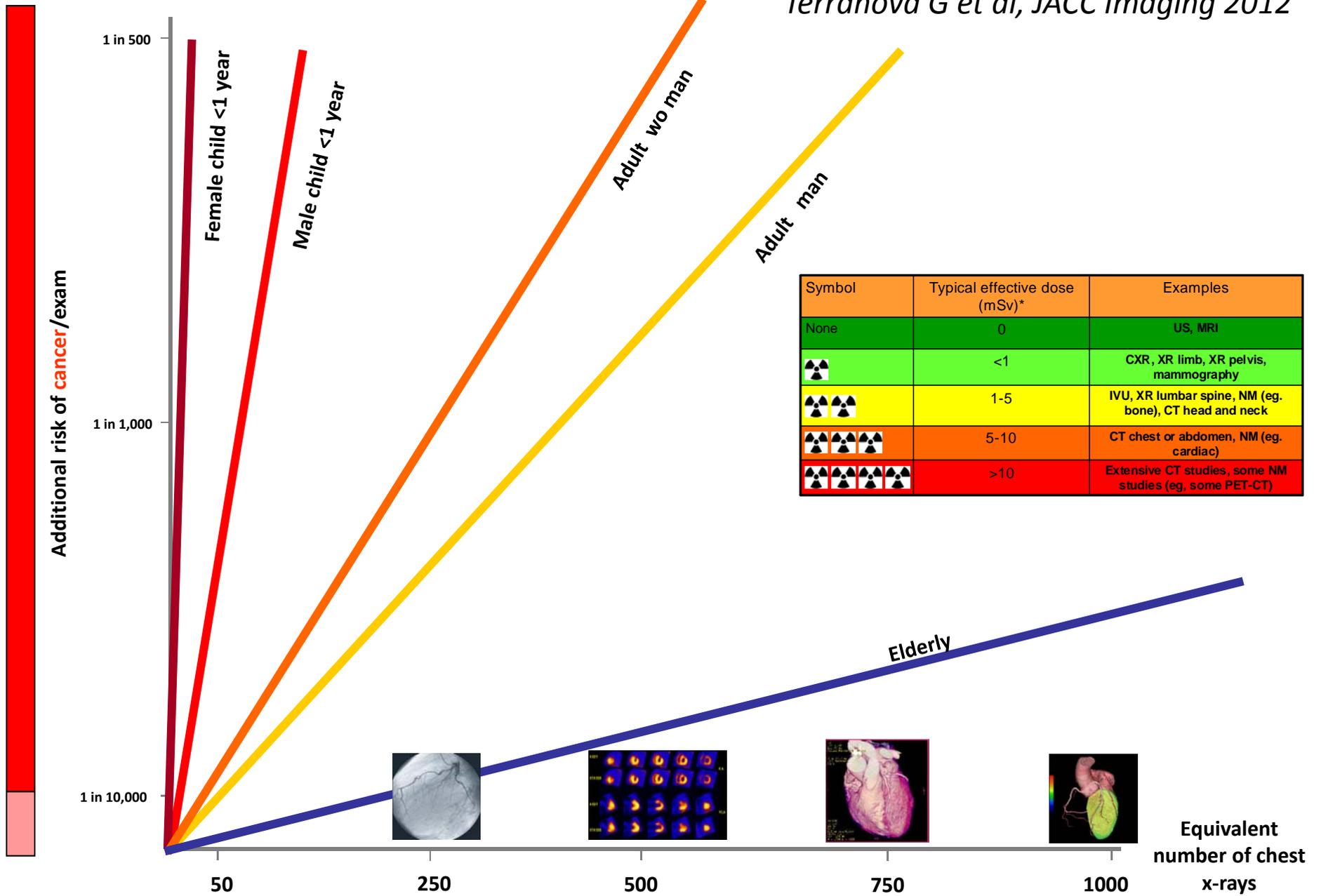
These examples relate to a healthy 50-year-old man. Multiply by 1.38 for women, by 4 for children, and by 0.5 (reduced by 50%) in an 80-year-old man. Adapted from references 18,48, and 49.

CXRs, chest X-rays; RCR, Royal College of Radiology; PCI, percutaneous coronary intervention.

 <0.1 mSv;  0.1–1 mSv;  1–10 mSv;  >10 mSv.

Picano E, et al. *Eur Heart J* doi: 10.1093/eurheartj/eh394

Terranova G et al, JACC Imaging 2012



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Be aware of the dose



- *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

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

Semelka RC, Armao DM, Elias J Jr, Picano E.

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.

January 2012

Radiology

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