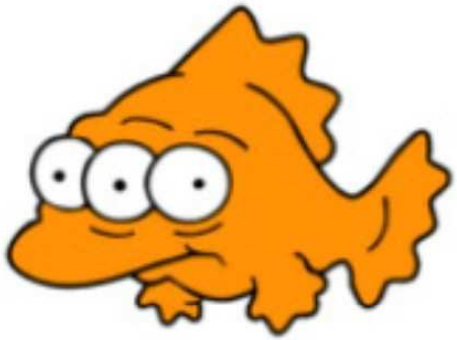
Giustificazione, ottimizzazione e livelli diagnostici di riferimento alla luce del D.Lgs. 101/2020

Bequerel [Bq]
How brightly your Cesium glows

Gray [Gy]
How brightly Cesium will make you glow



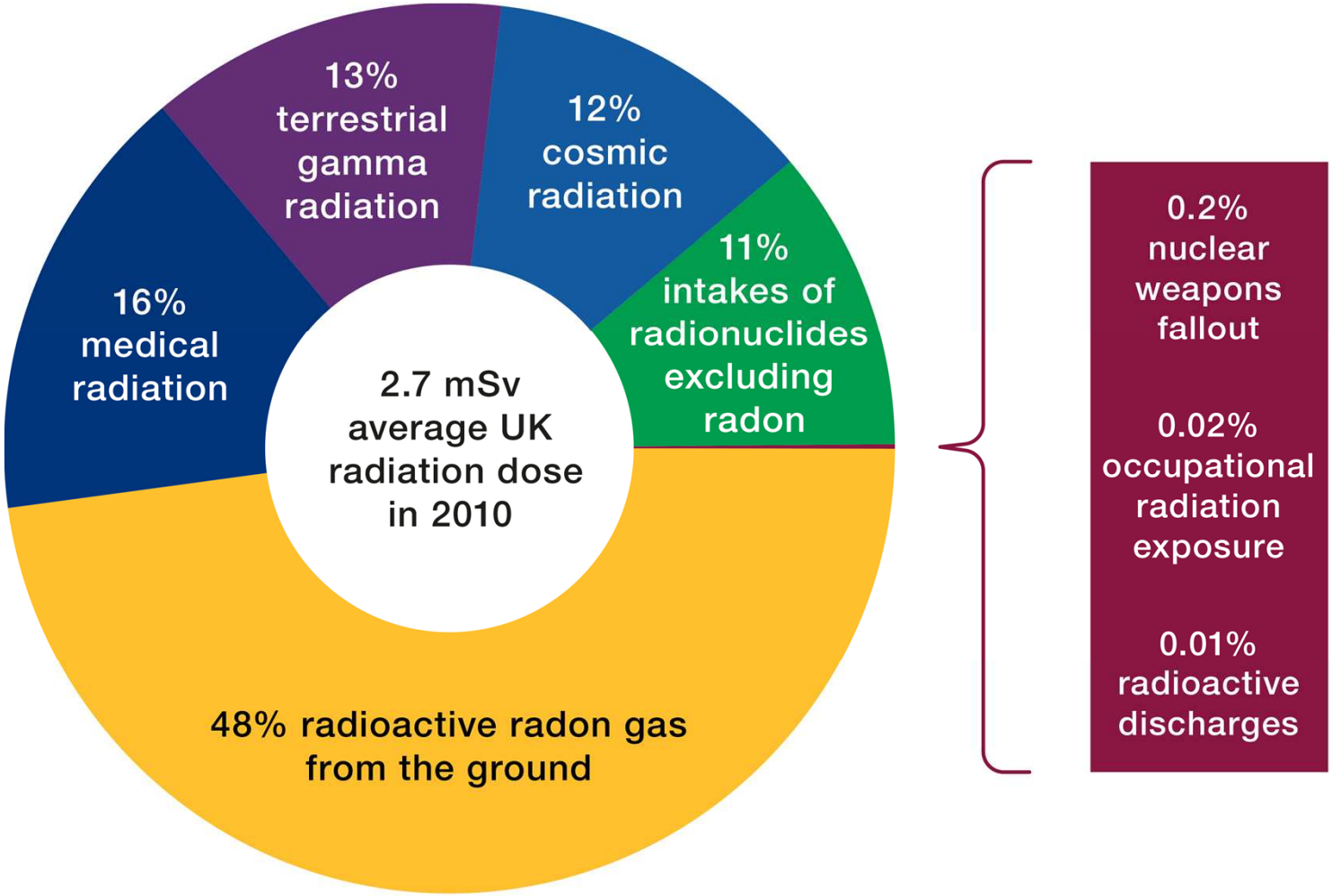
Sieverts [Sv]
How many extra eyes will you have after glowing?

The Simpsons' Guide to Radiation

Radiation exposure and risk

- Stochastic risk:
  - has probability of occurrence depending on the irradiated doses without threshold
  - shows up years after exposure
  - consists primarily of cancer and genetic effects such as inherited mutations
- Deterministic effects:
  - malfunctions of organs by irradiation more than a threshold
  - skin burns, cataract, cardiovascular diseases, intestinal damage, hemopoietic system and CNS system failure

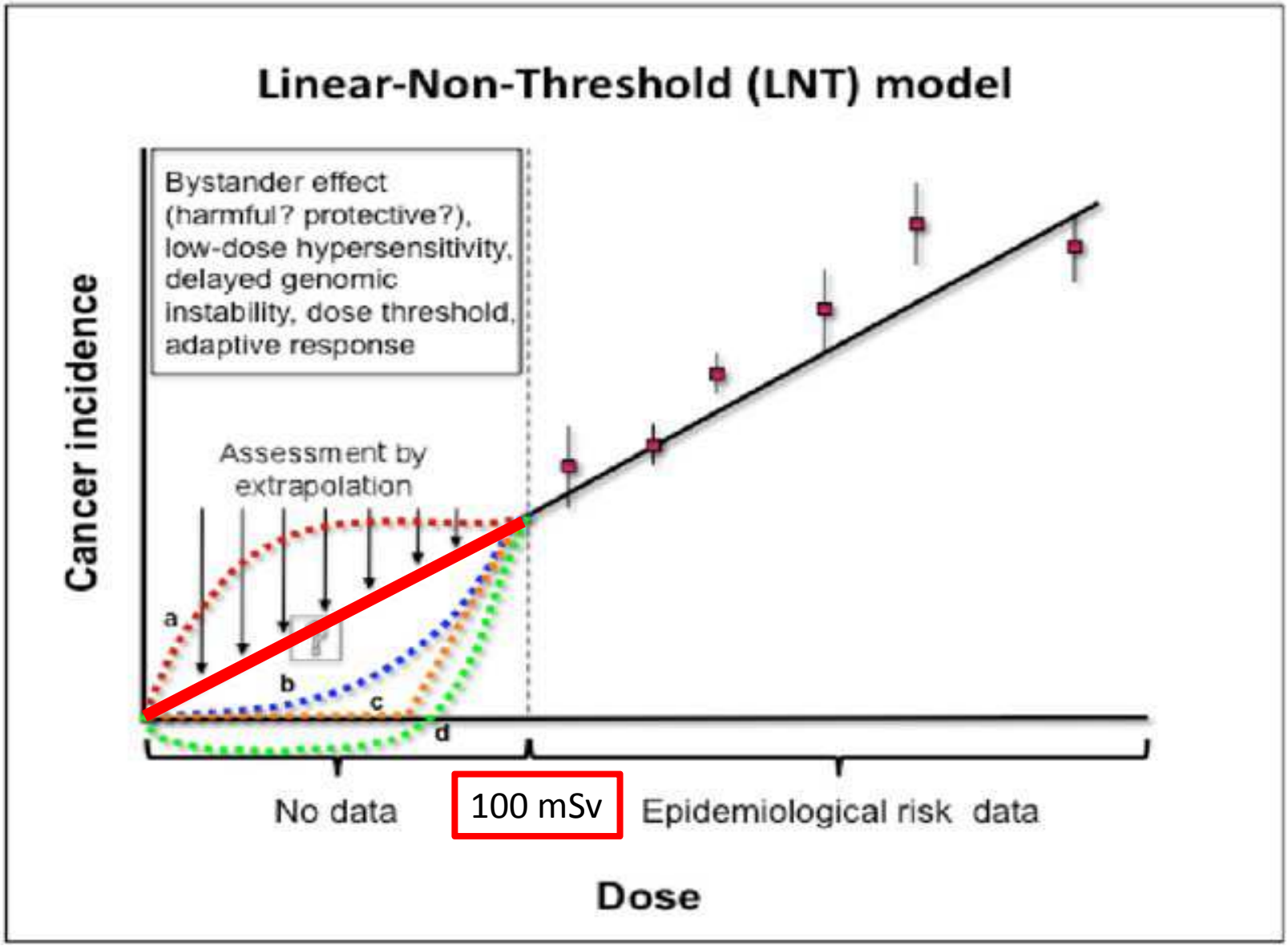
Source of ionizing radiation to the population



Public Health England

For more information please visit: goo.gl/OWBcV3

Radiation exposure and risk



Risk estimation: why so difficult?

- Extremely large sample size needed to ensure statistical significance at low dose levels:
  - sample size of 500.000 and 2.000.000 are required with lifetime follow-up for exposure levels of 20 mSv and 10 mSv respectively, which rend a decent epidemiological study unfeasible*
- Uncertainties in radiation dosimetry cannot be avoidable and influence every aspect of studies
- Issues of confounding factors such as smoking, genetic variation and socioeconomic status are very important
- Statistical uncertainties in dose response model

**National Research Council (US) Committee on Assessment of CDC Radiation Studies, 1995*

Risk estimation: why so difficult?

- Despite a variety of studies, understanding of health effects of low dose radiation – less than 100 mSv – is still incomplete
- For this reason, the LNT approach is the most reasonable risk model at low dose levels and remain fundamental in terms of radiation protection and safety

MEDIRAD

Implications of Medical Low Dose Radiation Exposure

A European, multi-disciplinary project to enhance the scientific bases and practice of radiation protection in the medical field

DECRETO LEGISLATIVO 31 luglio 2020, n. **101.**

Attuazione della direttiva 2013/59/Euratom, che stabilisce norme fondamentali di sicurezza relative alla protezione contro i pericoli derivanti dall'esposizione alle radiazioni ionizzanti, e che abroga le direttive 89/618/Euratom, 90/641/Euratom, 96/29/Euratom, 97/43/Euratom e 2003/122/Euratom e riordino della normativa di settore in attuazione dell'articolo 20, comma 1, lettera *a)*, della legge 4 ottobre 2019, n. 117.

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Legislation

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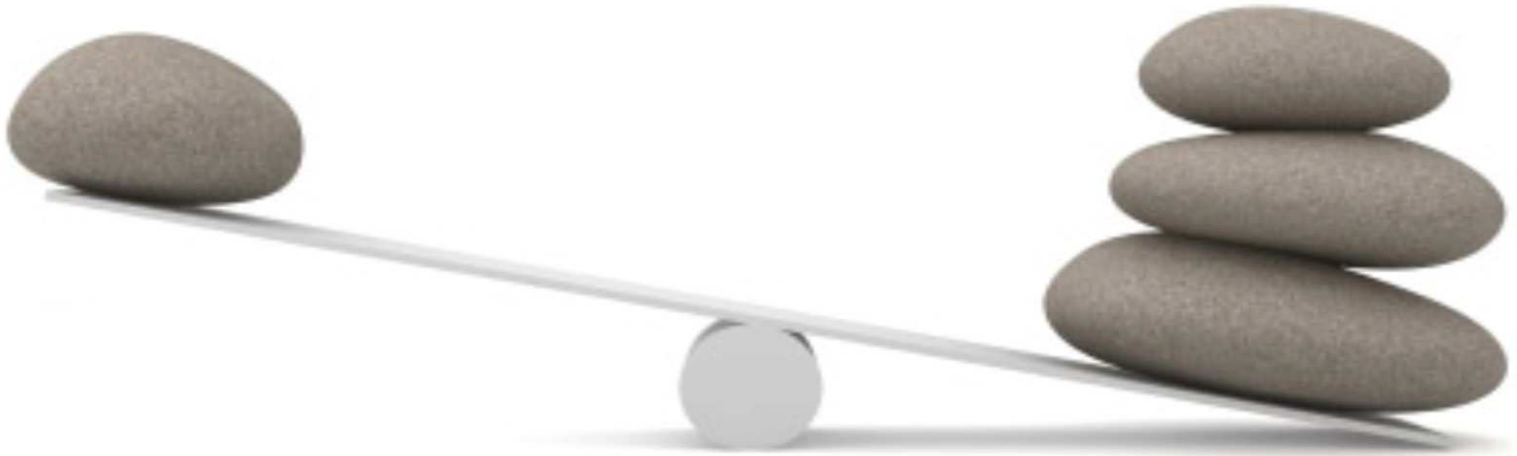
Contents

D.Lgs. 101/2020. Art.1 – Finalità e principi del sistema di radioprotezione

- Il sistema di radioprotezione si basa sui principi di giustificazione, ottimizzazione e limitazione delle dosi
- …le esposizioni mediche non sono soggette a limitazioni delle dosi…

Justification



- Any exposure from diagnostic imaging is justified if it can provide the benefits of a prompt diagnosis and adequate treatment: these benefits always outweigh any associated risk such as a small additional risk of cancer due to the exposure to radiation

D.Lgs 101/2020 - Art. 4: Giustificazione delle pratiche

- 1. Nuovi tipi di pratiche … debbono essere giustificate prima di essere adottate
- 2. Le pratiche esistenti sono sottoposte a riesame ogni qualvolta emergano nuove evidenze sulla loro efficacia e potenziali conseguenze, ovvero si rendano disponibili altre pratiche …

Art. 156 e 157 – Ambito di applicazione del principio di giustificazione

- pazienti nell'ambito della rispettiva diagnosi o trattamento
- sorveglianza sanitaria dei lavoratori
- persone nell'ambito di screening sanitari
- asintomatici e pazienti che volontariamente partecipano a programmi di ricerca
- persone nell'ambito di procedure a scopo non medico condotte con attrezzature radiologiche

Art. 156 e 157 – Ambito di applicazione del principio di giustificazione

- E' vietata l'esposizione non giustificata
- Tutte le esposizioni mediche individuali devono essere giustificate preliminarmente, tenendo conto degli obbiettivi specifici dell'esposizione e delle caratteristiche della persona interessata. Una pratica non giustificata in generale potrebbe esserlo nel singolo individuo in circostanze particolari

Art. 161 – Procedure

- Il Ministero della salute… adotta linee guida per le procedure inerenti le pratiche radiologiche clinicamente sperimentate e standardizzate
- Nelle linee guida sono altresì fornite raccomandazioni ai medici prescriventi relative ai criteri di appropriatezza e giustificazione, nonchè indicazioni sull'entità delle dosi assorbite dai pazienti... Tali linee guida sono pubblicate nella *Gazzetta Ufficiale*
- Fino alla pubblicazione in GU…

La diagnostica per immagini

Linee guida nazionali di riferimento

Presidenza del Consiglio dei Ministri

CONFERENZA PERMANENTE PER I RAPPORTI
TRA LO STATO, LE REGIONI E LE PROVINCIE AUTONOME
DI TRENTO E BOLZANO

Accordo, ai sensi dell'art. 4 del decreto legislativo 28 agosto 1997, n. 281, tra il Ministro della salute e le Regioni e Province autonome di Trento e di Bolzano sul documento relativo alle "Linee guida per la diagnostica per immagini".

Atto rep. n. 2113 del 28 ottobre 2004.

GRUPPO DI LAVORO

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ASSR
Donato ANTONELLIS
Francesco Nicola LAURIA

Adapted from EC RP 118, 2000

PEDIATRIA

Problema clinico	Indagine	Raccomandazione	Commento	Dose
TORACE-CUORE				
Infezione toracica acuta	RXT	non indicata di routine A	indicata quando i sintomi persistono o in caso di bambini gravemente ammalati. Se RX torace documenta polmonite non complicata RX torace di controllo non sempre necessaria.	I
Tosse produttiva ricorrente	RXT	non indicata di routine C	i bambini con infezioni toraciche ricorrenti di solito hanno RX normale o mostrano ispessimento delle pareti bronchiali. Non utili RX di controllo a meno che nell'esame di base non fosse presente atelettasia. Nel sospetto di fibrosi cistica necessaria consulenza specialistica.	I

Linee guida nazionali di riferimento

SIRM, AINR, AIMN, FISM, SIMI, ISS, Ministero della Salute, ASSR

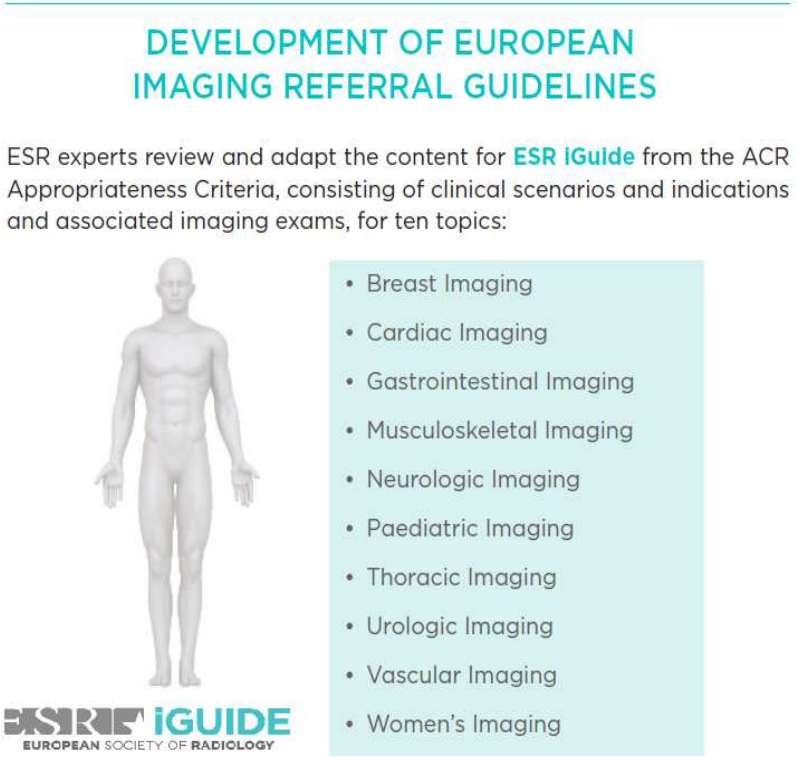
(2004)

ESR iGuide

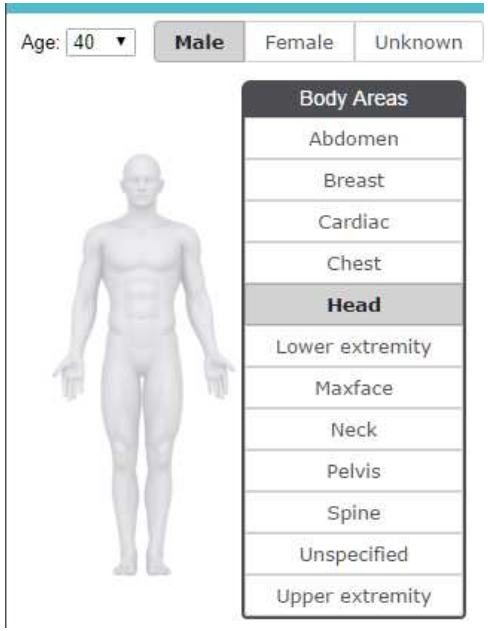
- ESR iGuide is based on the Appropriateness Criteria developed by the American College of Radiology (ACR), reviewed by a team of senior radiologists
- Recommendations for topic groups including Breast, Cardiac, Gastrointestinal, Musculoskeletal, Neurologic, **Paediatric**, Thoracic, Urologic, Vascular and Women's Imaging are provided
- **Separate guidance for children includes 320 indications/scenarios with a number of 2465 scored decision rules**
- Annual update are provided in cooperation with the ACR's Rapid Response Committee

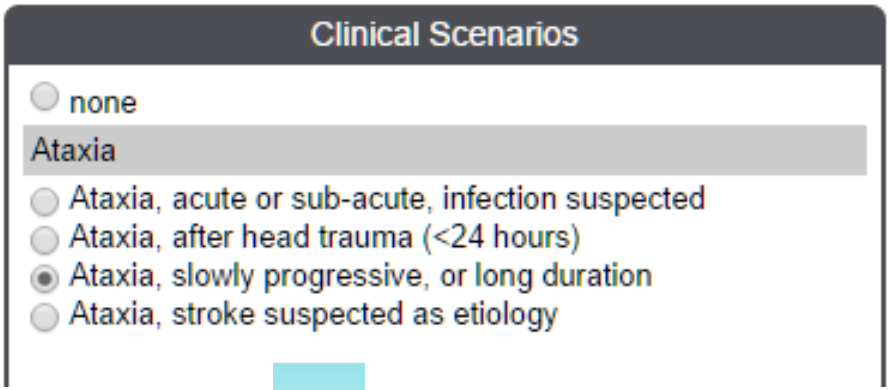
ESR iGuide
CLINICAL DECISION SUPPORT

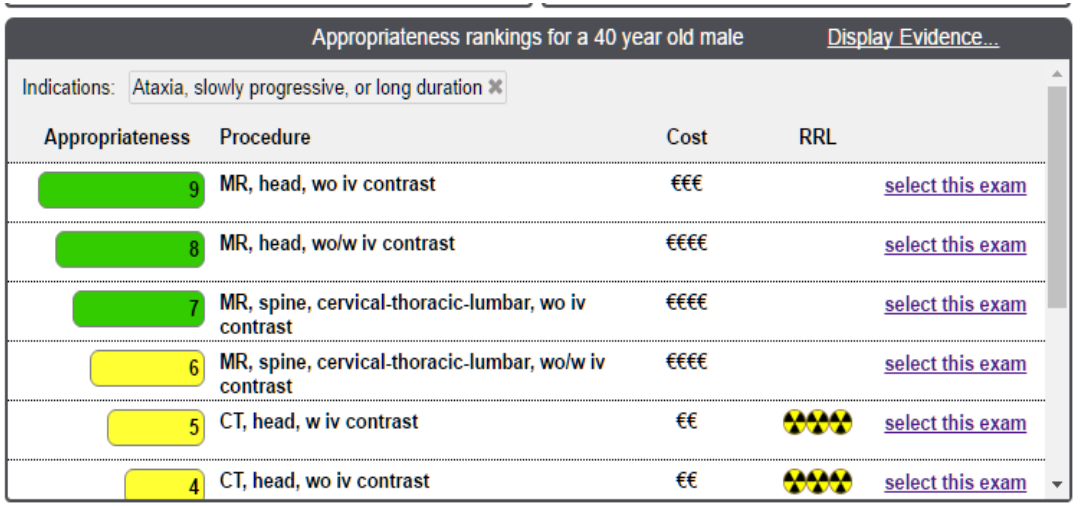
- 1800 indications with associated exams including appropriateness ratings for defined patient groups
  - Age range 0-150 years
  - Sex: male female, unknown
- Age range 0-18: paediatric guidelines
  - 320 indications, 2465 scored rules
- Appropriateness ratings:
  - 1-3 (red): usually not appropriate
  - 4-6 (yellow): may be appropriate
  - 7-9 (green) usually appropriate



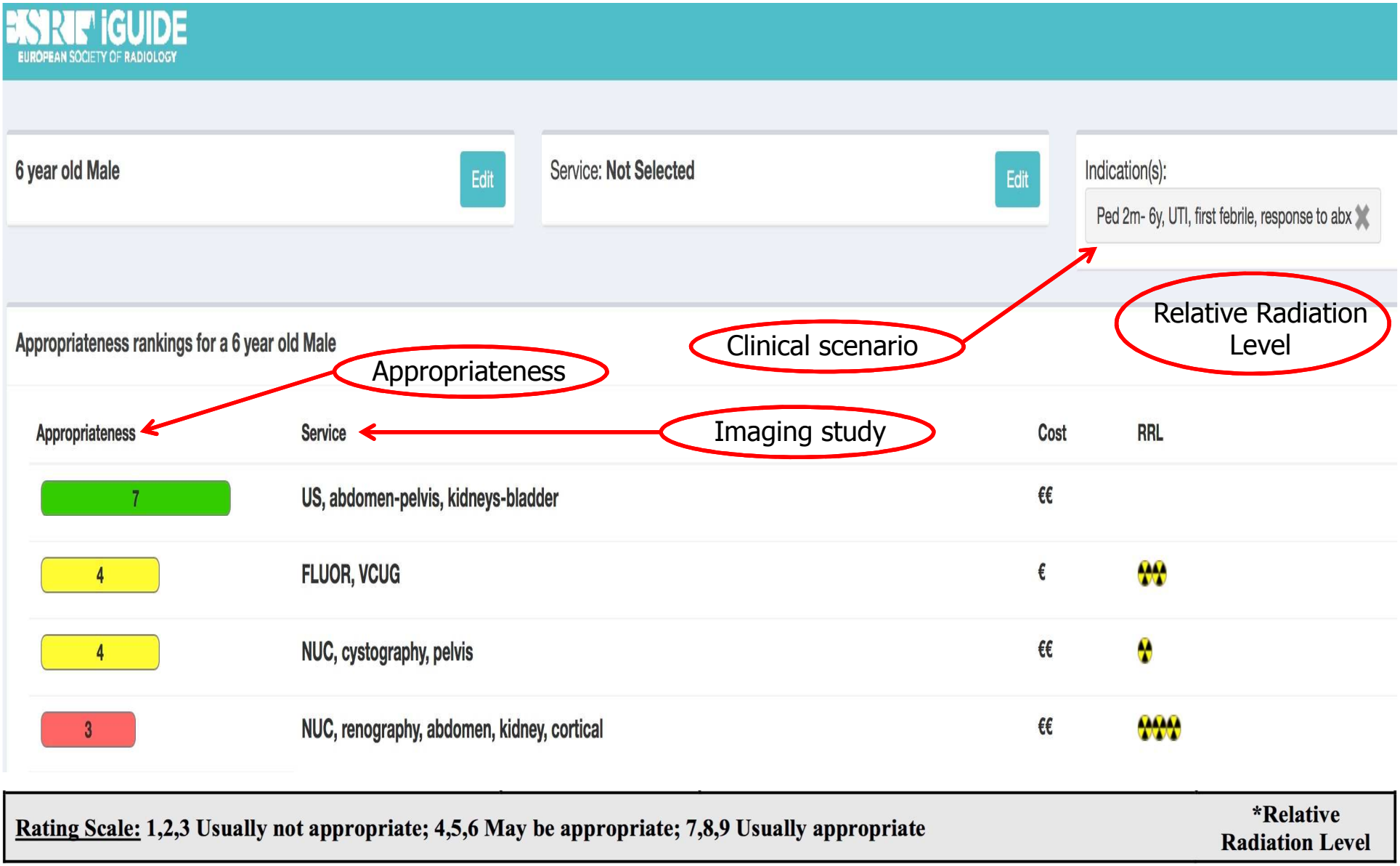
ESR iGuide workflow







ESR iGuide: an example of clinical scenario. First febrile urinary infection in a 6-y-old male



ESR iGuide: head trauma in a 1-y-old male

ESR iGUIDE
EUROPEAN SOCIETY OF RADIOLOGY

1 year old Male — Edit

Service: **Not Selected** — Edit

Indication(s):
Ped <2yo, head trauma, minor, GCS>13, not abuse ✖

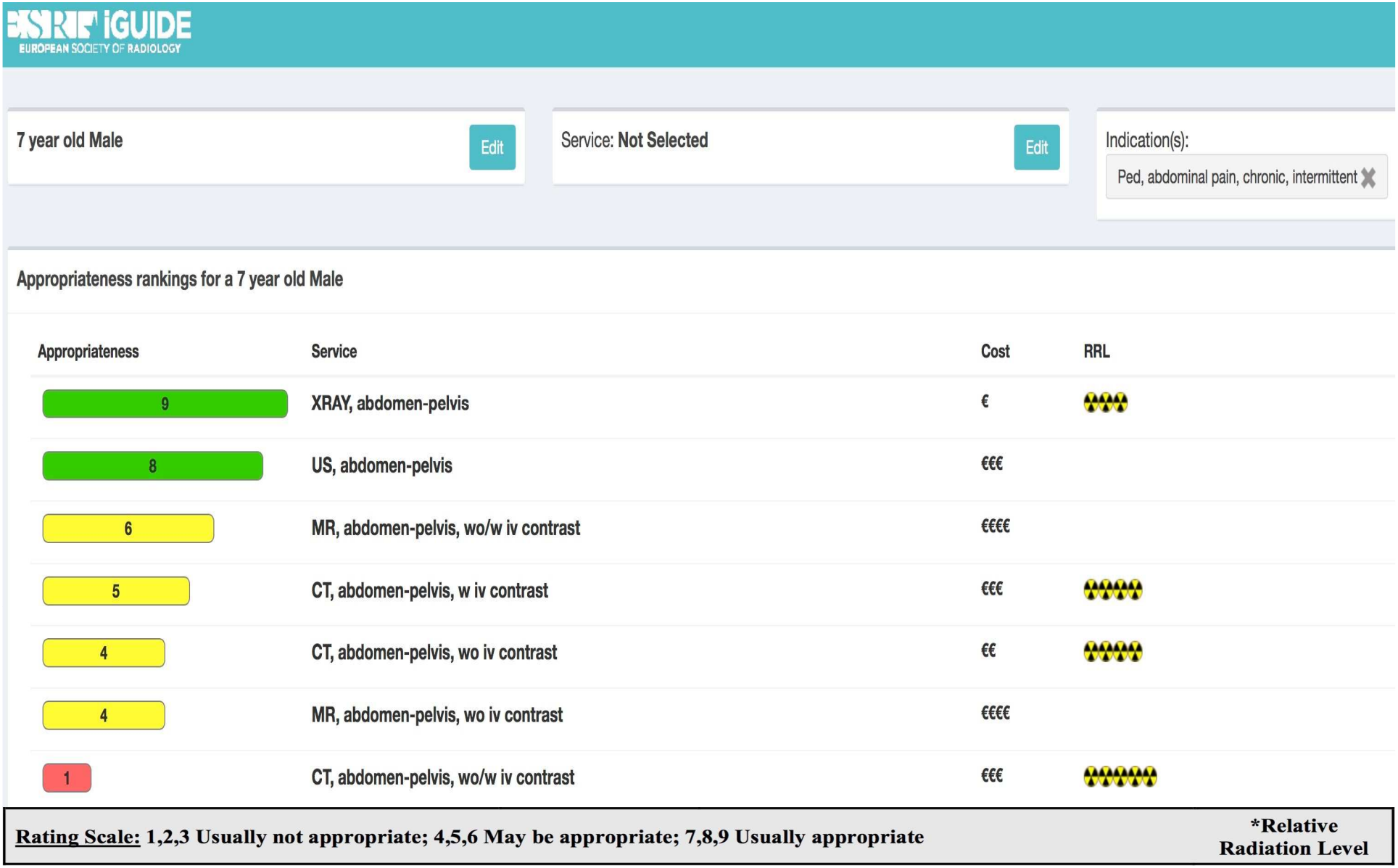
Appropriateness rankings for a 1 year old Male

Appropriateness	Service	Cost	RRL
3	CT, head, wo iv contrast	€€	☢☢☢
3	MR, head, wo iv contrast	€€€	
3	XRAY, head, skull	€	
2	CT, angiography, head, w iv contrast	€€€€	☢☢☢☢
2	MR, angiography, head, wo iv contrast	€€€€	
1	CT, head, w iv contrast	€€	☢☢☢
1	CT, head, wo/w iv contrast	€€€	☢☢☢☢
1	INV, angiography, head, cerebral	€	☢☢☢☢
1	MR, angiography, head, wo/w iv contrast	€€€€	
1	MR, head, wo/w iv contrast	€€€€	
1	NUC, brain scan, head, Tc-99m HMPAO, SPECT	€€€	☢☢☢☢
1	PET-CT, head, FDG	€€	☢☢☢☢
1	US, head	€€	

Rating Scale: 1,2,3 Usually not appropriate; 4,5,6 May be appropriate; 7,8,9 Usually appropriate

*Relative Radiation Level

ESR iGuide: chronic abdominal pain in a 7-y-old male

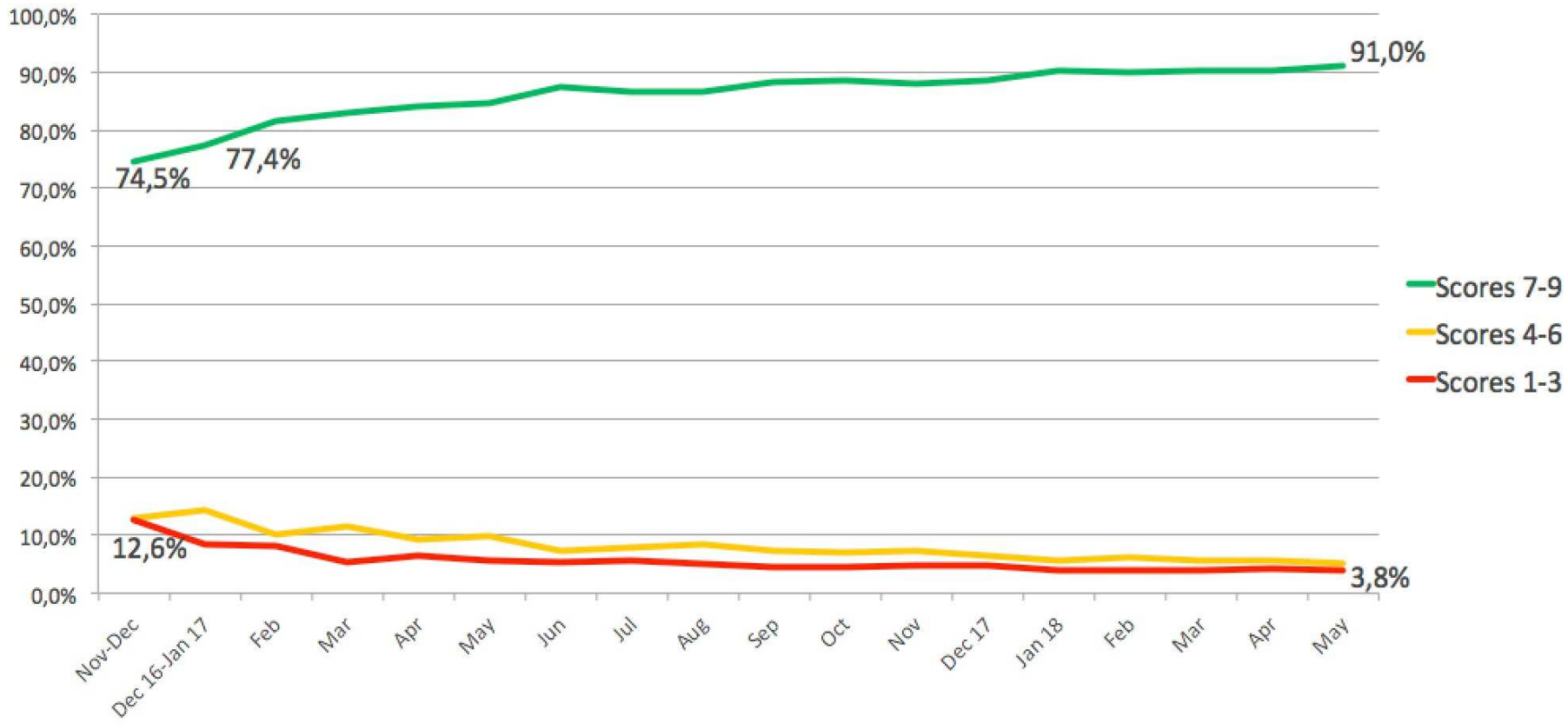


ESR iGuide implementation
Croatia pilot project (ECR 2019)

Appropriateness of referrals with ESR iGuide

November 2016-May 2018

Approximately 100.000 decision support sessions for all modalities



Art. 166 – Protezione particolare durante la gravidanza e l'allattamento

- In gravidanza il medico specialista porrà particolare attenzione alla giustificazione, alla necessità o all'urgenza, considerando la possibilità di procrastinare l'indagine. Nel caso in cui l'indagine diagnostica non possa essere procrastinata, il medico specialista informa la donna dei rischi derivanti al nascituro. Nel caso in cui si debba procedere comunque all'esposizione, il medico specialista e il tecnico sanitario di radiologia medica devono porre particolare attenzione al processo di ottimizzazione riguardante sia la madre che il nascituro

Optimisation

- All doses due to medical exposure for radiodiagnostic, interventional radiology,…, are kept **A**s **L**ow **A**s **R**easonably **A**chievable consistent with obtaining the required medical information, taking into account economic and societal factors

ALARA

Optimisation

240 mAs

120 mAs

- Optimisation means applying **the ALARA concept**
- Applying the ALARA concept means using ***a sound technique*** and accepting the highest image noise consistent with obtaining the required medical information

Art. 158 – Applicazione del principio di ottimizzazione alle esposizioni mediche

- Tutte le dosi dovute alle esposizioni di cui all'articolo 156, a eccezione delle procedure radioterapeutiche, devono essere mantenute al livello più basso ragionevolmente ottenibile e compatibile con il raggiungimento dell'informazione diagnostica richiesta, tenendo conto di fattori economici e sociali

Art. 158 – Applicazione del principio di ottimizzazione alle esposizioni mediche

- Il responsabile dell'impianto radiologico, ai fini dell'ottimizzazione dell'esecuzione degli esami in radio-diagnostica… nonchè delle procedure di radiologia interventistica, garantisce che si tenga conto dei livelli diagnostici di riferimento, laddove disponibili, tenendo conto delle indicazioni più aggiornate pubblicate dall'Istituto Superiore di Sanità

RAPPORTI ISTISAN 20|22

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Livelli diagnostici di riferimento per la pratica nazionale di radiologia diagnostica e interventistica e di medicina nucleare diagnostica

Aggiornamento del Rapporto ISTISAN 17/33

Art. 165 – Pratiche speciali

- L'esercente e il responsabile dell'impianto radiologico, nell'ambito delle rispettive competenze, individuano gli interventi da attuarsi ai fini dell'applicazione del principio di giustificazione e di ottimizzazione alle pratiche che comportano, in particolare, esposizioni di soggetti:

  a) in età pediatrica;

  b) esposti nell'ambito di programmi di *screening*;

  c) esposti nell'ambito di pratiche radiologiche comportanti alte dosi quali: radiologia interventistica, TC, medicina nucleare;

  d) sottoposti a trattamenti radioterapeutici

Livelli diagnostici di riferimento (LDR)

- Introdotti nel 1996 nella pubblicazione ICRP n 73
- Definiti come (Art. 7 D.Lgs 101/2020) come "livelli di dose nelle pratiche radiodiagnostiche mediche o interventistiche… per esami tipici per gruppi di pazienti di corporatura standard o fantocci standard"
- **NON SI APPLICANO AL SINGOLO PAZIENTE E NON RAPPRESENTANO LIMITI DI DOSE**

Livelli diagnostici di riferimento (LDR)

- Rappresentano uno ***strumento essenziale nei processi di ottimizzazione delle esposizioni***, individuando quelle pratiche radiologiche che richiedono interventi tecnici e/o metodologici atti a ridurre la dose mediana ai pazienti sottoposti ad indagine diagnostica in una installazione radiologica
- Qualora il valore di LDR venga ecceduto in modo significativo deve essere intrapresa una revisione e vengono adottate azioni correttive (Art. 161 D.Lgs 101/2020)
- Responsabilità del RIR e dello specialista in fisica medica

Procedure di interesse per gli LDR (ISTISAN 20/22)

- Gli LDR vengono determinati per esami che:
  - sono eseguiti spesso (almeno 15 pazienti in un bimestre all'interno della struttura)
  - hanno una denominazione univoca
  - consentono di eseguire verifiche in una elevata percentuale di installazioni radiologiche
  - o erogano una dose potenzialmente elevata

Gli LDR nella pratica clinica (ISTISAN 20/22)

Tabella 5.2. Denominazione, modalità di individuazione e campo di utilizzo dei diversi livelli di riferimento

Denominazione	Dimensione del campione	Valore nella distribuzione utilizzato per definire la quantità di interesse	Campo di applicazione
LDR regionale (es. LDR europeo)	Un campione regionale rappresentativo di installazioni	Terzo quartile dei valori mediani di ogni installazione (ad es. sala radiologica)	Per Paesi nella regione che non hanno identificato LDR nazionali
LDR nazionale	Un campione nazionale rappresentativo di installazioni	Terzo quartile dei valori mediani di ogni installazione	Uso nazionale, per identificare installazioni che richiedono interventi di ottimizzazione
LDR locale	Un campione limitato di installazioni (ad es. 20-30 sale radiologiche) in un'area limitata	Terzo quartile dei valori mediani di ogni installazione	Uso locale, per identificare installazioni che richiedono interventi di ottimizzazione
Valore tipico	Sale radiologiche di una struttura sanitaria o numero limitato di installazioni che utilizzano una nuova tecnologia	Valore mediano della distribuzione (dati insufficienti per l'utilizzo del terzo quartile)	Uso locale, per identificare installazioni che richiedono interventi di ottimizzazione

ISTISAN 20/22

Tabella 4.1. Valori di LDR per la radiografia proiettiva dell'adulto nella pratica radiologica italiana

Regione anatomica	Proiezione	Valori LDR	
		$K_{a,e}$ *mGy*	KAP o P_{KA} *Gycm²*
Cranio	AP o PA	3,5	1,0
	LAT	2,5	1,0
Torace	PA	0,4	0,25
	LAT	1,2	1,0
Addome	AP o PA	6	3,0
Rachide lombare	AP	7	1,5
	LAT	18	4,0
Pelvi	AP	6	3,0
Intra-orale	Molare della mandibola	1,2 ($K_{a,i}$)	
Ortopantomografia			0,081

ISTISAN 20/22

Tabella 4.4. Valori di LDR per la tomografia computerizzata dell'adulto nella pratica radiologica italiana

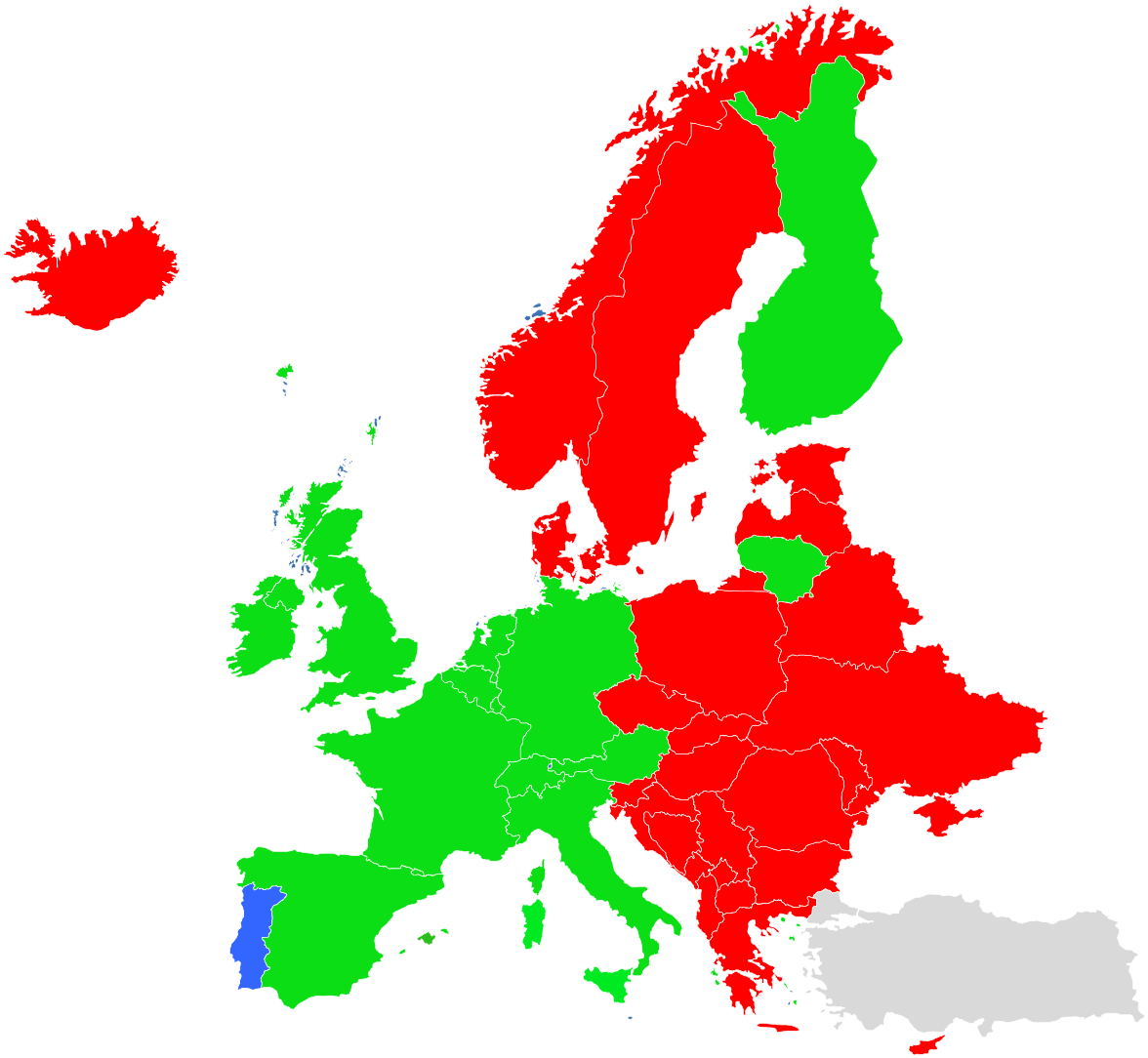
Regione anatomica	Valori LDR		
	CTDIvol* *mGy*	**DLP** *mGycm*	**DLPtot** *mGycm*
Cranio	70	1300	1400
Torace	15	600	750
Addome**	18	550	800
Addome e pelvi**	18	900	
Torace, addome, pelvi**	18	1200	2100
Colo-TC (Colonscopia virtuale)	11		950
Uro-TC			950
Coronaro-TC***	60	1200	

Gli algoritmi iterativi di ricostruzione delle immagini consentono di ridurre in modo significativo la dose al paziente rispetto alla tecnica di retroproiezione filtrata. I valori di dose qui riportati e risalenti ad indagini di alcuni anni fa risentono probabilmente in minima misura dei vantaggi degli algoritmi iterativi. Conseguentemente ogni centro potrà adottare LDR locali o tipici tenendo conto della tecnologia disponibile.

* CTDIvol: riferito per la testa al fantoccio dosimetrico di 16 cm ∅, per le altre procedure al fantoccio di 32 cm ∅

** con mezzo di contrasto organo-iodato e.v.

*** I valori LDR locali dovranno essere adattati alla tecnologia e al metodo di scansione impiegati.



Existing DRLs set in children by competent authorities for body regions for CT studies

- DRLs set by an authoritative body
- Other published/available data
- Not available

Radiation Protection N° 185, 2018

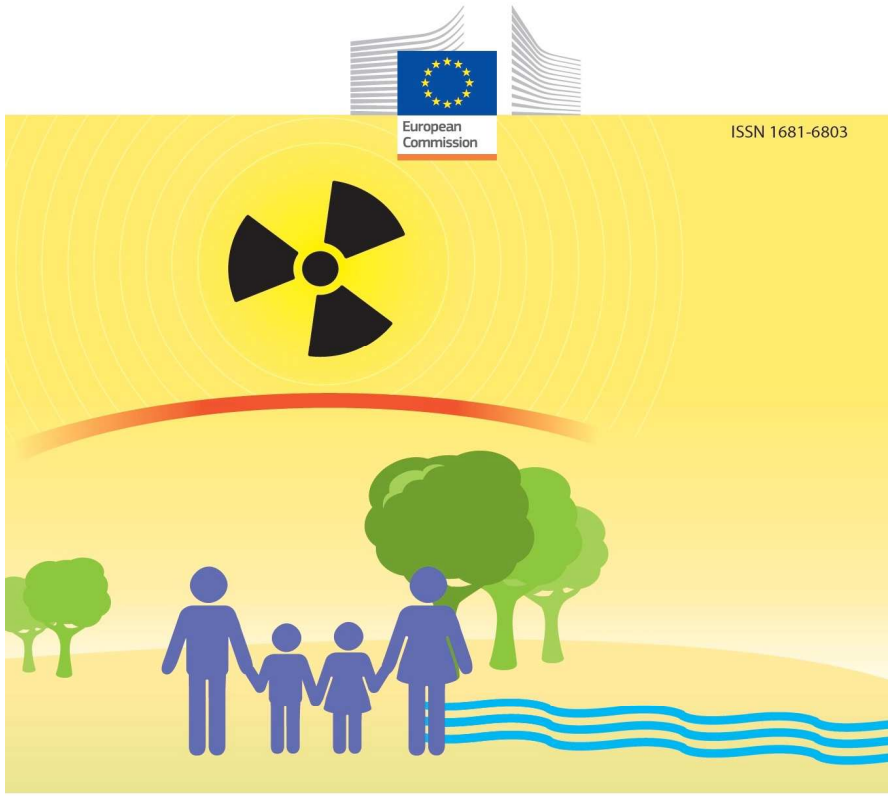
- Despite recommendations, few paediatric DRLs are set in less than half of EU countries, and many of them are obsolete
- Paediatric DRLs should have been implemented by February 2018 (BSS Euratom directive 2013/59)

- **Why?**
  - the number of paediatric examinations is lower than in adults
  - the paucity of dose data in children makes difficult to collect sufficient data to establish DRLs

DRLs: grouping in children

- Traditionally based on age
- Children can vary in weight by a factor of 200:
  - premature baby (400 gr)
  - obese adolescent (>80 kg)

European Commission RP 185 (2018)



http://www.eurosafeimaging.org/wp/wp-content/uploads/2018/09/rp_185.pdf

European DRLs for radiography and fluoroscopy in children (RP 185)

Radiography and fluoroscopy			
Examination	Age or weight group	EDRL	
		$K_{a,e}$, mGy	P_{KA}, mGy cm^2
Head AP/PA	3 months-<1 y		215
	1-<6 y		295
	≧6 y		350
Head LAT	3 months-<1 y		200
	1-<6 y		250
Thorax AP/PA**	<5 kg		15
	5-<15 kg	0,06	22
	15-<30 kg	0,08	50
	30-<50 kg	0,11	70
	50-<80 kg		87

European DRLs for radiography and fluoroscopy in children (RP 185)

Pelvis AP	15-<30 kg		180
	30-<50 kg		310
MCU	<5 kg		300
	5-<15 kg		700
	15-<30 kg		800
	30-<50 kg		750*

*Based on 4 NDRLs, range 400-2000 mGy cm^2; **AP/PA: DRL applies to both AP and PA projections

European Diagnostic Reference Levels

- **European DRLs:** based on the median (the 50th percentile) value of the distribution of the NDRLs for a defined clinical imaging task surveyed for standardised patient groupings
- 16 cm phantom for head studies, 32 cm phantom for chest and abdomen studies
- **These values refer to a single acquisition, not to the entire examination**

Computed tomography			
Exam	Age or weight group	EDRL	
		$CTDI_{vol}$, mGy	DLP, mGy cm
Head	0-<3 months	24	300
	3 months-<1 y	28	385
	1-<6 y	40	505
	≥6 y	50	650
Thorax	<5 kg	1,4	35
	5-<15 kg	1,8	50
	15-<30 kg	2,7	70
	30-<50 kg	3,7	115
	50-<80 kg	5,4	200
Abdomen	<5 kg		45
	5-<15 kg	3,5	120
	15-<30 kg	5,4	150
	30-<50 kg	7,3	210
	50-<80 kg	13	480

ISTISAN 20/22

Tabella 4.7. Valori LDR per radiografia proiettiva pediatrica nella pratica radiologica italiana

Procedura	Età (anni)	Valori LDR	
		$K_{a,e}$ *mGy*	KAP o P_{KA} *mGycm²*
Cranio	<1		220
	1-5		300
Torace PA/AP	neonati	0,08	10
	<1	0,08	25
	1-5	0,10	25
	6-10	0,10	50
	11-15	0,10	70
Torace LAT	1-5	0,20	60
	6-10	0,30	80
Addome	<1	0,70	25
	1-5	1	250
	6-10	1,5	350
Pelvi	1-5	0,9	200

ISTISAN 20/22

Tabella 4.8. Valori LDR per tomografia computerizzata pediatrica nella pratica radiologica italiana

Procedura	Età (anni)	Valori LDR		
		CTDIvol *mGy*	DLP *mGycm*	DLPtot *mGycm*
Cranio	<1	25	300	
	1-5	30	510	510
	6-10	55	850	880
	11-15	58	990	990
Torace	<1	1,5	35	
	1-5	3	50	80
	6-10	4	110	110
	11-15	7	200	200
Addome	<1		50	
	1-5	6	150	190
	6-10	7	230	400
	11-15	14	600	700

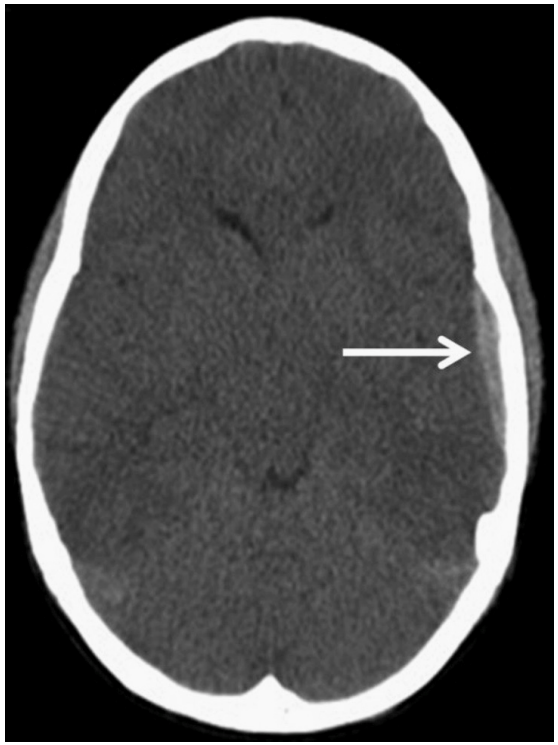
Gli LDR nella pratica clinica (ISTISAN 20/22)

- Un LDR è da considerarsi superato **quando il valore mediano per un campione rappresentativo di pazienti di corporatura normale**, oppure di pazienti all'interno di un intervallo eventualmente specificato di peso e/o dimensioni e/o età, **è maggiore del corrispondente valore di LDR**
- La propria pratica radiologica deve essere confrontata con gli LDR disponibili almeno ogni 4 anni per la radiologia convenzionale, ogni due anni per la TC e annualmente per la radiologia interventistica

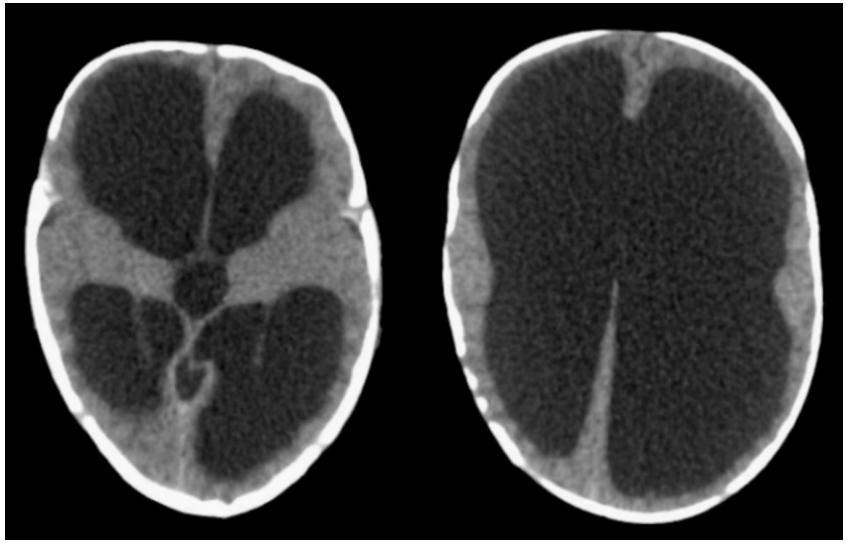
Gli LDR nella pratica clinica (Art. 164 e allegato XXVIII D.Lgs 101/2020)

- Nel manuale di qualità della struttura vanno inseriti i riferimenti bibliografici dai quali sono stati tratti gli LDR e i risultati della verifica degli LDR, da conservare almeno 10 anni

DRLs: present limitations

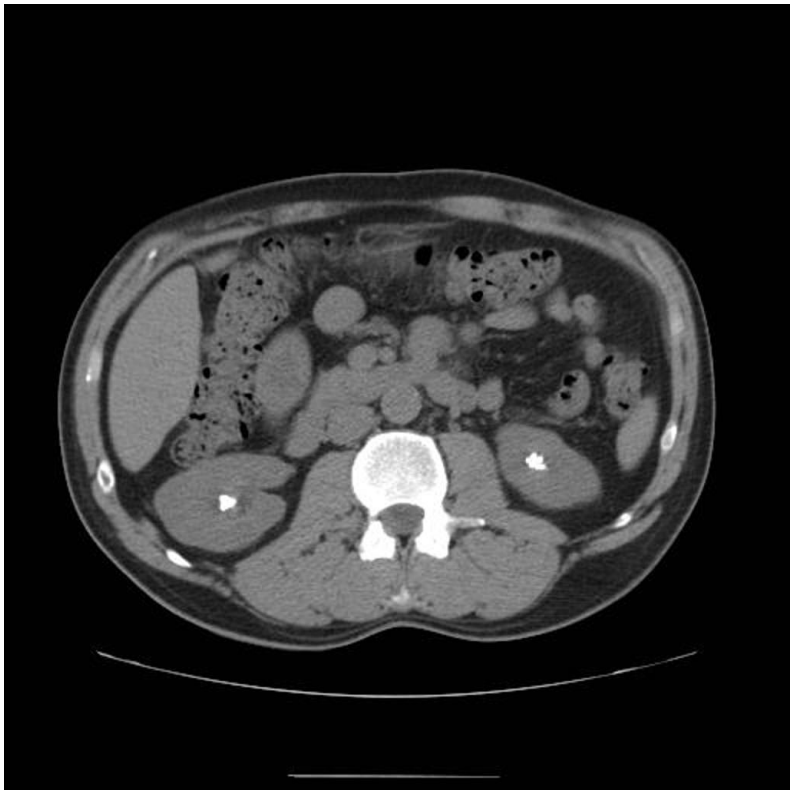


Head trauma with
epidural haematoma



Hydrocephalus

DRLs: present limitations

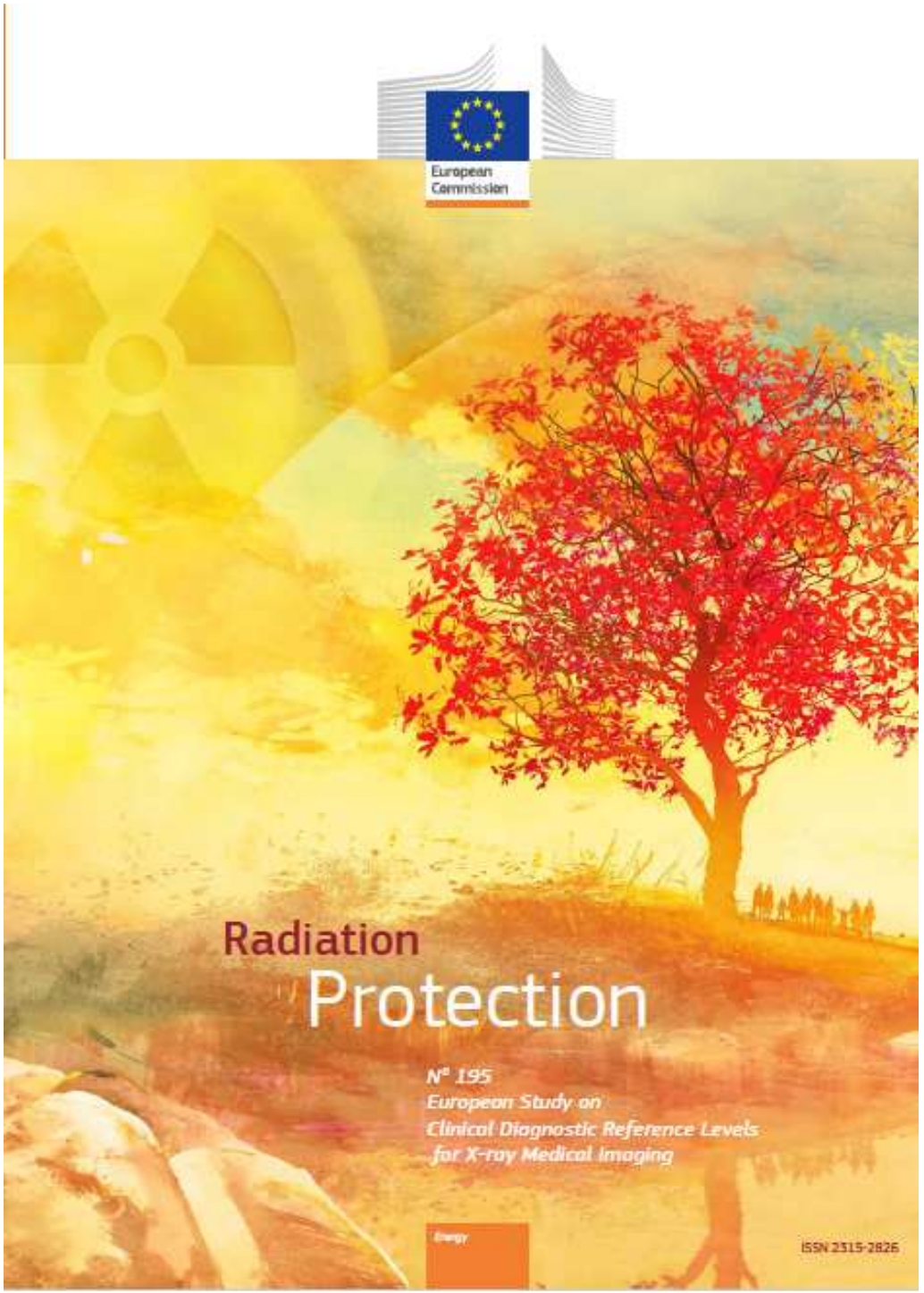


Kidney stones

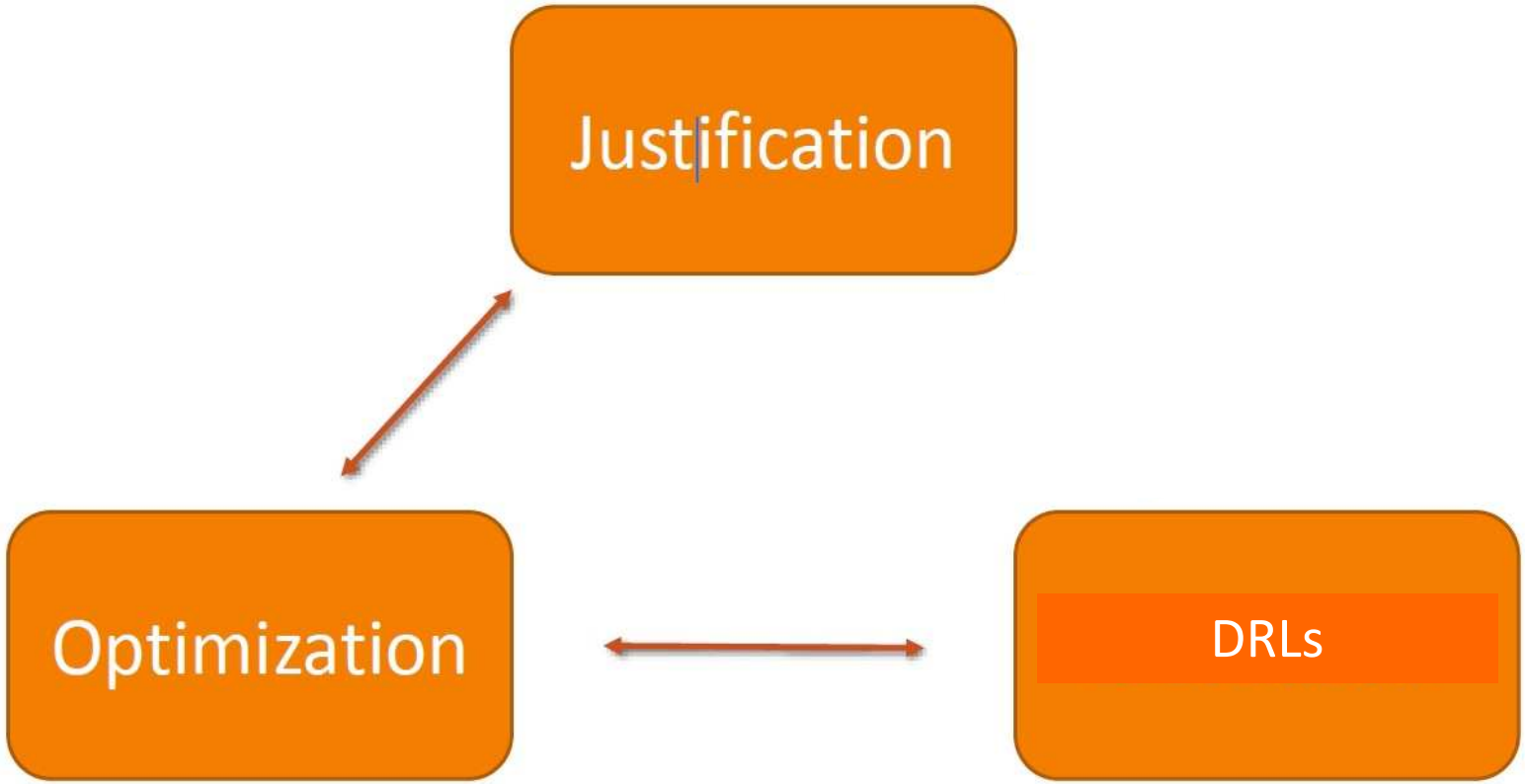
Haepatoblastoma

DRLs: present limitations

- Presently, DRLs for CT studies are established in relation to body region
- It is common experience that in "real life" CT protocols are differentiated – and consequently delivered dose – according to the clinical indication of the study
- Clinical based DLRs for CT studies are presently missing
- EC funded EUCLID European Study on Clinical DRLs in adults presently ongoing
- **A similar study in children is very much needed**


European Commission
Radiation Protection
N° 195
European Study on Clinical Diagnostic Reference Levels for X-ray Medical Imaging
Energy
ISSN 2315-2826

Radiation protection mainstays

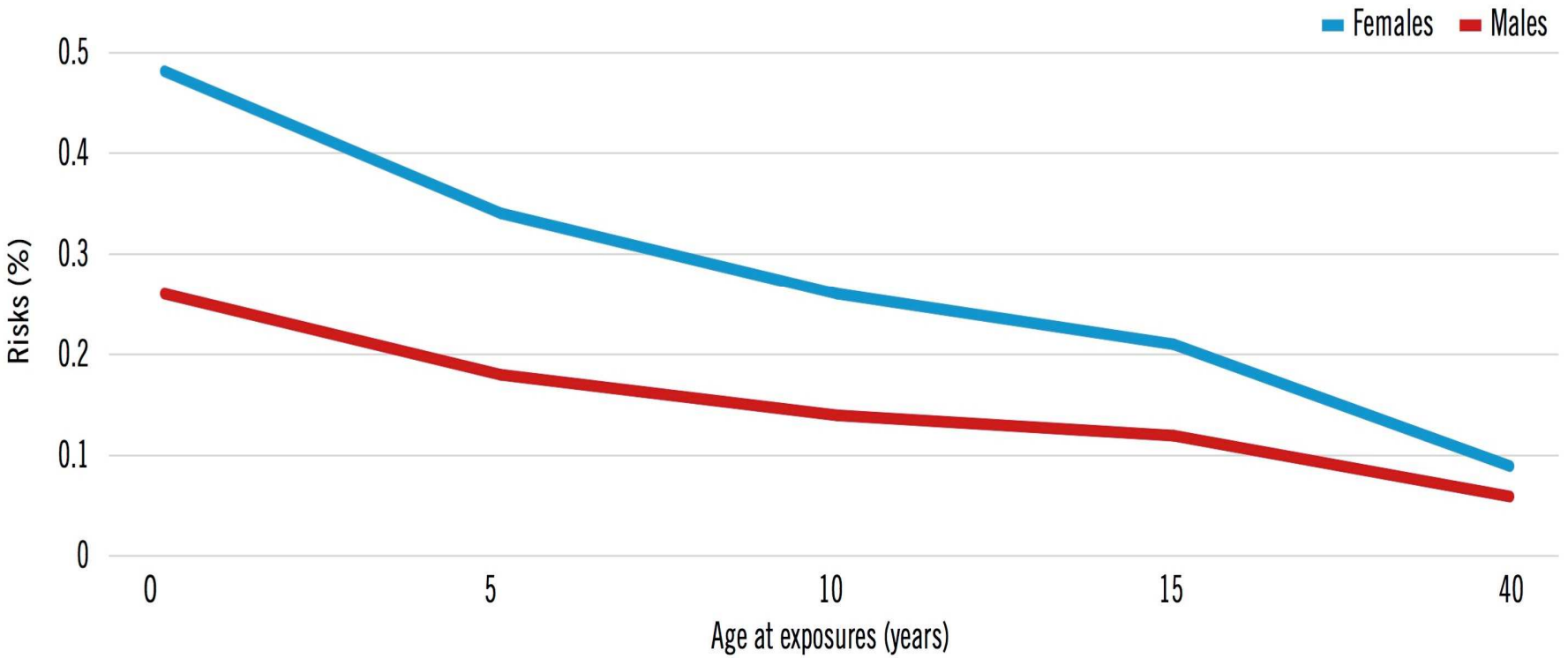


Radiation Risk and children

- Children are potentially more vulnerable to radiation exposure:
  - they grow quickly, and their cells are more sensitive to radiation
  - have longer lifespans to develop long-term radiation-induced detrimental effects
  - are more vulnerable than adults to the development of certain cancer types

Radiation Risk

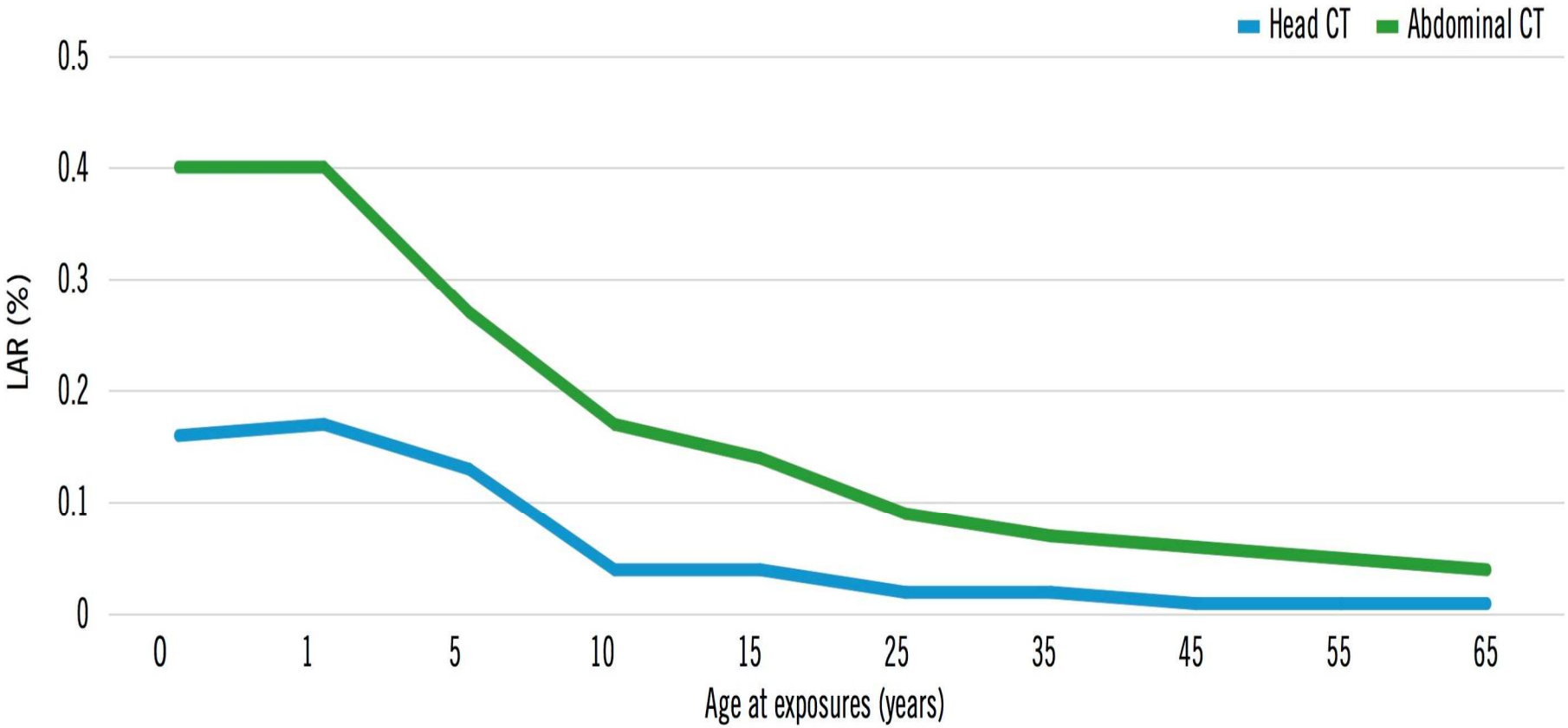
Figure 8: Lifetime attributable risk of cancer incidence as a function of sex and age at exposure for a single whole-body dose of 10 mSv, based on estimates for the USA population



Source: BEIR (2006)

Radiation Risk

Figure 9: Sex-averaged lifetime attributable risk of cancer incidence associated with radiation exposure during head and abdominal CT, as a function of the age at exposure



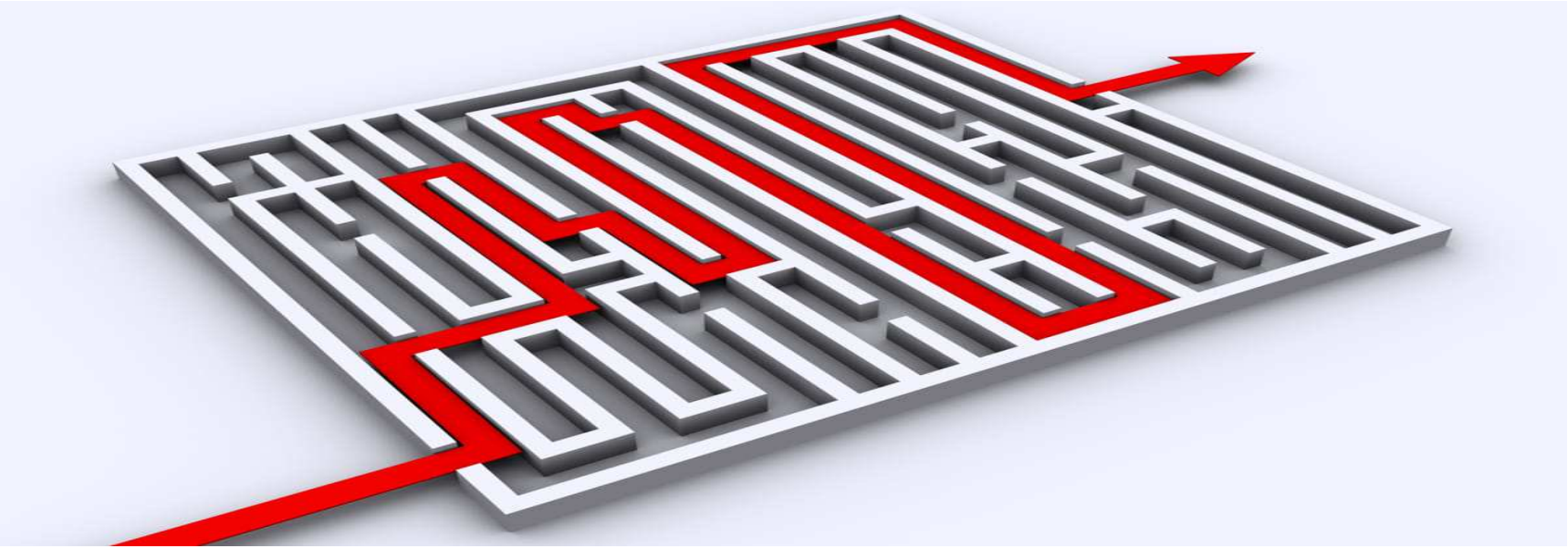
Radiation Risk

Risk qualification	Probability of cancer incidence in the general population (% LBR)	Probability of cancer incidence in the general population if adding this extra level of risk (% LBR + % LAR)	Proposed risk qualification
CT chest	42	42.15	Low
CT abdomen	42	42.12	Low
CT angiography abdomen	42	42.12	Low
CT pelvis	42	42.10	Low
CT head	42	42.06	Low
Barium swallow oesophagus	42	42.05	Low
Barium enema colon	42	42.04	Low
Chest PA and lateral	42	42.00	Negligible

Euratom Directive 2013/59/EURATOM: Justification

- **Article 55** requires that Medical exposure shall show a sufficient net benefit, weighing the total potential diagnostic or therapeutic benefits it produces… against the individual detriment that the exposure might cause, taking into account... alternative techniques having the same objective but involving no or less exposure to ionising radiation
- **Article 57** requires that the referrer and the practitioner are involved, as specified by Member States, in the justification process of individual medical exposures

Euratom Directive 2013/59/EURATOM: Referral Guidelines



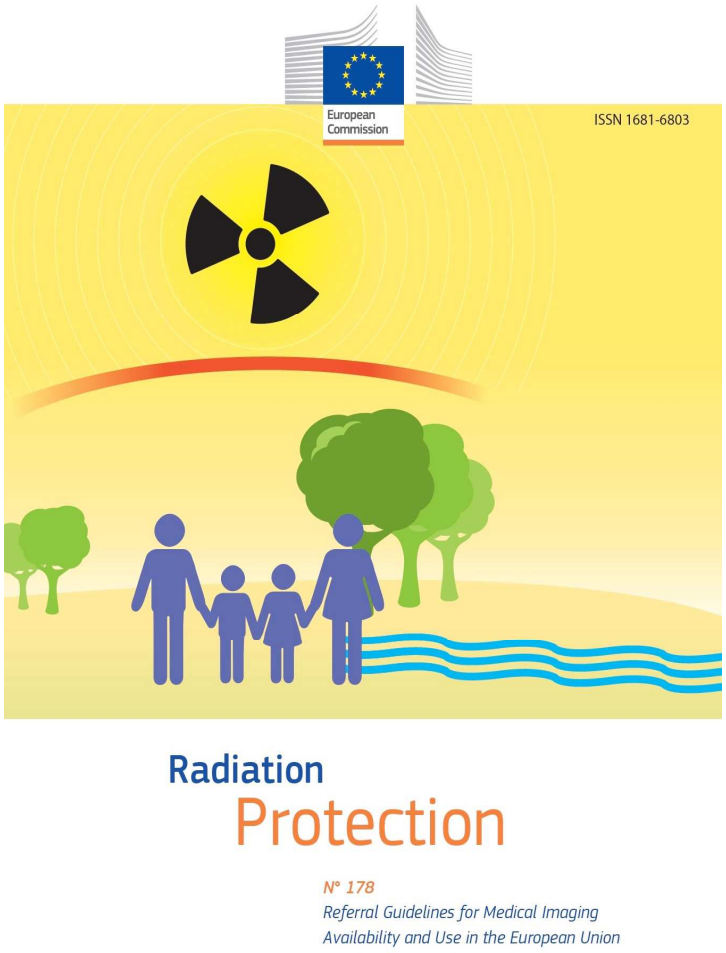
- **Article 58** requires that Member States shall ensure that referral guidelines for medical imaging, taking into account the radiation doses, are available to the referrers

Referral guidelines for diagnostic imaging

- Referral guidelines for diagnostic imaging support the best use of clinical radiology as long as they:
  - conform to the best evidence-based standards
  - protects the patient from unnecessary exposure to ionising radiation
  - provide dedicated guidance for children and pregnant women/unborn child
  - provide the evidence for which imaging resources can be used efficiently and effectively

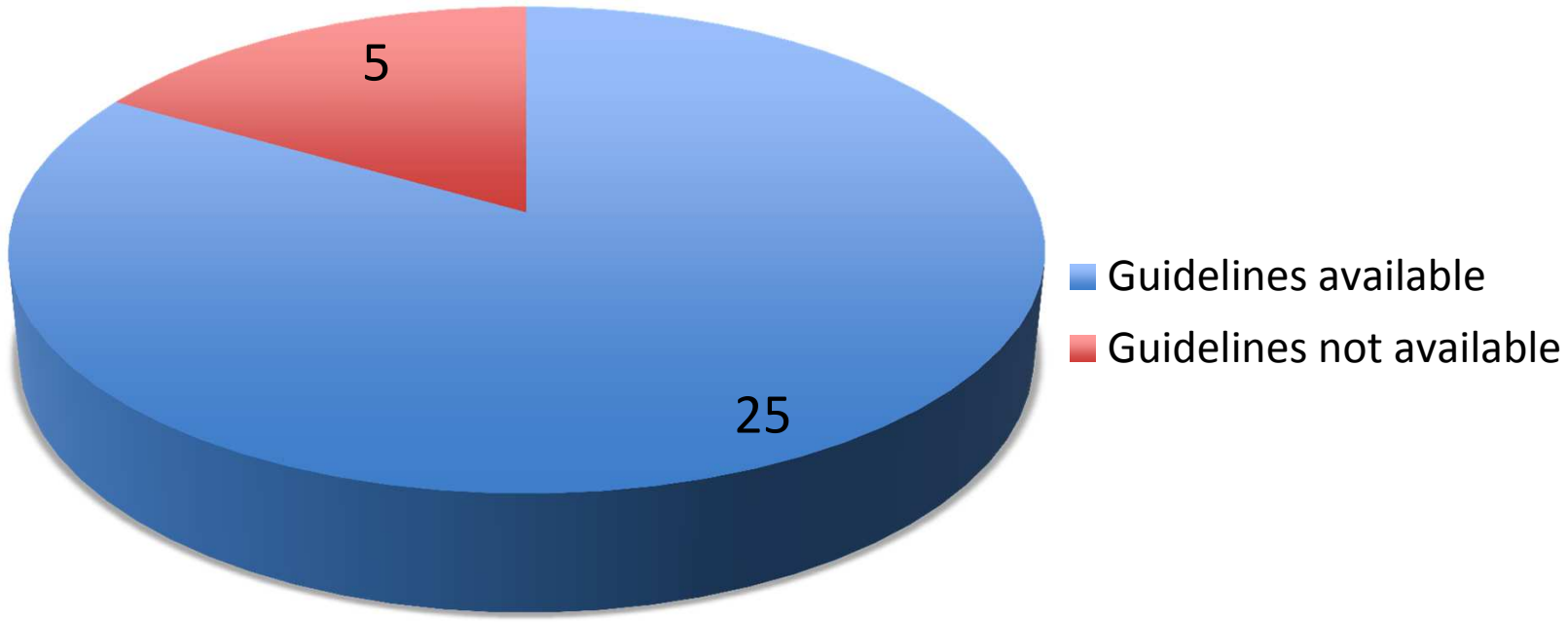
Radiation protection N°178 (2014)

- RP 178 (2014) provides information on Referral Guidelines for Medical Imaging availability and use in the European Union based on a European-wide survey



Availability of RG in Europe

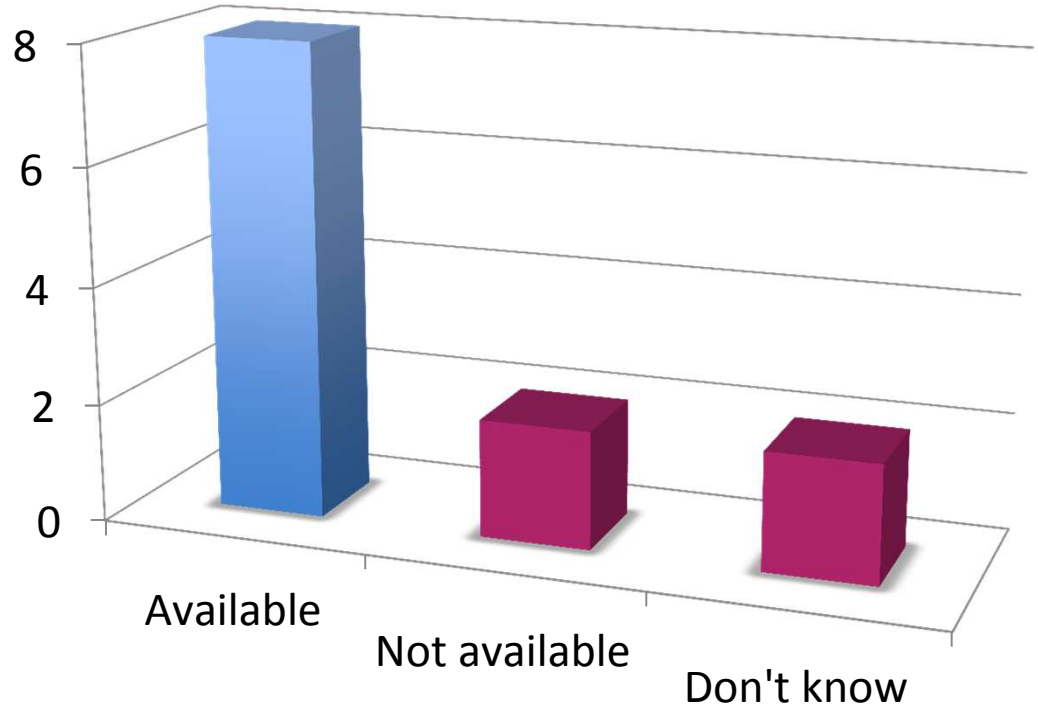
- 30 European Countries provided information



RP 178, 2014

Availability of separate guidance for children

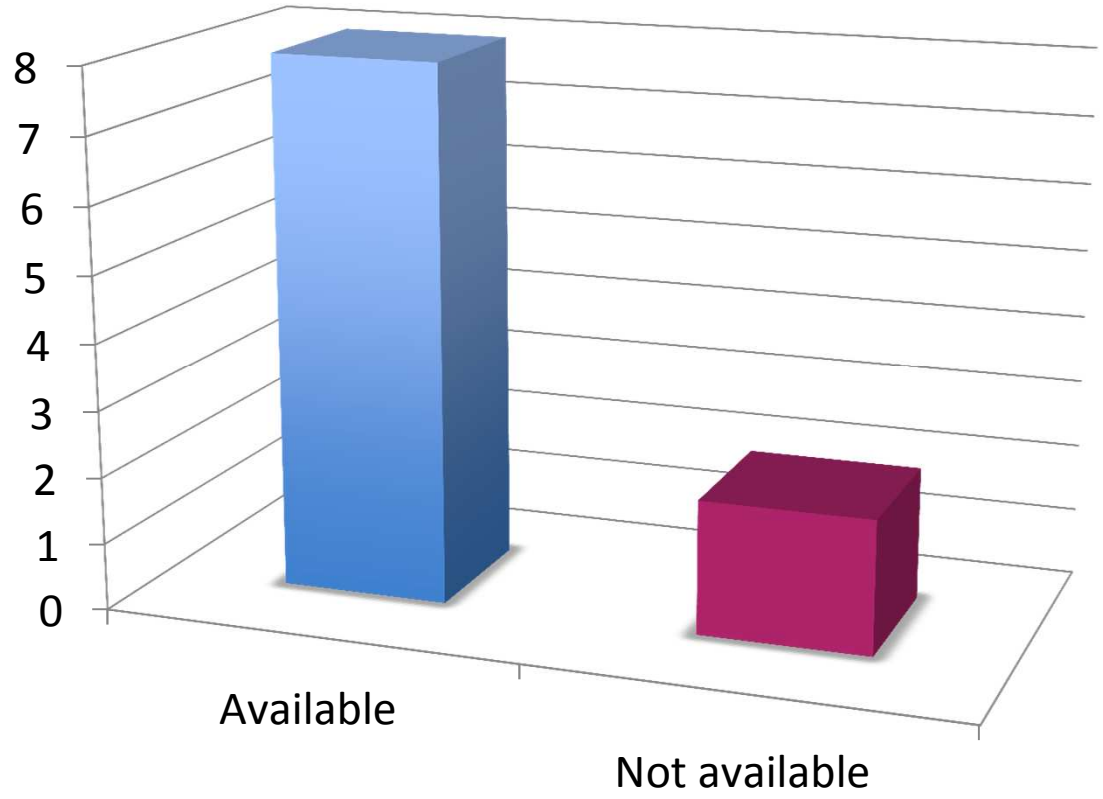
- Only 12 out of 30 EU Countries provided information



RP 178, 2014

Availability of separate guidance for pregnant women /unborn children

- Only 12 answers were provided



RP 178, 2014

Guidelines availability and update

- **It appears from RP 178 document that in several European countries referral guidelines for children may be not available or regularly updated**
- The year of the first edition of imaging guidelines varied from 1989 to 2005
- The approximate duration of the review cycle has varied between countries from 3-4 years to > 6 years, being in some countries older than 10 years

RP 178, 2014

RP 178: conclusions and recommendations

- Imaging referral guidelines were available in most European countries, although in many cases detailed information about these guidelines were not provided
- A single set of European guidelines should be preferred
- National guidelines, developed de novo through accepted methodology or adopted or adapted are alternatives
- Separate advice for children and pregnant women / unborn child must be included
- Additional measures are needed to reinforce the use of guidelines
- Clinical Decision Support systems interfacing with RIS and electronic requesting systems should be implemented

ESR iGuide

- ESR iGuide is freely available through the ESR website since 2018
- ESR iGuide is the ESR solution to make imaging referral guidelines – **including separate guidance for children** – readily available and easily usable across Europe
- ESR iGuide guidelines are embedded in a clinical decision support platform, which allows users to localise the recommendations according to their needs starting from an evidence-based-core
- ESR iGuide is designed to be a user-friendly system available to referring physicians at the point of care

Euratom Directive 2013/59/EURATOM: Optimisation

- **Article 56** requires that all doses due to medical exposure for radiodiagnostic, interventional radiology,…, are kept **A**s **L**ow **A**s **R**easonably **A**chievable consistent with obtaining the required medical information, taking into account economic and societal factors

ALARA

Euratom Directive 2013/59/EURATOM: Diagnostic Reference Levels (DRLs)

- **Article 56** requires that Member States shall ensure the **establishment, regular review and use of DRLs** for radiodiagnostic examinations, having regard to the recommended European DRLs where available…
- **National DRLs:** dose levels in diagnostic practices for typical examinations for groups of standard-sized patients or standard phantoms for broadly defined types of equipment. These levels are expected not to be exceeded for standard procedures when good and normal practice regarding diagnostic and technical performance is applied

Setting of DRLs

- **National DRLs (NDRLs):**
  - based on the 3rd quartile value of the median values of the distributions of patient doses from a representative sample of RX departments in the country, for a defined clinical imaging task surveyed for standardised patient groupings
  - set by an authoritative body, based on national patient surveys
  - NDRLs should be compared with the European DRLs
  - institutions must carry out regular comparison of their LDRLs with NDRLs

Setting of DRLs

- **Local DRLs (LDRLs):**
  - based on the median values of patient dose distribution from examinations from the healthcare facility
  - set by a given hospital or group of hospitals for their own use to improve optimisation
  - set to correspond to the level of technology and local achievements of optimisation

Setting of DRLs

- **European DRLs (EDRLs):**
  - based on the median value of the distribution of NDRLs for a defined clinical imaging task surveyed for standardised patient groupings
  - EDRLs provide an interim solution for countries with no NDRLs, until such NDRLs become available

Dosimetric quantities to be used

- Radiography:
  - $P_{KA,}$ ($K_{a,e}$)
- Fluoroscopy and IR:
  - $P_{KA,}$ ($K_{a,r}$, fluoroscopy time, number of images)
- CT:
  - $CTDI_{vol}$ referred to phantom size (16 or 32 cm)
  - DLP

Recommended patient grouping

- Chest and abdomen:
  - weight
  - age (to be used just to make comparison between old and new paediatric DRLs)
- Head:
  - age

Recommended weight groups (intervals) for *body* examinations	Recommended age groups (intervals) for *head* examinations
< 5 kg	0 - < 3 months
5 - < 15 kg	3 months - < 1 y
15 - < 30 kg	1- < 6 y
30 - < 50 kg	≥ 6 y
50 - < 80 kg	

Tabella 4.6. Valori LDR per radiografia proiettiva pediatrica nella pratica radiologica italiana

Procedura	Età (anni)	Valori LDR	
		Ke *mGy*	KAP o P_{KA} *mGycm²*
Cranio	<1		230
	1-5		300
Torace PA/AP	neonati		14
	<1		20
	1-5	0,08	40
	6-10	0,11	40
	11-15	0,11	70
Torace LAT	1-5	0,14	40
	6-10		60
Addome	<1		150
	1-5	0,75	250
	6-10		425
Pelvi	1-5	0,5	200

Tabella 4.7. Valori LDR per tomografia computerizzata pediatrica nella pratica radiologica italiana

Procedura	Età (anni)	Valori LDR		
		CTDIvol *mGy*	DLP *mGycm*	DLPtot *mGycm*
Cranio	<1	25	300	
	1-5	30	420	510
	6-10	56	850	870
	11-15	58	980	990
Torace	<1	2,7	45	
	1-5	3	50	80
	6-10	4	110	110
	11-15	7	200	200
Addome	<1		90	
	1-5	6	150	190
	6-10	7	230	390
	11-15	14	600	700

Pediatr Radiol (2015) 45:695–705
DOI 10.1007/s00247-014-3201-z

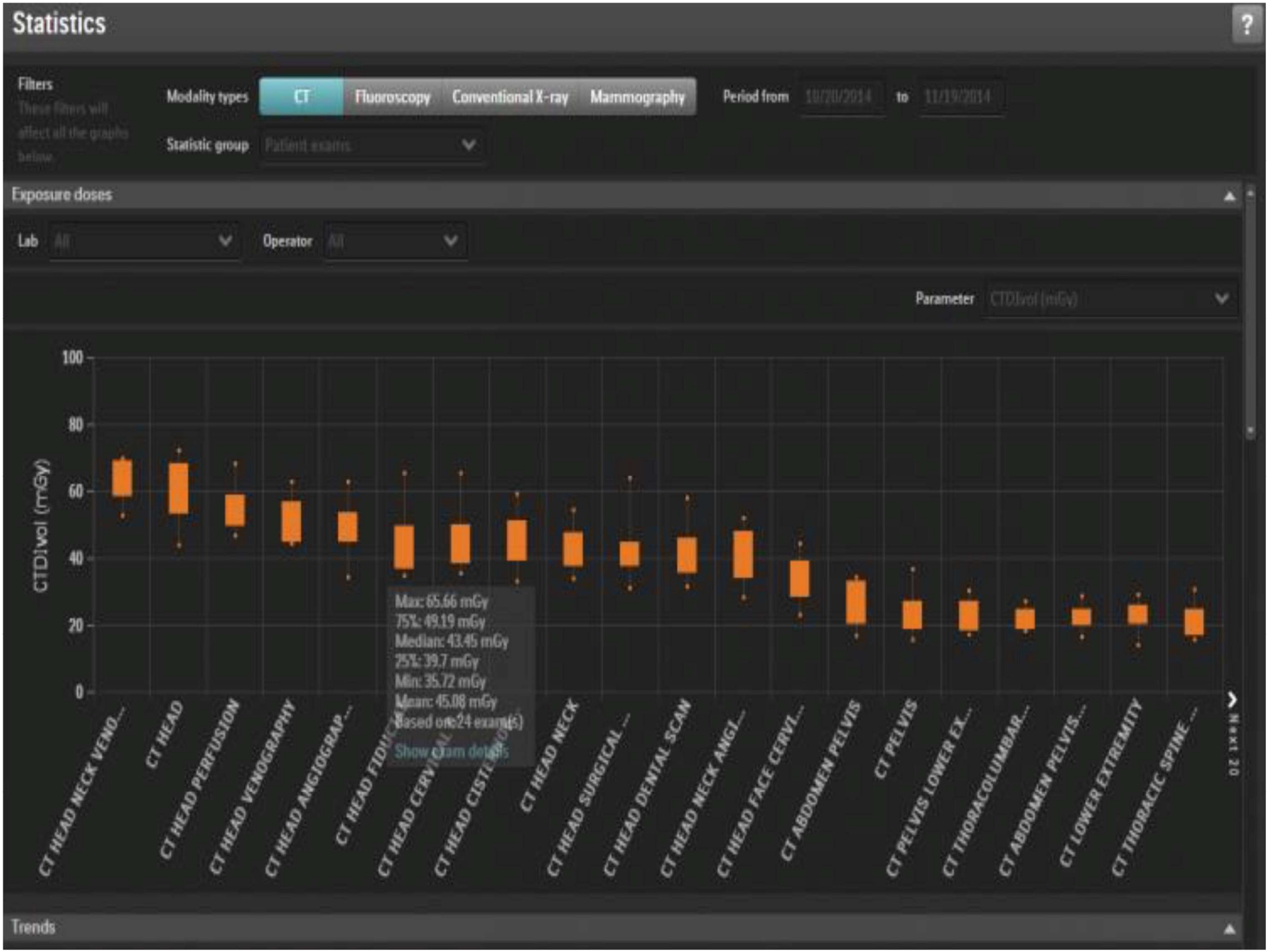
ORIGINAL ARTICLE

Radiation dose from multidetector CT studies in children: results from the first Italian nationwide survey

Claudio Granata · Daniela Origgi · Federica Palorini · Domenica Matranga · Sergio Salerno

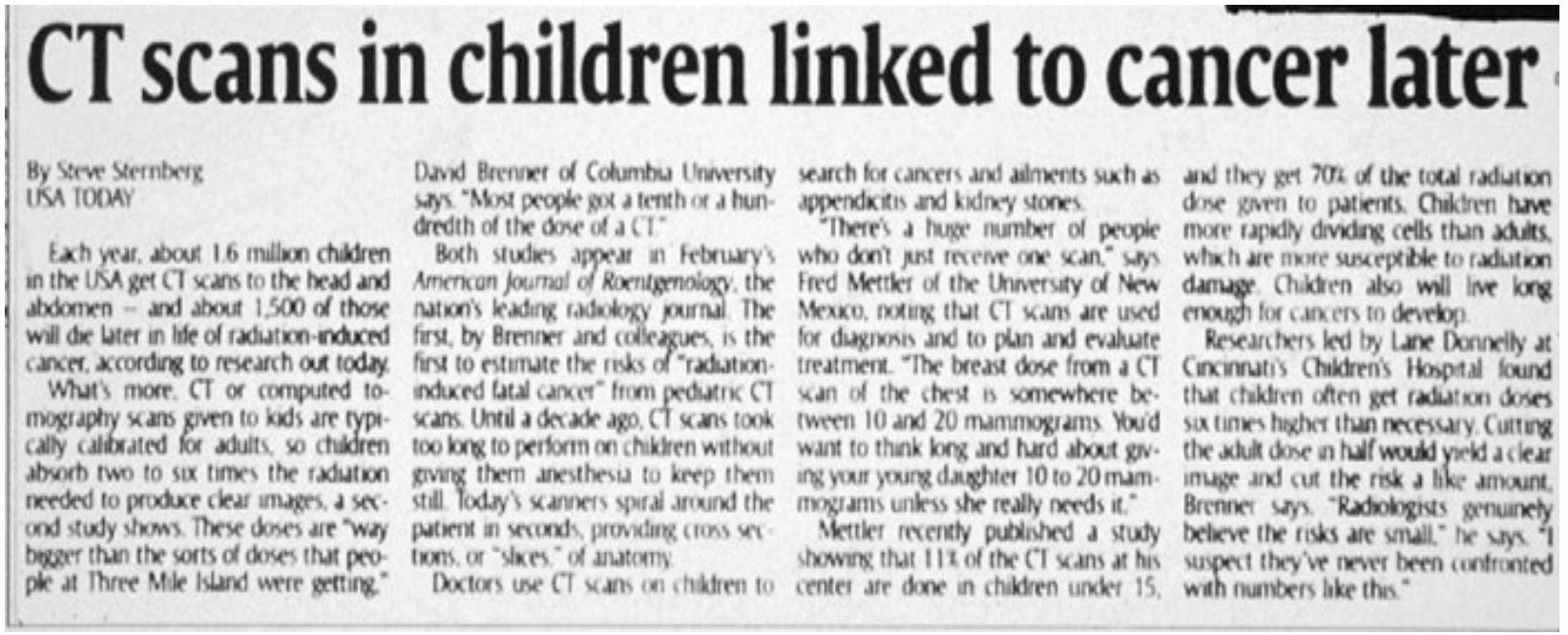
DRLs and Dose Management Systems

- DMSs allow automatic recording, retrieval and analysis of dosimetric data from radiological studies
- They allow establishing of local DRLs, which can be used for comparison with national or European DRLs
- DMSs are an excellent tool for optimisation and compliance with established DRLs


Statistics
?
Filters
These filters will affect all the graphs below
Modality types
CT
Fluoroscopy
Conventional X-ray
Mammography
Period from
10/20/2014
to
11/19/2014
Statistic group
Patient exams
Exposure doses
Lab
All
Operator
All
Parameter
CTDIvol (mGy)
100
80
60
40
20
0
CTDIvol (mGy)
Max: 65.66 mGy
75%: 49.19 mGy
Median: 43.45 mGy
25%: 39.7 mGy
Min: 35.72 mGy
Mean: 45.08 mGy
Based on 24 exam(s)
Show exam details
CT HEAD NECK VENO...
CT HEAD
CT HEAD PERFUSION
CT HEAD VENOGRAPHY
CT HEAD ANGIOGRAP...
CT HEAD FIDUCIAL
CT HEAD CERVICAL
CT HEAD CISTERNOG...
CT HEAD NECK
CT HEAD SURGICAL ...
CT HEAD DENTAL SCAN
CT HEAD NECK ANGI...
CT HEAD FACE CERVI...
CT ABDOMEN PELVIS
CT PELVIS
CT PELVIS LOWER EX...
CT THORACOLUMBAR...
CT ABDOMEN PELVIS...
CT LOWER EXTREMITY
CT THORACIC SPINE ...
NEXT 20
Trends


DANGER
RADIATION

"Harm and alarm"



CT scans in children linked to cancer later

By Steve Sternberg
USA TODAY

Each year, about 1.6 million children in the USA get CT scans to the head and abdomen – and about 1,500 of those will die later in life of radiation-induced cancer, according to research out today.

What's more, CT or computed tomography scans given to kids are typically calibrated for adults, so children absorb two to six times the radiation needed to produce clear images, a second study shows. These doses are "way bigger than the sorts of doses that people at Three Mile Island were getting," David Brenner of Columbia University says. "Most people got a tenth or a hundredth of the dose of a CT."

Both studies appear in February's *American Journal of Roentgenology*, the nation's leading radiology journal. The first, by Brenner and colleagues, is the first to estimate the risks of "radiation-induced fatal cancer" from pediatric CT scans. Until a decade ago, CT scans took too long to perform on children without giving them anesthesia to keep them still. Today's scanners spiral around the patient in seconds, providing cross sections, or "slices," of anatomy.

Doctors use CT scans on children to search for cancers and ailments such as appendicitis and kidney stones.

"There's a huge number of people who don't just receive one scan," says Fred Mettler of the University of New Mexico, noting that CT scans are used for diagnosis and to plan and evaluate treatment. "The breast dose from a CT scan of the chest is somewhere between 10 and 20 mammograms. You'd want to think long and hard about giving your young daughter 10 to 20 mammograms unless she really needs it."

Mettler recently published a study showing that 11% of the CT scans at his center are done in children under 15, and they get 70% of the total radiation dose given to patients. Children have more rapidly dividing cells than adults, which are more susceptible to radiation damage. Children also will live long enough for cancers to develop.

Researchers led by Lane Donnelly at Cincinnati's Children's Hospital found that children often get radiation doses six times higher than necessary. Cutting the adult dose in half would yield a clear image and cut the risk a like amount, Brenner says. "Radiologists genuinely believe the risks are small," he says. "I suspect they've never been confronted with numbers like this."

- "… about 1500 of those children will die later in life from radiation induced cancer…"

USA Today, January 22nd, 2001

Communicating risk to parents

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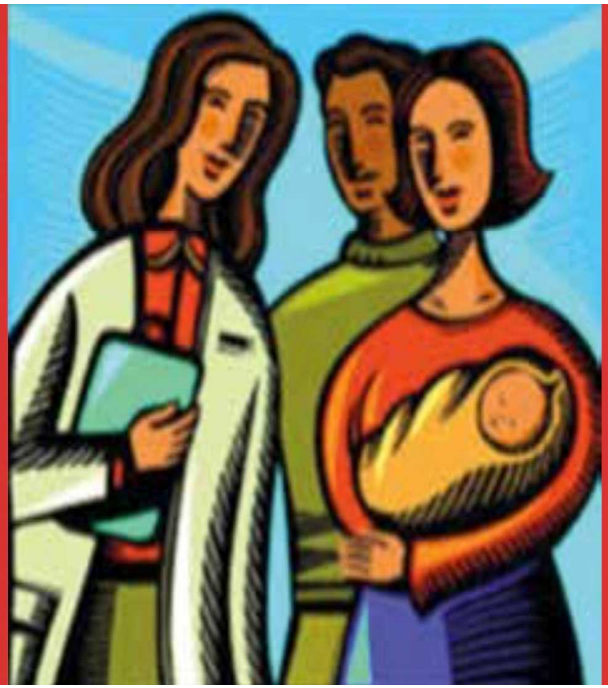
How the experts perceive risk

Hazard x exposure x susceptibility



How the public perceive risk

Hazard + [fear, anger, outrage]

WHO, 2016

Responsibilities

- Directive 2013/59/EURATOM:
  - Art. 56 (1 d): wherever practicable and prior to the exposure taking place, the practitioner or the referee, as specified by Member States, ensures that the patient or their representatives is provided with adequate information relating to the benefits and risks associated with the radiation dose from the medical exposure. Similar information as well as relevant guidance shall be given to carers and comforters…

Establishing a patient-centred communication

- Speak slowly, use plain language and avoid medical terms
- Explain the rationale of the procedure, emphasizing its benefits
- Illustrate the potential risks by comparing them with other kinds of common risks
- Explain what will be done to minimize risk to the patient
- Repeat key messages
- Encourage questions, and be prepared to address them
- Cards/leaflets for patients/parents may be helpful

Some practical examples

Questions	Possible response
Why is this radiological examination recommended?	This examination can rapidly clarify your child's diagnosis
Is there any risk from this radiological examination	One concern is the possibility of cancer resulting from the radiation
How great is this risk?	The risk is very small, if any. We are not sure that there is a risk at very low dose, like those with CT or most X-ray studies
When will these risks occur?	The risk of missing a serious diagnosis will occur now. The potential effects of radiation – if any - would take years/decades

Some practical examples

Questions	Possible response
Why can't we do a procedure that does not use radiation instead?	We have considered using examinations that do not require radiation, but we have determined this is the best procedure to answer the clinical question and plan treatment
Can the dose be adjusted so that my child receives the lowest possible dose?	There are many techniques to lower dose and risk without compromising the diagnostic quality of images. Our facility uses appropriate protocols for children
What are the consequences of not doing the procedure?	Your child's health may be affected through incorrect or delayed diagnosis and treatment

Adapted from Broder et al, 2014, and WHO, 2016

Some practical examples

Pediatric examination	Risk			Typical Effective Dose (mSv)
XR Arm, Dental, Skull, Chest	Negligible	hours/days	Chance of dying from flu, firework	< 0.02 </=1 CXR
XR Abdomen, Pelvis **NM** Bone densitometry, **IGT** Central line	Minimal	weeks	Chance of dying from general anesthetic	0.02 – 0.2 1–10 CXR
FL VCUG, UGI, Enema **CT 3D** Head, Chest **NM** DMSA, Cardiac Angio	Very low radiations from 10 long haul flights	months	Cosmic	0.2 – 2 10–100 CXR
NM Bone Scan, MIBG, PET **CT** Chest/Abd/pelvis	Low	few years	Lifetime risk of dying from drowning	2 – 10 100-500 CXR
NM/CT PET CT	Low	> 3 years	10 x less than lifetime risk of dying in motor vehicle accident	>10 > 500 CXR

Some practical examples

- A 2-year-old child underwent CT scan of the skull, chest and abdomen after an accident. The family doctor stated the following:
  - a) the CT scan has possibly tripled the risk for your child of developing cancer within 18 years of age (from 0.5% to 1.5%)
  - b) the CT scan proved essential to evaluate your child's conditions and to treat his wounds, which otherwise would have put his health at risk. The probability of your child having a normal development has remained almost the same

Resources

http://www.eurosafeimaging.org

Take home points

ESOR
EUROPEAN SCHOOL OF RADIOLOGY

- Understanding of health effects of low dose radiation – as used in medical imaging – is still incomplete
- For this reason, the linear no-threshold NT approach is the most reasonable risk model at low dose levels
- Justification and optimisation are the mainstays of radiation protection
- DRLs and dose management systems are excellent tools for optimisation
- Effective communication of benefits and risk of medical imaging to parents is fundamental