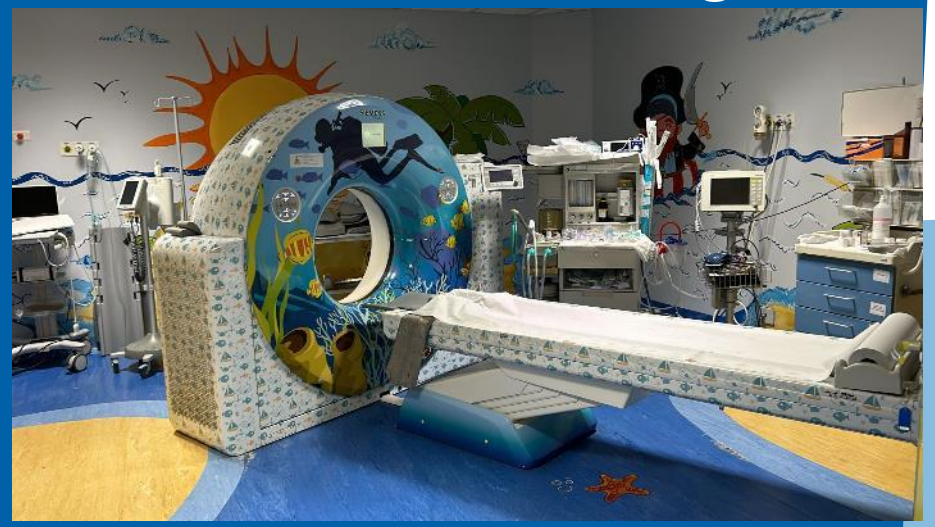
TG 124, Application of the Principle of Justification

Why we need to reinforce and actualize the principle of justification in medical setting?



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Contents

A. Justification in Medicine: unique aspects

B. Challenges and Opportunities since Pub103

C. Measuring Patient Outcomes

- NCRP Commentary 13 (1995)

D. Considerations across populations and generations: ethics and sustainability concerns

3 Pillars of ICRP

Science, Experience, Ethics

- Knowing the science
  - appropriate education and training throughout career
- Learning from experience
  - Use of QA/QI (e.g., Pub135, TG108)
- Ethics training
  - RP in medicine (TG109)

Courtesy of K Applegate

Improving RP in Medicine: Iterative Steps Over Time

- ICRP Publication 73 (1996) set out stronger guidance in medicine than elsewhere for both justification and optimization:

  3 levels of justification

  2 levels of optimization

- Pub 73 also established DRLs
- Since Pub 103 (2007), 25 Annals publications on medical RP:
  - Clarify guidance, e.g., how to develop DRLs (Pub 135)
  - Mainly topical, systems integration, teamwork, continuous improvement in complex environments (TG 108)
  - Recommend education and training in RP (Pub 113; collaborations with IAEA)

Courtesy of K Applegate

Principle of Justification

Any decision that alters the radiation exposure situation should do more good than harm. [P103, para.203]

Challenges

- More than scientific and technical rationality
- Societal and ethical values increasingly important

ICRP Task Group 124

Application of the Principle of Justification

Mandate of TG124

- Deliberate on application of the principle of justification in all three types of exposure situations.
- Consider all categories of exposure for humans (workers, members of the public, and **patients**) and non-humans.
- Take particular note of situations where societal and ethical values are considered to have important implications.
- Emphasise the ethical values described in P138.

What ‘more good than harm’ means in society today?

On what basis the judgement should be made

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- Julie Burtt (Secretary)
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Consider Opportunities for Research on Justification: Worldwide "Insatiable Appetite" for Imaging

- 4.2 billion exams/year (UNSCEAR 2020*)

  *does not include RT imaging or radionuclide Tx

- Majority of ICRP publications focus on optimization, not justification

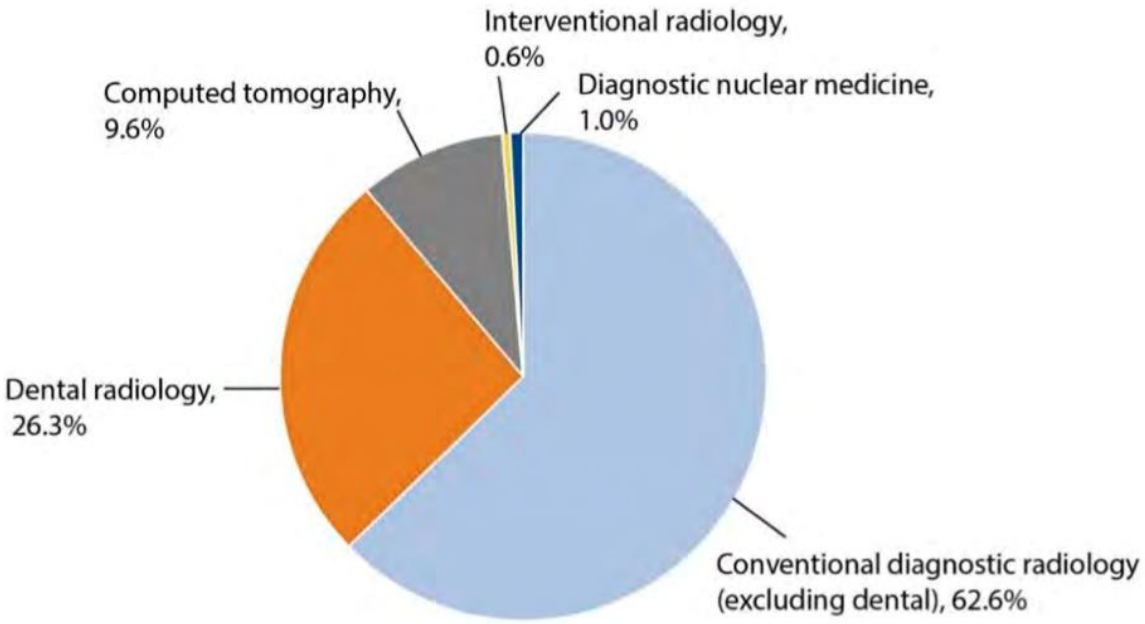
- Perhaps 1/3 of what we do is excessive/unneeded…

  25% waste in USA healthcare system

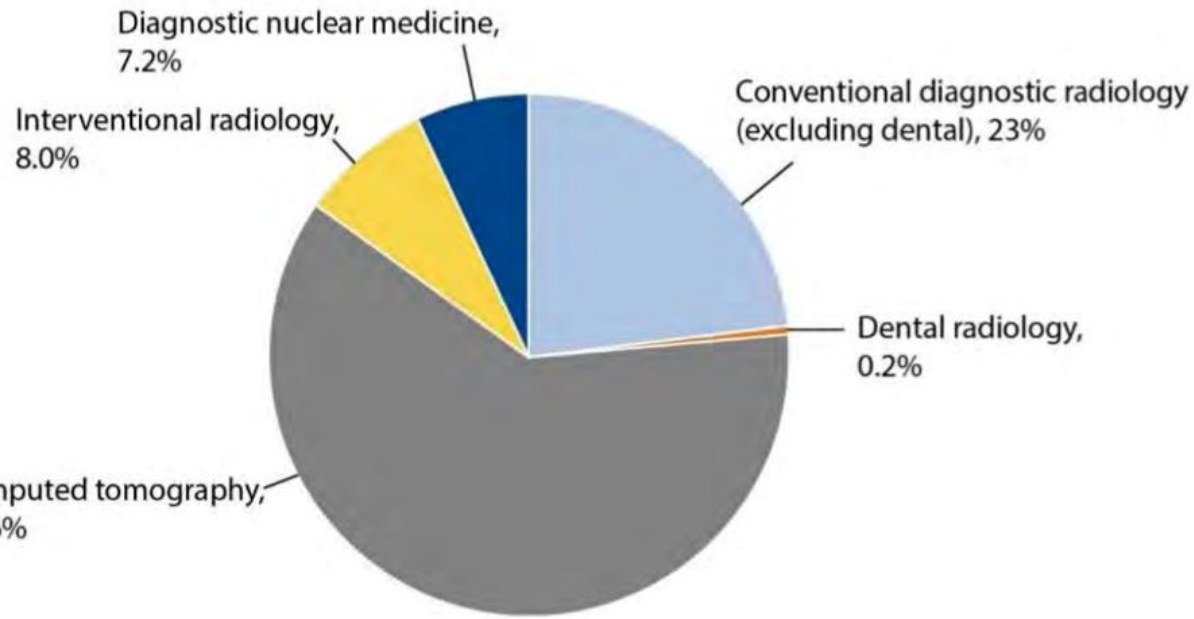
  (Waste in the US Health Care System Estimated Costs and Potential for Savings. Shrank WH et al JAMA 2019)

Courtesy of K Applegate

(a) Annual number of examinations/procedures



(b) Annual collective effective dose



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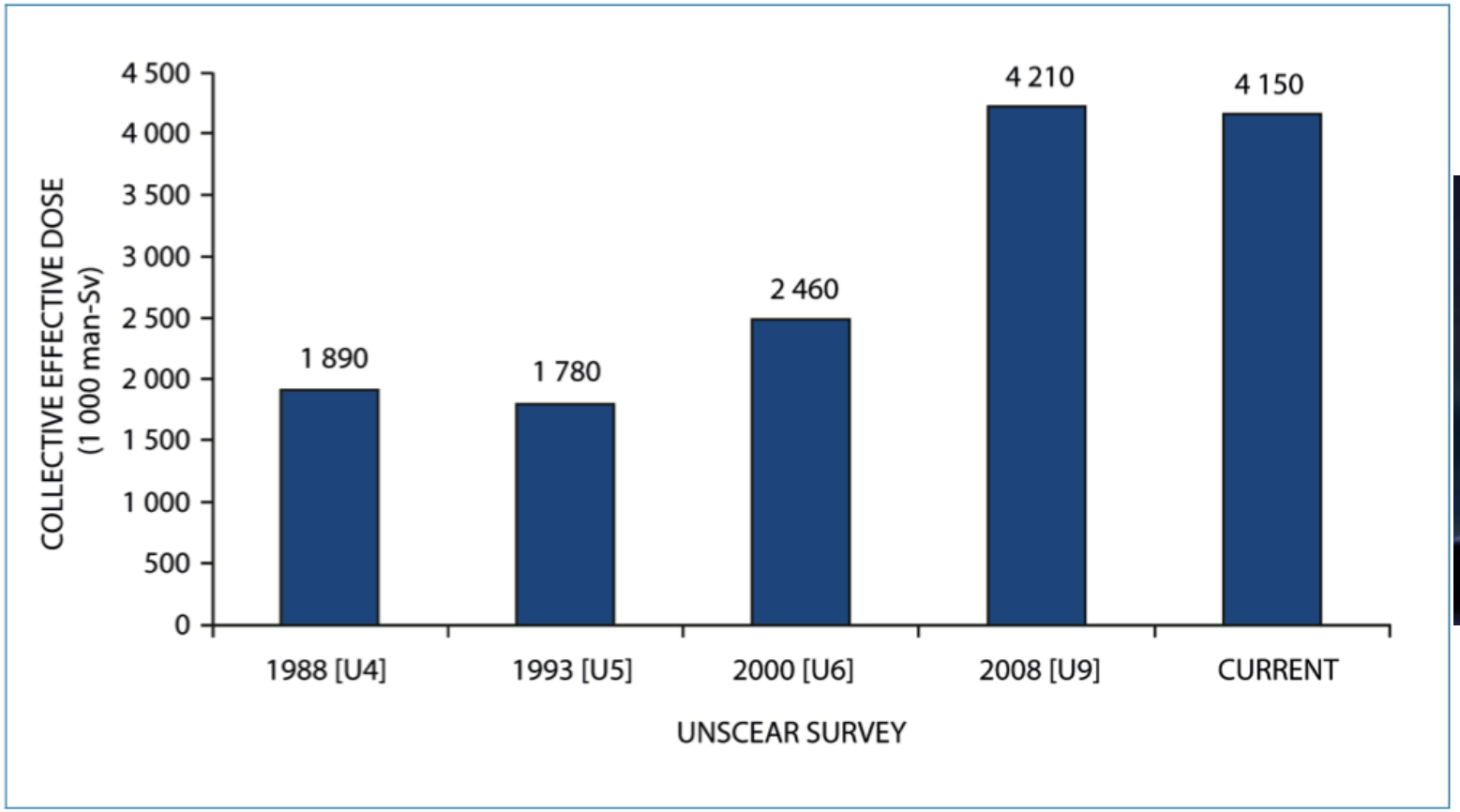
SOURCES, EFFECTS AND RISKS OF IONIZING RADIATION

UNSCEAR 2020/2021 Report

Figure VII. Trend in global annual collective effective dose from medical radiological examinations



Optimization, partially a machine tools and works

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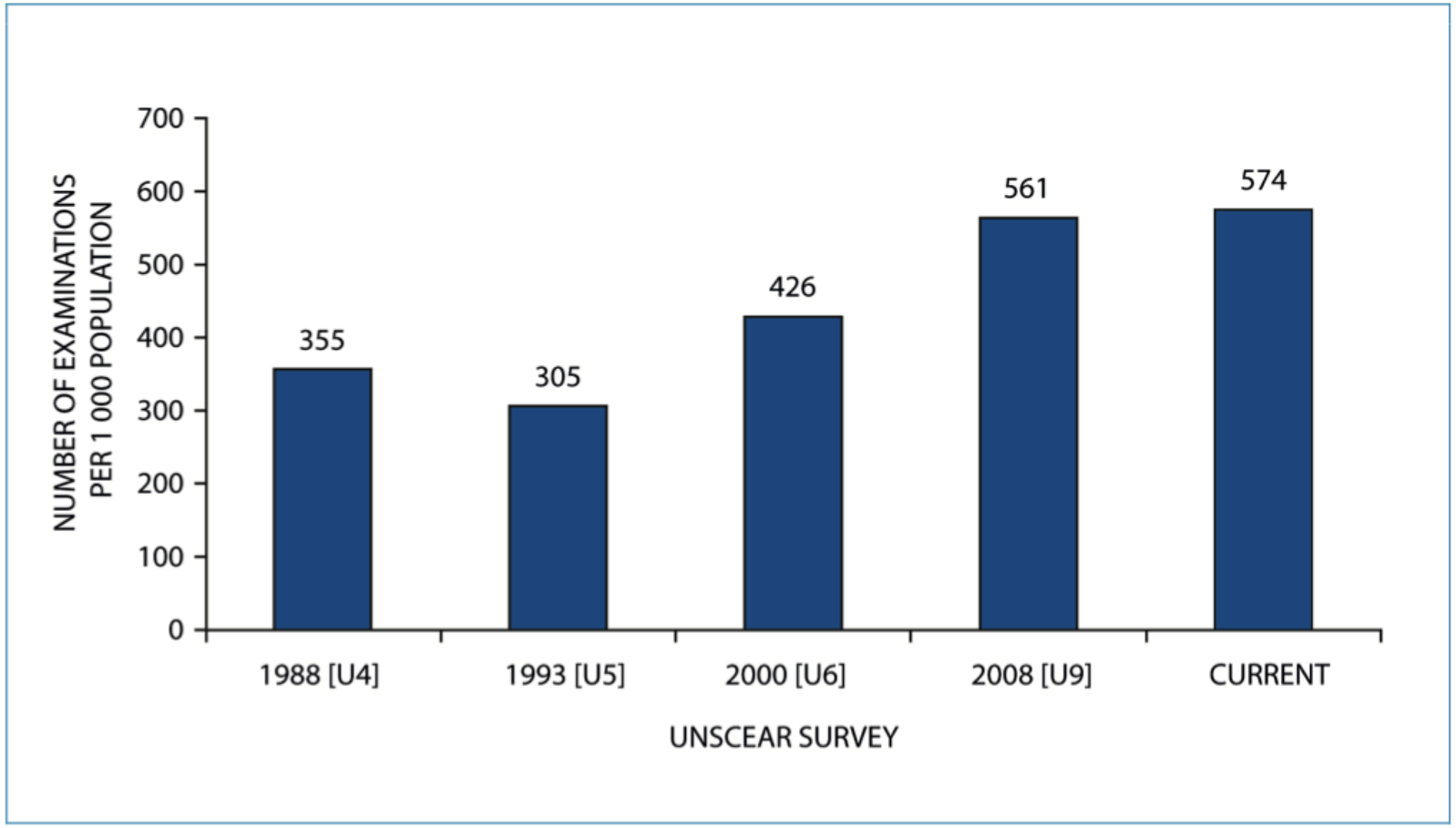
Figure VI. Trend in global annual frequency per 1,000 population of medical radiological examinations



Justification that is mainly a physician and works less

SOURCES, EFFECTS AND RISKS OF IONIZING RADIATION

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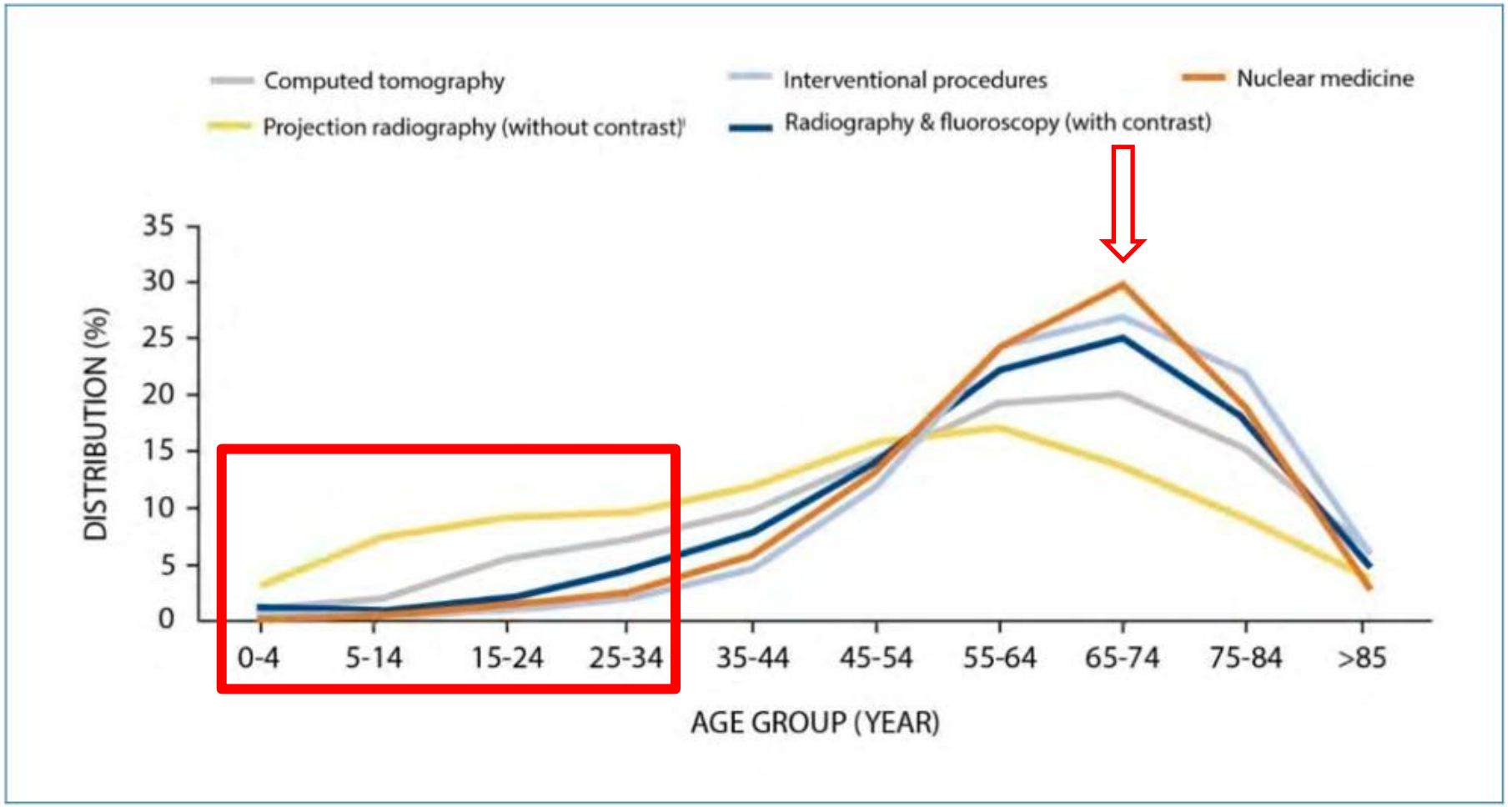
Figure III. Comparison of age distributions for examinations/procedures by modality categories, averaged across countries reported data to UNSCEAR Global Survey



The assesment of risk in pediatric

Brain cancer after radiation exposure from CT examinations of childr study

Michael Hauptmann
Christoffer Johansen
Isabelle Thierry-Chef
Richard W Harbron,

Summary

Background The
adults. Here, we

2023; 24: 45–53
nline
2022

Interpretation
cancer in this
CTs and use of

exposure and brain
cation of paediatric

Implications of all the available evidence

Our study findings emphasise the need to adhere to the basic principles of radiological protection in the medical setting; namely, the need for justification of diagnostic procedures involving ionising radiation (that the procedure is appropriate and in accordance with national and international guidelines) and optimisation of scanning protocols (that the dose should be as low as reasonably achievable). Despite various efforts for dose reduction, CT remains the main contributor to the population diagnostic medical radiation dose, particularly in middle-income and high-income countries.

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Cumulative radiation dose in pediatrics and young adult

CONTEMPORARY ISSUES IN RADIATION PROTECTION IN MEDICAL IMAGING SPECIAL FEATURE: REVIEW ARTICLE

The cumulative radiation dose paradigm in pediatric imaging

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Kim et al[24]	"Pediatric Patients"	12 years	Mean CED 40.2 mSv	(63 patients)	Neuroblastoma; multiple modalities. 44% also had radiation therapy with mean dose of 32 Gy
Johnsen et al[25]	<30 years	8 years	Mean CED 34 mSv	No patient >70 mSv (20 patients)	Ewing sarcoma; multiple modalities
Lee et al[26]	≤18 years	5 years	"High" considered ≥30 mSv. Median CED 37.1 mSv	No child had CED >50 mSv (from publication's figure 6)	58% of "high" dose patients in malignancy population
Özyörük et al[27]	≤18 years	5 years	62.9 median CED for all diagnoses	No diagnosis upper quartile exceeded 100 mSv (from publication's figure). (88 children)	seven cancer diagnoses. Multiple modalities

Cumulative radiation dose in pediatrics and young adult

Cumulative Radiation Dose from Medical Imaging in Children with Congenital Heart Disease: A Systematic Review

Emer Shelly [1], Michael G. Waldron [2,*], Erica Field [1], Niamh Moore [1], Rena Young [1], Andy Scally [1], Andrew England [1], Michael Maher [2,3] and Mark F. McEntee [1]

Author (Year)	Study Type	Number of Participants	Age of Participants, Years	Radiation Source	Overall Cumulative Effective Dose (mSv)	[1] Participants Cumulative Effective Dose >20 mSv
Ait-Ali (2010) [22]	Prospective cohort	59	2.8 (mean)	All ionising radiation	7.7 (median)	0/59
Jones (2017) [23]	Retrospective cohort	117	0–17 (range)	Interventional procedures	16.5 (median)	14/117
Ubeda (2019) [24]	Prospective/ retrospective cohort	1521	2–8 (range)	Interventional procedures	8.7 (>four procedures) (mean)	0/1521
McDonnell (2014) [25]	Retrospective cohort	31	13.6 (median at heart transplant)	All ionising radiation	53.5 (mean)	Unknown
Glatz (2014) [26]	Retrospective cohort	4132	0.3 (mean)	All ionising radiation	0.96 (median)	218/4132
Downing (2015) [27]	Retrospective cohort	38	[2] Birth-Fontan closure	All ionising radiation	25.7 (mean)	2.9
Johnson (2014) [28]	Retrospective cohort	337	0.24 (median at heart transplant)	All ionising radiation	2.67 (median)	94/337

Pub 73, 1996: Justification for Patient Imaging Procedures

Most benefits and risks apply to the patient

1. Level 1: any exposure should do more good than harm
   - Taken for granted but…
   - This is why a solid foundation in medical and RP ethics is essential (P138 and TG109), codes of ethics, safety culture

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2. Level 2: Evidence based imaging protocols
   - Provide e-CDS imaging guidelines (at point of care)

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3. Level 3: Individualized approach

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Courtesy of K Applegate modified

Three levels of justification brings us to the work of new TG124

- Level 1: Ethical view to do more good than harm (beneficence/non-maleficence)
- Level 2: Use of evidence-based referral guidelines or protocols. This is stratification of radiological protection of sub-populations or groups of patients based on what we know
- Level 3: Individualized approach is the situation where we use our experience, judgement, and ethics to create appropriate care in shared decision-making with patient/family; sometimes this is due to standards for radiation therapy individualized treatment plans; at other times, there may be a lack of evidence-based guidelines for rare conditions.

Courtesy of K Applegate modified

Changes since Publication 103

- Pub 138, TG109 on **ethics** in medical RP (patient focus)
  - Strengthening ethics training will improve justification in medicine
- Enormous increase in technologies/complexity and volumes of imaging but strengthened **optimisation** has stabilized* population exposures
- Increasing expectations, patient shared-decisions and engagement with stakeholders
- New domains of medical RP research (e.g., Artificial intelligence, Photon-counting CT, heavy ion radiotherapies, targeted alpha radiotherapies)
- Interest and concern in cumulative exposure

Courtesy of K Applegate modified

Points to Be Emphasised

- Justification is ultimately judged by society.
- Ethical considerations are essential.
- Sustainable development can guide justification decisions.
- Doing good and avoiding harm often belong to different dimensions.
- A wide range of factors/aspects need to be considered, with radiation exposure often a relatively minor issue.
- Rigour of the justification process should be proportionate to the magnitude of radiation risk and complexity of the issue.
- There is overlap between justification and optimisation.
- Justification decisions always entail uncertainty.

Application of the Principle of Justification

1. Setting the Scene

1.1. Justification as a decision-making process

1.2. Factors to consider and uncertainties

1.3. Relationship to other ICRP Publications

2. Framework of the Principle of Justification

2.1. Scope of decision making

2.2. Relation to SDGs

2.3. Spatial and temporal domain

2.4. Integration into the overall decision

3. Basis for Judgement

3.1. Ethical considerations

3.2. Health detriment of radiation

3.3. Concept of well-being

3.4. Sustainable development

4. Relation to Other Concepts for Radiological Protection

4.1. Exposure situation

4.2. Optimisation of protection

4.3. Numerical protection criteria

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Application of the Principle of Justification

5. Procedural Consideration

5.1. Assessment of benefits and detriments
5.2. Quantitative and qualitative approach
5.3. Distribution of benefits and detriments in the population
5.4. Vulnerable populations
5.5. Risks from concurrent events
5.6. Uncertainty in assessments
5.7. Potential events to consider
5.8. Stakeholder involvement
5.9. Roles and responsibilities
5.10. Review of justification decision
5.11. Graded approach

6. Practical Aspects of Justification

6.1. Planned exposure medical situation
6.2. Planned exposure non-medical situation
6.3. Emergency exposure situation
6.4. Existing exposure situation

Controversial Issues

- **Scope of justification**

  … the Commission only recommends that justification require that the net benefit be positive. [P103, para.205]

  Is it beyond the scope to consider alternative methods or approaches?

- **Potential exposure**

  In order to maintain a strict coherence in the treatment of actual and potential exposures, it would be necessary to extend the concept of detriment to include the probability of occurrence of the situation giving rise to the detriment. [P60, para.196]

  Is it practical to handle actual and potential exposures on the same footing?

спасибо
GRACIAS
谢谢
THANK YOU
ありがとうございました
MERCI
DANKE
धन्यवाद
شُكراً
OBRIGADO

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