TGI 24 Workshop on Justification
Session 1:

Planned Exposure Situation
Medical Patient Applications

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Chair Committee 3

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A. Defining Justification in Medicine
B. Challenges and Opportunities since Pub103
C. Measuring Patient Outcomes
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3 Pillars of ICRP
Science, Experience, Ethics

- Knowing the science
- Learning from experience (QA/QI)
- Ethics training in RP in medicine
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)
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

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

3. Level 3: Individualized approach

4. No dose limits*
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., AI/ML, registries, heavy ion radiotherapies, targeted alpha radiotherapies

*similar to MEDIRAD, other
Pairing the ethical values in TG109

Radiological protection

- beneficence
- non-maleficence
- justice
- dignity
- prudence

Procedural values
- inclusiveness
- accountability / transparency

Core values

Biomedical ethics

- beneficence
- non-maleficence
- justice
- autonomy

Other values
- solidarity
- precaution
- empathy
- honesty

Core values

ICRP
Opportunities (P135, TG108) – Justification in Medicine

Collaboration

• Widen education and training to all stakeholders, ensure access throughout career, include ethics and measurement of patient outcomes for justification
  • Vassileva et al. JRP 42; 2022
• Learn from each other (flatten authority gradient)
• Create safe learning environments without blame
• Develop dose registries, especially for vulnerable populations (children), linked to clinical data
How Can We Assess Imaging Procedures in Healthcare?

Avedis Donabedian, a pediatrician and public health expert, developed a quality model allowing assessment (qualitatively/quantitatively) in 1966 that endures today:

- **Structure** (access to care; resources)
- **Process** (patient, family, and referring provider experience)
- **Outcomes** (appropriate imaging and care)
Consider opportunities for research on justification: Worldwide “Insatiable Appetite” for Imaging

- 4.2 billion exams/year (UNSCEAR 2020*)
  - *does not include RTx imaging or radionuclide Tx

- Majority of ICRP publications focus on optimisation, not justification

- Perhaps 1/3 unneeded...
  - 25% waste in USA healthcare system
    JAMA 2019; Oct 7. WH Shrank et al
Opportunity: Geographic Variation in Cost of Care Among Medicare Enrollees, 2002 -2003

Standardized Discharge Ratio (Log scale)

- Hip Fracture (14.3)
- Knee Replacement (53.6)
- Hip Replacement (69.5)
- Back Surgery (103.8)

Source: Dartmouth Atlas Project, 1996-present; slide courtesy C Blackmore.
NCRP: Measuring Justification

How do we measure justification for imaging (radiology procedures and nuclear medicine)?

- Research methods focus on outcomes, cost effectiveness research, and efficacy model by Fryback and Thornbury (1991).
- Discusses the limitations of RCTs for radiology and nuclear medicine, and tests in general.
- Also advocates and explains role for systematic reviews and meta-analyses.
Fryback & Thornbury
6-Tier Hierarchical Model of Efficacy

LEVEL 1: Technical Performance

2: Diagnostic Accuracy

3: Diagnostic Thinking

4: Therapeutic Thinking

5: Patient Outcome

6: Societal Effect
Radiology imaging is part of a larger system of health care

Efficacy goes beyond quality & accuracy (levels 1, 2)—necessary, not sufficient

Applicable to any dx test—history, physical, labs, clinical scores, ‘test of time’

Summary

• Justification in medicine has 3 levels
• There are several strategies to measure patient outcomes but limited research training
  • Donabedian Model
  • Continuous Process/Quality Improvement
  • Variation in Use of Imaging (‘Waste’)
  • Fryback and Thornbury Model of Efficacy
  • Systematic Review/Meta-analysis
Questions for Discussion

• How is the level 2 justification currently applied in your country?
• When is justification more carefully individualized (level 3), rather than protocoted (level 2)?
• What are the challenges and obstacles for applying the principle of justification?
• What guidance would be helpful to improve the application of the justification principle?
Value of Imaging

CT/MRI most important innovation in medicine in the 20th century*

*Fuchs V and Sox HC, Health Affairs 2001;20:30-42

Image courtesy C Blackmore
Value of Imaging?

Ottawa Ankle Rules

Image courtesy C Blackmore
Value of Imaging?

Image courtesy C Blackmore
How Hazardous Is Health Care?

Number of encounters for each fatality

- **DANGEROUS** (>1/1000)
  - Health Care

- **REGULATED** (1/100K)
  - Driving
  - Scheduled Airlines
  - European Railroads
  - Nuclear Power

- **ULTRA-SAFE** (<1/100K)
  - Mountain Climbing
  - Bungee Jumping
  - Chemical Manufacturing
  - Chartered Flights
Thank you

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Examples of Appropriate Decreased Use of Imaging in Children

Imaging not needed or imaging with ionizing radiation has been replaced with non-ionizing radiation imaging:

- CT/US follow up of body trauma is rarely needed (solid organ)
- Multi-phase CT in children (any body part) also rarely needed
- ‘Some’ use of abdominal radiographs for pyloric stenosis, intussusception, appendicitis ultrasound
- Small Bowel Follow Through studies (especially for IBD) MRE
Efficacy

- Can it work?
  - Ideal, controlled setting (e.g., research, publication, or subspecialty radiology)
- Efficacy is defined as the probability of benefit to individuals in a defined population from a medical technology applied for a given medical problem under ideal conditions of use.
Effectiveness

- Does it actually work?
- Everyday ‘messy’, ordinary, real life conditions (e.g., clinical setting, general radiologists, community practice)
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