TG124 Workshop on Justification Session 1:

Planned Exposure Situation Medical Patient Applications

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Chair Committee 3

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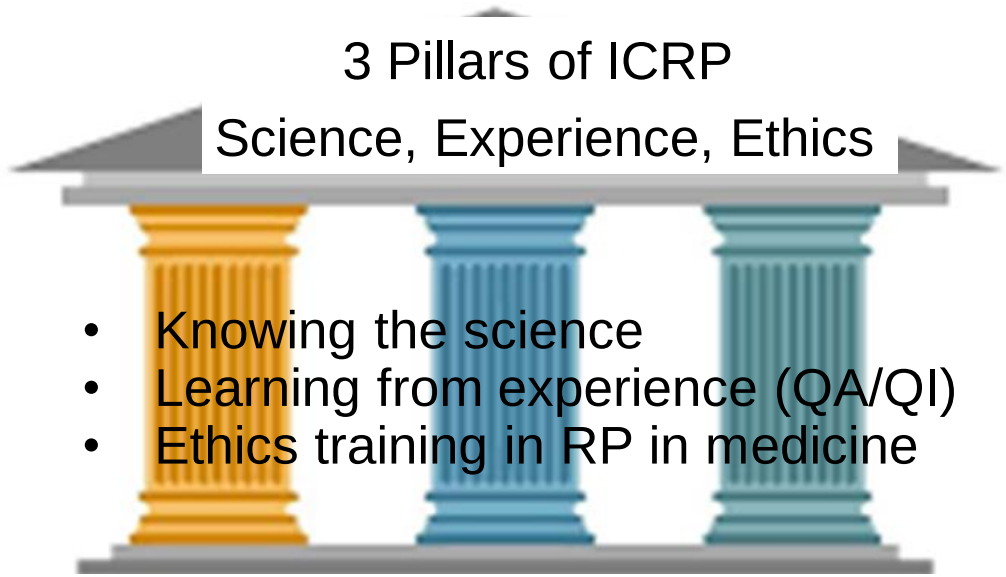


Improving RP in Medicine: Iterative Steps Over Time

- 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)

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
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*

NRDR CDSR® Clinical Decision Support Registry
American College of Radiology

ESR iGuide Clinical Decision Support

ICRP

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

biomedical ethics

core values

beneficence
non-maleficence
justice
dignity
prudence

procedural values
inclusiveness
accountability / transparency

other values

solidarity
precaution
empathy
honesty

core values

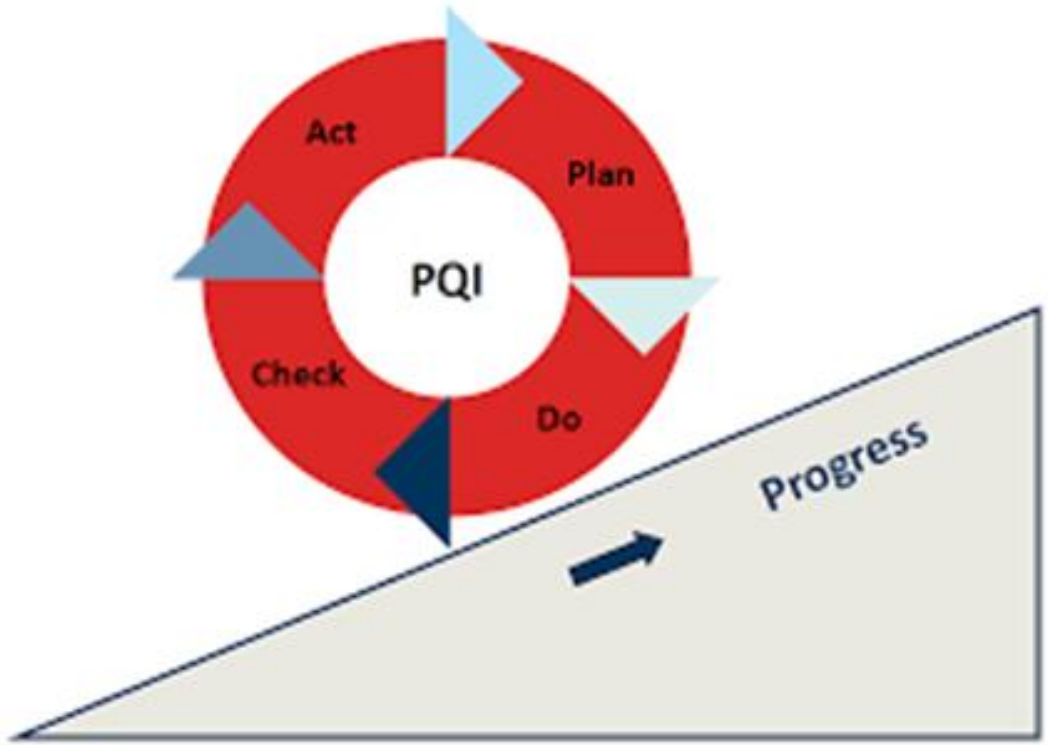
beneficence
non-maleficence
justice
autonomy

ICRP

Opportunities (P135, TG108)— Justification in Medicine

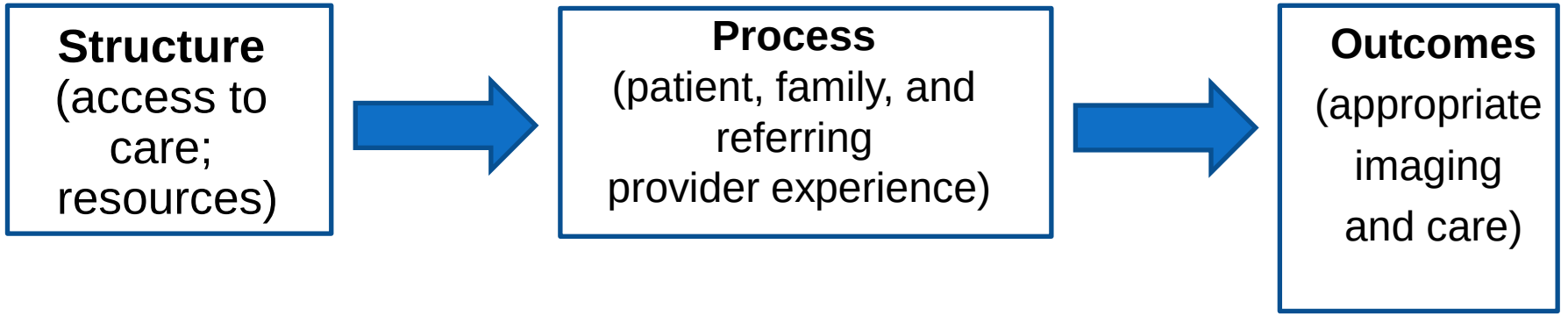
Collaboration

- 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:

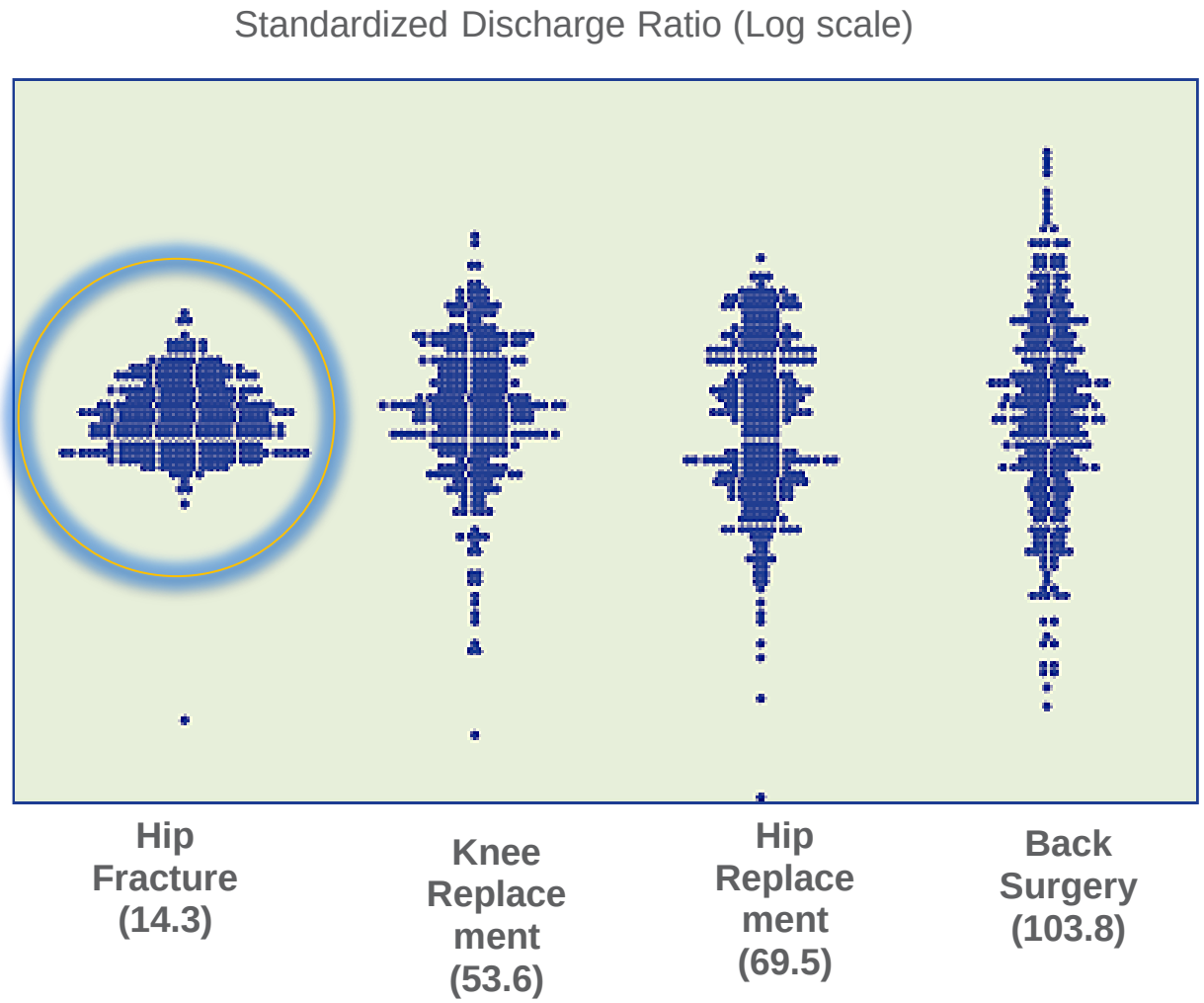


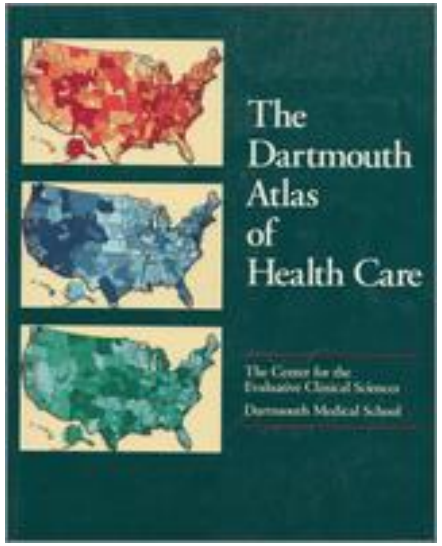
Consider opportunities for research on justification: Worldwide "Insatiable Appetite" for Imaging

- 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





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

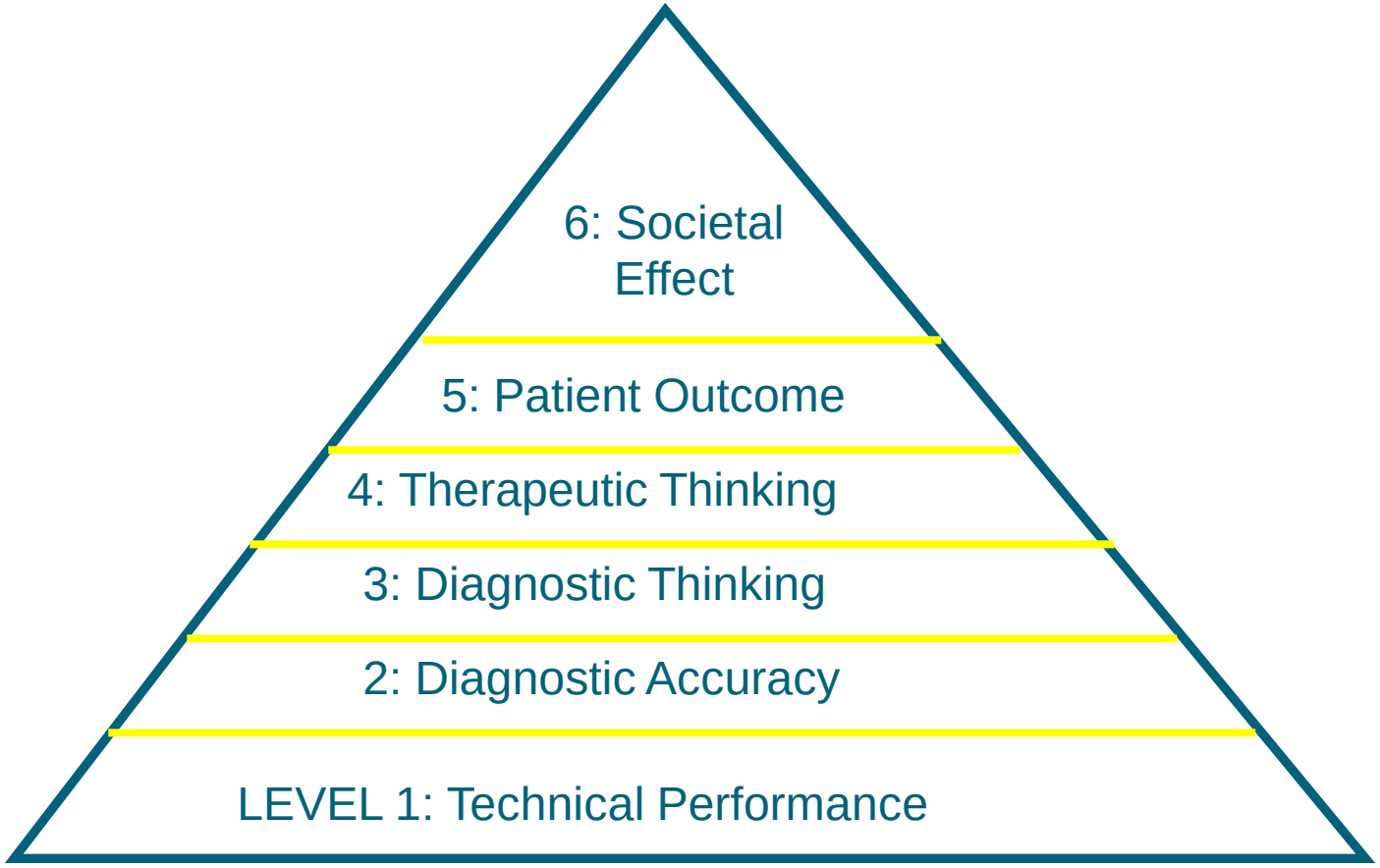
NCRP: Measuring Justification

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

- NCRP Commentary 13 (1995) introduces discussion with concern of rising US health care costs
- 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



Fryback & Thornbury Model

Radiology imaging is part of a larger system of health care

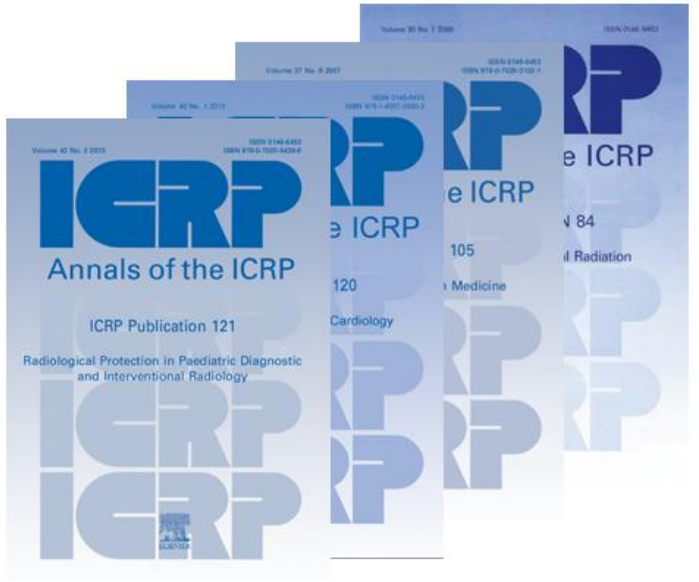
Efficacy goes beyond quality &accuracy (levels 1,2)—necessary, not sufficient

Applicable to any dx test--history, physical, labs, clinical scores, 'test of time'

Medical Decision Making. Apr-Jun 1991;11(2):88-94

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 protocoled (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*

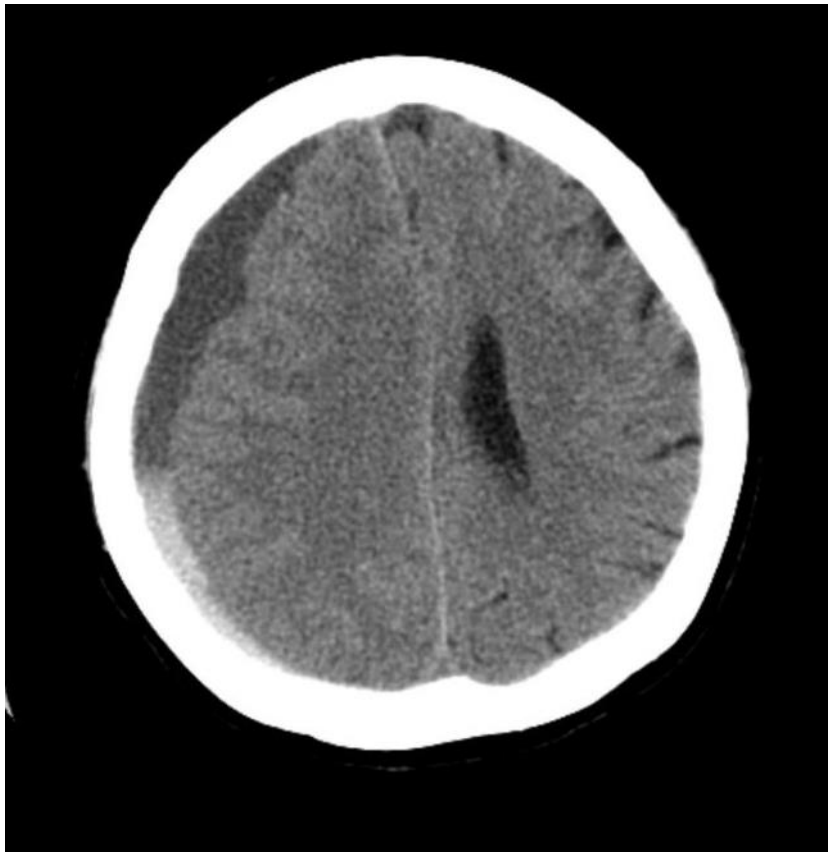


Image courtesy C Blackmore

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

Value of Imaging?

Ottawa Ankle Rules

Image courtesy C Blackmore

Value of Imaging?

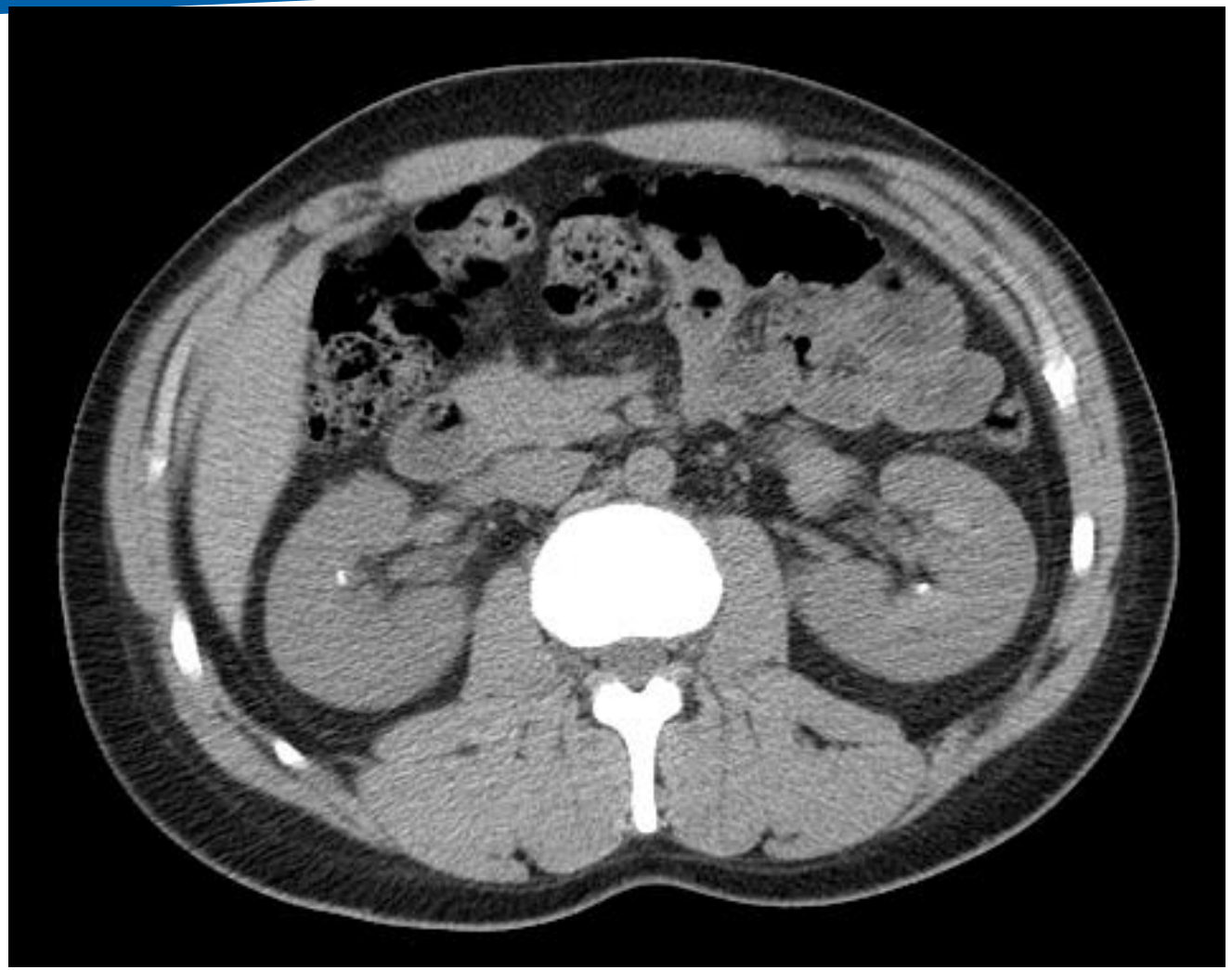
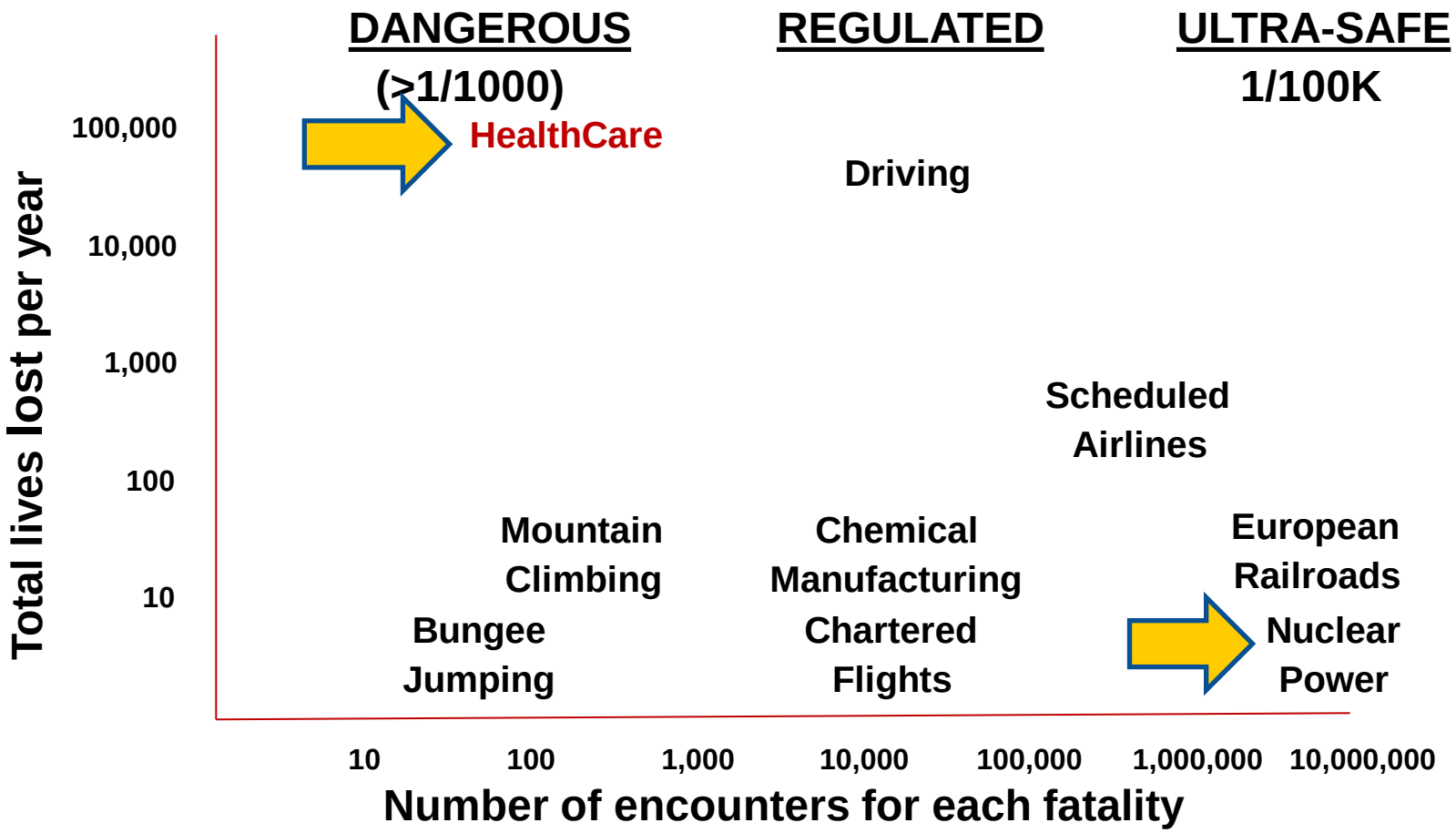


Image courtesy C Blackmore

How Hazardous Is Health Care?



Thank you

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Committee 3 Medicine and Veterinary RP,
2021-2025 (and 9 task groups)

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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)

25 ICRP Publications on RP in Medicine since 2000

Publication 84 Pregnancy	**Publication 85** Radiation Injuries Interventional	**Publication 86** Accidents in Therapy	**Publication 87** CT
Publication SG 2 Radiation and your Patient--updated 2018	**Publication 93** Digital Radiology	**Publication 94** Release of Patients	**Publication 97** HDR Brachy-therapy Accidents
Publication 98 Prostate Brachy-therapy	**Publication 102** Multi-detector CT	**Publication 106** Radiopharma-ceuticals	**Publication 112** External Beam RT Accidents
Publication 113 Education and Training	**Publication 117** Fluoroscopy	**Publication 105** RP in Medicine	**Publication 120** Cardiology
Publication 121 Paediatric Radiology	**Publication 127** Ion Beam Radiotherapy	**Publication 128** Radiopharmaceuticals Compendium	**Publication 129** Cone Beam CT
Pub 135 DRLs Med Imaging	**Pub 139** Occupational RP Intervent Fluoro	**Pub 140** RP in Therapy with Radiopharmaceuticals	**Pub 147** Dose Quantities in RP

Pub 153 Veterinary RP