Concepts in Risk-based Assessment

Risk in Medical Imaging

Ehsan Samei, PhD

DukeMedicine

Outline

- Why of talk about risk?
- Science of risk and risk assessment
- Risk in imaging
  - Radiation risk
  - Risk in terms of patient welfare

Outline

- Why of talk about risk?
- Science of risk and risk assessment
- Risk in imaging
  - Radiation risk
  - Risk in terms of patient welfare

Overarching need/presuppositions

Medicine should discern relevant state of health and intervention with sufficient accuracy and precision for definitive and effective clinical outcome

Healthcare must be oriented more towards the patient than the particularities of the techniques – techniques are valued to the extent they benefit patient care

Role of imaging

Imaging should discern relevant state of health and intervention with sufficient accuracy and precision for definitive and effective clinical outcome

Reality check 1:
Clinical practice

- **Heterogeneous, Compounded, Complex**
  - Varying technological offerings
  - Varying technological parameters
  - The patient factor
    - limited dynamic adaptation of systems to the patient
  - The human factor
  - Competing interests (vendors, insurance companies, employers, etc)

Reality check 2:
Cultural shifts in healthcare

- **Evidence-based medicine**
  - Practice informed by science
- **Precision medicine**
  - Quantification and personalization of care
- **Value-based medicine**
  - Scrutiny on safety, performance, consistency, stewardship, efficiency (leanness), ethics
- **Comparative effectiveness and meaningful use**
  - Enhanced focus on actual utility

What is the role of medical physicist?

Medical Physics 3.0

- Serve as an agent of innovation of precision and innovation in the practice of medicine
  - Personalized and consistent care
  - Relevant physics practices
  - Evidence-based physics practices

Make the care more about the patient

Minimize and manage the risks

Do we need to talk about risk?

- Medicine provides much benefit
- There is no such think as harm-free interventions
- We are healthcare providers bound by an ethical obligation
  - ***Primum non nocere,*** **"first, do no harm"**
- **In spite of benefits and uncertainty we are morally bound to take the safest path**
- **Many uncertainties persist, but we are morally bound to apply what we do know**

Mandate for risk management

- Economic
  - Reduce misdiagnosis
  - Reduce litigation risk
  - Improve equipment lifespan
- Ethical
  - Trust between provider and patient
  - Doing the right thing
- Professional
  - Consistency in medicine – managing variability
  - Excellence in medicine

Outline

- Why of talk about risk?
- **Science of risk and risk assessment**
- Risk in imaging
  - Radiation risk
  - Risk in terms of patient welfare

What is risk?

The possibility that something bad or unpleasant (such as an injury or a loss) will happen

Marriam-Webster

Some key references

- TG 100!
- ISO 14971:2007 Medical Devices – Risk Management – Application of risk management to medical devices
- ISO 13485:2003(E) Medical Devices – Quality Management systems – Requirements for regulatory purposes
- Medical Devices Directive (MDD) for CE marking products in the European Union
- IEC 60601-x, Specifically, 601-1 & 601-1-6

Basic risk definitions

Harm	Physical injury or damage to health, property, or the environment.
Safety	Freedom from unacceptable harm
Hazard	A potential source of harm. (e.g., sharp object, electrical shock, loss of data…etc.)
Hazardous Situation	Circumstance in which people, property or the environment are exposed to one or more hazard(s)
Risk	Combination of the probability of occurrence of harm and the severity of that harm

Basic risk definitions

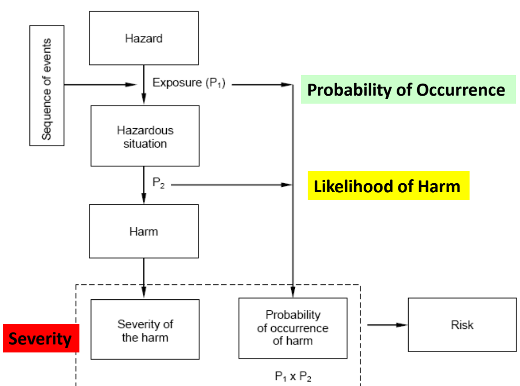
Risk Analysis	Systematic use of available information to identify hazards and estimate the risk
Risk Evaluation	Process of comparing the estimated risk against given risk criteria to determine the acceptability of the risk
Risk Assessment	Overall process comprising a risk analysis and a risk evaluation.
Residual Risk	Risk remaining after risk control measures have been taken

ISO 14971:2007 Medical Devices – Risk Management – Application of risk management to medical devices

Risk evaluation

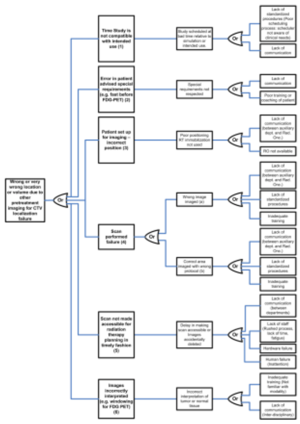
Quantity	Definition	Degree
Probability of occurrence of the hazardous situation (P1)	Rate at which the hazard occurs based on random or systematic failure.	Frequent, Occasional, Remote, Improbable
Likelihood of harm (L2)	Estimation of rate at which physical injury, or damage to health, would actually occur, once the hazard has occurred.	Likely, Unlikely, Rare
Severity (S)	Measure of the possible consequences of a hazard.	Catastrophic, Critical, Serious, Minor

ISO 14971:2007 Medical Devices – Risk Management – Application of risk management to medical devices



Risk = Probability of Occurrence (P1) x Likelihood of Harm (P2) x Severity (S)

Imaging fault tree



Errors in imaging

Agent	Hazard
Ordering system	Wrong patient
Ordering physician	Wrong order
Radiologist	Wrong protocol
Physicist	**Sub-optimal protocol**
Technologist, Nurse	Poor execution
Physicist	**Poor equipment**
Radiologist	Poor interpretation
All - communication	Poor timing
All - communication	Poor access

Outline

- Why of talk about risk?
- Science of risk and risk assessment
- **Risk in imaging**
  - **Radiation risk**
  - **Risk in terms of patient welfare**

Imaging risk

- Radiation risk
- Clinical risk

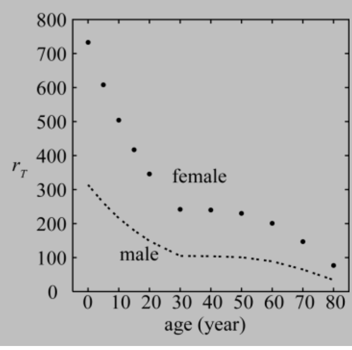
Radiation risk

- Radiation burden associated with imaging
- Not the purpose but a corollary to imaging
- Imaging (dose) is on the rise (NCRP)
- Proportionality, organ sensitivity, age, gender, genetic disposition

What do we know about radiation risk?

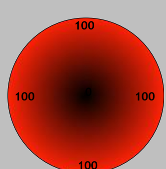
- Proportionality
- Organ sensitivity
- Age dependency
- Gender dependency
- Genetic disposition

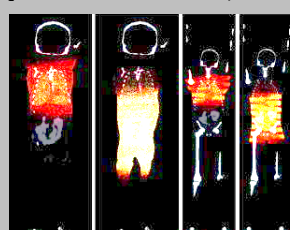
Cancer incidence per 100,000 persons per 100 mGy (BEIRVII)



What is the right dose metric?

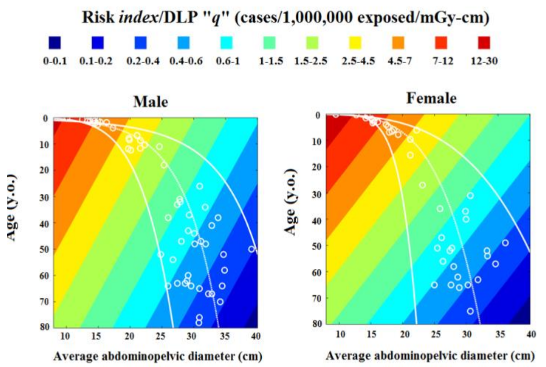
1. **Patient-centric (not modality or machine)**
2. **Accountable quantification and uncertainty**
3. **Scalar-izable (for management, communication)**





Dose metrics attributes

Metric	Physical OR Derived	Patient Attributes				Scalar
		Patient Size	Patient anatomy	Patient age	Patients Gender	
CTDI, DAP, EE, Activity	P					✔
SSDE	P	✔				✔
Organ dose	P	✔	✔	✔	✔	?
Effective Dose	D					✔
Risk index	D	✔	✔	✔	✔	✔

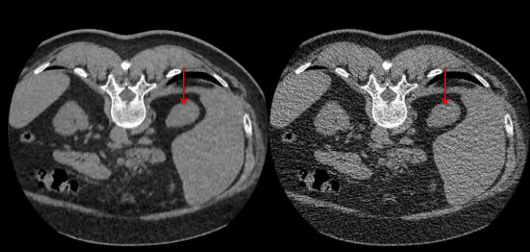


Tian, Samei, PMB, 2014

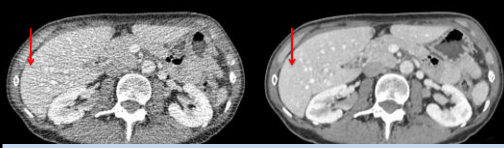
Mitigating radiation risk

- Meaningful radiation dose and risk quantification
- Exposure limits?
- ALARA: As a <u>low</u> as <u>reasonably</u> achievable
- What ALARA means?

What dose is optimum?



What dose is optimum?



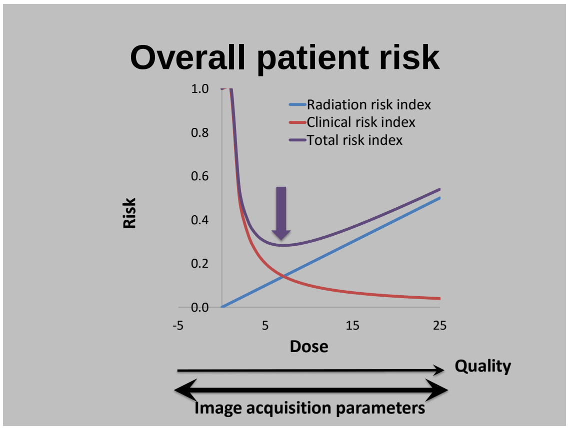
- Optimum dose
  - is inherently linked to image quality
  - needs to address variability across patients

Clinical risk

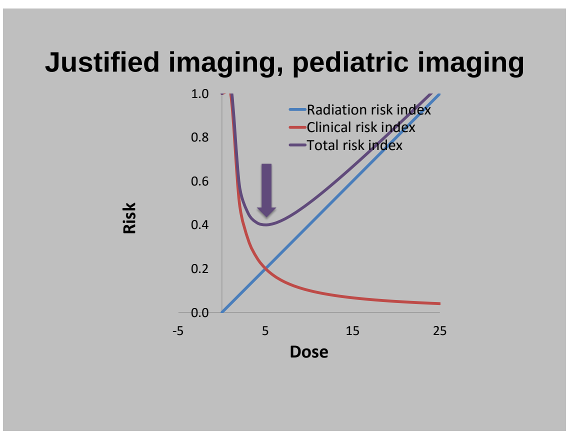
- Insufficient diagnostic quality or confidence leading to erroneous or sub-optimal care
  1. Uncertainty in knowing what's going on (w/o imaging)
  2. Uncertainty in detecting/locating pathology of interest (indication-specific)
  3. Uncertainty in excluding possible pathology of concern (indication-specific)
  4. Uncertainty in picking up incidentals (indication-generic)
  5. Information overload and cognitive bandwidth

Risk optimization

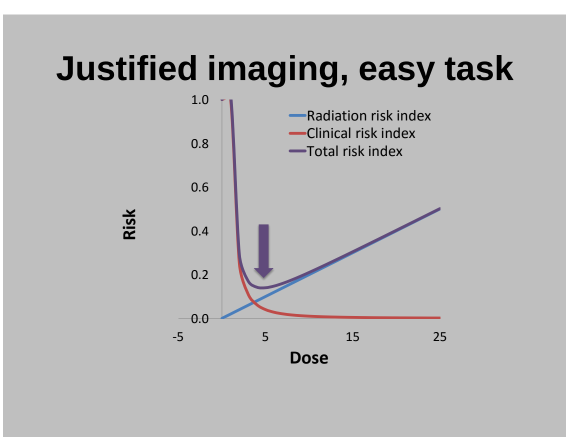
- Aiming for lowest combined radiation risk and clinical risk
- Optimizing patient's overall welfare



Overall patient risk
Radiation risk index
Clinical risk index
Total risk index
Risk
1.0
0.8
0.6
0.4
0.2
0.0
-5
5
15
25
Dose
Quality
Image acquisition parameters

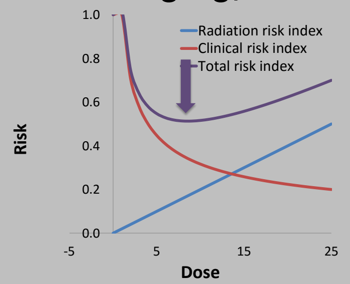


Justified imaging, pediatric imaging
Radiation risk index
Clinical risk index
Total risk index
Risk
1.0
0.8
0.6
0.4
0.2
0.0
-5
5
15
25
Dose

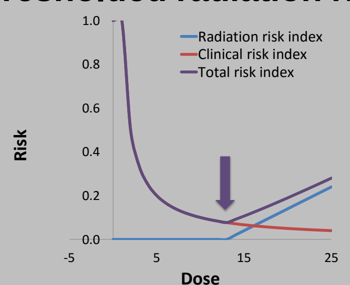


Justified imaging, easy task
Radiation risk index
Clinical risk index
Total risk index
Risk
1.0
0.8
0.6
0.4
0.2
0.0
-5
5
15
25
Dose

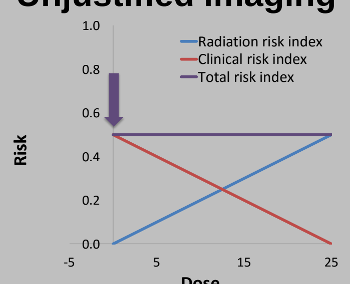
Justified imaging, hard task



Thresholded radiation risk



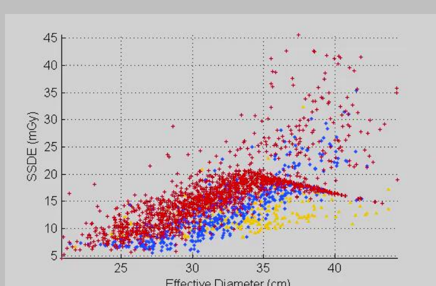
Unjustified imaging



Risk reduction

- Targeted definition and use of proper procedures
- Clinical and radiation risk quantification
- Quality and safety monitoring

Trends in dose and noise



Risk reduction

- Quality and safety monitoring
  - To bring the mean of the risk-dose data to the mean of the optimization minimum (accuracy of risk optimization)
  - To reduce the range of radiation doses and move doses toward “ideal” value based on optimum minimum of the optimization curve (precision of risk optimization)

Caveats and limitations

- Need to stratify data based on
  - Indication
  - System
  - Protocol
  - Patient factors
- Data starved stratification (pediatrics?)
  - More pooling reducing the quality of the risk targeting
- Temporal dimension of risk perception

Conclusions

- **Risk assessment and evaluation involves**
  - **Integrated-contextual view of patient welfare, radiation AND clinical risk**
  - **Meaningful quantification of metrics of care**
  - **Achieving targeted goals with accuracy AND precision**
- **Medical physicists are the most appropriate professionals to bring scientific rigor and relevance in the risk discussion and mitigation**