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 (leaness), 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

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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

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

Basic risk definitions

<table>
<thead>
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<th>Term</th>
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<tbody>
<tr>
<td>Risk Analysis</td>
<td>Systematic use of available information to identify hazards and estimate the risk</td>
</tr>
<tr>
<td>Risk Evaluation</td>
<td>Process of comparing the estimated risk against given risk criteria to determine the acceptability of the risk</td>
</tr>
<tr>
<td>Risk Assessment</td>
<td>Overall process comprising a risk analysis and a risk evaluation.</td>
</tr>
<tr>
<td>Residual Risk</td>
<td>Risk remaining after risk control measures have been taken</td>
</tr>
</tbody>
</table>
Risk evaluation

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

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

Risk = \text{Probability of Occurrence (P1)} \times \text{Likelihood of Harm (P2)} \times \text{Severity (S)}
Imaging fault tree

Errors in imaging

<table>
<thead>
<tr>
<th>Agent</th>
<th>Hazard</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ordering system</td>
<td>Wrong patient</td>
</tr>
<tr>
<td>Ordering physician</td>
<td>Wrong order</td>
</tr>
<tr>
<td>Radiologist</td>
<td>Wrong protocol</td>
</tr>
<tr>
<td>Physicist</td>
<td>Sub-optimal protocol</td>
</tr>
<tr>
<td>Technologist, Nurse</td>
<td>Poor execution</td>
</tr>
<tr>
<td>Physicist</td>
<td>Poor equipment</td>
</tr>
<tr>
<td>Radiologist</td>
<td>Poor interpretation</td>
</tr>
<tr>
<td>All - communication</td>
<td>Poor timing</td>
</tr>
<tr>
<td>All - communication</td>
<td>Poor access</td>
</tr>
</tbody>
</table>

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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
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

<table>
<thead>
<tr>
<th>Metric</th>
<th>Physical OR Derived</th>
<th>Patient Attributes</th>
<th>Scalar</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>Patient Size</td>
<td>Patient anatomy</td>
</tr>
<tr>
<td>CTDI, DAP, EE, Activity</td>
<td>P</td>
<td>✔</td>
<td>✔</td>
</tr>
<tr>
<td>SSDE</td>
<td>P</td>
<td>✔</td>
<td>✔</td>
</tr>
<tr>
<td>Organ dose</td>
<td>P</td>
<td>✔</td>
<td>✔</td>
</tr>
<tr>
<td>Effective Dose</td>
<td>D</td>
<td>✔</td>
<td>✔</td>
</tr>
<tr>
<td>Risk index</td>
<td>D</td>
<td>✔</td>
<td>✔</td>
</tr>
</tbody>
</table>
Mitigating radiation risk

- Meaningful radiation dose and risk quantification
- Exposure limits?
- ALARA: As a low as reasonably 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

Justified imaging, pediatric imaging

Justified imaging, easy task
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