Ethical aspects of radiological protection of patients exposed to radiation in imaging and therapy

ICRP Task Group 109
A Joint Task Group of Committees 3 and 4

Frederic Fahey, DSC, FAAPM
TG 109 Member

Kimberly Applegate, MD, MS
ICRP Main Commission

AAPM 2022 Spring Educational Meeting
March 28

No COI
Members of the Task Group 109

Marie Claire Cantone (Co-chair) C3, Univ. Milan, IT
Francois Bochud (Co-chair) C4, IRA CHUV, CH
Kimberly Applegate, Univ. of Kentucky COM, USA
Mary Coffey, Trinity Health Sciences, Ireland
John Damilakis, Univ. of Crete SOM, Greece
Maria del Rosario, WHO, Switzerland
Frederic Fahey, Boston Children’s Hospital, USA
Chieko Kurihara-Saio, NIRS, Japan
Bernard Le Guen, IRPA, France
Jim Malone, Trinity College Dublin, Ireland
Lynette Reid, Dalhousie University, Canada
Manvir Jesudasan, Patient for Patients Safety Malaysia, UK
Friedo Zölzer, University South Bohemia, CZ
Alberto Lachos-Davilla, Peru
Margaret Murphy, Ireland
ICRP TG 109 Goals

TG to clarify ethical aspects in the use of radiation in medicine

- Addressed to the radiological protection of patients

- Intended for radiological/medical professionals, managers/administrators, vendors, and authorities as well as patients/families, and the public)

- Based on ICRP Publication 138 (2018), which identifies core values and procedural values associated with the System of RP:
  - Dignity, Beneficence/Non-maleficence, Prudence, Justice
  - Accountability, Transparency, Inclusiveness (stakeholder involvement)

- Occupational exposure and research related exposures (update of Pub 62 will be occurring) are not in scope
The core values underpinning the ICRP System of RP

Four core ethical values permeate the current System of RP, and their relationship with the three principles of Justification, Optimisation, and Limitation (Publication 138)

<table>
<thead>
<tr>
<th>Core Ethical Values</th>
<th>Description</th>
<th>Justification</th>
<th>Optimisation</th>
<th>Prudence</th>
<th>Justice</th>
<th>Dignity</th>
</tr>
</thead>
<tbody>
<tr>
<td>Beneficence/non-maleficence</td>
<td>Promoting or doing good, and avoiding doing harm</td>
<td>Reflecting the principle <strong>justification</strong>, and process of <strong>optimisation</strong> in non-maleficence.</td>
<td><strong>optimisation</strong> in non-maleficence.</td>
<td>Prudence in <strong>justification, optimisation</strong>, e.g. associated to LNT model as prudent basis of RP.</td>
<td>Burdens/benefits in <strong>optimisation</strong> within patient vulnerability and need to benefit from medical procedures.</td>
<td>Dignity supports right to know, informed consent and is related to <strong>procedural ethical values</strong>.</td>
</tr>
<tr>
<td>Prudence</td>
<td>Making informed and carefully considered choices without full knowledge of the scope and consequences of an action</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Justice</td>
<td>Fainess in the distribution of advantages and disadvantages</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Dignity</td>
<td>The unconditional respect every person deserves, irrespective of personal attributes or circumstances.</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
ICRP Publication 138 and TG109 recognise procedural and organizational aspects of the implementation of policy in accordance with ethical values: **accountability**, **transparency**, and **inclusiveness**.

**Accountability**, the procedural ethical value that people who are in charge of decision making must answer for their actions to all those who are likely to be affected by these actions.

**Transparency**, the openness about decisions and activities that affect society, the economy and the environment, and willingness to communicate these in a clear, accurate, timely, honest and complete manner. In the medical field it is implemented according to different procedures, such as through training for workers and informed consent of patients has been developed in the biomedical ethics.

**Inclusiveness**, the involvement of all relevant parties in the decision-making processes related to radiological protection, and in medical facilities, among others has proven to be an effective to keep occupational and patient exposure ALARA.
Further interpretation of these values

Need for additional values, paired with existing ones:

- **Solidarity (links with Justice)**, the common good, as mutual recognition and support.

- **Empathy (relates to inclusiveness)**, contributes to understand the patient’s perspective in the decision-making process.

- **Precaution (links to prudence)**, to take measure to prevent or reduce risks for which we have no direct scientific evidence.

- **Autonomy (as corollary of human dignity)**, relates also to stakeholder participation and empowerment of individuals.
TG 109 report aims to (outline of contents):

- Introduce core and procedural values in the context of diagnostic radiology and radiation therapy
- Increase familiarity of professionals with ethical foundations of RP
- Integrate ethical considerations in RP in medicine

When these ethical values may be practical and useful:
- lack of scientific evidence about patient care
- disagreement between patient/family and care team
- disagreement within care team
TG 109 report aims to:

- Promote an evaluation method to analyse specific clinical situations from an ethical point of view
  - Tabulate paired ethical values for compliance/non-compliance in scenarios
- Provide teaching scenarios where clinical teams face ethical challenges
- Endorse education and lifelong commitment to training of ethics in RP in medicine, in formal and continuing education, for all professionals involved in medical use of radiation
  - Rationale, evidence, free programs and tools
  - Professional codes of ethics, hospital ethical review committees
Background and Approach

- Beauchamp (utilitarian) and Childress (deontologist) Principles of Biomedical Ethics, (2019) 8th ed
  - Defines a set of principles that suited both of their outlooks without referring to a single theory of ethics upon which all persons committed to morality could agree

- Biomedical ethics is derived from an ethics of care, based on a feminist perspective, and often overlooked (B&C)

Outline TG109

1. Introduction and goals
2. Ethics in RP
3. Practical developments in biomedical ethics
4. Medical use of radiation relevant to ethical clinical decision-making
5. Reviewing practice from an ethical perspective
   - Evaluation method of ethical values
6. Case based examples in diagnostic
7. Case based examples in therapy
8. General discussion on the scenarios
9. Education and training in ethics

setting the scene

case based examples
Evaluation method of ethical values of scenarios

- Provides a **practical context** that allow professionals, patients/families to consider the **relevance of ethical perspectives to different cultures and situations**.
- A limited set of **paired values** to assess the scenario for its compliance or non-compliance with those values.

<table>
<thead>
<tr>
<th><strong>compliance</strong></th>
<th>strong (😊😊), weak (😊) or neutral (-)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>non-compliance</strong></td>
<td>strong (😢😢), weak (😢) or neutral (-)</td>
</tr>
</tbody>
</table>

- A case may be both in compliance and noncompliance of a value.
- There is no single ‘right answer’ but a balancing of values used to reach a solution.
- The scenarios are based on real cases but simplified.
Mrs. Mary Jane, a 39-years old mother, is proud of Jack, her little 1.5-month-old baby. She is a single mother, and carefully planned to find, in the next month, a babysitter who will care for Jack. A $^{18}$F-FDG PET study for suspected vertebral osteomyelitis is prescribed for Mary Jane. The radiopharmaceutical used is known to have a low activity concentration in milk and thus no interruption of breastfeeding is required. She is given this information and happy to receive it. However, after completing the exam, she received a leaflet with instructions to limit close direct contact with infants for 12 hours after the scan. The suggested approach is to extract milk, and to let another person feed the baby, via a bottle.

She is surprised and concerned, since she is not prepared to pump her breast milk and does not have a person for taking care of Jack. It is likely that if she had been aware of these instructions prior to the exam, she would have declined the appointment or postponed it until she could find a person to take care of Jack.

The example shows the importance of addressing the needs of patients, not only with respect to recognised benefits and harms, but also with respect to the practicalities of their personal situations, concerns, and points of view.
Good communication should respect the dignity of patient and their living situation, in a structured way and with proper timing. Dignity was not properly considered (⊙). Compliance with respect to B/nM is good for this exam (<bits>😀😀</bits>), while some noncompliance (⊙) emerges as info regarding contact with child is provided after exam, creating anxiety/concern. Good compliance is recognised (<bits>😀😀</bits>) for P/P in limiting unnecessary exposure to the child. Family environment is not always the same, attention to possible diversity and to equity should be part of information process (justice). The fact that complete information was not given before the exam, in order to allow patient to be organised, indicated (⊙⊙) in T/A, and also in I/E.
Education and Lifelong Training in Ethics

• Societal values evolve: Artificial intelligence, genetics, personal health information privacy
• Should be supported by employer
• Supports informed consent and shared decision-making
• Empathy improves patient satisfaction, diagnostic accuracy and patient outcomes
• Empathy can be taught and learned, and every health professional should continuously strive to achieve it
“Radiation protection is not only a matter of science. It is a problem of philosophy, and morality, and the utmost wisdom.”

Lauriston S. Taylor, HPS President 1958-1959; Founder and First President of NCRP

THANK YOU!
www.ICRP.org
5th European Radiation Protection Week (ERPW)
Vienna, 22-24 November 2021

**ERPW Invited Scientific Session:** Envisioning the Future of Radiation Protection Research

---

**ETHICS IN RADIOLOGICAL PROTECTION IN MEDICINE - ICRP TG 109**

Marie Claire CANTONE1, François BOCHUD2, Kimberly APPLEGATE3, Mary COFFEY4, John DAMILAKIS5, Maria del ROSARIO PEREZ6, Frederic FAHEY7, Cheiko KURIHARA-SAI08, Bernard LE GUEN9, Jim MALONE10, Lynette REID11, Friedo ZÖLZER12

---

**IRPA - RADIATION PROTECTION FOR EVERYONE**

**6TH EUROPEAN CONGRESS ON RADIATION PROTECTION**

30 May – 3 June 2022

Budapest Congress, Hungary

---

**2022 AAPM Spring Clinical Meeting**

March 26 – 29 • New Orleans, LA

Ethics in Radiological Protection for Medical Diagnosis and Treatment: The ICRP task group work in progress
## Value Descriptions for Scenario Assessment

<table>
<thead>
<tr>
<th>Term</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Dignity</strong></td>
<td>is the value and respect that every person has and deserves. <strong>Autonomy</strong> is the capacity of individuals to act freely, decide for themselves, and pursue a course of action in their lives.</td>
</tr>
<tr>
<td><strong>Beneficence</strong></td>
<td>and <strong>non-maleficence</strong> refer to the duty to promote doing good and avoiding harm.</td>
</tr>
<tr>
<td><strong>Prudence</strong></td>
<td>is the making of informed and carefully considered choices without the full knowledge of the consequences of an action.</td>
</tr>
<tr>
<td><strong>Precaution</strong></td>
<td>are measures taken to prevent or reduce risk in the absence of scientific certainty.</td>
</tr>
<tr>
<td><strong>Justice</strong></td>
<td>is the upholding of what is right, equitable, and fair for the individual and the community.</td>
</tr>
<tr>
<td><strong>Solidarity</strong></td>
<td>is the consideration of the common good and societal structures that ensure it, as well as interpersonal relations of recognition, reciprocity and support</td>
</tr>
<tr>
<td><strong>Accountability</strong></td>
<td>is the obligation of professionals to answer for their decisions and actions to those who are affected, and to accept the consequences.</td>
</tr>
<tr>
<td><strong>Transparency</strong></td>
<td>is a component of accountability referring to accessibility of information about the deliberations, decisions, and honesty with which this information is shared.</td>
</tr>
<tr>
<td><strong>Honesty</strong></td>
<td>is the professional and personal commitment to candid and truthful sharing of information.</td>
</tr>
<tr>
<td><strong>Inclusiveness</strong></td>
<td>is ensuring that all concerned are given the opportunity to participate in discussions, deliberations, and decision-making concerning situations that affect them.</td>
</tr>
<tr>
<td><strong>Empathy</strong></td>
<td>is sharing another’s emotional response or understanding their feelings and perspectives.</td>
</tr>
</tbody>
</table>
Imaging Procedure Scenario: Dr John Cinnamon

The hospital interventional radiology suite recently had to replace an x-ray tube. The vendor delivered and installed the tube 3 days later. The medical physicist, Dr Russet, was contacted then to test the equipment and certify it was safe for clinical use. However, he was working elsewhere and would not be available for 4 days. As Dr John Cinnamon, head of interventional radiology, did not view the situation as urgent, he left calling Dr Russet until the last minute.

Dr Cinnamon was assured by the vendor’s engineer that it would be all right to accept patients once the tube was replaced. Given these circumstances, he decided that procedures would started immediately, and 35 patients were imaged prior to Dr Russet’s arrival. Upon testing, he found a filter missing among other issues leading to patients receiving doses 2–10 times higher than those typical before the tube replacement. Thus 35 patients received significantly higher doses. Dr Cinnamon was upset, but decided the patients would not be told, as the information might worry them. Dr Russet advised that there was an obligation to let the patients know, and a duty to inform both the hospital and the regulator. Dr Cinnamon decided to do neither referring the matter to the radiation safety committee scheduled to meet in 3 months. Incidentally, the engineer was inexperienced and was assigned in response to Dr Cinnamon’s insistence on immediate tube replacement.
Therapy Procedure Scenario: Paul Trenton

Paul Trenton (50 y) was in poor general health with an advanced tumour in his left lung. He was unfit for surgery and was referred for palliative radiotherapy. The busy clinic had limited equipment and full treatment planning was not carried out for palliative cases. Paul was prescribed 20 Gy in ten treatments, using anterior and posterior opposing fields with the option to consider further treatment later. The clinic was exceptionally hierarchical, teamwork was poor, and questioning was discouraged. The simulator staff noted the posterior field was marked incorrectly for the right side. They raised their concerns but were dismissed by the consultant.

At treatment, Paul was the day’s last patient, and no medical staff were on duty. The radiation therapists noted that the posterior field was drawn on the wrong side, contacted the patient’s doctor by phone but were instructed to treat the patient as marked. Treating as instructed would have given an unnecessary dose to the right lung and deprived the left lung treatment. They considered giving the anterior field only, but this would have contradicted their explicit instructions. They were not inclined to mistreat the patient and decided to treat the anterior field as marked, and to reposition the posterior field on the left side as per the prescription. The following day they approached a second doctor on the team with whom they had a good working relationship, and the fields were corrected.
Now it is your turn!