ICRP TG109

Ethics in Radiological Protection for Medical Diagnosis and Treatment

Groupe de travail CIPR, 27 Septembre 2022

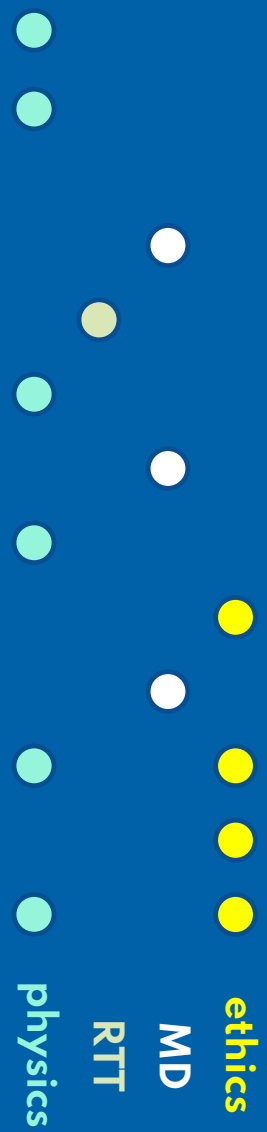
François BOCHUD

ICRP – TG109 Co-chair

TG 109

Members
of the TG

and their
core competences



- François Bochud
- Marie-Claire Cantone

- Kimberly Applegate
- Mary Coffey
- John Damilakis
- Maria del Rosario Perez
- Frederic Fahey
- Chieko Kurihara-Saio
- Bernard Le Guen
- Jim Malone
- Lynette Reid
- Friedo Zölzer

ICRP

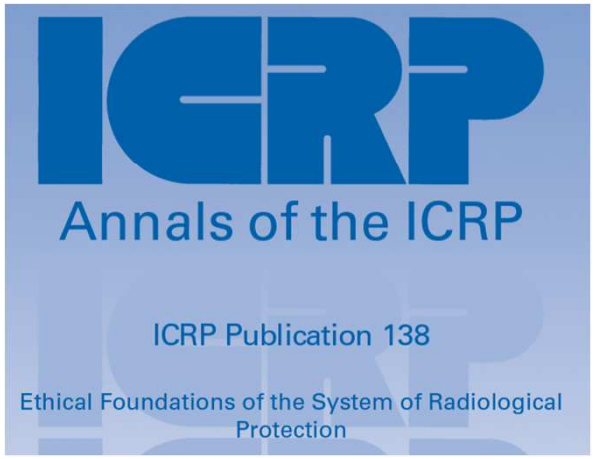
Mandate of the TG

- **To develop an ICRP publication presenting the ethical aspects in the use of radiation in medicine**
  - addressed to the radiological protection of **patients**
  - intended for medical professionals, patients, the public, and authorities

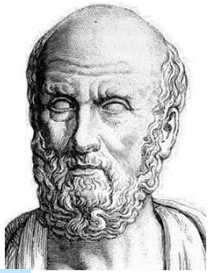
not just for us

Mandate of the TG

- **To develop an ICRP publication presenting the ethical aspects in the use of radiation in medicine**
  - addressed to the radiological protection of **patients**
  - intended for medical professionals, patients, the public, and authorities
  - build upon **Publication 138**



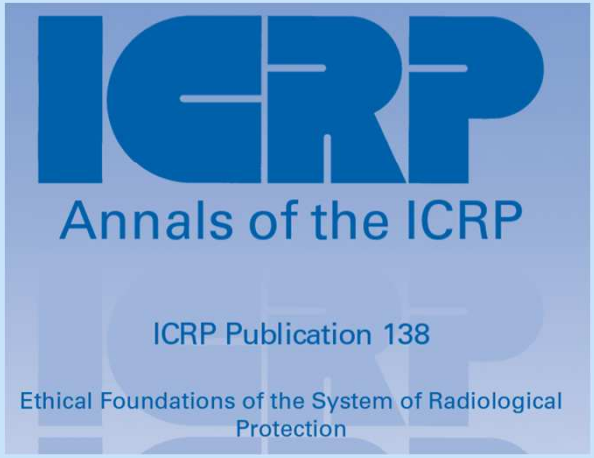
Why is it important?



values made explicit only in 2018

different needs

long explicit history & living culture of ethics



what is **already there**

specificities of RP

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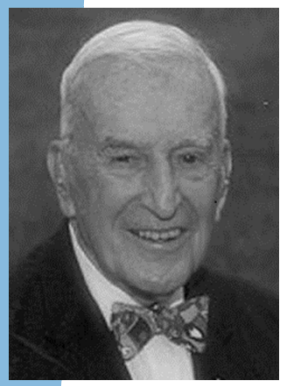
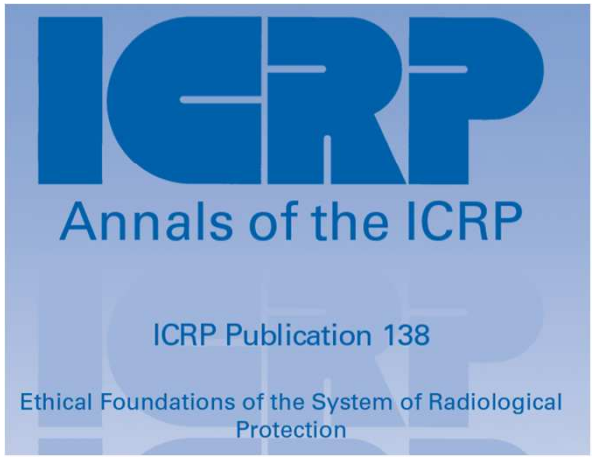
Why is it important?



Radiation protection is not only a matter for science. It is a problem of philosophy, and morality, and the utmost wisdom

Lauriston Taylor, 1957, address to the Ninth Annual Conference on Electrical Techniques in Medicine and Biology in 1956



Purpose of the report

- **Bridge the gap** between the **communities** in terms of ethics
  - build on P 138

medical community

RP community

Purpose of the report

- **Bridge the gap** between the **medical and RP communities** in terms of ethics
  - build on P 138
- Propose an **evaluation method** to analyze **specific situations** from an ethical point of view
- Put the method into practice with **scenarios**
  - **10** in imaging
  - **10** in therapy
- Integrating ethics into **education & training**

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Wider goals of the report

to increase **familiarity**

with **biomedical ethics**
(its current state across health care)

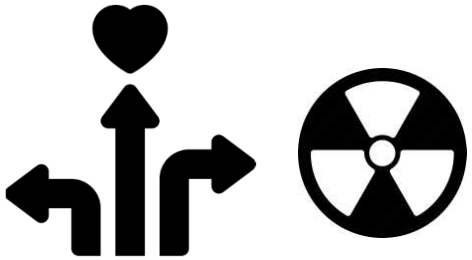
with the **ethical foundations of RP**

to help them **integrating ethical considerations** into RP in medicine

to **assist** all stakeholders

whose **clinical decision-making**
has an **impact on RP**

to **integrate RP considerations** into their
ethical and clinical **decision-making**



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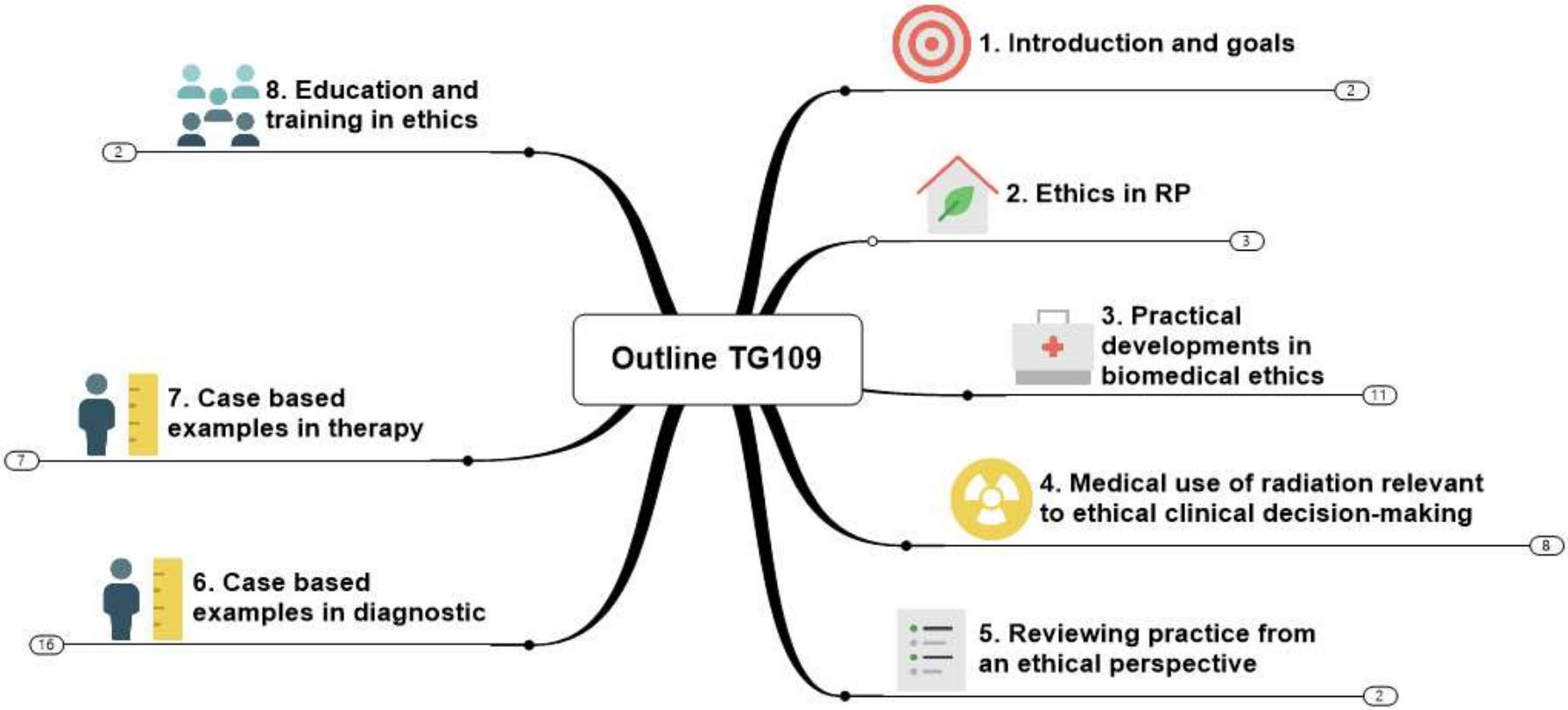
Outline TG109
1. Introduction and goals
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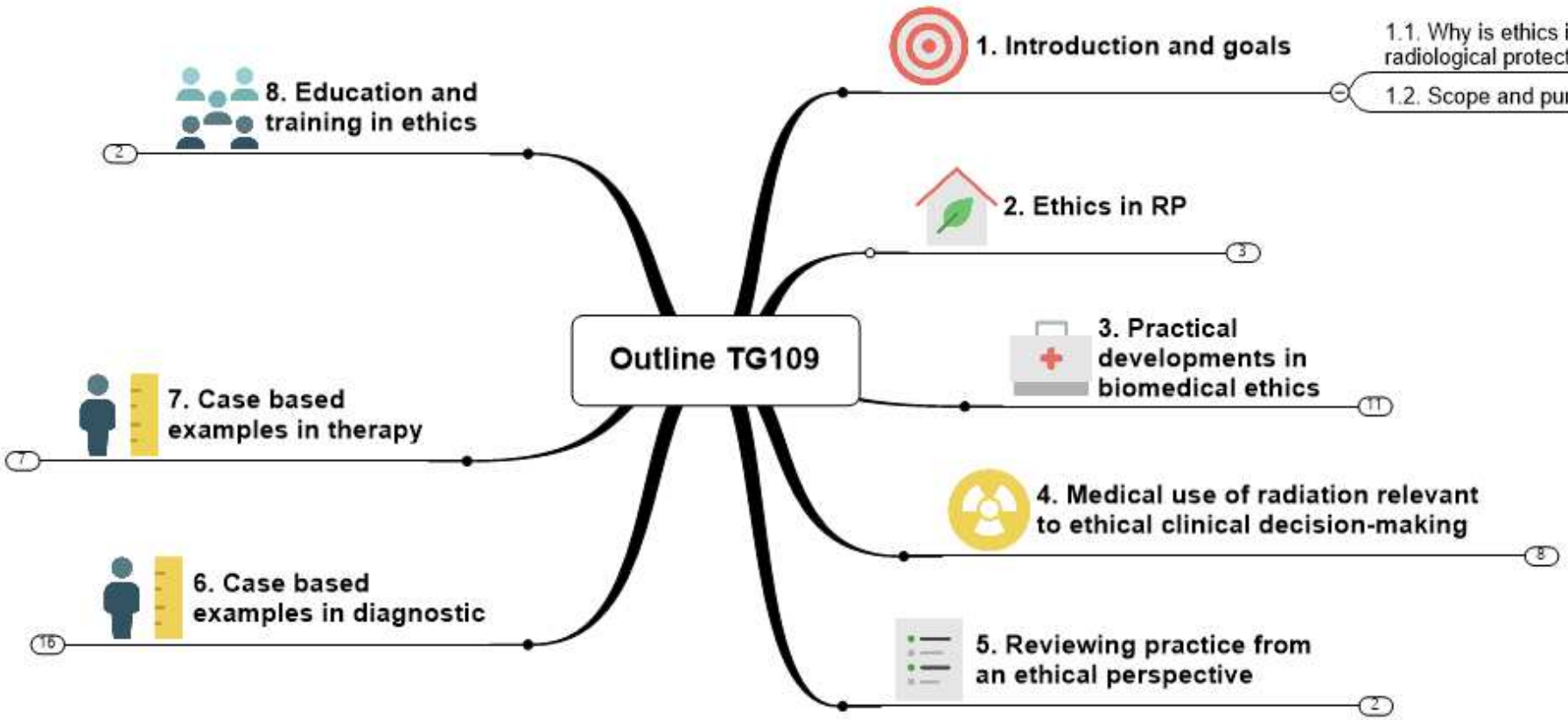
2. Ethics in RP
3
3. Practical developments in biomedical ethics
11
4. Medical use of radiation relevant to ethical clinical decision-making
8
5. Reviewing practice from an ethical perspective
2
6. Case based examples in diagnostic
16
7. Case based examples in therapy
7
8. Education and training in ethics
2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1.1. Why is ethics in medical radiological protection important?
1.2. Scope and purpose of this report
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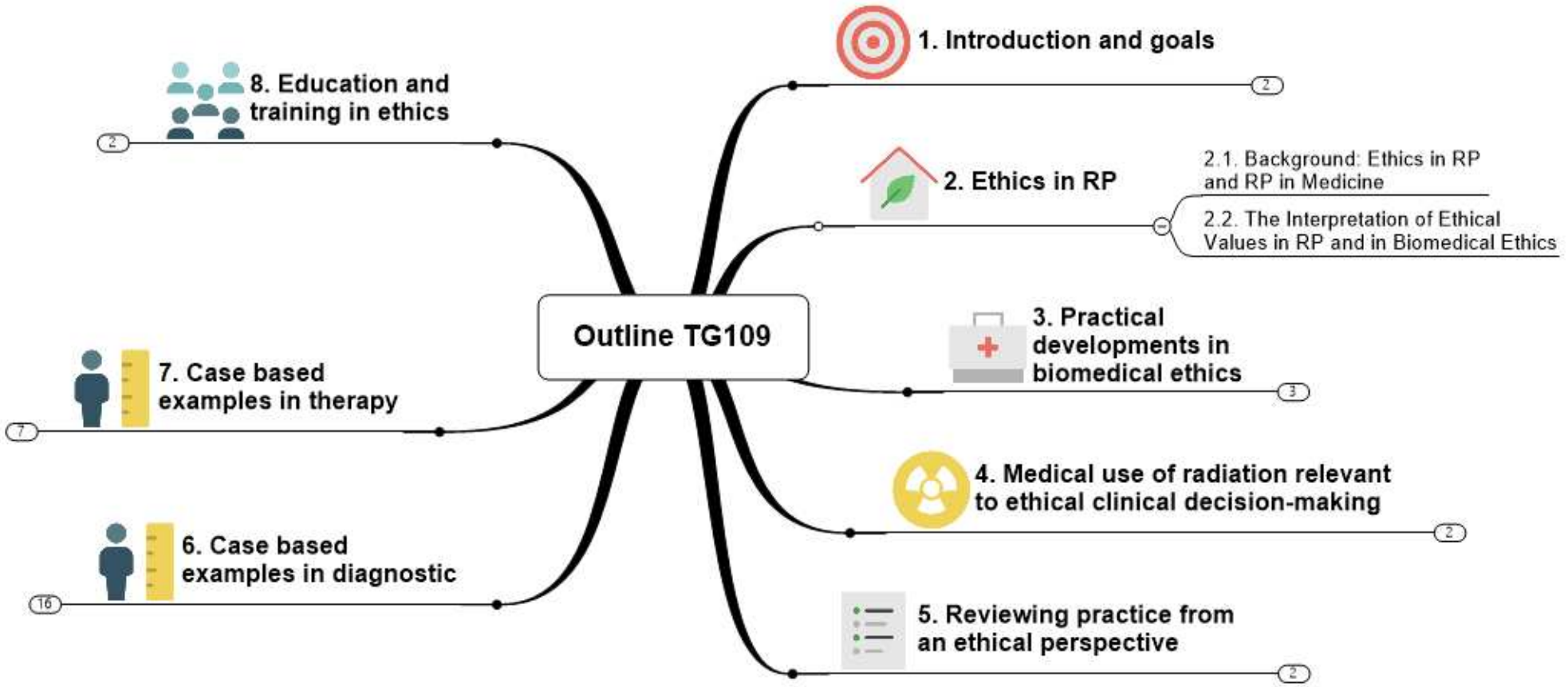
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2.1. Background: Ethics in RP and RP in Medicine
2.2. The Interpretation of Ethical Values in RP and in Biomedical Ethics
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Values of RP & medicine

radiological protection  **values**

beneficence
non-maleficence

justice

dignity

prudence

Promoting or doing **good**, and avoiding doing **harm**

The primary aim of the system of radiological protection: … an appropriate level of protection… without unduly limiting… desirable human actions

Values of RP & medicine

radiological protection  **values**

beneficence
non-maleficence

justice

dignity

prudence

Fairness in the **distribution** of **advantages** and **disadvantages**

Individual dose restrictions to prevent any individual from receiving an unfair burden of risk

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Values of RP & medicine

radiological protection  **values**

beneficence
non-maleficence

justice

dignity

prudence

The **unconditional respect** that every person deserves, irrespective of personal attributes or circumstances

Stakeholder participation and the empowerment of individuals to make their own informed decisions

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Values of RP & medicine

radiological protection

values

beneficence
non-maleficence

justice

dignity

prudence

Making **informed** and carefully considered **choices** without full **knowledge** of the scope and consequences of an action

Consideration of uncertainty in radiation risks for both humans and the environment

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Values of RP & medicine

radiological protection

values

core values

- beneficence non-maleficence
- justice
- dignity
- prudence

procedural values

- accountability
- transparency
- inclusiveness

The obligation of individuals or organizations who are in charge of decision making to **answer for their actions** to all those who are likely to be affected, including **reporting** on their activities, **accepting responsibility**, and accounting for actions taken and the consequences, if necessary

Exercising accountability to future generations for waste management and the protection of the environment

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Values of RP & medicine

radiological protection

values

core values

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

procedural values

- accountability
- transparency
- inclusiveness

Accessibility of **information** about the **deliberations** and **decisions** concerning potential or on-going activities, and the **honesty** with which this information is transmitted

Informing radiological workers of hazards and precautions

disclosing all relevant information about radiation risks and benefits to patients in informed consent

environmental impact assessments

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Values of RP & medicine

radiological protection  **values**

core values

- beneficence
  non-maleficence
- justice
- dignity
- prudence

procedural values

- accountability
- transparency
- inclusiveness

Ensuring that **all those concerned** are given the opportunity to **participate** in discussions, deliberations, and decision making concerning situations that affect them

Empowering the public in the wake of an accident

engaging stakeholders to keep workplace exposures as low as reasonably achievable

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Values of RP & medicine

radiological protection

values **principles**

biomedical ethics

beneficence
non-maleficence

justice

dignity

prudence

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Values of RP & medicine

radiological protection

values

principles

biomedical ethics

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

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Values of RP & medicine

radiological protection

values

principles

biomedical ethics

beneficence non-maleficence		beneficence non-maleficence
justice		justice
dignity	Personal autonomy is a **corollary** of dignity	autonomy
prudence		

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Values of RP & medicine

Solidarity refers to consideration of the **common good** and the societal structures that ensure it, as well as **interpersonal relations** of recognition, **reciprocity** and **support**

Solidarity in health care refers to the efficiency and sustainability of the health care system for all and also to social relations of mutual recognition and support, including support for the most vulnerable

biomedical ethics

four principles

- beneficence
- non-maleficence
- justice
- autonomy

other principles

- solidarity
- precaution
- empathy
- honesty

Values of RP & medicine

Precaution refers to **measures taken** to prevent or reduce **risk** in the **absence** of scientific **certainty**

Medical decision-making involves the integration of multiple sources and kinds of information with patient values in situations of uncertainty

In decision-making about medical radiation use, the LNT model supports reducing exposures insofar as this is consistent with good clinical care

biomedical ethics

four principles

- beneficence
- non-maleficence
- justice
- autonomy

other principles

- solidarity
- precaution
- empathy
- honesty

Values of RP & medicine

Empathy can take emotive and cognitive forms: **sharing** another's **emotional response** and/or **understanding** their feelings and perspectives.

Empathy for patients and carers is important for the recognition of their feelings and perspectives in their care. It should be developed in professional education and supported institutionally in practice.

biomedical ethics

four principles

- beneficence
- non-maleficence
- justice
- autonomy

other principles

- solidarity
- precaution
- empathy
- honesty

Values of RP & medicine

Honesty is the professional and personal commitment to **candid and truthful sharing of information**

Honesty in health care is the personal and institutional commitment to foster the patient's accurate understanding of their own medical condition, and their diagnostic and treatment options, including the risks involved. This includes when appropriate the understanding of others involved in the patient's care.

biomedical ethics

four principles

- beneficence
- non-maleficence
- justice
- autonomy

other principles

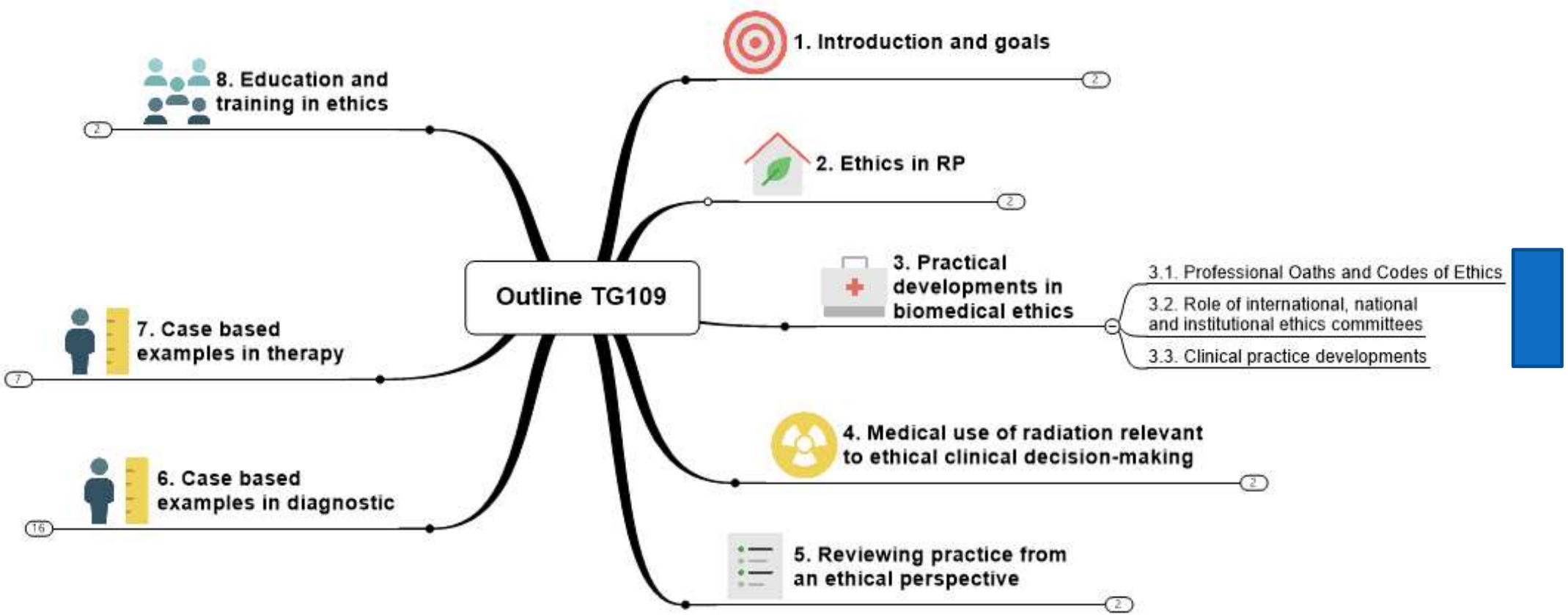
- solidarity
- precaution
- empathy
- honesty

In order to **help the reader** grasp concepts that are sometimes abstract and complex, **key messages** are provided at critical points in the report

Key message: Health care professionals **respect dignity and autonomy** through enabling the patient to participate in **informed consent** for procedures. They also respect dignity and autonomy through adapting **radiological procedures** to the specific cultural and medical **needs of the patient** and ensuring **confidentiality** in patient-professional interactions.

Key message: **Beneficence and non-maleficence** (i.e. benefits and risks) cannot be disaggregated for use of radiation technologies. In justification, **sparing the patient radiation exposure** but failing to answer the clinical question **does not benefit the patient**.

Key message: The use of **non-ionizing radiation imaging** where possible is **prudent** and good practice **but** must be balanced in the context of the individual patient needs and should not be detrimental to **early diagnosis** or **accurate treatment**.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3.3. Clinical practice developments
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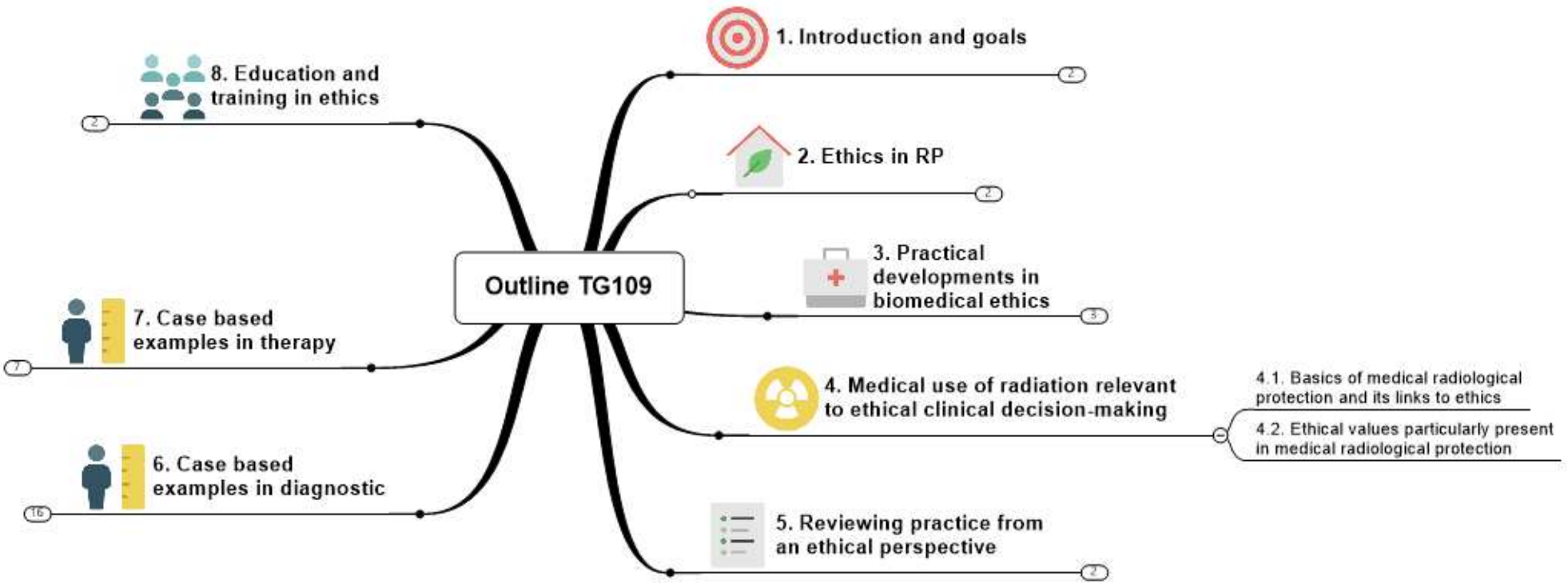
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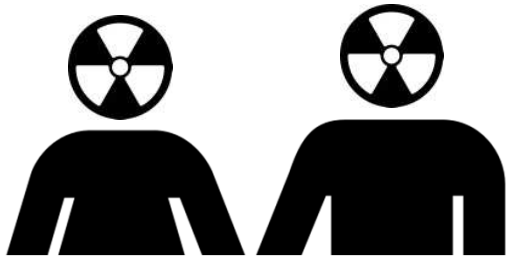

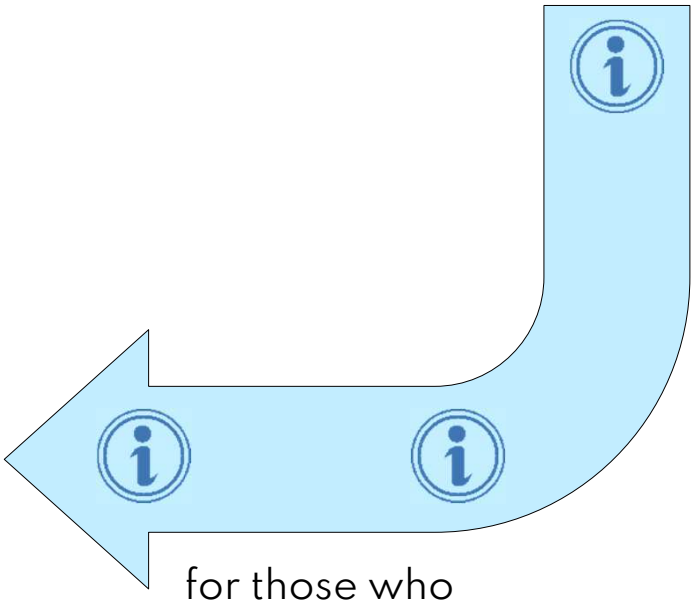

for those who
know more about ethics

4.1. Basics of medical radiological protection and its links to ethics

4.2. Ethical values particularly present in medical radiological protection

For those who know more about biomedical ethics than RP

Stochastic effects & Tissue reactions

classical RP subject
with an ethical approach
precautionary principle
dose threshold

Particular factors affecting radiation sensitivity

age and gender
individual sensitivity

Uncertainties

of the dose received
of the risk associated to the dose
integrating them to education & training

Powell's principle could help

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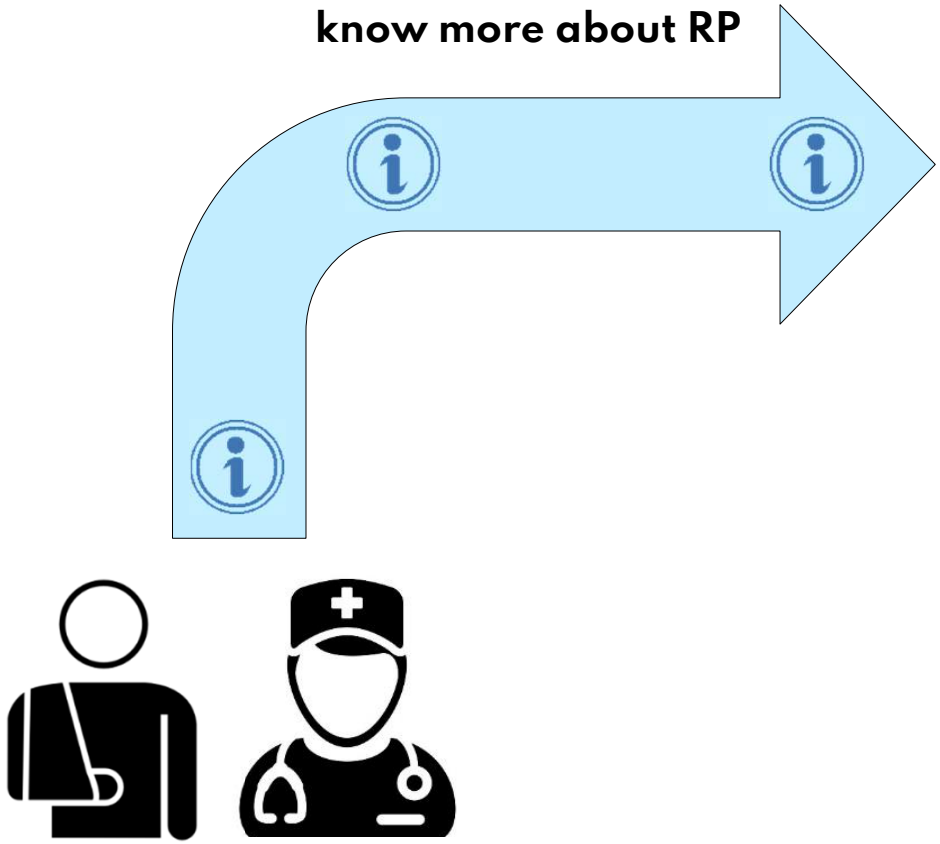
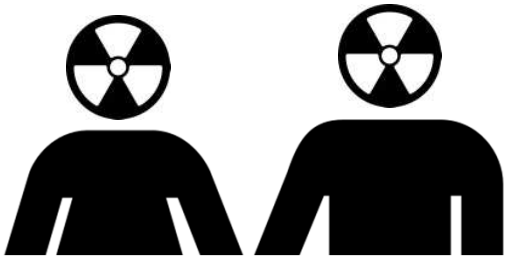
for those who
know more about RP





4.1. Basics of medical radiological protection and its links to ethics

4.2. Ethical values particularly present in medical radiological protection

For those who know more about RP than biomedical ethics

Special aspects of medical use of radiation

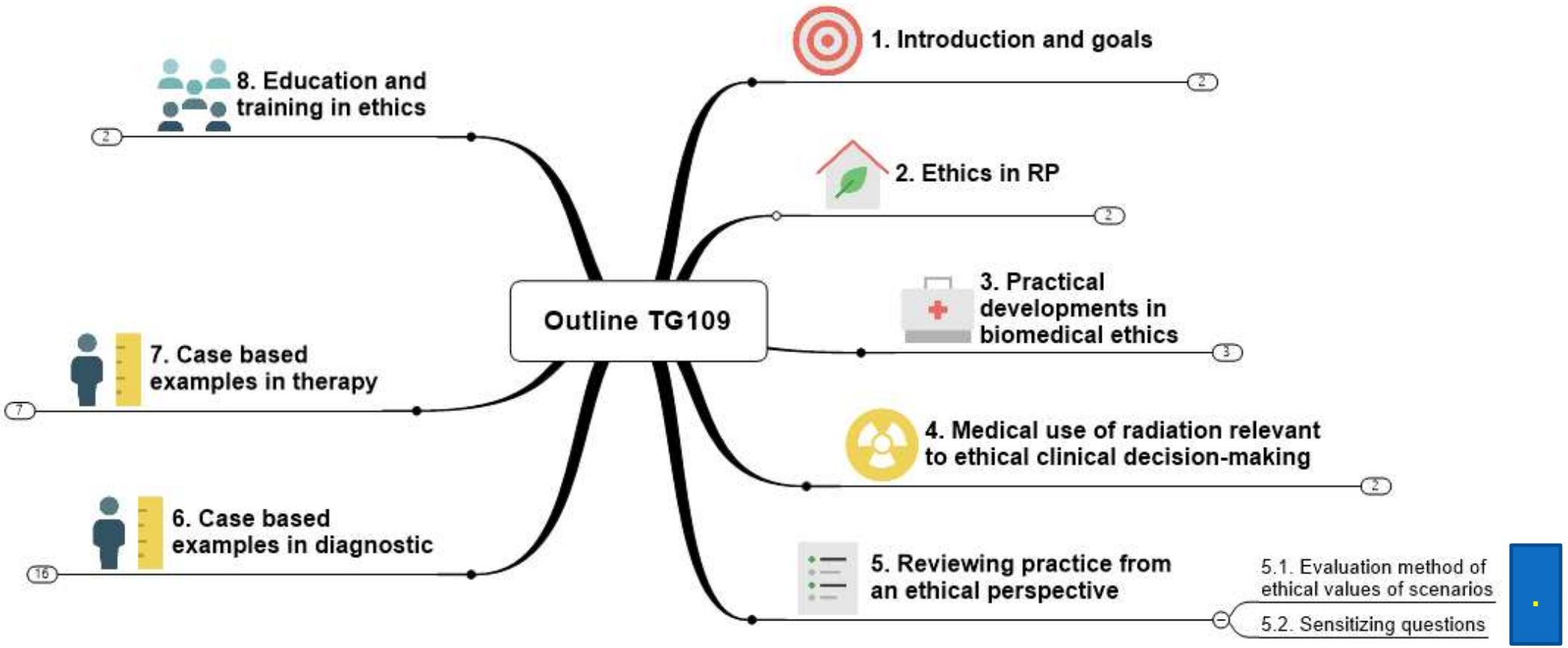
deliberate exposure
voluntary (informed consent)
demography (different than usual RP population)

Medical ethics and application of the principles of RP

justification
optimization
level of efficacy (image quality)

Key message: ICRP considers the linear no-threshold model (**LNT**) as the **best practical approach** to manage stochastic risks from radiation exposure. This is based on the ethical value of **prudence/precaution**.

Key message: When an individual is exposed to ionizing radiation, it is important to take into consideration the **characteristics of that person**. The ethical values of **justice** and **solidarity** and the principle of **optimization** need to be put into practice when, for example, **pregnant patients** and **children** need an X-ray examination.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Pairing the values

radiological protection

biomedical ethics

beneficence
non-maleficence

justice

dignity

prudence

inclusiveness

accountability / transparency

other principles

solidarity

precaution

empathy

honesty

four principles

beneficence
non-maleficence

justice

autonomy

ICRP

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ICRP

Pairing the values

radiological protection

biomedical ethics

beneficence non-maleficence			beneficence non-maleficence
justice		solidarity	justice
dignity			autonomy
prudence		precaution	
	inclusiveness	empathy	
	accountability / transparency	honesty	

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Pairing the values

radiological protection

biomedical ethics

beneficence & non-maleficence

justice		solidarity	justice
dignity			autonomy
prudence		precaution	
	inclusiveness	empathy	
	accountability / transparency	honesty	

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Pairing the values

radiological protection

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beneficence & non-maleficence

justice & solidarity

dignity	autonomy
prudence	precaution
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ICRP

Pairing the values

radiological protection

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beneficence & non-maleficence

justice & solidarity

dignity & autonomy

prudence		precaution
	inclusiveness	empathy
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ICRP

Pairing the values

radiological protection

biomedical ethics

beneficence & non-maleficence

justice & solidarity

dignity & autonomy

prudence & precaution

inclusiveness	empathy
accountability / transparency	honesty

ICRP

Pairing the values

radiological protection

biomedical ethics

beneficence & non-maleficence

justice & solidarity

dignity & autonomy

prudence & precaution

inclusiveness & empathy

accountability / transparency honesty

Pairing the values

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biomedical ethics

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prudence & precaution

inclusiveness & empathy

accountability / transparency & honesty

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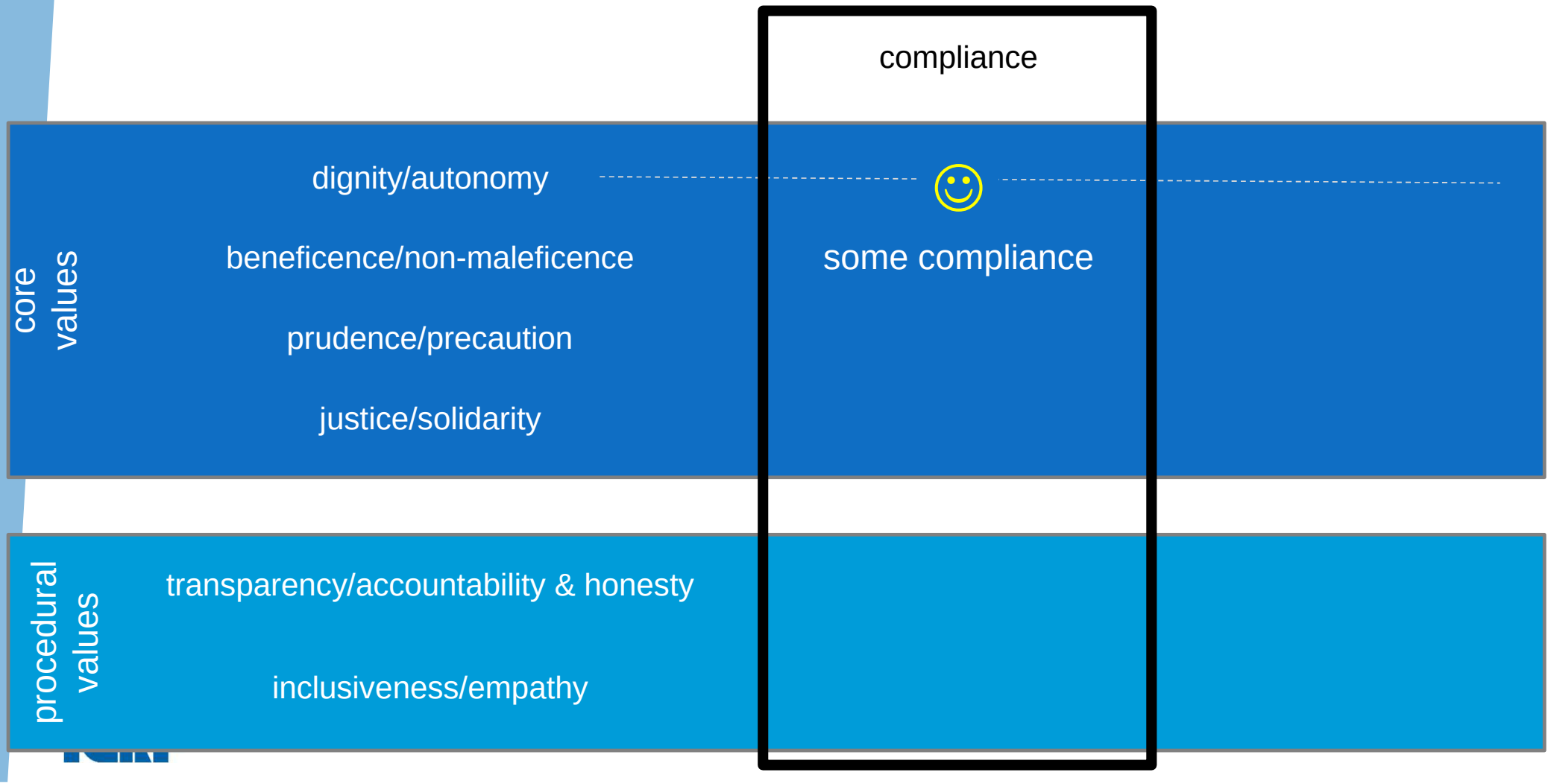
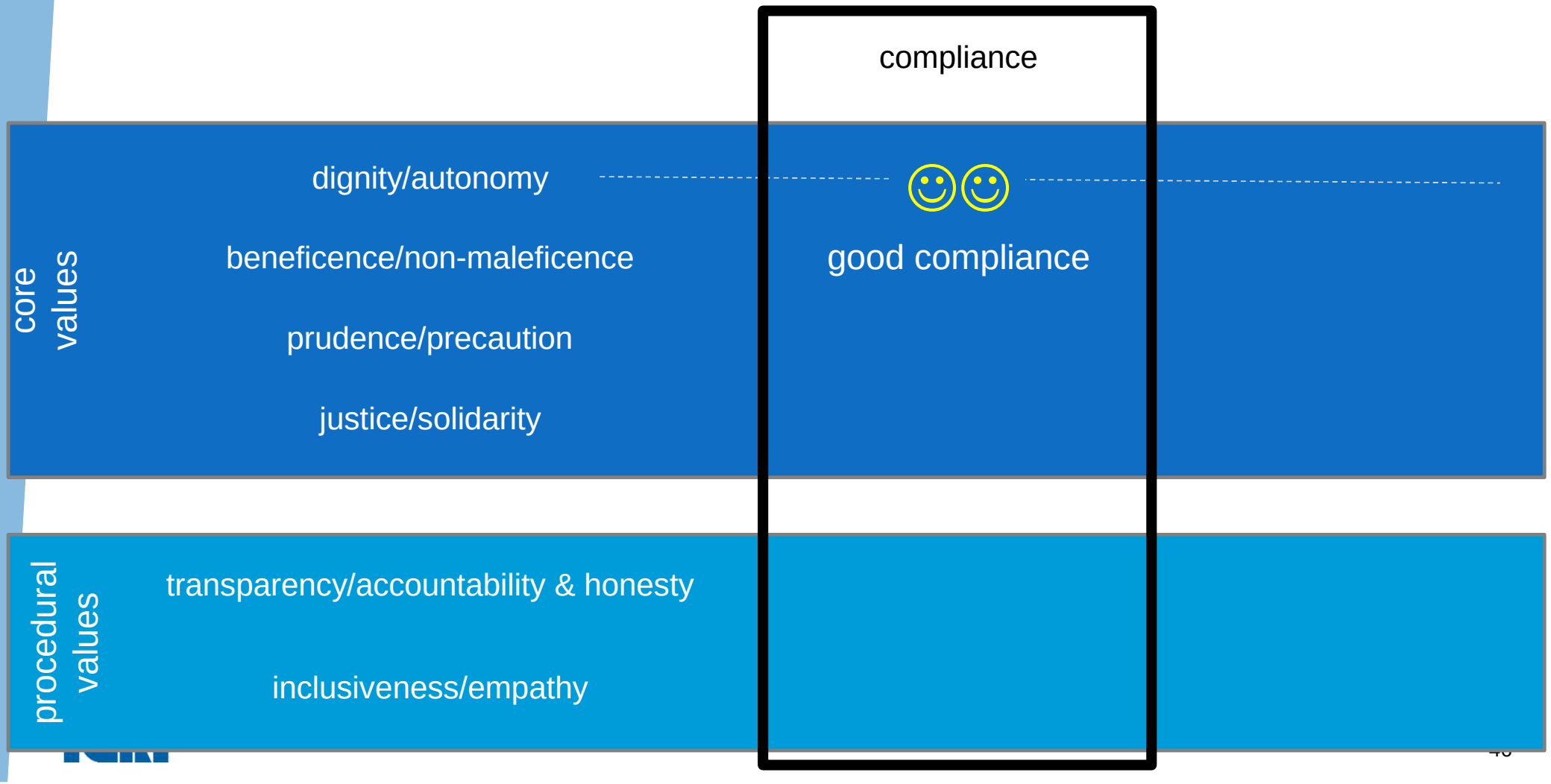
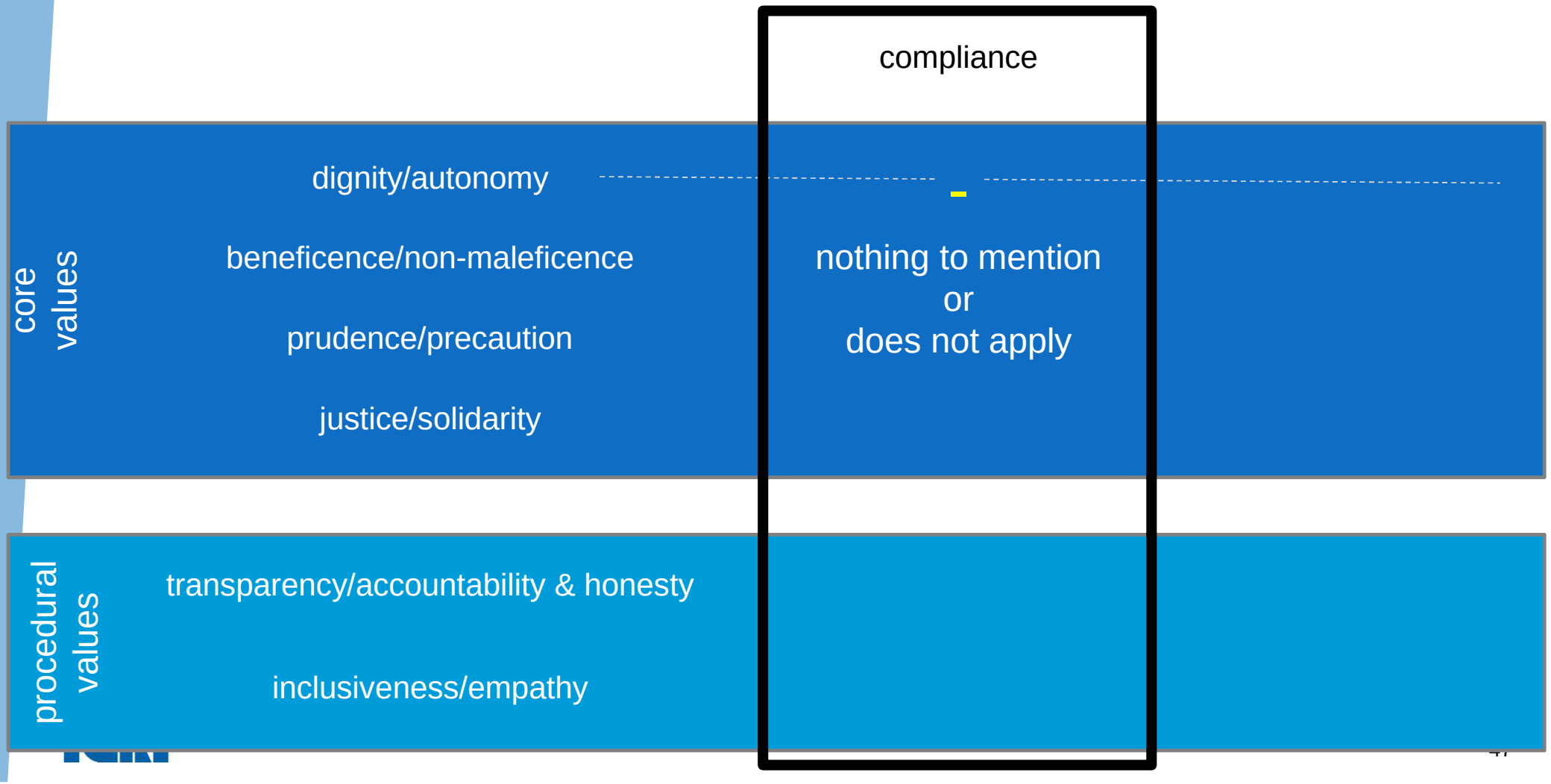
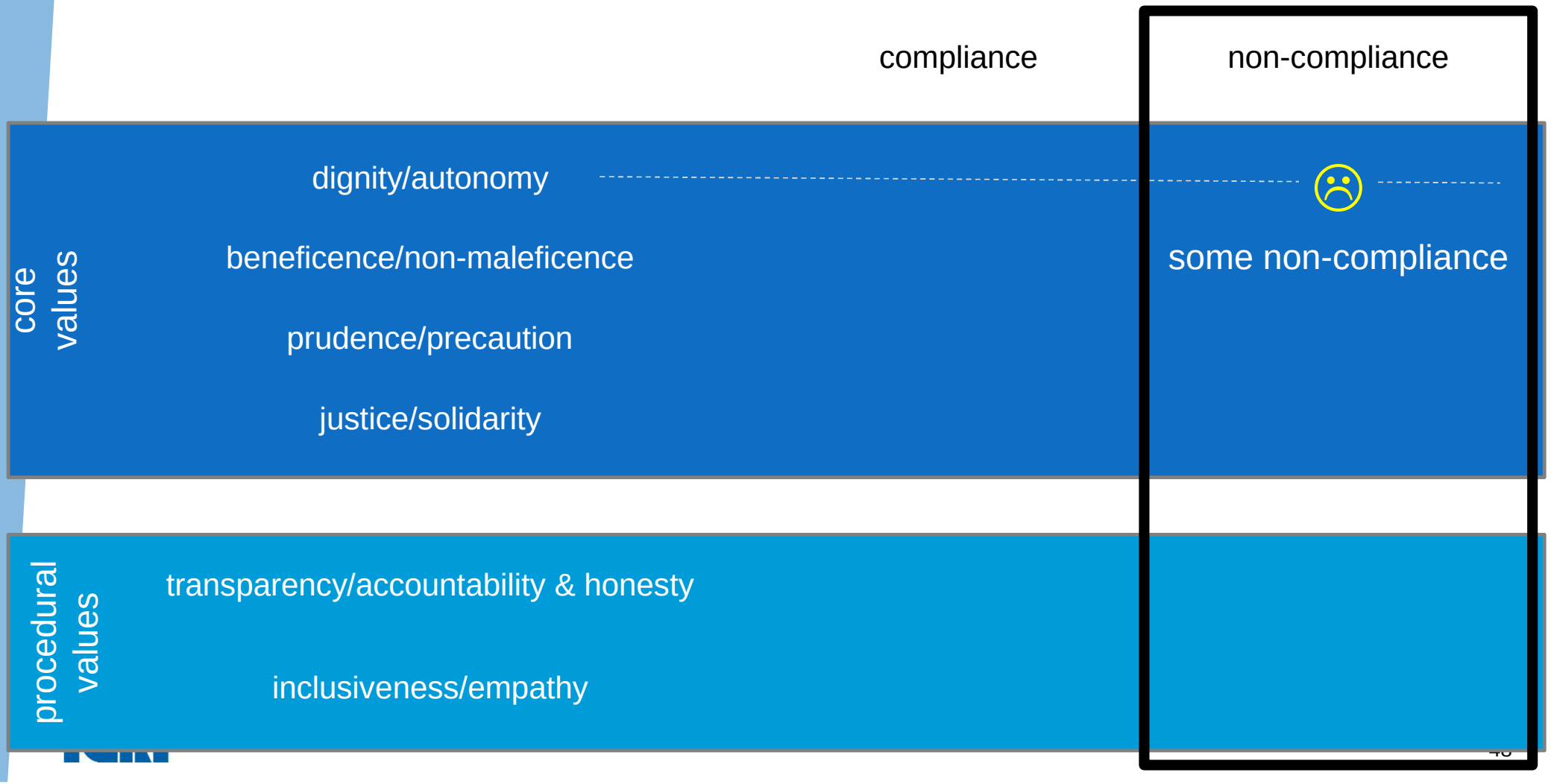
Evaluation method




compliance
core values
dignity/autonomy
beneficence/non-maleficence
prudence/precaution
justice/solidarity
good compliance
procedural values
transparency/accountability & honesty
inclusiveness/empathy


compliance
core values
dignity/autonomy
beneficence/non-maleficence
prudence/precaution
justice/solidarity
nothing to mention
or
does not apply
procedural values
transparency/accountability & honesty
inclusiveness/empathy


compliance
non-compliance
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justice/solidarity
some non-compliance
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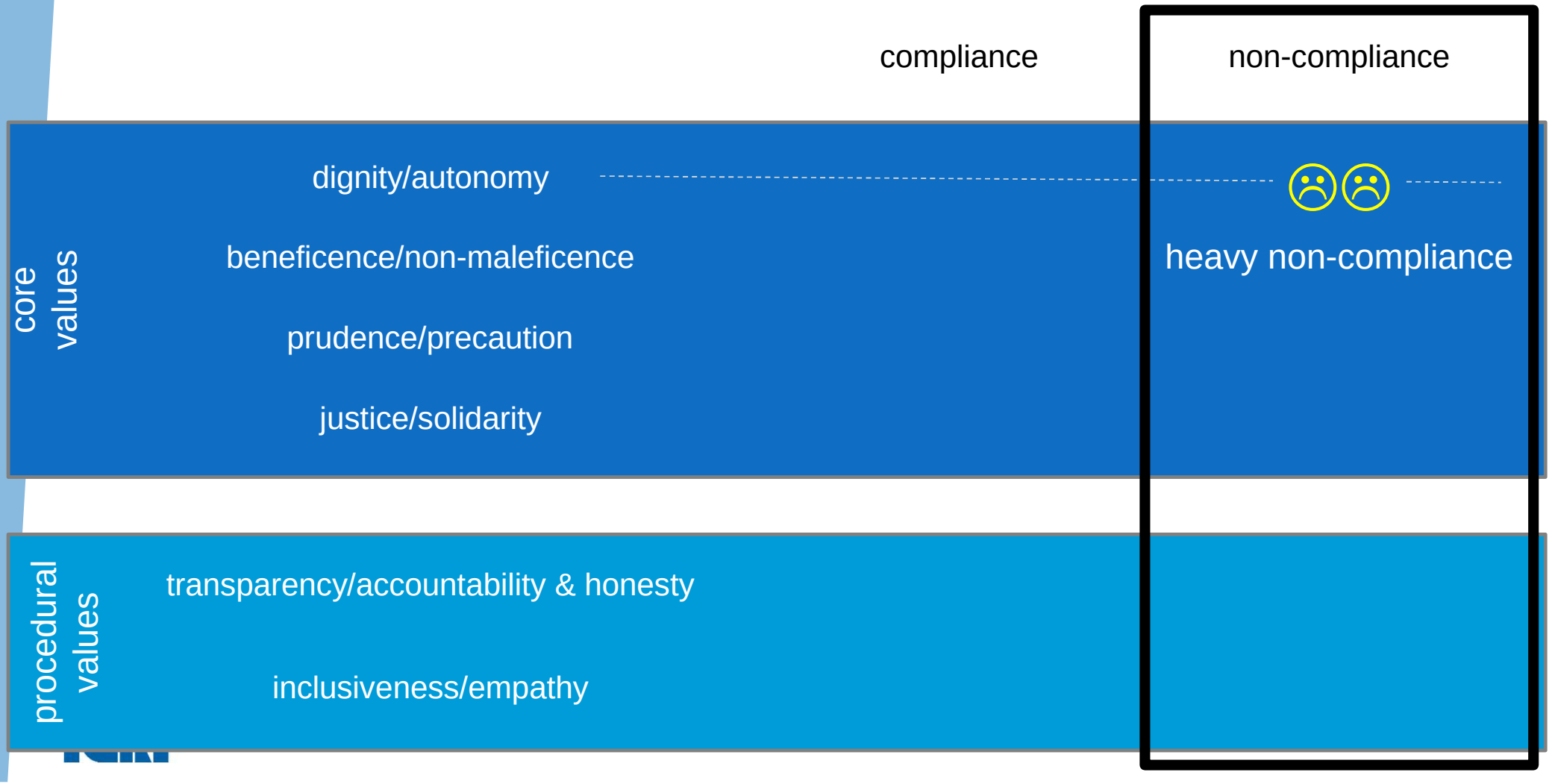
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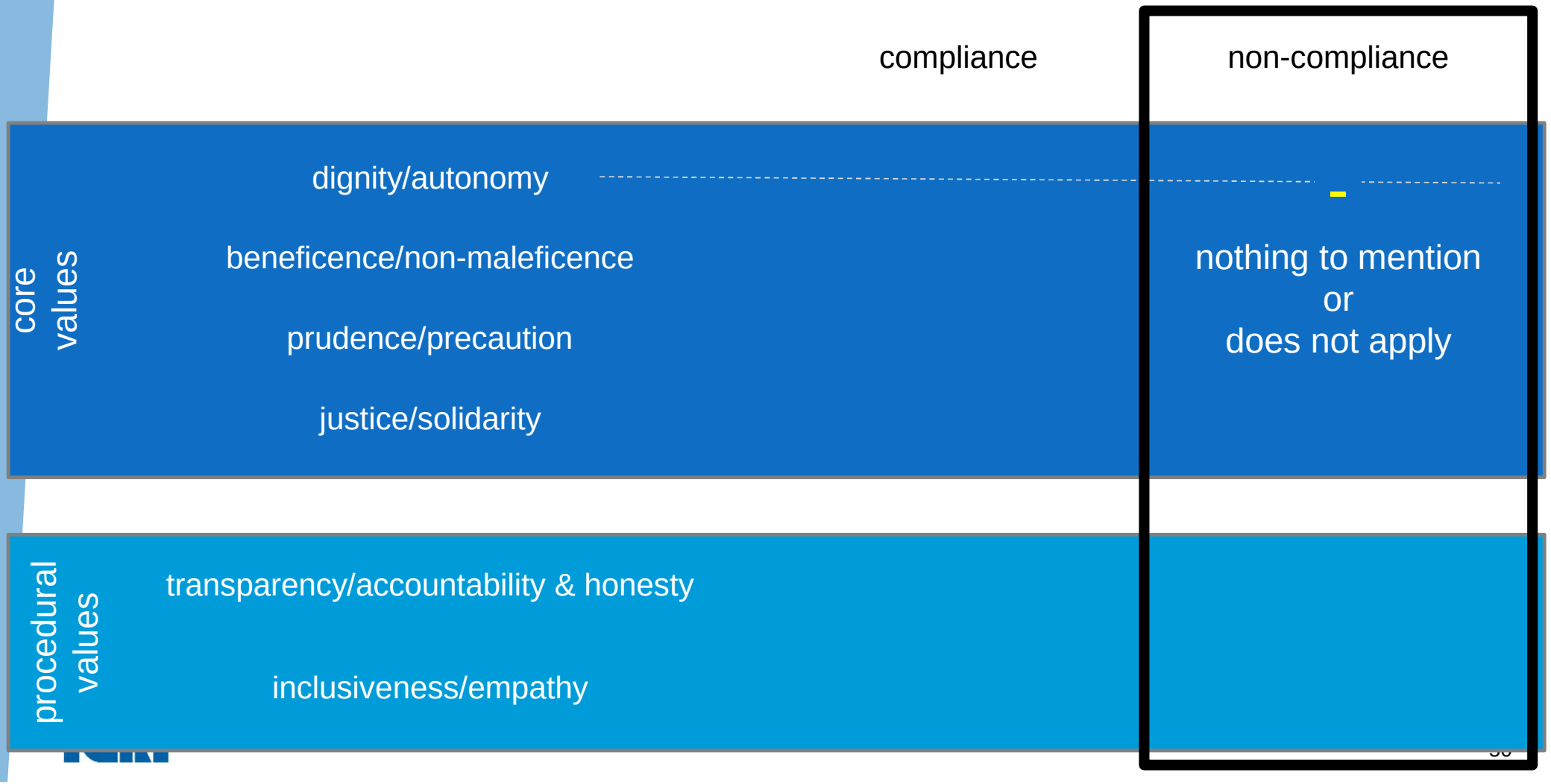
inclusiveness/empathy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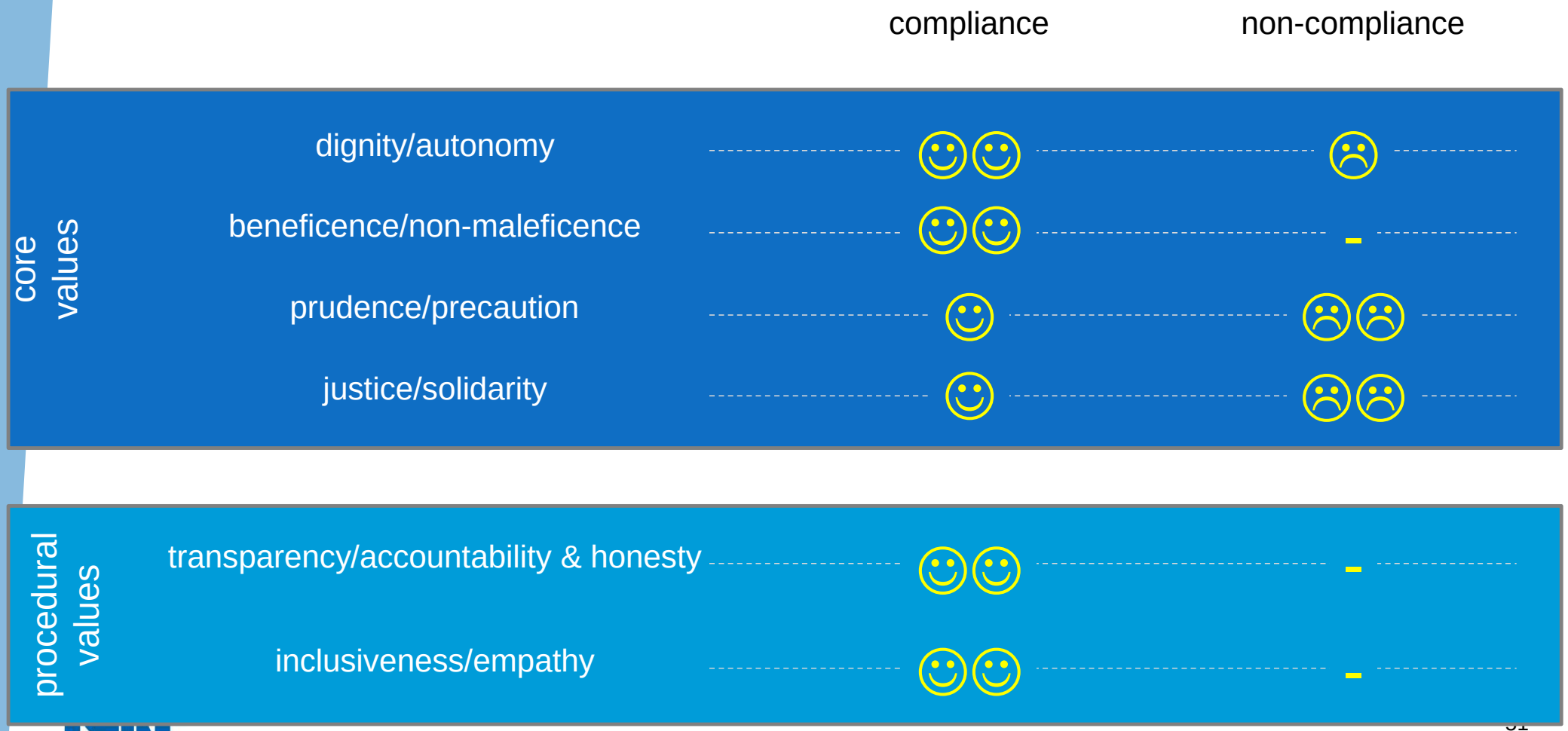
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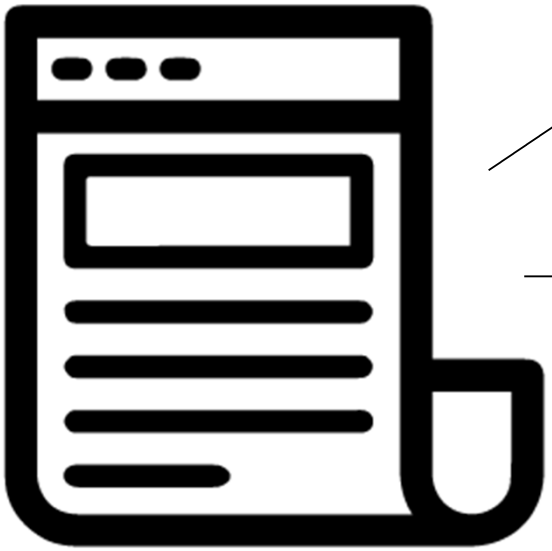
Evaluation method



one-page scenario

Description of the scenario

Table of compliance

Proposed analysis of scenario and justification of the table

Sensitizing questions

example
for beneficence / non-maleficence

- Does the **risk outweigh** expected **benefit**?
- Is the procedure aimed at **prevention**, **cure**, **palliation**, **rehabilitation**, or **enhancement**?
- What are the **patient's goals** of care?
- Is there a risk of **medicalizing**, **overdiagnosing**, or **overtreating** the patient?
- Will the **additional information** provided by the test **change the treatment** approach?
- Are we **educating** the patient or caregivers about the **limitations of testing**?

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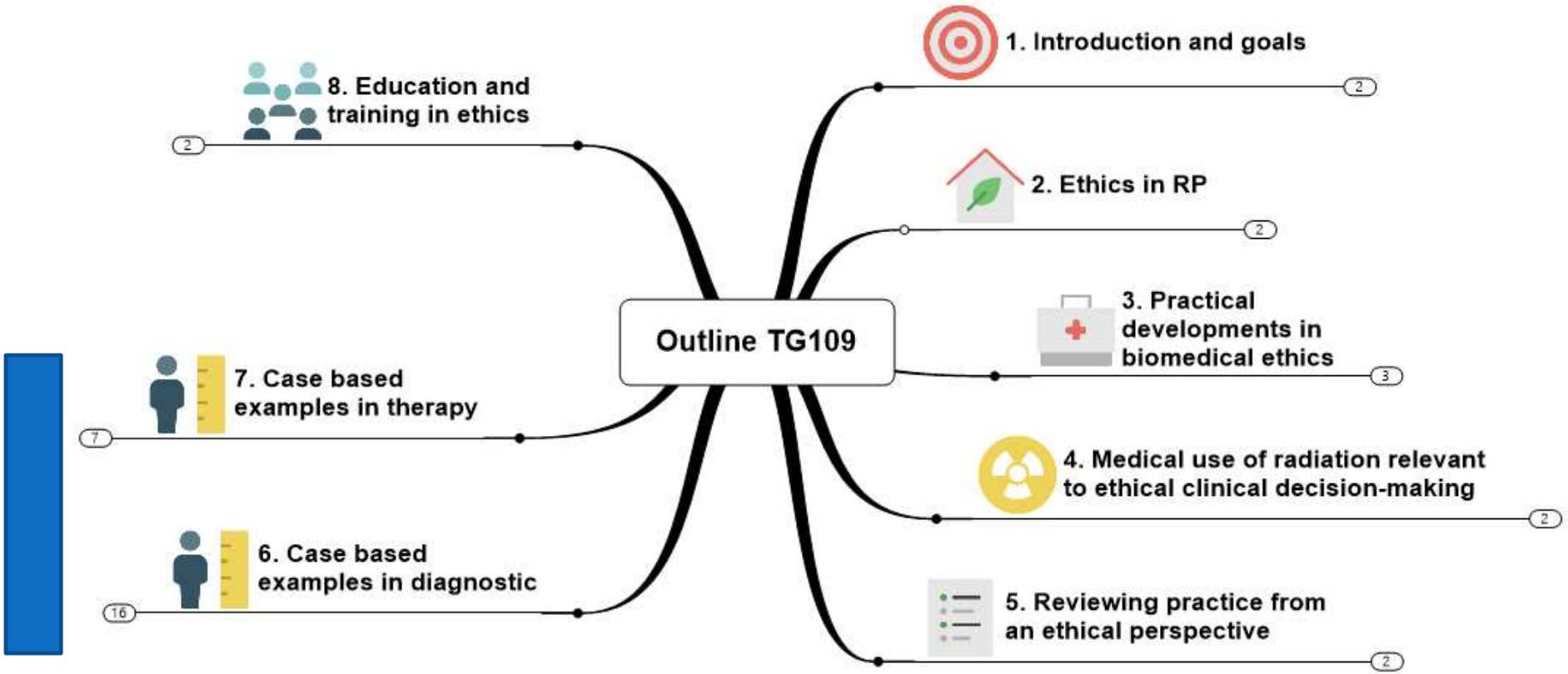
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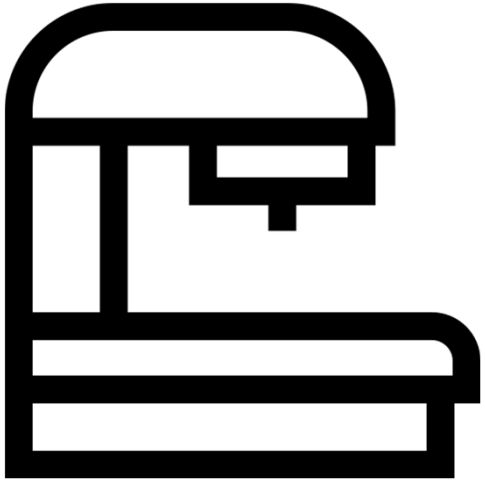
Scenarios covering many practical situations

10

in imaging procedures



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in therapy

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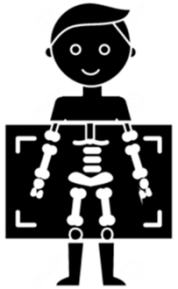
Scenarios covering many practical situations

Pregnancy

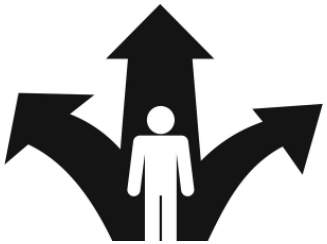
Breast feeding



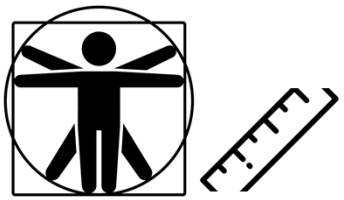
Children

Elderly

No guidelines



Protons or x-rays?



Health assessment

Chronic disease

End of life

Organized screening

Multifraction instead of monofraction

Incorrect field placement

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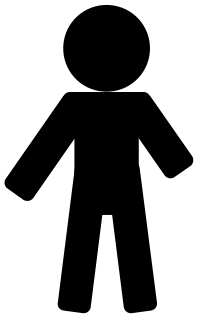
Example of scenario

6.10. Alpa Pennia: Abdominal lead shielding used due to pregnancy

informed consent

let's be prudent



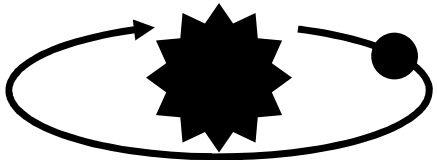
malformation at birth

???

not us!

Example of scenario

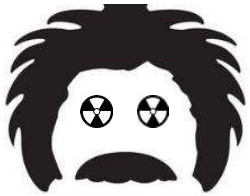
6.10. Alpa Pennia: Abdominal lead shielding used due to pregnancy



one year later, the mother still has doubts

no blame for the radiologist

but for her, because she accepted the exam

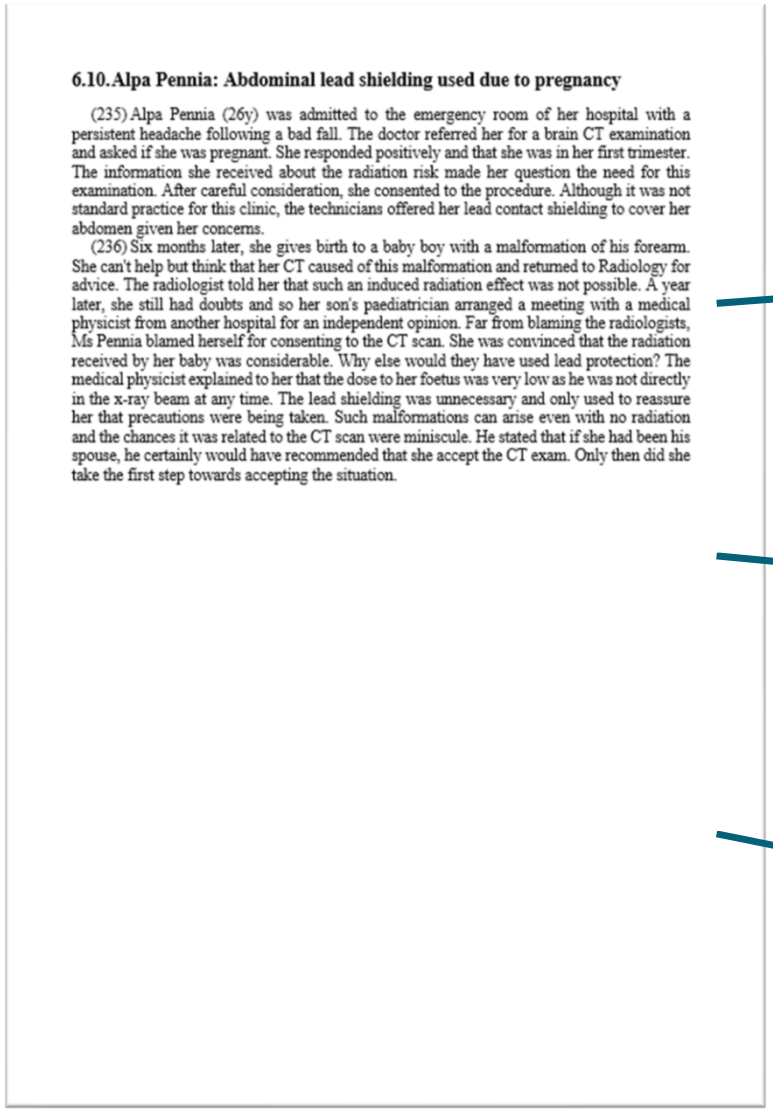


medical physicist from another hospital

dose to fetus minuscule

unnecessary not good practice (just to reassure)

he would have recommended that she accepted the exam



6.10. Alpa Pennia: Abdominal lead shielding used due to pregnancy

(235) Alpa Pennia (26y) was admitted to the emergency room of her hospital with a persistent headache following a bad fall. The doctor referred her for a brain CT examination and asked if she was pregnant. She responded positively and that she was in her first trimester. The information she received about the radiation risk made her question the need for this examination. After careful consideration, she consented to the procedure. Although it was not standard practice for this clinic, the technicians offered her lead contact shielding to cover her abdomen given her concerns.

(236) Six months later, she gives birth to a baby boy with a malformation of his forearm. She can't help but think that her CT caused of this malformation and returned to Radiology for advice. The radiologist told her that such an induced radiation effect was not possible. A year later, she still had doubts and so her son's paediatrician arranged a meeting with a medical physicist from another hospital for an independent opinion. Far from blaming the radiologists, Ms Pennia blamed herself for consenting to the CT scan. She was convinced that the radiation received by her baby was considerable. Why else would they have used lead protection? The medical physicist explained to her that the dose to her foetus was very low as he was not directly in the x-ray beam at any time. The lead shielding was unnecessary and only used to reassure her that precautions were being taken. Such malformations can arise even with no radiation and the chances it was related to the CT scan were miniscule. He stated that if she had been his spouse, he certainly would have recommended that she accept the CT exam. Only then did she take the first step towards accepting the situation.

Description of the scenario

Table of compliance

Proposed analysis of scenario and justification of the table

☺☺ good compliance

☺ some compliance

\- nothing to mention

	dignity/ autonomy	beneficence/ non-maleficence	prudence/ precaution	justice/ solidarity	transparency/ accountability/ honesty	inclusiveness/ empathy
Compliance						
Non compliance						

\- nothing to mention

☹ some non-compliance

☹☹ heavy non-compliance

What is your opinion?

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Suggestion of answers

The medical staff were **transparent** about the **radiation risks** and **respected** the patient's dignity and autonomy without pressuring her to accept the CT exam. Faced with a worried patient, they showed **empathy** by offering **lead shielding** that was not recommended by their institutional guidelines

The staff acted with **caution**

	dignity/ autonomy	beneficence/ non-maleficence	prudence/ precaution	justice/ solidarity	transparency/ accountability/ honesty	inclusiveness/ empathy
Compliance	☺☺	☺☺	☺	—	—	☺☺
Non compliance	☹	☹	☹	—	☹	—

Offering **unnecessary protection** reinforced Ms Pennia in her belief that the radiation delivered to her child was considerable. The clinic's actions resulted the patient's **feeling of being alone** to bear the weight of the decision.

The staff might have **anticipated** the patient's **reaction**

The staff chose **not to tell** Ms Pennia (even after she gave birth) that the **lead shield** was only used **to mitigate her fear** of radiation although it seemed to have had the opposite effect.

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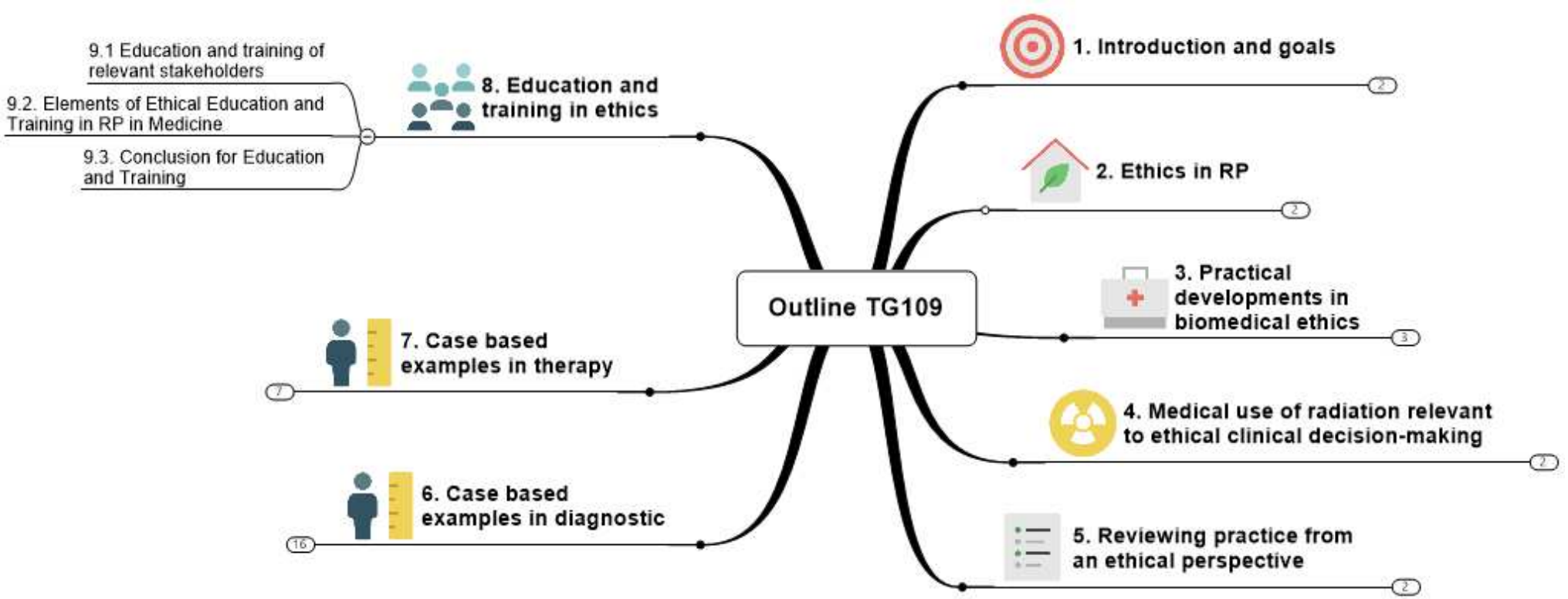
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9.1 Education and training of relevant stakeholders
9.2. Elements of Ethical Education and Training in RP in Medicine
9.3. Conclusion for Education and Training

E&T of relevant stakeholders

Key message: **Everyone** in the diverse groups of relevant stakeholders is **responsible** for assuring strong **radiological protection and ethics** in health care. Each **target group** needs to be **empowered and educated** to ensure that patients are imaged and treated correctly.

Key message: Although it **may be of value** to integrate the ethics teaching into **everyday practical education**, it is **necessary** to provide specific, practical **teaching on ethics**.

Elements of Ethical E&T in RP in Medicine

Key message: An **understanding** of the basic principles of **radiological protection** is an **absolute pre-requisite** – it is **necessary** but not sufficient without also including **ethical training** – for **all health professionals** working with radiation for the purpose of diagnosis or treatment.

Elements of Ethical E&T in RP in Medicine

Key message: The **Bloom taxonomy** model enables the educator **to define learning outcomes** based on the knowledge, skills and competences that are necessary for health professionals to make carefully considered ethical decisions when using radiation in medicine

Level	Definition
Remembering	is retrieving information from long-term memory
Understanding	is constructing meaning from instructional messages including oral, written and graphic communication
Applying	is carrying out a procedure in a given situation
Analysing	is breaking the material into its constituent parts and determining how the parts relate to one another and to the overall structure or purpose
Evaluating	is making judgements based on criteria and standards
Creating	is putting elements together to form a coherent whole function: reorganizing elements into new patterns of structure

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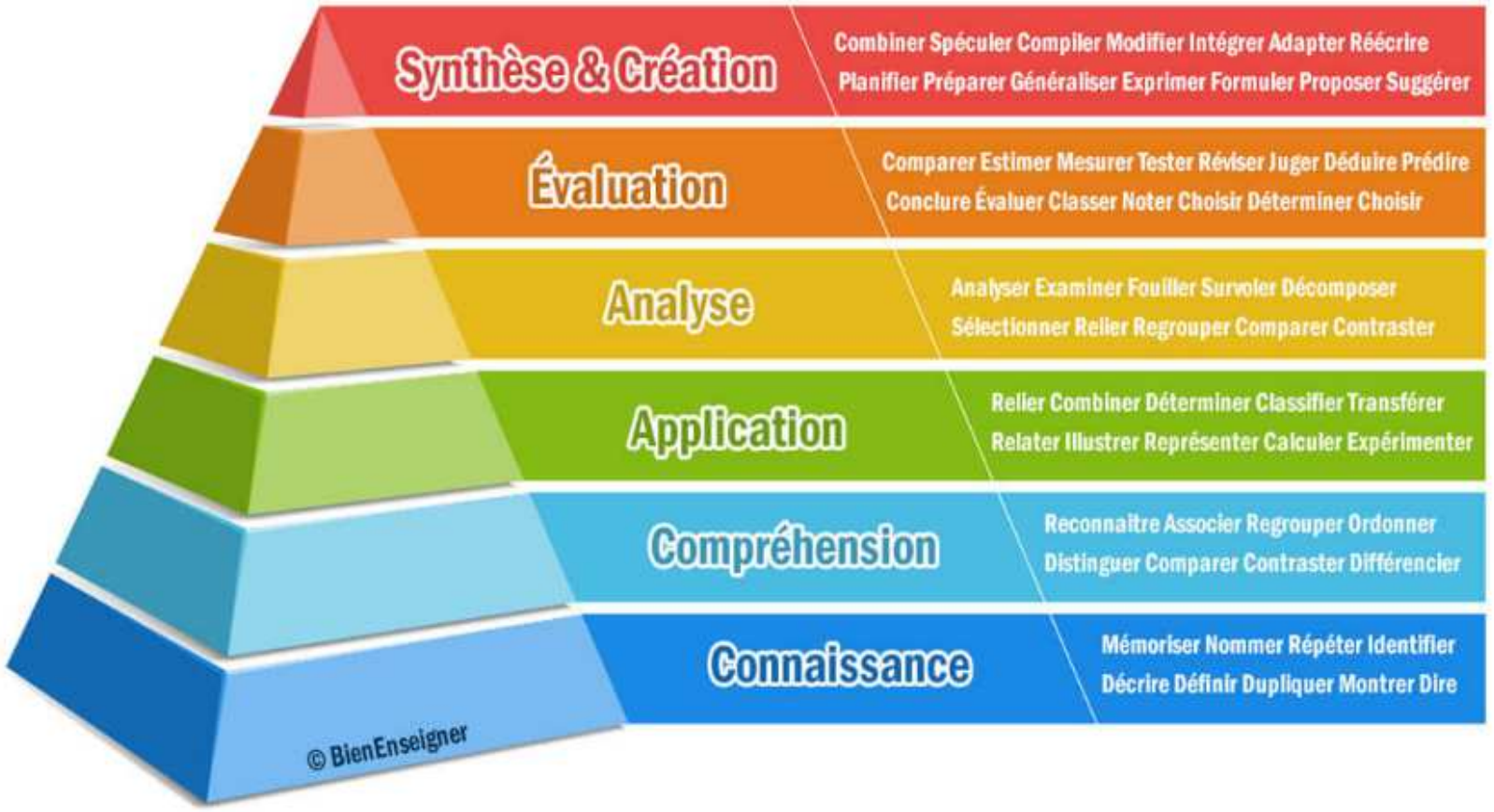
Elements of Ethical E&T in RP in Medicine



https://www.bienenseigner.com/taxonomie-de-bloom/

Elements of Ethical E&T in RP in Medicine

Example of a framework of knowledge, skills, and competencies (KSCs) for ethics learning by radiation protection students and health professionals

Knowledge	Skills (ability to apply knowledge)	Competencies, (Attitudes/Behaviours)
• Define the core ethical values of **beneficence/non-maleficence** • Identify the relevant evidence-based clinical referral guidelines. • List the benefits of performing a given procedure • Recognize radiation risks associated with the procedure • Recognize the potential harm from not performing the procedure. • Identify examples where public/patient information may differ from evidence-based medical opinion	• Determine how the value of beneficence/non-maleficence can be applied in the process of justification • Ensure that the procedure conforms to the clinical referral guidelines and the departmental protocols. • Explain the benefits and the potential harm associated with the procedure to the patient. • Ask the patients what they understand about the proposed procedure.	• Apply the value of beneficence when weighing benefit/risk in recommending radiological management • Validate the requested procedure's appropriateness Ensure that the patient understands the options necessary to make an informed decision.
· Define the core ethical values of **prudence/precaution** · Identify the purpose of the proposed procedure · List the consequences of an inappropriate procedure that uses ionising radiation · Define the known benefits of the procedure relative to the patient condition • Define the known risks associated with the procedure relative to the patient condition	• Identify sources of uncertainty about radiation risks associated with the procedure. • Explain the factors considered in selecting a procedure • Appraise any unintended consequences of the selected procedure in the medical and societal domains • Discuss any uncertainties associated with the proposed procedures with the patient	• Evaluate the information provided in deciding to proceed with an imaging procedure • Assess if the patient and family are comfortable with the decision (shared decision-making) • Analyse possible risks and benefits on the basis of the characteristics of a specific scenario set • Carefully consider all choices and take a prudent action acknowledging the uncertainty

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