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Ethics in the medical sector

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Classical ethical lecture of the current RP System for med.exp.

- Justification:
  - individual exposures : deontological ethics (net benefit for the patient; not unduly harmed);
  - screening: utilitarian ethics: do globally more good than harm
- Optimisation:
  - individual exposures : deontological ethics (as low as compatible with good enough image)
  - utilitarian ethics: ALARA: R= financial limitations (equipment; physicists)
  - Diagnostic reference levels: equity
- The system should include some consideration of precaution: use of LNT with DDREF of 2 for eval. of harm in just/opt
- But ……

Important ethical issues in the current system

- As well the justification process as the optimization efforts ask for balancing advantages vs disadvantages (harm) for the patient : right balancing relies **almost only** on the **practioner's judgment and motivation**
- The practioner's motivation is frequently absent due to his **risk unawareness (or negation):**

  Cfr workshop justification Brussels 2009:

  AAA : Awareness, Auditing, Appropriateness
- Another consequence of this risk unawareness or negation is unadequate communication to the patient. The lack of **right/fair information** does not allow patients to take informed decisions regarding their health (dignity, sovereignty)

Obstacles in the way of risk awareness

- Mass of information and lack of time
- Insufficient education and training programs for specialists; frequently no education at all for general physicians
- Pride; touchiness; collective reluctance (and resistance..) to imposed refresher courses
- Lack of ALARA and Radiological Protection Culture in the field
- Conflicts of interest: fundamental *tools* (source of income) potentially harmfull; fear of legal proceedings; fear of patient's reactions
- Thresholds would be benediction: frequently inclined to refer only to publications minimizing the risk or expressing doubts about risks
- **Major issue :** Current international lobbying in favour of a 100 mSv « level of concern » (for cancer-induction and for embryo and fœtus): **the « 100 mSv magic number » jeopardizes motivation**

The 100 mSv magic number

- frequently presented as a **“level of concern”** for radiation effects on human health,

- under this level the possibility of **“any health effect”** would be **“purely hypothetic”.**

Coming back of the « 100 mSv » in UNSCEAR (and IAEA)

- At stake in a (still discussed) draft report about attributability, lying at the basis of the conclusions of the UNSCEAR Fukushima report and implicit in the recent UNSCEAR Children report
- Rationale of this coming back is:
  - « there is no **compelling epidemiological** evidence of radiation-induction of cancer in a **mixed** population under 100 mSV »
  - As a consequence no effect could be « attributed » to radiation under 100 Sv and even inference of risk for the future under this dose would be « non-scientific » …..!
- But this is an unjustified simplification:

As formulated by a participant in the debates: « They forget decades of biological research »

(as well as results of epidemiological studies after children and fœtus exposure and in populations with genetic susceptibilities)

In utero irradiation

- BEIR VII: « Studies of prenatal exposure to diagnostic X-rays have, despite long-standing controversy, provided important information on the existence of a significantly increased risk of **leukaemia and childhood cancer** following diagnostic doses of **10-20 mGy** in utero »

New data:
Pearce 2012 (Lancet)

Radiation exposure from CT scans in childhood and risk of leukaemia and brain tumours:

- Retrospective study (based on NHS UK): **180 000** patients < 22 y with CT (1985-2002); cancers 1985-2008
- Relative risk of leukaemia for patients who received a cumulative dose of about **50 mGy**: 3·18 (**95% CI 1·46–6·94**)
- Relative risk of brain cancer for cumulative dose of **about 60 mGy**: 2.82 (**1.33 - 6.03**)

Linear dose –response; supports LSS extrapolations

Cancer-proneness

Human genetic disorders affecting DNA-repair genes and cell-cycle regulation genes

Exposure to diagnostic radiation and risk of breast cancer among carriers of BRCA1/2 mutations: retrospective cohort study (Pijpe 2012 GENE-RAD-RISK)

In this large European study among carriers of BRCA1/2 mutations,

" **any** exposure to diagnostic radiation before the age of 30 was associated with an increased risk of breast cancer."

There is compelling evidence
that there **are** observable effects
(well below) under 100 mSv,
and consistent biological explanations.

Then why this come-back
of the 100 mSv « level of concern » ?

An insidious issue
(frequently underlying):

« science-based decisions »

« Who » tells the « scientific truth »?

- « Reassuring » experts and « anxiety-provoking » experts all claim being following only « science »
- Both groups are demonizing each other
- Political reasons or conflicts of interest play an important role but there are also deep epistemological and ethical issues hidden
- Need for respect and listening to each other

Epistemological/ethical questions: challenges for the Radiological Protection for the next 50 years

- Use and misuse of the « evidence-based approach »
- Adequacy and legitimacy of precautionary attitude within scientific evaluation
- Fairness of risk communication allowing informed decision-making, incl. by patients and members of the affected populations

Evidence-based approach

This is the current dominant scientific paradigm in the medical field (drugs, treatment) and by many radiation experts.

The almost only concern is to avoid concluding that a causal relationship exists before it is firmly proved

(**hard evidence** required).

The main concern is:

Avoiding the false positives

Misuse of evidence-based approaches

In (the currently frequent) new situations with potential long term effects.

decisions are to be made while strong evidence is lacking.

Such decisions must be based on

« available » evidence,

even if there persists uncertainties.

Informed decision-making requires then

science-based balanced information including:

Avoiding the false negatives!

A blameworthy use of the evidence-based approach: Strategy of doubt

The (hard) evidence-based approach is frequently misused as a strategy for delaying unpleasant decisions as long as « some doubt » exists.

(cfr tobacco,climate)

UNSCEAR 2012: agreed on the principle …..

The strategic objective for the period 2009-2013, endorsed by the General Assembly, is "to increase awareness and deepen understanding among authorities, the scientific community and civil society with regard to levels of ionizing radiation and the related health and environmental effects as a sound basis for informed decision-making on radiation related issues".

As underlined in a recent report to the General Assembly , "that strategic objective highlighted the need for the Committee to provide information on the strengths and limitations of its evaluations, which are often no fully appreciated. This involves avoiding unjustified causal associations (false positives) **as well as unjustified dismissal of real health effects (false negatives)**."

…but the culture did not change!

In many parts of the UNSCEAR documents , too much importance is given to the avoidance of false positives (by highlighting all possible bias for an association between effect and exposure) in comparison with the avoidance of false negatives, while possible dismissal of real health effect of radiation is a major concern for responsible decision-makers.

- **Good illustrated by the exclusively critical reaction about the new low dose reports (Pearce, Kendall, …) in the UNSCEAR « children » report**

- **And by the…. come-back of the 100 mSv magic number**

Misunderstanding of the precautionary principle: Precaution in Science **is** relevant!

Although frequently limited to the decision-making processes in situations of uncertainty, the precautionary approach is also relevant and appropriate in science.

As underlined in the COMEST report from UNESCO, the precaution approach in science includes:

- a focus on risk plausibility rather than on hard evidence
- a responsiveness to the first signals ("**early warnings")**
- a systematic search for surprises ("**thinking the unthinkable**"), particularly for possible long term effects

Precaution within science: thinking the unthinkable

- Irradiation in utero: there are still many uncertainties: radiation effects on gene expression, long term effects of NCS irradiation, chronic internal expos. (OBT,..), genetic susceptibilities
- Long term hereditary effects : also large uncertainties
- These effects are currently somewhat out of concern, but could cause bad surprises in the future.

Fairness of risk communication

- Informed decision requires science-based balanced information (as well for decision-makers as for population and patients)
- Communication such as “no detectable (or discernible) effect is expected” or “safe under 100 mSv” is misleading
- Unbalanced reassuring information is not only misleading but also counterproductive as it provokes contesting reactions, distrust in experts and finally more anxiety

The right way to communicate about risks should be discussed with human science specialists (not only in communication) but also with stakeholders , including representatives of the affected population

Conclusions (1)

- The current RP system for medical exposures is based essentially on justification and optimisation, with the underlying paradigm of a (corrected) LNT for risk evaluation.
- The application of the system relies frequently almost only on the physician's judgment and motivation.
- There are a lot of obstacles in the way of risk awareness and motivation by the medical doctors , among which the current international lobbying in favour of a 100 mSv « level of concern » (for cancer-induction and for embryo and fœtus) plays a major role.

Conclusions (2)

- Apart from blameworthy reasons linked to conflicts of interest, there are insidious ethical and epistemological issues explaining the come-back of the 100 mSv magic number:
  - the misuse of the (hard) evidence-based approach in situations implying potential long term detriment
  - and the unjustified rejection of the precaution within scientific evaluations
- A consequence of this risk unawareness or negation is unadequate communication to the patient. The lack of right/fair information does not allow patients to take informed autonomous decisions regarding their health