The Ethics for Justification of Radiological Procedures

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Hippocratic Oath

Do good, not harm

- Lars Persson
- K Shrader-Frechette
- Per Wikman-Svahn
- Carl Cranor

A Definition of Ethics

Ethics is a branch of philosophy

Its object is the study of both moral and immoral behaviour in order to make well founded judgements and to arrive at adequate recommendations

Ethics has a two fold objective:

- it evaluates human practices by calling upon moral standards. It may give prescriptive advice on how to act morally in a specific kind of situation
- it provides therapeutic advice, suggesting solutions and policies.

The Issues

- Equity v. Efficiency:
  the justification principle
- Health v. Economics:
  the optimisation principle
- Individual rights v. Societal benefits:
  the dose limitation principle
- Due process v. Necessary sacrifice:
  liability principles

The Issues

- Stakeholder consent v. Management decisions:
  controlling exposures
- Psychology:
  fear of radiation more harmful than radiation
- Psychology:
  fear of radiation as a contribution to genocide
- Science: the question of truth

Two other issues

- Communication:
  the need to communicate with the public v. lack of will to seek public consent
- Standards for workers v public

Equity v efficiency (Justification)

The benefits to society of radiation outweigh the detriment to individuals. But it could also be said that this must not be achieved by the misery of a minority or even future generations. With current radiation protection practice today, the risks are considerably less than in many other walks of life.

New ethical issues in Radiation Protection (ICRP new ideas)

- Previous approach to RP primarily aimed at reducing magnitude of individual doses and the number of people exposed: ALARA Principle
- New approach based on defining basic levels of protection, with individual 'sufficiently protected', known as 'constraints'.

This work was carried out on the most recent draft of the new ICRP recommendations.

I have not seen the new recommendations which have been announced by ICRP recently, so have no idea if the following ethical observations have been taken on board

New ethical issues in Radiation Protection

- Proposed that 'sufficiently protected' is on the basis that the risk to individual is *small* in terms of *probability or in comparison to natural background.*
- This is a change from *utilitarian ethics* to *rights- or duty based ethics.*
- The former is impersonal and the later very individual.

Utilitarianism or Utilitarian Ethics

is the ethical view that maintains that the total 'utility' in terms of e.g. happiness, preferences or welfare ought to be maximised. Utilitarianism is strictly impersonal in that decreases in utility for some persons can be outweighed by increases in utility for other persons (this is allowed or even required by utilitarianism if the total utility increases.)

Rights-based ethics

is ethical theories that emphasise restrictions on what we may do towards other individuals. These theories typically stress concepts like individual *rights* and our *duties* towards other individuals.

New ethical issues in Radiation Protection

- New approach based on idea that an unequivocal exposure limit can be defined.
- This leads to conflicts between the values of efficiency and equality.
- Trivial risks to some may not be so to all.
- This type of approach may lead to higher overall doses, as efforts to continuously reduce doses are not required.

Remember

- An insignificant or negligible risk is not necessarily acceptable.
- An acceptable risk is not necessarily negligible.
- To decide what is acceptable involves value judgements and qualifications.
- Allowing for very small risks just because they are small would allow exposure to risks that do not benefit the person exposed.
- Exposing me to a risk of harm, without any personal benefit, is highly questionable in a rights-based ethical setting, even if very small in terms of probability

Remember

- Acceptability of risks requires a complex description of an exposure situation
- 9 factors to be considered when judging whether a particular risk is acceptable of not.

- Is the risk being imposed or is it taken
- Is it required to live with as a matter of public policy or is it permissible for individuals to take on their own
- Is the risk from natural phenomena or caused by human activity
- The magnitude of individual benefits and negative consequences
- Is the risk taking central to the individual's personal projects or life-plan

- Who is creating or imposing the risk
- The degree of control over the risks
- Is the risk transparent or is it hard to detect or understand
- Is the risk incurred voluntarily or not
- Also, remember individuals have different susceptibility to radiation.

- So an approach to radiation risk management based on the protection of the individual's rights means stronger requirements of individual ethical justification of exposure.

Background to Justification

Council Directive 97/43/Euratom

Translation by EU Countries

Ionising Radiation (Medical Exposure) Regulations 2000
(UK)

Directive 97/43/Euratom

Article 3

Justification

Justification

Medical exposures shall show a sufficient net benefit, weighing the total potential diagnostic or therapeutic benefits it produces, including the direct health benefits to an individual and the benefits to society, against the individual detriment that the exposure might cause, taking into account the efficacy, benefits and risks of available alternative techniques having the same objective but involving no or less exposure to ionising radiation.

4 aspects

1. All new types of practices involving medical exposure shall be justified in advance before being generally adopted

2. All individual medical exposures shall be justified in advance taking into account the specific objectives of the exposure and the characteristics of the individual involved.

3. Medical exposure for biomedical and medical research shall be examined by an ethics committee, set up in accordance with national procedures and/or by the competent authorities.

4. Special attention shall be given to the justification of those medical exposures where there is no direct health benefit for the person undergoing the exposure and especially for those exposures on medico-legal grounds

What does this all mean in actual practice?

It means that good ethical practice requires us to review and check every request for an X-ray procedure.

Diagnostic, Interventional and Therapeutic

Explanation(s) to Patient (and advocate)

Patient consent

NHS LANARKSHIRE RADIOLOGY REQUEST

CHI No.
Hospital No.
X-RAY No.
Surname:
First name
Address:
D.O.B.
Tel no. **Ward No.**
Consultant/
GP Stamp
(inc. tel no.)
Referring Clinician:
Status:
SIGNATURE:_____
Date **Page/ext no.**
Transport (please tick)
Walking **Chair**
Trolley **Ambulance**

Vetted/Authorised by *Justified by:*
Prep: *Appoint:*
Operator:
Pat ID: *LMP* *Ref Sig*

Contrast Exams (CT, MR and IVU)
Previous Contrast Media Reactions **Yes / No**
Renal Impairment **Yes / No**
Serum creatinine Level _____
Date obtained _____
Is patient diabetic **Yes / No**

LMP To be completed for all female patients between the age of 12 to 55 years
Is Patient Pregnant **Yes / No**
Date of LMP _____
Sign _____
In a clinical emergency and in the absence of a Radiologist the referrer may overrule the need to provide LMP and pregnancy info.
Overrule **Yes / No**
Sign _____

MR Exams:
Pacemaker **Yes / No**
Foreign Bodies/Implant **Yes / No**
Cerebral aneurysm clip **Yes / No**
Recent Surgery **Yes /No**
(Detail Below)

EXAMINATION REQUESTED:

Clinical Information **What question should this examination answer?**

Due to imaging table weight limits please contact the X-ray department before submitting requests for patients weighing over 20 stones (127 KG).

UNJUSTIFIED IMAGING EXAMINATION

This imaging request has been rejected because the examination could not be justified on at least one of the following grounds.

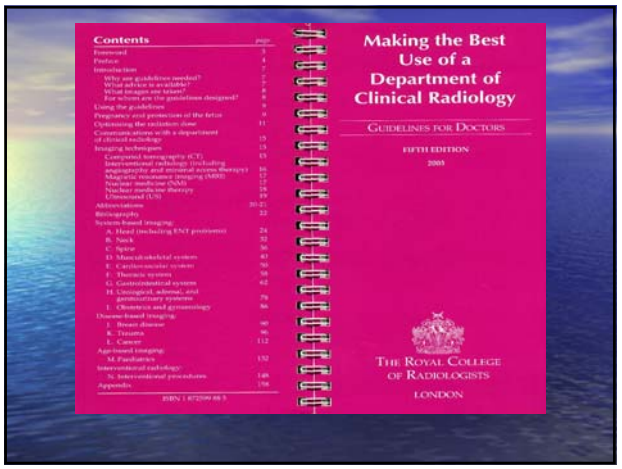
1. Incomplete Demographic Details Given ☐
2. Serum Creatinine Level Not Given ☐
3. Inadequate Clinical History Given ☐
4. Examination Previously Carried Out ☐
5. Date of Patient's Last Menstrual Period Was Not Recorded ☐
6. Illegible Handwriting. ☐
7. You Have Not Signed The Request Card ☐
8. Please Discuss This Request With Dr. Ext ☐

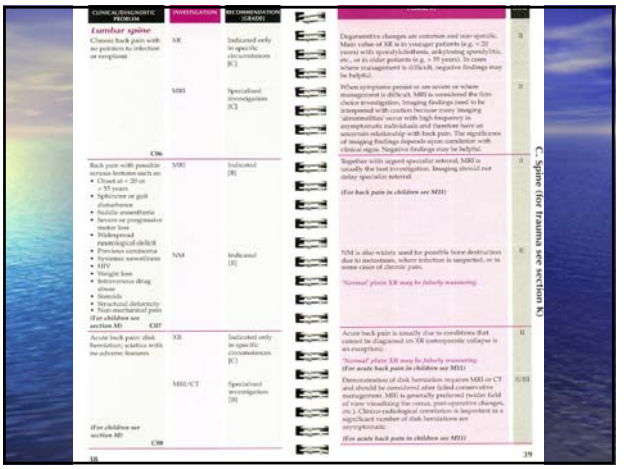
If you wish this examination to go ahead please re-request the examination with full details and send to the X-ray department.

Signature ..... **Name (Print)** ..... **Date** .....
Official Use Only

Examination Details *Patient Identification Label*

Clerical Information.





References and further reading

Thank you for listening.