

Clinical Justification of the examinations with ionizing radiation: How do we behave in the clinical routine?

Seminar of the Federal
Commission on
Radiation Protection (KSR)
Radiation Protection in Medicine

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MK der Berner Truppen/Seminarraum 010
Papiermühlestrasse 15, Bern



Schweizerische Eidgenossenschaft
Confédération suisse
Confederazione Svizzera
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Eidgenössische Kommission für Strahlenschutz
Commission fédérale de radioprotection
Commissione federale della radioprotezione
Federal Commission on Radiation Protection



Clinical Radiation Protection Research: European Radiology during 2019

G. Frija, European Radiology (2021) 31: 599

Increasing number of RP articles over years

Subjects predominantly covered:

Radiation dose optimisation: DRLs, dose variation in similar situations, dose reduction software

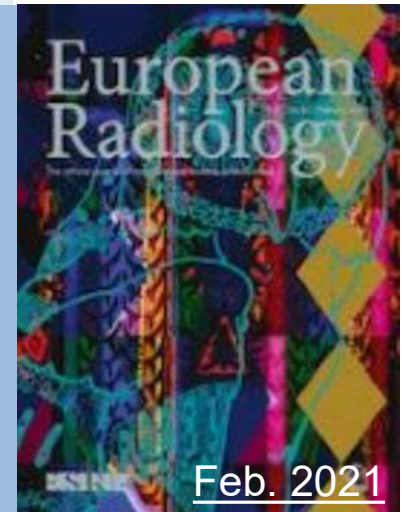
Technical advances: dual energy imaging, photon-counting detectors, improving dose measurement

Emerging concern of increasing repeated exposure

Subjects neglected:

Implementation of justification

Epidemiological risk assessment of low dose exposure



*Importance
of
Justification*

PEAKS OF OUR TOUR

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1. Recommendations **2.** Legislation **3.** Guidelines **4/5.** Practice

ICRP 105: Radiological Protection in Medicine

Ch.8: Justification of a Radiological practice in medicine

MORE BENEFIT THAN DETRIMENT?

Art.60 **THREE LEVELS** of justification of radiological practice:

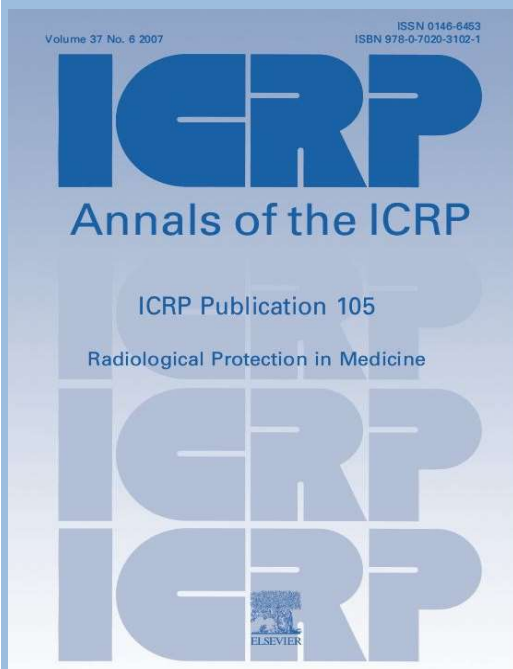
L.1: proper use of radiation in medicine is accepted as doing more good than harm to society. This general level of justification is taken for granted

L.2: **specified procedure** with a **specified objective** is defined and justified

L.3: application of the procedure to an **individual patient** should be justified (i.e. the particular application should be judged to do more good than harm to the individual patient), may differ from L.2

ALL procedures must be justified **IN ADVANCE**

L.2 justification is a matter for *national and international professional bodies*, in conjunction with *national health and radiological protection authorities*, and the *corresponding international organisations*
It *may differ* in different situations (countries)



European Union: COUNCIL DIRECTIVE 2013/59

EURATOM, 5 December 2013

Ch.III, Art.5 General Principles of Radiation Protection:

Justification: to ensure that the individual or societal benefit resulting from the practice outweighs the health detriment that it may cause

Ch.VII, Art.55 Justification of Medical Exposures:

sufficient net benefit, **weighing** the total potential diagnostic or therapeutic **benefits** it produces, including the direct benefits to health of 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

New types of practices involving medical exposure are to be justified **in advance** for levels general (2) and individual (3)

J. **based on preexisting information** (medical records)

J. for health **screening** programmes / asymptomatic individuals

Exposure of **carers and comforters**

Medical exposure for **research**: Ethics Committee



Swiss Federation: Radiation Protection Ordinance

2017, version 2021
based on Radiation Protection Act of 1991

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UNIVERSITÄT
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Ch.4: Medical Exposure

Art.26 Low / middle / high exposure: **<1/1-5/>5mSv** (eff.dose)

Justification Levels:

- **fundamental L1** Art.27,

- **general diagnostic/therapeutic use L2** Art.28

review when new knowledge about efficacy or sequelae of existing procedure

Federal Commission for Radiological Protection (**KSR**) shall publish

recommendations in collaboration with professional and specialists' bodies

- **individual use, L3** Art.29

based on pre-existing medical information; **compulsory documentation** of indication

L2/L3: justification **in advance**, following **the state of the art** defined by guidelines and recommendations

Clinical audits (->to verify correct justification/optimis., CT, nucl.m., intervention, Art.41)

Guidelines for Switzerland

Requirements for Guidelines

- Coverage of 1 specific clinical question each
- Based on scientific knowledge (literature)
(quality: randomised prospective trial, metaanalysis > case studies > expert opinion)
- Delphi procedure respecting all different stakeholders
- Respect local/regional specifics, such as the health system
- Regular revision

Swiss Situation:

- Small country with 4 languages
- Cultural relations to neighbouring countries impacting medicine
- Many different medical specialists performing imaging exams
- Difficulty of practically realising requirements
- Fact: there exist no national guidelines for imaging

Approach taken by KSR's medical expert group:

- Allow for use of a range of different recognised guidelines
- But practitioners have to define their policy, will be tested accordingly

KSR Recommendations: Guidelines for Justification at Level 2

(Feb. 2020, elaborated by «medical experts' group» MEG)

1. Strong suggestion to consistently follow Guidelines (GL)

- Every institution is free to choose from widely recognised GL
- In cooperation with local partners, imaging in every clinical question (indication) will then have to follow this GL
- If documented and consistently applied, specific (e.g. subspecialist) GL may cover specific questions
- Clinical audits will test the quality and consistency of use of the local GL

2. Proposals for Radiology (covering all anatomical areas, all types of disease)

- **ACR Appropriateness Criteria**: score 1-9 for exams (7-9 appropriate), USA
- **ESR i-Guide Appropriate Use Criteria**: European version, similar, app.
- **SFR Guide du bon Usage des examens d'imagerie médicale**: indicates whether a method is justified generally/conditionally/not justified for the specific medical problem
- **CAR Diagnostic Imaging Referral Guidelines**, Canada (similar to UK)

3. Additional GL for specific specialties/methods:

- e.g. **cardiology, dento-maxillo-facial imaging, nuclear medicine**

Alarming literature: REPORTS OF INADEQUATE JUSTIFICATION 1

1. Oikarinen H, Unjustified **CT** examination in **young** patients, *Eur Radiol* 2009;19:1161 <35y, CT head n=50, other areas n=30 2005. **Rate of unjustified exams**: lumbar spine 77%, head 36%, abdomen 37%, nasal sinuses 20%, cervical spine 3%. Conclusion: CT→MRI
2. Borgen L, Clinicians' justification of imaging: do radiation issues play a role ? *Ins.Imag* 2010;1:193 Norwegian questionnaire to 213 referrers. Underestimation of doses. Only 20% of physicians and 72% of non-physicians used **referral guidelines**.
3. Portelli JL. **Paediatric** imaging radiation dose awareness and use of referral guidelines amongst radiology practitioners and radiographers. *Insights Imaging* 2016;7:145 Malta, prospective survey asking practitioners for typical dose of 5 exams and for use of referral guidelines. Poor dose awareness (20% correct), poor use of **guidelines** (77% no use/«not sure»).
4. Vilar-Palop J, Appropriate use of medical imaging (2 Spanish public hospitals). *BMJ Open* 2018;8:e019535. 2022 radiation exams: **48% appropriate**, 31% inappropriate for guideline, 5% for repetition, 8% for insufficient clinical information; **8% not covered by guideline**. Higher inappropriateness for women, for general practitioner referrers, for x-rays vs. mammography/CT

Alarming literature: REPORTS OF INADEQUATE JUSTIFICATION 2

5. Rawle M, Prevalence of unjustified emergency department x-ray examination referrals Regional Queensland hospital, *J Med Radiat Sci* 2018;65:184

With regard to **legal diagnostic imaging pathways (GL)**, 75% of 186 referrals not compliant (49% after review of medical records of referrers). Conclusion: **lack of information transfer** and **of compliance with justification requirements**.

- *This overview of the literature is incomplete*
- *Experience usually was retrospective, from 1 institution*
- *Some criteria for appropriateness might have been too narrow*
- *Individual justification (level 3) was neglected*
- *Data were not representing the Swiss clinical routine*

**But: before having proven a different Swiss reality,
we have to be aware of them**

Swiss Reality: Referral Criteria for CT

Autumn 2019 before the introduction of Clinical Audits

Survey by KSR's Medical Experts' Group

- Standardised questionnaire sent to all Swiss centers practising CT
- Main question: justification criterium for CT exams?
own and referrer's specialist knowledge – own written guideline – national guideline – international guideline – subspecialists' guideline
- Statistics for 3 language regions

Participation:

- German speaking part: 79/168 47%
- French speaking part: 41/82 50%
- Italian speaking part: 3/11 27%
- Switzerland: 123/261 47%

*>1/3: knowledge only!
nearly 1/2: national GL
(ge.: US, GE, fr: FR, US)
specialised service/univ.:
subspecialty GL
No info about quality!*

Results:	knowledge	own GL	natl.GL	internatl.GL	subspecialists GL	Σ
- German p.:	28	6	37	4	4	79
- French p.:	16	1	18	3	3	41
- Italian p.:	1	1	1	0	0	3
- Switzerland:	45	8	56	7	7	123
	37%	7%	45%	6%	6%	

Justification in clinical routine: Next steps for Switzerland

1. Most important step: Clinical Audits (s. afternoon session)

- Justification is part of the **local culture** in public + private medicine
- Justification is the **result of cooperation between referrer and imager**
- Likely, there is **wide variation** in Switzerland in the practice of justification
- Currently, **we do not have reliable data** on the quality of justification in CH
- As **Clinical Audits** address the **whole imaging process**, verifying – among other aspects – correct justification and optimisation, there is a good chance that they **will objectively identify local strengths and weaknesses**
- The **cyclical repetitive** character of clinical audits offers a huge **chance to learn and to improve** over time.

2. Clinical Decision Support (an app. in digital medicine)

- Combines history + clinical/lab findings + referral guideline → next exam.
- Offers alternatives, allows for incentives and «brakes» (e.g. 2nd opinion)
- Offers statistics for management. Mostly in pilot phase.

3. Further approaches

- Education (medical school, all referrers, staff), incentives, tarif, AI...

CONCLUSIONS OF THE TOUR

Justification follows
science + innovation

Legislation sets
clear justif. rules

Justification is
demanding

Despite the lack of statistics, clinical justification has deficits

Tools to improve routine justification exist, above all:

Referral
Guidelines (level2)

Clinical Audits are
diagnostic + therapeutic

+ Education, decision
support, incentives, ...