Justification of new types of practices involving medical exposure

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Eva G. Friberg, Norwegian Radiation Protection Authority (NRPA) – Norway
Ritva Bly, Radiation and Nuclear Safety Authority (STUK) – Finland
Torsten Cederlund, Swedish Radiation Safety Authority (SSM) – Sweden
Nellý Pétursdóttir, Icelandic Radiation Safety Authority (IRSA) – Iceland
Hanne Waltenburg, Danish Health Authority, Radiation Protection – Denmark
Medical exposure

• Essential tool in diagnosis and treatment
  – Largest man-made source of radiation to the population
  – Largest contributor to occupational exposure

• Associated with cancer induction and acute tissue reactions (high dose procedures)

• Fast technological development, new health technologies continuously introduced to clinical practice

• Need to ensure for **safe** use of medical exposure

Wall et al., HPA-CRCE-028 (2011)
Principle of justification: Medical field

Medical exposure **shall** show a **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,*

*taking into account the efficacy, benefits and risks of available alternative techniques having the same objective but involving *no or less* exposure to ionizing radiation.*

*against the individual detriment that the exposure might cause,*
IAEA-BSS: Generic justification of a radiological procedure shall be carried out by the health authority in conjunction with appropriate professional bodies, and shall be reviewed from time to time, with account taken of advances in knowledge and technological developments.

EU-BSS: MS shall ensure that new types of practices involving medical exposure are justified in advance before being generally adopted.
Nordic position statement on justification of new types of practices involving medical exposure

The Nordic radiation protection authorities recommend: integration of generic justification into established methods for assessments of new health technologies

- Like HTA or similar methodologies

A Nordic cooperation has been established between the national radiation protection authorities within the Nordic Group on Medical Applications (NGMA) to:

- support and harmonize the national implementation of this recommendation
- strengthen the dialogue with other relevant national bodies
  - preferably competent health technology assessment (HTA) bodies
Integration of generic justification into established assessment methods

Rationale:

• Risk-benefit evaluation in generic justification similar to total risk/benefit evaluation already performed in assessments like HTAs
  – Integration of radiation detriment into total risk-assessment

• Bringing together all assessments and evaluations in one decision-making process
  – Generic justification becomes part of a coordinated evaluation process, not evaluated in an isolated parallel system
  – Avoiding conflicting conclusions
  – Foster cooperation between radiation protection competent authorities and relevant bodies like HTA-bodies
Strengths and challenges with this approach

**Strength**

- Assessments and competent authorities/bodies are coordinated in a predictable and transparent way
- Assessments can be done at different levels (e.g. mini-, rapid- or full-HTA)
  - Graded approach of assessment to maximize use of available resources

**Challenge**

- Assessments may be time consuming and hinder innovation and fast access to new methods
- Relative new concept for medical devices (HTA well established for drugs)
- Limited recourses, need for clear criteria for when an assessment is needed and at what level
Limited available resources for assessments

- Unrealistic for any country to perform comprehensive assessments of all new health technologies involving medical exposure
- As a first approach, comprehensive assessment (e.g. full-HTA) should be carried out for
  - Methods involving high level of exposure to the patient
  - New screening methods and programmes
  - Methods associated with high occupational or public exposure
- Other methods to be assessed at lower levels (e.g. mini-HTA)
- Best use of available resources
  - Evaluation of the evidence (risks and clinical effect) should preferably be carried out through European or international cooperation
  - Evaluation of the consequences associated with the decision to implement the practice should be made nationally (cost-effectiveness)
Call for European and global cooperation

- European Commission recommend MS to cooperate in the process of generic justification
  - EC council conclusions on justification (2015)

- Already established networks, like EUnetHTA and others, can facilitate European and global cooperation and harmonization of the implementation of generic justification into ongoing assessments of new health technologies

- European HTA network (EUnetHTA):
  - Responsible for European cooperation on HTA production and promotion of good practice in HTA methods and processes
  - Perform European Joint Actions on HTA, like EUnetHTA Joint Action 1, 2, and 3 (EC founded projects)
Situation in Norway

- A national system for managing the introduction of new health technologies within the specialist health service (Nye Metoder), was launched in 2013

- The system consist of four phases:
  - Horizon scanning: Fast introduction
  - Health Technology Assessment: 3 levels (mini, rapid, full-HTA)
  - Priority setting Decisions: Based on HTA
  - Implementation: Coordinated with national guidelines

- Norwegian radiation protection authority (NRPA) became part of the system in 2014
  - **Role:** ensure that generic justification and radiation protection for patient and staff are taken into account and evaluated for methods and procedures involving medical exposure

- NRPA partner in EUnetHTA Joint Action 3
Conclusions

- The Nordic radiation protection authorities recommend the integration of generic justification into established methods for assessment of new health technologies
  - RP risk/benefit evaluation part of total risk/benefit assessment
  - RP evaluated in a coordinated process, not in an isolated parallel system
- This approach fosters cooperation/dialogue between RP authorities and other relevant bodies, like HTA competent bodies
- European Commission recommend MS to cooperate in the process of generic justification
  - Already established networks, like EUnetHTA and others, can facilitate European and global cooperation on generic justification
Thank you for your attention!

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