Health technology assessment
Could RP influence the choice of medical technologies and methods

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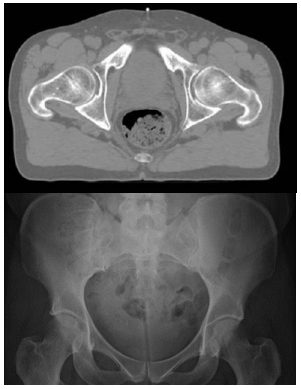
DSA Direktoratet for strålevern og atomsikkerhet

Medical Exposure – Benefit

- Essential tool in diagnosis and treatment



X-ray diagnostic

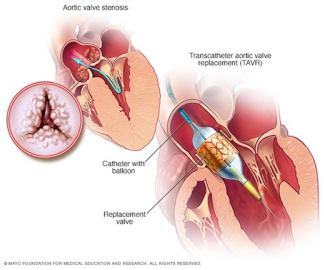
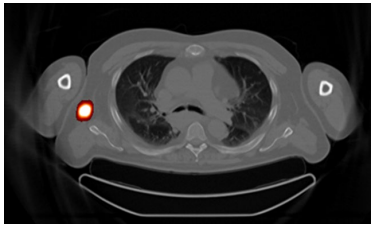
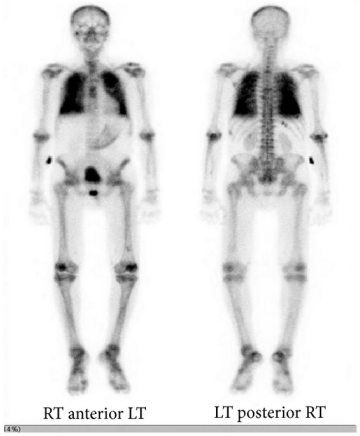
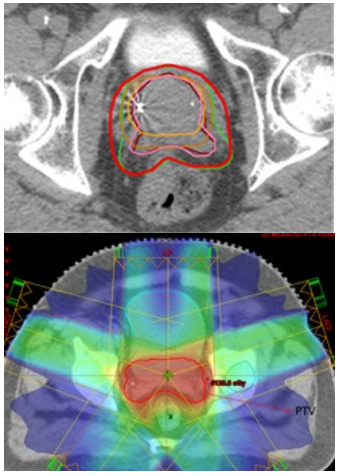


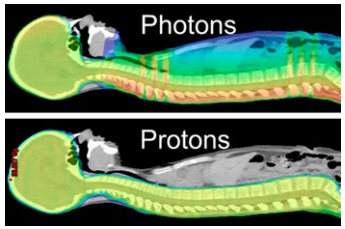
Image guided interventions





Nuclear medicine and hybrid imaging (PET/CT)





Radiation therapy

- Largest man-made source of radiation to the population
- Largest contributor to occupational exposure

Medical exposure – Harm

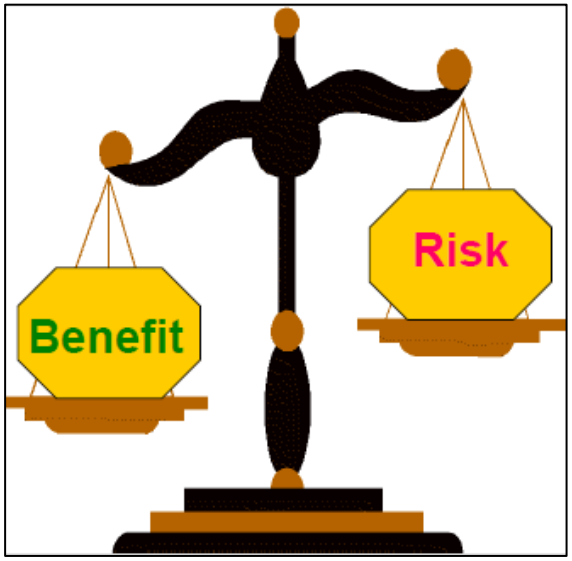
- Associated with cancer induction and acute tissue reactions (high dose procedures)
  - Radiation harms
- Potential for overdiagnosis and overtreatment
  - Clinical harms
- Unjustified exposures effects health economics and resources
  - Economical harms

Challenge:

- Fast technological development, new health technologies and methods continuously introduced to clinical practice
- Need to ensure for safe use of medical exposure

The principle of justification

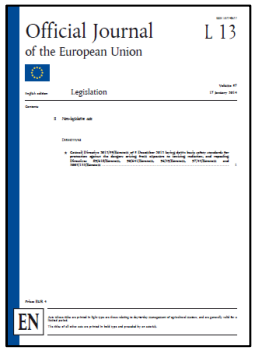
- Medical exposure shall show a sufficient net benefit



Generic justification

- Ensure that new types of practices involving medical exposure are justified in advance before being generally adopted

➢ Requirement in new European Radiation Protection Directive (EU-BSS)

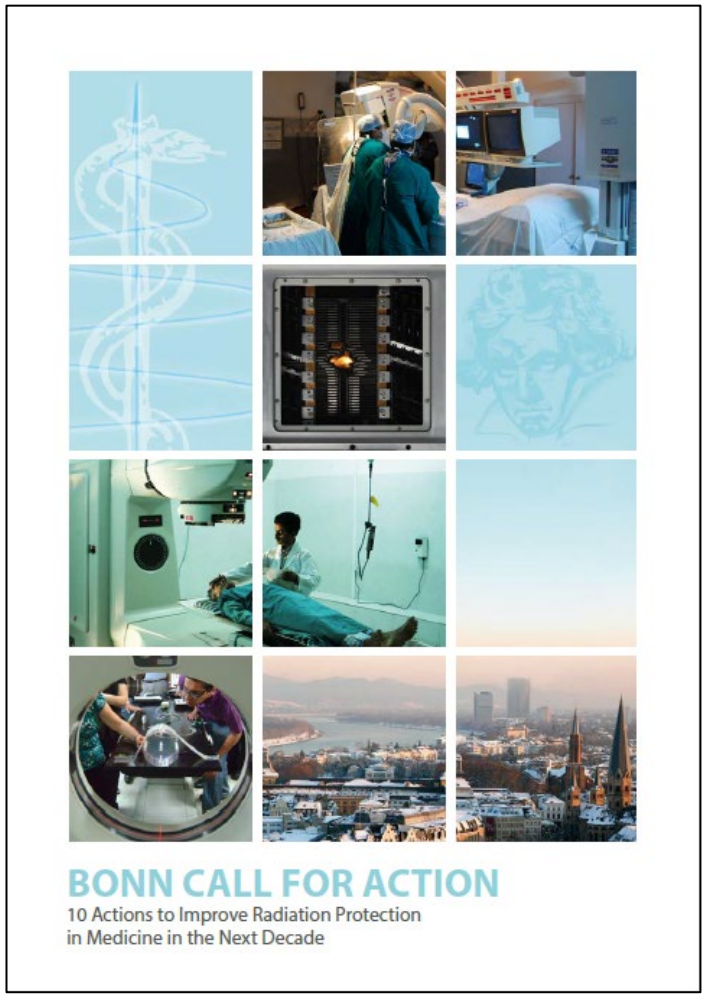


- To ensure for safe introduction of new health technologies
  - Need to address and evaluate the radiation detriment associated with medical exposure
- Health Technology Assessment (HTA) is recognized as a valuable tool in promoting generic justification of medical exposure

Health Technology Assessment (HTA)

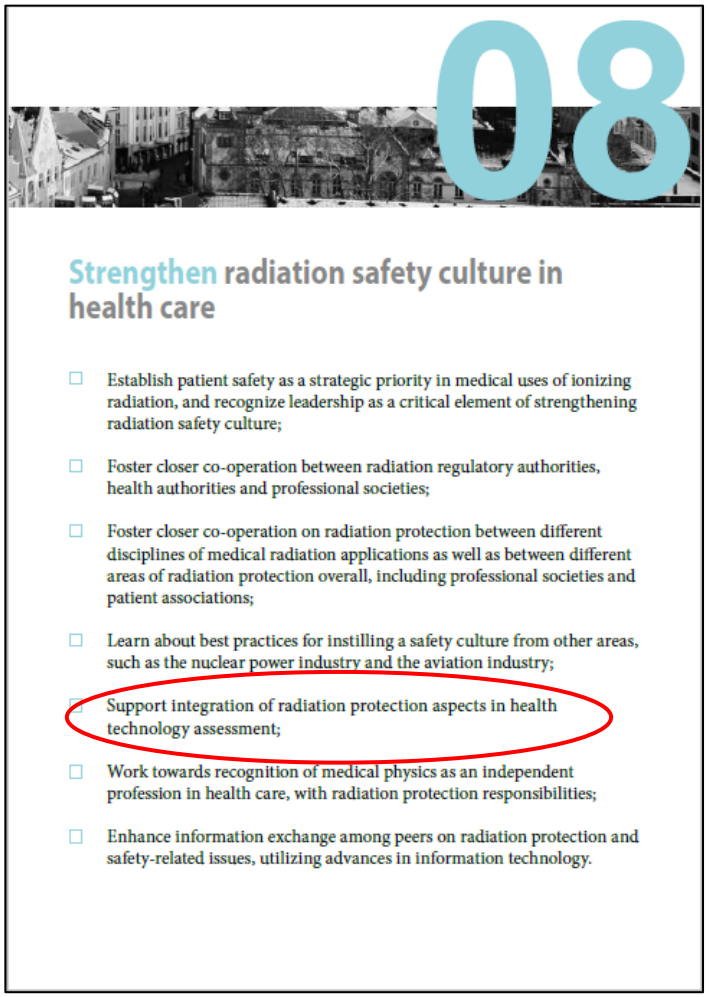
- HTA – a systematic evaluation of
  - Available knowledge on safety and clinical effect
  - Cost-effectiveness
  - Ethical, social, organizational and juridical aspects
- HTA – a tool for decision-making
  - Introduction of new technologies and methods
  - Phase-out of technologies and methods no longer considered clinical effective or safe

WHO support integration of RP into HTA



BONN CALL FOR ACTION

10 Actions to Improve Radiation Protection in Medicine in the Next Decade



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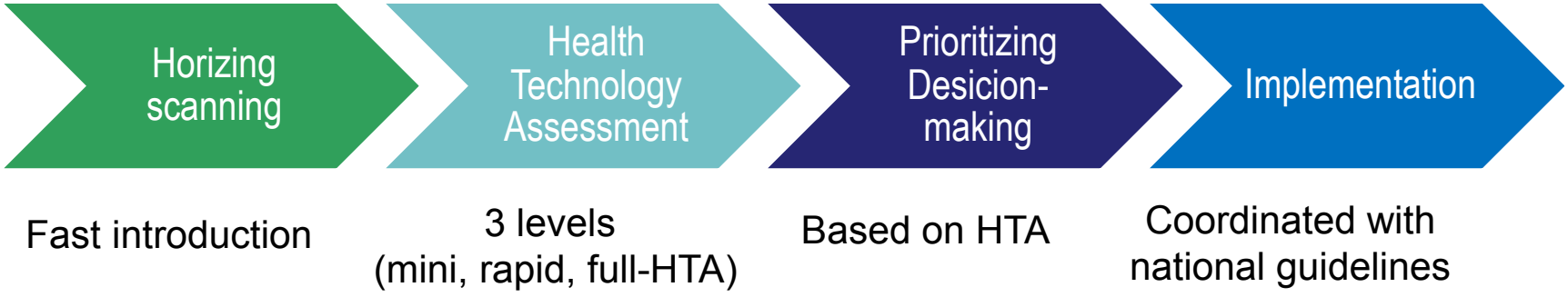
Strengthen radiation safety culture in health care

- Establish patient safety as a strategic priority in medical uses of ionizing radiation, and recognize leadership as a critical element of strengthening radiation safety culture;
- Foster closer co-operation between radiation regulatory authorities, health authorities and professional societies;
- Foster closer co-operation on radiation protection between different disciplines of medical radiation applications as well as between different areas of radiation protection overall, including professional societies and patient associations;
- Learn about best practices for instilling a safety culture from other areas, such as the nuclear power industry and the aviation industry;
- Support integration of radiation protection aspects in health technology assessment;
- Work towards recognition of medical physics as an independent profession in health care, with radiation protection responsibilities;
- Enhance information exchange among peers on radiation protection and safety-related issues, utilizing advances in information technology.

Nye Metoder (New Methods)

Norwegian national system for introducing new methods

- Introduced in 2013
- Standardized process for evaluation of effect, safety and costs
- Predictable and transparent process with stakeholder involvement
- HTA a tool for decision-making and prioritizing in health care
- Four different processes



- All steps and involved authorities/institutions/stakeholders are coordinated at a national level
- All information available on web (www.nyemetoder.no)

Why integrate generic justification into HTA

Rationale:

- Risk-benefit evaluation in generic justification similar to total risk/benefit assessment already performed in HTA
  - Integrate radiation detriment in 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 (HTA vs. RP)
  - Foster cooperation between radiation protection competent authorities and HTA-bodies
  - All aspects taken into account in the final decision-making process

DSA part of Nye Metoder since 2014

Norwegian Radiation and Nuclear Safety Authority (DSA)

DSAs role:

- Ensure that generic justification and radiation protection issues for patient and staff are evaluated and taken into account in the total risk-benefit evaluation of the method (all levels: mini, fast, full-HTA)
  - Important to involve medical physicists and radiation protection experts/officers in the evaluation of radiation detriment
- Being part of the system ensure that DSA are properly informed and involved in all processes related to the introduction of new methods associated with medical exposure
- DSA get a national overview of local mini-HTA performed for equipment, radio-pharmaceuticals and procedures within medical exposure through a national database

Which topics should be evaluated

- Description of method, equipment and procedure
  - Including control regimes (like CT controls for cancer)
- For patient
  - Type of patients (population), age, gender
  - Overview of typical doses, including doses to radiosensitive organs
  - Overview of the occurrence of deterministic effects (like skin burns)
- For staff
  - Overview of typical doses, including dose to eye lens and fingers
  - Overview of numbers of procedures per operator – not exceeding dose limits
  - Identified need for competence and personal protective equipment (optimisation)
- Litterateur search
  - Doses and risks associated with the method
  - Change in dose compared to comparator (old method)
  - Other radiation protection issues?
- Compliance with RP regulations – organisational changes

Different categories of methods

- When the method make use of radiation
  - Like: X-ray, CT, MR, NM, RT
- When radiation is a tool to perform the method
  - Like: Image guided interventions or operations
- When radiation is used to verify the method
  - Like: Radiologic controls of pharmaceuticals
- When the method replace a method using radiation
  - Like: MR and US replace CT, tests that replace radiological images
- PR issues should be evaluated in all categories
  - Content of assessment will depend on category

Rapid-HTA: Tomosynthesis in screening

Executive summary

Radiation dose and risk assessment

When compared to the current practice with DM, introducing the Hologic Selenia Dimensions DBT-system into the Norwegian Breast Cancer Screening Programme (NBCSP) will result in an increased radiation dose followed by an increased risk of radiation-induced cancer for all the evaluated interventions defined by the PICO.

Beslutning

Dato: 25.09.2017

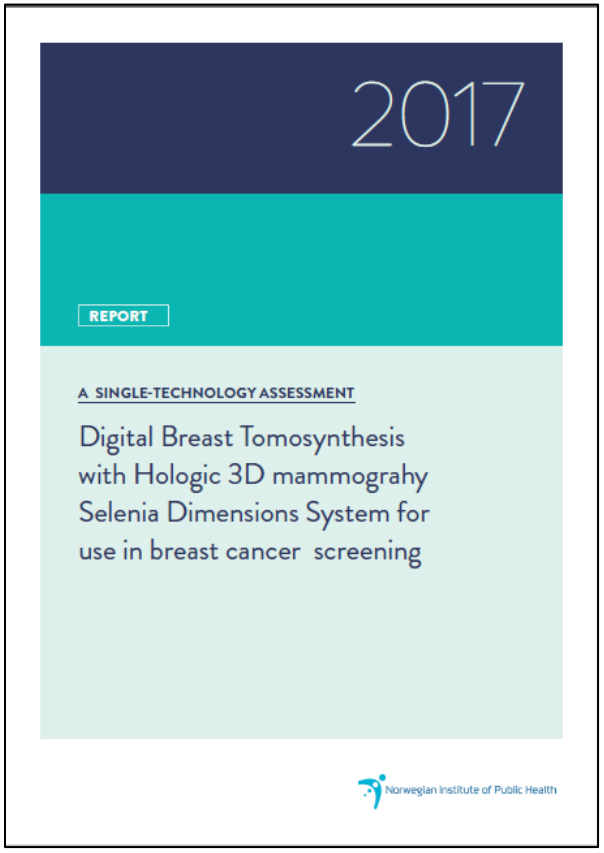
Ansvarlig: Beslutningsforum for nye metoder

Beslutning i Beslutningsforum for nye metoder (25.09.2017)

Bruk av tredimensjonal digital brysttomosyntese skal ikke innføres som en obligatorisk del av Mammografiprogrammet på grunn av usikkerhet i datagrunnlaget.

Protokoll fra Beslutningsforum for nye metoder 25.09.2017 finner du her, se sak 79-2017.

Decision: Not implemented



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Strengths and challenges with HTA-approach

Strengths:

- 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
- Lack of evidence, collect data through clinical trails

Challenges:

- 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

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

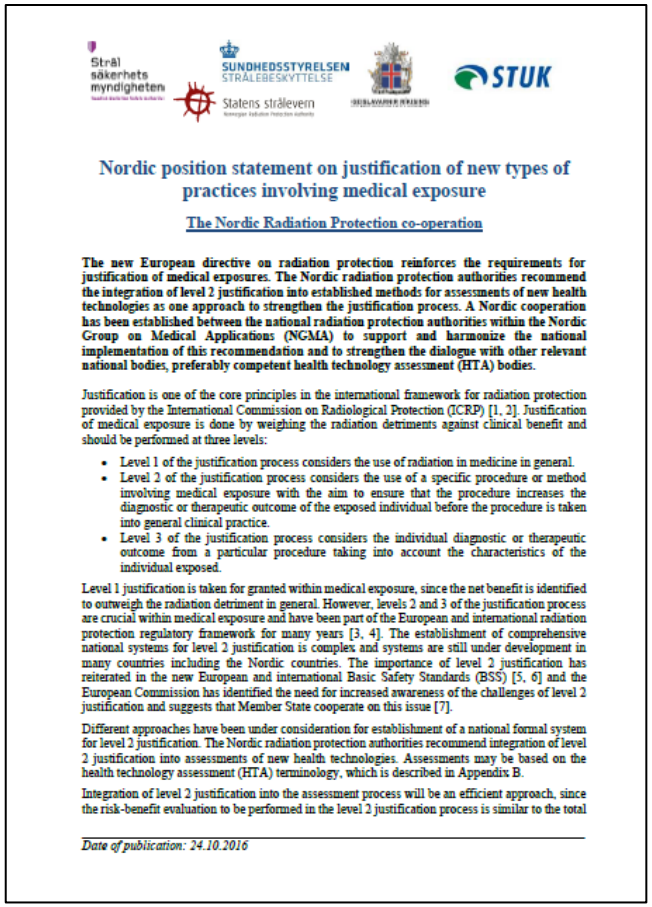
- Like HTA or similar methodologies

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 HTA bodies

Nordic HTA workshop in 2018 (Oslo)

- Nordic RP-authorities were invited



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Nordic position statement on justification of new types of practices involving medical exposure

The Nordic Radiation Protection co-operation

The new European directive on radiation protection reinforces the requirements for justification of medical exposures. The Nordic radiation protection authorities recommend the integration of level 2 justification into established methods for assessments of new health technologies as one approach to strengthen the justification process. 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 and to strengthen the dialogue with other relevant national bodies, preferably competent health technology assessment (HTA) bodies.

Justification is one of the core principles in the international framework for radiation protection provided by the International Commission on Radiological Protection (ICRP) [1, 2]. Justification of medical exposure is done by weighing the radiation detriments against clinical benefit and should be performed at three levels:

- Level 1 of the justification process considers the use of radiation in medicine in general.
- Level 2 of the justification process considers the use of a specific procedure or method involving medical exposure with the aim to ensure that the procedure increases the diagnostic or therapeutic outcome of the exposed individual before the procedure is taken into general clinical practice.
- Level 3 of the justification process considers the individual diagnostic or therapeutic outcome from a particular procedure taking into account the characteristics of the individual exposed.

Level 1 justification is taken for granted within medical exposure, since the net benefit is identified to outweigh the radiation detriment in general. However, levels 2 and 3 of the justification process are crucial within medical exposure and have been part of the European and international radiation protection regulatory framework for many years [3, 4]. The establishment of comprehensive national systems for level 2 justification is complex and systems are still under development in many countries including the Nordic countries. The importance of level 2 justification has reiterated in the new European and international Basic Safety Standards (BSS) [5, 6] and the European Commission has identified the need for increased awareness of the challenges of level 2 justification and suggests that Member State cooperate on this issue [7].

Different approaches have been under consideration for establishment of a national formal system for level 2 justification. The Nordic radiation protection authorities recommend integration of level 2 justification into assessments of new health technologies. Assessments may be based on the health technology assessment (HTA) terminology, which is described in Appendix B.

Integration of level 2 justification into the assessment process will be an efficient approach, since the risk-benefit evaluation to be performed in the level 2 justification process is similar to the total

Date of publication: 24.10.2016

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 can facilitate European and global cooperation and harmonization of the implementation of generic justification into HTA
  - EUnetHTA: European platform of HTA-bodies
  - HTAN: European network for HTA-authorities
- Best use of resources
  - Evaluation of the evidence (risks and clinical effect) should preferably be carried out through European or international cooperation (reuse)
  - Evaluation of the consequences associated with the decision to implement the practice should be made nationally (cost-effectiveness)

Conclusions and recommendations

- Need to ensure for safe use of medical exposure
- Implementation of generic justification in established HTA-systems is an efficient approach
  - RP risk/benefit evaluation part of total risk/benefit assessment
  - RP evaluated in a coordinated process, not in a isolated parallel system
- Norway: national system that combine RP and HTA (Nye Metoder)
- Nordic statement and cooperation on generic justification and HTA
- Foster cooperation/dialogue between RP authorities and HTA bodies
  - Most European countries have HTA competent bodies
  - Established Nordic cooperation between RP and HTA
  - Cooperation in the process of generic justification is recommended by EC

If generic justification fail: harm > benefit

- Radiation protection can indeed influence the choice of medical technologies and methods