Plenary Session 1:

Case Study: National System on HTA in Norway

The HTA-approach from a RP point of view

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Statens strålevern
Norwegian Radiation Protection Authority

National system (HTA-approach)

GOALS:

- Ensure that patients get **fast** and equal access to new methods showing a **safe** and evidence based **clinical effect** *(risk/benefit-assessment, Article 55)*
- Avoid introduction of unsafe and non-effective methods
- **Standardized process** for evaluation of effect, safety and costs
- **Predictable** and **transparent** process with **stakeholder involvement** (*Article 77*)
- Tool for **decision-making** and prioritizing in health care

Generic justification (EU-BSS)

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

Rationale behind the HTA-approach:

- Evaluation of risk/benefit should not be an isolated, parallel process
- RP detriment and issues should be integrated in already established systems for assessing new health technologies

➢ NRPA part of Nye Metoder since August 2014

NRPAs role in the system

- Ensure that radiation protection issues for patient and staff are taken into account and evaluated for methods involving radiation
- Setting up a national "panel of experts" in RP to assist in evaluations involving radiation
- Member of Nye Metoder ensure that NRPA are properly informed and involved in all processes related to the introduction of new methods

HTA-approach – Strength

- All processes, assessments and stakeholders are coordinated at a national level in a predictable and transparent way (Article 77)
- Foster cooperation between competent authorities/bodies/stakeholders
- HTA at different levels (Mini-, Rapid-, Full-HTA)
  - Graded approach related to content and depth of assessment to maximize use of available resources
- If evidence base is not sufficient, implementation only through pathway of research (ethics committee)

HTA-approach – Challenges

- Nye Metoder cover only specialist health services, financed by public health care system
  - Need to be extended to cover primary health care and private sector
- Most in use for pharmaceuticals
  - HTA methodology well established for pharmaceuticals
- More challenging and new for medical devices
  - Manufacturer not used to provide necessary documentation, often multiple vendors
  - Need for clear criteria for when HTA and at what level
  - How to including assessment of alternative techniques (in definition of PICO?)

Methods suggested for HTA in Norway

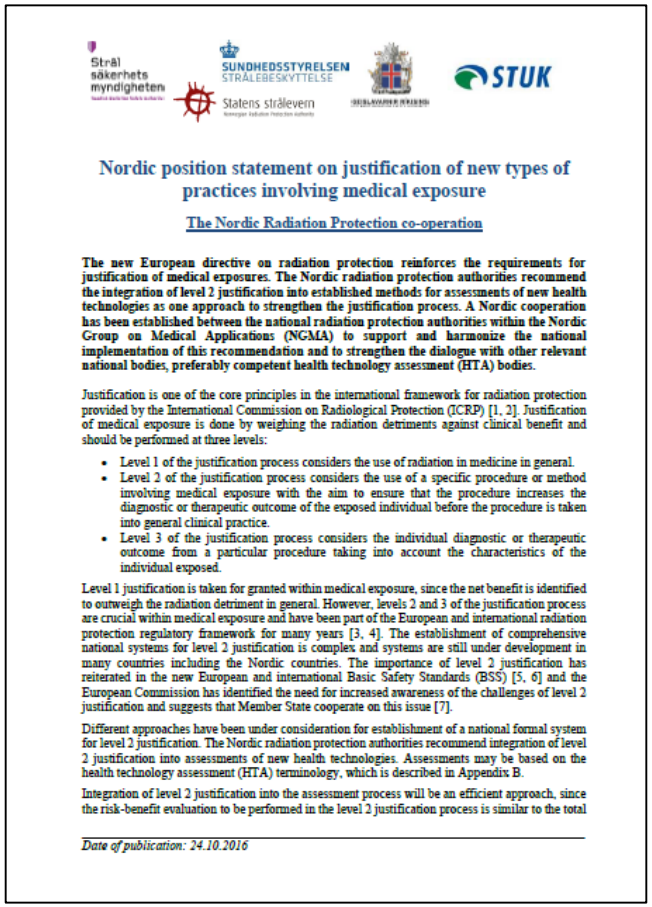
- Xofigo – Rapid (finalized)
- Different methods using interventional radiology as a tool (pacemaker, AAA, rotor ablation, balloon catheters, etc.) – Full and Rapid
- Cyberknife & Tomotherapy for cancer – internal assessment
- Tomosynthesis in mammography (clinical & screening) – Rapid
- CT for stroke in mobile unites (ambulance) – Full
- Peptide receptor radionuclide therapy (PRRT) of neuroendocrine cancer – Full
- Proton therapy of cancer – No evaluation (political decision)

Role of HERCA in HTA

- EC Council Conclusion on generic justification recommend cooperation between MS
  - HERCA can facilitate such cooperation
- HERCA can be a stakeholder/observer in EUnetHTA and HTAN to put RP on the HTA agenda
- HERCA can develop a common understanding of how RP should be integrated and harmonize criteria for HTA from a RP point of view
- HERCA can facilitate the cooperation with HTA-bodies in HTA performance

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

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.



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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

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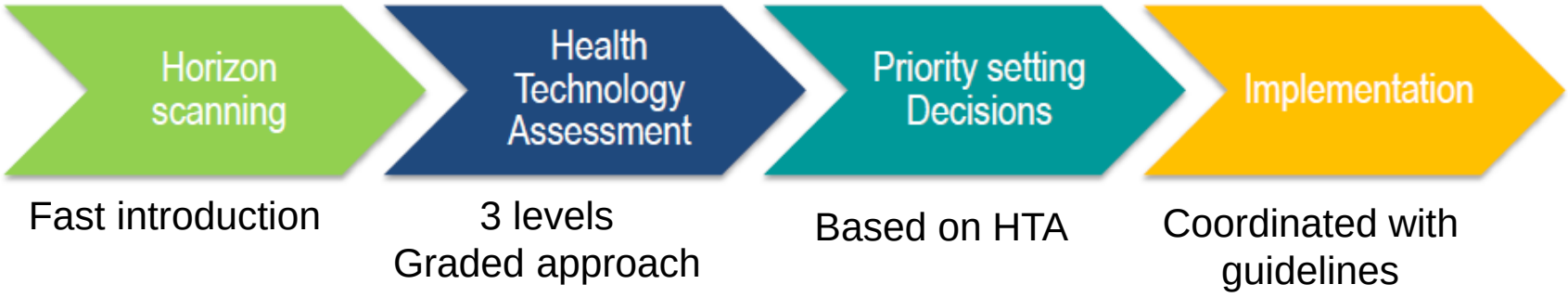
EC Council Conclusions – recommend cooperation between MS

Conclusions and recommendations

- Implementation of generic justification in established HTA-systems is an efficient approach
  - RP risk/benefit evaluation part of total risk/benefit assessment
- Foster cooperation/dialogue between RP authorities and HTA bodies
  - Most European countries have HTA competent bodies
- Important to distinguish between health technology regulations (Medical Device Directive) covering all devices and HTA covering more complex problems
- Best use of available resources
  - Evaluation of the evidence (safety 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)

The main components of the system



- All steps and involved authorities/institutions/stakeholders are coordinated
- All information, evaluations, decisions are available on the web-page: www.nye.metoder.no
- National database on Mini-HTA

Topics to be evaluated

Evaluation of methods

- Clinical effect
- Safety

Systematic overview

- Cost effectiveness
- Costs for health care or the society

Health economic model

- Ethical considerations
- Organizational considerations
- Social considerations
- Juridical considerations

Consequences

Mini-HTA
1-2 weeks

Fast-HTA
180 days

Full-HTA
360 days