The National System for Introduction of New Health Technologies within the Specialist Health Service

Nasjonalt system for INNFØRING AV NYE METODER i spesialisthelsetjenesten

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Background

- Varying or lacking practice for evaluation of methods before they were introduced or outsourced within the specialist health service
- Different processes for decision-making
- Introduced in 2013
- NRPA full-part member in August 2014
Main goals

- Ensure that patients get fast and equal access to new methods showing a safe and evidence based clinical effect
- Avoid introduction of unsafe and non-effective methods
- Standardized process for evaluation of effect, safety and costs
- Predictable and transparent process with stakeholder involvement
- Tool for decision-making and prioritizing in health care
Motivation to become a part of the system

Justification

• Level 1: Use of radiation in medicine - OK

• Level 2: Generic justification (RP regulation §37)

«The justification of new methods and applications in medical use of radiation shall be evaluated on a general basis before such methods and applications become available for general use. Existing areas for use and methods shall be reassessed when new information emerges about their justification.»

• Level 3: Individual justification

Supported by IAEA/EU-BSS
Overall system

- Evaluation of methods as part of an overall system for introducing new methods
- Four different processes

- All steps and involved authorities/institutions/stakeholders are coordinated

Diagram:
1. Alert of methods
2. Evaluation of methods
3. Prioritizing Decision-making
4. Implementation
Broad definition of method

Include all actions to:

• Prevent
• Diagnose
• Treat
• Rehabilitation
• Organizing of health services

Examples of methods:

– Medical equipment
– Procedures (diagnostic, medical, surgical, etc.)
– Pharmaceuticals
Alerts of new methods

- Part of national system in 2014 and implementation-phase in 2015

**Purpose:** To assure the identification of new methods and make a prioritizing for evaluation of methods

- Evaluates:
  - Available clinical data
  - On-going clinical studies
  - Cost impact on society
  - Premises for effective implementation

**Steps in the alert function:**

- Identification of methods
- Level 1 filtration
  - Most important methods
- Production of alert
- Level 2 filtration
  - Methods actual for the Hospital Trusts
- Evaluation of method

Publication of alerts: [www.mednytt.no](http://www.mednytt.no)
Evaluation of methods

- Follows international principles of health technology assessment and are performed at three levels

**Mini-HTA**
- **Local** evaluation of a method (equipment, procedure, organization)
- Carried out in the Hospital Trusts (HT) in a limited format by experts
- Carried out in dialogue with support functions

**Fast-HTA**
- **National** evaluation of a method (equipment, procedure, organization)
- Carried out by Norwegian Medicines Agency for pharmaceuticals
- Other methods carried out by Norwegian Knowledge Centre for the Health Services (NOKC)
- NRPA assist on medical use of radiation
- Vendors provide necessary information (template)

**Full-HTA**
- Comprehensive **national** evaluation of alternative methods against each other within a treatment area (comparative effectiveness)
- Carries out by NOKC who provide necessary information
- NRPA assist on medical use of radiation
Topics to be evaluated

- Clinical effect
- Safety
- Cost effectiveness
- Costs for health care or the society
- Ethical considerations
- Organizational considerations
- Social considerations
- Juridical considerations

Systematic overview
- Fast-HTA 180 days
- Full-HTA 360 days

Evaluation of methods
- Mini-HTA 1-2 weeks

Health economic model

Consequences
Methods to be evaluated at a national level

- Methods involving **screening**
- Methods involving **high specialised medical treatment** and should be established at a national level
- Methods involving **pharmaceuticals**
- When **social economic** or **health economic** evaluations of the method is required
Prioritizing and decision-making

Prioritizing and decision-making are placed at the RHTs

• For local evaluations (Mini-HTA):
  – The RHTs are responsible for its own evaluation and implementation of new methods
  – The system recommends all RHTs to evaluate Mini-HTA performed by other RHTs

• Two important fora for national evaluations (Fast and Full-HTA):
  – **RHT Order-Forum** for the ordering of evaluation of new methods
    • **Tasks**: Regional meetings, evaluate received proposal for method evaluations (non, Fast-HTA, Full-HTA), order evaluation of methods, submit final method evaluation to RHT Decision-Forum
  – **RHT Decision-Forum** for the implementation of new methods
    • **Tasks**: Regional meetings, decide implementation of new method or out-phasing of old methods on national level, agreement of all four RHTs
Implementation

- **Specialist Health Service** shall be performed in compliance with the decisions taken locally at the RHTs or nationally by RHT Decision-Forum

- Decisions taken by the RHT Decision-Forum are coordinated with the development of [national guidelines](#) by the Health Authority
Overview of the system

1. Systematic implementation based on mini-HTA in Hospital Trusts

2. Systematic implementation based on evaluation of methods (fast-HTA, full-HTA) in national institutions
NRPA’s role in the system

- Ensure that radiation protection issues for patient and staff are evaluated and taken into account in the total risk-benefit evaluation of the method in all three levels of evaluation (mini, fast, full)
  - Important to involve medical physicists and radiation protection experts/officers at HTs for Mini-HTA

- Full member of the system ensure that NRPA are properly involved in all processes related to the introduction of new methods
  - Aptitude assessment of proposed methods for evaluation
  - Participate in national evaluation of methods
  - Observer in RHTs Ordering-Forum and RHTs Decision-forum

- NRPA get a national overview of local mini-HTA performed on the different HTs for equipment, radio-pharmaceuticals and procedures within medical exposure

- **Ongoing work:** Development of forms to include RP, identify role and responsibilities with other parties of the system
Identified challenges

• RP regulation cover all use of radiation
  – Primary- and Specialist Health Services
  – Public and private sector

• National system cover only Specialist Health Services

• System most in use for pharmaceuticals

• Difficult to define new methods for medical equipment

• Difficult to get vendors to provide necessary information
Summary and conclusions

• Overall transparent system for the introducing of new methods within the specialist health service
  – Four processes: Alert of methods, evaluation of methods, prioritizing and decision-making, implementation

• Evaluation of methods
  – Mini-HTA local at HTs
  – Fast-HTA national, information provided by vendors (180 days)
  – Full-HTA, national, information provided by NOKC (360 days)

• NRPA full member since August 2014
  – Generic justification implemented in national system for evaluation of new methods

• For more information: https://nyemetoder.no/
Mini-HTA (local evaluation)

- A task for the Regional Hospital Trusts (RHT)
  - Ensure for available local competence at Hospital Trusts (HTs)
  - Assist HTs with research librarian and economic analysis

- NOKC responsible for the Mini-HTA system
  - Framework, form and evaluation

- National database - [www.minimetodevurdering.no](http://www.minimetodevurdering.no)

Good documented method or need for further research to reveal effect and safety

Mini-HTA into database. Local decision at RHT or lifted to national level