Hospital-based HTA – a part of the Norwegian system for introduction of new health technologies

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Health Tech Event 2016 - Eindhoven
Agenda

– The Norwegian system for introduction of new health technologies
  • Background
  • Elements of the system
– Mini-HTA - a part of the system
  • Criteria - when should medical devices be assessed in HTA?
– Does the Norwegian model work?
The Norwegian system for introduction of new health technologies

• The Norwegian Ministry of Health and Care established a **formal system** for introduction of new health technologies in cooperation with:
  – The Directorate of Health
  – HTA-organisations
  – Regional Health Authorities
  – Other stakeholders

• Officially opened by the Minister of Health in January 2013
Why establish a formal system for introduction of health technologies in Norway?

Variation in practice between hospitals regarding introduction of new health technologies:

• Medical devices
• Diagnostic technologies
• Complex interventions

Many clinicians, hospital leaders and politicians realized that introduction of new health technologies had to be regulated.
Why establish a system for introduction of health technologies in Norway?

It was decided that the HTA-principles should be used in a more systematic way:

«Good and useful health technologies should be accessible for patients as soon as possible» (HTAi)
Which health technologies are assessed in the system?

We assess new technologies (i.e. not in routine use today) and existing technologies (before disinvestment):

- Pharmaceuticals
- Medical devices
- Diagnostics
- Complex interventions
- Organisational measures
The purpose of the system

HTA should precede introduction of new health technologies in order to:

– Support decision making regarding introduction
– Increase patient safety:
  • New technologies must be effective and safe
– Increase transparency, predictability and equity
Norwegian system for introduction of new health technologies

Establishing the system was a political decision

The design of the system was based on:

1. **Research** prior to the establishment of the system
   - Worldwide systems for mini-HTA were identified and assessed
   - A pilot study of mini-HTA was performed in one region in Norway

2. **Consensus**
   - Among all involved parties, i.e. hospitals, health authorities, HTA-organisations, industry, other stakeholders
The national system for introduction of new health technologies in Norway

Main elements of the system:

- **Horizon Scanning**: Established 2014
- **HTA**: Established 2013
- **Prioritization Decision Making**: Established 2014
- **Implementation**: Ongoing
HTA-products within the system

National level

1. Full HTA
2. STA (single technology assessment)
3. Horizon scanning

Local level (hospitals)

4. Mini-HTA
Medical devices, complex interventions, diagnostics
NOT pharmaceuticals
# Full HTA and STA

## Single technology assessment (STA)
- Effectiveness
- Safety
- Cost-effectiveness

The **producer** (industry) performs the assessment
- NIPH or Norwegian Medicines Agency evaluate
- Within 180 days

## Full HTA
- Effectiveness
- Safety
- Cost-effectiveness
- Ethics
- Legal, organisational or social consequences
- Performed by NIPH
Prioritisation Forum

- 4 medical directors from regional health authorities
- 2 representatives from the Directorate of Health
- Observers: HTA-agencies

Topic selection for national HTA
Decision Maker`s Forum

- 4 directors of the regional health authorities
- 1 patient representative (observer status)

Decision-making on introduction of new health technologies based on HTA
Mini-HTA within the system

The key elements of the system are:

- Horizon Scanning
- HTA
- Prioritization Decision Making
- Implementation

- Mini-HTA in hospitals
- HTA at the national level
Which health technologies are evaluated in mini-HTA?

- Medical devices
- Complex interventions (therapeutic, diagnostic and rehabilitation)
- Organisational measures

Different technologies:
Criteria for medical devices
Mini-HTA or national HTA?

Check list:
– New technology?
– Innovative technology?
– Sufficient evidence for performing HTA?
  • At least one clinical study
– Large budget impact?
– The disease is serious
  • Loss in future QALYs
– Potential effect?

Assessment at national level
– All pharmaceuticals
– National screening programs
– Highly specialised treatments
– Health economic model is necessary
– High risk technologies
  • Class III, active implantable, list A (IVD)
– Ethical consequences

All other devices: Mini-HTA
The Norwegian mini-HTA form

**Part 1: Completed by the proposer**
- Clinical effectiveness
- Safety
- Evaluation of ethical aspects
- Economy
- Organizational consequences

**Part 2: Completed by a peer reviewer**
- An “unbiased” person, for instance from another hospital
- Is the assessment in part 1 performed satisfactorily?

**Part 3: Recommendation for decision-maker**
Mini-HTA

- Define PICOS
- Perform literature search
  - Ask a librarian!
  - Systematic reviews or primary studies
- Effect estimates
  - Fill in tables with the results from the studies
- Quality assessment:
  - Relevant study design?
  - Do the results point in the same direction?
  - Are the patients, the intervention, the comparisons and the outcomes representative?

P: Population
I: Intervention
C: Comparison
O: Outcomes
S: Study design
What is included in a mini-HTA?

A systematically prepared decision basis that provides an overview of:

- What is the **effectiveness** of the new technology?
- Is the new technology **safe**?
- Is the use of the new technology **ethically acceptable**?
- What are the **costs** of introduction and use of the new technology?
- Does introduction of the new technology cause any **organizational changes**?
Publication of mini-HTAs

All completed mini-HTAs must be published at a national website:

– Avoid duplication of work
– Transparency
## Den nasjonale databasen for mini-metodevurderinger

Du er her: Forsiden - Database for ferdigstilte mini-metodevurderinger

### Database for ferdigstilte mini-metodevurderinger

Kvalitetsvurdering av mini-metodevurderingene i denne databasen har vært gjort av en uavhengig fagfelle (del 2 av skjemaet for mini-metodevurdering).

Folkehelseinstituttet har ikke foretatt noen kvalitetsvurdering av innholdet i mini-metodevurderingene før publisering.

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<th>Data</th>
<th>Mini-metodevurdering</th>
<th>Helseforetak</th>
<th>Kontakt</th>
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<td>Nov 2016</td>
<td>Pheosopraphic optimisering av hemoglobininnå</td>
<td>OSLO UNIVERSITYSYKEHUS</td>
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<td>Forebygging og behandling av migrane ved supersorbitall transcutan nervostimering med Cately</td>
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<td>Organisering med bruk av normovens regional perfusion hos pasienter der av hjerte- og respirasjonsforsk εr bruksbegrensende behandling avsløettes</td>
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<td>Barotroffale aktivering terapi (BAT) for pasienter med uktalt behandlingsresistens hyperestesjon</td>
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<td>Lymphangiografisk Veledret lymphovenous Bypass for Stadium 1 og 2 (MD Andersen Klassifikasjon) Kronisk Sekundær Lymphstørrelse</td>
<td>SYKEHUSMET TELDARK</td>
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### Påbegynte mini-metodevurderinger

Oversikt over påbegynte mini-metodevurderinger

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<td>Er det faglige grunner til å endre kirurgiske metoder for genital kjønnkonvertering fra kvinne til mann?</td>
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<td>HELSE BERGEN</td>
<td>Khanh Do-Cong Pham</td>
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Does the Norwegian model work?

- Mini-HTAs are being produced

- National HTA is being produced

- Prioritization Forum/Decision Makers' Forum prioritize among the most relevant technologies and make decisions regarding introduction of new technologies

- Hospital leaders and many clinicians are very positive, whereas some clinicians are sceptical (professional autonomy, increased bureaucracy etc)
AdHop HTA
Adopting hospital-based Health Technology Assessment in EU

Duration: 01/09/2012 – 31/08/2015
Coordinator: Laura Sampietro-Colom (FCRB)

www.adhophta.eu
Thank you for your attention!