kunnskapssenteret
Nasjonalt kunnskapssenter for helsetjenesten

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HTA and market access issues for a complex intervention

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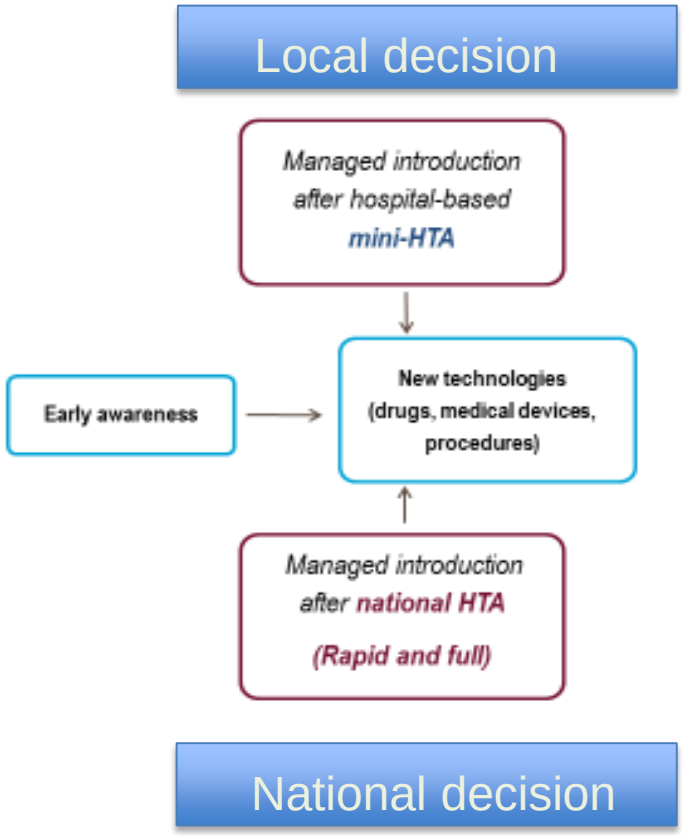
Example

- For the purpose of illustrating these challenges through a concrete example, a complex intervention is presented:

- A pulmonary heart sensor for the telemonitoring of heart failure patients (CardioMEMS) produced by the company St. Jude Medical

Managed introduction of new technologies in Norway



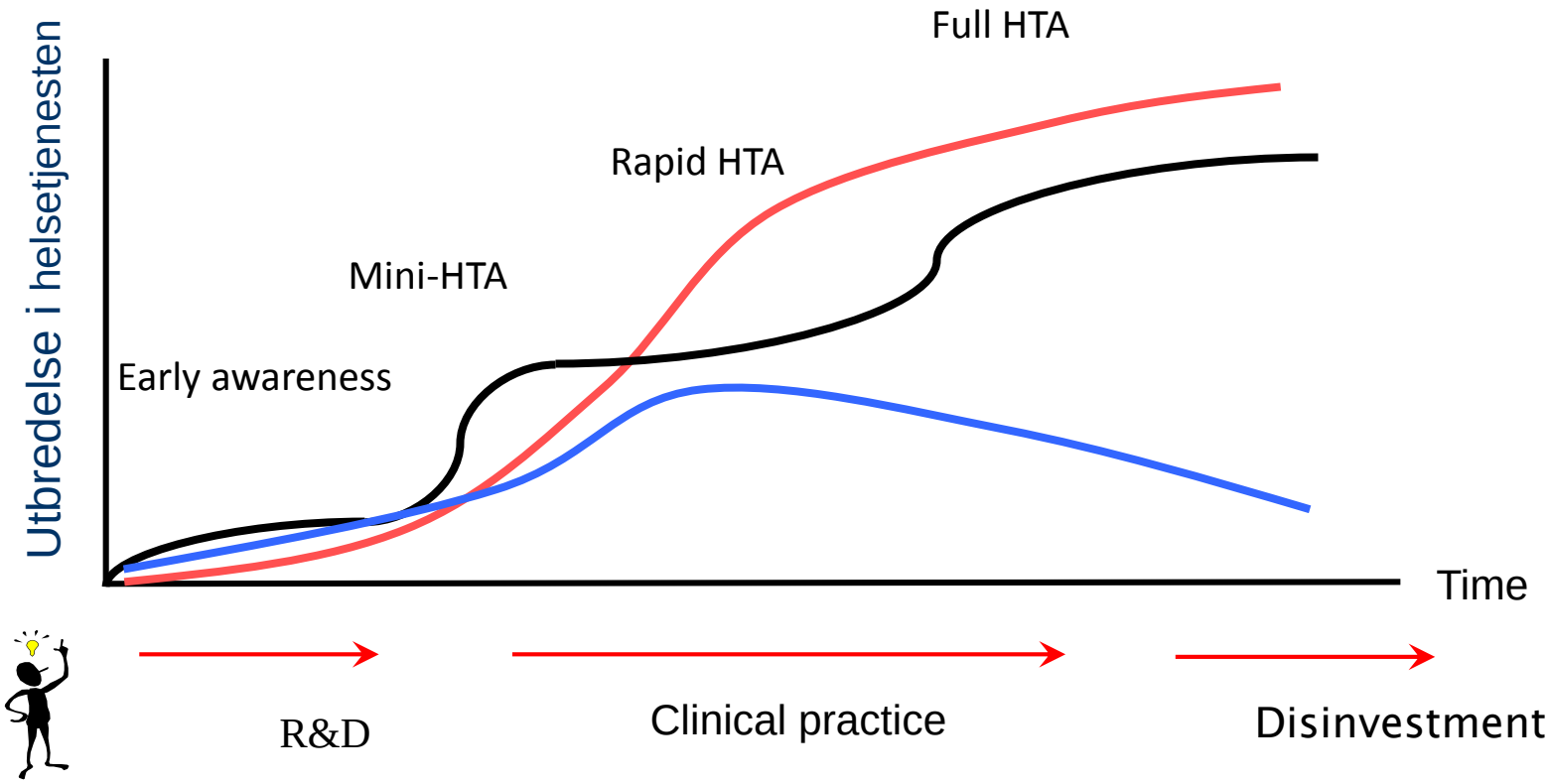
Background

- It is important that methods which will be publicly funded in a country are effective and cost-effective.
- To assure this we have implemented an EAA-HTA system to make sure we select and assess the relevant new methods before they are implemented and paid for in the clinical setting.

Objectives

- To evaluate effectiveness and cost-effectiveness of new methods (drugs, medical devices, procedures) before implementation/coverage in the specialist health care.

When should new methods be evaluated?



Tasks for the Norwegian Knowledge Centre to perform within the national system

- Early Awareness and Alert (EAA) activity of new methods (drugs, devices, procedures)
- Sampling of mini-HTAs produced at the local hospitals (database to reduce duplication)
- Rapid HTA assessment
- Full HTA assessment

Rapid HTA assessment process

Systematic review	Produced by the manufacturer
Health economic model	Produced by the manufacturer
Assessment of the documentation	Performed by NOKC (using national and international methodological guidelines)
Writing of the report and review process	Performed by NOKC Internal and external review process
Publishing	NOKC web pages
Decision-making	Hospital payers Directorate for Health (National treatment guidelines)

Participants from the manufacturer are participating in the scoping

They are asked to submit their questions 1-2 weeks in advance

Structure of the scoping meeting

- One to two informal meetings, more if necessary
- 2 hours
- Discussions regarding PICO
- Questions regarding the evidence package to be submitted including implications for the HE analysis
- Formal questions regarding the template to be used

9 Methodological Guidelines for Rapid REA

Endpoints used for REA of pharmaceuticals

1. Clinical endpoints
2. Composite endpoints
3. Surrogate endpoints
4. Safety
5. Health-related quality of life

Comparators and comparisons

6. Criteria for the choice of the most appropriate comparator(s)
7. Direct and indirect comparison

Levels of evidence

8. Internal validity
9. Applicability of evidence in the context of a relative effectiveness assessment

Link to the guidelines:

http://www.eunethta.eu/eunethta-guidelines

PICO CardioMEMS

Population	Patients with a diagnosis of moderate to severe HF (NYHA class III) for 3 months, on a stable and optimised medication regimen, and who have had a HF-related hospitalisation within the previous 12 months
Intervention	CardioMEMS™ HF System, in addition to usual practice
Comparator	Usual practice
Outcomes to be assessed	HF-related hospitalisations HR-QoL Mortality Safety (device-related and procedure-related)
Healthcare resources to be considered	Hospital stay Medical staff Nursing staff Medication use Surgical devices and consumables

Timelines for submitting the documentation

- Assessment is comissioned by hospital payers
- Contact with possible manufacturers established
- Manufacturers have 4 weeks for responding to the call
- Scoping meetings with manufacturers
- 4 months for submitting the documentation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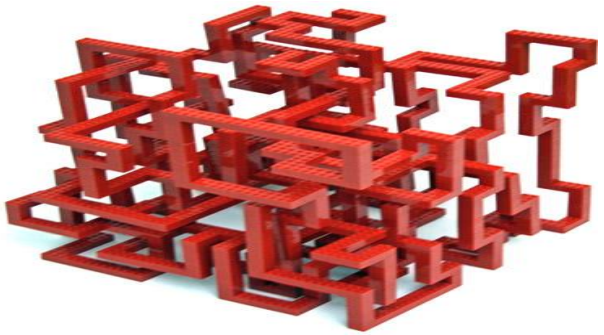
Participation of stakeholders in the subsequent review process

- Only clarifying questions asked to the manufacturer during the 180 days assessment period
- We use clinicians as experts during the process
- We might also use stakeholders from patient organisations if needed

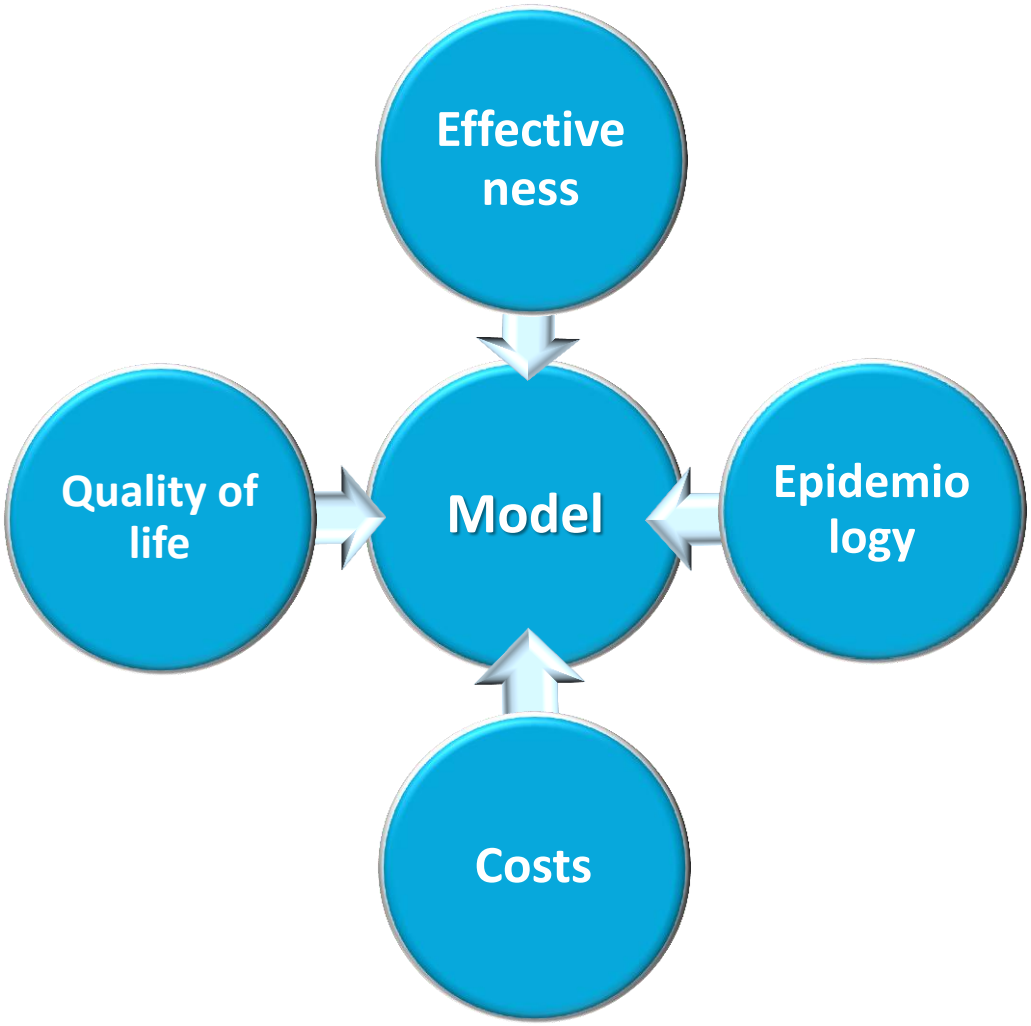
Management of Conflict of Interest

- The assessment report will be published in full by NOKC when final
- All documentation submitted will be subject to transparency
- All participating assessors and reviers have to complete CoI templates before comencing work
- Participants having CoI with the current assessment will be removed from the project

Economic modeling



- Models are an oversimplification of reality – which simulate outcomes and costs over time
- We do it to better investigate uncertainties both on costs and outcomes
- Needs assumptions and extrapolations from clinical data
- Timehorizon should be long enough to capture all relevant differences between intervention and compartor due to treatment



Models are an oversimplification of reality – which simulate outcomes and costs over time

Outputs from the evaluation

- YES
- YES with price negotiation
- NO

Future improvements and learnings

- To better select the most important new methods for assessment
  - Large patient groups
  - Costly methods (large budget impact)
  - Inequalities in health
  - Differences in usage to be expected
  - Use input from stakeholders also in the selection process