Developing New HTA Methodology for Policy Decisions
Results of Health Technology Assessment (HTA) methodology development grant program

The ZonMw HTA-methodology grant program attracts applicants from all national research centers and received until now a high number of research proposals for funding. The Health Care Insurance Board (CVZ) is involved in the assessment of the relevance of these research proposals in relation to the outcomes research that is performed as part of policy regulations but also for her own assessment and appraisal procedures. A final grant is approved based on the decision of the ZonMw program committee incorporating clinical and scientific HTA-experts.

So far a total of 60 research projects have been granted and are now ongoing.

### Table 1

<table>
<thead>
<tr>
<th>CVZ priority topics</th>
<th>Number of ZonMW HTA-methodology studies (n)</th>
<th>Examples of projects</th>
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<tr>
<td>Decision making/Appraisal</td>
<td>n=13</td>
<td>– The role of severity of disease</td>
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<td>– To value different factors in the appraisal process</td>
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<td>Costs and Outcomes</td>
<td>n=29</td>
<td>– The Q in the QALY</td>
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<td>– When is it too expensive?</td>
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<tr>
<td>Design and Analysis (Outcomes Research)</td>
<td>n=18</td>
<td>– Value of Information</td>
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<td>– Optimizing collection of information</td>
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<td>– Clinical Practice</td>
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<td>– Productivity costs in cost-effectiveness studies on expensive drugs</td>
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<td>– Proxy HRQOL in Alzheimer</td>
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<td>– Prioritizing and designing outcomes research</td>
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<td>– Optimal design and clinical trials in orphan drugs</td>
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<td></td>
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<td>– Confounding in real-life cost-effectiveness studies</td>
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Review of results

Recent evaluation of the HTA-methodology program has provided insight in the position of different stakeholders on the value of the research that is currently going on in the program. Conclusions are:

- Most CVZ priority topics are being covered by ZonMw HTA-methodology research;
- Most HTA-methodology studies concern outcomes research and cost-effectiveness in daily practice. In some cases the level of detail of the research is probably too high in relation to HTA-issues that are relevant for decision making;
- CVZ indicated lack of research mainly on topics for the process of appraisal:
  - Severity of disease
  - Multiple criteria decision analysis.

Recommendations

Following evaluation and the consequent expert meetings, key recommendations on optimizing the utilization of methodological assessments products are:

- The link between HTA-methodology research, policy and practice needs to be improved;
- All HTA-studies should encompass recommendations on how their results can be used to improve reimbursement decisions;
- HTA-experts should structurally analyze to what extent (updates of) national pharmaco-economic guidelines are necessary as results of outcomes of HTA-methodology research;
- Participation in the European Network on HTA (EUnetHTA) and other international endeavors fosters efficient utilization of newly developed instruments in assessments.
Dutch policy regulations for expensive and orphan inpatient drugs were implemented in 2006. If a drug is included in these regulations, hospitals temporarily receive an additional ear-marked budget of 80% (100% for orphans) of its acquisition costs. The criteria for conditional inclusion in this policy regulation are:

- the drug has market authorization for a specific indication and has a therapeutic added value compared to usual care for this indication;
- expected drug costs are estimated to represent more than 0.5% of the average national hospital pharmaceutical budget;
- a clear research proposal for outcomes research that addresses appropriate drug use and cost-effectiveness in daily practice.

If the drug has been included in one of these policy regulations, there is an obligation to collect data on appropriate drug use and comparative (cost-) effectiveness in everyday practice (outcomes research). After four years of conditional use, a reassessment based on this evidence will determine whether or not additional funding will be continued. This type of funding new medical technologies, such as pharmaceuticals, is also known as coverage with evidence development (CED).

The Dutch Health Care Insurance Board (CVZ) is responsible for the evaluation of the therapeutic value, the estimation of expected costs and the proposal on evidence development on appropriate use and (cost-) effectiveness that is the basis for the outcomes research that needs to be performed in this period of four years. It is the responsibility of parties with vested interest in the use of the drug, such as the pharmaceutical company and the relevant healthcare providers (treating physicians and their hospitals) to adequately organize this outcomes research. After the end of the four-year period, all results from the outcomes research are re-evaluated by CVZ in order to advise whether the inclusion of the drug in this policy regulation should be continued indefinitely.

Final decisions on the conditional and indefinite inclusion of drugs in the policy regulations are made by the Dutch Health Care authority (NZa) based on the advice of CVZ.

However, for several reasons different parties like the pharmaceutical industry do not always see the benefit of undertaking outcomes research needed for continuation of the inclusion of their drugs in the policy regulation.

That was the reason for the Dutch Ministry of Health, Welfare and Sports to ask and finance the Netherlands Organization for Health Research and Development (ZonMw) to set up a grant program allowing funding of:

- outcomes research on drugs that have been conditionally included in these policy regulations for inpatient expensive and orphan drugs;
- development of HTA-methodology to be used as an instrument in outcomes research.

In this leaflet we would like to present you some insight in the second part of the grant program devoted to the development of HTA-methodology.

* NZa reimbursement list CI-1099 (expensive drugs) and CI-1061 (orphan drugs)
** NVZ = Dutch Hospitals Association / NFU = The University Medical centers of the Netherlands
Progress requires research and development. ZonMw funds health research and stimulates use of the knowledge developed to help improve health and healthcare in the Netherlands.

CVZ – Health Care Insurance Board

The tasks of the Health Care Insurance Board (CVZ) include providing advice and implementing the Dutch statutory health insurance. CVZ has a major role in maintaining the quality, accessibility and affordability of health care in the Netherlands. CVZ’s advice is based not only on care-related considerations, but also on considerations relating to finance and society.

More information can be found on following websites:
www.zonmw.eu/ES
www.cvz.nl/en