NVTAG

Nederlandse Vereniging voor Technology Assessment in de Gezondheidszorg

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Broadening HTA for the healthcare package

12:30-13:00	Arrivals & **lunch**
13:00-13:15	**Welcome** and introduction by Prof. Dr. Judith Bosmans (NVTAG)
13:15-14:00	**Policy keynote**. Dr. Saskia Knies (Zorginstituut) and Dr. Joost Enzing (Zorginstituut) on a better and broader assessment of the Dutch basic benefit package (VVTB; verbeteren en verbreden toets op het basispakket)
14:00-15:00	**Methodology contest**. NVTAG prize pitches by the nominees.
15:00-15:15	**Coffee** break
15:15-16:45	**Research panel**. Challenges when conducting HTA research in specific domains. Researchers reflecting on their HTA domain starting with a short (5 minute) presentation per researcher.
➢ Dr. Thea van Asselt (UMCG) - Screening/diagnostistics ➢ Dr. Hanneke van Dongen (VU) - Physiotherapy ➢ Dr. Janneke Grutters (RUMC) - Widely applicable medtech ➢ Prof. Dr. Leona Hakkaart (ESHPM) - van Roijen - Mental health care ➢ Prof. Dr. Erik Koffijberg (HTSR) - Digital innovations	
16:45-17:00	**Awarding** of the NVTAG Prize proudly sponsored by Lumanity.
17:00-17:30	**Drinks**

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Zorginstituut Nederland

Broadening Health Technology Assessment

To support setting boundaries to the basic benefit package

a policy perspective

Joost Enzing, PhD

National Health Care Institute

| Van goede zorg verzekerd |

Reimbursement decision-making process

- In the Dutch context, a **reimbursement decision-making process** has been gradually developed in which the evidence obtained in **Health Technology Assessment (HTA)** research plays an important role.

To be transparent, consistent and involve all relevant societal values

- This process has been operationalised and is currently most systematically applied for the evaluation of **new outpatient pharmaceuticals**.

Basic benefit package (Zvw & Wlz) expenditures 2023

Broadening HTA for the healthcare package

- Exploring why the process works well for pharmaceutical products may be useful when broadening its use to non-pharmaceuticals.
- The relative ease of applying the process to pharmaceutical products has to do with **laws and regulations**, **market situation** and the **characteristics of these products**.
- Let's look at some of these aspects and see why broadening may be a challenge.

Closed system for reimbursement

- Outpatient pharmaceuticals are covered in a '**closed system**', which is called the Drug Reimbursement System (GVS).
- Only when an outpatient pharmaceutical is on the 'positive list', it is reimbursed. To get on the list, the manufacturer needs to **request admission**.

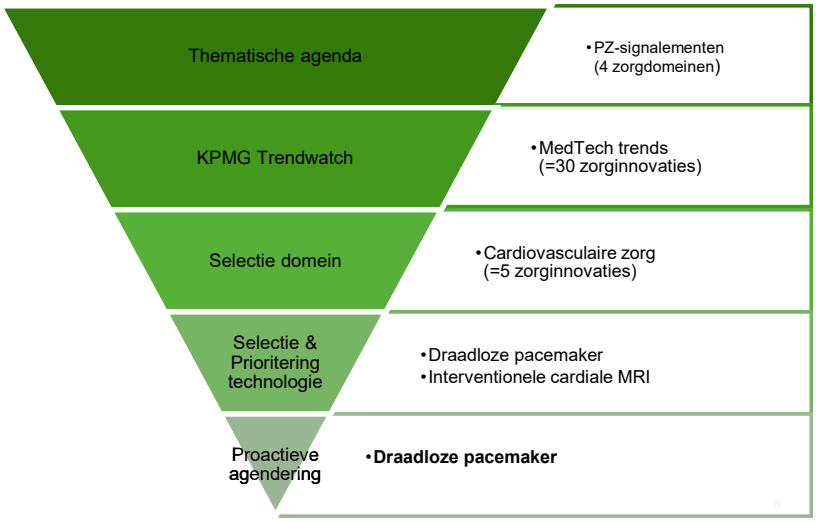
- **Strong incentive** for stakeholders to contribute to the HTA process.
- No need for policy makers to **actively search** for new interventions that could be made subject to HTA.

Open system for reimbursement

- Other types of care (e.g. medical devices) are part of the '**open system**' for reimbursement.
- Consequently, policy makers are not 'automatically' provided with an **inventory** of subjects for assessment, let alone with **HTA dossiers** for these technologies.
- So, how to identify interventions for assessment?

enter …… the Horizonscan MedTech

- **Objective**: proactive identification and agenda-setting of new and emerging medical technological innovations in the open system
- **Scope**: MedTech products that will have an impact on the insured healthcare package in the coming years.



Identifiable and accountable counterparty

- Many manufacturers of pharmaceuticals have the **resources** to initiate and finance the studies needed to obtain evidence on effectiveness and cost-effectiveness of their products.
- A manufacturer is typically holder of a patent which provides the **exclusive right** to manufacture and market this new intervention. Consequently, the expected financial revenues of reimbursement of the intervention will **benefit a single, identifiable entity**.

Identifiable and accountable counterparty

- Manufacturers in the MedTech sector are for a large part **small and medium enterprises** (SMEs) and **may lack the resources** (financial and knowledge) to produce the evidence required in a common HTA process.
- No identifiable and accountable counterparty may be present for other types of care.
- So, who will initiate and finance HTA research?

enter ….. The ‘Potentially Promising Care’ program

Veelbelovende zorg - Bronchiale thermoplastiek (BT) voor ernstig astma in het tijdperk van biologicals: een gerandomiseerd gecontroleerd onderzoek (BOOSTER-studie)

Via de subsidieregeling Veelbelovende zorg wordt onderzoek gesubsidieerd naar de (kosten)effectiviteit van bronchiale thermoplastiek bij volwassenen met ernstig, ongecontroleerd astma met 2 of meer exacerbaties in het afgelopen jaar, ondanks optimale therapie (inclusief een biological als zij daarvoor in aanmerking komen). Het project is gestart op 1 juli 2023 voor een periode van 6 jaar. Na afronding van het project worden de onderzoeksresultaten rond juli 2029 bij het Zorginstituut ingediend. We gebruiken deze onderzoeksgegevens om te beoordelen of deze behandeling bij de genoemde groep patiënten vergoed kan worden uit het basispakket van de zorgverzekering.

De aandoening en behandeling

Astma is een veelvoorkomende aandoening en is meestal goed onder controle te houden

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‘Potentially Promising Care’ program

- This research program can offer temporary **funding for potentially promising interventions** that are not reimbursed from the Dutch standard healthcare package.
- Funding is only granted if high-quality research data are collected during the subsidy period which can be used in the future to assess the **effectiveness and cost-effectiveness** of the intervention. (*Not for R&D*)
- A subsidy is granted for a **maximum of 6 years**.
- E.g. administering bacteriophages, physio and exercise therapy, medical Aids. (N*ot for on-label pharmaceuticals*)
- **€70 million per year** for total program.
- Within six months after a project has ended, Zorginstituut Nederland will use the research data to assess **whether or not** the treatment can be **reimbursed** from the Dutch standard healthcare package.

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Product characteristics of pharmaceuticals

- Pharmaceutical interventions are often **standardised products** with clearly defined use and functioning, which are aimed at improving patients' **length and health-related quality of life**.
- Their **effectiveness is mainly determined by the active substance**, or substances, they contain.
- Consequently, when these products are correctly dosed, their **effectiveness is relatively independent** of the person administering them or the organisational context in which they are provided.

Product characteristics of non-pharmaceuticals (1/4)

- First, their outcomes may be more **context-dependent**: personal characteristics of the care provider and the organisational context can influence how a device is used and hence the associated costs and effects.

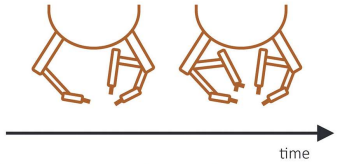
The Use of Decision Analytic Modeling in the Evaluation of Surgical Innovations: A Scoping Review
Mirre Scholte, MSc, Maroeska M. Rovers, PhD, Janneke P.C. Grutters, PhD
Value in Health / Volume 24 Issue 6 Pages 884-900 (June 2021) / DOI: 10.1016/j.jval.2020.11.020

Product characteristics of non-pharmaceuticals (2/4)

- Second, medical devices may **evolve** in daily practice. As a result, a device may develop during evidence collection, or the studied device might **not be equal** to its current version.
- In such contexts, research findings have a **lower external validity** and policy decisions may be based on outdated information.

Incremental innovation

The adaptation of the technique during the innovation process



Consequences for evaluation

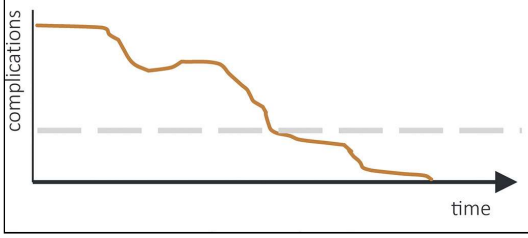
Technical specifications of a procedure might change during the research process, which influences trial outcomes over time.

Product characteristics of non-pharmaceuticals (3/4)

- Third**, learning effects** in their use add to the complexity. The (cost-)effectiveness of an intervention may improve over time due to such **individual or organisational** learning effects, raising questions about for instance optimal timing of data collection.

Learning curve

The time taken and/or the number of procedures an average surgeon needs to be able to perform a procedure independently with a reasonable outcome



Product characteristics of non-pharmaceuticals (4/4)

- In long-term care, the primary goal of the intervention to be evaluated is **not** always **health-related quality of life** (as measured by the EQ-5D-5L) and/or life extension, but well-being. The aim is not always improvement, but rather (learning to) live with a disability or specific retention of control.

- So, how to address al these challenging product characteristics?

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Guideline for economic evaluations in healthcare 2024 version

– More guidance for empirical evaluations and concerns related to non-pharmaceuticals.


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6 Areas of concern

Economic evaluations for decision-making in the Netherlands must be performed in accordance with the reference case (see **Chapter 1**). Specific areas of concern apply to a number of situations. These areas of concern are discussed in this chapter.

6.1 Sequential elements

The use of a certain intervention can affect the choice of a subsequent action. For example, in diagnostics and screening, different test results can lead to different types of follow-up examinations and other treatment strategies. In addition, using a certain intervention can affect the effectiveness of a subsequent intervention. Sequential consequences like these must therefore be part of the economic evaluation.

For model-based economic evaluations of diagnostics, where numerous successive tests are used, it is important to use conditional probabilities of test outcomes instead of independent probabilities.[75] Not only can a test lead to a (further) selection of tests (a negative test will not be followed by further tests, in contrast to a positive test), the probability of an outcome of a follow-up test is often dependent on the outcomes of one or more previous tests (for example the probability of a positive CT scan if lung cancer is suspected is, for example, greater after a positive x-ray than after a negative x-ray).

6.2 Incremental innovation

For some healthcare interventions, incremental innovation throughout their life cycle is expected. This is not exceptional in the case of medical devices, but it can also apply to other interventions. The intervention could be improved further during or after an economic evaluation has been performed. As a result it may be necessary to create a dynamic model for the effectiveness and the costs. It is important that the specifications of the care intervention investigated and any assumptions about (phased) innovation are accurately reported. The effect of any assumptions should be investigated in scenario analyses.

6.3 Learning curve

For many care interventions, such as medical devices, screening and surgical interventions, there is a learning curve which has an effect on the outcomes. This may have an impact on the external validity of the study results, such as when the findings of a study involving experienced users are generalised to the entire population. The opposite applies in the event that outcomes of a short-term study with inexperienced users are extrapolated over a longer time horizon. It is important that the effect of any learning curve is clarified using a scenario and/or uncertainty analysis, where the learning period is excluded.

6.4 Alternative outcomes

The primary aim of interventions in healthcare is not always to improve the health-related quality of life or extend the life expectancy of the patient. For some interventions, such as diagnostic tests and medical devices, effects may be achieved in terms of broader value components.[76, 77] Examples include convenience for the caregiver, or a reduction in the time

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ZonMW HTA methodology program

- Round 1: Methodology for valuation of **incrementally developing medical technology** (MedTech)
- Round 2: Methodology for valuation of technologies used within **non-curative care**
- Round 3: Methodology for measuring and evaluating labor input

- Estimating the (cost-)effectiveness of **e-health interventions** in mental health using **real-world data**
- W-MIC: multi-instrument comparison study for **well-being measurement** in the Netherlands
- Development of a multi-stakeholder **outcome measure** for the value of **remote patient management**
- New standard for assessing **Mental Health QoL for youth**; Development and Validation of the MHQoL-Y

Conclusion

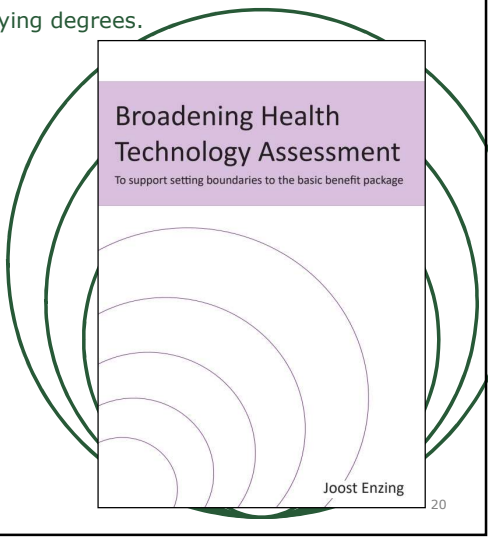
Other types of care deviate from pharmaceutical products - to varying degrees.

This makes assessing them - to varying degrees - challenging.

Some solutions are there, however a lot of questions remain:

Luckily we can ask the **research panel** today!

Thanks for your attention!



Improving and broadening the assessment of the Dutch basic benefit package

VVTB: Verbeteren en verbreden van de toets op het basispakket

Karen van Liere-Visser

Inhoudelijk secretaris VVTB, VWS, directie Zorgverzekeringen

NVTAG - 11 april 2024

Ministerie van Volksgezondheid, Welzijn en Sport

Package management …
What and why?

- What does it entail?
- Health Insurance Act & Long-Term Care Act
- Policy drivers for better package management
- Improving and broadening the assessment of the basic benefit package

Improved and broader assessment… How? We work along three lines:

1. Clear rules

- Clear frameworks on Effectiveness, Cost-Effectiveness, Necesssity, Feasibility (also integral) for which care is insured
- In progress: Labour deployement & Sustainability
- Starting: Amending laws and regulations

2. Everyone in his strength

- Parties are strengthened in their role of managing the basic benefit package
- Dialogues with parties, 1 on 1 and workgroup about their role and responsibility

3. Implementation better package management

- Improved assessment will be broader applied
- More often package advice from ZIN* AND assessment of effectiveness by parties
- Knowledge is needed: investments in more research and knowledge infrastructure, also Long-Term Care

VVVVTB – NVTAG- 11 april 2024

* ZIN: National Health Care Institute

We are open for questions and suggestions

Contact us at:

VVTB@minvws.nl

VVTB – NVTAG - 11 april 2024

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Zorginstituut Nederland

VVTB: What is the National Health Care Institute (ZIN) doing?

Saskia Knies
Coördinator VVTB
National Health Care Institute/Zorginstituut Nederland

| Van goede zorg verzekerd |

Package management in 2024

Healthcare should be of good quality, accessible and affordable

– Safeguard solidarity

Basic benefit package

– By law flexible system

– Largely an 'open' system and partly a 'closed' system

– Open system may lead to 'negative list' and closed system may lead to 'positive list'

Only smart part of basic benefit package assessed by National Health Care Institute (ZIN)

- Pharmaceuticals (outpatient and selection of inpatient)
- Interventions in hospitals/hospital care
- Physiotherapy

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IZA: Covenant on healthcare between VWS and healthcare parties

- Signed in September 2022
- Who signed: VWS, healthcare professionals, healthcare providers, health insurers, municipalities, patient federation

Example of agreements made:

- Stop paying for interventions that add no value
- **More evaluations of healthcare, not only of pharmaceuticals**
- **Use more criteria: need for staff, cost-effectiveness and sustainability**
- Work together on agenda of issues with most impact
- More evidence for and adherence of clinical guidelines
- More use of shared decision making/choosing aids for patients
- Substitution from hospital care to primary care and from physical care to e-health
- Concentration of expensive/high performance care

VVTB program VWS and ZIN

- Goal: Promoting substantiation of choices about which care should be reimbursed within all healthcare sectors
- Verbeteren en verbreden toets op het basispakket (VVTB)
  - Program till end 2025
  - VWS and ZIN working together with each different tasks

ZIN VWS

- For ZIN two main parts: **improving** and **broadening**

Datum 1 3 JULI 2023
Betreft Verzoek Zorginstituut inzake VVTB

Geachte heer Wijma,

Passende zorg moet nu en in de toekomst beschikbaar, toegankelijk en betaalbaar zijn. Met het 'verbeteren en verbreden van de toets op het basispakket' (hierna: VVTB) wordt hieraan bijgedragen. Hierbij is het essentieel om binnen álle zorgsectoren op een consistente en transparante wijze keuzes te maken over welke zorg vergoed moet worden binnen het basispakket. Over de voortgang van het VVTB heb ik de Tweede Kamer recent geïnformeerd[1]. Ik wil het Zorginstituut Nederland (hierna: het Zorginstituut) vragen om binnen de reguliere taken mede uitwerking te geven aan VVTB. Deze brief ziet voornamelijk toe op het onderdeel 'verbeteren' binnen VVTB, waarbij een aantal activiteiten onder het 'verbreden' van de toets ook al moet worden opgepakt. Begin volgend jaar verwachten we u een aanvullende brief te sturen waar het onderdeel 'verbreden' verder wordt ingevuld. Voor het duiden van de hoofdactiviteiten van verbreden in deze brief kort benoemd.

Verzoek aan Zorginstituut
Zoals al in de Kamerbrief aangegeven vraag ik het Zorginstituut zorg om verdere uitwerking te geven aan VVTB. Ik wil daarbij de volgende aandachtspunten meegeven.

Verbeteren van de toets op het basispakket
Ik verzoek het Zorginstituut zich te richten op het aanscherpen en concreter uitwerken van de bestaande pakketcriteria. Daarmee kunnen deze eenduidiger worden toegepast in de praktijk. Het uiteindelijke doel is een samenhangend geheel van eenduidige afwegingskaders van alle pakketcriteria, met ondersteunende handleidingen en informatiemateriaal voor veldpartijen. Daarnaast verzoek ik het Zorginstituut om te komen tot een kader op welke wijze de afzonderlijke criteria ten opzichte van elkaar worden gewogen in een pakketbeoordeling.

What do we mean with improving and broadening?

Improving (a.o.)

- Clarify the current package criteria (framework)
- Adding two new (sub)criteria
- Overall framework for all criteria
- Manuals for specific healthcare sectors
  - Focus on effectiveness

Broadening (a.o.)

Package management in the whole healthcare sector

- More assessments (non-pharmaceuticals) including mental healthcare and long-term care
- Elaboration criteria for long-term care

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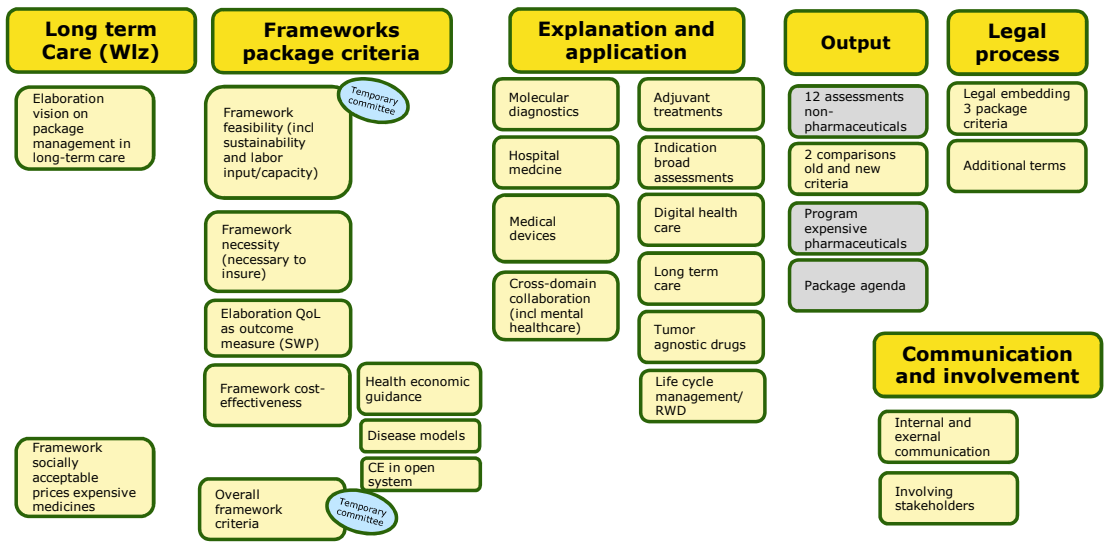

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Improving

Current criteria used in Dutch HTA process

1. Effectiveness (*knock-out criterion*): does the treatment do what it is supposed to do?

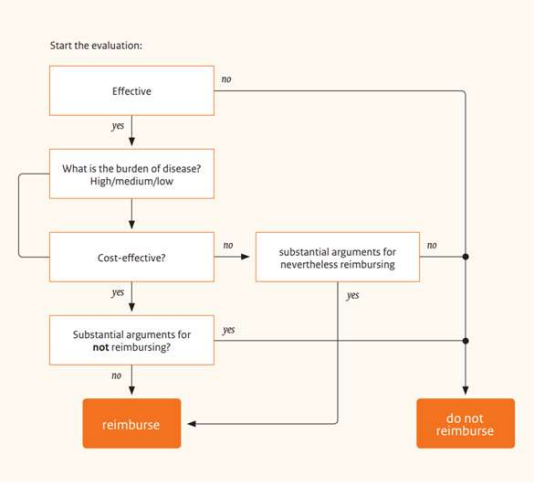
2. Necessity:

a) is the disease serious enough?

b) is health insurance the right instrument?

3. Cost-effectiveness: are the additional effects of a new treatment worth the additional investment compared to other available treatments?

4. Feasibility: is including a given treatment in the basis benefit package sustainable and feasible?



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HTA definition from 2020

Note 3: The dimensions of value for a health technology may be assessed by examining the intended and unintended consequences of using a health technology compared to existing alternatives. These dimensions often include clinical effectiveness, safety, costs and economic implications, ethical, social, cultural and legal issues, organizational and environmental aspects, as well as wider implications for the patient, relatives, caregivers, and the population. The overall value may vary depending on the perspective taken, the stakeholders involved, and the decision context.

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Looking at including two new criteria – why

Environmental sustainability (ecologische duurzaamheid)

- Climate change has an impact on health, and healthcare has impact on climate change
- Dutch healthcare sector is responsible for 7% of CO2-emissions, 4% of waste and 13% of resource usage
- Green Deal for healthcare sector

Labour input (arbeidsinzet)

- 1 in 7 (15%) of workforce works in healthcare sector, without change 1 in 4 (25%)
- Scarcity of healthcare personal (e.g. long-term care, home care) and informal caregivers
- Healthcare staff retiring in coming years or shortly after

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Broadening

Expenditures Health Insurance Act & Long-Term Care Act 2023

Broadening HTA or package management

Number of assessments done in 2023

- Approximately 50 pharmaceuticals (outpatient and inpatient)
- Approximately 10 hospital care/health insurance act
- None in long-term care

Assessments not only method used for package management

- Disputes (between health insurer and patient/client)
- Guidance (explanation of law)
- Standards (minimum requirements)

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Ideas within VVTB on broadening

- Specifying effectiveness for healthcare sectors
  - Molecular diagnostics
  - Digital healthcare
  - Long-term Care
  - Mental Health Care

- More assessments in other sectors especially
  - Mental health care
  - Long-term care
    - Elderly care
    - Disability care (mental, physical, blind, deaf)
    - Long term mental health

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Background information about long-term care

- Paid via income dependent premium from your gross salary and co-payments for users
- Total costs in 2022 around €30 billion
  - €15 billion elderly care, €9 billion disability care, €1.7 billion mental health
- Financed using care profiles (ZZP), e.g. ZZP 5 dementia without serious behavioural issues, ZZP 9 rehabilitation
- Why package management:
  - Long-term care should be accessible and available
  - Preventing ineffective care
  - Care placing disproportionate burden on people and resources
  - Care should be used appropriately and working at a reasonable price

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Assessments in long-term care: some difficulties

Methodological challenges within long-term care:

- Heterogeneous and complex patient population
- Several factors could cause variation in care delivery: difficulty to determine effectiveness of both intervention as control
- Outcomes not always objective: quality of existence, maintaining control (regie houden) or coping with disease

Other challenges:

- Most expected added value in long-term care: more integrated care
  - Assessing organisation of care has its own challenges
- Relative effectiveness: information is limited, not so much focus of research

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Core of VVTB for ZIN

- The package criteria have all been clearly developed using assessment frameworks (improvement)
- The criteria (ecological) sustainability and labor input are added to the package criteria (improvement)
- All package criteria are used across healthcare (broadening)

How:

- Develop assessment frameworks for all 4 package criteria
  - Effectiveness, cost-effectiveness, necessity and feasibility
- Temporary committee set up for advice on criteria environmental sustainability and labor input

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Methodology contest

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Methodology contest

www.Menti.com

Code: 6124 2413

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Coffee break

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25

Research panel

Challenges when conducting HTA research in specific domains

- Dr. Thea van Asselt - Screening/diagnostistics
- Dr. Hanneke van Dongen – Physiotherapy
- Dr. Janneke Grutters - Widely applicable medtech
- Prof. Dr. Leona Hakkaart - van Roijen - Mental health
- Prof. Dr. Erik Koffijberg - Digital innovations

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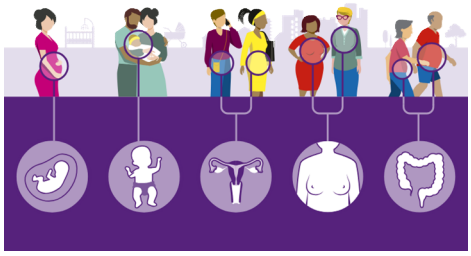
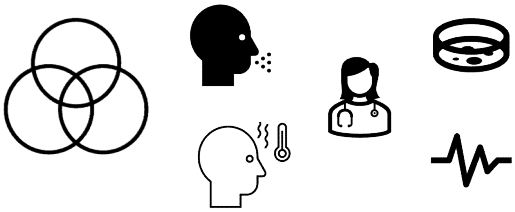
HTA in screening & diagnostics

Thea van Asselt
NVTAG Spring symposium
April 2024

umcg

Screening versus (?) diagnostics





https://www.rivm.nl/bevolkingsonderzoeken-en-screeningen/welke-bevolkingsonderzoeken-zijn-er

PharmacoEconomics (2021) 39:1411–1427
https://doi.org/10.1007/s40273-021-01054-1

Abstract

Background Diagnostic testing for respiratory tract infections is a tool to manage the current COVID-19 pandemic, as well as the rising incidence of antimicrobial resistance. At the same time, new European regulations for market entry of in vitro diagnostics, in the form of the in vitro diagnostic regulation, may lead to more clinical evidence supporting health-economic analyses.

Objective The objective of this systematic review was to review the methods used in economic evaluations of applied diagnostic techniques, for all patients seeking care for infectious diseases of the respiratory tract (such as pneumonia, pulmonary tuberculosis, influenza, sinusitis, pharyngitis, sore throats and general respiratory tract infections).

Methods Following the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guidelines, articles from three large databases of scientific literature were included (Scopus, Web of Science and PubMed) for the period January 2000 to May 2020.

Results A total of 70 economic analyses are included, most of which use decision tree modelling for diagnostic testing for respiratory tract infections in the community-care setting. Many studies do not incorporate a generally comparable clinical outcome in their cost-effectiveness analysis: fewer than half the studies (33/70) used generalisable outcomes such as quality-adjusted life-years. Other papers consider outcomes related to the accuracy of the test or outcomes related to the prescribed treatment. The time horizons of the studies generally are limited.

Conclusions The methods to economically assess diagnostic tests for respiratory tract infections vary and would benefit from clear recommendations from policy makers on the assessed time horizon and outcomes used.

UMCG, Sector F, afdeling Gezondheidswetenschappen,
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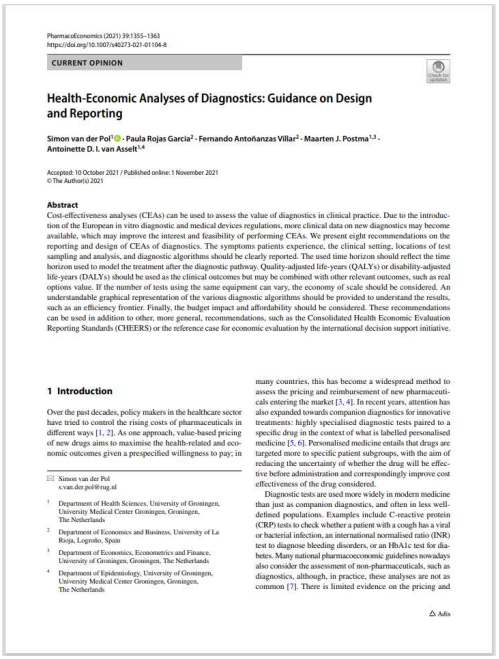

PharmacoEconomics (2021) 39:1355–1363
https://doi.org/10.1007/s40273-021-01104-8

CURRENT OPINION

Health-Economic Analyses of Diagnostics: Guidance on Design and Reporting

Simon van der Pol[1] · Paula Rojas García[2] · Fernando Antoñanzas Villar[2] · Maarten J. Postma[1,3] · Antoinette D. I. van Asselt[1,4]

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Abstract
Cost-effectiveness analyses (CEAs) can be used to assess the value of diagnostics in clinical practice. Due to the introduction of the European in vitro diagnostic and medical devices regulations, more clinical data on new diagnostics may become available, which may improve the interest and feasibility of performing CEAs. We present eight recommendations on the reporting and design of CEAs of diagnostics. The symptoms patients experience, the clinical setting, locations of test sampling and analysis, and diagnostic algorithms should be clearly reported. The used time horizon should reflect the time horizon used to model the treatment after the diagnostic pathway. Quality-adjusted life-years (QALYs) or disability-adjusted life-years (DALYs) should be used as the clinical outcomes but may be combined with other relevant outcomes, such as real options value. If the number of tests using the same equipment can vary, the economy of scale should be considered. An understandable graphical representation of the various diagnostic algorithms should be provided to understand the results, such as an efficiency frontier. Finally, the budget impact and affordability should be considered. These recommendations can be used in addition to other, more general, recommendations, such as the Consolidated Health Economic Evaluation Reporting Standards (CHEERS) or the reference case for economic evaluation by the international decision support initiative.

1 Introduction

Over the past decades, policy makers in the healthcare sector have tried to control the rising costs of pharmaceuticals in different ways [1, 2]. As one approach, value-based pricing of new drugs aims to maximise the health-related and economic outcomes given a prespecified willingness to pay; in many countries, this has become a widespread method to assess the pricing and reimbursement of new pharmaceuticals entering the market [3, 4]. In recent years, attention has also expanded towards companion diagnostics for innovative treatments: highly specialised diagnostic tests paired to a specific drug in the context of what is labelled personalised medicine [5, 6]. Personalised medicine entails that drugs are targeted more to specific patient subgroups, with the aim of reducing the uncertainty of whether the drug will be effective before administration and correspondingly improve cost effectiveness of the drug considered.

Diagnostic tests are used more widely in modern medicine than just as companion diagnostics, and often in less well-defined populations. Examples include C-reactive protein (CRP) tests to check whether a patient with a cough has a viral or bacterial infection, an international normalised ratio (INR) test to diagnose bleeding disorders, or an HbA1c test for diabetes. Many national pharmacoeconomic guidelines nowadays also consider the assessment of non-pharmaceuticals, such as diagnostics, although, in practice, these analyses are not as common [7]. There is limited evidence on the pricing and

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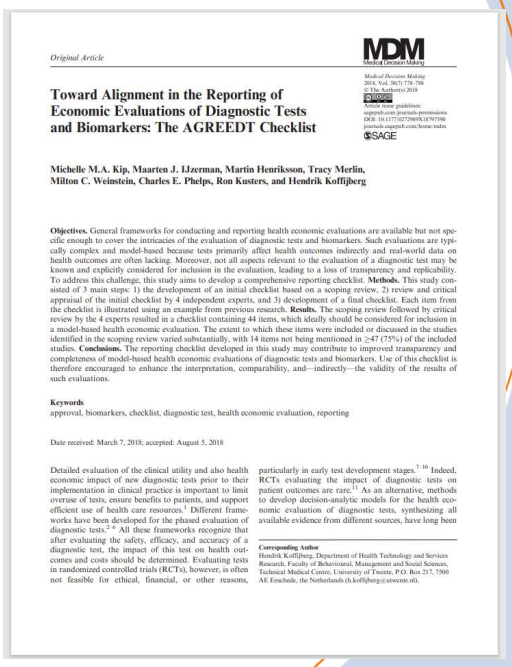

Original Article

MDM Medical Decision Making

Toward Alignment in the Reporting of Economic Evaluations of Diagnostic Tests and Biomarkers: The AGREEDT Checklist

Medical Decision Making
2018, Vol. 38(7) 778–788

DOI: 10.1177/0272989X18797596
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Michelle M.A. Kip, Maarten J. IJzerman, Martin Henriksson, Tracy Merlin, Milton C. Weinstein, Charles E. Phelps, Ron Kusters, and Hendrik Koffijberg

Objectives. General frameworks for conducting and reporting health economic evaluations are available but not specific enough to cover the intricacies of the evaluation of diagnostic tests and biomarkers. Such evaluations are typically complex and model-based because tests primarily affect health outcomes indirectly and real-world data on health outcomes are often lacking. Moreover, not all aspects relevant to the evaluation of a diagnostic test may be known and explicitly considered for inclusion in the evaluation, leading to a loss of transparency and replicability. To address this challenge, this study aims to develop a comprehensive reporting checklist. **Methods.** This study consisted of 3 main steps: 1) the development of an initial checklist based on a scoping review, 2) review and critical appraisal of the initial checklist by 4 independent experts, and 3) development of a final checklist. Each item from the checklist is illustrated using an example from previous research. **Results.** The scoping review followed by critical review by the 4 experts resulted in a checklist containing 44 items, which ideally should be considered for inclusion in a model-based health economic evaluation. The extent to which these items were included or discussed in the studies identified in the scoping review varied substantially, with 14 items not being mentioned in ≥47 (75%) of the included studies. **Conclusions.** The reporting checklist developed in this study may contribute to improved transparency and completeness of model-based health economic evaluations of diagnostic tests and biomarkers. Use of this checklist is therefore encouraged to enhance the interpretation, comparability, and—indirectly—the validity of the results of such evaluations.

Keywords
approval, biomarkers, checklist, diagnostic test, health economic evaluation, reporting

Date received: March 7, 2018; accepted: August 5, 2018

Detailed evaluation of the clinical utility and also health economic impact of new diagnostic tests prior to their implementation in clinical practice is important to limit overuse of tests, ensure benefits to patients, and support efficient use of health care resources.[1] Different frameworks have been developed for the phased evaluation of diagnostic tests.[2–6] All these frameworks recognize that after evaluating the safety, efficacy, and accuracy of a diagnostic test, the impact of this test on health outcomes and costs should be determined. Evaluating tests in randomized controlled trials (RCTs), however, is often not feasible for ethical, financial, or other reasons, particularly in early test development stages.[7–10] Indeed, RCTs evaluating the impact of diagnostic tests on patient outcomes are rare.[11] As an alternative, methods to develop decision-analytic models for the health economic evaluation of diagnostic tests, synthesizing all available evidence from different sources, have long been

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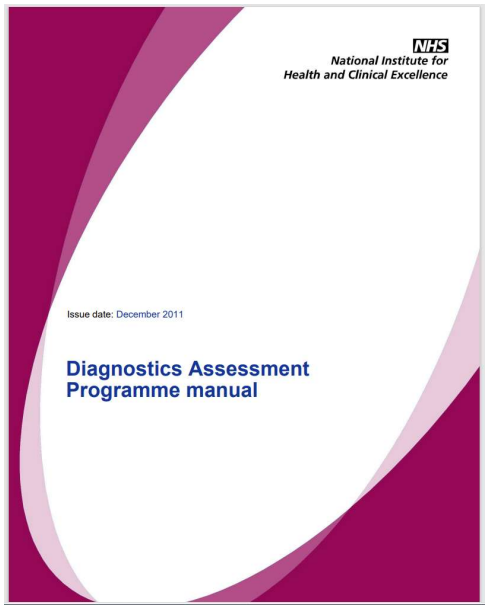
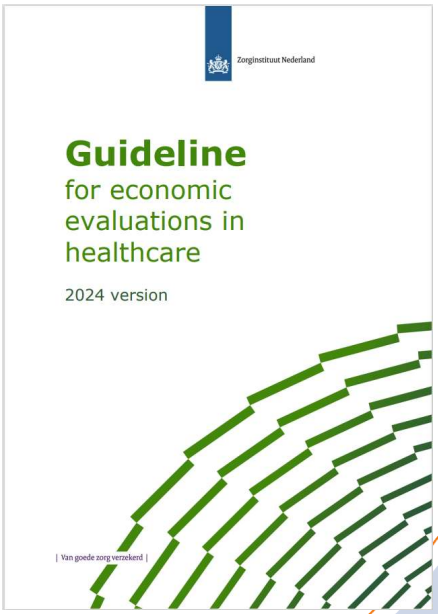


NHS
National Institute for Health and Clinical Excellence

Issue date: December 2011

Diagnostics Assessment Programme manual



Zorginstituut Nederland

Guideline
for economic evaluations in healthcare

2024 version

| Van goede zorg verzekerd |

Challenges

- Lack of clear guidance/sense of relevance for HTA
  - May improve over time with MDR/IVDR?
- Time horizon should include treatment pathway up to final patient outcomes
  - Difficult to link final patient outcomes to diagnostic test
  - Who is responsible for collecting the evidence?
- QALY? Also broader values
  - Value of knowing, spillover effects, fear of contagion/disease, etc

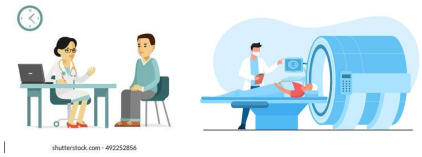
MUSCULOSKELETAL HEALTH AND REHABILITATION

Allied healthcare

Devices

Operating procedures

Patient follow-up and imaging



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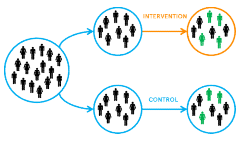
MUSCULOSKELETAL HEALTH AND REHABILITATION

Strong tradition of conducting clinical trials/RCTs



Children, adults, and older adults

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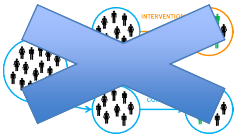
CHALLENGES

Randomization not always possible



Manufacturers & patients sometimes resistant/hesitant to participate

Manufacturers & healthcare providers sometimes resistant/hesitant to provide unit price information

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NEEDS

Methods for non-randomized studies

Real-world data sources/methods

How to deal with missing intervention cost info?

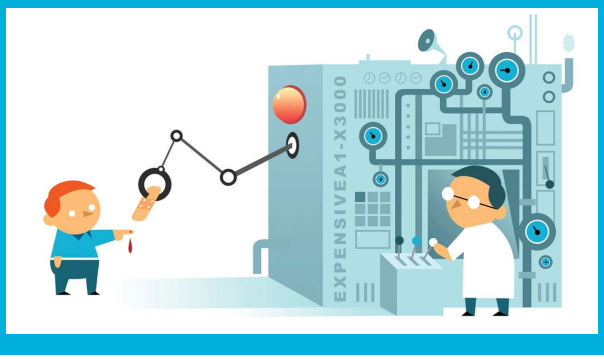
How to deal with hesitancy to using EQ-5D-5L?

EQ-5D

58

Widely applicable medtech

Janneke Grutters



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EUROPEAN UROLOGY 64 (2013) 361–369

available at www.sciencedirect.com
journal homepage: www.europeanurology.com

European Association of Urology

Platinum Priority – Prostate Cancer

Editorial by Anders S. Bjartell, Gunnar Steineck and Eva Haglind on pp. 370–371 of this issue

Comparative Cost-effectiveness of Robot-assisted and Standard Laparoscopic Prostatectomy as Alternatives to Open Radical Prostatectomy for Treatment of Men with Localised Prostate

Conclusions: Higher costs of robotic prostatectomy may be offset by modest health gain resulting from lower risk of early harms and positive margin, provided >150 cases are performed each year. Considerable uncertainty persists in the absence of directly comparative randomised data.

Craig Ramsay[b], *Robert Pickard*[a,*]

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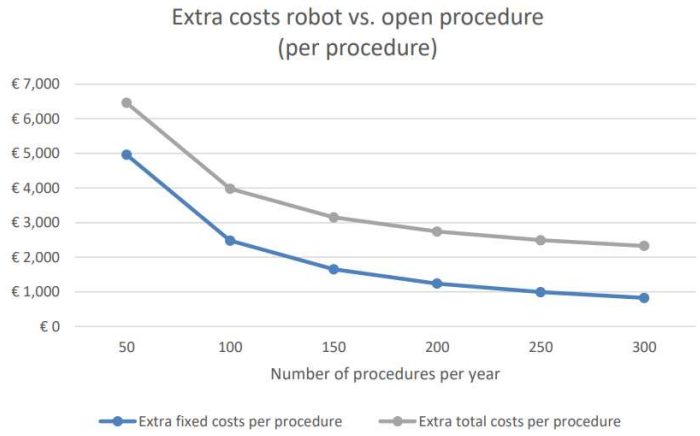
Higher utilization = more cost-effective?



Patel et al, BMJ Surg Interv Health Technol 2021

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Challenges

- Costs depend on utilization (e.g. indications, number of patients, learning curve, …)
- Benefits depend on context (e.g. indication, position in pathway, learning curve, …)
- Benefits often other (broader?) than survival or quality of life
- Sunk costs of empirical research
- Incremental innovation

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Needs

- Awareness that it is not possible to determine *the* value of widely applicable technologies

- In need of flexible tools to facilitate flexible analyses
- Technology-specific HTA?
- Optimization vs. assessment

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Erasmus School of Health Policy & Management

institute for Medical Technology Assessment

HTA in mental health care; taking the societal perspective

NVTAG panel Broadening HTA

11 April 2024

Erasmus University Rotterdam

Background

- High prevalence and incidence of mental problems
- High societal burden
- Inefficient care
- Adults and children
- HTA challenges

HTA methodology

- Somatic care
- Societal perspective
- eHealth interventions
- Tools

Erasmus School of Health Policy & Management

Tools

- iPCQ
- TiC-P
- Decision tools
- MHQoL & MHQoL-Y
- Wellbeing instrument-Y

Challenges

- Improve quality and cost-effectiveness of mental health care
- Evidence based
- Societal perspective
- Tools (costs & effects)

Save the date 13 December 2024!

- What: HTA symposium on mental health; taking a societal perspective
- Where: Erasmus University Rotterdam: Het Paviljoen (from 11.30 hours)
- Chair Prof. Werner Brouwer, speakers e.g. Prof . Jan van Busschbach, prof Loes Keijzer (KNAW prize winner)
- Including lunch
- Inauguration lecture Prof. dr. Leona Hakkaart (16.00 hours)

Invitation symposium HTA & mental health

- **hakkaart@eshpm.eur.nl**

Technology Assessment of Digital Health Innovations

Erik Koffijberg

NVTAG Spring Symposium

Broadening HTA for the healthcare package

UNIVERSITY OF TWENTE. | Health Technology & Services Research

Digital health innovations

Digital remote care (ICT)

Home monitoring (sensors)

Self-management (wearables, apps)

Personalized care (data & AI)

Algorithms processing data: input to output

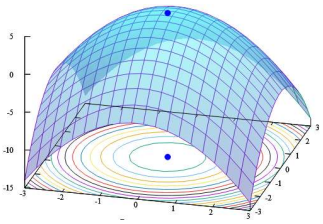
25

HTA of digital innovations

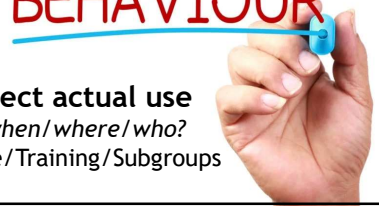
	Challenges
1.	- The continuous rapid updating of innovations - The black box nature of some algorithms (AI)
2.	Optimal conversion of output to recommendations (e.g. risk thresholds)
3.	Optimal visualization of results and recommendations (GUI)
4.	The unprecedented development speed

New HTA methods are needed

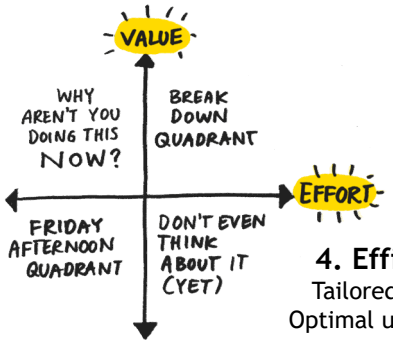
1. Living HTA
"It's always outdated unless it's automated"©



2. Optimization
$\mathcal{M}$
metamodels



3. Reflect actual use
How/when/where/who?
Adherence/Training/Subgroups



4. Efficient HTA
Tailored assessments
Optimal use of your time

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25

Research panel

Challenges when conducting HTA research in specific domains

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Broadening HTA for the healthcare package

12:30-13:00	Arrivals & **lunch**
13:00-13:15	**Welcome** and introduction by Prof. Dr. Judith Bosmans (NVTAG)
13:15-14:00	**Policy keynote**. Dr. Saskia Knies (Zorginstituut) and Dr. Joost Enzing (Zorginstituut) on a better and broader assessment of the Dutch basic benefit package (VVTB; verbeteren en verbreden toets op het basispakket)
14:00-15:00	**Methodology contest**. NVTAG prize pitches by the nominees.
15:00-15:15	**Coffee** break
15:15-16:45	**Research panel**. Challenges when conducting HTA research in specific domains. Researchers reflecting on their HTA domain starting with a short (5 minute) presentation per researcher.
➢ Dr. Thea van Asselt (UMCG) - Screening/diagnostistics ➢ Dr. Hanneke van Dongen (VU) - Physiotherapy ➢ Dr. Janneke Grutters (RUMC) - Widely applicable medtech ➢ Prof. Dr. Leona Hakkaart (ESHPM) - van Roijen - Mental health care ➢ Prof. Dr. Erik Koffijberg (HTSR) - Digital innovations	
16:45-17:00	**Awarding** of the NVTAG Prize proudly sponsored by Lumanity.
17:00-17:30	**Drinks**

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And the winner is …

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