JOURNAL CLUB:

BROADENING THE APPLICATION OF HEALTH TECHNOLOGY ASSESSMENT IN THE NETHERLANDS: *A WORTHWHILE DESTINATION BUT NOT AN EASY RIDE?*

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INTRODUCTION

- **Societal problem:** Healthcare costs constitute a significant part of total public spending in the Netherlands → policy instruments to limit costs but maintain an efficient and equitable healthcare system → E.g., Health technology assessment (HTA)
- **Scientific problem:** Main application of HTA → Outpatient pharmaceuticals→

  "only a limited number of other health care technologies have been subject to an HTA process in the Netherlands"

  - International phenomenon
  - Worldwide initiatives started to work on this.

Pharmaceuticals provided by community pharmacists or dispensing general practitioners: contrary to drugs provided by hospital pharmacists, medical devices, mental health interventions, etc.

Aim: broadening use of HTA →

- better use of HTA as a policy instrument
- more comprehensive evaluation of technologies
- Fairer use of the decision-making process across different technologies

CHALLENGE

AIMS

- Identify important challenges of broadening the application of HTA research and the decision-making process based upon it
- Specifically for the Dutch context
- Present an overview of HTA challenges → explore possible solutions

Structure:

1. Dutch reimbursement system and HTA process
2. Characteristics of outpatient pharmaceuticals
3. Characteristics and challenges of the five types of health technologies which could be subject to Dutch HTA.

REIMBURSEMENT DECISIONS AND HTA IN THE NETHERLANDS

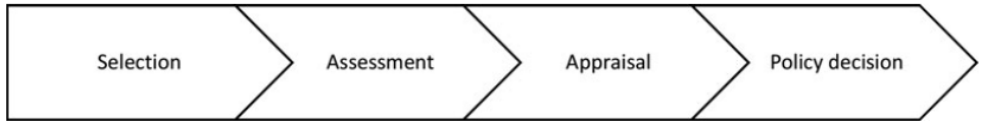

Figure 1. Phases in the reimbursement decision-making process.

Based on income and risk solidarity through insurance schemes

Health Insurance Act: insurers are obliged to cover the basic benefit package (BBP)

Content of BBP → Minister of Health (MoH)

Open system: follows the development w/o interference of MoH

- MoH can **intervene** by making changes in the legal framework (excluding selected interventions from reimbursement → placing them on a negative list) or postpone its reimbursement if there are disproportionately high costs

Outpatient drugs → covered in the **closed system** (unlike the other technologies)

- **Positive list:** the MoH positive → the drug is placed on the list → reimbursed
- **MoH can use an HTA-based reimbursement decision-making process.**

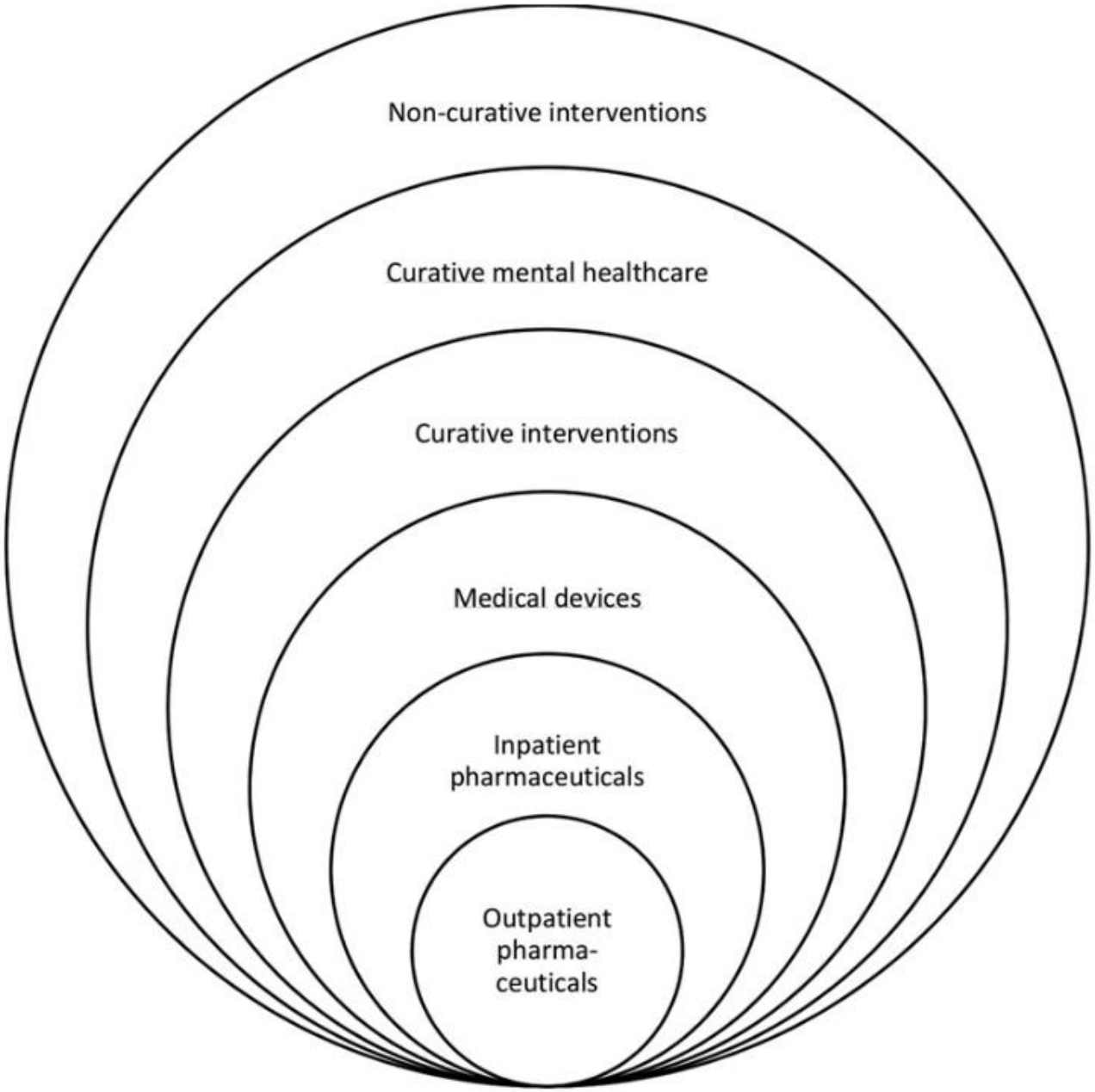

Figure 3. Illustration of five types of health technologies and their relative distance from outpatient pharmaceuticals.

Characteristics	Outpatient pharmaceuticals	Others
Closed system for reimbursement	-Stakeholders are obliged to use HTA -Policy makers not required to actively search for new interventions	-Open system -No requirement of submitting evidence on effectiveness and cost-effectiveness -Policy makers are not ‘automatically’ provided with evidence → need to screen and select
Absence of alternative policy measures		
Marketing authorization		
Identifiable and accountable counter party		
Product characteristics of pharmaceuticals		

CHARACTERISTICS OF THE DUTCH OUTPATIENT PHARMACEUTICAL SECTOR

Problem	Effect
Closed system for reimbursement	-Horizon scanning? → Also limited to new pharmaceuticals -Specific methodologies and process → national programmes to identify low-value care -Withdrawal of established interventions? -Challenge to obtain cooperation An open system does not financially incentivise stakeholders to enrol in an HTA process, also because the intervention is already reimbursed during its assessment. Hence, the only change relative to that status quo resulting from an HTA **would be negative**

Points to discuss:
Is horizon scanning enough? How can we improve cooperation between stakeholders?

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Absence of alternative policy measures	-Need to apply HTA is likely to increase -Once BBP are admitted, no specific budgeting policies are in place → not optimal	-Budget restrictions exist for each of the other types of health technologies, in the Dutch setting -Require local budget holders to make choices, based on relevant criteria (for them)
Marketing authorization		
Identifiable and accountable counter party		
Product characteristics of pharmaceuticals		

CHARACTERISTICS OF THE DUTCH OUTPATIENT PHARMACEUTICAL SECTOR

Problem	Effects
Absence of alternative policy measures	-Not perceived need to apply HTA in other technologies (compared to the outpatient pharma) -Lower engagement in HTA -Differences between care provided (budget holders may make different choices) -Not alignment with central level

Points to discuss:
Is expanding the use of HTA the solution? How to do so? Challenges?

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Marketing authorization	Provides evidence on the safety and efficacy that can be used later on for HTA	-No market authorization procedure is in place for most non-pharma interventions → cannot be used for HTA (exception of Med Devices)
Identifiable and accountable counter party		
Product characteristics of pharmaceuticals		

CHARACTERISTICS OF THE DUTCH OUTPATIENT PHARMACEUTICAL SECTOR

Problem	Effects
Marketing authorization	-Information need to be obtained from other sources (e.g., scientific literature) → may be lacking, differ in strength, not easily available -Need of public funding for evidence generation -Some of the interventions, including authorized devices, may not be suitable for common types of evaluation (like RCTs) → need of new methodoloiges to scan new or “risky” interventions

Points to discuss:
System to focused on pharmaceuticals? How to deal with differences in evidence (generation)?
When is the tipping point for accepting “lower” evidence?

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Identifiable and accountable counter party	-Manufacturer is capable of producing required evidence -They will benefit from the financial revenues of the intervention being used → clear who needs to produce the evidence (risk outside ZIN)	-Similar case for Medical devices → but SME → lack the financial and knowledge resources for HTA -In other tech, a single manufacturer may not even exist → who is responsible for evidence gathering and HTA processes?
Product characterisrics of pharmaceuticals		

CHARACTERISTICS OF THE DUTCH OUTPATIENT PHARMACEUTICAL SECTOR

Problem	Effects
Identifiable and accountable counter party	-no single entity may own the exclusive right to market the intervention →Creating evidence in the absence of an accountable counterparty then logically would become a **public task** **-Programmes**. E.g. Potentially promising care → annual budget of €69 million to provide temporary public funding for research into potentially promising intervention • However, the funding of research activities is limited to 20% of the total grant.

Points to discuss:
How to aid SME working in Medical devices? Are programmes enough?

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Product characteristics of pharmaceuticals	-Often standardised products with clearly defined use and functioning, -Aimed at improving patients' length and health-related quality of life.	-Only for inpatient pharmaceuticals. -Medical devices: context-dependent, learning curves, evolve -(Non) curative and mental healthcare: often intangible

CHARACTERISTICS OF THE DUTCH OUTPATIENT PHARMACEUTICAL SECTOR

Problem	Effects
Product characteristics of pharmaceuticals	-Need for alternative adaptative HTA processes -Diversity of the intendeded outcomes → methodological challenge. • E.g., mental health may be aimed at improve outcomes beyond HRQoL of the individual patient, such as well-being, autonomy, reduce criminality or drug abuse, etc. → need of further research: new instruments/alternative HTA processes

Points to discuss:
Is HTA too focused on one type of outcome? How can it be expanded without losing validity?

CONCLUSION

- Heterogeneity of health technologies in terms of (intensity of) deviations from the characteristics of outpatient pharmaceuticals, broadening the scope of HTA may be challenging – and more so in some areas than in others.
- it is important for (Dutch) policy makers aspiring to broaden the application of HTA, to do so gradually and aware of the various challenges they are likely to face. A logical route forward may be to start the expansion in those areas in which the number and difficulty of the existing challenges may be least
- Such a route forward in the broader application of HTA is encouraged. While a bumpy road may lay ahead, a conscious planning may ease the travel, and the destination certainly is worthwhile

THANKS

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