



---

TANDVÅRDS- OCH

---

LÄKEMEDELSFÖRMÅNSVERKET

---

# Stakeholders' perspectives on real-world evidence generation – HTA

Niklas Hedberg

Chief Pharmacist, TLV, Sweden

EMA Workshop, 2025-12-15

# Alzheimers disease, the perfect storm?



# Challenges from four perspectives

## **The patient perspective and follow up**

- Control group (MCI)
- Claims data
- Adequate registers
- Resources
- QoL PRO

## **Cost perspective**

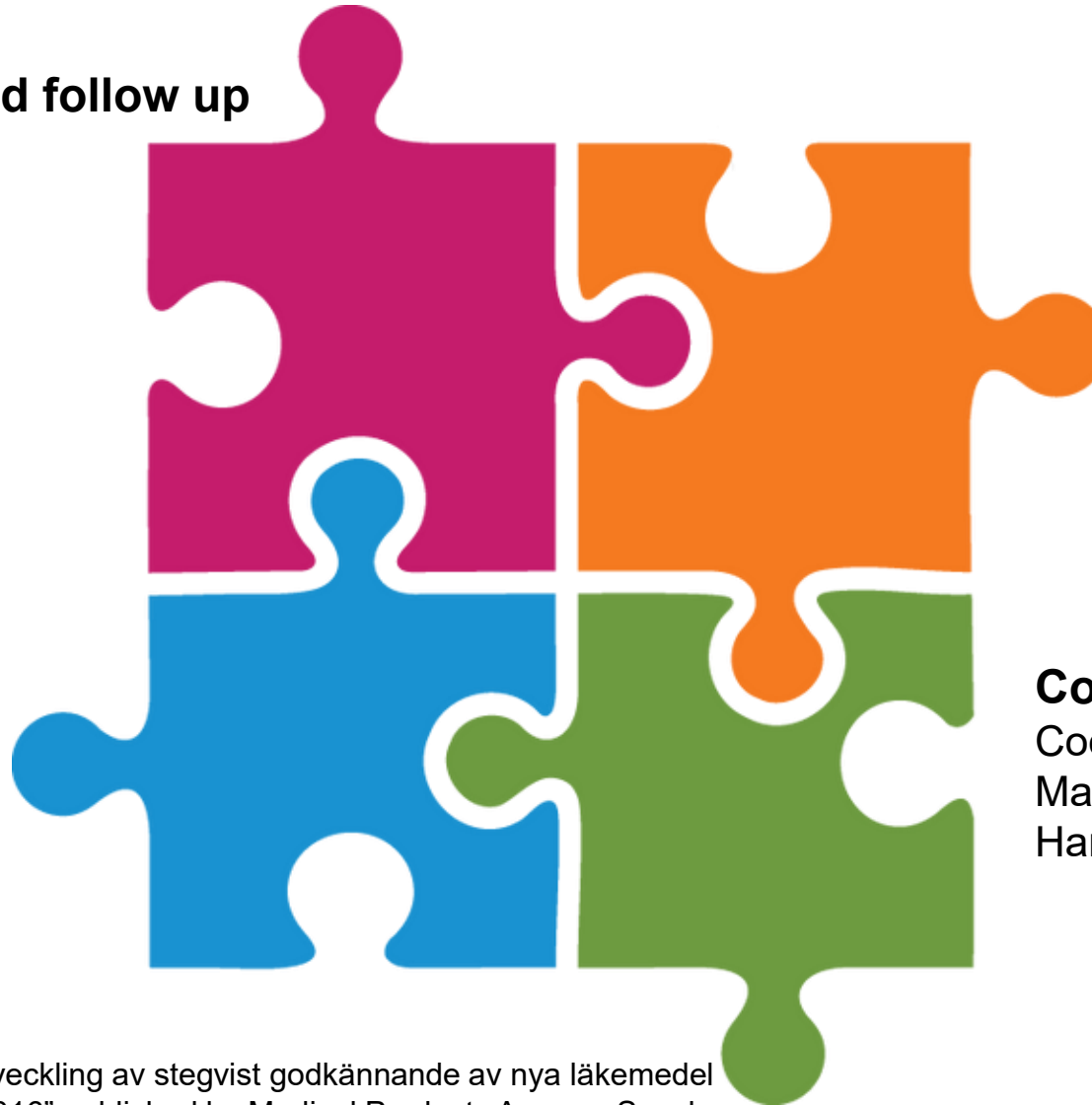
- Societal perspective
- Payment model
- Link prescription – register
- Health care perspective  
(regions – municipalities)

## **Diagnosis perspective**

- Start treatment
- Stop treatment
- Equitable care
- Diagnostics
- New or off label use

## **Communication Perspective**

- Coordination
- Manage expectations
- Handle high demand



# What do I (still) think that we need to do?

- Invest in registries, both for historical data and for treated patients.
- Make sure to follow the indication and use.
- Clarify start and stop criteria and make them well known and accepted.
- Sort out if costs can truly be avoided or rather postponed.
- Engage in discussions about new payment models and/or risk sharing programs.
- Handle the ethics concerning the need and solidarity principle.
- Compare the effectiveness of treatments as a course vs continuous
- Continue cooperation or exchange of information between different stakeholders.



# Thank you!

