



La sfida dell'innovazione terapeutica  
centrata sui bisogni della persona:  
aspetti regolatori e accesso alle terapie

# La declinazione del valore per le agenzie di HTA: una visione globale

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Prima Sessione:  
Innovazione  
farmaceutica e  
personalizzazione  
nell'era post Covid-19

HTA and its definition

What has changed with COVID if any?

What should HTA do?

- From single Technology appraisal to the assessment of interventions
- The Management of complexity
- Scoping
- Values and value



*INAHTA*

# HTA and its definition. Back to the roots

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- *HTA is a multidisciplinary process that uses explicit methods to determine the value of a health technology at different points in its lifecycle. The purpose is to inform decision-making in order to promote an equitable, efficient, and high-quality health system.*
- Note 1: A health technology is an intervention developed to prevent, diagnose or treat medical conditions; promote health; provide rehabilitation; or organize healthcare delivery. The intervention can be a test, device, medicine, vaccine, procedure, program, or system (definition from the HTA Glossary; <http://htaglossary.net/health+technology>).



Even more...

- 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**.

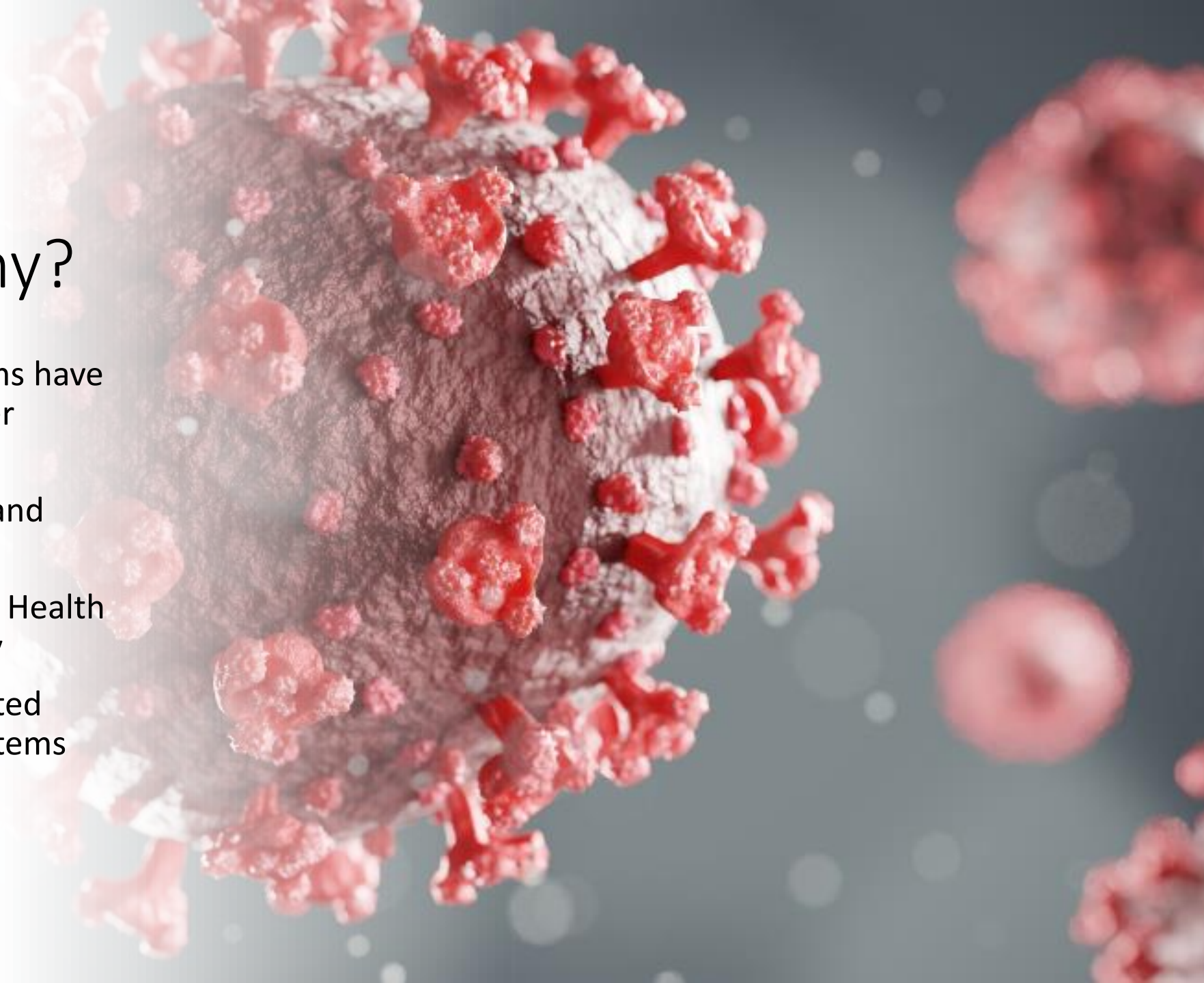


# The life cycle

- Note 4: HTA can be applied at different points in the **lifecycle** of a health technology, that is, pre-market, during market approval, post-market, through to the disinvestment of a health technology.

# What has changed with COVID19, if any?

- The change in how systems have been in need to face other pathologies but COVID19
- The focus on prevention and rehabilitation
- The need to assess Public Health Interventions as a priority
- The impact of COVID related investment on Health systems budget



# What is the key question?



- How comfortable could we live with uncertainty?
- Which level of uncertainty is acceptable?
- When?

# Does it only relate to COVID19?

- No, it has been also seen with new therapies (disruptive)
  - High Price
  - Uncertainty on mid long-term benefits
  - Need of combinations
  - Personalized management







# What should HTA do?

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- Trying to avoid single Technology appraisals
  - Technologies did not act separately,...
  - Diagnostics + drugs
  - Diagnostics + devices + drugs
  - Combination of drugs
- Recognizing complexity
  - The value of a single technology could not be separated from the context, the life cycle, the characteristics of the patients,...
- Analyzing the problem and the questions to be made in a holistic way
- Applying the definition

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# Addressing complexity

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- The INTEGRATE HTA model
- Technologies can not be individually interpreted
- Outcomes are related to a combination of circumstances
- Technologies act within a framework that is called intervention

INTEGRATE-HTA



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# Scoping

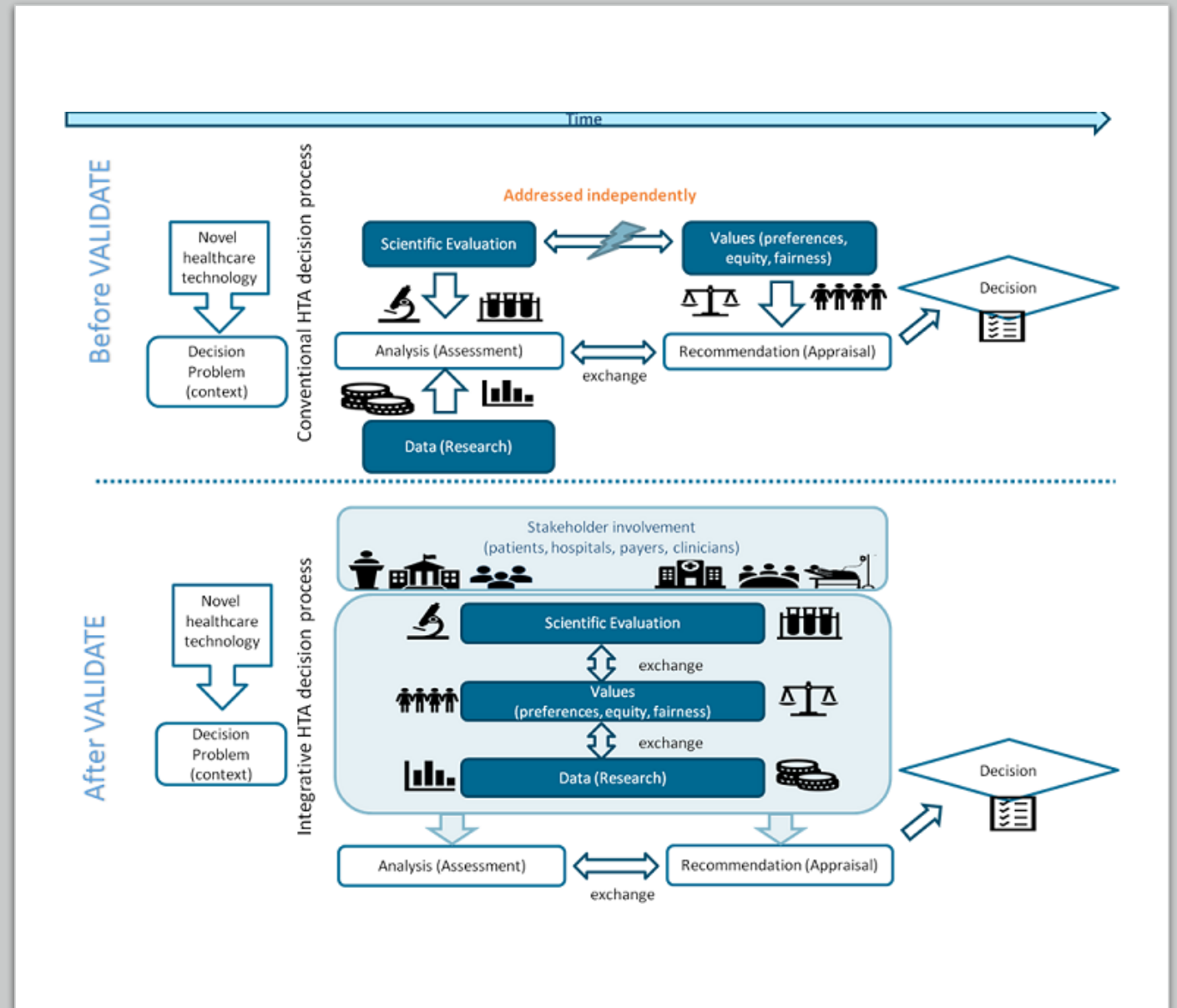
- Which are the differential aspects related to the problem?
- Which are the important questions?
- For whom?
- How do they relate to the outcomes?
- Which are the interactions among technologies?





# Values and value

- When to include values?
- How to consider those values?
- How influential they are in the determination of value?
- Does the context differ in the consideration of value?
- VALIDATE-HTA





# Aspects that could aid

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- Horizon scanning
- Early dialogue
- Harmonization of Regulatory and HTA processes
- Digitalization and data analysis
  - From administration to management
  - Big data and AI
- Post-introduction monitoring
- Reassessment



# Other considerations...

- RWD... RWE
- Fast track adoption or adaptive pathways
- PROMs and PREMs
- Anticipation of how value will be judged
  - Early advice
- Uncertainty management
  - Checklist of factors to be considered

# Some messages to bring back home

- Value depends on the perspective, the time and the context
- Values should be considered at the beginning
  - Stakeholders' involvement
- Avoiding single technologies analysis
- Intended and unintended consequences ... (environmental,...)







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