VALues In Doing Assessments of healthcare TEchnologies (VALIDATE)

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COLOGNE

HTAi 2019 ANNUAL MEETING · GERMANY

HTAi

Panel overview

- Moderator: Gert Jan van der Wilt
- Introduction (15 min.): Bart Bloemen
- Preview of the E-learning course (15 min.): Gert Jan van der Wilt

- Reflections from different perspectives (15 min.):
  - o Iñaki Guttierez (ES): HTA agency (Osteba)
  - o Dario Sacchini (IT): academic setting (philosophy / ethics department)
  - o Rabia Kahveci (UA): hospital-based HTA unit
  - o Lars Sandman (SE): national priority setting centre

- Reflections from the audience, interaction with VALIDATE team (25 min.)
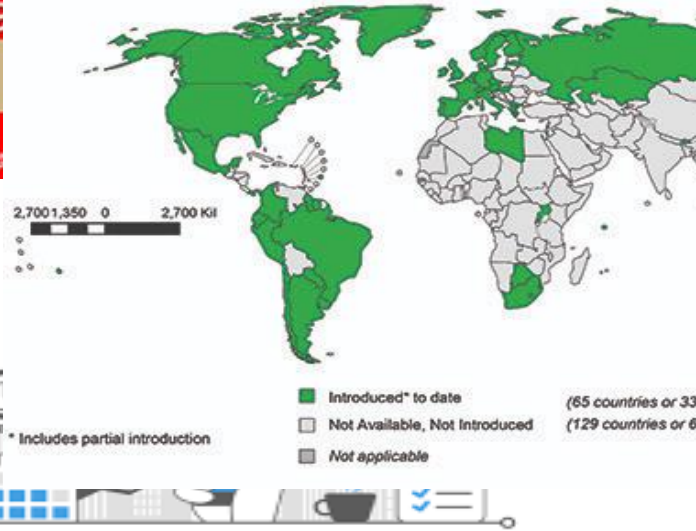- Wrap-up (5 min.)

Introduction

Bart Bloemen
Radboud university medical centre
Nijmegen, The Netherlands

Radboud umc

A drug that cures doesn't do any good if the people ... ca...

Countries with HPV vaccine in the national immunization programme

2,700 1,350 0 2,700 Kil

* Includes partial introduction

Introduced* to date
Not Available, Not Introduced
Not applicable

(65 countries or 33...
(129 countries or 6...

DA VINCI SURGICAL ROBOT
IS HIGH COST JUSTIFIED BY BENEFITS?

Positives or benefits

Negatives or costs

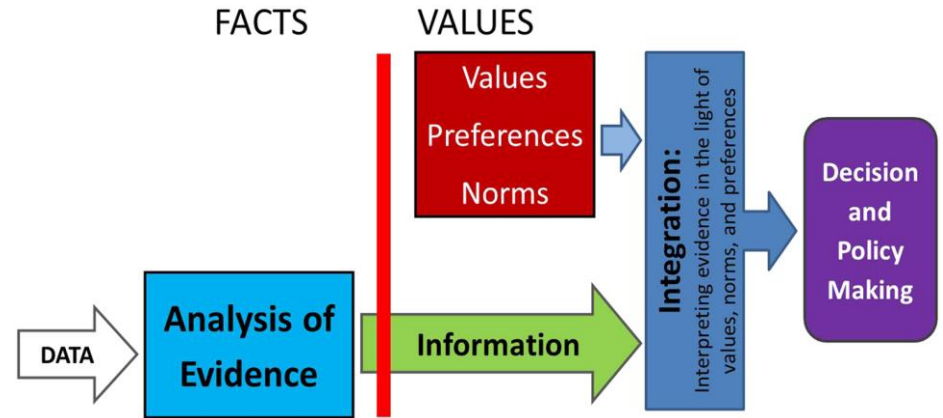*Information technology*

Facts and values in HTA

- Criteria traditionally considered in HTA:
  - Safety
  - Effectiveness
  - Cost-effectiveness
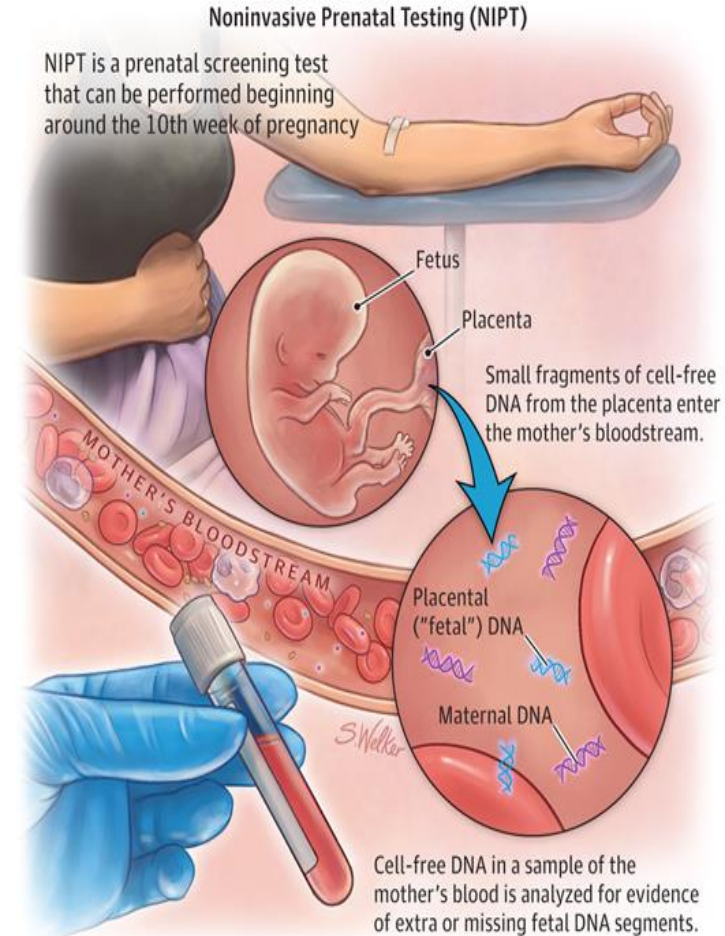 - *Social, ethical, legal aspects*

- Traditional view:
  - Distinction between assessment and appraisal
  - Facts | Values

Sources: Hofmann, B., Cleemput, I., Bond, K., Krones, T., Droste, S., Sacchini, D., & Oortwijn, W. Revealing and acknowledging value judgments in health technology assessment. *International Journal of Technology Assessment in Health Care,* 2014*; 30*(6), 579-586.
Hofmann B, Bond K, Sandman L. Evaluating facts and facting evaluations: On the fact-value relationship in HTA. *J Eval Clin Pract*. 2018; 1–9.

Current HTA practices

E.g. Noninvasive Prenatal Testing (NIPT):

➢ Often the focus lies on:

  ➢ What is the cost-effectiveness of NIPT?

  ➢ Aspects indeed often safety, effectiveness and CEA

  ➢ €/*additional chromosomal abnormalities detected*;

  ➢ € / QALY (mother)

➢ Social / ethical studies: informed choice; reproductive autonomy

Noninvasive Prenatal Testing (NIPT)

NIPT is a prenatal screening test that can be performed beginning around the 10th week of pregnancy

Fetus

Placenta

Small fragments of cell-free DNA from the placenta enter the mother's bloodstream.

MOTHER'S BLOODSTREAM

Placental ("fetal") DNA

Maternal DNA

Cell-free DNA in a sample of the mother's blood is analyzed for evidence of extra or missing fetal DNA segments.

Kibel, M., & Vanstone, M. Reconciling ethical and economic conceptions of value in health policy using the capabilities approach: A qualitative investigation of Non-Invasive Prenatal Testing. *Social Science & Medicine*, 2017, *195*, 97-104.

Source: Thompson AE. Noninvasive Prenatal Testing. *JAMA.* 2015;314(2):198.

How to avoid giving the right answer to the wrong question?

Going back to the basics of HTA!

Gerhardus, A., Oortwijn, W., van der Wilt, G.J. How to avoid giving the right answers to the wrong questions: the need for integrated assessment of complex health technologies. International Journal of Technology Assessment in Health Care, 2017, 33:5; 541-543.
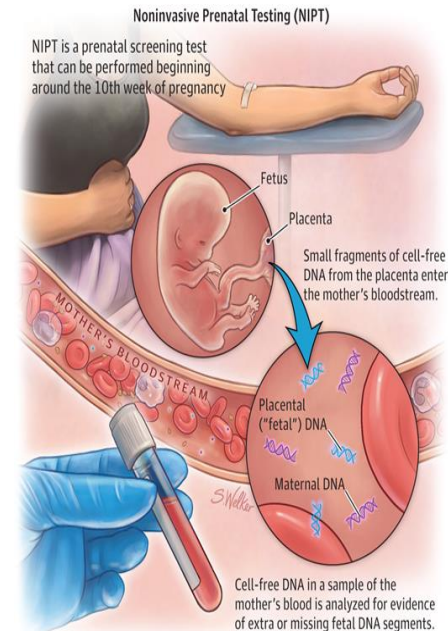Giacomini, M., Winsor, S. and Abelson, J. Ethics in health technology assessment: Understanding health technologies as policies. Healthcare Management Forum, 2013, 26:2, 72-76.

What is it that we want to realize, or avoid, by using a specific health technology?

E.g. Noninvasive Prenatal Testing (NIPT):

➢ Do we want to ***prevent the birth of foetuses with chromosomal abnormalities***?

➢ Do we want to ***avoid distress associated with an unexpectedly adverse outcome*** (for women and their partners)?

➢ Do we want to ***facilitate reproductive autonomy***?
➢ Do we want to ***facilitate informed choice***?

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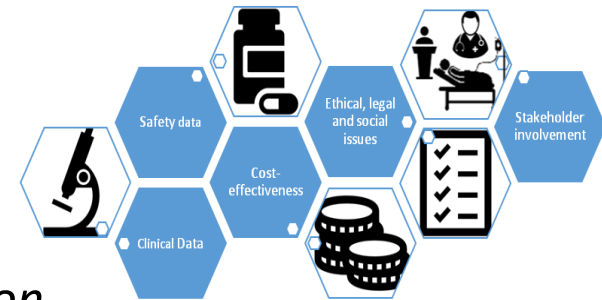
• Answering the policy-relevant question(s) by identifying relevant criteria for which evidence needs to be collected

Does NIPT facilitate informed choice?

➢ NIPT should provide more reliable information compared to existing alternatives
   ➢ Evidence: test accuracy (false positives/false negatives)

➢ NIPT should offer understandable information
   ➢ Evidence: interpretation of the test; genetic counselling
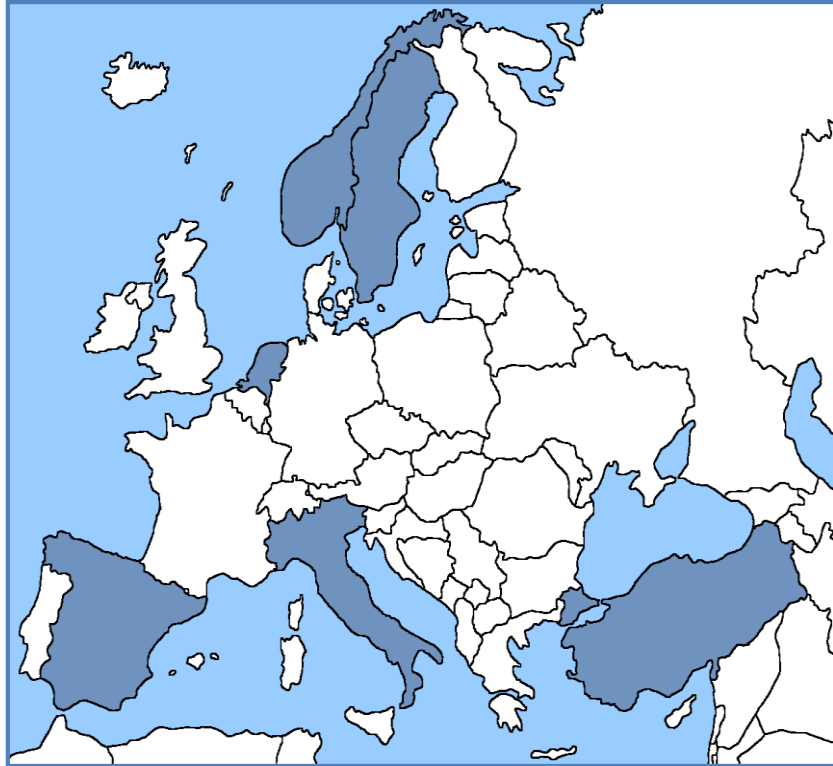
Values in doing assessments of healthcare technologies (VALIDATE)

- EU Erasmus⁺ Call Strategic Partnerships Higher Education

- September 2018 – August 2021

- Goal of the project: *to prepare the next generation of HTA experts for an integrative approach of HTA*

VALIDATE consortium

Timeline

September 2018: start of the project

December 2018: draft consensus statement

>September 2019:

E-learning module available; participation of students

March 2020: start of internships

February 2021: end of internships

March – August 2021: writing academic paper; final version of consensus statement

August 2021: end of the project
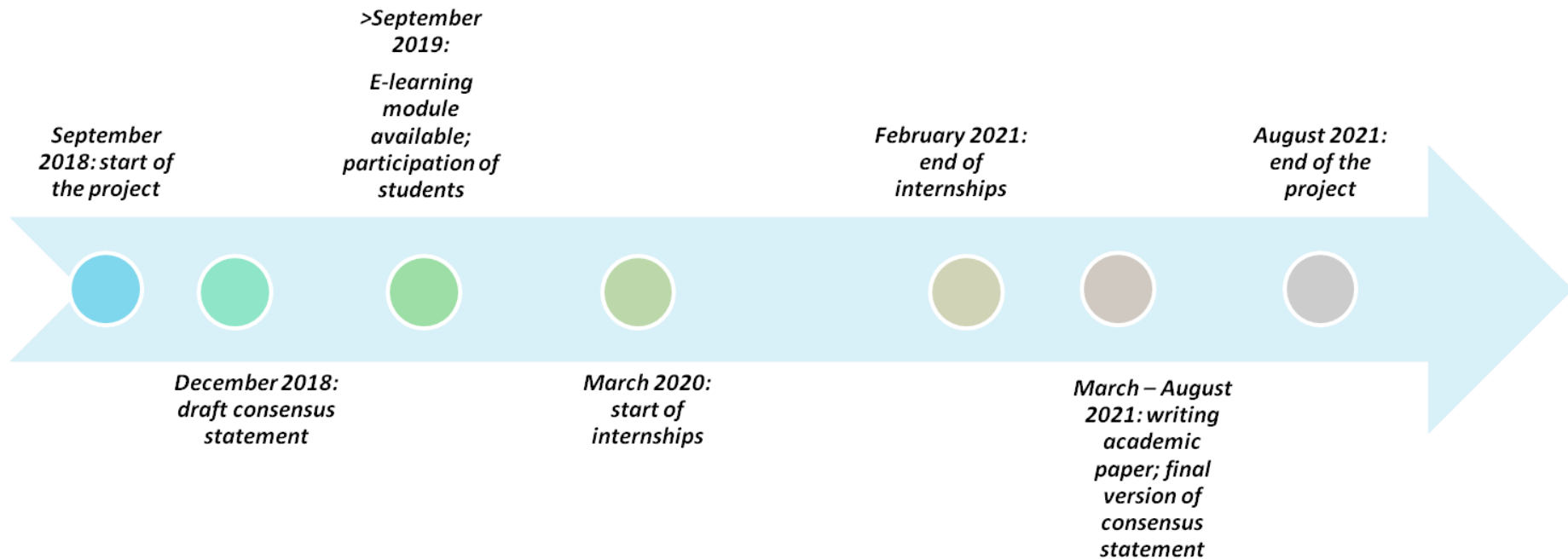
Intellectual outputs
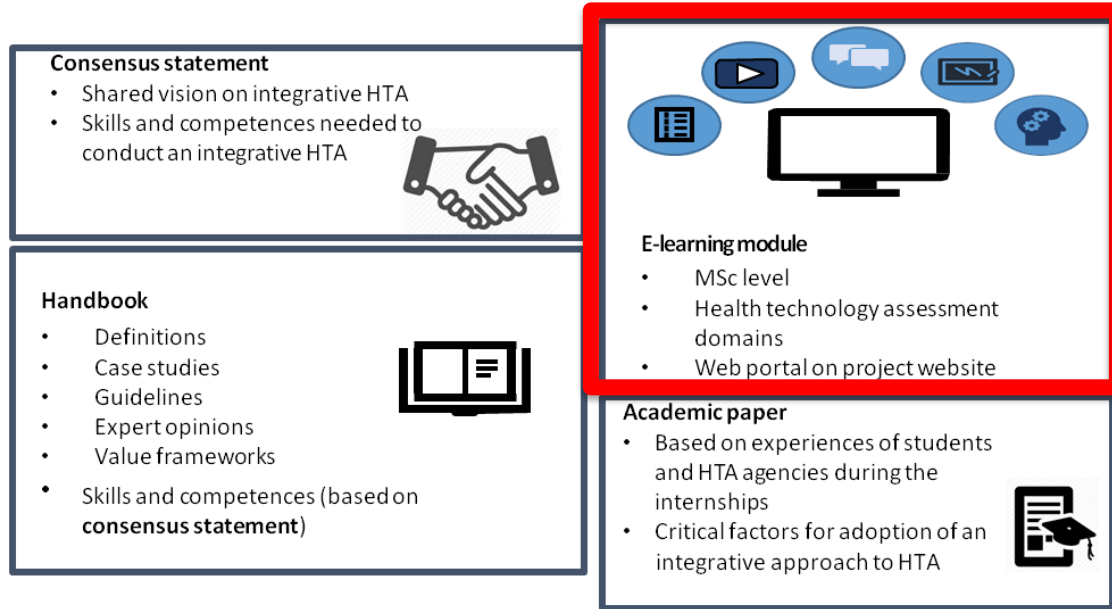
For more information: www.validatehta.eu

Preview of the VALIDATE e-learning course

Gert Jan van der Wilt
Radboud university medical centre
Nijmegen, The Netherlands

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Overview

- HTA: a specific type of policy analysis

- Policy problems come into different types

- What types are there?

- Why is it important for students of HTA to know about this?

- What can HTA students do to find out what sort of problem they are dealing with?

- How to discuss this with commissioning organizations?

- What types of policy analysis exist?

- Which types of policy analysis are appropriate for which type of policy problems?

- What does this add to existing methods and approaches in HTA?

- What does it require in terms of knowledge and skills on the part of the HTA student?

- How does the VALIDATE course provide for this?

HTA:

'Technology assessment is a form of policy research that examines short- and long-term consequences (for example, societal, economic, ethical, legal) of the application of technology.'

H David Banta & Bryan R Luce, Health Care Technology and its Assessment. An International Perspective. Oxford, Oxford University Press, 1993, p. 61.

Policy problems come into different types

	Little consensus about the values and aims involved	High degree of consensus about the values and aims involved
Little consensus about the knowledge involved	Unstructured problem (1) *Policy-making as learning → very suited to interactive policy-making*	Reasonably structured problem (2) *Policy-making as negotiation → limited suitability for interactive policy making*
High degree of consensus about the knowledge involved	Problem cannot be structured (3) *Policy-making as pacification → limited suitability for interactive policy-making*	Structured problem (4) *Policy-making as managing → unsuited to interactive policy-making*

Relation between types of policy problem & type of policy analysis

Mayer et al, 2004
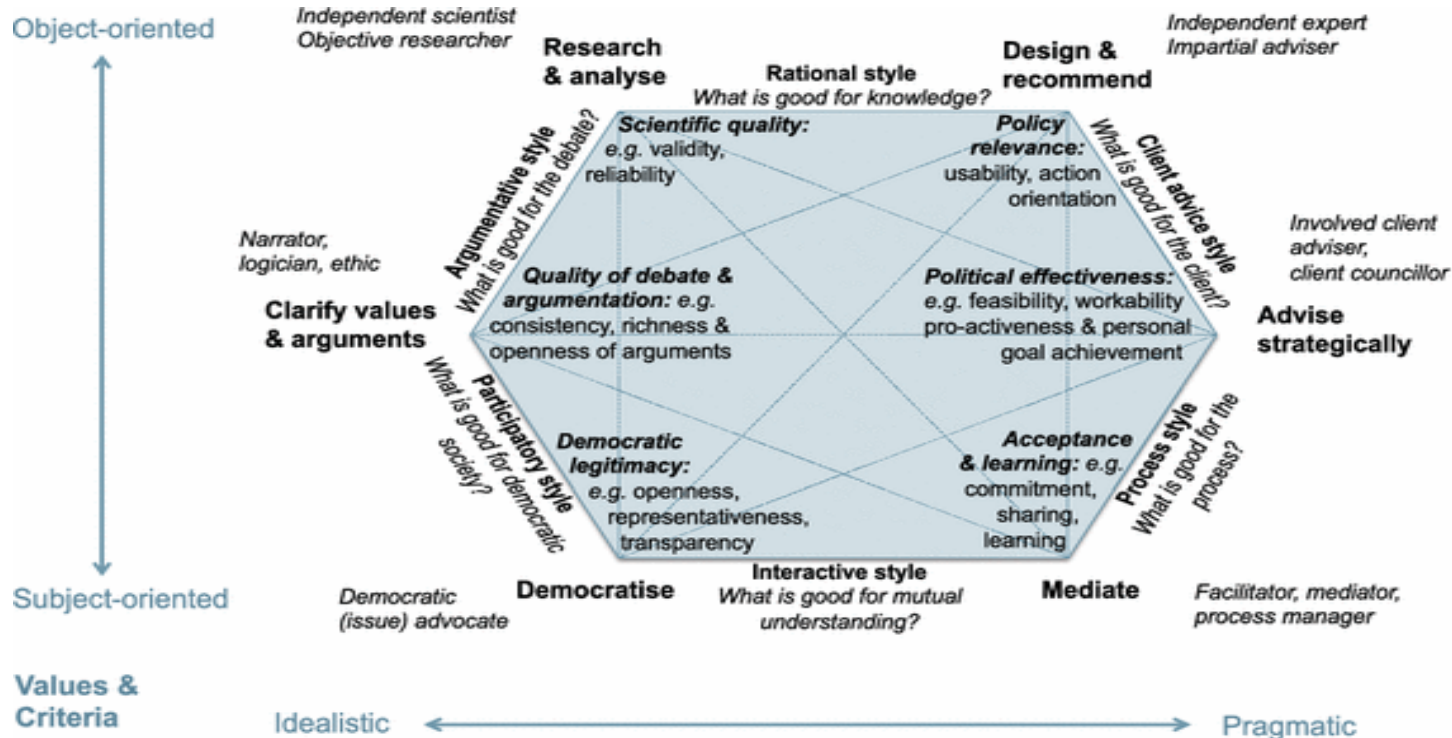
The method of reconstructing interpretive frames

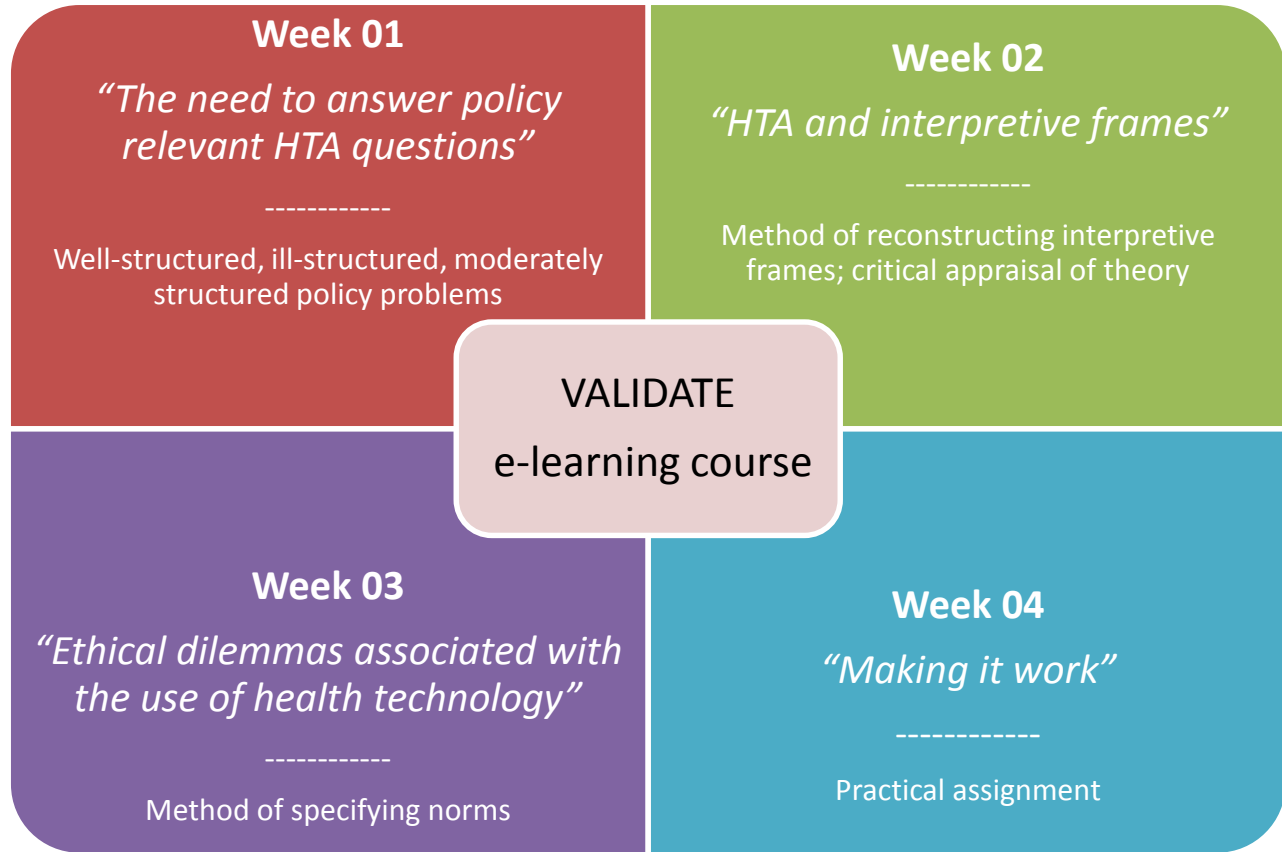| PROBLEM DEFINITION (what are the key problems of the current situation?)	JUDGMENT OF SOLUTIONS Is this technology likely to be effective, appropriate, feasible in this context?
BACKGROUND THEORY (What mechanisms are responsible for the current burden of disease?)	NORMATIVE PREFERENCES (What is it that we would like to achieve and what is it that we would like to avoid?)

Critical appraisal

- Critical review of *theory* (e.g., Campbell et al, 2014)

- Improving the quality of normative argumentation (e.g., Richardson, Practical reasoning about final ends. Cambridge University Press, 1997)

Technology assessment as *learning*

(Grin & Van de Graaf, 1996)

Structure of the e-learning course

Week 01

"The need to answer policy relevant HTA questions"

Well-structured, ill-structured, moderately structured policy problems

Week 02

"HTA and interpretive frames"

Method of reconstructing interpretive frames; critical appraisal of theory

VALIDATE

e-learning course

Week 03

"Ethical dilemmas associated with the use of health technology"

Method of specifying norms

Week 04

"Making it work"

Practical assignment

Internship

- 3 months
- In one of the participating HTA agencies
- Apply the VALIDATE theory and methods in a real-world setting
- Feedback from VALIDATE faculty
- Selection of best fulfillment for presentation at HTAi

Please let us know your interest in the course by filling in the contact form!

www.validatehta.eu