Workshop:
An integrated approach to the assessment of health technologies

**INTEGRATE-HTA**

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Dario Sacchini, Gert Jan van der Wilt, Petra Schnell-Inderst

HTAi, Rome, 18th June 2017
Aims of the Workshop

After the workshop participants

- are sensitized towards considering contextual issues when assessing technologies
- understand that the assessment of different aspects needs to be done in an integrated way, not side-by-side
- have enhanced competencies to assess complex technologies
### Program for this afternoon

<table>
<thead>
<tr>
<th>Time</th>
<th>Topic</th>
</tr>
</thead>
<tbody>
<tr>
<td>13:00</td>
<td>Welcome and introduction</td>
</tr>
<tr>
<td>13:15</td>
<td>Introduction to INTEGRATE-HTA</td>
</tr>
<tr>
<td>13:40</td>
<td><strong>Real world application: Hemodialysis</strong> (Ken, please insert your preferred title)</td>
</tr>
<tr>
<td>13:50</td>
<td>The EUNetHTA HTA Core Model</td>
</tr>
<tr>
<td>14:00</td>
<td>Group work on a real topic from your own projects</td>
</tr>
<tr>
<td>15:00</td>
<td>Break</td>
</tr>
<tr>
<td>15:15</td>
<td>Presentations of the group work</td>
</tr>
<tr>
<td>15:45</td>
<td>Concluding remarks</td>
</tr>
</tbody>
</table>
Introduction of facilitators and participants

- Name
- Organization
- Motivation
Aim of INTEGRATE-HTA

To develop concepts and methods for a comprehensive, patient–centred, and integrated (as opposed to side-by-side) assessment of complex technologies that includes and considers

• effectiveness and economic, sociocultural, ethical, and legal issues,
• patient preferences and patient-specific moderators of treatment,
• context and implementation issues.
Complexity: Definition of the UK-MRC

Box 1 What makes an intervention complex?

- Number of interacting components within the experimental and control interventions
- Number and difficulty of behaviours required by those delivering or receiving the intervention
- Number of groups or organisational levels targeted by the intervention
- Number and variability of outcomes
- Degree of flexibility or tailoring of the intervention permitted

Craig et al. 2008, BMJ
## Palliative care as a complex technology

<table>
<thead>
<tr>
<th>Patient characteristics &amp; preferences</th>
<th>Early or late stage? In pain? In despair? Family around?</th>
</tr>
</thead>
<tbody>
<tr>
<td>Comparator</td>
<td>Another complex technology?</td>
</tr>
<tr>
<td>Topics for assessment</td>
<td>(Cost-)effectiveness, social, cultural, legal impact? Impact on relatives?</td>
</tr>
<tr>
<td>Outcome</td>
<td>&gt; 500 outcome parameter, e.g. quality of life, spiritual improvement, etc.</td>
</tr>
<tr>
<td>Implementation</td>
<td>By a nurse? A doctor? A relative? At home? In a hospice?</td>
</tr>
<tr>
<td>Context</td>
<td>Rural area? Degree of professionalization of services?</td>
</tr>
</tbody>
</table>
Patient characteristics
- Early or late stage
- Personal preferences

Implementation
- Professionals
- Relatives
- Non-related lay persons

Context
- Elaborated palliative care system at place?

Results (evidence informed)

Effectiveness
Economic
Ethical
Social/Cultural
Legal

INTEGRATE-HTA
<table>
<thead>
<tr>
<th>Patient characteristics</th>
<th>Implementation</th>
<th>Context</th>
<th>Results (evidence informed)</th>
</tr>
</thead>
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<tr>
<td>Early or late stage</td>
<td>Professionals</td>
<td>Elaborated palliative care system at place?</td>
<td></td>
</tr>
<tr>
<td>Personal preferences</td>
<td>- Relatives</td>
<td></td>
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<td></td>
<td>- Non-related</td>
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<td></td>
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<tr>
<td></td>
<td>lay persons</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Modyfing factors**

**Effectiveness** How do you consider patient-specific characteristics, context and implementation issues?

**Economic** and

**Ethical**

**Social/Cultural**

**Legal**

**INTEGRATE-HTA** How do you integrate this information?
The approach in INTEGRATE-HTA

- Make **stakeholders** part of the assessment – a **defined perspective** is necessary for an integrated assessment
- **Identify and model relationships** between the intervention, patient characteristics, implementation issues, and context
- Offer an **integrated assessment** to decision-makers - integration needs to start from the beginning
1) Involve stakeholders to elicit needs, topics, outcomes and likely scenarios

2) Model the complexity (including patient characteristics, context, and ways of implementation)

3) Assess the evidence regarding effectiveness, and economic, ethical, socio-cultural, and legal aspects

4) Integrate the evidence in a structured way to respond to the needs of the stakeholders

5) Structured process of decision-making (not part of the HTA in a narrow sense)
The INTEGRATE-HTA Model

<table>
<thead>
<tr>
<th>Step 1</th>
<th>Step 2</th>
<th>Step 3</th>
<th>Step 4</th>
<th>Step 5</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>HTA Objective and Technology</strong></td>
<td><strong>Logic Model to define evidence needs</strong></td>
<td><strong>Evidence assessment</strong></td>
<td><strong>Mapping of the evidence</strong></td>
<td><strong>HTA decision-making</strong></td>
</tr>
<tr>
<td>HTA: Health Technology Assessment</td>
<td>Logic: Logical structure and attributes of specific technologies considering HTA and patient perspectives, identification, control, and implementation</td>
<td>Evidence: Specific requirements and evidence needs according to the specific logic model</td>
<td>Evidence: Sums up the different assessment aspects (e.g., effectiveness, ethics)</td>
<td>HTA: Results obtained from steps 3 and 4 lead to a decision, considering the input of stakeholders (decision-makers)</td>
</tr>
<tr>
<td>HTA research</td>
<td>Logic: Initial logic model including the themes of specific technologies identified in step 1</td>
<td>Evidence: Evidence collection for all assessment aspects (effectiveness, ethics, etc.) into a final logic model</td>
<td>Evidence: Mapping the evidence results (effectiveness, ethics, etc.)</td>
<td>HTA: Decision-making and implementation</td>
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<td>Logic: Initial logic model for all assessment aspects and evidence needs</td>
<td>Evidence: Assessment of evidence according to specific criteria</td>
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<td>HTA: Decision-making and implementation</td>
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**RESULT**

Definition of HTA research question and preliminary definition of specific technologies

**RESULT**

Initial logic model to start evidence collection including specific technologies

**RESULT**

Evidence reports and evidence summaries for each assessment aspect

**RESULT**

Extended logic model and synthesis of evidence according to the HTA research question

**RESULT**

HTA decision / recommendation
Step 1: Bring the generation of evidence into perspective

Input through Stakeholder Advisory Panels (SAPs) on:
Topics, objectives, patients, context and implementation

- Example:
  135 individuals (professionals, voluntary workers, patients, and relatives) from 7 European countries

Common issues (selection):
- Availability & accessibility
- Effectiveness
- Ethical & legal concerns
Step 2: Identify patient characteristics, context, implementation to create a logic model

Identify patient-related moderators and preferences, context and implementation issues

- **Examples**
  - **Patients** and relatives with or without social support
  - **Implemented** by a relative or by a professional caregiver
  - Professional caregiving already established or not (**context**)

- **Create a logic model** covering patient characteristics, context and implementation issues
Step 3: Assess the available information/evidence

Assess information/evidence considering patient characteristics, context, implementation issues

- Systematic reviews
- Economic analyses
- Focus-group discussions
- Etc.
Step 4: Insert the evidence into the logic model

- Example - Patient characteristic as a modifier for the socio-cultural analysis:

  Socio-economic status is a **moderator** on the ability of relatives to take over home-based care
Extended logic model for palliative care

**Context**

**Epidemiological**
- Access and availability to health care (ethics, socio-economic, geographical, political)

**Political**
- Autonomy and shared decision making (legal, ethical, preferences)

**Socio-cultural**
- User-professional relationships and decision making
- Autonomy and shared decision making (legal, socio-cultural, preference)
- Knowledge and understanding of the technology
- Perceived usefulness and the idea of benefit

**Ethical**
- Changing roles and relationships for caregiver
- Changing roles and relationships for patients
- Autonomy and shared decision making (legal, socio-cultural, ethical, preference)
- Access to, and availability to healthcare (ethics, socio-economic, geographical, political)
- Voluntariness
- Vulnerability

**Geographical**
- Access to, and availability to healthcare (ethics, socio-economic, geographical, political)

**Socio-economic**
- Access to, and availability to healthcare (ethics, socio-economic, geographical, political)
- Socio-economic status of recipient of care
- Economic climate

**Participants**

**Patients, informal caregivers**
- Preferences for:
  - Pain: Death at home (outcomes, preferences)
  - Caregiver: Psychological health (preferences, outcomes)

**Implementation**

**Funding**
- Financial support for informal caregiver
- Availability of resources for care provision
- Not supported by the investment

**Organisation and structure**
- Continuity of care and supervision and guidance

**Policy**
- Meeting a society’s demands
- Facilitation of death at home
- Navigating the health care system
- Social protection of informal caregiver

**Provider**
- Characteristics of provider
- Team dynamics
- Interaction with care recipients
- Training needs

**Outcomes**

**Health outcomes**
- Caregiver
  - Quality of life
  - Response outcomes
  - Satisfaction with care
  - Psychological health (outcomes, preferences)

**Patients**
- Pain
- Symptom control
- Quality of life
- Psychosocial health
- Hospitalisation
- Response
- Satisfaction with care
- Death at home (outcomes, preferences)

**Delivery agent**
- Generalist and/or specialist health and social care professional
- Lay caregivers
- Others: Self-care, complementary alternative therapists, charity workers/volunteers

**Delivery mechanisms**
- Face-to-face (hospital, online, mobile)
- Individual patient
- Care-team dynamics

**EFFECTIVENESS**

**ACCEPTABILITY**

**FEASIBILITY**

**ECONOMICS**

**MEANINGFULNESS**

**APPROPRIATENESS**

Key to sources assigned within the system: evidence informing the extended logic model derived from the application of the following guidance:
- 1: Lomas et al. (2014) Guidance for assessing effectiveness, economic aspects, ethical aspects, socio-cultural aspects and legal aspects in complex technologies (online). Available from: http://www.iscg.org/mta/mta/mta14/wg4/1.4/1.4.2/7.2.1/1.4.2.4/3.1.4.2.4.2/3.1.4.2.4.2.1/guidance.pdf
- 2: Brereton et al. (2016) A guide to palliative care (online). Available from: http://www.iscg.org/mta/mta/mta14/wg4/1.4/1.4.2/7.2.1/1.4.2.4/3.1.4.2.4.2/3.1.4.2.4.2.1/guidance.pdf
- 3: Pharaoh et al. (2016) Guidelines for the assessment of treatment effectiveness of health care interventions (online). Available from: http://www.iscg.org/mta/mta/mta14/wg4/1.4/1.4.2/7.2.1/1.4.2.4/3.1.4.2.4.2/3.1.4.2.4.2.1/guidance.pdf
- 4: Gordon et al. (2016) Guidelines for the assessment of treatment effectiveness of health care interventions (online). Available from: http://www.iscg.org/mta/mta/mta14/wg4/1.4/1.4.2/7.2.1/1.4.2.4/3.1.4.2.4.2/3.1.4.2.4.2.1/guidance.pdf

Brereton et al. 2016
Step 5: Structured deliberative decision-making

Structured process of decision-making taking uncertainty, unanswered questions, and limitations into account.
All guidances are available from the website:
http://www.integrate-hta.eu/downloads/
CONSORTIUM

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Ulrich Mansmann
Kati Mozygemba
Martina De Nicola
Bill Noble
Per Nortvedt
Wija Oortwijn
Lisa Pfadenhauer
Stephanie Polus
Pietro Refolo
Eva Rehfuess
Anke Rohwer
Dario Sacchini
Imke Schilling
Antonio G. Spagnolo
Peep Stalmeier
Marcia Tummers
Adriana Turriziani
Gert Jan van der Walt
Philip Wahler
Vivienne (Viv) Walker
Sue Ward
Kim Weistra

This project is co-funded by the European Union under the Seventh Framework Programme (Grant Agreement No. 306141)
Pictures

Patient: Kzenon from www.fotolia.com
Decision-making: CandyBox images from www.fotolia.com
Real world application
EUNetHTA HTA Core Model
INTEGRATE Workshop
EUnetHTA HTA Core Model

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HTAi 2017, June 18th, Rome
EUnetHTA HTA Core Model
The HTA Core Model® (HCM)

**Description**

The HTA Core Model® is a methodological framework for shared production and sharing of HTA information.

**Purpose**

To enable production of high quality HTA information in a structured format to support the production of local (national or regional) HTAs and reuse of existing information.
The Structure of the HTA Core Model®

**Ontology**

Questions that an HTA should answer

**Methodological Guidance**

How to answer the questions

Common reporting structure that enables standardised reporting of HTAs. Results are presented as collections of result cards. The theme of each result card is outlined by the assessment element cards.
The Domains of the HTA Core Model®

**DOMAINS**

1. Health problem and current use of technology
2. Description and technical characteristics
3. Safety
4. Clinical effectiveness
5. Costs and economic evaluation
6. Ethical analysis
7. Organisational aspects
8. Social aspects
9. Legal aspects
# Topics

<table>
<thead>
<tr>
<th>Clinical effectiveness</th>
</tr>
</thead>
<tbody>
<tr>
<td>Topic 1: Mortality</td>
</tr>
<tr>
<td>Issue 1: What is the effect of the intervention on overall mortality?</td>
</tr>
<tr>
<td>Issue 2: What is the effect of the intervention on mortality caused by the target disease?</td>
</tr>
<tr>
<td>Issue 3: etc…</td>
</tr>
</tbody>
</table>

- Health problem and current use of technology
- Technical characteristics
- Safety
- Clinical effectiveness
- Costs and economic evaluation
- Ethical analysis
- Organisational aspects
- Social aspects
- Legal aspects
Assessment elements

• Combination of domain-topic-issue
• The basic unit of the model. It defines a piece of information that describes the technology or the consequences or implications of its use, or the patients and the disease for which it is applied.
• Nature of elements may vary across domains, since the consequences and implications are understood and studied differently
• The common denominator for all elements is that they outline a set of information that may be useful when deciding on the use or non-use of technology
Core HTA Structure

Pool of structured HTA Information

Collections
Serve also as project platforms

Official EUnetHTA
- Core HTA
- Rapid HTA

Other
- Full domain
- Free set (≥ 1)
- My collection

Local products

Local Tools

HTA Core Model
Online Tool & Service
Group Work
Group work

1) Build groups of 6-8 each who work together on one topic

2) Define the relevant issues, the technology(ies), the target groups and the aims. Consider all relevant aims which might include effectiveness, economic, social, organizational, and/or ethical aspects.

3) Think about the theory of change (logic model), the ways of implementation and contextual issues. Use table 4 (CICI-checklist) and figure 2 (extended logic model) for structuring your efforts (see handout).

4) Prepare a graphical representation for all relevant factors and kindly present it to the audience.
CICI-checklist

Pfadenhauer et al 2016
# Extended logic model for palliative care

**Figure 2** The extended logic model to assist decision making showing the assessment results on reinforced models of palliative care (sources of evidence are highlighted by numbers).

## Context

### Epidemiological
- Access and availability to healthcare (ethics, socio-economic, geographical, political)

### Political
- Access and availability to healthcare (legal, ethics, preferences)

### Legal
- Autonomy and shared decision making (legal, ethical, preferences)
- Autonomy and shared decision making (legal, socio-cultural, ethics, preferences)
- Knowledge and understanding of the technology
- Perceived usefulness and the idea of benefit

### Socio-cultural
- User-professionals-relationships and decision making (legal, socio-culture, ethical preferences)
- Autonomy and shared decision making (legal, socio-cultural, ethical preferences)
- Access to, and availability to healthcare (ethics, socio-economic, geographical, political)
- Voluntariness
- Vulnerability

## Participants

### Patients, informal caregivers
- **Moderators for**
  - Patients: Death at home (outcomes, preferences)
  - Caregivers: Psychological health (preferences, outcomes)

### Preferences for
- Autonomy and shared decision making (legal, socio-cultural, ethics, preferences)
- Location of death
- Preference for survival

### Implementation

#### Funding
- Financial support of informal caregivers
- Availability of resources for care provision
- Net benefit of the investment

#### Organisation and structure
- Continuity of care
- Supervision and guidance

#### Policy
- Meeting a society’s demands
- Facilitation of death at home
- Navigating the health care system
- Social protection of informal caregiver

### Intervention

#### Intervention Theory, aim & scope
- Holistic approach to improve quality of life and to enable a good death for patient
- Aim to allow the patient to be treated and die at home, if desired
- Explicit, structured support for the lay caregiver to alleviate burden due to caregiving

#### Components
- Services addressing physical, psychological, social and spiritual needs of patients
- Services explicitly addressing psychosocial or psychosocial support to lay caregivers

#### Execution
- Timing, duration and frequency
- May commence at any time from diagnosis to end of life and bereavement
- Models of transition to palliative care e.g. concurrent palliative and curative care, palliative care upon cessation of curative care

#### Delivery agent
- Generalist and/or Specialist in health and social care professional
- Lay caregivers
- Others: Self-care, complimentary and alternative therapists, charity volunteers

#### Delivery mechanisms
- Face-to-face, telephone, internet
- Individual or multi-patient delivery

## Outcomes

### Health outcomes

#### Caregiver
- Quality of life
- Response outcomes
- Satisfaction with care
- Psychological health (outcomes, preferences)

#### Patients
- Pain
- Symptom control
- Quality of life
- Psychosocial health
- Hospitalisation
- Response
- Satisfaction with care
- Death at home (outcomes, preferences)

### Costs
- Costs per patient
- Resources impact (e.g. Specialist Nurse time)
- Budget impact

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**Key to sources used within the system:** Evidence informing the extended logic model resulted from the application of the following guidance:


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Brereton et al. 2016
Optional Topic: Patient access to EHR
Adult Patient Access to Electronic Health Records

Background

- With progress in IT-applications health-related information is stored in electronic health records (EHR) maintained by health-care providers.
- Patient-centered care might be supported by sharing information and knowledge by clinician and patient and encourage patients in shared decision-making.
Break
Presentations of the Group Work
Conclusion