



INTEGRATE-HTA

Changing the content of palliative care and the law

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Agenda

- Developed Method
- Application on Palliative Care
- Finding of Case Study
 - Relevant legal aspects
 - Other findings
- Conclusions

Developed Method I

- Aim of the Method is to enable non-lawyers to identify legal issues relevant for the specific HTA
- Method is focussed on nine potentially affected aspects
- Guidance for each aspect allows identification as well as further decisions on how to assess the aspect

Developed Method II

- Nine core aspects:
 1. Autonomy of the Patient I: Informed Consent
 2. Autonomy of the Patient II: Alternative Forms of Consent
 3. Autonomy of the Patient III: Privacy and Data Protection
 4. Market Authorisation I: Medical Devices
 5. Market Authorisation II: Medicinal Products
 6. Clinical Trials: (Rights of persons, ethical standards)
 7. Intellectual Properties (Potentially protected under intellectual property laws?)
 8. Reimbursement in Public Health Care Systems (eligibility)
 9. Special Medical Fields

Developed Method III

- For each aspect, the guidance indicates:
 - A. The initial question to start identification
 - B. Explanation of the legal issue, including examples where applicable
 - C. Legal sources relevant for the affected legal aspects
 - D. Relations to other parts of the HTA
 - E. Reference on relevant decision level as well as on the necessity of professional legal advice

Application on Palliative Care

- Guidance has been applied on reinforced models of home-based palliative care
- Aim of the case study was test whether guidance enables non-lawyers to identify relevant legal issues
- Ideally users of the guidance should be able to decide on whether a further legal inquiry has to be done by a lawyer or not

Relevant legal aspects I

- Five aspects of high relevance:
 1. Autonomy of the Patient I: Informed Consent
 2. Autonomy of the Patient II: Alternative Forms of Consent
 3. Autonomy of the Patient III: Privacy and Data Protection
 4. Reimbursement in Public Health Care Systems
 5. Special Medical Fields

Relevant legal aspects II

- Autonomy of the patient identified as being of paramount relevance
- Example: Integration of relatives in reinforced home based palliative care can potentially oppose the patient's autonomous informed consent as well as his/her (data) privacy

Other findings

- Autonomy of the patient is highly related to similar ethical and socio-cultural aspects
- Reimbursement is highly related to clinical effectiveness
- Combined assessment may be useful

Conclusions

- New methods in palliative care (e.g. reinforced models of home-based palliative care) have to ensure proper obtainment of patients' informed consent or appropriate alternative (e.g. by procedural mechanism)
- Methods that fail to comply might not qualify for implementation in a health care service



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