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