Challenges to clinical decision support (CDS)

- mental
  - necessity or imperative not recognized (fatalistic attitude towards risk/suffering)
  - factual incomprehension (don’t understand it)
  - emotional refusal (don’t want it)
  - insufficient endorsement (don’t do it)

- clinical
  - too simplistic or insufficient quality (lack of content quality)
  - lack in workflow integration (lack of process quality)

- technical
  - lack in structured patient data (documentation)
  - insufficient data/semantic interoperability (data and terminology standards)

- financial
  - insufficient funds (often not true!)

⇒ How to overcome these barriers? By clinically useful solutions.
Regulatory framework for clinical decision support software: Present uncertainty and prospective proposition

1. Transparency

2. Competent Human Intervention

3. Adequate Time to Reflect

Not Substantially Dependent

Fig 1. The “substantial dependence” standard.

Regulatory affairs—I

- stand-alone software
  - **Meddev 2.1/6**: Guidelines on the qualification and classification of stand-alone software used in healthcare within the regulatory framework of medical devices (MDs) (January 2012)
Regulatory affairs—II

- MDD 93/42/EEC

Article 1, Paragraph 2a (art. 1.2a of MDD):
Medical device (MD) means any instrument, apparatus, appliance, **software**, material or other article, whether used alone or in combination, ... intended by the manufacturer to be used for human beings for the purpose of:

  - diagnosis, prevention, monitoring, treatment, or alleviation of disease
  - ...

medical device
ARDEN_SUITE software: generic technology platform for clinical decision support
Moni-ICU: surveillance of healthcare-associated infections

Stat. 39690

- BSI-A (primary sepsis)
- BSI-4 (primary sepsis)
- POS: blood culture (6-7d - t)
- POS: blood culture (1-7d - t)

Moni-NICU: (surveillance of and) alerts for healthcare-associated infections