Benefit and risk considerations in medical decision making

The assessment of benefits and risks is a central element in clinical practice. Benefit-risk assessment also plays an important role in the development and introduction of new treatments, reimbursement decisions by health technology assessment bodies, and in decision making on the ethics of research by research ethics committees. Benefit-risk assessments consist of three ingredients: data about the favourable and unfavourable effects of a product; uncertainties about these effects; and judgments about the clinical relevance of effects based on data accompanied by uncertainty. A properly conducted benefit risk assessment should have important qualities like based on a rational process of combining objective elements (data and uncertainties) with subjective elements (clinical judgment), leading to consistent decisions and it should be a transparent process, making it communicable and accountable. Benefit-risk assessment is a complex, multi-person process that requires the evaluation of a large amount of data on multiple kinds of effects and transformation into an overall balance, usually resulting in a simple 'yes/no' decision. Quantitative instruments promise more consistent and transparent decision making. The logic of quantitative instruments is to distinguish three steps in decision making: (1) decompose problematic situations into its constituent pieces; (2) make assessments about these pieces; and (3) recompose the pieces to a whole. The first step is descriptive, but step 2 and 3 are 'quantified'. Explication and exploration of value judgments is e.g. especially valuable in cases where high medical need can form the basis for adjusting evidence requirements. Furthermore, quantitative instruments can play-back the results of the model and the Decision makers could explore how changes in value judgments or (uncertainty about) data affect the overall benefit risk balance by simulating scenarios.