DECIDE: policymakers and managers

The DECIDE project included six research Work Packages (WPs), the first five of which aimed to develop and evaluate strategies for presenting evidence-based recommendations in guidelines to different types of user:

1. Health professionals.
2. **Policymakers and managers [covered by this summary]**.
3. General public.
4. Users of diagnostic tests.
5. People developing health system policies.

The 6th Work Package was a toolkit that packaged much of the work coming from the first five Work Packages together. One of the key results of DECIDE was to deliver information in layers, most important first. So, in that spirit, the key findings of the whole DECIDE project are summarised in Figure 1. If you read no more, look at least at Figure 1.

Key findings:

- Guideline users – health professionals, patients and policymakers – want information delivered to them in layers, most important first.

- Guideline producers value structure when working through evidence to make recommendations and decisions.

- Numerical summaries of research findings can be understood by diverse audiences, including the public, but it is best if those summaries allowed users to interact with them so that they can choose the level of detail they require.

- Health professionals and their patients want materials that can be used in consultations to support their discussions.

- Guideline information about medical testing has to move beyond accuracy and precision and start talking about the effect on important patient outcomes.

Key tools:

- The Evidence to Decision framework to support guideline producers make evidence informed decisions.

- The interactive Summary of Findings tables to support interactive presentations of research findings to diverse types of user.

- The DECIDE/G-I-N public toolkit chapter for guideline producers on how to produce patient versions of guidelines.

- There are many ways information can be presented to users but we have not found a 'magic bullet' that always works for all users, especially members of the public. Guideline producers would be wise to do at least some testing of their materials with potential future users.

- The GRADEPro guideline development tool to package the bulk of DECIDE's work and to support guideline producers through the whole guideline process.

Figure 1: Key DECIDE findings and tools

Presenting evidence-based recommendations to policymakers and managers

Early in the DECIDE project we decided that it would be sensible to concentrate our policymaker work on coverage decisions. By coverage decisions we mean decisions by third party payers - public or private health insurers - about whether and how much to pay for interventions (including drugs, tests, devices and services) and under what conditions. The decision to focus on coverage

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was taken because there has been little work done on how to make evidence-informed policy decisions about coverage of interventions and technologies. This therefore seemed an area where DECIDE could have most impact. With this in mind, we agreed that the three main priorities for work with policymakers were:

- Development of an appropriate 'conceptual framework' to inform the process that starts with an assessment of evidence through to making a coverage decision about an intervention or technology.
- Development of appropriate tools to present the results of evidence assessment, together with other information that may be relevant to inform policy makers and managers when they have to make decisions.
- Develop approaches for how to deal with information regarding resources and costs.

The target population for the Work Package was agreed to be policymakers but also managers and their support staff who together have responsibility for coverage decisions. Developing the conceptual framework, and in particular identifying its key dimensions, formed a substantial part of our work with these stakeholders. It involved review of the literature to identify reviews, primary studies and relevant editorials about information needs and preferences of policy makers and managers. It built on tools developed in the SUPPORT project (a completed FP6 project led by DECIDE's Norwegian partner). Other activities performed in order to develop the conceptual framework were:

- Brainstorming activity to generate ideas
- An international survey
- Stakeholder feedbacks collection
- Formal user testing
- Dissemination workshops
- Applications of the EtD in a real world setting

Dimensions of the framework that were present from very early on included information on the seriousness on the condition (e.g. is it life-threatening?), the quality of the evidence (i.e. can we trust what it says?), the size of any benefits compared to adverse events, cost effectiveness, feasibility and equity. Presentation of information in a tabular format that asked policymakers to make judgements on each of these dimensions also emerged.

This structure eventually became the Evidence to Decision (EtD) frameworks, one of DECIDE's most important outputs and which involved all members of the DECIDE consortium. The general structure of the EtD framework is common to all DECIDE' WPs and tailored for different target audiences (e.g. clinicians, policy makers, guidelines' developers, patients). There are 16 frameworks, each with its own template, the selection of which depends on the question being addressed. For example there is a template for '*Clinical recommendation – individual patient perspective*' as well as '*Clinical recommendation – population perspective*'. An important difference between these two is the extent to which costs are taken into account when making a decision. These are generally less relevant when taking an individual perspective but key when taking a population perspective. Another important discussion during the development on the frameworks regarded intellectual and financial conflicts of interest, which are common and can affect judgments and recommendations or decisions. Panel members need to report potential conflicts of interest when formulating each question and using the framework helps to make these conflicts explicit, aiding transparency.

The EtD is intended to:
- Provide information on the pros and cons of each option (intervention) that is considered
- Ensure that important factors that determine a decision (criteria) are considered
- Provide a concise summary of the best available research evidence to inform judgements about each criterion
- Help structure discussion and identify reasons for disagreements
- Make the basis for decisions transparent

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The latest version of the EtD for coverage includes 12 criteria deemed as essential for taking this type of decision. The main considerations for the EtD collected through different type of stakeholders consultations are listed below:

- The main strengths of the EtD for coverage are its design and structure, summarising in a logical and transparent way all the elements of a complex decision-making process.
- The EtD guides consideration of the important factors that should determine a decision about coverage, and can help to avoid potentially inappropriate influences.
- The application of a structured and transparent approach to coverage decisions is perceived as a strong point in favour of using the EtD framework, and its innovative nature was particularly appreciated by participants in user-testing and pilot tests.
- From the perspective of clinicians and patients affected by coverage decisions, use of the EtD framework can help to ensure that decisions are fair. It is a clear document that helps to ensure consistent use of appropriate criteria for assessing interventions and for the transparent use of evidence to inform judgements for each criterion. It can facilitate identification of reasons for disagreements and feedback on a draft decision prior to making a final one.
- The main weakness is the usability of the framework by stakeholders with different levels of methodological knowledge. However, it might also be considered a potentially useful instrument to facilitate better understanding of the methodological considerations that are inherent in evidence-based coverage decisions.
- The criteria that are used to assess interventions in the EtD framework for coverage decisions are not new. They are similar to criteria already used by many organisations and to the criteria suggested by the GRADE Working Group for clinical recommendations. However, the structure of the EtD framework, linking criteria to explicit jugements and to the evidence available to inform each of them is innovative.
- The framework offers a way for organisations to monitor their decisions, and it can facilitate sharing, comparing and learning across organisations.

Guidance on the evidence decision frameworks is available at http://ietd.epistemonikos.org/#/help/guidance.

The EtD framework was recently used in a real-life setting to take a coverage decision about trans-catheter aortic valve implantation (TAVI) for patients with severe aortic stenosis in Lazio Regional Health Service, Italy. Two EtD were prepared comparing TAVI vs traditional surgery and vs medical therapy. They were presented and discussed with a panel of regional health system representatives involving both regional decision makers as well as clinicians. The EtD were then included in the final regulatory document of Lazio Region. The EtD framework will be used also for future coverage decisions in Lazio Region.

More information on the Evidence to Decision frameworks is given in our summary of work with those producing health systems policies (i.e. the summary for DECIDE's Work Package 5). Figure 2 shows one of the opening screens of an interactive Evidence to Decision framework.
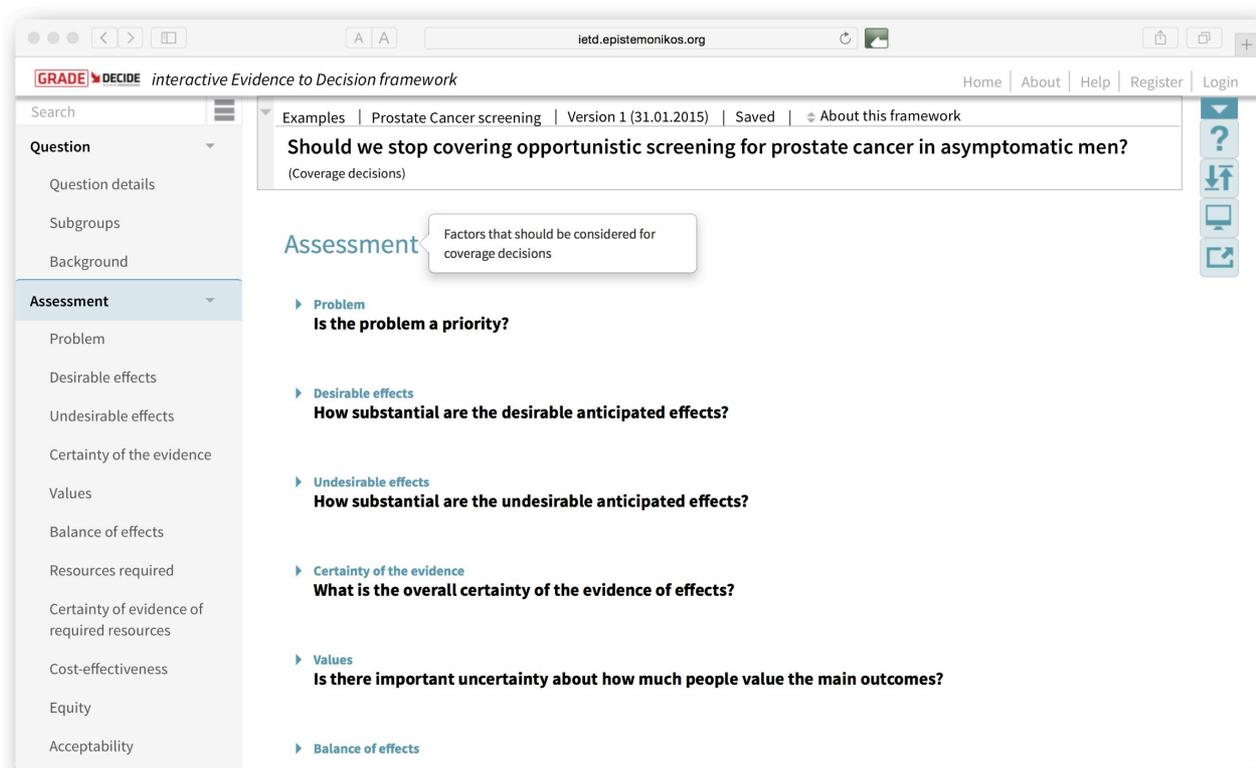
Figure 2 *The interactive Evidence to Decision framework tool for a coverage decision*