PROJECT FINAL REPORT

Grant Agreement number: 258583

Project acronym: DECIDE

Project title: "Developing and Evaluating Communication strategies to support Informed Decisions and practice based on Evidence."

Funding Scheme: THEME [HEALTH.2010.3.1-1] [Better understanding of dissemination and implementation strategies. FP7-HEALTH-2010-two-stage]

Period covered: 01/01/2011 to 31/12/2015

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This project has received funding from the European Union's Seventh Framework Programme for research, technological development and demonstration under grant agreement no 258583

EXECUTIVE SUMMARY

All of us - health professionals, patients, policymakers and the public - want to make healthcare decisions based on the best available research evidence. Guidelines aim to support these decisions but are generally developed as a one-size-fits-all package, with no attempt at tailoring to the needs of different types of user. This means that the substantial work that guideline producers put into guideline production may not translate into the hoped-for health care benefits.

The 5-year EU-funded project **Developing and Evaluating Communication strategies to support Informed Decisions and practice based on Evidence (DECIDE; http://www.decide-collaboration.eu)** has worked on innovative ways to present research evidence in guidelines that is specifically tailored to meet the needs of different types of user. The work was divided into five parts, each focused on a different type of guideline user: health professionals; policymakers and managers; patients and public, people making diagnostic decisions and people making decisions about health system interventions. How information is presented needs to be tailored to the user.

Development was an iterative process involving all or some of brainstorming with users, formal user-testing of prototypes, and trials. User-testing in particular was central; people from a user group were asked to look at a prototype and then gave their comments and opinions on it. Prototypes were modified in light of what was learnt from testing and then re-evaluated.

DECIDE has some substantial outputs. A multi-layered approach to presenting guideline information to health professionals has been developed (http://journal.publications.chestnet.org/article.aspx?articleid=1916306). DECIDE has contributed to new international guidance on how to produce patient versions of guidelines through a collaboration with the Guideline International Network (http://www.g-i-n.net/working-groups/gin-public/toolkit). Literature reviews of grading systems for diagnostic tests (http://www.implementationscience.com/content/8/1/78) and the public's attitudes to, and awareness of, guidelines have been published (http://bmchealthservres.biomedcentral.com/articles/10.1186/1472-6963-14-321). Our Evidence to Decision Frameworks (BMJ in press) have been developed to support guideline panels to explicitly consider research evidence in their judgements and were tested with the World Health Organisation (WHO) guideline panels and others. A DECIDE tool to present interactive versions of evidence summaries called an interactive Summary of Findings (iSoF) table allows users to tailor a presentation to their own needs. An online randomised trial of the iSoF found that people want numbers in health information (rarely provided now) and that members of the public could not answer questions about benefits and harms with the current versions of patient information used in the trial. The GRADEpro Guideline Development Toolkit (GRADEproGDT, http://gradepro.org) has been developed by DECIDE and a key collaborator, the GRADE Working Group, to package much of DECIDE's work into a single tool and currently has over 11,000 users.

Dissemination has been key throughout the project and has been helped through the substantial collaboration with the GRADE Working Group, the work of which underpins many guidelines and much of DECIDE. DECIDE partners have presented work to the European Commission's European Monitoring Centre for Drugs and Drug Addiction (EMCDDA), the European Commission Initiative on Breast Cancer (ECIBC), WHO and DECIDE had a major presence at the annual Guidelines International Network conferences. A DECIDE international conference was held in Edinburgh in 2014 to further disseminate results to 270 international participants.

DECIDE has provided new information for guideline producers about how they can best meet the needs of the different users of their guidelines as well as how they can be more systematic about using research evidence when making their recommendations. GRADEproGDT, and the link to the GRADE Working Group, means that guideline producers and others will benefit from DECIDE's results well beyond the end of the project. For more information see http://www.decide-collaboration.eu.

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PROJECT CONTEXT AND OBJECTIVES

Project Context

Health professionals, patients, policymakers and the public aspire to making healthcare decisions on the basis of the best available research evidence. However, experience shows that this is frequently not achieved. Reasons for this deficiency include the overwhelming amount of research literature that is sometimes contradictory and presented in ways that are difficult for non-researchers to understand. Clinical guidelines and health technology assessments (HTAs) (we will use 'guideline' to describe both guidelines and HTAs) have emerged as a source of support, i.e. recommendations that have been systematically developed by panels of people with access to the available evidence, an understanding of the clinical problem and research methods, and sufficient time for reflection.

Guidelines might seem a convenient means by which to package evidence and present recommendations to healthcare decision makers; nevertheless, there is a problem. Decisions should be influenced not only by the best estimates of the expected advantages and disadvantages of a therapy or intervention but also by the confidence in these estimates. Guideline developers have been inconsistent in how they rate quality of evidence and grade strength of recommendations despite of the critical role of these processes in guideline production. As a result, guideline users face challenges in understanding the guideline's messages. Additionally, guidelines are typically developed as a one-size-fits-all package with no attempt at tailoring the guideline for particular audiences, based on little or no attempt to gain empirical evidence regarding what users need and want to support their decisions.

The GRADE system

To address these problems, the GRADE Working Group - a widely representative international group of guideline developers, health professionals, epidemiologists and statisticians - has spent over a decade developing an approach towards assessing and communicating the quality of evidence and the strength of recommendations (www.gradeworkinggroup.org). GRADE is now used by a wide range of organisations in Europe and elsewhere, including the World Health Organisation, Cochrane, the UK National Institute of Health and Clinical Excellence (NICE), the Spanish Guideline National Programme of Guideline development, the Scottish Intercollegiate Guidelines Network (SIGN), The German Agency for Quality in Medicine, the Swedish Council on Technology Assessment in Health Care (SBU), the American College of Physicians (ACP), BMJ Publishing, Clinical Evidence and UpToDate. The enthusiasm with which GRADE has been adopted underlines the limitations of alternative systems.

DECIDE's objectives

DECIDE aimed to improve the dissemination of evidence-based recommendations by building on the work of the GRADE Working Group, of which most DECIDE partners are members. Our aim was to optimise the spread of knowledge and use of evidence-based interventions in a sustainable way, move shared decision making forward and reduce the use of interventions where benefits are uncertain, particularly in relation to harms.

DECIDE's objectives were to develop and evaluate strategies that effectively present research evidence in guidelines to the key stakeholders who determine what happens in clinical practice. More specifically, we aimed to develop and evaluate strategies for effectively and efficiently communicating and supporting the uptake of evidence-based recommendations to:

- Healthcare professionals
- policymakers and managers
- patients and the general public

In addition to addressing recommendations about prevention, treatment and rehabilitation, we aimed to develop strategies for recommendations about:

- diagnostic tests
- health system policies that enable or inhibit evidence-based clinical practice

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To ensure wide dissemination of DECIDE's results we aimed to:

- develop a tool kit for preparing and disseminating evidence-based recommendations
- develop a database of evidence profiles
- host a European conference on promoting the use of evidence-based interventions
- have a multifaceted dissemination plan

Although DECIDE focused its work around the needs of different types of stakeholder, the approach taken to identify these needs were generally similar for each stakeholder group.

Literature reviews and brainstorming

The starting point for much of our work was to review the existing literature to examine what is already known about research presentation methods for particular target groups. This work avoided reinventing the wheel. Our work reviewing the literature covering the evidence around patient and public understanding and knowledge of healthcare guidelines, for example, identified well over 5000 articles, of which 26 met all the inclusion criteria and involved 24,887 individuals. Overall, participants had mixed attitudes towards guidelines; some participants found them empowering but many saw them as a way of rationing care. Awareness of guidelines amongst the public was generally low. Work with health professionals suggested that guidelines had a tendency do you overload them with information. The grading systems used to grade evidence on diagnostic tests was reviewed, which informed work on how this process might be improved and how the results of the grading might best be presented.

Brainstorming was used across DECIDE and throughout the project as a rapid way to generate ideas that can then be tried out in user-testing and other evaluations. Four example, our work with health professionals discovered that they found presentations to be too complex, wordy and crowded. Policy makers and those making decisions around health systems provision tended to find current evidence summaries overwhelming, as well as missing out information on things such as applicability of the evidence to their own context and the impact on inequality. Brainstorming was also an effective way for members of the project to take diverse research findings and focus on those which were likely to have the greatest relevance and impact.

This work also led to the choice of clinical topics to focus on. This was done in several phases with the aim being to choose topics that would be of wide interest to all countries involved. The initial list included, for example, diabetes and acute respiratory tract infections, as well as obesity for our work with patients and atrial fibrillation for work with policymakers. This list evolved as the project progressed and became more driven by topics that were of current and real interest to real guideline developers. So, for example, a Scottish glaucoma guideline was updated in 2014/15 so we worked on glaucoma, several dental topics were covered for the same reason. The use of lay health workers was a topic of importance for policymakers working with WHO and was an opportunity to test some DECIDE strategies and tools; the same was true for breast cancer screening. So, while topics were initially selected as likely to be of general interest, we moved to topics that were of present importance to our guideline producer partners and other stakeholders.

Testing DECIDE presentation strategies

Once an idea for a presentation method or format was developed, DECIDE got the opinion of our stakeholders through user-testing. Indeed, user testing became one of our most important and valuable evaluation methods for emerging presentation strategies because of its ability to provide a rich and actionable results with relatively few participants. Each user-test took around one hour, we generally audio-record each test, and an observer took notes. Using a semi-structured interview guide, we then explored both immediate first impressions as well as detailed descriptions of users' reactions to the presentation method or format. The format of user-testing varied but we found that one-to-one worked best.

The results of user testing can be striking. With health professionals and the public, user-tests have provided clear messages. First and most important they liked our layered approach where

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information is presented in stages rather than all at once. Key information is presented first, users then select what else they want to see, if anything. Many users do not want more than the key information, which is why many guidelines appear overwhelming to them. User-testing with policymakers found that they needed better definitions of concepts such as inequity and desirable effects, as well as more information on costs. Work with policymakers and those responsible for implementing care at the health systems level led to work developing new ways of presenting research summaries called Summary of Findings tables. An interactive Summary of Findings (iSoFs) table tool was developed, which supports a layered approach to presenting research evidence guidelines where the user decides how much (or how little) information to review.

The iSoF was evaluated in a large online trial online trial involving 2,194 members of the public, the key finding being the key findings being that when presented with standard patient information or a static SoF without the absolute effect, participants were, for the most part, not able to answer questions about the size of the benefits and harms or the certainty of the evidence correctly. When presented an iSoF or static SoF with the absolute effect, most patients were able to answer questions about the size of the benefits and harms correctly compared to standard patient information or a SoF without absolute effect for benefits.

Another finding from user-testing was that health professionals and patients wanted materials to support shared decision-making in the consultation. Together with a collaborator called MAGIC (MAking GRADE the Irresistible Choice) we have user-tested shared decision-making tools, involving both health professionals and patients, for a range of decisions including whether to continue anticoagulation treatment and whether to extend tamoxifen treatment from five years to 10 years as part of breast cancer management. The intention is that such tools could be linked to an electronic guideline, meaning that a shared decision-making tool could be routinely available for many or all recommendations in the guideline.

Brainstorming and user-testing also made it clear how evidence is presented to and assessed by members of guideline panels was an area where DECIDE could make a difference. This led to the development of Evidence to Decision frameworks, which provide a structured approach to using evidence in guideline panel discussions to reach decisions. The frameworks differ depending on the type of decision being made but share many features such as a clear structure to which factors need to be considered when reaching judgements about the impact of a treatment or other healthcare initiative on, for example, patient outcomes, patient preferences, equity and costs. They support consistency with regard to what is considered by panels as well as making the decision process transparent. DECIDE has produced an interactive version of the Evidence to Decision framework, which also includes interactive Summary of Findings tables.

A toolkit for preparing and disseminating evidence-based recommendations

DECIDE has developed a wide range of outputs, in particular layered presentation formats for recommendations, Evidence to Decision frameworks and interactive Summary of Findings tables. The majority of DECIDE outputs have been packaged into the GRADEPro Guideline Development Tool (GRADEproGDT) (http://gradepro.org). The GRADEproGDT is the replacement for the GRADEprofiler software developed by the GRADE Working Group but unlike the old software, GRADEproGDT supports the whole guideline production process as well as providing evidence profiles and Summary of Findings tables support.

GRADEproGDT assists guideline developers in preparing summaries of the evidence according to the DECIDE presentation strategies and in using the systematic and transparent process for moving from evidence summaries to final health care decisions. The toolkit includes templates for presentations of research evidence and recommendations (including text, tables and, if appropriate, figures) developed in DECIDE, which can be tailored by toolkit users if required. The toolkit can be used to prepare evidence-based recommendations and supporting materials in English, German and Spanish. Support for Dutch, French, and Italian is being implemented. DECIDE's toolkit also includes training material in English, Dutch, French, Italian, German and Spanish. GRADEproGDT allows users at different sites to collaborate on preparing summaries of evidence and sharing this information electronically in a database of evidence profiles. The tool

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now has over 11,000 users and is used for numerous guideline projects including the European Commission Breast Cancer guidelines initiated in 2015.

Database of evidence profiles
The primary reason for having a database of evidence profiles is to facilitate collaboration across European guidelines developers and to avoid duplication of effort. A database would need to accept input in a common data format to allow interoperability between a variety of electronic tools used by European and international guideline developers. The profile database accommodates the changing and evolving nature of the grading methodology over time (such as new empirical evidence from DECIDE). This makes storing static documents (such as pdf files of finished evidence profiles) less appealing. Instead, the database stores the individual data points, for example, effect sizes, and the evidence profile is re-created on demand. This allows for the highest flexibility in providing different profile presentations that can be utilized for targeted user testing in randomised trials and allows the creation of different output formats, such as pdf files, rich text formats, or graphical forms. In addition, the original data set can be downloaded at any time for reuse and for easy updating at a later time point.

A European conference to promote DECIDE strategies
Dissemination has been a central component of the DECIDE project. One of the biggest dissemination activities was the DECIDE conference held in Edinburgh, Scotland in June 2014. The conference was attended by delegates representing guideline producers from across Europe and beyond - together with representatives of those who use guidelines such as professional societies, medical charities, patient organisations, funders and policy makers.

The objective of the event was twofold:

- To showcase the work coming from the project
- To be a forum for international colleagues to influence the final stages of DECIDE

The conference was a great success with over 270 registered delegates from 20 countries attending. In addition to plenary presentations from external speakers and members of the decide group, there were 29 parallel workshops showcasing and discussing DECIDE work. Feedback on the conference was overwhelmingly positive, it led to additional collaboration and workshop discussions lead to changes in some of DECIDE's outputs. In addition to those physically present at the conference, the conference was well represented on twitter with the conference hashtag being used in 715 tweets from 117 people with 267,596 impressions.

Future dissemination
Starting from DECIDE's initial press releases and the creation of the project website, we subsequently delivered 37 workshops, 74 oral presentations, 18 poster presentations, videos, flyers and other materials to promote the project. In addition to our International Conference we have also produced 17 peer reviewed publications (including accepted / in press). DECIDE's work is now embedded in the GRADEproGDT and the link to the GRADE Working Group means that guideline producers and others will benefit from DECIDE's results well beyond the end of the project. DECIDE guidance summarising how guideline producers should present materials aimed at patients and the public is part of the Guidelines International Network Public Toolkit, again ensuring dissemination beyond the life of the project. DECIDE's work has now been summarised as a series of dissemination packages available on the DECIDE website (http://www.decide-collaboration.eu).

The DECIDE protocol was published in the Open Access journal Implementation Science: http://www.implementationscience.com/content/8/1/6.

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MAIN SCIENTIFIC RESULTS

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.
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 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.

More information is available at http://www.decide-collaboration.eu.

***Figure 1**: Key DECIDE findings and tools*

A more detailed summary of what each of the six DECIDE Work Packages did and found is given below.

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Work Package 1: Presenting evidence-based recommendations to health professionals

Health professional are key users of guidelines, indeed they are perhaps the most obvious users of guidelines produced by organisations such as the World Health Organisation (WHO) and the UK's National Institute for Health and Care Excellence (NICE). DECIDE's initial work for health professionals was based on work done by the GRADE Working Group (http://www.gradeworkinggroup.org) and Cochrane (http://www.cochrane.org), both of which were partners in the project. In particular, we used their 'Summary of Finding tables', tabular summaries of research information that both groups had developed and tested. From this starting point, we used multiple methods to develop templates for presenting evidence-based recommendations, supporting material, and communication strategies to health professionals:

- Brainstorming workshops (e.g., with DECIDE partners) to generate ideas.
- Review of published work (such as tests of Summary of Findings tables) to inform development of our communication strategies.
- Stakeholder feedback (e.g., from health professionals, policymakers, guideline authors) to inform development and revisions from diverse perspectives.
- User-testing (e.g., with general practitioners). To guide our revisions from a user perspective.

We also put together an Advisory Group, comprising individuals who were purposely selected to ensure a breadth of perspectives and who could give guidance on strategy, protocols and specific approaches and tools. This was especially useful at the start of the project.

The key findings from the above activities were:

1. Current guideline presentations are often overwhelming.
2. To be useful, it must be possible to quickly find guideline information relevant to a clinical decision ('EBM [evidence-based medicine] at 3am' as one family doctor described it).
3. Health professionals want a layered presentation that gives key information first (generally a guideline recommendation) with other information (e.g. information on why the recommendation is what it is) available if required.
4. Health professionals would value resources to support their conversations with patients during consultations.
5. The way evidence is presented and used in guideline panels could be improved, in particular help to make the decision-making process consistent from recommendation to recommendation.

Many of these findings were also found in the other Work Packages, especially the desire for a layered presentation of guideline information. This finding was so strong that it drove much of DECIDE's work, not only with health professionals but with other types of guideline user as well. In concrete terms, for a guideline based on the GRADE system (a system used by many international guideline producers, see http://www.gradeworkinggroup.org/society/index.htm), this meant that the 'Top Layer' would be the recommendation itself, followed by information supporting the rationale for this recommendation. This would include the quality of the evidence, the balance between harms and benefit and information on patient values and preferences. Digging deeper into the layered structure would provide, for example, the full evidence profile behind the recommendation and links to references. Making information available quickly also points towards electronic guideline formats rather than paper.

The work on layered presentations led to a collaboration with the MAGIC research and innovation program (http://magicproject.org) to develop the Top Layer for health professionals. An example of how this multilayered presentation would look for a real guideline is shown in Figure 2 which shows the DECIDE layered approach used in a real Norwegian guideline. An article describing the approach was published in CHEST in 2014 (http://journal.publications.chestnet.org/article.aspx?articleID=1916306). Several guidelines have been published with the multilayered formats developed in DECIDE and MAGIC and two

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innovation projects have been launched in Scandinavia to further develop strategies and tools. Also in Scandinavia, health authorities are also now applying DECIDE strategies to collaborate on the creation, dissemination and dynamic updating of trustworthy clinical practice guidelines. This will include the publication of guidelines in multilayered formats as developed in DECIDE.

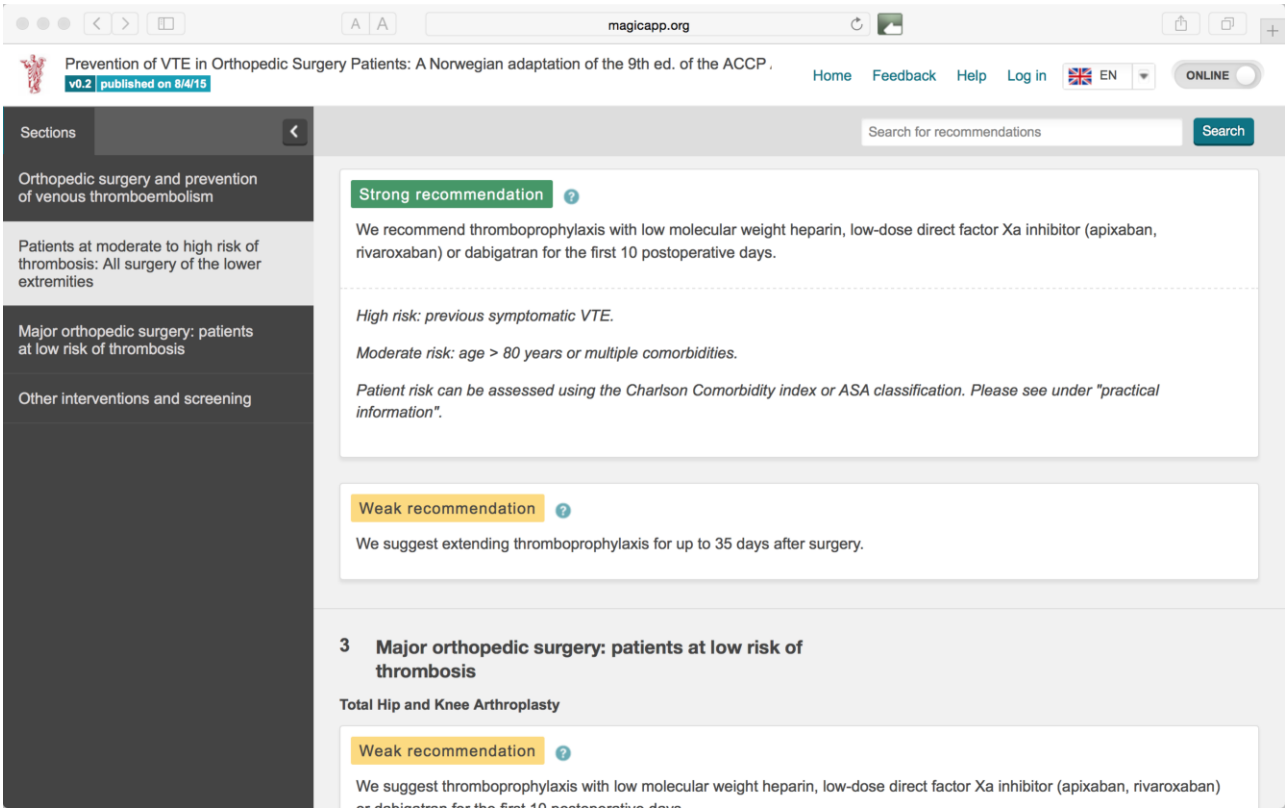

Figure 2: *The WP1 layered presentation, here showing the Top Layer, essentially the recommendation itself*

The finding that health professionals would value materials to use in consultations with patients was mirrored in our work with the public and patients (Work Package 3), which found that they too would value this. Together with MAGIC we have user-tested shared decision-making tools, involving both health professionals and patients, for a range of decisions including whether to continue anticoagulation treatment and whether to extend tamoxifen treatment from five years to 10 years as part of breast cancer management. Feedback from participants has been positive. Patients in Scotland, for example, really liked the clarity of the presentation shown in Figure 3 for decisions around the extension of tamoxifen treatment in breast cancer management. The intention is that such tools could be linked to an electronic guideline, meaning that a shared decision-making tool could be routinely available for many or all recommendations in the guideline. A paper describing the general approach was published in the BMJ early in 2015 (http://www.bmj.com/content/350/bmj.g7624.long).

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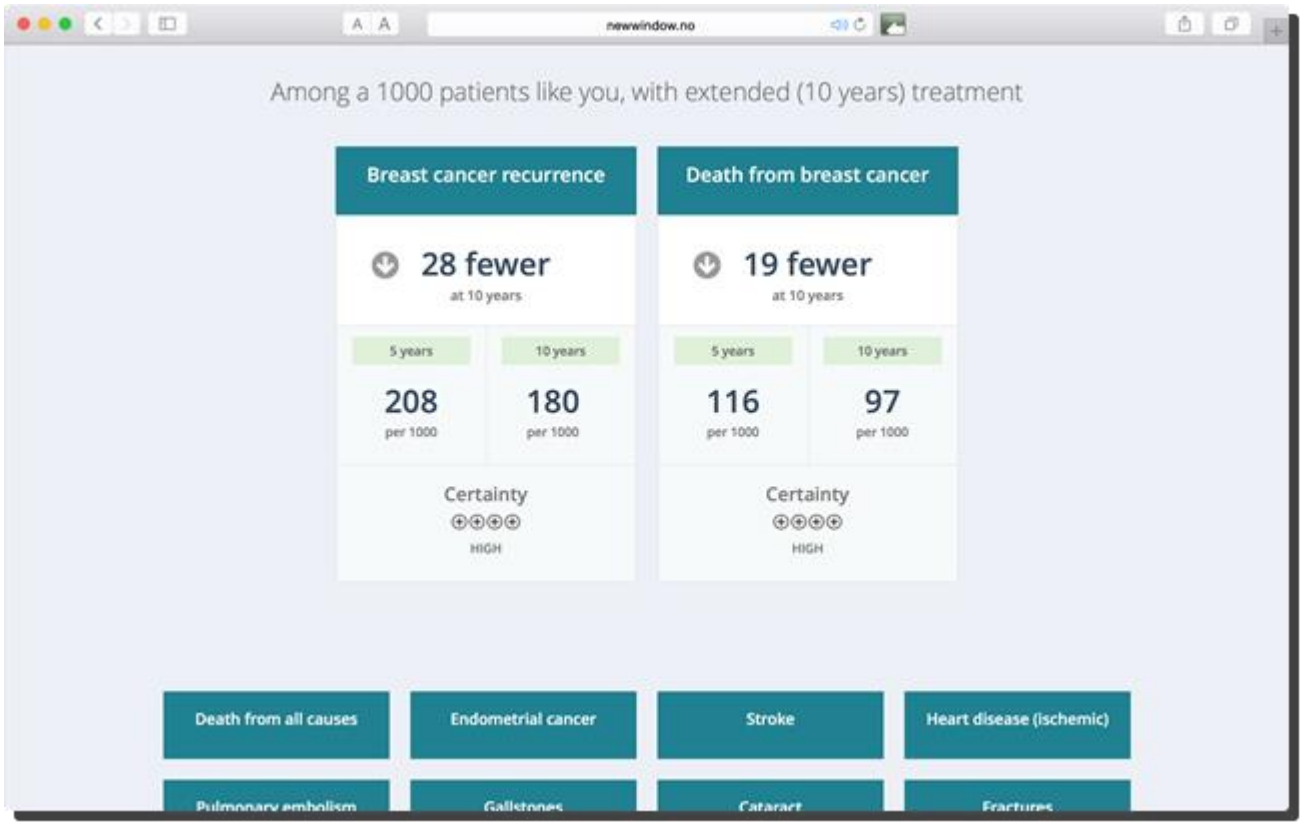

Figure 3 *The decision tool tested in Scotland for decisions around the extension of tamoxifen treatment in breast cancer management from five years to ten.*

Improving the way evidence is used by guidelines panels when drawing up recommendations was addressed by DECIDE through the development of a new tool called the Evidence to Decision framework. This is described in more detail in the Work Package 2 summary.

Work Package 2: 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 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

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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

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

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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 4 shows one of the opening screens of an interactive Evidence to Decision framework.

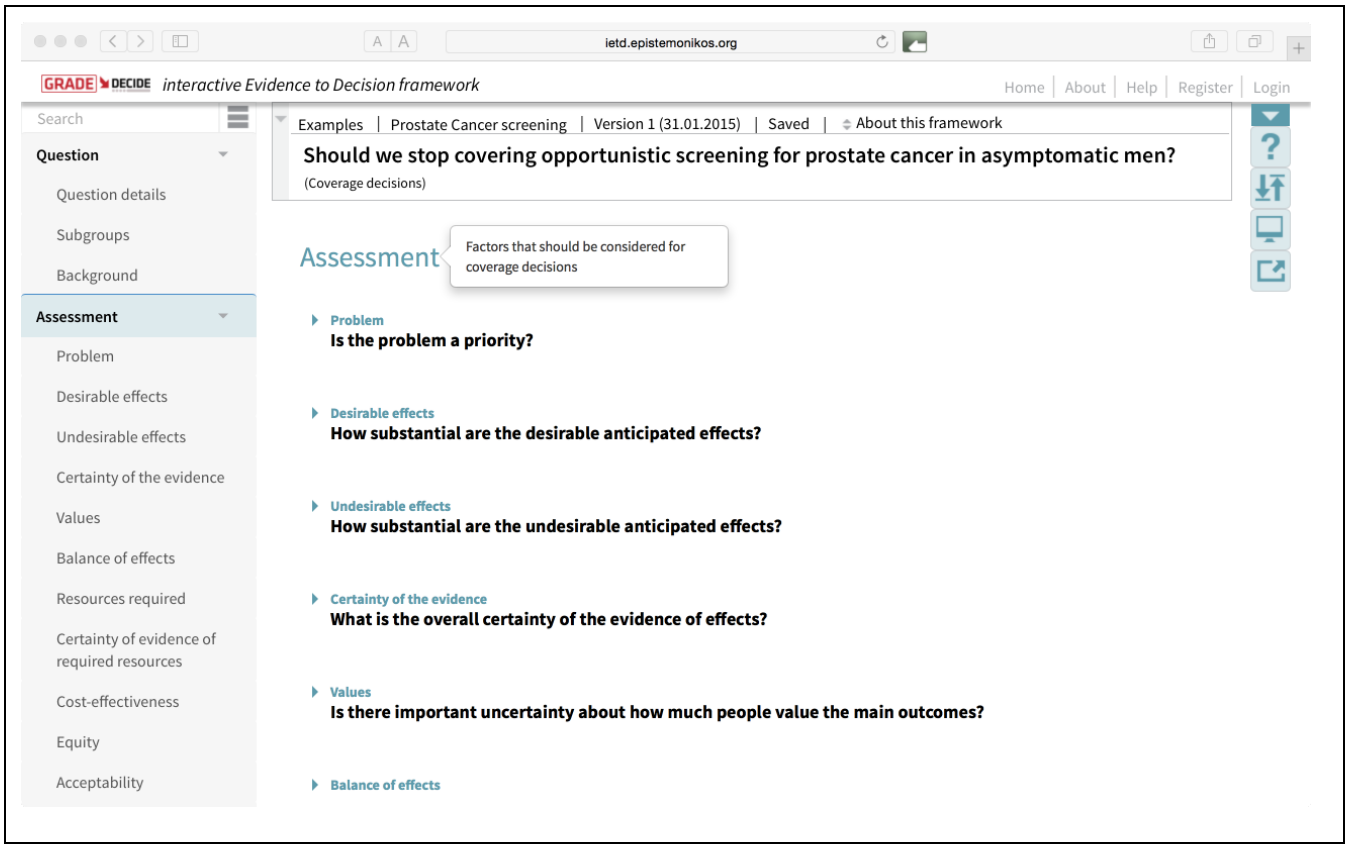

Figure 4 *The interactive Evidence to Decision framework tool for a coverage decision*

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Work Package 3: Presenting evidence-based recommendations to patients and the general public

A survey conducted by the UK National Institute for Health and Care Excellence (NICE) and the Scottish Intercollegiate Guidelines Network (SIGN), both DECIDE partners, done at the start of the project demonstrated a demand for guidance on healthcare among members of the public. People were interested in using clinical guidelines in their care and treatment. However, many respondents were unclear about the role and sources of information on guidelines. Many guideline producers are starting to produce versions of their guidelines meant for patients, carers and the public. However, it was clear that guideline producers were themselves not clear about how they intended these to be used, or why they chose to make them look the way they did. To address this problem, we began by doing a systematic review of the literature on patient and public attitudes to, and awareness of, guidelines. The search identified 26 studies that met all the inclusion criteria and involved a total of almost 25,000 individuals. Overall, participants in the included studies had mixed attitudes towards guidelines; some participants found them empowering but many saw them as a way of rationing care. Patients were also concerned that the information may not apply to their own health care situations. It is important that patient versions are clear about who the information is for so that potential users know what the information has to do with 'someone like me' and how it can be used to make healthcare improvements. With the exception of a survey conducted through a national guideline producer's website, awareness of guidelines amongst the public was extremely low to non-existent. The full results were published in 2014 (http://bmchealthservres.biomedcentral.com/articles/10.1186/1472-6963-14-321).

We supplemented the literature review with a series of focus groups with patients and members of the public, plus one group with professional health care writers and communicators such as journalists and people who write content for health charities' websites. This allowed us to explore general issues around guidelines, as well as considering in more detail a few issues that are known to be problematic, such as how to present information about uncertainty to the public. A survey of international guideline producers also confirmed the need for guidance with regards to how patient versions of guidelines should be put together. For example, only 21 of 34 (62%) patient versions from 17 producers stated their purpose clearly (something patients and the public want) and none presented numerical information linked to the recommendations (which is known to increase understanding). Presenting information regarding uncertainty was also rare.

Using findings emerging from the reviews and survey, together with brainstorming and consultation with our Advisory Group, we developed a range of alternative presentation strategies that could be used in patient versions of guidelines. These strategies were discussed with focus group participants as well as in user-tests where we asked participants to provide feedback on particular elements of the presentations, as well as overall impressions. This work found that the following issues are considered important when using guidelines

- Context: who is the information for?
- Background information about the condition: What are the risk factors? How will the condition progress? How long will the condition last? What is the risk of other problems arising from the condition?
- Information about the treatments and interventions: What are the treatments, including the alternatives? What are the risks associated with treatments? What can I do for myself (i.e. self-management)?
- Where can I find more help (e.g. phone numbers and website for sources of support)?
- How are guidelines produced?

This information, together with the literature review and our survey, helped us to develop guidance for how a guideline producer should present patient versions of their guidelines. The DECIDE presentation strategies for patient versions of guidelines include changes to how information is organised, making it clearer who the information is for and what information is being provided, making it clear what the recommendations are and favouring self-management recommendations. We also developed different ways of presenting numerical information as well as information

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regarding uncertainty. Figure 4 is an example of one way of presenting recommendations; this presentation makes it clear what the recommendations are, as well as being a format that uses a structured 'words only' method to present the recommendation. The sentence structure and words used are linked to the size of effect and the quality of the underlying evidence. This presentation went on to be used in real patient version of guideline produced by the Scottish Dental Clinical Effectiveness Program (SDCEP) (http://www.sdcep.org.uk/published-guidance/periodontal-management/).

A randomised comparison of two versions of the same real SDCEP patient version of a guideline on dental care and bisphosphonates, one produced before working with DECIDE, and one using DECIDE strategies, involving 90 people in Scotland found that using DECIDE strategies made the intended purpose of the information clearer (69% found the old version very clear or clear; this increased to 92% for the DECIDE version), increased confidence in picking out the most important information (increased from 55% to 67%) and was easier to understand (increased from 55% to 72%). It is important to note that the basic information remained the same in both versions; the crucial difference is that presenting that information according to DECIDE ideas helped make the information more useful.

These strategies have become a central part of the updated chapter on producing patient versions of guidelines in the Guidelines International Network (G-I-N) Public Toolkit. The new version was launched at the G-I-N 2015 conference held in Amsterdam in October 2015. The DECIDE innovation is to connect the advice in the Public Toolkit to research evidence generated by DECIDE and other research groups. The chapter is a template for guideline producers working on their own patient versions.

The new version of the Toolkit, including the new Chapter 7 on patient versions of guidelines is freely available at http://www.g-i-n.net/working-groups/gin-public/toolkit. A Scottish national glaucoma guideline, incorporating DECIDE strategies from the Toolkit, has also been published (http://sign.ac.uk/guidelines/fulltext/144/index.html) along with a publication describing the user-testing done to develop the guideline (http://bmchealthservres.biomedcentral.com/articles/10.1186/s12913-016-1287-8).

Figure 5 shows the main findings from the user-testing. Following from this work, NICE is undertaking a major review of all presentation formats of guidelines and findings from DECIDE are being incorporated into revised information for patients.

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Theme	Findings
Usefulness / Value	• Patient versions of guidelines can inform and empower people to ask questions. • They can help people to anticipate what to expect when seeing a healthcare professional or having an intervention. • They may be most useful to patients around the time of their diagnosis. • Information about risks is most useful if directly associated with information about self management or any form of action. • Simple diagrams and charts can communicate information clearly. • It is helpful to flag clearly any important areas not covered by the guideline. • Signposting to organisations that can provide help and further information is valued.
Usability	• Language should be kept as simple as possible • User testing may help to identify how much technical information to include. • Small font size, use of light/pale colours, and too much material on a page were major barriers to use of the guideline by this patient group. • Clear flagging of recommendations using headings/icons works well. • A risk of 2 in 100 was interpreted by some as very high and others as very low. • Icons for levels of recommendation worked best when kept recognisable, with a clear link to the intended message. • Vague or generic icons can cause confusion and be misinterpreted e.g. a blue circle can be interpreted as a zero. • Uncertainty was effectively communicated by the “?” icon but people may not know how to respond to this information.
Credibility	• Credibility arose from information on the guideline production process, and the involvement of qualified professionals. • The status of the guideline is important (do health services recognise the recommendations). • Credibility may be threatened by pathways or recommendations that do not fit with the patient’s own experiences.
Desirability	• Participants were very positive about the look and feel of this patient version. • Aspects that increased desirability included a friendly tone, simple language, chunking of text, the use of colour, glossy “high quality” look, and use of icons/images. • A friendly feel is achieved by informal language, use of colour, and the inclusion of quotes and images/icons. • Negative language or images, and a bureaucratic/dogmatic tone were disliked. • Quotes can personalise the material, giving it an engaging and friendly tone, and emphasising a particular message.
Accessibility/ Findability	• The brief contents page, with simple question based headings was clear and facilitated flicking to relevant sections. • The participants were very concerned about the apparent lack of dissemination of patient versions of guidelines. • It is important for printed copies of the guideline to be available. • The patient version must be tailored to the intended audience’s needs (e.g. font size, language/numerical information). • Information on how to access the services/interventions recommended is important. • Clear branding as a patient version is required. • Clear information on “who this booklet is for” encouraged people to read and share the guideline. • It is important to give telephones numbers and addresses as well as websites for signposted organisations.

Figure 5: *Summary of the main findings from the SIGN user-testing of their national glaucoma guideline. The full publication is at* http://bmchealthservres.biomedcentral.com/articles/10.1186/s12913-016-1287-8

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Our work with patients, together with our work with health professionals, suggested that both patients and health professionals would appreciate resources to support their discussions during consultations. This led to the development of tools to support shared decision-making that are linked directly to guidelines. The reaction from patients to these materials has been very positive, with the very clear presentation of the numerical information (which is rarely presented in patient versions of guidelines) coming in for particular praise. More information about this work is presented in our summary of work with health professionals. Recent NICE guidelines often have accompanying tools to support decision making and again, findings from DECIDE may be incorporated.

Also of relevance to patience is DECIDE's work the interactive Summary of Findings (iSoF) table. The iSoF was evaluated in an online trial run in Scotland using the SHARE register (http://www.registerforshare.org). The trial involved a close collaboration with the SHARE team to email almost 50,000 members of the public in Scotland who had expressed an interest in taking part in health research. The trial was by far the biggest study done using the SHARE register to date. A total of 2,194 people responded during the one month trial: see the summary of our work with health systems policy for more information.

Figure 6: *An example of one DECIDE strategy for how recommendations can be presented in a patient version of guideline.*

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Work Package 4: Presenting evidence-based recommendations about diagnostic tests

We planned our work in three phases. In a first phase we aimed at identifying current strategies to develop and communicate evidence-based recommendations about diagnostic tests. In a second phase we wanted to enhance these strategies and/or fill the identified gaps. In a third step, we moved to user testing for refining the strategies. Because the development of evidence-based recommendations of diagnostic tests is less well understood compared to recommendations for therapeutic interventions, we spent some time fine-tuning and elaborating the methods for arriving at diagnostic recommendations, to achieve effective presentation strategies.

Two systematic reviews were performed. In the first we compared grading systems for medical tests on how they use evidence in guideline development. Twelve grading systems were included in the review. They varied in the degree to which methodological and process characteristics were addressed. Five systems for grading evidence about medical tests in guideline development addressed - to differing degrees of explicitness - the need for and appraisal of different bodies of evidence, the linking of such evidence, and the translation into recommendations. At present, no one system addressed the full complexity of gathering, assessing and linking different bodies of evidence for making recommendations about tests. The review was published in 2013 in Implementation Science (http://www.implementationscience.com/content/8/1/78).

The second systematic review (submitted for publication) was aimed at methods used by organisations developing recommendations about diagnostic tests. We found 44 tools and modifications therefor to assess the quality of evidence supporting diagnostic tests and testing strategies. These tools used inconsistent terminology and the criteria for moving from evidence to recommendations were found incomplete for most guideline development frameworks that were evaluated.

One of the better known and developed grading systems is GRADE. Originally developed for evaluating and making recommendations around interventions, GRADE is now working towards a system that is also applicable for diagnostics. As part of our work in understanding current strategies in phase 1, we applied the GRADE for Diagnostics approach on three Cochrane diagnostic test accuracy reviews to further enhance understanding around the ‘‘practical’’ application of the approach and identify real-life challenges and considerations a user of this approach may encounter. By doing so, we aimed to provide suggestions on how the GRADE for diagnostic approach may be enhanced. This work was published in 2014 in the Journal of Clinical Epidemiology (http://www.sciencedirect.com/science/article/pii/S0895435614000444).

We then conducted two qualitative interview studies (submitted for publication) involving guideline developers and experts with a variety of backgrounds, formal training and experience in methods of evaluating evidence and making recommendations about diagnostic tests. In these we found that diagnostic test accuracy – based on comparisons between test results and the gold or reference standard – was the factor most commonly considered by organisations when formulating recommendations. The majority of experts pointed out that accuracy alone is not sufficient and that recommendations based on accuracy only may be misleading. From the analysis of the interviews we learned that the challenges guideline developers currently face are interlinked; these challenges can be found in methodological issues (e.g. how to link different types of evidence), resource limitations (e.g. the limited time and money for developing a guideline) and a lack of awareness regarding using patient important outcomes, instead of diagnostic accuracy, as the criterion for making recommendations.

The central and recurrent theme of the DECIDE approach with regard to diagnostic testing is the need to widen the focus of test evaluations, from relying on diagnostic test accuracy only to using the effect on patient important outcomes as the decisive factor. Similar to the development and presentation of recommendations about treatment interventions, the central question when building recommendations about diagnostic tests is the existence and magnitude of health benefits for the patients in whom testing is considered.

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When evaluating potential benefits one should not only focus on the test, but also consider the clinical management that follows from the test result. Since studies that present direct effects from testing on health outcomes our rare, any methodology for evaluating tests or for building recommendations should consider using, assessing and possibly linking different types of evidence. This may include evidence about test performance, but also evidence about the effectiveness of downstream actions, guided by the test results.

This complex process can be facilitated by adopting the test-treatment pathway approach and a diagnostic Evidence to Decision framework. The pathway starts with how and where patients disease present themselves, and runs via testing to management decisions and ultimately to patient outcomes. The pathway approach can be used to clarify differences between alternative and existing testing strategies. It can also be used to describe how the introduction of a new test change current management pathways.

At present, some guideline producers mention the identification of such pathways in their guidance. It can be an element of a scoping exercise, or a part of key question development. Explicit instructions on how to map the pathway are usually missing, unfortunately.

We used the Patient–Index test–Comparator–Outcome (PICO) elements, which are well known from questions about the effectiveness of therapeutic interventions. From these we developed a structured set of trigger questions that can be used as an initial starting point to identify the test-treatment pathway for a medical test. PICO is already a common feature in evidence-based medicine methodology. The Cochrane handbook for systematic reviews of diagnostic test accuracy studies also recommends the PICO system to define the pathway. PICO is also used in the GRADE approach for diagnosis.

The basic framework for starting to build test-treatment pathways and the corresponding PICO elements in it are shown in Figure 7.

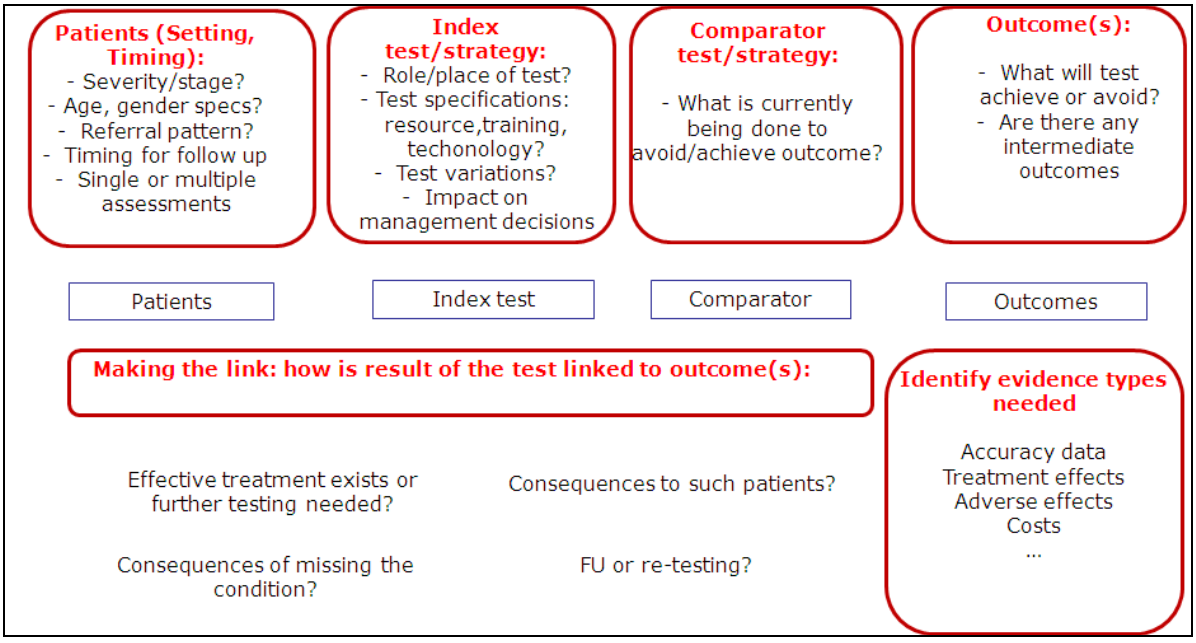

Figure 7: *Framework built on the PICO elements for identifying the test-treatment pathway*.

In a number of workshops and other applications we have done user testing of the PICO approach for identifying the test-treatment pathway. This led to a further refinement of the triggering questions to clarify the respective elements in the pathways. We also found out that graphical tools, borrowed from decision trees as used in decision analysis, help to clarify the structure and the possible alternatives in test-treatment pathways. In these tools, time runs from left to right, with

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patient presentation starting left and possible outcomes towards the right end. Branches in the trees indicate alternative lines of actions, guided by the results from testing.

Work Package 5: Presenting evidence-based recommendations about health system policies

In common with other Work Packages, our work for people working on health system or public health policies used brainstorming, a survey, a literature review, its Advisory Group, prototyping and user testing to steer its direction. We did not find any published evaluations of strategies for disseminating health technology assessments or recommendations to policymakers and managers. As became clear from our work, recommendations and decisions depend on information and judgements that are beyond the scope of systematic reviews. Issues in need of consideration include the applicability of the evidence, costs, impacts on equity, acceptability and feasibility. Even when specific answers are not available; when the evidence is too uncertain to provide clear answers, or decision makers' settings vary greatly from those in the studies, policymakers still must make decisions. When there are important uncertainties, as is often the case, they may still decide to implement a change. Being clear about what those uncertainties are can help ensure appropriate monitoring and evaluation when changes are implemented, so that future decisions, such as whether to continue, modify or discontinue changes that were made, will be better informed.

DECIDE addressed the challenges that policymakers face by building on previous work, and developing and evaluating three strategies to communicate evidence-based health system and population (public) health recommendations effectively and efficiently:

- interactive Summary of Findings to facilitate understanding and use of the results of systematic reviews in health system and population health recommendations and decisions
- interactive Evidence to Decision frameworks to facilitate going from evidence to health system and population health recommendations and decisions
- explanations of terms relevant to health system and population health recommendations and decisions

The majority of this work had relevance to other Work Packages and was therefore done in collaboration with them.

Interactive summary of findings (iSoF)
A SoF table presents the key messages from a systematic review in a concise format. The table is an output from the Grading of Recommendations Assessment, Development and Evaluation (GRADE) system. SoF tables include seven elements that have been judged to be most critical when making a health care decision (see Figure 8). These judgments are the cumulative result of efforts over the last decade of the GRADE working Group and the Cochrane Applicability and Recommendations Methods Group.

1. A list of the most important outcomes, both desirable and undesirable
2. A measure of the typical burden of these outcomes (e.g. control group, estimated risk)
3. A measure of the risk in the intervention group or, alternatively or in addition, a measure of the difference between the risks with and without intervention
4. The relative magnitude of effect
5. Numbers of participants and studies addressing these outcomes
6. A rating of the overall confidence in the effect estimate for each outcome (which may vary by outcome); and possibly
7. Comments

Figure 8*: Seven elements of a Summary of Findings table*

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We have improved the SoF format by making it both simpler and more comprehensive, as well as more flexible. Our goal has been to make the table compatible with the needs of a wide range of users (e.g. health professionals, the public and policymakers with different levels of experience reading research results), as well as with different types of data and use contexts. To achieve this, we designed an electronic, interactive Summary of Findings table (iSoF) that allows table producers to tailor the presentation to their target audience by adjusting which outcomes and how much information about those outcomes are displayed. More importantly, the new solution allows users themselves to interact with the table by adding or hiding outcomes, by adding or hiding information about those outcomes, by viewing results as numbers, text or graphic representations, and by accessing explanations of standard concepts (such as confidence intervals) and topic specific explanations provided by the producer. For a more detailed list of specifications for development, see Figure 9.

Figure 12 is a screenshot of an iSoF for a health systems decision, showing all of the information for each outcome. Figure 13 is a screenshot of the same iSoF but now with some of the columns closed down. We developed the iSoF through iterative cycles of user-centred design, prototyping and user testing. We also gathered feedback from key stakeholders at several intervals.

Features for users:

- Simple, user-friendly interface
- Layered presentation of information, allowing users to initially view a simple table with a minimum amount of information and (if desirable) drill down to more details, including links to reviews and full evidence profiles
- Providing users with control over their viewing choices, including which outcomes to show in detail and how to view the results for these outcomes (as text, numbers or graphic representations)
- Providing step-by-step visual presentation of the absolute effects and absolute differences, that includes an explanation of the confidence intervals in a way that makes them easy to grasp and see why they are important
- Providing interactive explanations of generic terms (replacing legends and glossaries)
- Providing interactive explanations of table-specific terms (replacing footnotes)
- Responsive formatting for use on different size screens/devices
- Availability in different languages

Features for producers:

- Template flexibility that can accommodate data from different kinds of reviews, including those without meta-analysis
- Ability to enter (and present) different levels of baseline (control group) risk for each outcome
- Control over which information is expanded/displayed (and which is collapsed/hidden) in the initial (default) presentation, including:
    - Which outcomes
    - What information about each outcome
    - Which baseline risk (including more than one for outcomes when this is relevant)
- Automatic reminders to include some information that is essential for understanding the findings of a systematic review, but is sometimes missing, including explanations about scales, about where the estimates of baseline risk came from, and about the reasons for downgrading or upgrading the certainty of evidence.
- Allowing producers to tailor their own template, for instance to rearrange the order of the columns, create a custom default presentation, or add organization logos
- Templates for table production in different languages

***Figure 9**: New iSoF features*

The iSoF was evaluated in a large online trial in Scotland using a register of members of the public who have expressed an interest in taking part in health research called SHARE (http://www.registerforshare.org). We emailed nearly 50,000 people to invite them to take part in the trial and a total of 2,194 people responded and when presented with standard patient information or a static SoF without the absolute effect, participants were, for the most part, not able to answer questions about the size of the benefits and harms or the certainty of the evidence correctly (Figure 10).

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	SoF without absolute effect		Standard patient information	
Outcome	N	% correct	N	% correct
Understanding the benefits	73	1.4	32	0
Certainty of the benefits	437	20.8	238	10.5
Understanding the harms	78	1.3	33	0
Certainty of the harms	432	20.8	238	6.3

***Figure 10**: Understanding of participants who were not shown the absolute effect*

Things improved when participants were shown absolute effects (Figure 11) although there was little difference between an iSoF and a static SoF that was showing absolute effects. However, nearly half did not answer questions about the size of the benefits correctly.

	iSof		SoF with absolute effect	
Outcome	N	% correct	N	% correct
Understanding the benefits	761	51.8	574	50.2
Certainty of the benefits	1144	31	805	36.6
Understanding the harms	740	62.7	566	70
Certainty of the harms	1112	29.8	783	38.6

***Figure 11**: Understanding of participants who shown the absolute effect*

Most participants were satisfied with the presentation to which they were allocated before seeing the other presentations. They were least satisfied with a static SoF without the absolute effect and most satisfied with the iSoF or static SoF with the absolute effect (difference 18.4 percentage points (95% CI -26.5 to -10.4)).

Interactive Evidence to Decision Frameworks

Healthcare decision-making is complex. Decision-making processes and the criteria that decision-makers should consider vary for different types of decisions, including clinical recommendations, coverage decisions, and health system decisions. However, some criteria are relevant for all of these decisions, including the anticipated effects of the options being considered, the certainty of the evidence for those effects (also referred to as quality of evidence or confidence in effect estimates), and the costs and feasibility of the options.

We have developed Evidence to Decision (EtD) frameworks to support the process of moving from evidence to decisions: for making clinical recommendations, coverage decisions, and health system or public health recommendations and decisions. Starting with the GRADE Working Group's approach for moving from evidence to clinical recommendations we iteratively developed the EtD frameworks based on reviews of relevant literature, a survey of policymakers, brainstorming, feedback from stakeholders, application of EtD frameworks to a variety of recommendations and decisions, and user-testing. A survey of stakeholders with health system decision experience from 15 countries and the World Health Organization provided us with 112 responses (70% response rate). Most respondents had healthcare (85%) and research (79%) experience. They (99%) indicated that systematic consideration of the available evidence would help to improve health system decision-making processes and supported the use of evidence from other countries (94%) and grading systems (81%). All ten criteria in the DECIDE framework were

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rated as important in the decision-making process. The survey results were published in 2013 (http://www.health-policy-systems.com/content/11/1/19).

EtD frameworks:

- Facilitate adaptation of recommendations and decisions to specific contexts.
- Inform panels about the relative pros and cons of the interventions or options being considered.
- Ensure that panels consider important criteria for making a decision.
- Provide panels with a concise summary of the best available evidence to inform their judgments about each criterion.
- Help panels structure discussion and identify reasons for disagreements, making the process and the basis for decisions structured and transparent.

EtD frameworks assist users of recommendations by:

- Enabling them to understand the judgments made by the panel and the evidence supporting those judgments.
- Helping them to decide whether recommendations can and should be implemented in their own settings.

Figure 14 shows the judgements that the EtD framework supports. The EtD framework was tested with real World Health Organisation guidelines on task shifting for maternal and newborn care, task shifting for contraception, and expanding training of health professionals. It was also tested with public health guidelines in Sweden and clinical practice guidelines produced by the Norwegian Directorate of Health. Another example of use was with a coverage decision about trans-catheter aortic valve implantation (TAVI) for patients with severe aortic stenosis in Lazio Regional Health Service, Italy. Two EtD frameworks were prepared comparing TAVI vs traditional surgery and vs medical therapy. They were presented and discussed with a panel of regional health system representatives that involved both regional decision makers as well as clinicians. The EtD frameworks were then included in the final regulatory document of Lazio Region. The EtD framework will now be used for future coverage decisions in Lazio Region. In addition, the EtD framework has been presented, tested and discussed at multiple international and national conferences, such as the Guidelines International Network, Cochrane Colloquium, and HTAi annual meetings.

Two publications describing the EtD are in-press at the BMJ.

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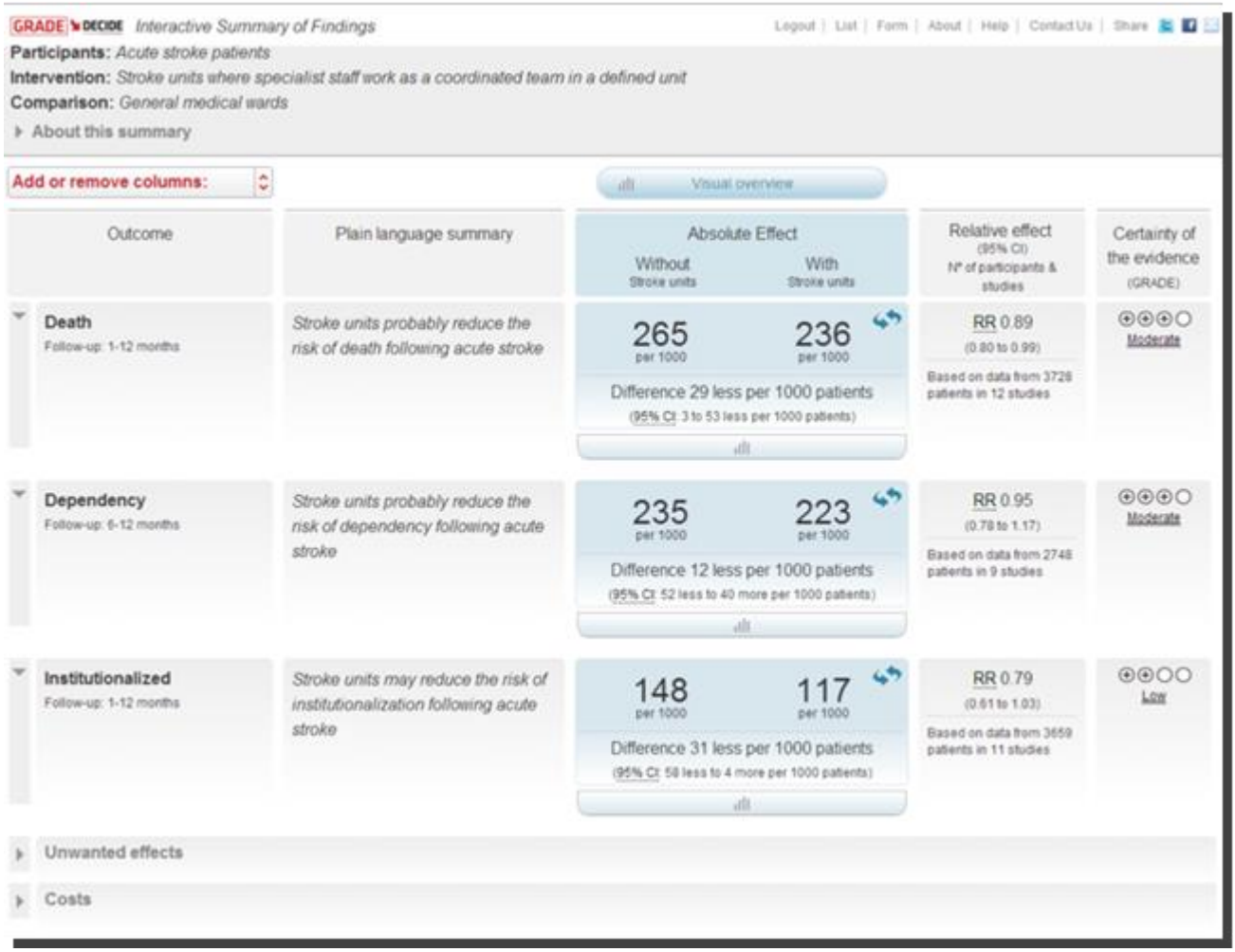

Figure 12 : *iSoF showing all columns open*

In order to facilitate flexibility both in preparation and use by groups, we developed the iEtD tool (interactive Evidence to Decision framework) through iterative cycles of brainstorming, design, user-testing, piloting and stakeholder feedback. iEtD has functionality for administrating, creating, and using frameworks as well as disseminating results, including resources for:

- Managing templates
- Filling in and managing EtD frameworks
- Presenting EtD frameworks (e.g. at face-to-face or online panel meetings)
- Voting on judgements and decisions by panel members
- Creating reports and interactive summaries for end users

It also enables organisations to create tailored templates for:

- ***EtD frameworks*** adapted to specific types of decisions or recommendations and remits
- ***Reports*** generated from EtD frameworks for consultations or final reports of guidelines or decisions
- ***Summaries for end-users***, including clinicians, patients and policymakers

iEtD end-user summaries can include interactive functions such as interactive Summary of Findings (iSoF) tables, layered information, scrollover explanations, hypertext links and the possibility of selecting or inserting specific information in decision aids. The iEtD tool has been released (http://ietd.epistemonikos.org/#/login), and further developed with feedback from use in public health and health system decisions and guideline processes by a number of organisations (including WHO, the Norwegian Knowledge Centre for Health Services and the Swedish National Institute of Public Health). WHO recommendations on antenatal care are using the iEtD website

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platform to provide both the guideline development panel with an online environment for deliberations on antenatal care recommendations, and also provide a public online forum for policymakers, clinicians and other stakeholders to navigate and utilise the recommendations. Figure 14 shows a summary of judgements screen from the iEtD for a guidelines developed by WHO.

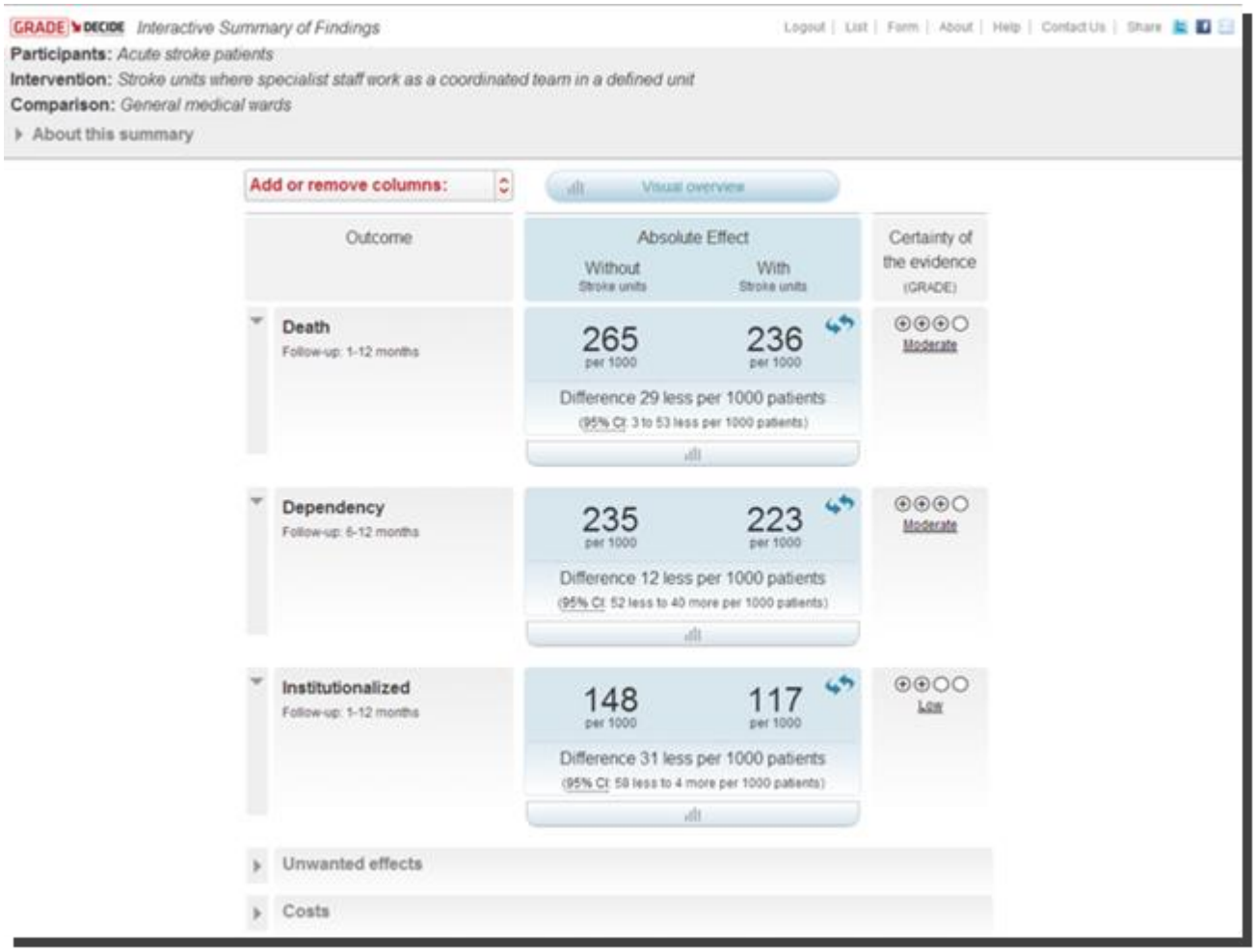

Figure 13: *iSoF showing just a few columns selected by the user.*

Explanations of terms: the GET IT glossary

Many people (not only the public, but health professionals and policymakers too) have problems understanding terminology linked to the evaluation of treatments. We have therefore developed a glossary to provide plain language explanations of terms such as '*certainty of the evidence*', '*false positive test result*' and '*P-value*'. Well-informed choices about how to intervene to improve health outcomes depend on access to good information, particularly research evidence. The use of jargon can be a barrier to people's understanding and use of research evidence to inform their choices. Inconsistent use of language also can cause confusion. The aim of this glossary is to facilitate informed healthcare choices by promoting consistent use of plain language and providing plain language explanations of concepts and terms that people might need to understand in order to assess claims about treatments. This includes claims arising from summaries of research evidence (systematic reviews) and evidence-informed recommendations that they find in guidelines.

The glossary includes:

- brief plain language definitions (that can be used as scroll over explanations)
- longer explanations
- links to resources such as illustrative examples, videos or interactive applications that help people to understand or apply the term or concept
- synonyms
- suggested plain language terms

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- technical definitions

The glossary is available at http://getitglossary.org and can be used by guideline producers, health technology assessment agencies and others providing support for evidence-informed healthcare decisions, including health system decisions. Among other uses, it provides explanations for terms used in interactive Summaries of Findings and interactive Evidence to Decision frameworks. Organisations can utilise some or all of those features and some or all of the terms that are included in the glossary. We have also developed technical tools that allow other organisations to embed the glossary on their own websites, as well as providing support for languages other than English. The glossary is currently being translated into Finnish and Spanish.

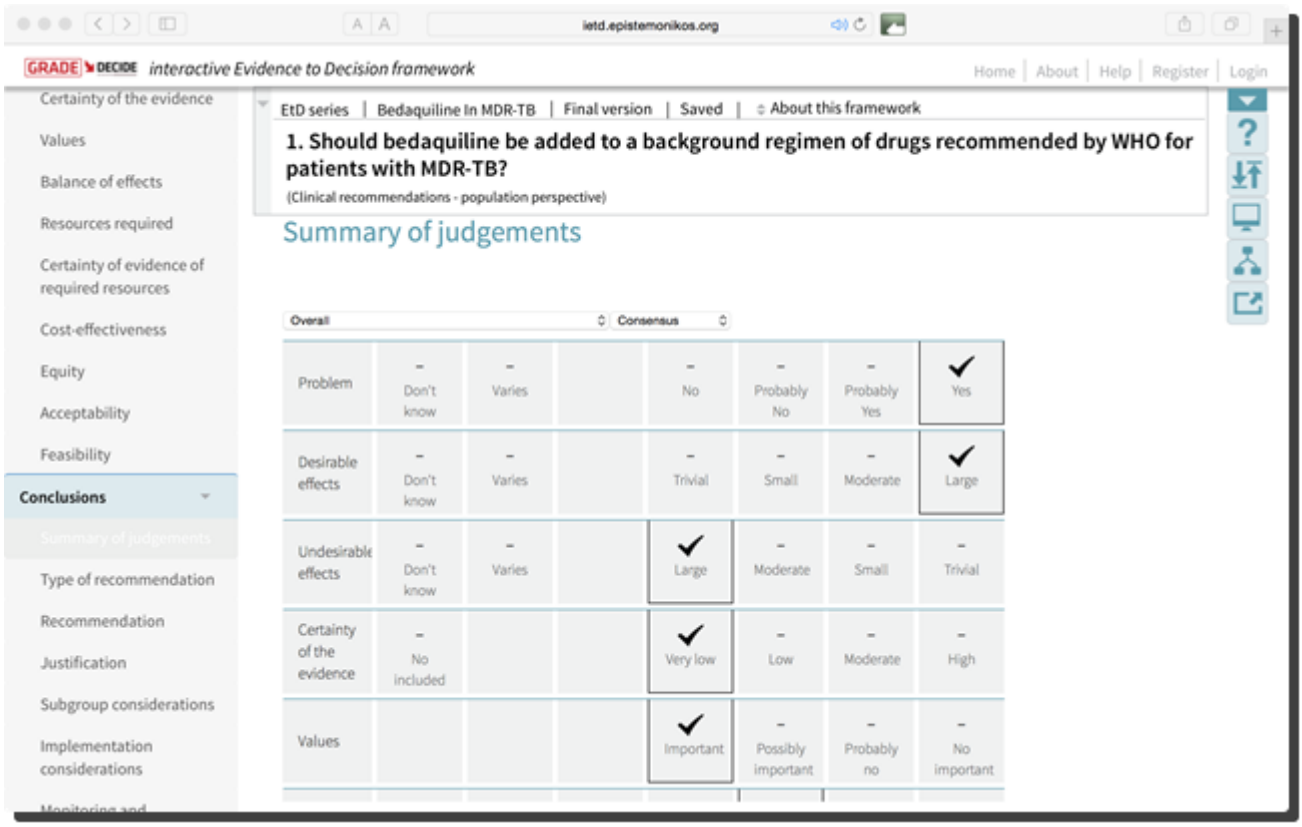

Figure 14: *Summary of judgements screen from the iEtD for a guidelines developed by WHO.*

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Criterion	Detailed judgments
Is the problem a priority?	• Are the consequences of the problem serious (i.e. severe or important in terms of the potential benefits or savings)? • Is the problem urgent? [not relevant for coverage decisions] • Is it a recognized priority (e.g. based on a political or policy decision)? [Not relevant when an individual patient perspective is taken]
How substantial are the desirable anticipated effects?	• Judgments for each outcome for which there is a desirable effect
How substantial are the undesirable anticipated effects?	• Judgments for each outcome for which there is an undesirable effect
What is the overall certainty of the evidence of effects?	• See GRADE guidance regarding detailed judgments about the quality of evidence or certainty in estimates of effects.
Is there important uncertainty about or variability in how much people value the main outcomes?	• Is there important uncertainty about how much people value each of the main outcomes? • Is there important variability in how much people value each of the main outcomes? [not relevant for coverage decisions]

Do the desirable effects outweigh the undesirable effects?	• Judgments regarding each of the four preceding criteria
	• To what extent do the following considerations influence the balance between the desirable and undesirable effects:
	  • How much less people value outcomes that are in the future compared to outcomes that occur now (their discount rates)?
	  • People's attitudes towards undesirable effects (how risk averse they are)?
	  • People's attitudes towards desirable effects (how risk seeking they are)?

How large are the resource requirements?	• How large is the difference in each item of resource use for which fewer resources are required? • How large is the difference in each item of resource use for which more resources are required?
What is the certainty of the evidence of resource requirements?	• Have all-important items of resource use that may differ between the options being considered been identified? • How certain is the evidence of differences in resource use between the options being considered (See GRADE guidance regarding detailed judgments about the quality of evidence or certainty in estimates)? • How certain is the cost of the items of resource use that differ between the options being considered? • Is there important variability in the cost of the items of resource use that differ between the options being considered?

Figure 15: *Detailed judgments in Evidence to Decision (EtD) frameworks.*

Work Package 6: Develop a toolkit for preparing and disseminating evidence-based recommendations using the DECIDE strategies developed in WPs 1-5

DECIDE has developed a wide range of outputs, in particular layered presentation formats for recommendations, Evidence to Decision frameworks and interactive Summary of Findings tables. The majority of DECIDE outputs have been packaged into the GRADEpro Guideline Development Tool (GRADEproGDT) (http://gradepro.org). The GRADEproGDT

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is the replacement for the GRADEprofiler (GRADEpro) software developed by members of the GRADE Working Group but unlike the old software, GRADEproGDT supports the whole guideline production process, including the development and preparation of (interactive) Summary of Findings tables and Evidence to Decision Frameworks. Many of the developments in GRADEproGDT are a direct result of the work done in the DECIDE project.

Previous GRADEpro versions supported the presentation of evidence from randomized controlled trials and was less detailed about the presentations of information from observational (non-randomized) studies or test accuracy studies. However, many of the decisions that are addressed in guidelines, in particular in surgical specialties, public health and in health policy and those about health care testes are based on observational studies. GRADEproGDT supports presentation of results from a number of observational study designs, including interrupted time series, before-after studies, cohort studies, case-control studies, cross-sectional studies, case series and case reports as well as the evidence from various types of study design simultaneously (figure 16). This functionality is essential for recommendations for public health, health systems and health policy where a large proportion of evidence is non-experimental. In relation to observational studies we have introduced the possibility to present results from studies that do not report any numerical variables, or in which numerical variables are reported in such a way that only descriptive summary of evidence is possible (figure 16).

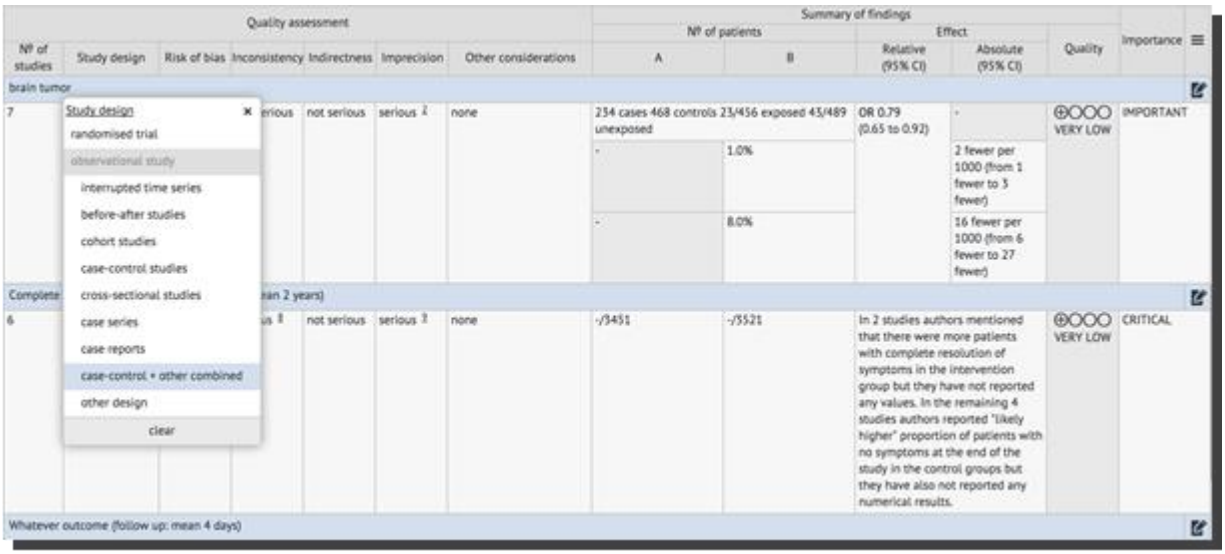

Figure 16: *Specifying observational study design in evidence profiles and support for narrative summary of the evidence*

GRADEproGDT includes products from our work on ways of presenting information about diagnostic tests and strategies when only test accuracy data are available. GRADEproGDT includes two layers of presenting the results that require decision makers to consider the downstream consequences of performing a test(s) on patient outcomes. It supports comparisons of single index tests against a reference standard as well as the comparative accuracy of two tests compared against a common reference standard. Interactive Summary of Findings table (iSoFs) and the Evidence to Decision frameworks (EtD) are produced within GRADEproGDT. Figure 17 is a screenshot of the EtD within GRADEproGDT. The development of SoFs and EtDs in GRADEPro is supported in several languages, including English, Spanish, German and Italian.

GRADEproGDT also supports the 'Top layer' presentation for health professionals. This approach allows clinicians, and other users, to access information in a layered, onion-like

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fashion – from the most important essential information, through to the complete rationale for the decision and then to the detailed evidence tables. GRADEproGDT includes a semi-automatic mechanism for preparing and previewing the mobile device applications with 'Top layer' summaries of health care decisions that are tailored and targeted at clinicians (figure 18).

Figure 17: *The Evidence to Decision framework within the GRADEproGDT.*

Figure 18: *Example of "top layer" presentation for clinicians in the form of a mobile device app for Apple iOS system*

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Database of evidence profiles
GRADEproGDT also allows users at different sites to collaborate on preparing summaries of evidence and to share this information electronically in a database of evidence profiles. The primary reason for having a database of evidence profiles is to facilitate collaboration across European guidelines developers and to avoid duplication of effort. A database would need to accept input in a common data format to allow interoperability between a variety of electronic tools used by European and international guideline developers. The central and most basic data item used in the database is an evidence profile, to which outcomes and recommendations are attached.

The profile database (http://dbep.gradepro.org/search) accommodates the changing and evolving nature of the grading methodology over time (such as new empirical evidence from DECIDE). This makes storing static documents (such as pdf files of finished evidence profiles) less appealing. Instead, the database stores the individual data points, for example, effect sizes, and the evidence profile is re-created on demand. This allows for the highest flexibility in providing different profile presentations that can be utilized for targeted user testing in randomized trials and allows creating different output formats, such as pdf files, rich text formats, or in graphical form. In addition, the original data set can be downloaded at any time for reuse and for easy updating at a later time point or by other authors.

GRADEproGDT now has over 11,000 users and is used for numerous guideline projects including the European Commission Breast Cancer guidelines initiated in 2015.

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POTENTIAL IMPACT, MAIN DISSEMINATION ACTIVITIES AND EXPLOITATION OF RESULTS

Potential Impact

A key aim of DECIDE was to increase understanding of the many factors that affect whether a given intervention will be used by healthcare professionals, patients and policymakers by studying in a structured and consistent way the effect, at person and organisation level and in varying cultural settings, of how research evidence is presented.

DECIDE has built on the substantial experience and knowledge of the GRADE Working Group through ongoing collaboration with GRADE; including in-depth discussion at annual GRADE meetings which were planned to run concurrently with DECIDE Consortium Meetings. Input at the GRADE meetings provided an overview of DECIDE work and research direction while assessing how this would fit into and benefit the wider GRADE Working Group. The emphasis of these discussions was about how information about health care interventions are created, packaged, transmitted, and interpreted among a variety of important stakeholder groups including healthcare professionals, healthcare managers, policymakers and patients.

GRADEproGDT (http://www.guidelinedevelopment.org), developed and refined as part of WP6, packages much of our work into a single tool - and the GRADE Working Group will continue to both promote and develop this tool beyond the end of the DECIDE project. This tool is already live and freely available for use. Many of the DECIDE products (e.g. the Evidence to Decision framework) are also being built into WHO processes such as those being used for the forthcoming guidelines on task-shifting provision of abortion services, which will be a similar website to the OptimizeMNH platform (http://www.optimizemnh.org).

GRADEproGDT now has over 11,000 registered users. It is being used for a number of high profile guidelines including the European Commission Breast cancer screening and diagnosis guidelines (http://ecibc.jrc.ec.europa.eu). For this project all aspects of the work including question formulation and outcome prioritization are being conducted using the online tool. It is also being used for the Allergic Rhinitis in Asthma (ARIA) Guidelines, which is conducted in collaboration with the MACVIA Integrated Care Pathways program led by Prof. Jean Bousquet in Montpellier, France. The ARIA guideline is among the most widely disseminated and implemented guideline worldwide and has been translated into over 40 languages. GRADEproGDT is used by the World Allergy Organization in a collaboration with Prof. Alessandro Fiocchi at the Hospital “Bambino Gesu” in Rome, Italy, for guidelines on allergy prevention. Several of these guidelines have been published already. GRADEproGDT is the tool of choice for the European Center for Disease Control and Prevention Refugee guidelines led by Dr. Kevin Pottie in Ottawa, Canada and the tool for guideline development and dissemination by the American Society of Hematology for its Venous Thromboembolism Guidelines. Applying state of the art (http://cebgrade.mcmaster.ca/guidecheck.html) through the use of GRADE (Grading of Recommendations, Assessment, Development and Evaluation) approach and its new Evidence-to-Decision frameworks, ten guidelines with over 200 recommendations covering related aspects of VTE management have been produced:

1. Prevention of venous thromboembolism in surgical hospitalized patients
2. Prevention of venous thromboembolism in medical hospitalized patients
3. Treatment of acute venous thromboembolism
4. Optimal management of anticoagulation therapy
5. Prevention and treatment of venous thromboembolism in patients with cancer
6. Heparin-Induced thrombocytopenia
7. Thrombophilia

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8. Pediatric venous thromboembolism
9. Venous thromboembolism in the context of pregnancy
10. Diagnosis of venous thromboembolism.

More information about the project is available at http://www.hematology.org/Newsroom/Press-Releases/2015/4715.aspx from ASH and McMaster's Faculty of Health Sciences.

DECIDE work more generally continues in the GRADE Working Group (http://www.gradeworkinggroup.org), which is an ongoing initiative, meaning that DECIDE ideas will continue to develop beyond the end of the project. The same is also true with regard to the MAGIC project (http://magicproject.org), which has been a major collaborator with DECIDE, especially with WP1, and is funded beyond the end of the DECIDE project. The Guidelines International Network (GIN) Public Toolkit includes Work Package 3 strategies (http://www.g-i-n.net/working-groups/gin-public/toolkit). Additionally, some of the ideas from WP3 are being discussed at present with the Cochrane Collaboration (http://www.cochrane.org) especially with regard to Cochrane's Plain Language Summaries, and discussions are planned to continue post-project also. Similar discussions are taking place between Cochrane and the WP5 team regarding iSoFs, with iSoFs looking likely to become a routine part of Cochrane reviews.

Based on actual collaboration in the European Commission Initiative on Breast Cancer (ECIBC) project between DECIDE and the JRC Healthcare Quality Team, DECIDE has been approached by the EC's JRC team to mutually promote project websites and project visibility. The use of the GRADE system and DECIDE ideas is now part of this initiative and Holger Schünemann (who led DECIDE's WP6) is part of the ECIBC Guideline Development Group. DECIDE has also been influential in the guideline approach taken by the European Monitoring Centre for Drugs and Drug Addiction (EMCDDA) with DECIDE presentation strategies being built into the EMCDDA 'Best practice in drug interventions' section of its website. At a health systems and policy level important collaborations were initiated with Swedish National Institute of Public Health and the Lazio Regional Health Service, Italy. DECIDE partners such as the World Health Organisation, the U.K.'s National Institute for Health and Care Excellence (NICE) and the Finnish Medical Association Duodecim will continue to use DECIDE strategies and tools in their work. We also anticipate that tools such as the Evidence to Decision framework and GRADEproGDT will become standards in the field (as GRADE has become an international standard) and will therefore have enormous impact.

Main dissemination activities

Dissemination has been absolutely central to DECIDE, with the ongoing objective being to ensure wide dissemination and use of the results of the project to stakeholders, especially guideline developers. Our main dissemination activities included;

- A regularly updated website;
- An international conference;
- Regular participation to relevant conferences and other events – for example, disseminating DECIDE by way of presentations, posters and through workshops;
- Publications. Note: The Evidence to Decision framework, a major product of DECIDE, is described in two publications to be published in the BMJ early in 2016. Other publications describing specific types of Evidence to Decision framework are planned. We plan to apply to the OpenAIRE initiative (https://www.openaire.eu) to cover the costs of three publications currently under review or being prepared post-project.

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The DECIDE project website (www.decide-collaboration.eu) was implemented as the main communication tool for the DECIDE consortium in Month 3 of the project, with the primary role being to engage with the wider public and to present the results of DECIDE. Functions supported and delivered by the website include:

- Background information about the project and partners;
- More detailed information about Work Packages and project aims including deliverable reports with a 'Public' (PU) dissemination level;
- Promotion of the DECIDE International Conference (general information, logistics, registration form). After the event a video from each day and a range of other materials was posted on the website and ;
- Communication: queries were received via a web-form from people who expressed an interest in the project. An email distribution list was maintained for those who have requesting to be kept informed about the project and regular 'flash reports' were sent to them. Also, those who connected with the project this way were also sent a direct invitation to the DECIDE International Conference;
- Generating feedback: Work Package 5 used the website to collect feedback on its Evidence to Decisions (EtD) framework;
- Providing links to publications and other dissemination activities arising from DECIDE.

Dissemination through publications and conferences has been a major part of DECIDE's dissemination strategy with the following delivered during the lifetime of the project and a list of publications (and other dissemination activities) is available on the project website at http://www.decide-collaboration.eu/dissemination-0

The biggest single dissemination event held during DECIDE was the DECIDE International Conference held in Edinburgh, Scotland in June 2014. The conference was attended by delegates representing guideline producers from across Europe and beyond - together with representatives of those who use guidelines such as professional societies, medical charities, patient organisations, funders and policy makers.

The objective of the event was twofold:

- To showcase the work coming from the project
- To be a forum for international colleagues to influence the final stages of DECIDE

The conference was a great success with over 270 registered delegates from 20 countries attending. In addition to plenary presentations from external speakers and members of the decide group, there were 29 parallel workshops showcasing and discussing DECIDE work. Information stands at the conference included Scottish Intercollegiate Guidelines Network (SIGN), NHS Inform: "Cancer Information Online at your fingerTIPS", Guidelines International Network (G-I-N) and Healthcare Improvement Scotland (HIS): "Getting Knowledge into action to improve healthcare quality in NHS Scotland". Delegates were encouraged to visit the stands to see if there was any information they might find useful and to ask questions if they had any. We also had over 20 posters summarising work from all of DECIDE Work Packages.

Feedback on the conference was overwhelmingly positive, it led to additional collaboration and workshop discussions led to changes in some of DECIDE's outputs. In addition to those physically present at the conference, the conference was well represented on twitter with the hashtag (#DECIDE_2014) being used in 715 tweets from 117 people with 267,596 impressions.

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The conference program, videos of the plenary presentations, slide sets and other information about the conference are available from the DECIDE website at http://www.decide-collaboration.eu/decide-international-conference.

Exploitation of Results
The DECIDE Grant Agreement clearly states that "**All DECIDE material will be owned by the project and made available at no cost and in perpetuity to individuals and non-profit organisations.**" This remains the absolute aim and all partners are in full agreement with this 'founding principle' of the project.

According to the DECIDE Consortium Agreement "**Joint owners** [i.e. all DECIDE partners] **can grant non-exclusive licenses to third-parties** [e.g. for-profit organisations] **so long as the other parties are compensated in a fair way**." To ensure that this is the case, the DECIDE Consortium has unanimously agreed that, in the event of third parties discussing the possibility of a fee-paying license for one or more DECIDE resources with a DECIDE partner, that partner will discuss this with the whole DECIDE consortium and the GRADE Guidance Group (which includes DECIDE beneficiaries).

Furthermore, the results of the project will be exploited in a number of ways:

- The academic and research partners will use the knowledge gained from the project through publication of the research findings in relevant journals. Indeed, publications are in preparation and will become available post-project;
- The GRADE Working Group will use the knowledge gained from the project to enhance guideline development

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