

DECIDE: GRADEproGDT

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 [covered by this summary]. One of the key results of DECIDE was to deliver information in layers, most important first. So, in that spirit, the key findings of the whole DECIDE project are summarised in Figure 1. If you read no more, look at least at Figure 1.

Key findings:

- Guideline users – health professionals, patients and policymakers – want information delivered to them in layers, most important first.
- Guideline producers value structure when working through evidence to make recommendations and decisions.
- Numerical summaries of research findings can be understood by diverse audiences, including the public, but it is best if those summaries allowed users to interact with them so that they can choose the level of detail they require.
- Health professionals and their patients want materials that can be used in consultations to support their discussions.
- Guideline information about medical testing has to move beyond accuracy and precision and start talking about the effect on important patient outcomes.

Key tools:

- The Evidence to Decision framework to support guideline producers make evidence informed decisions.
- The interactive Summary of Findings tables to support interactive presentations of research findings to diverse types of user.
- The DECIDE/G-I-N public toolkit chapter for guideline producers on how to produce patient versions of guidelines.
- There are many ways information can be presented to users but we have not found a ‘magic bullet’ that always works for all users, especially members of the public. Guideline producers would be wise to do at least some testing of their materials with potential future users.
- The GRADEPro guideline development tool to package the bulk of DECIDE’s work and to support guideline producers through the whole guideline process.

Figure 1: Key DECIDE findings and tools

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://grade.org>). The GRADEproGDT is the replacement for the

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GRADEpro (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 2).

N° of studies	Study design	Quality assessment					Summary of findings				Quality	Importance	
		Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	N° of patients		Effect	Relative (95% CI)			Absolute (95% CI)
brain tumor													
7	randomised trial	x	serious	not serious	serious ²	none	234 cases 468 controls	23/456 exposed 43/489 unexposed	1.0%	OR 0.79 (0.65 to 0.92)	-	⊕○○○ VERY LOW	IMPORTANT
	observational study										2 fewer per 1000 (from 1 fewer to 3 fewer)		
	interrupted time series										16 fewer per 1000 (from 6 fewer to 27 fewer)		
	before-after studies												
	cohort studies												
	case-control studies												
	cross-sectional studies												
Complete	case series		serious ³	not serious	serious ²	none	-/3451	-/3521		In 2 studies authors mentioned that there were more patients with complete resolution of symptoms in the intervention group but they have not reported any values. In the remaining 4 studies authors reported "likely higher" proportion of patients with no symptoms at the end of the study in the control groups but they have also not reported any numerical results.		⊕○○○ VERY LOW	CRITICAL
	case reports												
	case-control + other combined												
	other design												
	clear												
Whatever outcome (follow up: mean 4 days)													

Figure 2: 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 3 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 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 4).

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CRITERIA	JUDGEMENTS	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS																									
Is there a problem priority?	<input type="radio"/> No <input checked="" type="radio"/> Probably no <input type="radio"/> Uncertain <input type="radio"/> Probably yes <input type="radio"/> Yes <input type="radio"/> Varies																											
What is the overall certainty of this evidence?	<input type="radio"/> No included studies <input type="radio"/> Very low <input type="radio"/> Low <input checked="" type="radio"/> Moderate <input type="radio"/> High	The relative importance or values of the main outcomes of interest: <table border="1"> <thead> <tr> <th>Outcome</th> <th>Relative importance</th> <th>Certainty of the evidence (GRADE)</th> </tr> </thead> <tbody> <tr> <td>Mortality</td> <td>CRITICAL</td> <td>⊕⊕⊕⊕ MODERATE</td> </tr> <tr> <td>Symptomatic VTE</td> <td>CRITICAL</td> <td>⊕⊕⊕⊕ HIGH</td> </tr> <tr> <td>Major bleeding</td> <td>IMPORTANT</td> <td>⊕⊕⊕⊕ MODERATE</td> </tr> <tr> <td>Health related quality of life</td> <td>IMPORTANT</td> <td>⊕⊕⊕⊕ LOW</td> </tr> </tbody> </table>	Outcome	Relative importance	Certainty of the evidence (GRADE)	Mortality	CRITICAL	⊕⊕⊕⊕ MODERATE	Symptomatic VTE	CRITICAL	⊕⊕⊕⊕ HIGH	Major bleeding	IMPORTANT	⊕⊕⊕⊕ MODERATE	Health related quality of life	IMPORTANT	⊕⊕⊕⊕ LOW											
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Is there important uncertainty about how much people value the main outcomes?	<input type="radio"/> Important uncertainty or variability <input type="radio"/> Possibly important uncertainty or variability <input checked="" type="radio"/> Probably no important uncertainty or variability <input type="radio"/> No important uncertainty or variability <input type="radio"/> No known undesirable	Summary of findings: no heparin <table border="1"> <thead> <tr> <th>Outcome</th> <th>Without heparin</th> <th>With heparin</th> <th>Difference (95% CI)</th> <th>Relative effect (RR) (95% CI)</th> </tr> </thead> <tbody> <tr> <td>Mortality</td> <td>649 per 1000</td> <td>604 per 1000 (552 to 662)</td> <td>45 fewer per 1000 (from 13 more to 97 fewer)</td> <td>RR 0.93 (0.85 to 1.02)</td> </tr> <tr> <td>Symptomatic VTE</td> <td>29 per 1000</td> <td>16 per 1000 (11 to 24)</td> <td>13 fewer per 1000 (from 5 fewer to 18 fewer)</td> <td>RR 0.55 (0.37 to 0.82)</td> </tr> <tr> <td>Major bleeding</td> <td>7 per 1000</td> <td>9 per 1000 (4 to 20)</td> <td>2 more per 1000 (from 3 fewer to 13 more)</td> <td>RR 1.30 (0.59 to 2.88)</td> </tr> <tr> <td>Health related quality of life</td> <td>0 per 1000</td> <td>0 per 1000 (0 to 0)</td> <td>not estimable</td> <td>not estimable</td> </tr> </tbody> </table>	Outcome	Without heparin	With heparin	Difference (95% CI)	Relative effect (RR) (95% CI)	Mortality	649 per 1000	604 per 1000 (552 to 662)	45 fewer per 1000 (from 13 more to 97 fewer)	RR 0.93 (0.85 to 1.02)	Symptomatic VTE	29 per 1000	16 per 1000 (11 to 24)	13 fewer per 1000 (from 5 fewer to 18 fewer)	RR 0.55 (0.37 to 0.82)	Major bleeding	7 per 1000	9 per 1000 (4 to 20)	2 more per 1000 (from 3 fewer to 13 more)	RR 1.30 (0.59 to 2.88)	Health related quality of life	0 per 1000	0 per 1000 (0 to 0)	not estimable	not estimable	
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Figure 3: The Evidence to Decision framework within the GRADEproGDT.

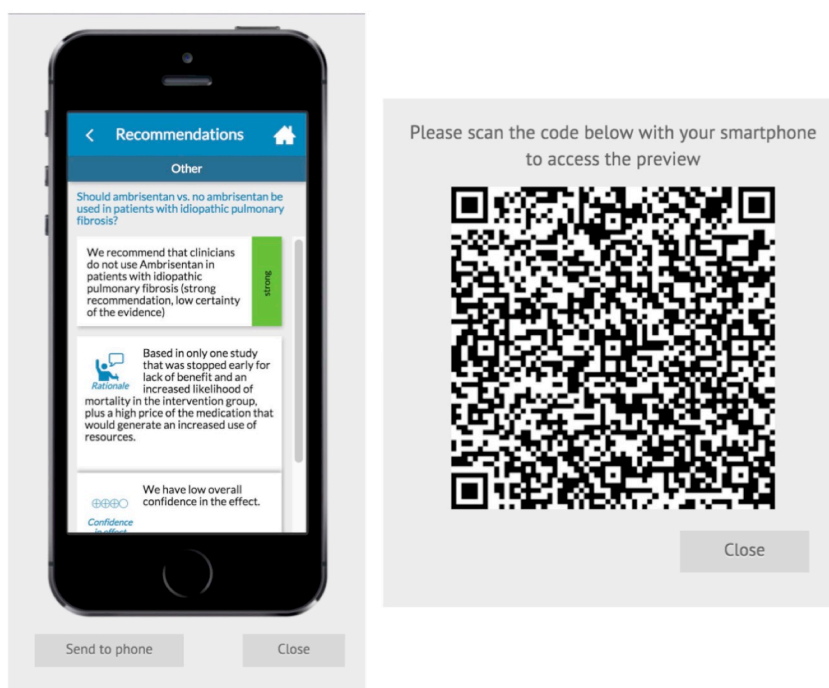


Figure 4: Example of “top layer” presentation for clinicians in the form of a mobile device app for Apple iOS system

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.

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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.