Deliverable 6.3 – Toolkit for preparing and disseminating evidence-based recommendations

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1. Introduction

The DECIDE project, which started on the 1st of January 2011, aims to build on the work of the GRADE Working Group (www.gradeworkinggroup.org) by developing and evaluating ways of effectively communicating and supporting the uptake of evidence-based recommendations about prevention, treatment and rehabilitation for different target groups. The project also develops strategies for recommendations about diagnostic tests and health system policies.

DECIDE's assessment of the effectiveness of communication strategies will provide an empirical, theoretically-informed basis for better understanding of the factors that influence the effectiveness of communication strategies on the various actors in healthcare.

DECIDE is structured in five main investigational workpackages (WPs), each aimed at a different target (stakeholder) group:

WP1: Healthcare professionals
WP2: Policymakers and managers
WP3: Public, patients and carers
WP4: Users of evidence on diagnostic tests
WP5: Users of evidence on health system policies

The ultimate objective of **WP6** is to develop a software Toolkit for authoring and disseminating evidence-based health care decisions and recommendations using the DECIDE strategies developed in WPs 1-5.

The **GRADEpro Guideline Development Tool** (www.guidelinedevelopment.org) includes the DECIDE **Toolkit** that assists guidance developers in preparing summaries of the evidence according to the DECIDE presentation strategies and using the systematic and transparent process for moving from evidence summaries to final health care decisions. The process informed by DECIDE WPs 1-5 asks decision makers to explicitly consider judgements that are needed in using research evidence in making recommendations. These judgements include weighing benefits against downsides of alternative health care interventions, integration of values and preferences of those affected by the decision and incorporating information about resource implications. The Toolkit includes templates for presentations of research evidence and recommendations (including text, tables and, if appropriate, figures) developed in WPs 1-5, which can be tailored by Toolkit users.

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. Finally, the GRADEpro Guideline Development Tool (GDT) allows users at different sites to collaborate on preparing summaries of evidence and sharing this information electronically in a database of evidence profiles (DBEP), see project deliverable 6.2 (D6.2).

2. Summary of WP6 deliverables

D6.1 "Version 4 of GRADEpro incorporating Phase 1 DECIDE strategies" – completed
D6.2 "Database of evidence profiles" – completed
D6.3 "Toolkit for preparing and disseminating evidence-based recommendations" – completed

3. Toolkit for preparing and disseminating evidence-based recommendations

3.1. Observational studies and narrative summaries of evidence

Previous GRADEpro versions supported the presentation of evidence from randomized controlled trials. Many of the decisions that are addressed in guidelines, in particular in surgical specialties, public health and in health policy, are based on observational studies. GRADEpro GDT 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 (fig. 1). 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 (fig.1).

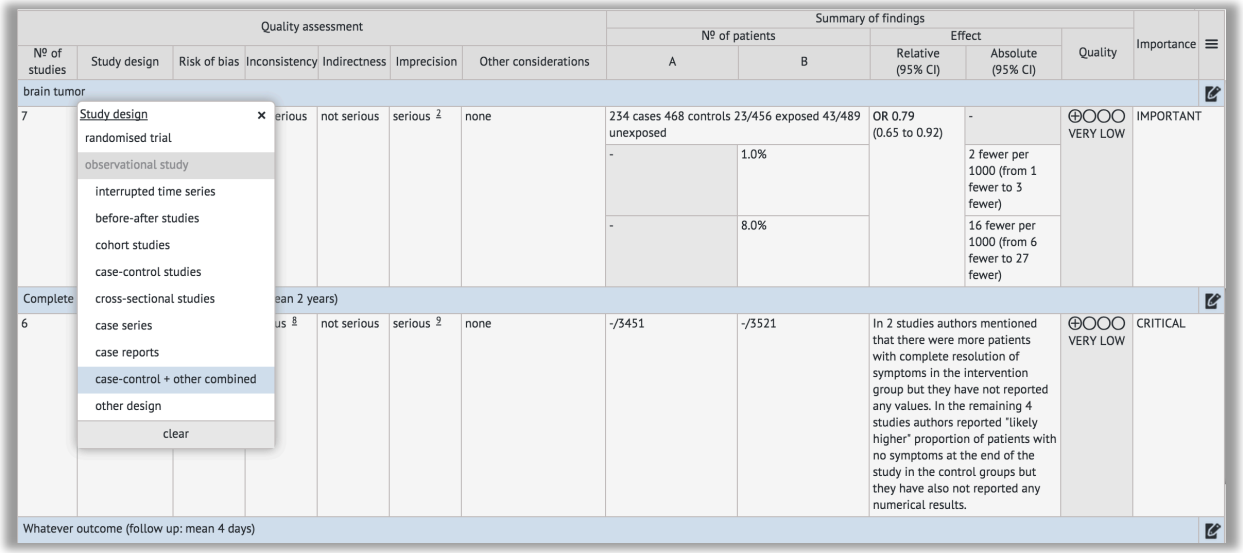


Figure 1. Specifying observational study design in evidence profiles and support for narrative summary of the evidence.

3.2. Support for health care questions using diagnostic test accuracy data

GRADEpro/GDT includes products from DECIDE WP4 that designed and user tested ways of presenting information about diagnostic tests and strategies when only test accuracy data are available. GRADEpro includes two layers of presenting the results that require decision makers to consider downstream consequences of performing a test(s) on patient outcomes (fig. 2, 3). It supports comparisons of single index tests against a reference standard as well as the comparative accuracy of two tests being compared against a common reference standard.

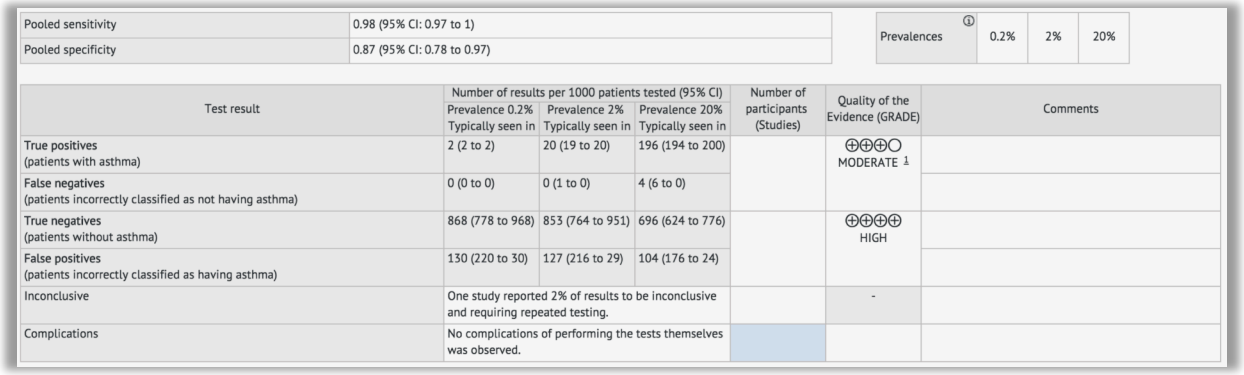
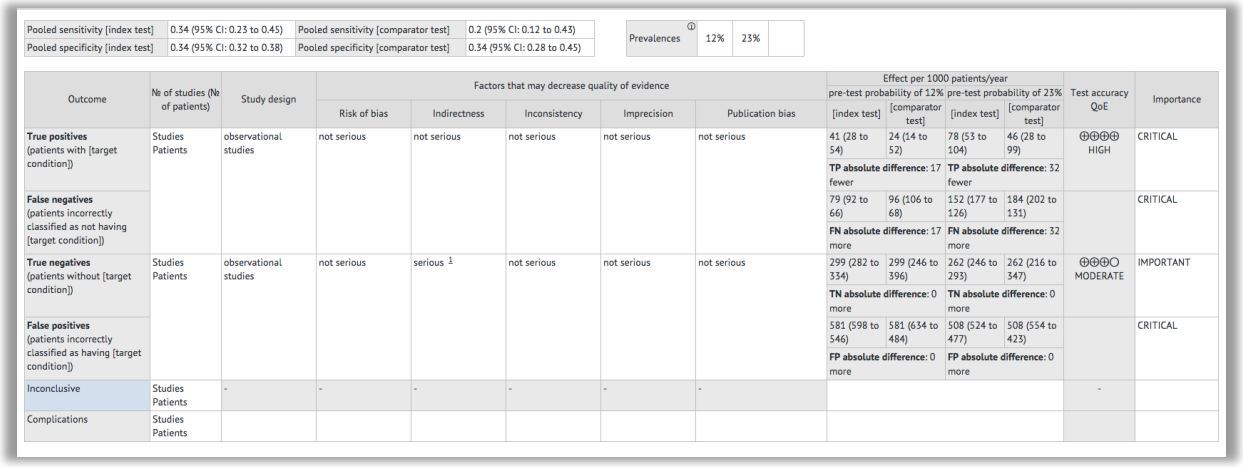


Figure 2. Summary of findings table of the accuracy of a diagnostic test and its complications ("layer 2" information).



Pooled sensitivity [index test]	0.34 (95% CI: 0.23 to 0.45)	Pooled sensitivity [comparator test]	0.2 (95% CI: 0.12 to 0.43)
Pooled specificity [index test]	0.34 (95% CI: 0.32 to 0.38)	Pooled specificity [comparator test]	0.34 (95% CI: 0.28 to 0.45)

Prevalences: 12% 23%

Outcome	№ of studies (№ of patients)	Study design	Factors that may decrease quality of evidence					Effect per 1000 patients/year				Test accuracy QoE	Importance
			Risk of bias	Indirectness	Inconsistency	Imprecision	Publication bias	pre-test probability of 12% [index test]	pre-test probability of 12% [comparator test]	pre-test probability of 23% [index test]	pre-test probability of 23% [comparator test]		
True positives (patients with [target condition])	Studies Patients	observational studies	not serious	not serious	not serious	not serious	not serious	41 (28 to 54)	24 (14 to 52)	78 (53 to 104)	46 (28 to 99)	⊕⊕⊕⊕ HIGH	CRITICAL
								TP absolute difference: 17 fewer		**TP absolute difference:** 32 fewer			
False negatives (patients incorrectly classified as not having [target condition])								79 (92 to 66)	96 (106 to 68)	152 (177 to 126)	184 (202 to 131)		CRITICAL
								FN absolute difference: 17 more		**FN absolute difference:** 32 more			
True negatives (patients without [target condition])	Studies Patients	observational studies	not serious	serious [1]	not serious	not serious	not serious	299 (282 to 334)	299 (246 to 396)	262 (246 to 293)	262 (216 to 347)	⊕⊕⊕◯ MODERATE	IMPORTANT
								TN absolute difference: 0 more		**TN absolute difference:** 0 more			
False positives (patients incorrectly classified as having [target condition])								581 (598 to 546)	581 (634 to 484)	508 (524 to 477)	508 (554 to 423)		CRITICAL
								FP absolute difference: 0 more		**FP absolute difference:** 0 more			
Inconclusive	Studies Patients	-	-	-	-	-	-					-	
Complications	Studies Patients												

Figure 3. GRADE evidence profile summarizing the accuracy of a diagnostic test and its complications ("layer 2" information).

An interactive Summary of Findings table (iSoF) for presentation of diagnostic test information has also been developed by WPs 1 and 4, and has been implemented and is available to users of the Toolkit (fig. 4). It supports the generation of a tailored, graphical representation of information that can be dynamically changed to test assumptions about different patient populations and to display different depths of information as required by various stakeholders.

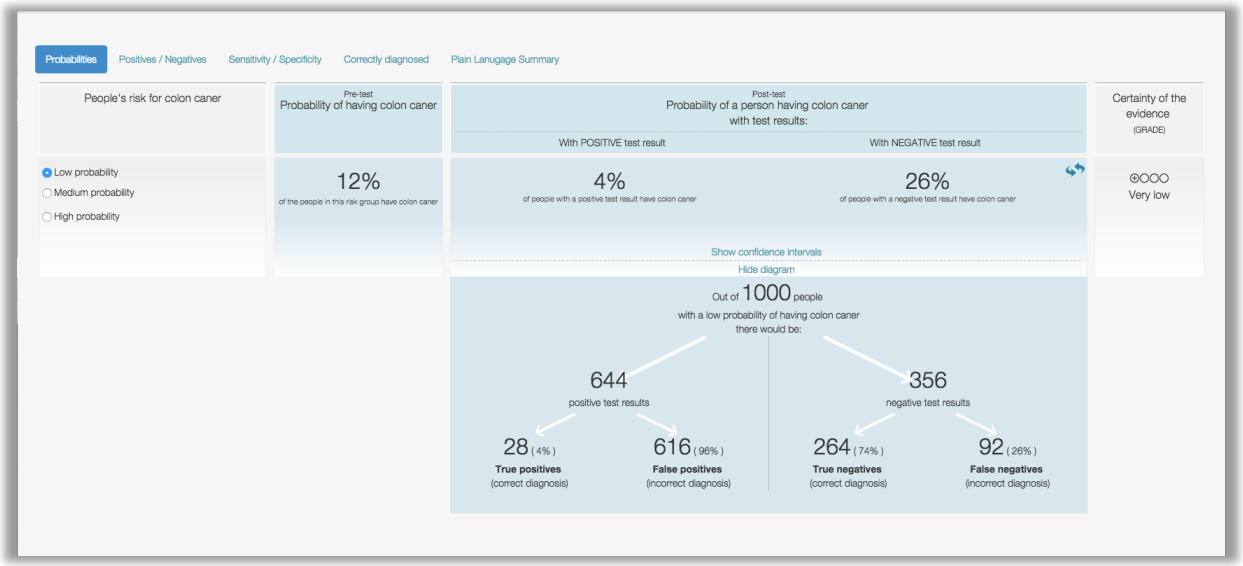


Figure 4. interactive Summary of Findings (iSoF) table for summarizing the accuracy of a diagnostic test and its complications. It allows users to choose the desired format of data presentation and to dynamically change it if required, e.g. during the decision makers' meeting.

3.3. Support for other presentations developed and tested in DECIDE

Workpackages 1 to 5 have been designing and testing strategies for communicating information about diagnostic and therapeutic management options to patients and lay public, clinicians, public health officers, health care policy makers and managers. The DECIDE Toolkit includes products from the DECIDE workpackages (see above). These DECIDE-designed and tested presentations of research evidence for various stakeholders include text, tables and, if appropriate, figures.

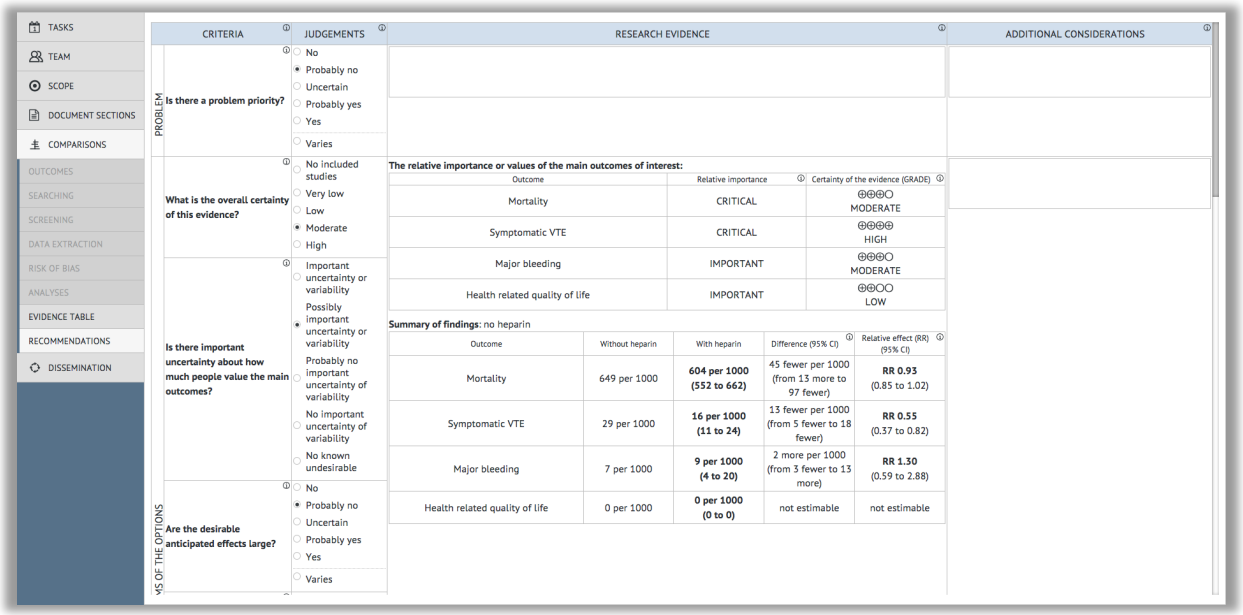
Several ways of presenting the results of multiple comparisons (network) meta-analysis are being tested in the DECIDE project. GRADEpro/GDT has programmed-in support for this presentation. A placeholder has been created in the software to include presentation of multiple comparisons once the final presentation(s) becomes available from WP1-3 and 5 scheduled for the last quarter of 2015.

The "top layer" presentation for clinicians developed in WP1 is also available. 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. GRADEpro/GDT 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 (fig. 5).

Figure 5. Example of "top layer" presentation for clinicians in the form of a mobile device app for Apple iOS system.

3.4. Evidence to Decisions framework

GRADEpro/GDT provides the DECIDE Evidence to Decision framework tools that support the systematic and transparent use of research evidence, values and preferences, and information about required resources, to support health care decision (or recommendation) by panels preparing guidelines. The Toolkit includes both static (fig. 6) and dynamic (interactive) frameworks developed in the DECIDE project. These frameworks are now available in the *Recommendations* module of the software. Final frameworks and templates are being fine-tuned in WPs 1-5 and the interactive versions (iEtD) for both therapeutic and diagnostic scenarios are being implemented in GRADEpro software.



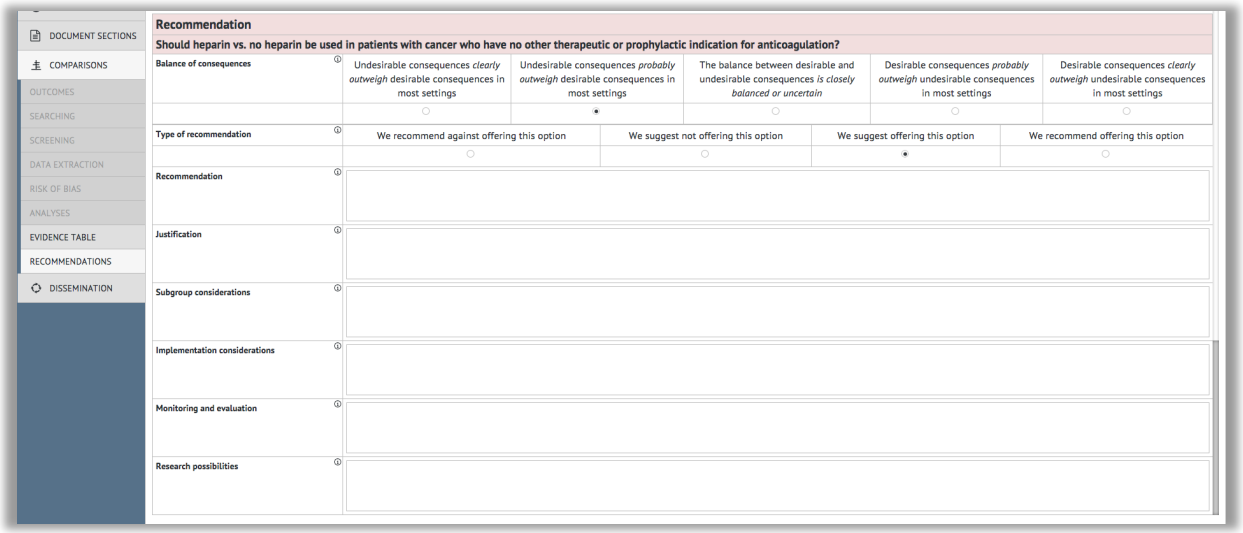


Figure 6. Example template for the EtD table showing integration with the summary of findings table and the systematic consideration and recording of judgments that decision makers go through when moving from the evidence to the decision (upper panel). The lower

panel shows a template for recording the final decision (recommendation) and additional information that may subsequently be used to build specific presentations tailored to various stakeholders (e.g. mobile apps, decisions aids) and/or to be shared with others in the database of evidence profiles (see below).

3.5. Collaboration, usability and communication across European countries

Integration with the Cochrane Collaboration's Review Manager

The current version of GRADEpro features improved integration with the Cochrane Collaboration's Review Manager (RevMan) statistical software, arguably the most widely used software to produce systematic reviews of health care interventions. GRADEpro supports import of data from RevMan that had previously not been available before (fig. 7). It supports import of all analysis methods and all types of variables. It is also possible to import data for diagnostic test accuracy. All variations of DECIDE presentations of SoF tables that have been accepted by Cochrane Collaboration can be exported back to RevMan and included in a systematic review performed for Cochrane Collaboration or any other review being prepared using RevMan software.

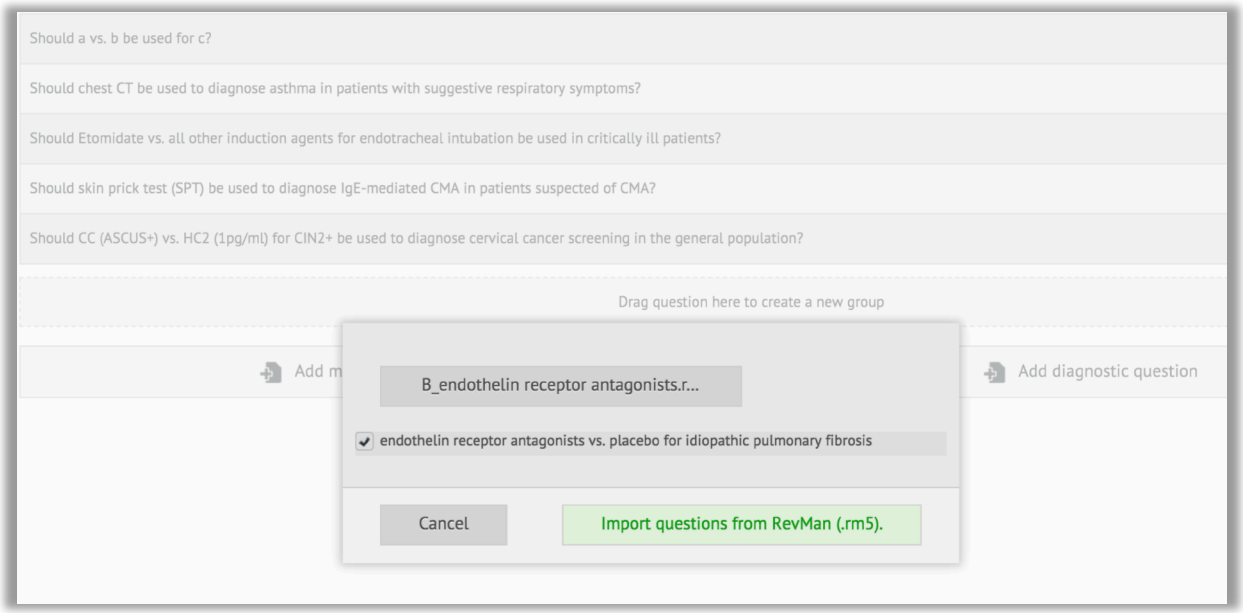


Figure 7. Example of importing data directly from a systematic review file from the Cochrane Collaboration RevMan software.

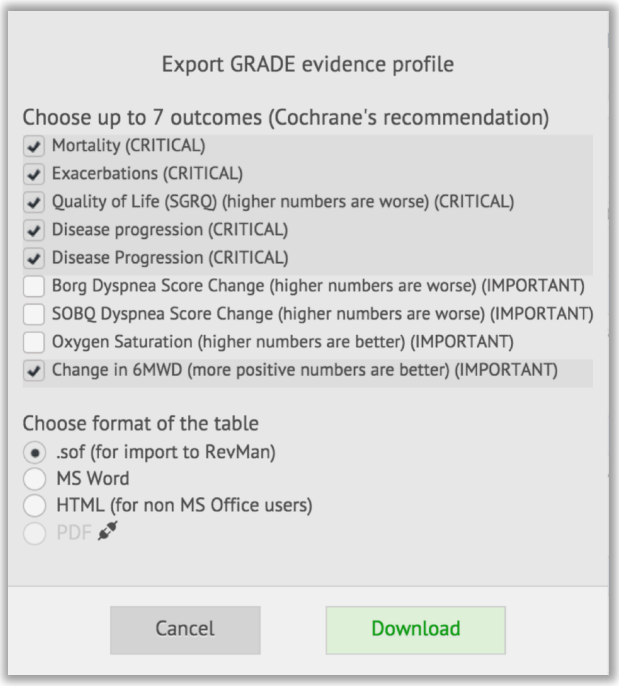


Figure 8. Example of exporting a DECIDE summary of findings table from GRADEpro to a Cochrane Collaboration RevMan file.

Multiuser collaboration on projects and sharing information electronically

One of the goals of the DECIDE project is to stimulate collaboration between European guideline developers. Thus, GRADEpro implements advanced sharing mechanisms (fig. 9) with conflict resolution (merging of data from different users) and real-time collaboration tools allowing guideline developers to simultaneously prepare evidence profiles and guideline documents. As of March 2015 there are 312 projects which are shared by users and being developed in a collaborative way. Additional features include support for full offline mode allowing users to work even in settings where Internet access is not available.

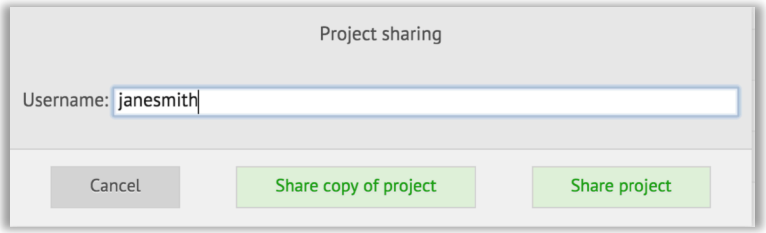


Figure 9. Sharing the access to a project for real-time collaboration with other users.

Support for European languages

GRADEpro provides templates for DECIDE presentation strategies in English and in other European languages. The document templates and the software interface are also available in German (fig. 10) and in Spanish (fig. 11). Dutch, French and Italian translations of DECIDE templates are being finalized and implemented. The software supports full internationalization and the Chinese version is being tested and will be available soon.

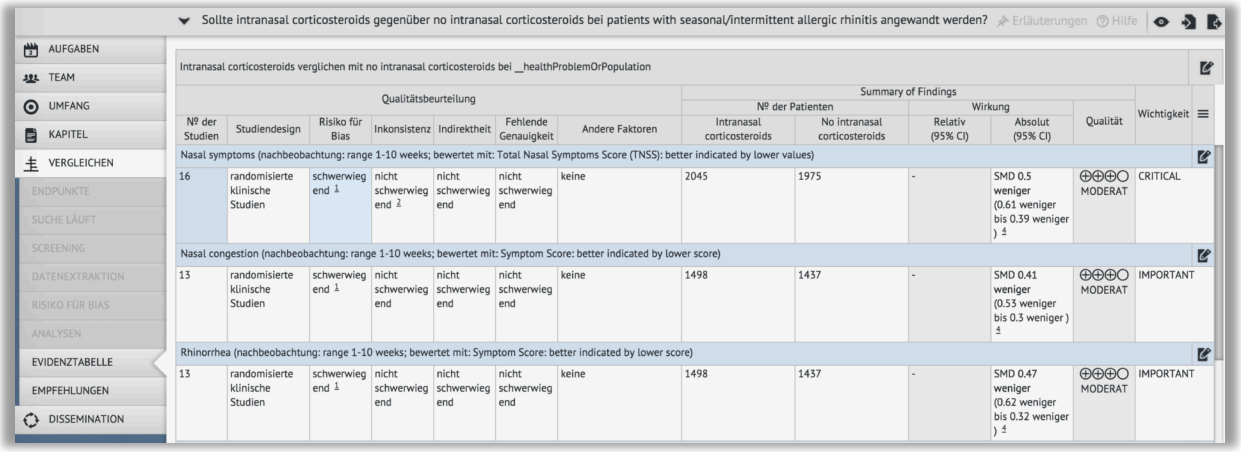


Figure 10. GRADEpro interface and DECIDE SoF template in German.

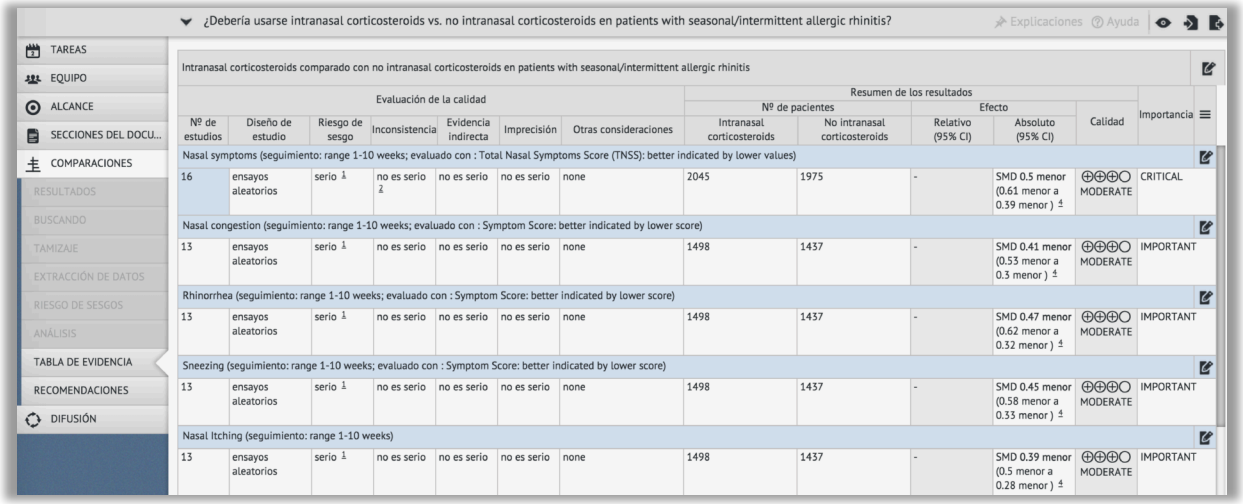


Figure 11. GRADEpro interface and DECIDE SoF template in Spanish.

Training materials

GRADEpro contains the GRADE Handbook, which explains both the theoretical underpinnings of the approach as well as the practical issues related to creation and presentation of evidence to various stakeholders (fig. 12). The Handbook is regularly updated. A contextual help for the software itself is also available for users, as well as an interactive tutorial for new users (fig. 13). Training materials, including handouts, checklists

and video seminars are being collected and linked to a software interface to facilitate learning of the approach (fig. 14).

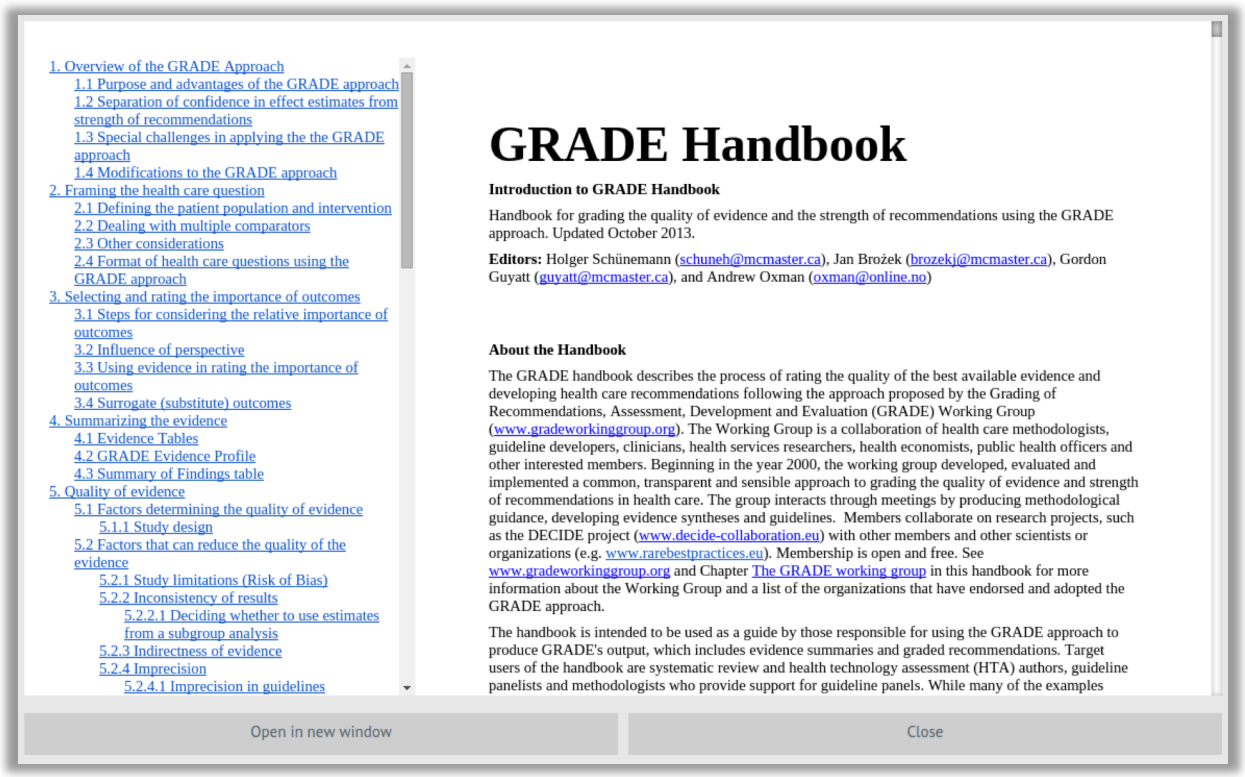


Figure 12. GRADE Handbook as part of the DECIDE Toolkit.

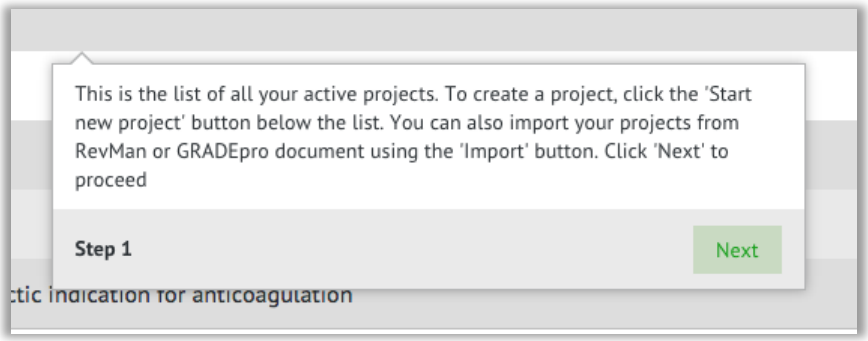


Figure 13. Interactive tutorial for new users.

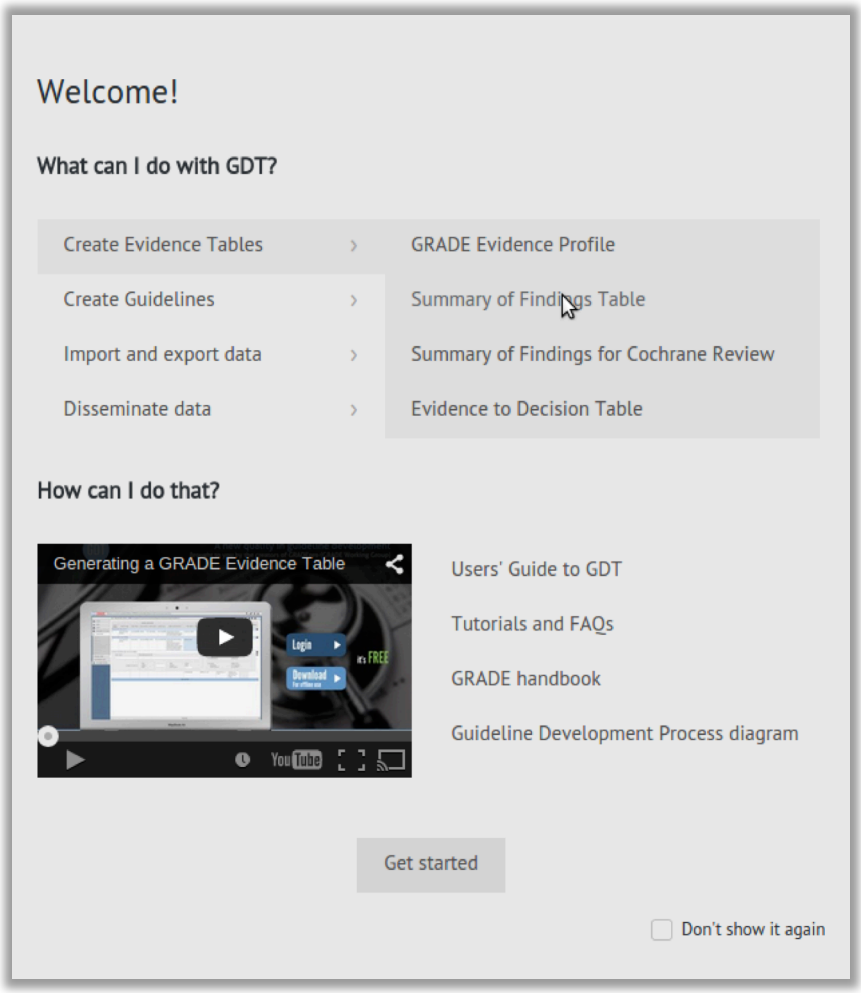


Figure 14. Welcome screen with links to various educational and supporting materials.

3.6. User testing and feedback from stakeholders

The DECIDE Toolkit has been formally user tested utilizing industry standard procedures (e.g. small groups in controlled environments, feedback sessions) as well as tested by the DECIDE partners, members of the GRADE Working Group and other users, including Cochrane Collaboration review authors (over 4200 unique users as of March 2015). Several health care guidelines were developed with the support of GRADEpro, including whole guidelines being disseminated as mobile apps using the presentation for health care professionals developed in the DECIDE WP1 (fig. 15).

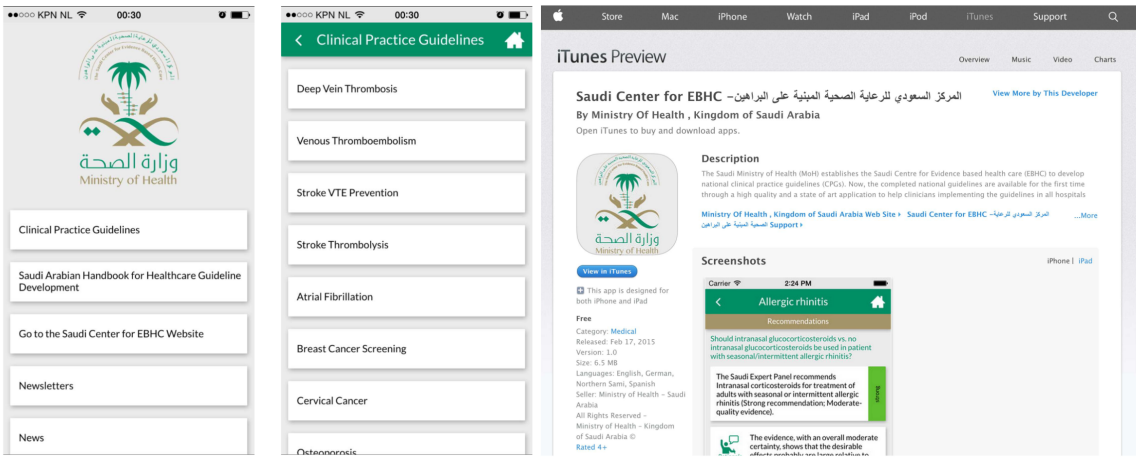


Figure 15. Example of a mobile device application created for the Saudi Ministry of Health using GRADEpro and the DECIDE presentation strategies.

3.7. Database of evidence profiles

The primary objective of the Database of Evidence Profiles (DBEP) (dbep.gradepro.org) is to facilitate collaboration and share information across European guidelines developers and their partners worldwide (fig. 16). To this extent, the DBEP accepts input in a common data format. This allows interoperability between a variety of electronic tools used by European and international guideline developers.

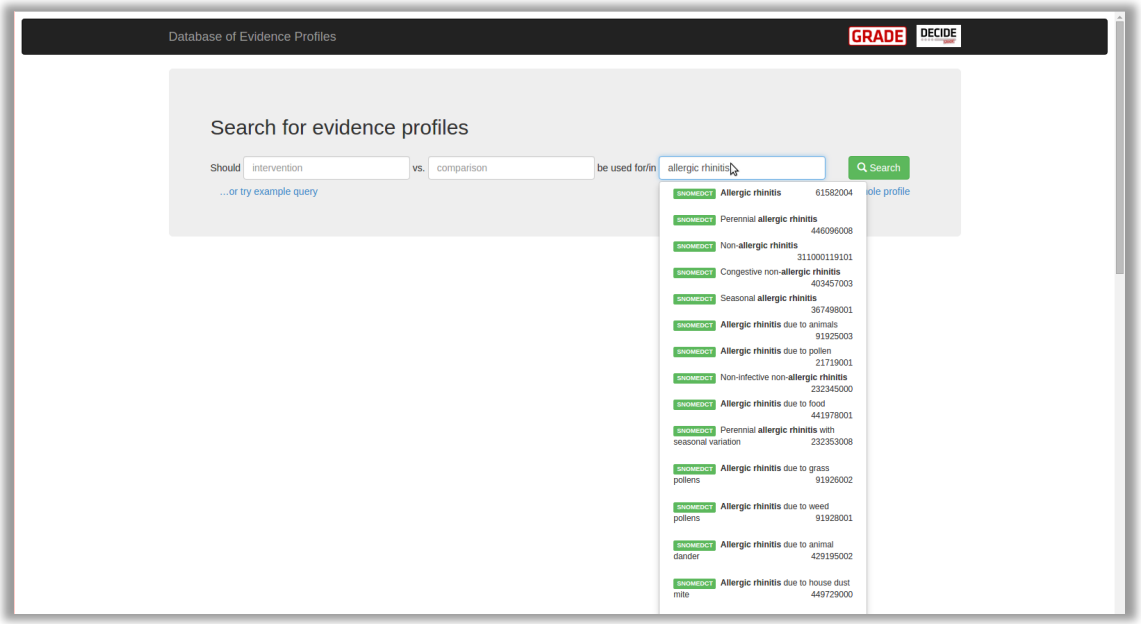


Figure 16. Example search in Database of Evidence Profiles (DBEP).

The central and most basic data item used in the DBEP is an evidence profile, to which outcomes and recommendations are attached. The profiles are linked conceptually by the guideline they come from. It is also possible to upload separate evidence profiles to the

database. The DBEP can also present guideline recommendation attached to the evidence profile (where available) in the form recommended by DECIDE WP1 (fig. 17). Other presentations of the evidence from the DBEP are also available (e.g. GRADE evidence profile, Cochrane Collaboration Summary of Findings table, Interactive Summary of Findings and interactive Evidence-to-Decision tables) (fig. 18).

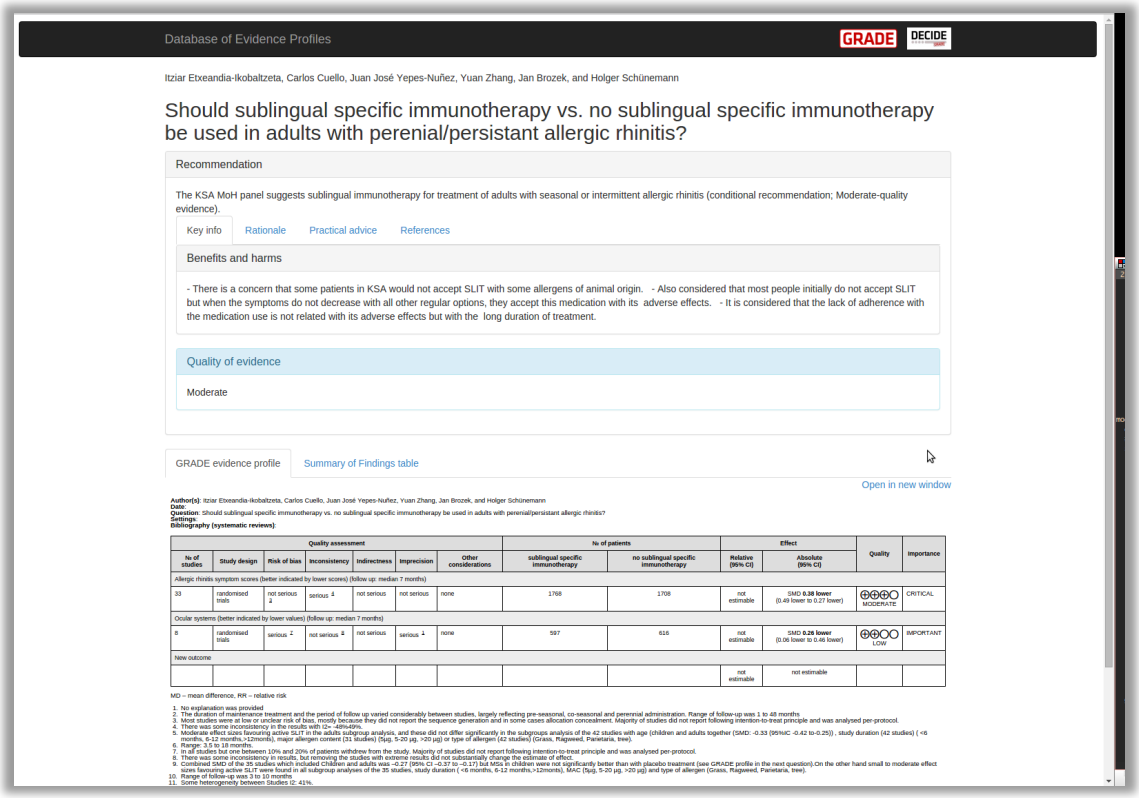


Figure 17. Example of content of Database of Evidence Profiles (DBEP).

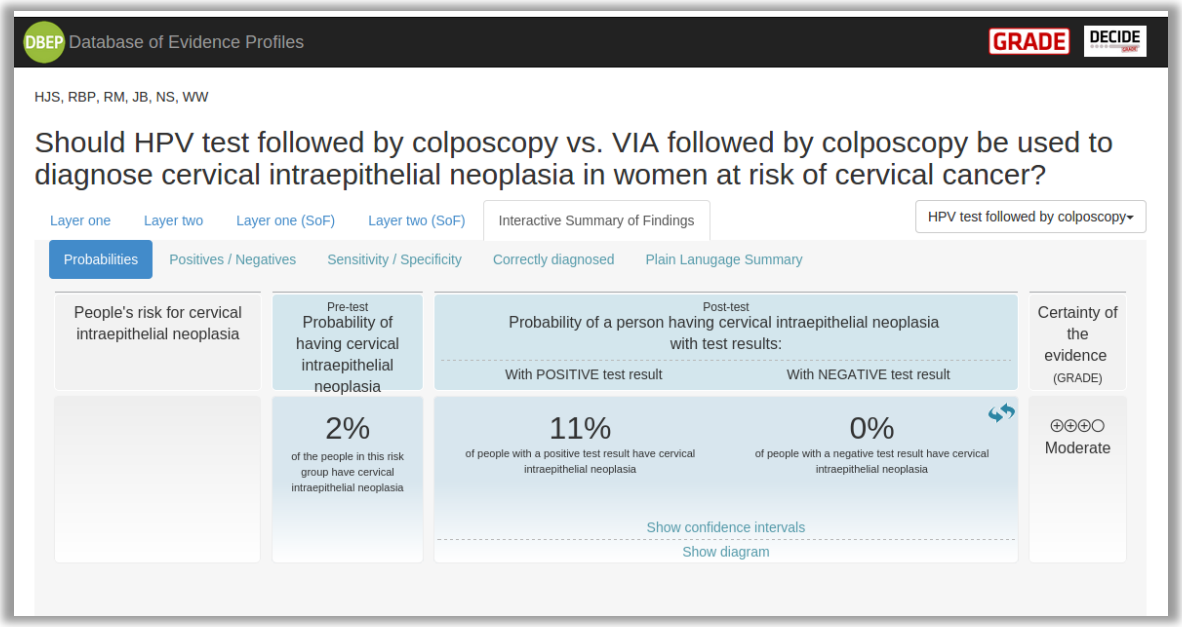


Figure 18. An interactive Summary of Findings (iSoF) table in Database of Evidence Profiles (DBEP).

An ontology-based coding system was implemented in order to tackle issues such as differences in terminology or languages used in different evidence syntheses and guidelines. The interface allows searching the database by ICD-10, SNOMED-CT and MESH codes, as well as plain language.

The content of the DBEP has been made machine-readable by the use of the Linked Data paradigm. All the database records come in a structured format that follows JSON-LD format. It makes it fully interoperable with a variety of systems supporting Resource Description Framework format. Attaching codes enables this representation to be queried against external databases, such as DBpedia.

4. Conclusion

As the Toolkit is operational and is being widely used we consider that D6.3 has been successfully completed and that the main objective of WP6 has been met.

To ensure fulfilment of the broader aims of WP6, we have well-developed plans in place for the remainder of the project with respect to ongoing enhancements and fine-tuning of the tools we have developed. These plans include implementation of the iSoF and iEtD in GRADEpro - and also for reviewing feedback, continued testing and further translation to European languages and possibly Arabic too.

