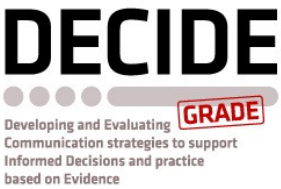

Project no. 258583
Project acronym: DECIDE
Project title: Developing and Evaluating Communication strategies to support Informed Decisions and practice based on Evidence

SP1 - Cooperation

Collaborative Project
Small or medium scale research project

FP7 – HEALTH – 2010 – two-stage

Deliverable 1.1 – Phase 1 DECIDE Strategies for Health Professionals

Due date of deliverable: 30 June 2012
Actual submission date: 25 June 2012

Start date of project: 01 January 2011 Duration: 60 Months

Organisation name of lead contractor for this deliverable: Dr Pablo Alonso, Research Institute of the Hospital of Santa Creu and Sant Pau

Coordinator: Dr Shaun Treweek
Signed: Date: 25/06/2012

Project co-funded by the European Commission within the Seventh Framework Programme (2007-2013)		
Dissemination Level		
PU	Public	X
PP	Restricted to other programme participants (including the Commission Services)	
RE	Restricted to a group specified by the consortium (including the Commission Services)	
CO	Confidential, only for members of the consortium (including the Commission Services)	

Deliverable 1.1 – Phase 1 DECIDE Strategies for Health Professionals

Nature: Report

Dissemination Level: Public (PU)

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Work Package:	WP1

Document Status

Version:	1.0
Last modified:	Saturday 23rd June 2012
Status:	Final
Approved by:	Shaun Treweek and Andy Oxman
Date Approved:	Monday 25th June 2012

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1. Introduction

The DECIDE project, 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.

The DECIDE project is structured in five main investigational workpackages, each aimed at a different target (stakeholder) group: Healthcare professionals (WP1), policymakers and managers (WP2), public, patients and carers (WP3), users of evidence on diagnostic tests (WP4), and users of evidence on health system policies (WP5). To achieve the objectives, each of these work packages is structured in three phases: Strategy development (Phase 1), Evaluating of the strategies in randomised clinical trials (Phase 2), and testing the strategies with real guidelines (Phase 3).

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.

In this deliverable we present the progress and achievements on the development of optimal presentation formats of health care recommendations for health professionals (WP1). Our work package identified the following priorities named here as working areas:

- Area 1: Top Layer (minimum set of information needed for point-of-care decisions)
- Area 2: Evidence to Recommendation table for guideline developers
- Area 3: Evidence to Recommendation framework for guideline users
- Area 4: Shared decision-making support tools
- Area 5: Electronic representation of the areas above.

2. Methods

The methods to develop optimal presentations to effectively communicate evidence-based recommendations to health professionals (target population for WP1) are similar to those used in other work packages and comprise three phases, which are iterative rather than linear (i.e. we might repeat Phases 1 to 3, or move from Phase 2 back to Phase 1):

- Phase 1: Strategy development
- Phase 2: Evaluating the strategies in randomised clinical trials
- Phase 3: Testing the strategies with real guidelines

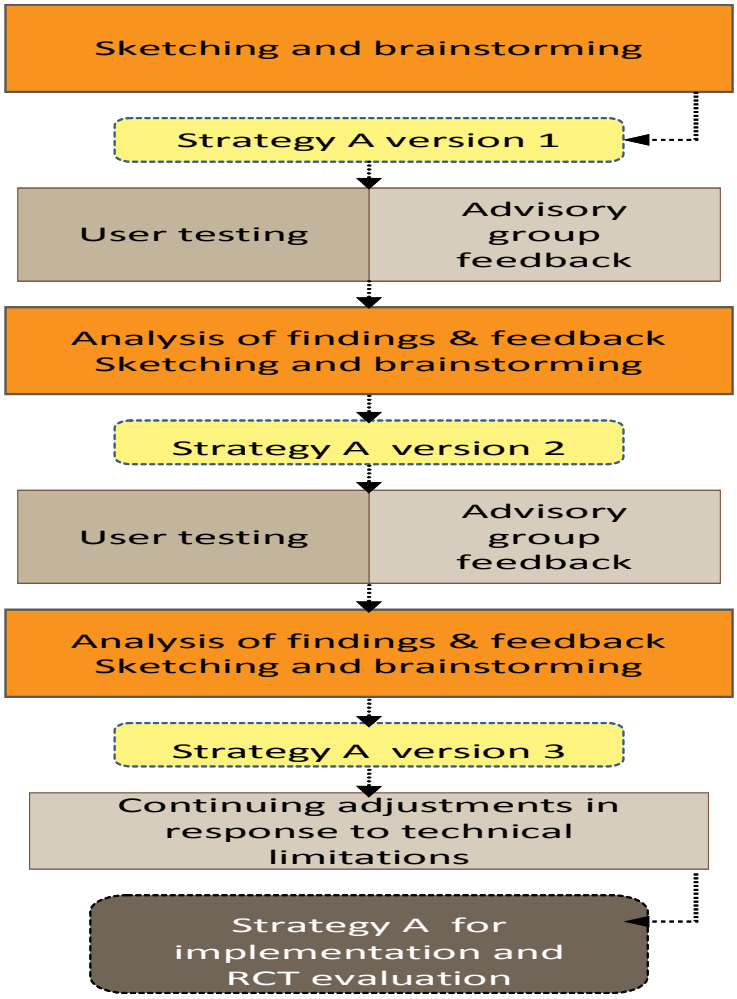
2.1. Strategy development (Phase 1)

The initial development of an optimal presentation format was based on the work of the GRADE working group (www.gradeworkinggroup.org) and includes:

- Brainstorming workshops to generate ideas and potential solutions
- Advisory group consultation
- User-testing to inform revisions from a user perspective
- User feedback

All these strategies are used in parallel and iteratively **(Figure 1)**.

Figure 1. : Iterative development process (Phase 1)



2.1.1. Brainstorming workshops

Six brainstorming workshop/meetings were held (face-to-face meetings or by teleconference) to identify problems and ways of improving each presentation format. Participants applied principles from their professional perspectives including clinical epidemiology and information design, as well as diverse clinical backgrounds and experience developing and using guidelines.

2.1.2. Advisory group consultation

Priorities and presentation formats were informed by means of consultation with key stakeholders. A common list of key stakeholders from Europe and America was generated for all work packages and then we selected those relevant to inform WP1 (30 in total). Stakeholders from WP1 included health professionals, guideline developers as well as researchers with expertise in clinical epidemiology and statistics, implementation science, communication and psychology. Groups were purposely selected to ensure a breadth of perspectives.

We contacted stakeholders once and gathered information by email, encouraging them to collect feedback from their colleagues in addition to providing their own feedback. Our analysis considered emerging issues with a high level of agreement or disagreement, issues we had not previously considered, or issues considered to be of critical importance.

2.1.3. User testing

Using a semi-structured interview guide, we explored both immediate first impressions as well as detailed descriptions during sessions of about one hour of duration that were audio-recorded (with participants' permission) and which also included an observer taking notes. The interview guide was designed to explore six of the seven different facets of "user experience" as described in a model by Peter Morville: usability (defined for our purposes as "correct understanding and ease of use"), credibility, usefulness, desirability, findability and value. The seventh facet from this model – accessibility – has not yet been addressed because user testing has to date been done on paper but will be explored when user testing is done with electronic presentations. Follow-up questions cover overall impressions and suggestions for improvement.

Interviews were transcribed and translated when done with non-English speaking users.
We reviewed notes and transcriptions, looking primarily for barriers and facilitators. For the analysis, we categorised comments as "show-stoppers", "big problems / frustrations", "minor issues or cosmetic things", "positive feedback" and "specific suggestions".

2.1.4. User feedback

In addition to user testing we collected user feedback at several workshops with healthcare professionals or methodologists, mainly taking advantage of national or

international meetings. We performed three of these sessions in groups of 7-10 professionals each time with a semi-structured process.

In these group sessions we explored both immediate first impressions and detailed descriptions during sessions of about one hour of duration. We collected feedback by taking notes and through the use of a booklet that participants filled in. We reviewed notes and replies, looking primarily for barriers and facilitators. For the analysis we categorised comments as “show-stoppers”, “big problems / frustrations”, “minor issues or cosmetic things”, “positive feedback” and “specific suggestions”.

3. Results

This document reports the results for Area 1 (Top layer) presentation up to this time. Areas 2 to 4 are being discussed and further developed. The common philosophy in WP1 is a layered approach for the presentation of information to users. We have developed most of the Top Layer and are also developing several other layers starting from the initial presentation of the recommendation down to evidence summary tables that report results for a particular body of evidence in greater detail.

The clinical topics that will be used through the development phase are:

- Acute respiratory tract infections
- Cervical cancer screening
- Depression
- Thrombosis
- Diabetes

Several of these clinical topics are shared with WP2-3 (they are part of DECIDE's Milestone 1) and will be developed in a coordinated fashion. Some will also be used by WPs 4 and 5. This will prove helpful regarding coherence and integration of methods, reporting and presentation of final strategies.

3.1. Top layer for health care professionals

3.1.1. Design

We developed an initial presentation of a "Top Layer" that includes the minimum amount of information that a health professional would need to understand a recommendation. Typically users would consult this after reading a recommendation (Figure 2). This Top Layer includes:

a) The recommendation(s) and its strength (Figure 3)
b) Key Information section with four key factors that influence the strength of recommendation:
    1. Confidence in the estimates of effect
    2. Balance between benefits and harms
    3. Values and preferences
    4. Resource use

c) The rationale for the recommendation: the guideline panels' integration of the four factors above. (Figure 4)

Guideline users can access more comprehensive information in deeper layers, such as detailed evidence summaries and decision aids to be used by patients and physicians.

We initially developed examples in the field of thrombosis (primary prevention with aspirin [cardiovascular] and warfarin versus aspirin for atrial fibrillation).

3.1.2. Results of user-tests of the Top Layer (Area 1)

We have run user tests with physicians with a variety of clinical backgrounds in four countries and two user feedback sessions with groups of primary care physicians. The results from these provide some clear messages. First and most important users like the layered approach we have adopted and they have different needs with regard to additional information. These different needs vary with the type of use, clinical circumstances, specialty or time.

Users generally liked the design of the Top Layer presentation format (Figure 3). However, they considered the information to be too comprehensive and sometimes too crowded, unclear or repetitive. Results of the Advisory Group consultation showed very similar results with generally positive feedback and similar areas of concern and suggestions for where improvements could be made.

Some users also had difficulties with conceptual understanding of the GRADE approach. The terminology used was sometimes not well understood or liked. Some of these concerns are explained in more detail below:

Confidence in the estimate of effect: several of the end-users misunderstood this term and the written explanation often did not succeed in clarifying the concept. Some guessed it reflected on the actual effect of the recommended treatment, one thought it was the guideline panel's confidence in their own recommendation.

Values and preferences: several stated that they found this category superfluous, confusing and too general to be informative. They missed not being presented with the background for the statements made in our example presentation, which made them highly suspicious of the validity and usefulness of the data provided.

Strong and weak terminology: (in particular the word 'weak') caused misunderstandings, frustration, uncertainty and reduced confidence in the guideline panel among users and stakeholders. Several went as far as to say that, as opposed to strong recommendations, they would ignore weak recommendations

Risk presentation: some users had difficulties understanding risk and uncertainty. We have so far only tested this through presenting absolute risk estimates of patient important benefits and harms as natural frequencies in the first layer.

Rationale: in this iteration we included the Recommendation Rationale, an explanation of how the panel integrates the different factors that bear on a recommendation, in a second layer (after presenting one by one the four key factors [e.g. quality of the evidence]). Some users would have preferred to have access to this rationale earlier in the process.

Summary of Findings table: in some of the tests users were presented with this table as it is now formatted in Cochrane reviews. The majority found it too crowded and complex.

3.1.3. Presentations

We include the different presentations evaluated below **(Figure 2 to 4)**. In the next iteration of user testing and advisory group consultation we will address the difficulties encountered. To do this we will prepare:

- Three additional presentations of weak and strong with the use of new symbols, terminology and use of colour.
- Presentation of more concise explanations of the different factors of the Top Layer. These will be evaluated and compared with the previous ones.

Figure 2. Top layer: Recommendation level

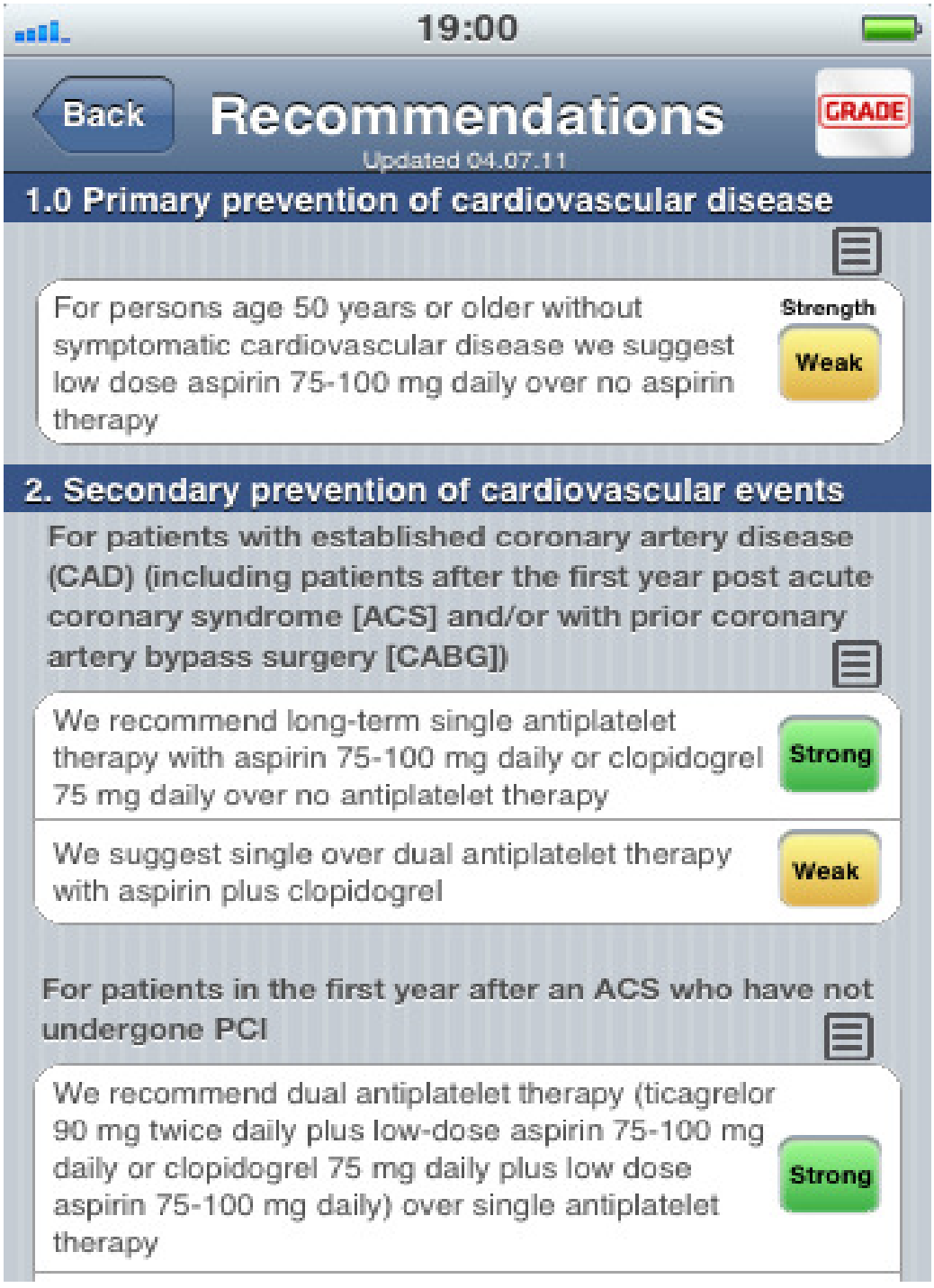


Figure 3. Top Layer: recommendation and key factors (first layer)

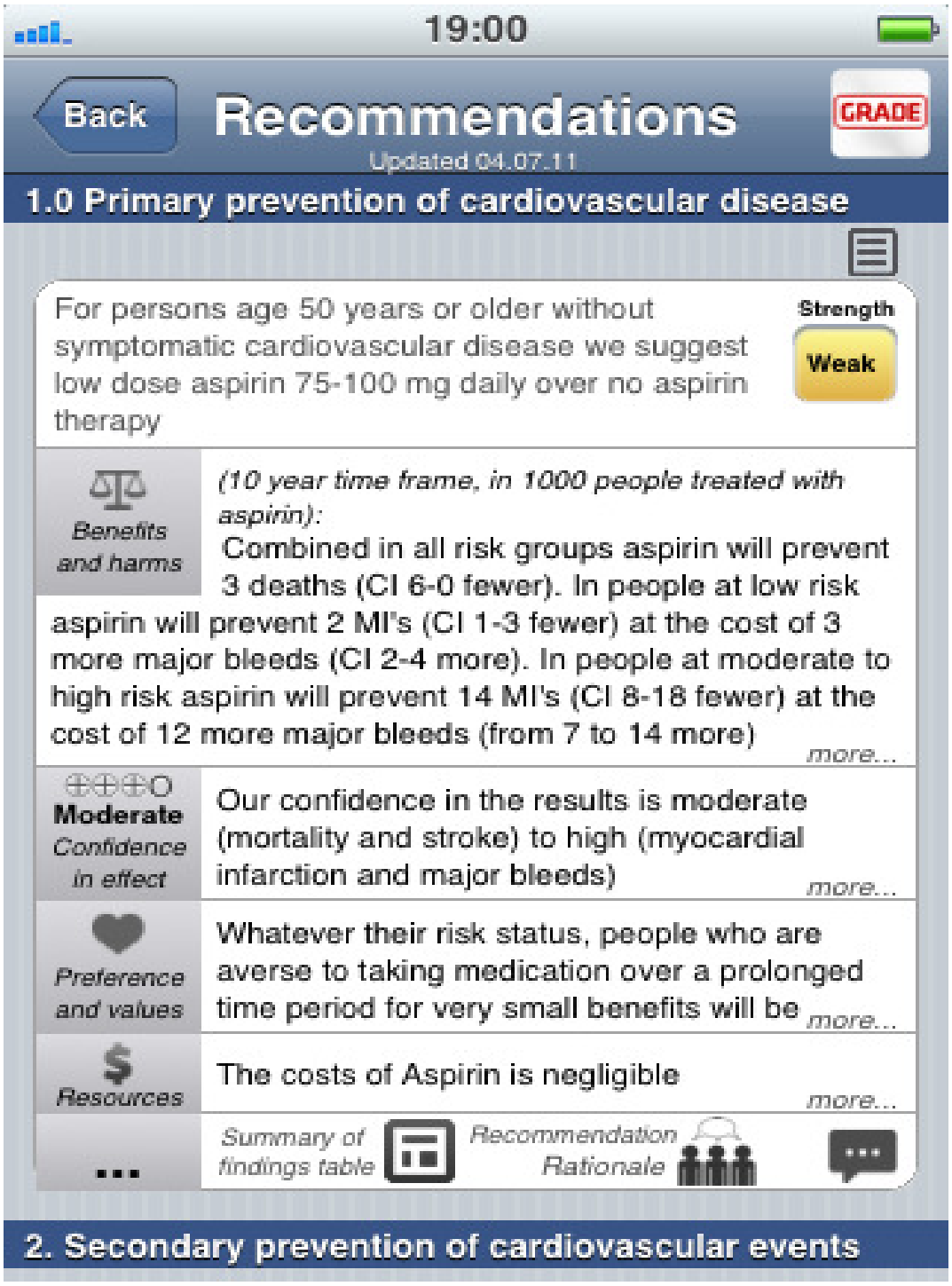
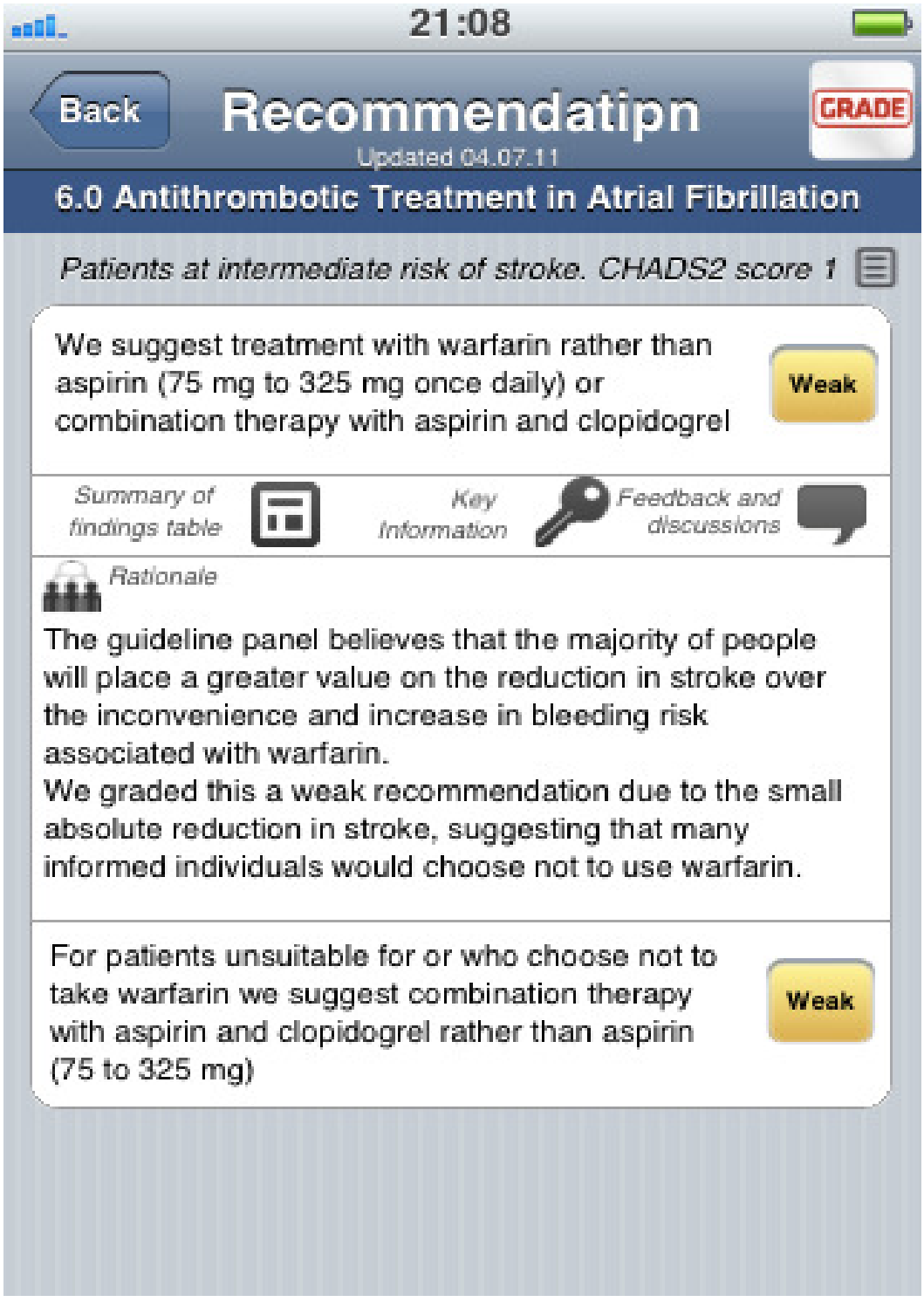


Figure 4. Recommendation and key factors (second layer) - Rationale



3.1.4. Proposed solutions

We are preparing the second iteration of user testing of this Top Layer where we plan to address the shortcomings of our previous designs. This proposal was developed during a face-to-face workshop in Oslo and three teleconferences. In brief our new presentations will include:

- Alternative presentations for the Recommendation level with alternative designs that are more actionable and include legends clarifying the implications of strong and weak recommendations.
- Inclusion of the Rationale in Layer 1. Evaluate to have access to it from the Recommendation level.
- More concise and plain language for the factors included in Layer 1 and 2 (e.g. “What do patients think?” instead of “Values and preferences”).
- Bulleted presentation of benefits and harms.
- Change of “confidence in effect” terminology and use of “quality of the evidence”. Will not include confidence intervals that we will use in deeper layer (Summary of Findings (SoF) or Evidence to Recommendation (EtR) tables. See 3.2).
- Alternative presentations of the headings for the different factors in Layer 1.
- Alternative presentations of results (e.g. graphical or alternative absolute effect estimates like number needed to treat)

3.2. Evidence to Recommendation for guideline developers (Area 2)

We developed an initial presentation of an Evidence to Recommendation (EtR) framework. This table was based on a previous one developed by the GRADE working group. We had three brainstorming sessions and user tested this table at three international meetings of methodologists and guideline groups.

The design of this framework (Table 1) is being discussed with other work packages that also include an EtR framework (1, 2, 4 and 5) with the goal of using a standard design across work packages. The table therefore will be modified in light of those discussions (see section 4.4.).

Table 1. Evidence to Recommendation framework for guideline developers

QUESTION: Should warfarin vs aspirin therapy be used for patients with atrial fibrillation?

***Population**:* patients at intermediate risk of stroke (CHADS2 score of 1)
***Intervention**:* warfarin
***Comparison**: aspirin*
Setting: outpatients

	CRITERIA	JUDGEMENT	DETAILS OF JUDGEMENT	EVIDENCE/EXPLANATION
QUALITY	**What is the overall quality of evidence?**	*Group:* ☐ High x Moderate ☐ Low ☐ Very low	*Group:* *Critical Outcomes:* — *High* — *Moderate* — *Low* — *Very low* 1. Death — ☐ — x — ☐ — ☐ 2. Non fatal strokes — x — ☐ — ☐ — ☐ 3. Non fatal extracraneal major bleeds — ☐ — x — ☐ — ☐ 4. Systemic embolism — x — ☐ — ☐ — ☐	• Imprecision was a reason for downgrading for nonfatal major bleeds, death and systemic embolisms • Resources not explicitly evaluated
BENEFITS & HARMS	**How is the balance between benefits and risks/ burden?**	*Group:* ☐ Benefits outweigh harms/ burden x Benefits slightly outweigh harms/ burden ☐ Benefits and harms/ burden are balanced ☐ Harms/ burden slightly outweigh benefits ☐ Harms/ burden outweigh benefits	*Group:* *Critical Outcomes:* — *Large/Modest benefit* — *Small benefit* — *No effect* — *Small harm/ burden* — *Modest/Large harm/ burden* 1. Death — ☐ — ☐ — x — ☐ — ☐ 2. Non fatal strokes — x — ☐ — ☐ — ☐ — ☐ 3. Non fatal extracraneal major bleeding — ☐ — ☐ — ☐ — x — ☐ 4. Systemic embolism — ☐ — ☐ — x — ☐ — ☐ 5. Burden of treatment — ☐ — ☐ — ☐ — x — ☐	

Outcome	Relative estimate (95% CI)	Absolute estimates (95% CI) Time frame: 1 year		Comments
		Intervention	Control	
Death	0.97	46/1000	47/1000	
Non Fatal strokes	0.47	8/1000	17/1000	
Non fatal major bleeding	1.5	12/1000	8/1000	
Systemic embolism	0.67	2/1000	3/1000	
Burden of treatment				The use of warfarin compared to ASA increases the burden of the treatment

VALUES AND PREFERENCES	**What are the patient's values and preferences, and what certainty do we have about them?**	*Group:* ☐ Little unceirtany and similar values x Some uncerntainty or some variation ☐ Significant uncerntainty or large variation	*Group:* High confidence in the tipical values: ☐ Agree ☐ Somewhat agree ☐ Uncertain x Somewhat disagree ☐ Disagree Values and preferences likely similar: x Agree ☐ Somewhat agree ☐ Uncertain ☐ Somewhat disagree ☐ Disagree	We are moderately confident that patients will place the greatest value on avoiding strokes. Our best estimate from a systematic review is that 1 stroke equals 1 major bleeds. There is wide variability in these values and preferences. Patients averse to taking oral anticoagulants for their potential of bleeding may be disinclined to use long-term warfarin therapy.
RESOURCES	**Is the incremental cost (or resource use) small relative to the benefits?**	*Group:* ☐ Cost is very small relative to the benefits x Cost is small relative to the benefits ☐ Cost is borderline relative to the benefits ☐ Cost is high relative to the benefits ☐ Cost is very high relative to the benefits	*Group:* Costs are low: ☐ Agree x Somewhat agree ☐ Uncertain ☐ Somewhat disagree ☐ Disagree Benefits are important: ☐ Agree x Somewhat agree ☐ Uncertain ☐ Somewhat disagree ☐ Disagree	Resources required seem to worth the net benefit. Resource use not explicitly evaluated. The resources needed are similar between warfarin and aspirin (both are of low cost although warfarin needs tight controls) and thus they are likely to be worth the potential benefits.

Balance of consequences	Undesirable consequences *clearly outweigh* desirable consequences	Undesirable consequences *probably outweigh* desirable consequences	The balance between desirable and undesirable consequences *is uncertain**	**Desirable consequences *probably outweigh* undesirable consequences**	Desirable consequences *clearly outweigh* undesirable consequences
	☐	☐	☐	☑	☐

Recommendation	*We recommend against the option*	*We suggest not considering the option*	***We suggest considering the option***	*We recommend the option*
	☐	☐	☑	☐

In patients at intermediate risk of stroke (CHADS2=1) we suggest treatment with warfarin (over aspirin)

Recommendation rationale The majority of patients place a higher value on avoiding a stroke than experiencing a bleeding and the inconvenience associated with warfarin. Given the absolute stroke reduction in stroke we suggest the use of warfarin (over aspirin) as most patients if informed would choose this treatment. However, this absolute stroke reduction is considered small for some patients, and many would not choose this treatment.

3.3. Evidence to Recommendation for health professionals (Area 3)

One of our priorities was developing a Summary of Findings (SoF) table that was more user-friendly that the original table developed by the GRADE working group. During the initial brainstorming process we introduced additional factors (Values and preferences and resource use) not considered in the original SoF table. We therefore developed an EtR table rather than a SoF table for this target group **(Table 2)**. At the moment we are planning to do user testing and consult our advisory group during this summer. The table will be modified accordingly after the analysis of the results.

Table 2. Evidence to Recommendation framework for health professionals

In patients at intermediate risk of stroke (CHADS2=1) consider treatment with warfarin (over aspirin)						
***Recommendation Rationale**:* The majority of patients place a higher value on avoiding a stroke than experiencing a bleeding and the inconvenience associated with warfarin. Given the absolute stroke reduction in stroke consider the use warfarin (over aspirin) as many patients if informed will choose this treatment. However, this absolute stroke reduction is considered small for some patients, and a reasonable proportion might not to choose this treatment.						
Outcomes	**What happens?**	**How confident are we?**	**1 year risk estimates**		**What do patients think about the different outcomes?**	**What are the resource implications?**
			With ASA	**Risk difference with warfarin *(compared with aspirin)***		
Warfarin decrease strokes and probably increases bleeding					We are moderately confident that typical patients with atrial fibrillation place three times more value on the avoidance of stroke than on the avoidance of bleeding. However, there is likely to be wide variability among patients.	We are moderately confident that warfarin is generally cost-effective in most situations
Nonfatal strokes *(Ischemic stroke and intracranial hemorrhage)*	The use of warfarin compared to ASA reduces the risk of non-fatal stroke in 9 fewer strokes per 1000 treated patient at 1 year	⊕⊕⊕⊕ Very confident	17 per 1000	9 fewer per 1000		
Nonfatal major extracranial bleeds	The use of warfarin versus ASA probably increases the risk of bleeding in 3 more bleeds per 1000 treated patients at 1 year	⊕⊕⊕O Moderately confident due to imprecision[1]	8 per 1000	3 more per 1000		
Probably warfarin has little or no effect in the risk of death or systemic embolism						
Death	The use of warfarin or ASA probably makes little or no difference in the risk of death	⊕⊕⊕O Moderately confident due to imprecision[1]	47 per 1000	1 fewer per 1000		
Systemic embolism	The use of warfarin or ASA probably makes little or no difference in the risk of systemic embolism	⊕⊕⊕O Moderately confident due to imprecision[1]	3 per 1000	1 fewer per 1000		
Warfarin increase the burden of the treatment						
Burden of treatment	The use of warfarin compared to ASA increases the burden of the treatment.	⊕⊕⊕⊕ Very confident	Daily pill	Lifestyle limitations, dietary restrictions, frequent blood testing and clinic visits	We are moderately confident that typical patients find warfarin low burden	

3.4. Links with other work packages and preliminary results

Table 3 provides an overview of the strategies currently being developed and user tested for work packages 1 to 5.

Presentation of evidence and recommendations

Apart from the presentations included in sections 4.1. to 4.3., that we have presented above, we are developing and testing explanations of key concepts and interactive SoF tables that will be adapted for use across all presentations in the five work packages. The explanations will be brief and include concepts such as “quality of evidence” or “confidence intervals” that can, for example, be used as ‘cursor over’ help in guidelines, EtR tables/frameworks, SoF tables, or guidelines. In addition, we will develop longer explanations using videos, interactive applications or other presentations to facilitate understanding. These can be provided as help using hypertext links in, for example, online guidelines, as resources or a help file on guideline producers’ websites or in resources, such as the Cochrane Library, as an open access online resource, or as an introduction to a group making recommendations or decisions. The objectives of the interactive SoF tables are to improve understanding and use of evidence of the effects of healthcare interventions allowing producers to tailor a presentation to a target audience and users to interact with the presentation.

Additional communication strategies for clinicians will include point of care applications to support the provision of clinical recommendations linked to medical records and on smart phones. Some of this work, for example that linked to medical records, is being done through collaborative links with other guideline projects (e.g. a Norwegian project called SNAP-IT). For patients, these will include access to decision aids to be used at the point of care together with their clinicians and tools to assist guideline developers in developing versions of guidelines that are easily accessible to targeted patients.

Table 3. Strategies being developed by DECIDE

<table>
<tr><th></th><th>WP1 clinicians</th><th>WP3 consumers</th><th>WP4 diagnostic tests</th><th>WP2 coverage decisions</th><th>WP5 health system decisions</th></tr>
<tr><td rowspan="3">Presentation of evidence and recommendations</td><td>Top Layer presentation</td><td colspan="4"></td></tr>
<tr><td colspan="5">Explanations of key concepts</td></tr>
<tr><td colspan="5">Interactive SoF tables/ videos</td></tr>
<tr><td rowspan="2">Frameworks for going from evidence to recommendations</td><td colspan="3">Evidence to recommendation frameworks</td><td>*</td><td>Evidence to recommendation framework</td></tr>
<tr><td></td><td></td><td></td><td colspan="2">Costing frameworks</td></tr>
<tr><td>Decision support</td><td colspan="2">Decision aids</td><td>Decision aids & Evidence to decision frameworks</td><td colspan="2">Evidence to decision frameworks</td></tr>
<tr><td>Communication strategies</td><td>Point of care applications</td><td>Point of care applications & Guidance and tools for guideline producers</td><td>Adaptation of point of care applications & guidance and tools for guideline producers</td><td></td><td></td></tr>
</table>

* Recommendations for coverage decisions are not common. Typically these decisions are made by responsible groups in each jurisdiction or organisation, although sometimes technical support staff will recommend a decision that is than considered by those responsible for making the decision.

3.5. Future plans

WP1 is actively working on the preparation of a new presentation format of the Top Layer for the second iteration of user testing. This will take place during the summer in several of our partners' countries.

Additionally we are optimising the development of the EtR frameworks, both for health professionals and guideline developers. We will be user testing these EtR frameworks and consulting our Advisory Group over the summer. In this area we are working in close coordination with WP2, 4 and 5 which also are developing their own customized frameworks. We are also working on the development of the shared decision-making support tools in coordination with WP3 (patients). All these presentations will be further developed, evaluated and tested during next year (2013).

