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Deliverable 3.1 – Collated DECIDE strategies for health professionals, policymakers and the public


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**Deliverable 3.1 – Collated DECIDE strategies for health professionals,
policymakers and the public**

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Table of contents

Deliverable 3.1 – Collated DECIDE strategies for health professionals, policymakers and the public	1
Table of contents	3
Introduction	4
1. Work Package 1: Health professional focused strategies for communicating evidence-based recommendations.....	5
Section 1 - Annexes	22
2. Work Package 2: DECIDE strategies for policy makers and managers)	29
Annex 2.1: Evidence to coverage decision framework.....	39
Annex 2.2: Feedback questionnaire	47
Annex 2.3: Feedback on DECIDE framework for going from evidence to coverage decisions	48
Annex 2.4: User testing guide	50
□DECIDE WP2 User testing: EtCD for policy makers and managers.....	50
□1. Checklist.....	50
□2. Introduction and instructions.....	50
□Background questions – 5 minutes.....	51
□Repeat instructions.....	52
□Scenario	53
□The EtCD table for policy makers and managers: first impressions	53
□The EtCD table for policy makers and managers: detailed questions	54
□The EtCD table for policy makers and managers: summing-up questions	56
3. Work Package 3: Patient and public focused strategies for communicating evidence-based recommendations.....	58
4. Conclusion.....	80

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.

The DECIDE project is structured around five main investigational work packages, 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); for policymakers and managers (WP2); and for patients and the general public (WP3).

1. Work Package 1: Health professional focused strategies for communicating evidence-based recommendations

1.1 Introduction

In this section 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 priority areas:

- Area 1: Top Layer (minimum set of information needed for point-of-care decisions)
- Area 2: Evidence to Recommendation framework for guideline developers
- Area 3: Evidence to Recommendation table for guideline users
- Area 4: Shared decision-making support tools
- Area 5: Electronic representation of the areas above (common to WPs 1 to 5: toolkit development to prepare and disseminate evidence-based recommendations using the DECIDE strategies)

1.2 Methods.

The methods to develop and assess these optimal presentations targeted to health professionals are similar to those used in other work packages in the DECIDE project and comprises three iterative phases:

- Phase 1: Strategy development.
- Phase 2: Evaluating the strategies in surveys and randomized clinical trials.
- Phase 3: Testing the strategies with real guidelines.

1.2.1 Strategy development (Phase 1)

Phase 1 (strategy development) has been previously described in Deliverable 1.1. In brief, the initial development of an optimal presentation format is based on the work of the GRADE working group and includes iterative steps of: brainstorming workshops, advisory group consultation, user-testing and user feedback.

1.2.2 Evaluating the strategies (Phase 2)

The objectives of the trials are to assess the impacts of the various DECIDE strategies on intended behavior and attitudes, as well as correct comprehension of key information and general satisfaction. We are and will conduct surveys and trials with health professionals, in their hospital or primary care centers, or take the opportunity to gather interested professionals in meetings, workshops and conferences in each of the DECIDE partner countries. For trials, in most cases we expect randomization to be at the level of the individual participant when the risk of contamination between intervention and control groups is minimal. However, where contamination is considered a potential issue (within hospital or primary care centers), cluster randomization will be considered.

The different strategies coming from Phase 1 will be evaluated in randomized controlled trials. Eligible participants will be randomized to receive a first clinical scenario through different presentation formats (strategies) and an alternative or a conventional strategy. The clinical topics will be selected to be of relevance to the target audiences. Each trial would be structured to take no more than two hours of participants' time. To make it possible we will use remote response and data collection systems which allow participants interactivity, blind answers, automatic data collection with no margin of error and minimum time spent. The questionnaires (whether printed or interactive) will include multiple-choice questions measuring correct comprehension, attitudes, hypothetical or intended behavior, and satisfaction.

1.2.3 Testing in real guidelines (Phase 3)

The most promising strategies - based on the results of Phase 2 trials – are being and will be tested in real clinical practice guidelines prepared (*de novo* or updates) by consortium partners and other developers in Europe and internationally. We will evaluate the impact of these strategies on knowledge, attitudes and self-reported behavior before and after the DECIDE strategies are used to disseminate recommendations.

1.3 Results

This document reports the results for Area 1 through Area 4. The common philosophy in WP1 is a layered approach for the presentation of information to users. In this approach, clinicians initially face short, relatively simple presentations of recommendations and the rationale for the recommendations, and then have the option to dig deeper into more detailed and complex presentations of evidence.

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 WPs 2-5 and will be developed in a coordinated fashion. This will prove helpful bringing standardization of methods, reporting and presentation of final strategies across work packages.

1.3.1 Top layer for healthcare professionals

Brainstorming, design, and first round of user tests.

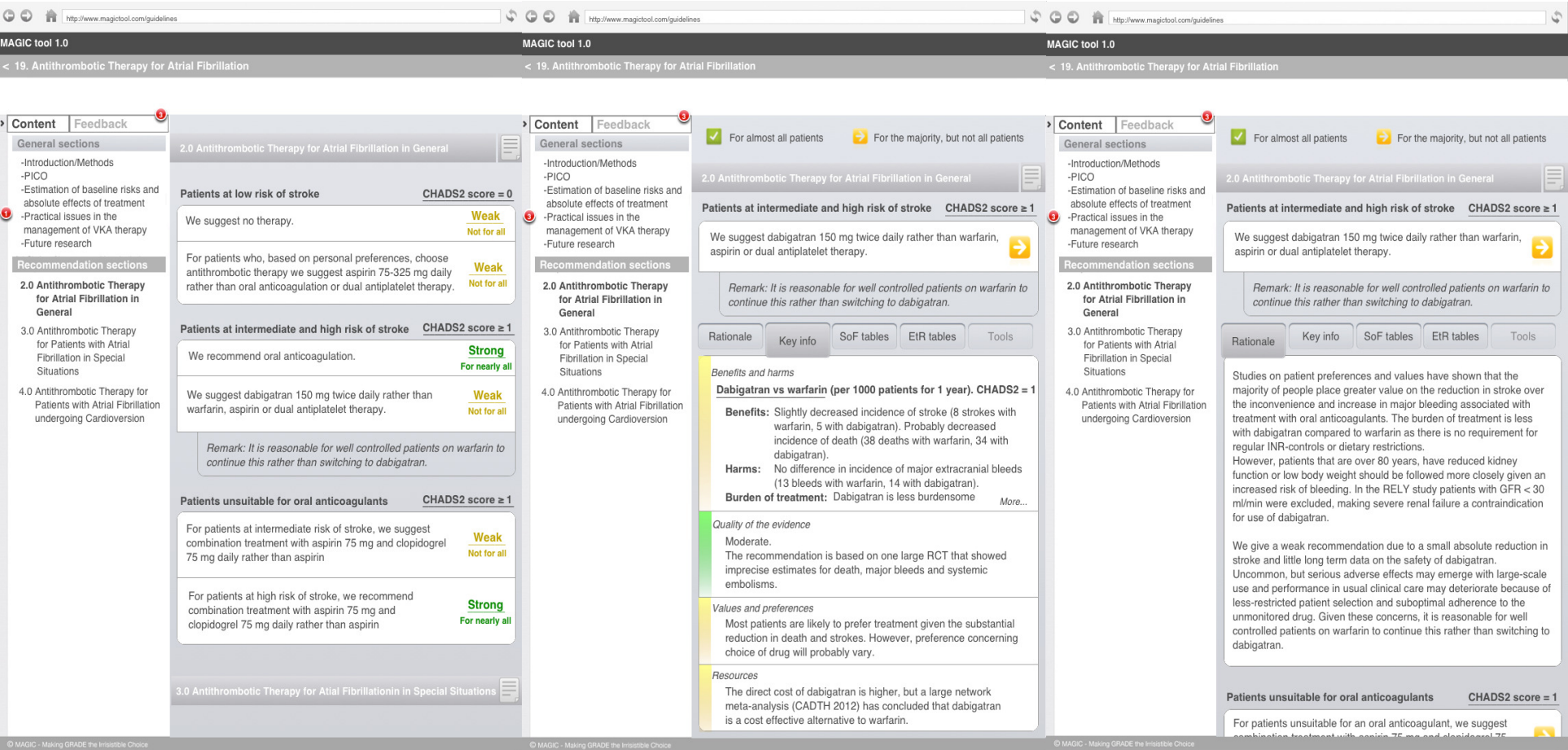
We have developed a multilayered guideline format tailored to the needs of healthcare professionals. Our proposed format aims to be adaptable to any electronic platform (web, tablets, and smart phones, directly linked to the electronic medical record). Quick and easy access and an adaptive format will facilitate dissemination and uptake of guidelines. The initial presentation of a “Top Layer” includes the minimum amount of information that a healthcare professional would need to understand a recommendation. Figures of the design that was initially tested are included in *Deliverable 1.1*. One key finding from the initial testing was that users found the presentation to be too complex, wordy and crowded. The end-users were confused by the methodology; the phrasing was unclear and repetitive. This issue was shared by several stakeholders in our Advisory board.

Design refinement

Several changes were introduced in the Top Layer from initial format before being further tested (see Figures 1.1 and 1.2)

- We adapted the display layout from a smart phone to a larger tablet screen.
- We provided both longer and shorter versions of the background information. The longer version included numerical data and relatively brief explanations for the key statements, while the shorter version did not.
- We changed the label of the “confidence in effect estimates” to “quality of evidence”. In the main text box we stated the level of quality and added important reasons for downgrading.
- Values and preferences: We added the gist of important aspects considered in making the recommendation.
- Strength of the recommendation: We tested three alternatives; two with legends at the top of the page giving a short explanation of the difference between strong and weak recommendations and one showing strong/weak with a legend directly underneath.
- We added information on the baseline risk, in addition to the risk difference.
- We provided pop-up aid displaying statistical data and graphical presentation of risk in addition to relative and absolute risk estimates as well as numbers needed to treat and baseline estimates.

Figure 1.1. Recommendation and longer format



http://www.magictool.com/guidelines

MAGIC tool 1.0

< 19. Antithrombotic Therapy for Atrial Fibrillation

http://www.magictool.com/guidelines

MAGIC tool 1.0

< 19. Antithrombotic Therapy for Atrial Fibrillation

http://www.magictool.com/guidelines

MAGIC tool 1.0

< 19. Antithrombotic Therapy for Atrial Fibrillation

Content **Feedback**

General sections

- Introduction/Methods
- PICO
- Estimation of baseline risks and absolute effects of treatment
- Practical issues in the management of VKA therapy
- Future research

Recommendation sections

2.0 Antithrombotic Therapy for Atrial Fibrillation in General

3.0 Antithrombotic Therapy for Patients with Atrial Fibrillation in Special Situations

4.0 Antithrombotic Therapy for Patients with Atrial Fibrillation undergoing Cardioversion

2.0 Antithrombotic Therapy for Atrial Fibrillation in General

Patients at low risk of stroke **CHADS2 score = 0**

We suggest no therapy. **Weak**
Not for all

For patients who, based on personal preferences, choose antithrombotic therapy we suggest aspirin 75-325 mg daily rather than oral anticoagulation or dual antiplatelet therapy. **Weak**
Not for all

Patients at intermediate and high risk of stroke **CHADS2 score ≥ 1**

We recommend oral anticoagulation. **Strong**
For nearly all

We suggest dabigatran 150 mg twice daily rather than warfarin, aspirin or dual antiplatelet therapy. **Weak**
Not for all

Remark: It is reasonable for well controlled patients on warfarin to continue this rather than switching to dabigatran.

Patients unsuitable for oral anticoagulants **CHADS2 score ≥ 1**

For patients at intermediate risk of stroke, we suggest combination treatment with aspirin 75 mg and clopidogrel 75 mg daily rather than aspirin. **Weak**
Not for all

For patients at high risk of stroke, we recommend combination treatment with aspirin 75 mg and clopidogrel 75 mg daily rather than aspirin. **Strong**
For nearly all

3.0 Antithrombotic Therapy for Atrial Fibrillation in Special Situations

Content **Feedback**

General sections

- Introduction/Methods
- PICO
- Estimation of baseline risks and absolute effects of treatment
- Practical issues in the management of VKA therapy
- Future research

Recommendation sections

2.0 Antithrombotic Therapy for Atrial Fibrillation in General

3.0 Antithrombotic Therapy for Patients with Atrial Fibrillation in Special Situations

4.0 Antithrombotic Therapy for Patients with Atrial Fibrillation undergoing Cardioversion

Why? For almost all patients

Why? For the majority, but not all patients

2.0 Antithrombotic Therapy for Atrial Fibrillation in General

Patients at intermediate and high risk of stroke **CHADS2 score ≥ 1**

We suggest dabigatran 150 mg twice daily rather than warfarin, aspirin or dual antiplatelet therapy. **Why?**

Remark: It is reasonable for well controlled patients on warfarin to continue this rather than switching to dabigatran.

Rationale & Key info **SoF tables** **EtR tables** **Tools**

What is the rationale?

Dabigatran is suggested over other antithrombotic agents due to the small, but significant reduction in stroke observed, that it is cost-effective and because the burden of treatment is considered less than for vitamin K antagonists.

However the fact that there is little data on long term safety for dabigatran makes this a weak recommendation.

What are the benefits and harms?

Dabigatran vs warfarin:

Benefits: Reduced number of strokes. No difference in the number of deaths or embolisms.

Harms: No differences in the number of extracranial bleeds. No long term data for adverse events.

Burden: Dabigatran is less burdensome

What is the quality of the evidence?

The quality of the evidence is moderate.

What are the values and preferences?

Dabigatran has few downsides and potential important benefits. Most patients are likely to prefer this treatment.

What are the resource implications?

Dabigatran, although more costly than warfarin, is likely to be cost-effective.

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User testing and feedback.

We conducted the second round of user testing in seven countries, performing 16 individual sessions using a tablet, 24 individual sessions using a Power point presentation and one group session. In general the feedback was more positive in this second round.

There was insufficient information on which of the longer or shorter format the participants preferred. Most of the users seemed to agree on two issues: there was positive feedback on use of absolute estimates, and several participants stated that they would use the information in shared decision making with a patient. There was an apparent preference for a short rationale. Several suggested that the comparator be omitted from the recommendation text (e.g. “we suggest dabigatran over warfarin in patients with atrial fibrillation”).

The meaning of quality of the evidence was easily understood. Conceptual understanding of the different reasons for down- or upgrading the quality of evidence has not been tested. The concept of values and preferences is still considered to be somewhat superfluous to healthcare professional and many users misunderstand it.

Regarding the “strength of the recommendation” concept users did not notice the legends on the top of the page. Several users disliked the different icons and the use of «why», and a majority seemed to prefer colour-coded strong/weak plus legend underneath. The explanation of the meaning of a strong and a weak recommendation was found to be vague and confusing. There was no consensus on graphical representation of effect estimates (pop-up aid) and several regarded it as uninformative. On the other hand, several others expressed that it was helpful, e.g. that it could be used to help explain risks visually to patients.

Several users specifically suggested that more practical information needed to be included (e.g. contraindications, dosage, rating of alternative treatments etc). Several users found it difficult to navigate from recommendation level to the background information. Several participants did not see that a risk stratification tool (CHADS-score) was provided through a link.

We have further refined the presentation format with these findings (Figure 1.3).

Figure 1.3. Top Layer final prototype

CHA2DS2-VASc score 2 or higher

Strong

We recommend treatment with oral anticoagulants (dabigatran, rivaroxaban, apixaban or warfarin).

Weak

We suggest treatment with dabigatran, rivaroxaban or apixaban (NOAC) rather than warfarin.

Remark: Patients who are established on warfarin with stable INR values can safely continue with warfarin.

PICO

Key info

Rational

Decision Aids

undefined

undefined

Practical advice

Discussion (0)

Tools

Medication

Benefits and Harms

Effect of dabigatran, rivaroxaban or apixaban (NOAC) vs warfarin over 1 year:

- Benefits: No significant difference in effect between the different drugs. With treatment the number of strokes is reduced from 51 to 33/1000 and mortality is reduced from 41 to 12/1000, compared to no treatment.
- Harms: No significant difference between the drugs, number of major extracranial bleeds is doubled from 10 to 20/1000 with treatment, compared to no treatment. Number of intracranial bleeds halved from 4 to 2 events/1000 patients with NOAC compared to warfarin.
- Burden of treatment: Daily medication with NOAC. Regular INR controls and dietary restrictions with warfarin.

Quality of Evidence

Overall the evidence is of moderate quality. The recommendation is based on a systematic review of warfarin vs no treatment of high quality with the exception of imprecise estimates for major bleeds (moderate), and a network metaanalysis of NOAC vs warfarin of moderate quality due to the use of indirect comparisons.

Preference and Values

Studies on patient preferences and values have shown that the average patient is prepared to suffer three major bleeds to avoid one stroke. These studies have guided our recommendation. They are however deemed to be of low quality and there was a high degree of variability in preferences. We therefore suggest that the decision regarding treatment options is made together with the patient.

Resources

Cost did not influence this recommendation.

Dosing and relative contraindications of NOAC

Strong

Dabigatran 150 mg x 2, rivaroxaban 20 mg x 1 and apixaban 5 mg x 2 is recommended for most patients.
A reduced dose of dabigatran 110 mg x 2, rivaroxaban 15 mg x 1 and apixaban 2.5 mg x 2 is recommended if:

- Age > 80 years old
- Concomitant use of interacting medication (e.g. verapamil)

Evaluating the strategy

During the last trimester of 2013 we have developed a protocol to evaluate this top layer presentation in an international randomized trial. We will compare it with an alternative presentation from a real guideline or electronic resource that physicians generally use (e.g. UptoDate). We will include understanding, preference and anticipated course of action as the main outcomes of interest.

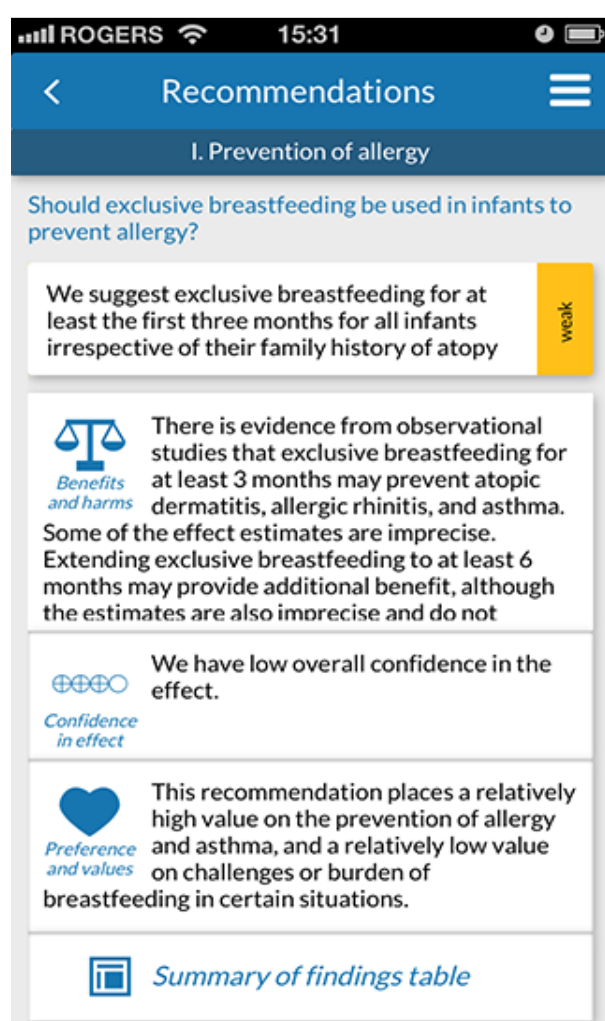
We will provide a short introduction to the concepts of GRADE system. We will present a clinical scenario followed by presentation of the alternative presentation formats (top layer and alternative) to participants. Feedback will be collected with remote response and data collection devices ('clickers', often used for teaching) during clinical sessions in hospitals and primary care centers.

We are also running another international trial with a similar design but with the objective to evaluate to what extent clinicians consider recommendations accompanying evidence summaries to be more helpful than evidence summaries

alone. We will evaluate preference, understanding of the evidence presented, interpretation of the balance of benefits and harms and clinicians' intended course of action to resolve the clinical scenario.

In collaboration with WP6 we have implemented the top layer in the guideline development tool that this work package is developing. This has been implemented in a real guideline about allergy from the Allergic Rhinitis and its Impact on Asthma initiative (Figure 1.4)

Figure 1.4. Top layer presentation in a smart phone



1.3.2 Evidence to Recommendation framework for guideline developers

Our work package has been user testing and developing further the evidence to recommendation framework. Better and more structured processes for developers means better guidelines for users. We have user tested and implemented

frameworks in real guidelines in Spain, with the World Health Organization, in Norway, Germany, North America, Asia and South America. With the collected feedback we have refined the framework.

We also led a harmonization process across work packages as there were four somewhat different frameworks being developed across WPs 1, 2, 4, and 5. Work packages 1 and 4 have two different frameworks, each depending on the perspective (health system or individual patient perspective). Work package 4 had also an additional framework for coverage decisions. Given that many of the criteria were common across work packages we organized periodic teleconferences where we discussed the extent to which we could harmonize the frameworks. After seven teleconferences we reached an agreement about a generic framework that each work package could work from and tailor as needed, depending on the target audience, goal and perspective (see Annex 1.1 below).

1.3.3 Evidence to Recommendation table for healthcare professionals.

One of our priorities was developing a Summary of Findings (SoF) table that was more user-friendly than 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 Evidence to Recommendation (EtR) table rather than a SoF table for this target group.

Brainstorming and design

This took place at the DECIDE Consortium meeting in January 2012 and continued within a smaller group through a series of e-mail discussions, face to face meetings, and on-line meetings. The Cochrane systematic reviews and GRADE Summary of Findings (SoF) tables offered a starting point to summarize the most important information by clinical outcome. An initial table design emerged from these initial rounds to be further tested

User testing and feedback

We have completed a first iteration of user tests that included six healthcare professionals (five in Spain and one in Canada) and gathered users' feed-back from nine healthcare professionals that participated in a group session in Chile. All participants were physicians, mostly from primary care.

Analysis of findings and design refinement

Overall the information provided was considered to be clear, easy to use and well structured. It was found useful to aid a deeper understanding of the rationale of the recommendation and useful in teaching sessions. Some users found the table potentially useful for shared decision making while others did not find it useful at the point of care (the table was too busy and they do not have the time needed to talk through it). Numerical sections were the highest rated by users. Most prefer to see absolute estimates as opposed to relative. Most frustrations came from misunderstanding some terms and wording especially from those participants not used to methodological jargon. Some participants felt it was useful to have explanations to give a better understanding of GRADE system. In addition it was difficult for users to get the meaning or purpose of some column headings (e.g. "how confident are we?" heading for the quality of the evidence).

End-users would to like see references, information about practical issues or more detailed information on resource implications. Many specific suggestions were about the need to include interactivity to the table (such as click-over function for more explanations or links to other guideline sections or references). To overcome the need for additional information and offer a busier table it was decided to design an interactive table and incorporate as much as possible of the users' feedback into this.

In coordination with WP5 and WP6 the terminology was changed from evidence to recommendation to evidence to decision table (as the EtR framework was for developers), and the design further improved. This prototype, still not interactive, now has a similar design to the interactive SoF (iSoF) table, including the possibility to display a customized iSoF for users needing more detailed information about the

benefits, harms/burden and quality of the evidence (Annex 1.2). We are going to user test (second iteration) this presentation starting December 2013.

1.3.4 Shared decision-making support tools

Current decision aids (DAs) suffer from major limitations: their uptake in real clinical practice has been suboptimal, and their production is time-consuming, often not based on the best available evidence, or rapidly out-dated. For these reasons, leaders of shared decision making (SDM) are increasingly recognizing the necessity to link DAs to trustworthy and regularly updated clinical practice guidelines. Conversely, translating guidelines into generic tools for SDM offers an opportunity to increase their dissemination to clinicians and their patients at the point of care. In other words, such integrated DAs could facilitate the uptake of current best evidence in a patient-centered manner.

Brainstorming, design and first round of user-test

We are proposing an approach with two main differences from existing DAs: (1) Generating DAs that can be briefly presented during the patient-clinician interaction; (2) DAs are directly produced from recommendations using the GRADE framework ensuring they are based on current best-evidence. This use of GRADE will facilitate the continuous updating of the DA. Updating will be further enhanced through an on-line CPG authoring tool that we are developing as part of the DECIDE project. In the present proposal the corresponding presentation formats will be further developed and tailored to lung cancer treatment decisions, which are clearly important and difficult decisions.

Inspired by state-of-the art methodology in the design of DA for the clinical encounter, the development process involves a participatory strategy that engages patients, clinicians and methodologists in the development and refinement the DA. Rather than linear, this process is meant to be iterative, achieving flexibility to optimize the information content and interface, and ensuring patient and clinician input throughout the process to enhance its acceptability. Consistent with the *International Patient Decision Aid Standards*, the development process includes the following steps:

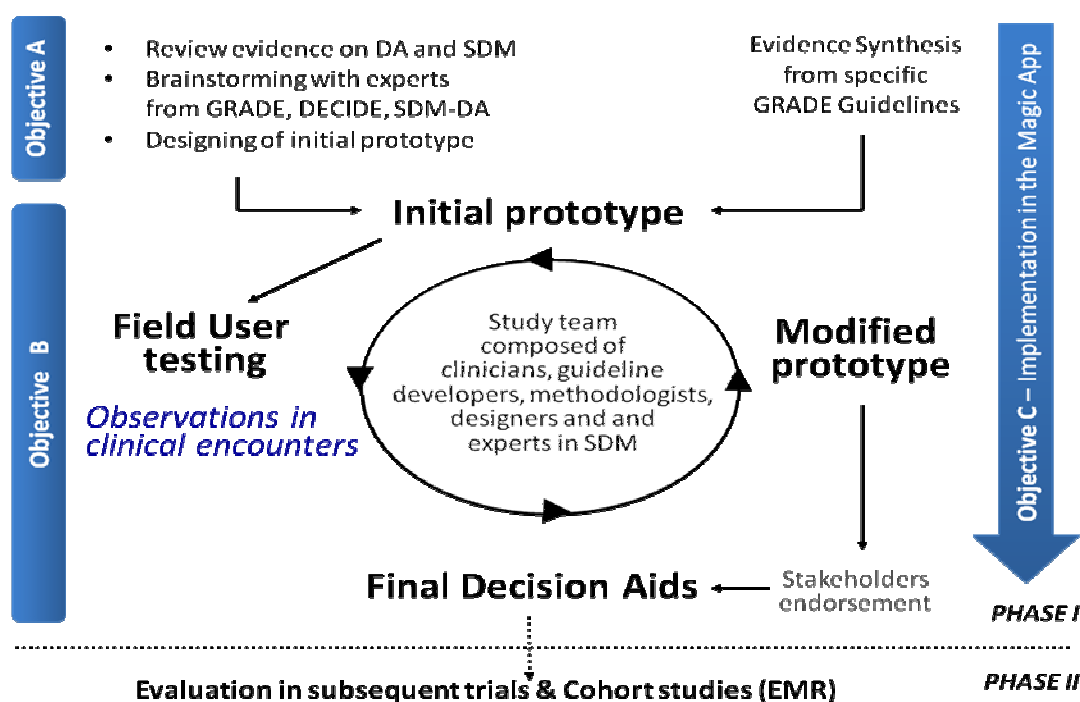
- a. Gathering background information and brainstorming on content and presentation formats of existing DA.
- b. Development of a framework for the translation of evidence summaries from guidelines recommendation that use the GRADE methodology into DA.
- c. Design of initial prototype
- d. Field user-testing of the DA-prototype in observations of real-life clinical encounters, followed by short individual interviews of patients and clinicians.
- e. Analysis of findings and feedback from team and advisory groups
- f. Modification / refinement of the prototype accordingly and new user-testing (→ d.)

The iterative user testing (phase d to f above) will be undertaken in the context of real life decision making with selected physicians and their patients who must make a choice between these two alternatives. Study team members will instruct clinicians on the use of the prototype DA. After obtaining written informed consent from both the patient and clinician, a study team member will then observe the encounter involving the use of the DA, looking for patterns of the conversations and documenting the issues, problems and challenges she or he witnesses. These sessions will also be audio-recorded (or video-recorded) for further analysis. At the completion of the encounter, the team member will conduct a semi-structured interview with the patient, starting with the administration of the 20-item COMRADE Scale and the 16 items Decisional Conflict Scale. These measures will be used to objectively track the performance of successive iterations of the prototype. We will also conduct semi-structured interview and “think aloud” session with clinicians, revisiting the clinical encounter separately, to elicit feedback on presentation formats and explore eight facets of “user experience” (findability, usefulness, usability, understandability, credibility, desirability, affiliation and accessibility).

In each iteration of the DA, after completion of the four to five user-test interviews, we will analyze and summarize findings, looking for barriers and facilitators to shared-decision making. We will rate findings in three categories according to the severity of any problems we find: high (causes incorrect interpretation, critical errors or high degree of uncertainty or dissatisfaction), medium (causes much frustration or unnecessarily slow use); or low (minor or cosmetic problems). Based on the

experiences with the prior prototype, we will design a new prototype. The process of field user-testing will resume, repeating the cycle until the team reaches consensus that the prototype is successful in involving patients in decision making and resulting in high decisional quality. Our prior experience suggests that three to four iterations will be required to reach this goal.

Figure 1.5. Overview of the methodology



At the moment we are undertaking the first round of user testing in two countries. We plan to do the second round after our next Consortium meeting in January 2014. There we will further develop our prototype with the information from the first iteration. Once we have a final design we will, as with other strategies, evaluate it in trials and real guidelines. We include below several snapshots of the different layer of the prototype we are user testing (Figures 1.6 to 1.10).

Figure 1.6. Layer 1 of the decision aid prototype.

Decision Aid - Layer 1

New oral anticoagulants vs warfarin

Choose and compare outcomes

Mortality Stroke Extracranial bleeding

Intracranial bleeding Burden of treatment Cost

Compare outcomes

Reset or Cancel

Aspirin vs warfarin

No treatment vs warfarin

No treatment vs aspirin

Figure 1.7. Layer 2 of the decision aid prototype.

Decision Aid - Layer 2

New oral anticoagulants vs warfarin

Among 1000 patients like you, with new oral anticoagulants

Mortality Stroke Major bleeding Burden of treatment

29 fewer over 1 year 18 fewer over 1 year 10 more over 1 year

Comparison Intervention Comparison Intervention Comparison Intervention

41 per 1000 12 per 1000 51 per 1000 33 per 1000 10 per 1000 20 per 1000

Certainty Certainty Certainty

+++○ Low Moderate Moderate

Choose more outcomes

Comparison: Warfarin

Intervention: New oral anticoagulants

Aspirin vs warfarin

Figure 1.8. Layer 3 of the decision aid prototype.

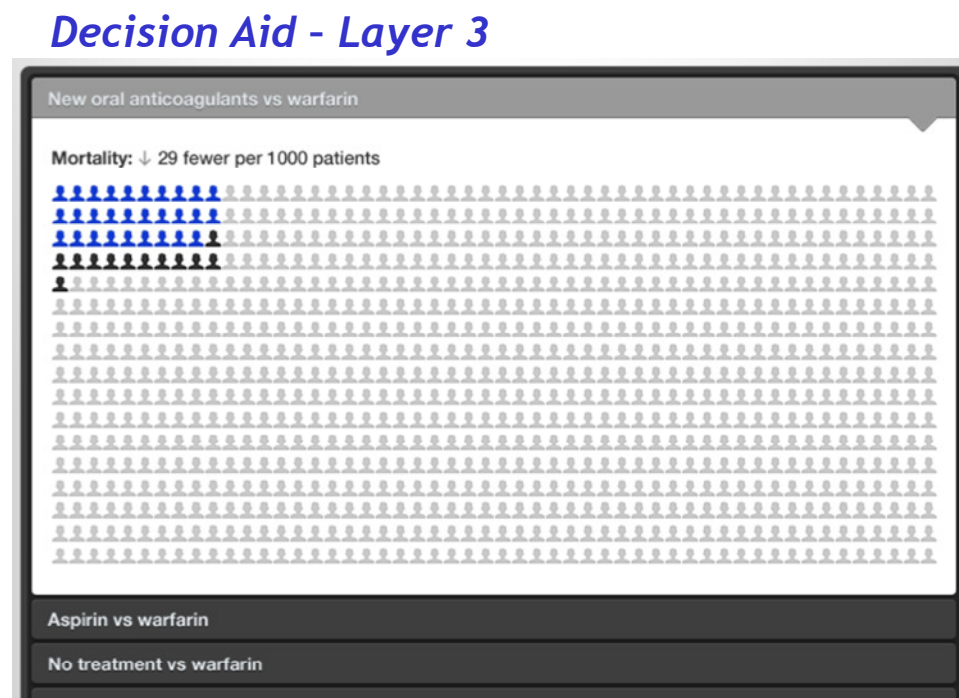


Figure 1.9. Layer 3 of the decision aid prototype.

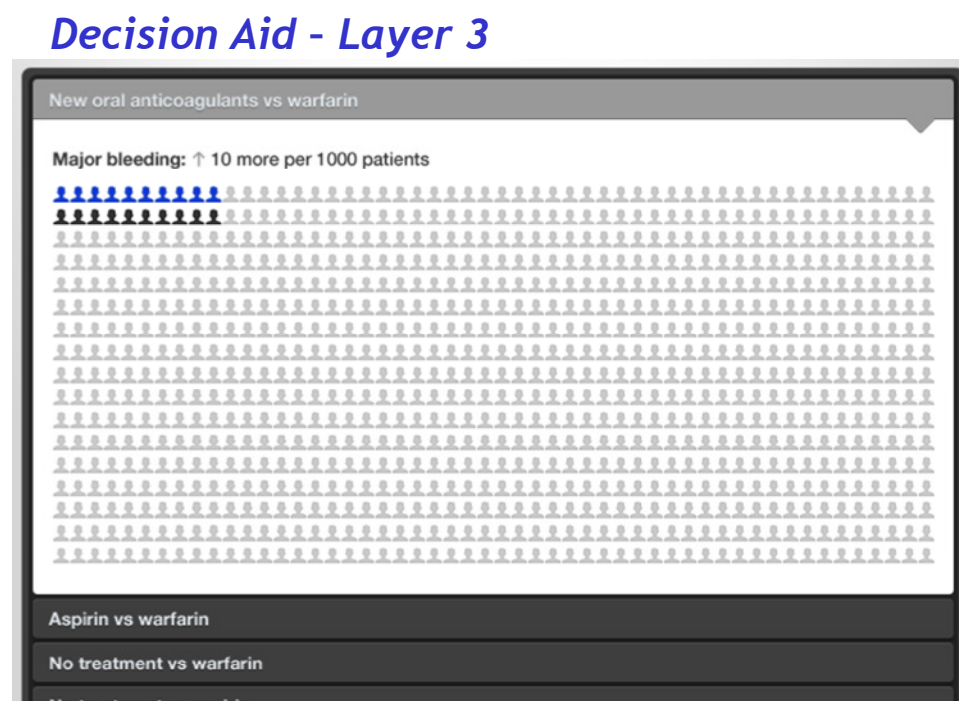
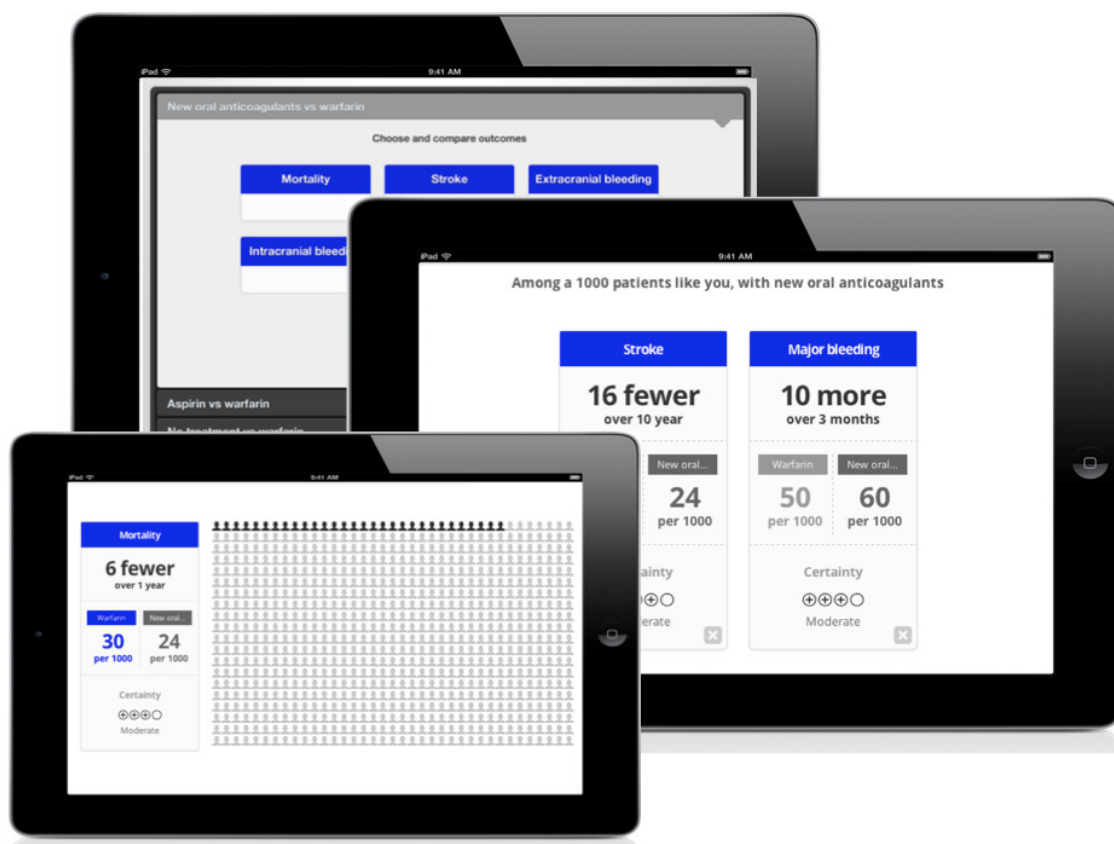


Figure 1.10. Decision Aids strategy displayed in an electronic tablets.



Section 1 - Annexes

Annex 1.1 – Evidence to decision framework

Evidence to decision framework

Problem: [Problem]

Background: [Background]

Option: [Option]

Comparison: [Comparison]

Setting: [Setting]

Perspective: [Perspective]

	<u>CRITERIA</u>	<u>JUDGEMENTS</u>	<u>RESEARCH EVIDENCE</u>	<u>ADDITIONAL CONSIDERATIONS</u>									
PROBLEM	Is the problem a priority?	<div> <div>No</div> <div>Probably No</div> <div>Uncertain</div> <div>Probably Yes</div> <div>Yes</div> <div>Varies</div> </div> <div> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> </div> <p><u>Detailed judgements</u></p>	[Evidence]	"[Additional consi									
VALUES	Is there important uncertainty or variability about how much people value the main outcomes?	<div> <div>Important uncertainty or variability</div> <div>Possibly important uncertainty or variability</div> <div>Probably no important uncertainty or variability</div> <div>No important uncertainty or variability</div> <div>No known undesirable outcomes</div> </div> <div> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> </div>	<p>The relative importance or values of the main outcomes of interest:</p> <table border="1"> <thead> <tr> <th>Outcome</th> <th>Relative importance</th> <th>Certainty of the evidence</th> </tr> </thead> <tbody> <tr> <td>[Outcome]</td> <td>-</td> <td>-</td> </tr> <tr> <td>[Outcome]</td> <td>-</td> <td>-</td> </tr> </tbody> </table>	Outcome	Relative importance	Certainty of the evidence	[Outcome]	-	-	[Outcome]	-	-	"[Additional consi
Outcome	Relative importance	Certainty of the evidence											
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[Outcome]	-	-											

		Detailed judgements	<div> <div>[Outcome]</div> <div>-</div> <div>-</div> </div> <div> <div>[Outcome]</div> <div>-</div> <div>-</div> </div>																									
BENEFITS & HARMS OF THE OPTIONS	What is the overall certainty of the evidence of effectiveness?	<div> <div>No included studies</div> <div>Very low</div> <div>Low</div> <div>Moderate</div> <div>High</div> </div> <div> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> </div>	<div>Summary of findings: [Comparison]</div> <table border="1"> <thead> <tr> <th>Outcome</th><th>Without [intervention] (per [#####])</th><th>With [intervention] (per [#####])</th><th>Difference (per [#####]) (95%CI)</th><th>Relative effect (RR) (95%CI)</th><th>Certainty (GRADE)</th></tr> </thead> <tbody> <tr> <td>[Outcome]</td><td>[#####]</td><td>[#####]</td><td>[#####] more/less</td><td>RR [#.#] ([#.#] to [#.#])</td><td>[R]</td></tr> <tr> <td>[Outcome]</td><td>[#####]</td><td>[#####]</td><td>[#####] more/less</td><td>RR [#.#] ([#.#] to [#.#])</td><td>[R]</td></tr> <tr> <td>[Outcome]</td><td>[#####]</td><td>[#####]</td><td>[#####] more/less</td><td>RR [#.#] ([#.#] to [#.#])</td><td>[R]</td></tr> </tbody> </table> <div> Link to detailed evidence profile Subgroup considerations: Link(s) to summary of findings and judgments for subgroups </div>	Outcome	Without [intervention] (per [#####])	With [intervention] (per [#####])	Difference (per [#####]) (95%CI)	Relative effect (RR) (95%CI)	Certainty (GRADE)	[Outcome]	[#####]	[#####]	[#####] more/less	RR [#.#] ([#.#] to [#.#])	[R]	[Outcome]	[#####]	[#####]	[#####] more/less	RR [#.#] ([#.#] to [#.#])	[R]	[Outcome]	[#####]	[#####]	[#####] more/less	RR [#.#] ([#.#] to [#.#])	[R]	"Additional considerations"
	Outcome	Without [intervention] (per [#####])		With [intervention] (per [#####])	Difference (per [#####]) (95%CI)	Relative effect (RR) (95%CI)	Certainty (GRADE)																					
	[Outcome]	[#####]		[#####]	[#####] more/less	RR [#.#] ([#.#] to [#.#])	[R]																					
	[Outcome]	[#####]		[#####]	[#####] more/less	RR [#.#] ([#.#] to [#.#])	[R]																					
[Outcome]	[#####]	[#####]	[#####] more/less	RR [#.#] ([#.#] to [#.#])	[R]																							
How substantial are the desirable anticipated effects?	<div> <div>Don't know</div> <div>Not important</div> <div>Somewhat important</div> <div>Moderately important</div> <div>Very important</div> <div>Varies</div> </div> <div> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> </div> <div>Detailed judgements</div>																											
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Do the desirable effects outweigh the undesirable effects?	<div> <div>No</div> <div>Probably No</div> <div>Don't know</div> <div>Probably Yes</div> <div>Yes</div> <div>Varies</div> </div> <div> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> </div> <div>Detailed judgements</div>																											
RESOURCE USE	How large are the resource requirements?	<div> <div>Large costs</div> <div>Moderate costs</div> <div>Small costs</div> <div>Moderate savings</div> <div>Large savings</div> </div> <div> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> </div> <div>Detailed judgements</div>	<div>Varies</div> <div>[Evidence]</div>	"Additional considerations"																								

	How large is the incremental cost relative to the net benefit?	<div> <div>Very large ICER</div> <div>Large ICER</div> <div>Moderate ICER</div> <div>Small ICER</div> <div>Savings</div> </div> <div> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> </div> <div> Varies <input type="checkbox"/> [Evidence] </div> <div> Detailed judgements </div>		"[Additional considerations]"
EQUITY	What would be the impact on health inequities?	<div> <div>Increased</div> <div>Probably increased</div> <div>Uncertain</div> <div>Probably reduced</div> <div>Reduced</div> <div>Varies</div> </div> <div> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> </div> <div> <input type="checkbox"/> [Evidence] </div> <div> Detailed judgements </div>		"[Additional considerations]"
ACCEPTABILITY	Is the option acceptable to key stakeholders?	<div> <div>No</div> <div>Probably No</div> <div>Uncertain</div> <div>Probably Yes</div> <div>Yes</div> </div> <div> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> </div> <div> Varies <input type="checkbox"/> [Evidence] </div> <div> Detailed judgements </div>		"[Additional considerations]"
FEASIBILITY	Is the option feasible to implement?	<div> <div>No</div> <div>Probably No</div> <div>Uncertain</div> <div>Probably Yes</div> <div>Yes</div> </div> <div> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> </div> <div> Varies <input type="checkbox"/> [Evidence] </div> <div> Detailed judgements </div>		"[Additional considerations]"

Overall judgement across all criteria	Undesirable consequences <i>clearly outweigh</i> desirable consequences in most settings	Undesirable consequences <i>probably outweigh</i> desirable consequences in most settings	The balance between desirable and undesirable consequences <i>is closely balanced or uncertain</i>	Desirable consequences <i>probably outweigh</i> undesirable consequences in most settings	Desirable consequences <i>clearly outweigh</i> undesirable consequences in most settings
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Type of recommendation	We recommend against the option or for the alternative	We suggest not to use the option or to use the alternative	We suggest using the option	We recommend the option	
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Justification	[Justification]				
	Detailed judgements				
Subgroup considerations	"[Subgroup considerations]"				
Implementation considerations	[Implementation considerations]				

[Monitoring and evaluation considerations](#)

[Monitoring and evaluation]

[Research priorities](#)

[Research priorities]

Annex 1.2. Interactive evidence to decision table for users (prototype).

GRADEDECIDE Evidence to Decision	Login List	GRADEDECIDE Evidence to Decision	Login List
<p>For patients with atrial fibrillation, who are at intermediate risk of stroke, we suggest treatment with dabigatran 150 mg twice daily rather than warfarin (weak recommendation)</p> <p>Justification: The panel graded this as a weak recommendation due to the small absolute reduction in stroke, suggesting that some informed individuals would choose not to use dabigatran.</p>		<p>For patients with atrial fibrillation, who are at intermediate risk of stroke, we suggest treatment with dabigatran 150 mg twice daily rather than warfarin (weak recommendation)</p> <p>Justification: The panel graded this as a weak recommendation due to the small absolute reduction in stroke, suggesting that some informed individuals would choose not to use dabigatran.</p>	
<p>▼ Detailed justification</p> <p>Uncertainty or variability on how much people value the main outcomes</p> <p>Patients value avoiding stroke more than avoiding a major bleed, but there is large variability in the relative importance of these two outcomes to patients.</p> <p>MORE INFORMATION</p> <p>The balance between the desirable and undesirable effects</p> <p>The guideline panel considered that in patients with atrial fibrillation at intermediate or high risk of stroke (CHADS2 score of 1) benefits of treatment with dabigatran slightly outweigh harms, compared to warfarin treatment.</p> <p>MORE INFORMATION</p> <p>Resource use</p> <p>Dabigatran may not be cost-effective in comparison to warfarin in some settings.</p> <p>MORE INFORMATION</p>		<p>▼ Detailed justification</p> <p>Uncertainty or variability on how much people value the main outcomes</p> <p>Patients value avoiding stroke more than avoiding a major bleed, but there is large variability in the relative importance of these two outcomes to patients. Patients considered that avoiding 1 stroke is approximately 3 times more important than avoiding a major bleed. Variability: there is a wide variability in the importance patients assign to the outcomes of interest. We are moderately confident about the relative importance for the outcomes of interest due to methodological limitations and heterogeneous results across studies.</p> <p>LESS INFORMATION</p> <p>The balance between the desirable and undesirable effects</p> <p>The guideline panel considered that in patients with atrial fibrillation at intermediate or high risk of stroke (CHADS2 score of 1) benefits of treatment with dabigatran slightly outweigh harms, compared to warfarin treatment.</p> <p>The use of dabigatran, compared to warfarin, avoids 3 to 6 non-fatal strokes per 1000 patients treated at 2 years, in moderate and high risk population, respectively. It may cause one additional nonfatal extracranial bleed per 1000 treated patient at 2 years, but with no significant differences between treatment groups. There are no differences between dabigatran and warfarin in deaths or systemic embolisms. Patients who place an exceptionally high value on stroke reduction or the burden associated with anticoagulant therapy with warfarin and a low value on avoiding bleeding are likely to choose dabigatran rather than warfarin therapy.</p> <p>LESS INFORMATION</p> <p>Resource use</p> <p>Dabigatran may not be cost-effective in comparison to warfarin in some settings.</p> <p>An economic analysis based on pricing of dabigatran in the United Kingdom (9.6 Euro per day) estimated that dabigatran 150 mg bid would cost 33,548 Euro more per QUALY gained compared with warfarin for patients with AF aged 65 years with risk factors for stroke (CHADS2 score of 1 or greater). The cost-effectiveness estimates in this model were sensitive to the pricing of dabigatran. These results were most influenced by treatment cost.</p> <p>LESS INFORMATION</p>	
<p>► Summary of findings</p>		<p>► Summary of findings</p>	

GRADE DECIDE Evidence to Decision				GRADE DECIDE Evidence to Decision			
<p>For patients with atrial fibrillation, who are at intermediate risk of stroke, we suggest treatment with dabigatran 150 mg twice daily rather than warfarin (weak recommendation)</p> <p>Justification: The panel graded this as a weak recommendation due to the small absolute reduction in stroke, suggesting that some informed individuals would choose not to use dabigatran.</p>				<p>For patients with atrial fibrillation, who are at intermediate risk of stroke, we suggest treatment with dabigatran 150 mg twice daily rather than warfarin (weak recommendation)</p> <p>Justification: The panel graded this as a weak recommendation due to the small absolute reduction in stroke, suggesting that some informed individuals would choose not to use dabigatran.</p>			
Detailed justification				Detailed justification			
Summary of findings				Summary of findings			
Outcome	Estimates		Certainty of the evidence	Outcome	Estimates		Certainty of the evidence
	With Dabigatran 150mg bid	With Warfarin adjusted-dose			With Dabigatran 150mg bid	With Warfarin adjusted-dose	
Death Follow-up: mean 2 years	34 per 1000	38 per 1000	⊕⊕⊕⊕ [Ⓜ] Moderate	Death Follow-up: mean 2 years	34 per 1000	38 per 1000	⊕⊕⊕⊕ [Ⓜ] Moderate
	NNTB: 250 patients 95% CI: 125 (NNTB) to 2631 (NNTH)				NNT: 250 patients would need to be treated with dabigatran for 2 years to prevent one additional death. Confidence interval: Due to the play of chance there is uncertainty about this number. The 95% confidence interval is from 125 patients needed to be treated to prevent one additional death to 2631 patients needed to be treated to cause one additional death.		
Non-fatal stroke Follow-up: mean 2 years <input checked="" type="radio"/> High risk population <input type="radio"/> Moderate risk population <input type="radio"/> Low risk population	11 per 1000	17 per 1000	⊕⊕⊕⊕ [Ⓜ] Moderate	Non-fatal stroke Follow-up: mean 2 years <input checked="" type="radio"/> High risk population <input type="radio"/> Moderate risk population <input type="radio"/> Low risk population	11 per 1000	17 per 1000	⊕⊕⊕⊕ [Ⓜ] Moderate
	NNT:167 patients 95% CI: 125 to 500				NNT:167 patients 95% CI: 125 to 500		
Non-fatal major extracranial bleeds Follow-up: mean 2 years	14 per 1000	13 per 1000	⊕⊕⊕⊕ [Ⓜ] Moderate	Non-fatal major extracranial bleeds Follow-up: mean 2 years	14 per 1000	13 per 1000	⊕⊕⊕⊕ [Ⓜ] Moderate
	NNTH: 1000 patients 95% CI: 1000 NNTB to 333 NNTH				NNTH: 1000 patients 95% CI: 1000 NNTB to 333 NNTH		
Systemic embolism Follow-up: mean 2 years	2 per 1000	2 per 1000	⊕⊕⊕⊕ [Ⓜ] Moderate	Systemic embolism Follow-up: mean 2 years	2 per 1000	2 per 1000	⊕⊕⊕⊕ [Ⓜ] Moderate
	NNTH: 2858 patients 95% CI: 1000 NNTB to 500 NNTH				NNTH: 2858 patients 95% CI: 1000 NNTB to 500 NNTH		
Burden of treatment Follow-up: mean 2 years	Daily medication, lifestyle limitations, dietary restrictions, frequent blood testing and clinic visits.		⊕⊕⊕⊕ [Ⓜ] Moderate	Burden of treatment Follow-up: mean 2 years	Daily medication, lifestyle limitations, dietary restrictions, frequent blood testing and clinic visits.		⊕⊕⊕⊕ [Ⓜ] Moderate

2. Work Package 2: DECIDE strategies for policy makers and managers)

WP2's target audience is policy makers, managers and their support staff with responsibility for making coverage decisions. These coverage decisions are defined as decisions by third party payers (public or private health insurers) about whether and how much to pay for drugs, tests, devices or services and under what conditions and can take place at national and/or regional level depending on the type of interventions.

In this deliverable we present the progress and achievements towards our objective of the development of communication strategies for policy makers and managers.

We identified the following priorities for WP2's objective:

- Development of an appropriate "*conceptual framework*" which includes criteria identified as necessary to inform the process that goes from the assessment of evidence to coverage decisions (EtCD framework);
- 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;
- Decide which type and format of information to put in the framework for each criterion.

The methods to develop communication strategies for policy makers and managers 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 randomized clinical trials
- Phase 3: Testing the strategies with real guidelines

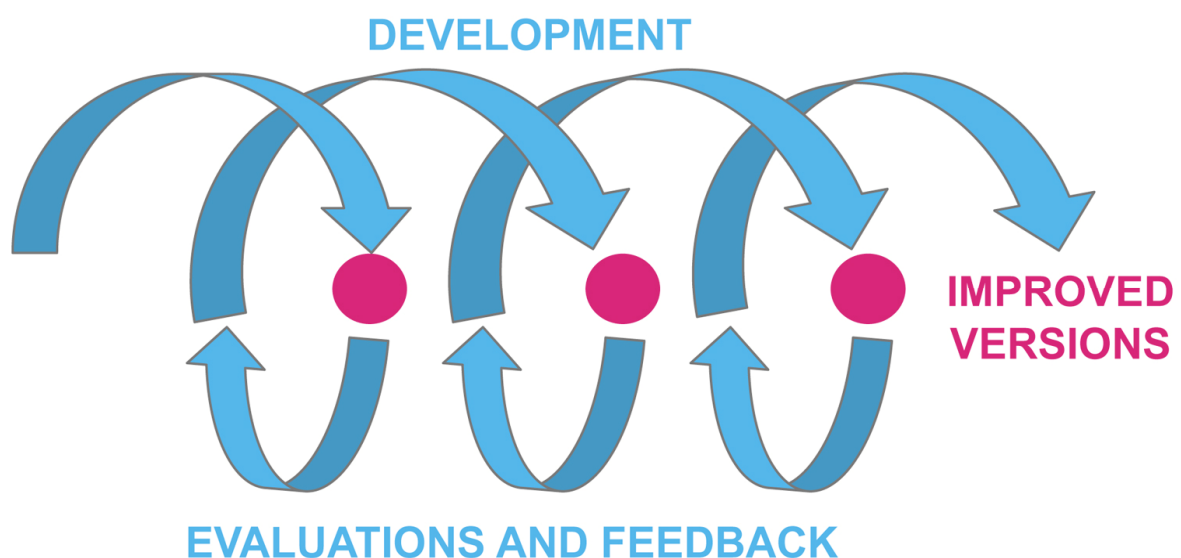
2.1 Strategy development methods.

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 2.1).

Figure 2.1: Iterative development process (Phase 1)



2.1.1 Brainstorming workshops

Eight brainstorming sessions were held (face-to-face or by teleconference) to discuss the different stages of the project: definition of the target audience, identification of the main features of the conceptual framework, problems and ways of improving the format, suggestion of practical examples of coverage decisions. The participation to the brainstorming sessions involved WP2 members, Italian members of the GRADE Working Group and a selected group of Italian policy makers and managers which bring their own experience for the development of the conceptual framework.

2.1.2 Advisory Board Consultation

Priorities and presentation formats were informed by means of consultation with key stakeholders. To do that we asked DECIDE Project partners to suggest possible stakeholders for WP2 to constitute an international Advisory Board (AB). Our AB consists of 45 people with different backgrounds (policy makers, managers, health services researchers, methodologists, communication experts) and were purposely selected to ensure a breadth of perspectives. We contacted AB members once by email, encouraging them to provide their feedback on the conceptual framework.

2.1.3 User feedback

We collected users' feedback at several national and international workshops with policy makers and managers, mainly taking advantage of national or international meetings. The workshops were structured with a brief introduction to the DECIDE Project, a short presentation of the conceptual framework applied to a practical example, and a group session during which we asked participants to take a coverage decision using the framework provided.

In these group sessions we explored immediate first impressions and collected feedback by taking notes and through the use of a questionnaire that participants were asked to fill in.

2.1.4 User testing

Using a semi-structured interview guide, we explored 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 will be transcribed; we will review notes and transcriptions, looking primarily for barriers and facilitators. For the analysis, we will categorize comments as “show-stoppers”, “big problems / frustrations”, “minor issues or cosmetic things”, “positive feedback” and “specific suggestions”.

2.2 Results

2.2.1 The conceptual framework

We developed an initial presentation of an Evidence to Coverage Decision (EtCD) framework building on the experience and method previously developed by the GRADE working group and the SUPPORT Project (an earlier FP7 project led by Partner 2). The framework is intended to:

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

The EtCD includes a structured PICO question about the coverage decision to be taken, a concise summary with all the background information needed and a *table* with the following columns:

- *Domains*: factors that should be considered for coverage decisions
- *Criteria*: specific aspects of each domain that are particularly important for taking coverage decisions
- *Judgments*: considerations that must be made in relation to each criterion taking into account the evidence available, which may include draft judgments suggested by the people who have prepared the framework
- *Research Evidence*: information about the available research evidence relevant for the decision - which may include links to more detailed summaries
- *Additional information*: any additional information, not “research evidence” or

comments by the people who have prepared the framework that can be useful to justify or better understand the judgment

The final section of the EtCD is designed to help the stakeholder with summarising the information reported above and taking the decision. This section may also include draft conclusions suggested by the people who have prepared the framework and consists of:

- *Balance of desirable and undesirable consequences* of covering the intervention in relation to the alternative (comparison)
- *Decision* (to cover, not to cover or coverage as evidence develops)
- *Restriction*, if any, to the adoption of the option/intervention
- *Justification* for the decision, flowing from the judgments in relation to the criteria
- *Implementation* considerations including strategies to address any concerns about the acceptability and feasibility of the option, if any.

An example of EtCD framework is shown in Annex 2.1.

The structure of the EtCD was initially discussed and developed during brainstorming sessions. Then in 2011 we had two workshop (one with national and another one with international stakeholders) during which we asked the participants to give their feedback about a preliminary version of the EtCD. During these workshops we collected feedback taking notes and through the questionnaire shown in Annex 2.2.

After these first sessions, during which the EtCD was iteratively refined, we prepared a structured format of workshop organised in a first introduction of the DECIDE project, a brief explanation of the main features of the framework, a small group session during which we asked the participants to mimic the process of taking a coverage decision using the EtCD applied to a practical example and a final plenary discussion. During these workshops feedback was collected during the small group and plenary discussion and then the participants were invited to fill in a structured questionnaire investigating important dimensions for the efficacy of the EtCD as communication and dissemination tool (see Annex 2.3). So far we have organised

four workshops (two national and two international) with small group sessions and the feedback collected during the discussion and through the questionnaire informed refinements of the EtCD.

We prepared 7 different practical examples of application of the EtCD to coverage decision:

1. Should robotic-assisted minimally invasive radical prostatectomy (using already purchased robots) be covered versus open surgery or laparoscopy in Emilia Romagna Region?
2. Should the utilization of Bevacizumab in combination with Paclitaxel be covered for the first line treatment of women with metastatic breast cancer?
3. Should Palivizumab be covered for immunoprophylaxis of respiratory syncytial virus (RSV) bronchiolitis in high-risk infants and young children? (Acute respiratory tract infection)
4. Should Doppler Ultrasound Screening (DUS) be covered as screening for DVT in asymptomatic patients following major orthopedic surgery before hospital discharge? (Thrombosis)
5. Should the inferior vena cava (IVC) filter be covered for venous thromboembolism (VTE) primary prevention in patients undergoing general and abdominal surgery? (Thrombosis)
6. Should new oral anticoagulants be covered for patients with atrial fibrillation? (Thrombosis)
7. Should coverage of MRI be withdrawn for patients aged >50 with undiagnosed knee problems?

Several clinical topics that will be used through the development phase are shared with the other WPs (they are part of DECIDE's Milestone 1) and will be developed in a coordinated fashion. The design of this framework (Annex 2.1) is being discussed with other work packages with the goal of using a standard design across work packages. The table therefore will be modified in light of those discussions. This will prove helpful regarding coherence and integration of methods, reporting and presentation of final strategies.

2.2.2 User Feedback

Users generally liked the design and the structure of the EtCD. The majority of them found the framework adequate for the intended purpose and gave positive judgments about its simplicity and usefulness.

According to the feedback collected all the factors included in the framework are relevant for taking coverage decisions and are presented and organized in a logical way to help the stakeholders through the process.

The structure of the EtCD was also judged to be quite flexible and applicable to different types of coverage decisions (i.e. different types of interventions, local vs regional, regional vs national) taking into account the volume and type of information reported in the content to the differences in reimbursement scheme. The main criticisms relate to the comprehensiveness of the information reported: more detailed information is required for cost effectiveness, feasibility, production capacity, and contextual factors that impact on the decision-making process, such as ability to implement the procedure.

Some concerns about the usability of the EtCD by people responsible for taking coverage decisions emerged. Methodological contents were not always easy to understand, there were difficulties with conceptual understanding of the GRADE approach and the terminology used sometimes not well understood or liked.

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.

2.2.3 User testing

An interview guide for the User Testing of the EtCD framework for policy makers and managers was developed (see Annex 2.4).

The user testing is performed individually with stakeholders by an interviewer and an observer. The interviews last approximately one hour. They are recorded, transcribed

and integrated with the notes taken by the observer. We plan to perform at least six interviews and to finalise the analysis by the end of April 2014. So far we have completed one interview, and planned another two by the end of 2013.

2.2.4 Dissemination

The DECIDE Project and the EtCD framework were presented at 7 congresses and meetings involving Italian and international communities of health professionals, policy makers and researchers. The presentations were structured to introduce the main features of the DECIDE Project, highlighting its added value for the health system and showing an example of an EtCD framework. These presentations were useful not only for disseminating the activity of the DECIDE Consortium, but also to gather contacts of people interested in being involved at different levels in the project or just staying up to date with progress.

To foster the dissemination of the EtCD framework in Italy we contacted regional commissions responsible for making coverage decision on different health topics (mainly about drugs) to present them practical examples of application of the EtCD to specific topics of interest to them. So far we have succeeded in having concrete contact with three of them. In one commission the framework was already presented and we are collecting feedback and information about possible future developments. In the other two the framework should be used to make a coverage decision in the next few months.

A survey to explore the current use of information and research evidence to make coverage decisions and to collect feedback about the EtCD framework was sent to 128 policy makers and managers (65 Italian and 63 European). We're now waiting for responses to the second reminder. So far the response rate has been quite low (19%) although this is not unusual for unsolicited surveys. We are planning to contact people more actively and also propose to use telephone interviews.

A paper about the DECIDE Project in general and the activity of WP2 was published on an Italian journal that has a good distribution among the Italian health community

and that is indexed in PubMed:

Parmelli E, Amato L, Saitto C, Davoli M per il Gruppo Italiano DECIDE - DECIDE: uno strumento per rendere trasparenti i criteri utilizzati per le decisioni in sanità. Recenti Prog Med 2013; 104: 522-7.

2.2.5 Links with other work packages

WP2 has strong connections with WP5 mainly because there are some similarities in our target audiences and in the type of frameworks we're developing. The WP5 group also provides help with the development of the user testing methodology, the design of the framework and the development and testing of an interactive format of the Summary of Findings Tables (iSoF) that will improve understanding and use of evidence of the effects of healthcare interventions within the frameworks allowing producers to tailor a presentation to a target audience and for users to interact with the presentation.

WP2 also has regular contacts with the other scientific WPs (1-5) for to discuss the harmonization of the frameworks. The goal is to use a standard and recognizable design across work packages.

Specific contacts are now in action with WPs 4 and 6 for the development of an example of EtCD framework applied to medical tests and with WP1 for user testing their framework in Italy.

We are now exploring the possibility to test the framework within WHO. The collaboration with all the partners of the project was essential for the setting up of the Advisory Board and the recruitment for the survey.

2.3 Future plans

- WP2 is actively working on the refinement and preparation of practical examples of application of the framework to be used for the user testing. We're also translating all the material into Italian.
- We will translate and integrate in our framework the iSoF and then test it; we

will also consult the Advisory Board about it.

- We will finalise the survey trying to reach a good response rate.
- We will develop an EtCD about medical tests together with WPs 4 and 6 to be presented in a workshop at the DECIDE International Conference in June 2014 in Edinburgh.
- We will explore ways to improve the contents of the EtCD framework in particular about costs, feasibility and equity contacting experts in these fields (i.e. Equity Method Group of the Cochrane Collaboration).

Annex 2.1 – Evidence to coverage decision framework (see over)

Should New Oral Anticoagulants (NOACs) be covered for patients with atrial fibrillation?

Patients: Patients with atrial fibrillation
Intervention: NOACs
Comparison: Warfarin

Background: Atrial fibrillation (AF) is the most common form of cardiac arrhythmia . 85 to 90% of cases occur as non-valvular AF, whereas only a small proportion of patients are associated with rheumatic valve disease (predominantly mitral stenosis). In Italy, the AF has a prevalence of 1 to 2 % (which increases with age , reaching around 8% in subjects over 80 years), and an incidence of approximately 3 cases per 1000 person years / person , while the average age of patients with AF is about 77 years. Approximately 70 % of patients with AF have an age between 65 and 85 years. AF increases the risk of ischemic stroke by about 5 times, and stroke associated with AF have increased morbidity and mortality compared to those with different etiology.

Warfarin: The standard of care for the prevention of ischemic stroke in patients with AF is warfarin which may reduce the risk by 64%. Warfarin however increases the risk of major and intracranial bleeding that, depending on the studies of drugs and analyzed, respectively, varies from 1 .3 % to 3.6 % per year, and from 0.2 % to 0.5% per year. The use of warfarin requires a periodic control of the International Normalized Ratio (INR), and has a number of interactions with other drugs and certain foods that can enhance or reduce the anticoagulant action. If there is a need to quickly neutralize the action of warfarin (bleeding), vitamin K can be used as an antidote.

New oral anticoagulants (NOACs): This includes 2 classes of drugs: inhibitors of factor Xa (FXa) and direct thrombin inhibitors (DTIS). Being endowed with a more predictable anticoagulant effect compared to warfarin, they have the advantage of not requiring periodic checks of blood coagulation, while requiring a routine monitoring of possible adverse effects. The main cause of concern during the use of NOACs is the absence of antidotes able to rapidly neutralize the action in case of need. This problem can be particularly serious in the presence of a reduced clearance of the drug, as in the elderly or in patients with impaired renal function. The FXa include rivaroxaban, apixaban, dabigatran, edoxaban, and betrixaban. All studies related to NOACs included patients with non-valvular AF, ie, in which a possible valvulopathy was not clinically significant. In Italy, for today dabigatran is already on prescription, and the rivaroxiban it will be soon, as it has passed the scrutiny of the Committee Pricing and Reimbursement AIFA.

	CRITERIA	JUDGEMENTS	RESEARCH EVIDENCE	ADDITIONAL INFORMATION
BURDEN OF ILLNESS OR PROBLEM	Is the condition severe?	No <input type="checkbox"/> Uncertain <input type="checkbox"/> Yes <input type="checkbox"/>	The risk of complications varies depending on how well INR is controlled with Warfarin. Average risks are 8.1% for death, 2.5% for nonfatal stroke, and 7% for nonfatal major extracranial bleeds over two years in the RE-LY (Randomised Evaluation of Long-Term Anticoagulation Therapy) trial.	

CRITERIA	JUDGEMENTS	RESEARCH EVIDENCE	ADDITIONAL INFORMATION
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CRITERIA		JUDGEMENTS			RESEARCH EVIDENCE										ADDITIONAL INFORMATION	
BENEFITS, & HARMS	Are the desirable anticipated effects large?	Favour to Warfarin	Uncertain	Favour to NOACs												The study included 3 randomized, controlled trials (RCTs) comparing NOACs with warfarin for management of AF and observational studies and FDA reports on adverse effects.
		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>												
	Are the undesirable anticipated effects small?	Favour to Warfarin	Uncertain	Favour to NOACs												RCT patients characteristics
		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>												50,578 patients; mean age >70ys; 63% men; CHADs2 index average 2,1 in the studies evaluating dabigatran and apixaban and 3,5 in the rivaroxaban studies.
																In the warfarin group the percentage of time in the INR target range was 55% to 66%.
	What is the overall certainty of this evidence (for our setting)?	Favour to Warfarin	Uncertain	Favour to NOACs												Subgroup analysis reported in 1 study no differential effects on stroke prevention (interaction effects) for individuals with a history of cerebrovascular accidents, impaired renal function, or older age. However, these analyses suggest that, compared with warfarin, dabigatran may increase some bleeding complications in patients older than 75 years and in those receiving warfarin who have good control. The effects of impaired renal function were mixed, showing no interaction effect in one analysis and a differential risk for gastrointestinal bleeding
		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>												

CRITERIA	JUDGEMENTS	RESEARCH EVIDENCE							ADDITIONAL INFORMATION		
		3.Gastrointestin al bleeding	RR 1.30 (0.97-1.73)	NS	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	LOW ⊕⊕⊕⊖	with rivaroxaban in another.
		4. Myocardial infarction	RR 0.95 (0.81-1.11)	NS	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	LOW ⊕⊕⊕⊖	In 2011, the FDA issued a notice that it was evaluating reports of serious bleeding with dabigatran.
		5.Discontinuati on due to adverse effects	RR 1.23 (1.05-1.44)		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	LOW ⊕⊕⊕⊖	For myocardial infarction in a subgroup analysis, the risk was increased with dabigatran (RR, 1.35 [CI, 0.99 to 1.85]) compared with FXa inhibitors (RR, 0.84 [CI, 0.70 to 1.01]) (P _ 0.010).
		6. Liver disfunction	RR 0.82 (0.56-1.18)	NS	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	LOW ⊕⊕⊕⊖	In subgroup analysis, rates of discontinuation were higher for dabigatran than for FXa inhibitors. Burden of treatment Warfarin: daily medication, lifestyle limitation, dietary restrictions,frequent blood testing and clinical visit NOACS: Apixaban: twice daily medication, Dabigatran: twice daily medication, Rivaroxaban: daily medication

	CRITERIA	JUDGEMENTS	RESEARCH EVIDENCE	ADDITIONAL INFORMATION						
VALUES	How certain is the relative importance of the desirable and undesirable outcomes?	<table><tr><td><i>Favour to Warfarin</i></td><td><i>Uncertain</i></td><td><i>Favour to NOACs</i></td></tr><tr><td><input type="checkbox"/></td><td><input type="checkbox"/></td><td><input type="checkbox"/></td></tr></table>	<i>Favour to Warfarin</i>	<i>Uncertain</i>	<i>Favour to NOACs</i>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<p><i>Quality of life measurement (measured with Long-term utilities using EuroQol ranging from death=0 to perfect life =1)</i></p>	<p>Quality of life information</p> <p>The impact of stroke outcome persists over a longer period of time (in term of disability) while other events are associated with impacts to quality of life that effect a finite period of time. It is assumed that there are minimal long term implications associated with bleeding events.</p>
	<i>Favour to Warfarin</i>	<i>Uncertain</i>	<i>Favour to NOACs</i>							
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>								
Would patients/caregivers feel that the benefits outweigh the harms and burden?	<table><tr><td><i>Favour to Warfarin</i></td><td><i>Uncertain</i></td><td><i>Favour to NOACs</i></td></tr><tr><td><input type="checkbox"/></td><td><input type="checkbox"/></td><td><input type="checkbox"/></td></tr></table>	<i>Favour to Warfarin</i>	<i>Uncertain</i>	<i>Favour to NOACs</i>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<p>Atrial fibrillation 0.81 Sullivan (2006)93</p> <p>Previous minor stroke 0.75 Gage (1996)94</p> <p>Previous intracerebral haemorrhage 0.75 Gage (1996)94</p> <p>Previous major stroke 0.33 Gage (1996)94</p> <p>Perspectives of patients on anticoagulation therapy</p> <p>Patients at high risk for atrial fibrillation placed more value on the avoidance of stroke and less value on the avoidance of bleeding than did physicians who treat patients with atrial fibrillation. The views of the individual patient should be considered when decisions are being made about antithrombotic treatment for people with atrial fibrillation.</p>	<p>Perspectives of patients on anticoagulation therapy</p> <p>A prospective observational study measured physicians' and patients' thresholds for how much reduction in risk of stroke is necessary and how much risk of excess bleeding is acceptable with antithrombotic treatment in people with atrial fibrillation in tertiary and peripheral referral centres in Nova Scotia, Canada on 63 physicians who were treating patients with atrial fibrillation and 61 patients at high risk for atrial fibrillation. Thresholds were determined for the minimum reduction in risk of stroke necessary and the maximum increase in risk of excess bleeding acceptable for treatment with aspirin and warfarin in people with atrial fibrillation.</p>	
<i>Favour to Warfarin</i>	<i>Uncertain</i>	<i>Favour to NOACs</i>								
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>								

	CRITERIA	JUDGEMENTS	RESEARCH EVIDENCE	ADDITIONAL INFORMATION																																																		
RESOURCE USE	Is the incremental cost small relative to the net benefits?	<table><tr><td>Favour to Warfarin</td><td>Uncertain</td><td>Favour to NOACs</td></tr><tr><td><input type="checkbox"/></td><td><input type="checkbox"/></td><td><input type="checkbox"/></td></tr></table>	Favour to Warfarin	Uncertain	Favour to NOACs	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<table><tr><td></td><td colspan="2">Yearly costs per patient</td><td></td></tr><tr><td></td><td>Warfarin</td><td>NOACs</td><td>Difference</td></tr><tr><td>Drugs (0,1€/die for warfarin 2€/die for NOACs)</td><td>36,5€</td><td>730€</td><td></td></tr><tr><td>INR test (including blood collection - 6€ twice month)*</td><td>144€</td><td>-</td><td></td></tr><tr><td>Drugs and monitoring costs</td><td>180,5€</td><td>730€</td><td>549,5€</td></tr><tr><td></td><td></td><td></td><td></td></tr><tr><td>Hospitalization (13 admission/1,000 pts fewer for NOACs – considering 20,000 € per admission and 2 years of follow RCTs)</td><td></td><td>-260€ total and -130€ per year</td><td>-130€</td></tr><tr><td>Total costs</td><td></td><td></td><td>419,5€ more for NOACs per patient</td></tr><tr><td></td><td></td><td></td><td></td></tr><tr><td>Cost effectiveness</td><td></td><td></td><td>419,5€ to save 9 patients every 1,000 treated 46,61€ per life saved***</td></tr><tr><td colspan="4">*We considered no difference in visits **Hospitalization included outcome that present statistically significant difference (All cause mortality, fatal bleeding and ischemic stroke).</td></tr></table>		Yearly costs per patient				Warfarin	NOACs	Difference	Drugs (0,1€/die for warfarin 2€/die for NOACs)	36,5€	730€		INR test (including blood collection - 6€ twice month)*	144€	-		Drugs and monitoring costs	180,5€	730€	549,5€					Hospitalization (13 admission/1,000 pts fewer for NOACs – considering 20,000 € per admission and 2 years of follow RCTs)		-260€ total and -130€ per year	-130€	Total costs			419,5€ more for NOACs per patient					Cost effectiveness			419,5€ to save 9 patients every 1,000 treated 46,61€ per life saved***	*We considered no difference in visits **Hospitalization included outcome that present statistically significant difference (All cause mortality, fatal bleeding and ischemic stroke).				This cost effectiveness results can consider NOACs as good value for money
	Favour to Warfarin	Uncertain	Favour to NOACs																																																			
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>																																																				
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	Is the total cost (impact on budget) small?	<table><tr><td>Favour to Warfarin</td><td>Uncertain</td><td>Favour to NOACs</td></tr><tr><td><input type="checkbox"/></td><td><input type="checkbox"/></td><td><input type="checkbox"/></td></tr></table>	Favour to Warfarin	Uncertain	Favour to NOACs	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<table><tr><td colspan="4">Total drug cost for 100,000 patients</td></tr><tr><td></td><td colspan="3">Yearly costs per 100,000 patient</td></tr><tr><td></td><td>Warfarin</td><td>NOACs</td><td>Difference</td></tr><tr><td>Drugs and monitoring costs</td><td>14,400,000€</td><td>73,000,000€</td><td>58,600,000€</td></tr><tr><td>Total costs (including hospitalization)</td><td>--</td><td>-13,000,000€</td><td>45,600,000€ more for NOACs</td></tr></table>	Total drug cost for 100,000 patients					Yearly costs per 100,000 patient				Warfarin	NOACs	Difference	Drugs and monitoring costs	14,400,000€	73,000,000€	58,600,000€	Total costs (including hospitalization)	--	-13,000,000€	45,600,000€ more for NOACs																									
Favour to Warfarin	Uncertain	Favour to NOACs																																																				
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Total costs (including hospitalization)	--	-13,000,000€	45,600,000€ more for NOACs																																																			
EQUITY	What would be the impact on health inequities?	<table><tr><td>Favour to Warfarin</td><td>Uncertain</td><td>Favour to NOACs</td></tr><tr><td><input type="checkbox"/></td><td><input type="checkbox"/></td><td><input type="checkbox"/></td></tr></table>	Favour to Warfarin	Uncertain	Favour to NOACs	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		NOACs might reduce inequities for people whose INR is poorly controlled and do not have easy access to testing, also due to social problem.																																												
Favour to Warfarin	Uncertain	Favour to NOACs																																																				
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>																																																				

FEASIBILITY	Is the option feasible to adoption in the actual setting?						<p>It might be difficult to restrict the use of NOACs to people who would benefit sufficiently to warrant the cost.</p> <p>Compliance potentially might be more of a problem with Dabigatran than Warfarin since monitoring and frequent clinic visit is not needed, but there's no evidence to support or refuse this.</p> <p>There is currently no antidote for NOACs. This is a concern for healthcare providers who have to manage bleeding patients receiving these drugs and may lead to worse outcome in such patients.</p>
		No	Probably no	Uncertain	Probably yes	Yes	
		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	

Balance of desirable and undesirable consequences of covering the intervention	Undesirable consequences <i>clearly outweigh</i> desirable consequences	Undesirable consequences <i>probably outweigh</i> desirable consequences	The balance between desirable and undesirable consequences is <i>closely balanced or uncertain</i>	Desirable consequences <i>probably outweigh</i> undesirable consequences	Desirable consequences <i>clearly outweigh</i> undesirable consequences
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<u>Decision</u>	Do not cover <input type="checkbox"/>	Coverage with evidence development (which Drug/s?) <input type="checkbox"/>		Cover (which Drug/s?) <input type="checkbox"/>	

Comments

Restriction
(any restriction on coverage of the intervention)

Justification

(reason for deciding the intervention should be covered, covered with evidence development or not covered)

Implementation considerations

(details regarding the decision, including any restrictions on coverage and conditions for coverage with evidence development)

2.1. References

2.2. Connolly SJ et al. Dabigatran versus warfarin in patients with atrial fibrillation. NEJM 2009; 361:1139-51.

2.3. Patel R et al. Rivaroxaban versus warfarin in nonvalvular atrial fibrillation. NEJM 2011; 365:883-91.

Granger CB et al. Apixaban versus warfarin in patients with atrial fibrillation. NEJM 2011; 365:981-92.

Soheir S et al. Comparative effectiveness of warfarin and new oral anticoagulants for the management of atrial fibrillation and venous thromboembolism. AnnIntMed 2012.

Annex 2.2: Feedback questionnaire

- 1) Do you think the “Criteria” proposed in the Framework cover all the range of information you need to take the decision? If not, please list further information/criteria you think should be included.
- 2) Do you think the type and style of the information about the evidence presented in the “Benefit and Harm” section are clear and complete? Would you have preferred another type of information (ie. numerical data, measure of effect, etc...)? Please explain
- 3) Do you think the “Judgement” section it’s helpful to summarise the information presented and to take the decision?
- 4) Do you like the three-level option for the “Judgement? Would you have preferred a two-level option (Yes/no) or a five-level one (yes/probably yes/uncertain/probably no/no)?
- 5) Do you think this framework could be a useful tool for policy makers and managers taking coverage decisions? Please comment

Annex 2.3: Feedback on DECIDE framework for going from evidence to coverage decisions

Purpose	The purpose of the framework is to help people responsible for coverage decisions to systematically and transparently consider factors that can (and should) influence decisions about whether to pay for the introduction of an intervention/option in a specific healthcare setting.
Coverage decision	Decisions by third party payers (public or private health insurers), which can take place at national and/or regional level, about whether and how much to pay for drugs, tests, devices or services and under what conditions.
Target audience	Policy makers, managers and their support staff with responsibility for making coverage decisions. Assuming that they have technical support to provide the evidence that is used in the framework.
Nature of evidence available to inform decisions	Typically complex information from diverse study designs regarding different aspects which could be relevant for the decision, with lots of uncertainty.
Decision making processes	Varies. Political or managerial processes. The use of research evidence is often optional and non-systematic.
Relevant factors	Factors that can determine the importance of paying for the introduction of an intervention/option and that should be considered as criteria in the framework for going from evidence to coverage decisions.
Evidence regarding costs	Cost-effectiveness and budget information are extremely relevant but often not available. Local costing studies are likely to be needed.

				Comments
Comprehensiveness				
1. Are there important relevant factors that are missing from the framework? If YES list them in the comments section.	Yes <input type="checkbox"/>	Uncertain <input type="checkbox"/>	No <input type="checkbox"/>	
Relevance				
2. Are there criteria included in the framework that should not have been? If YES list them in the comments section.	Yes <input type="checkbox"/>	Uncertain <input type="checkbox"/>	No <input type="checkbox"/>	
Applicability				
3. Is the framework applicable to different types of coverage decisions?	Yes <input type="checkbox"/>	Uncertain <input type="checkbox"/>	No <input type="checkbox"/>	
4. Is the framework applicable to different types of decision-making processes?	Yes <input type="checkbox"/>	Uncertain <input type="checkbox"/>	No <input type="checkbox"/>	
Simplicity				
5. Is the framework more complicated than necessary?	Yes <input type="checkbox"/>	Uncertain <input type="checkbox"/>	No <input type="checkbox"/>	
Logic				
6. Is the framework organised in a logical way that is easy to understand?	Yes <input type="checkbox"/>	Uncertain <input type="checkbox"/>	No <input type="checkbox"/>	
Clarity				
7. Are the criteria labelled and explained in a way that is easy to understand?	Yes <input type="checkbox"/>	Uncertain <input type="checkbox"/>	No <input type="checkbox"/>	
Usability				
8. Would it be easy for people responsible for coverage decisions to use the framework?	Yes <input type="checkbox"/>	Uncertain <input type="checkbox"/>	No <input type="checkbox"/>	
Suitability				
9. Is the framework suitable for informing and helping people to make coverage decisions?	Yes <input type="checkbox"/>	Uncertain <input type="checkbox"/>	No <input type="checkbox"/>	
Usefulness				
10. Is the framework likely to be useful to people responsible for coverage decisions?	Yes <input type="checkbox"/>	Uncertain <input type="checkbox"/>	No <input type="checkbox"/>	
Overall assessment				
11. Overall, is the framework adequate for its intended purpose?	Yes <input type="checkbox"/>	Uncertain <input type="checkbox"/>	No <input type="checkbox"/>	
Strengths				
12. What do you like about the framework?				
Weaknesses				
13. What don't you like about the framework and what suggestions do you have for improving it?				
Anything else				
14. Please include any other comments you have regarding the framework.				

Annex 2.4: User testing guide

<ul style="list-style-type: none">• DECIDE WP2 User testing: EtCD for policy makers and managers	
Test person no.:	
Place:	
Date:	
Interviewer/notetaker:	

- **1. Checklist**

For facilitator, bring:

- Printed copy / tablet version of EtCD table

For observer/note taker, bring:

- Paper and pen to take notes
- Tape recorder

- **2. Introduction and instructions**

- > *Go through the* written information they have already received
- What we are doing
- Who is participating, why we invited you
- How the test is conducted
- What happens to the data/recording
- Rights to quit or retract recording
- Questions?
-
- > *Turn on audiorecorder.*

• Background questions – 5 minutes

A	<p>Ask: How many years of experience in decision making in healthcare setting do you have?</p> <p>.....Years of decision making experience</p>
	<p>Ask: What is your training in health research methodology (academic background)?</p> <p><input type="checkbox"/> Never done a formal course in HRM</p> <p><input type="checkbox"/> Done 1 or more formal courses but no masters/ Ph.D degree</p> <p><input type="checkbox"/> I have a masters/ Ph.D degree in HRM</p>
	<p>Ask: What is your background and current position?</p> <p>Background:</p> <p><input type="checkbox"/> Medical</p> <p><input type="checkbox"/> Psychological/ Social</p> <p><input type="checkbox"/> Legal</p> <p><input type="checkbox"/> Administrative</p> <p><input type="checkbox"/> Economic</p> <p><input type="checkbox"/> Other (specify)</p> <p>Current position:</p>

B	<p>Ask: When you have to take a coverage decision and you don't know the answer to, what do you most often do? (Check all that apply if more than one action)</p>
	<p><input type="checkbox"/> Consult a senior colleague or specialist</p> <p><input type="checkbox"/> Consult your staff</p> <p><input type="checkbox"/> Consult/organise specific commissions</p> <p><input type="checkbox"/> Consult guidelines or HTA documents</p> <p><input type="checkbox"/> Other, please specify:</p>

C	<p>Ask: How often do you on average consult guidelines when you're taking coverage decision?</p>
	<p><input type="checkbox"/> Seldom or never</p> <p><input type="checkbox"/> Monthly</p>

<input type="checkbox"/> Weekly <input type="checkbox"/> Daily

D	Say: Think to a coverage decision you were involved in. Explain very briefly what sort of information you needed to make an informed one.
	<i>Notes:</i>

● Repeat instructions

- No right or wrong answer

You are not being tested, it is our material we are testing.

There are no right or wrong answers to our questions.

If you think something is easy or difficult, clear or confusing, if you understand or don't understand, we just want to know about it.

-

- Think out loud

Think out loud. Tell me what you are thinking, what you see, what you find confusing or surprising, even the least little bit. For instance:

- What you are looking at, describe your experience of it.
- If you are unsure about anything
- If you are surprised by anything
- If there are things you don't understand, just say "I don't know what this means..."

-

-

- My role

My role is to ask questions. But, since it is your opinion we are interested in, I will be otherwise saying as little as possible.

If you have any questions not regarding navigational issues, I will try to answer them after the test.

● Scenario

1	<p>Let the participant select an appropriate clinical scenario with a question about therapy at the end.</p> <p>Ask: "Which of the following scenarios do you wish to look at?" (tick off for selected scenario)</p> <p><i>Scenario 1 is about</i> <input type="checkbox"/></p> <p><i>Scenario 2 is about</i> <input type="checkbox"/></p> <p><i>Scenario 3 is about</i> <input type="checkbox"/></p>
---	---

● The EtCD table for policy makers and managers: first impressions

> Wait before showing the EtCD table, read first part of section 2:

2	<ul style="list-style-type: none"> ● First impressions <p>Say: I'm going to show you what we call an Evidence to Coverage Decision table.</p> <p>We are most interested in the content and structure of the table you will be looking at.</p> <p>We would like your first immediate impression, your spontaneous reaction to it when I show it to you. Don't think, just tell me the first thing that comes into your head when you see it.</p> <p>> Now show the table.</p> <ul style="list-style-type: none"> ● ● ● Ask: What is your first reaction? <p>Ask:</p> <ul style="list-style-type: none"> ● Can you explain what it means to you, using your own words? ● How easy is this table to understand?
<ul style="list-style-type: none"> ● Notes: 	

• The EtCD table for policy makers and managers: detailed questions

3	Table in more detail: <ul style="list-style-type: none"> • Keep encouraging the participant to think aloud and to give his / her impressions. • We would like you to comment of the individual components (see below) 						
	<table> <tr> <td>Headers</td><td>Easy to understand? Helpful?</td></tr> <tr> <td>Decision header</td><td>Anything lacking?</td></tr> <tr> <td>Column headings</td><td>Anything superfluous?</td></tr> </table>	Headers	Easy to understand? Helpful?	Decision header	Anything lacking?	Column headings	Anything superfluous?
Headers	Easy to understand? Helpful?						
Decision header	Anything lacking?						
Column headings	Anything superfluous?						
	<table> <tr> <td>Severity</td><td>Easy to understand? Helpful? Anything lacking? Anything superfluous?</td></tr> </table>	Severity	Easy to understand? Helpful? Anything lacking? Anything superfluous?				
Severity	Easy to understand? Helpful? Anything lacking? Anything superfluous?						
	<table> <tr> <td>Outcomes</td><td>Easy to understand? Helpful? Anything lacking? Anything superfluous?</td></tr> </table>	Outcomes	Easy to understand? Helpful? Anything lacking? Anything superfluous?				
Outcomes	Easy to understand? Helpful? Anything lacking? Anything superfluous?						
	<table> <tr> <td>Estimates</td><td>Explain in your own words what it means: Easy to understand? Helpful? Anything lacking? Anything superfluous?</td></tr> </table>	Estimates	Explain in your own words what it means: Easy to understand? Helpful? Anything lacking? Anything superfluous?				
Estimates	Explain in your own words what it means: Easy to understand? Helpful? Anything lacking? Anything superfluous?						
	<table> <tr> <td>Quality of evidence</td><td>Explain in your own words what it means:</td></tr> <tr> <td>Certainty of the evidence</td><td> Easy to understand? Helpful? Anything lacking? Anything superfluous? <i>(Ask about additional explanations about certainty of the evidence and about each quality of the evidence)</i> </td></tr> </table>	Quality of evidence	Explain in your own words what it means:	Certainty of the evidence	Easy to understand? Helpful? Anything lacking? Anything superfluous? <i>(Ask about additional explanations about certainty of the evidence and about each quality of the evidence)</i>		
Quality of evidence	Explain in your own words what it means:						
Certainty of the evidence	Easy to understand? Helpful? Anything lacking? Anything superfluous? <i>(Ask about additional explanations about certainty of the evidence and about each quality of the evidence)</i>						
	<table> <tr> <td>Values and preferences</td><td>Explain in your own words what it means: Easy to understand?</td></tr> </table>	Values and preferences	Explain in your own words what it means: Easy to understand?				
Values and preferences	Explain in your own words what it means: Easy to understand?						

	Helpful? Anything lacking? Anything superfluous?
Resource use	Easy to understand? Helpful? Anything lacking? Anything superfluous?
Equity	Easy to understand? Helpful? Anything lacking? Anything superfluous?
Feasibility	Easy to understand? Helpful? Anything lacking? Anything superfluous?
Balance of desirable and undesirable consequences	Easy to understand? Helpful? Anything lacking? Anything superfluous?
Decision	Easy to understand? Helpful? Anything lacking? Anything superfluous?
<ul style="list-style-type: none"> <i>Notes:</i> 	

• The EtCD table for policy makers and managers: summing-up questions

4	<i>Summing-up questions</i>														
	<p>Summing up understandability</p> <p><i>Say:</i> I would like to ask you a few questions about the information included in the table</p> <p><i>Ask:</i> What is the overall effect of the intervention? Can you elaborate where do you get your answer from?</p> <p><i>Ask:</i> Did you find the information generally <u>easy or difficult to understand</u>?</p>														
	<p>Summing up usefulness</p> <p><i>Say:</i> The goal of this table is to provide additional information on those factors that are considered / pondered before taking a coverage decision, in a tabular format</p> <p><i>Ask:</i> Is this table valuable or useful?</p> <p><i>Ask:</i> Do you think this way of forming information would be useful for you and your colleagues if you were going to take a coverage decision? (why?)</p>														
	<p>• <i>Do you feel that the table is overall....</i></p> <table> <tr> <td><input type="checkbox"/></td> <td><input type="checkbox"/></td> <td><input type="checkbox"/></td> <td><input type="checkbox"/></td> <td><input type="checkbox"/></td> <td><input type="checkbox"/></td> <td><input type="checkbox"/></td> </tr> <tr> <td>Totally useless</td> <td>Useless</td> <td>Somewhat Useless</td> <td>Undecided</td> <td>Somewhat Useful</td> <td>Useful</td> <td>Very usefull</td> </tr> </table>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Totally useless	Useless	Somewhat Useless	Undecided	Somewhat Useful	Useful	Very usefull
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>									
Totally useless	Useless	Somewhat Useless	Undecided	Somewhat Useful	Useful	Very usefull									
	<p>Summing up completeness</p> <p><i>Ask:</i> After seeing this table, <u>would you want to see more information</u> for decision making?</p> <ul style="list-style-type: none"> What kind of information would you want to see? , in any particular circumstances? 														
	<p>• <i>Do you feel that the table is overall....</i></p> <table> <tr> <td><input type="checkbox"/></td> <td><input type="checkbox"/></td> <td><input type="checkbox"/></td> <td><input type="checkbox"/></td> <td><input type="checkbox"/></td> <td><input type="checkbox"/></td> <td><input type="checkbox"/></td> </tr> <tr> <td>Totally incomplete</td> <td>Incomplete</td> <td>Somewhat incomplete</td> <td>Undecided</td> <td>Somewhat complete</td> <td>Complete</td> <td>Very complete</td> </tr> </table>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Totally incomplete	Incomplete	Somewhat incomplete	Undecided	Somewhat complete	Complete	Very complete
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>									
Totally incomplete	Incomplete	Somewhat incomplete	Undecided	Somewhat complete	Complete	Very complete									
	<p>• <i>Summing up credibility</i></p> <p><i>Ask:</i> If this table will be used in your institution to help taking coverage decisions, would you feel it is an add value or may gain credibility to users?</p>														

5	<p>Participants suggested alternative presentations of information</p> <p>Ask: What do you think about the presentation of the information in this table?</p> <p>Ask: Do you think there could be a different ideal design of this table ?</p> <p>Say: Consider those things that particularly confused or frustrated you, you didn't like, you felt missing or especially liked you</p> <p><i>> Present the test subject with blank papers and ask them to draw their ideas or concepts.</i></p>
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Say: Thank you very much – that's all. But we also would like your feedback on how we might have organised this session better. Any suggestions for improving the user testing?

3. Work Package 3: Patient and public focused strategies for communicating evidence-based recommendations

Work Package 3 (WP3) is led jointly by Duodecim in Finland, and Healthcare Improvement Scotland (HIS) in Scotland (NICE has been an active participant in the work done by HIS, to provide a UK rather than purely Scottish perspective). While sharing objectives and methods, the two organisations have of necessity operated in parallel for most of the work. Their contributions are accordingly reported separately in this report.

Following brainstorming sessions at the opening meeting of the project in 2011 WP3 participants agreed on an approach that involved establishing what kind of information patients or members of the public want or need from guidelines before developing strategies to address those needs. Other groups, particularly WP5, have identified similar issues in relation to their target groups but it was seen as a particular issue for WP3 given that the target audience is so varied in their level of knowledge and understanding in relation to healthcare issues, and guidelines in particular.

It was also recognised early in the process that information from evidence-based guidelines will appear to the public alongside a multitude of other sources of advice and information. Any strategies need to emphasise our ‘unique selling point’ that advice from guidelines is based on a thorough review of the evidence.

3.1 Healthcare Improvement Scotland

3.1.1 Methods

The methods to develop optimal presentations to effectively communicate evidence-based recommendations to patients and members of the public (target population for WP3) are similar to those used in other work packages and comprise three phases:

- Phase 1: Strategy development
- Phase 2: Evaluating the strategies

- Phase 3: Testing the strategies with real guidelines

These phases are not linear, and may overlap, or be repeated depending on feedback or learning following each stage.

3.1.2 Strategy development.

Following the decision at the first brainstorming session to start by establishing the needs and wants of patients and members of the public a four-pronged strategy was developed.

1. Brainstorming / public discussion sessions.
2. Recruit and consult an advisory group consisting of experts in the field of patient information / communication and practitioners in that field.
3. Carry out a survey to establish the level of general knowledge and understanding of guidelines and their purpose.
4. Conduct a literature review on the subject of patient knowledge and understanding of guidelines, and methods of communicating their recommendations to patients and the public.

An advisory group was established made up from nominations from participants in DECIDE and a central list produced by the DECIDE office. WP3 invited 21 people from European countries or international groups interested in getting information to patients. A list of members of this group and their affiliations is attached as Annex 1 to this report. The advisory group was initially consulted on the general approach being proposed by the working group, and once an initial strategy was developed they were again consulted on whether the group was going in the right direction. Feedback from these consultations was generally favourable but resulted in some redirection of later work.

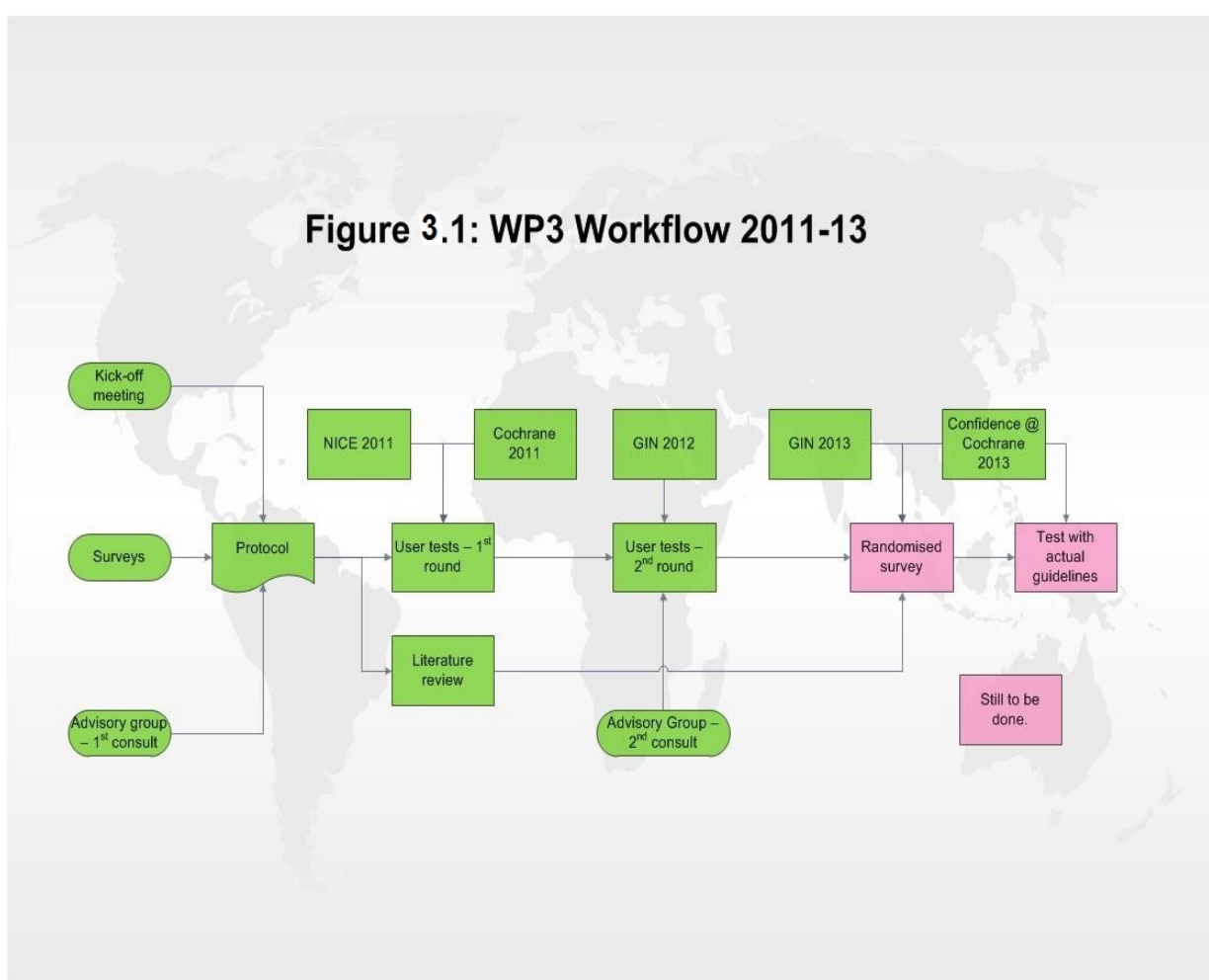
Further consultation on the issues that should be addressed in the design of patient materials was undertaken through workshops held during the 2011 NICE conference, and the 2011 Cochrane Colloquium.

At the time of the launch of DECIDE, SIGN* was in the process of evaluating a survey

seeking the view of patients and members of the public in Scotland on guidelines and what they wanted or expected to get from them. This survey was subsequently repeated by NICE for people in England and Wales.

In parallel with other work, a systematic review of published literature on the topic '*Public attitudes to and knowledge of healthcare guidelines, and methods to communicate guideline recommendations to patients and the public*' was undertaken.

Workflow to this point in the project is shown graphically in Figure 3.1.



*SIGN (Scottish Intercollegiate Guidelines Network) changed to HIS (Healthcare Improvement Scotland) ("beneficiary no. 9") via a universal transfer of rights and obligations. European Commission letter of 30/05/2012 refers.

3.1.3 Evaluating the strategies

Strategies were developed through production of a series of draft example patient versions of guidelines that were then tested with focus group, and through conference workshops.

Draft patient versions based on the SIGN guidelines on depression and obesity were tested with a number of focus groups that included general practitioners (GPs) and journalists as well as small groups of patients. Feedback from these sessions led to changes in drafts produced for the next round of consultation.

For subsequent rounds of testing the topics covered were breast cancer, depression, diabetes, and obesity. These topics were selected on the basis that they are long term conditions where patients have a continuing interest in issues related to their health. Cervical cancer screening was also considered but given the high quality patient information already available in this area it was decided not to pursue that topic. Similarly, flu vaccination was dropped as a topic following some early focus group work that suggested there was little demand from patients for information in that area. Patients with different conditions are likely to have different information needs, and collectively this range of topics is expected to involve a broad spectrum of patient perspectives.

Revised draft patient versions of these guidelines were tested across a number of focus groups in different parts of Scotland. Locations of the focus groups were selected to cover urban, rural, and remote settings. They also aimed to cover groups where there are equity issues such as specific ethnic groups, and people for whom English was not their first language. An additional group was organised specifically for young people, given the relatively high average age of patients on other groups.

Further consultation on the coverage and presentation of patient versions of guidelines was carried out during workshops at the 2012 and 2013 Guidelines International Network (GIN) conferences.

The issue of how to express confidence in evidence or recommendations has

emerged as a major issue for WPs 1, 3 and 5. A workshop specifically addressing this issue was arranged in collaboration with WP1 at the 2013 Cochrane Colloquium. Progress was made but this remains an important challenge.

3.1.4 Results

The surveys carried out by Voluntary Health Scotland (In conjunction with SIGN) and NICE used the same questions, slightly tailored to take account of local circumstances. The following conclusions are extracted from the report of the survey:

“... The response group was predominantly white, female and older, with experience of illness. ... Nevertheless, a number of observations can be made, with pointers for ongoing activity. Awareness of SIGN Guidelines appears to be reasonably high in certain sections of the community, including those with experience of the NHS as patients, carers, members of health charities and support groups. The purpose of SIGN seems well understood by them. Guidelines are predominantly accessed electronically and SIGN is developing new e-applications. It is possible that paper-based patient versions may continue to be valued. ... Efforts should be made to inform and encourage both health professionals and patients about the value of SIGN Guidelines being applied to individual care – doctors and nurses so that they can inform patients so that they may request, since application appears to increase confidence. Finally, it seems that people across Scotland strongly believe that SIGN Guidelines can make a significant difference to care and treatment for a wide range of health conditions, but remain concerned that implementation should be assured and evidence of effectiveness established. “

Results of the NICE survey were reported at the 2011 GIN conference. The following is an extract from the conference abstract:

“Results: 1675 responses were received. 83% of respondents were aware of NICE clinical guidelines through various sources including the internet, national media or patient support groups. Respondents viewed the guidelines in an electronic format (74%) or printed leaflet (25%). 85% considered that NICE guidelines had improved care and treatment; specific examples of using NICE guidelines to obtain better care were cited. However, many respondents were unclear about the role of NICE and

were confused about the different types of NICE guidance.

Discussion: Our survey demonstrated a demand for guidance on healthcare among members of the public with people interested in using clinical guidelines in their care

and treatment. However, there is room to improve the public's understanding of the role of clinical guidelines."

Unfortunately neither of the surveys achieved a high enough response rate to produce definitive conclusions **so it was decided not to publish them independently**. They have, however, fed into planning and design of later stages of the project, and the results of the survey are included in the literature review.

The literature review "*Patient and public attitudes to and awareness of clinical practice guidelines: a systematic review and thematic analysis*." has been completed and submitted for publication; 5,415 records were identified, and from that set 26 studies involving a total of 24,887 individuals were included in the review.

The principal findings are as follows:

- Patient versions of guidelines need to be written in a way that makes individual patients feel 'special'. (Often referred to as 'personalisation' or 'affiliation').
- Part of addressing the previous issues is to ensure that patient values and preferences are taken into account in producing guidelines (this is a core part of the GRADE process).
- Information has to be of high quality, evidence-based and presented in an appealing way that encourages trust by patients or their carers and the confidence to use the information by themselves, or when speaking to their health care workers.
- There is an urgent need to raise awareness of guidelines and their purpose among the general population across all countries if delivery of information from guidelines is to be delivered effectively.

Preliminary results of the systematic review and thematic analysis were reported at the 2013 GIN conference in San Francisco.

Results of the user testing are still being analysed but should be made ready for publication in the first half of 2014. The key themes that have emerged from preliminary analysis of the results are listed in Annex 2 to this report. These were also presented at the 2013 GIN conference.

The workshop on confidence at the 2013 Cochrane Colloquium was successful, certainly in revealing how complex an issue this is, but also helping to identify specific issues that need to be addressed. Again, the results are still being analysed but the following are key points that have been identified so far:

- Using text alone is not helpful: people do not read things word by word.
- Traffic lights are the most popular way of expressing confidence
 - But there are issues relating to colour (colour blindness)
- Using a balance (as in scales of justice) or a 'speedometer' are helpful in expressing balance of risk vs benefit
- Need to bear in mind that consumers interpret language differently – e.g. 'bias' means something different to most people to its meaning in relation to EBM
- Probably need different approaches for shared decision making and self help materials.
- There are cultural differences that need to be taken into account when designing patient materials. e.g. some nationalities are not at all keen on 'personalisation' whereas others prefer it.
- Most guideline developers and users present supporting evidence as well as recommendations, but are unsure of how to present confidence in these two different contexts.

This topic will be further discussed at the DECIDE meeting in Barcelona in January 2014 and in a workshop at the DECIDE conference in June 2014.

The above, together with the results of the literature review, have led to discussions with guideline producers with regard to using DECIDE strategies in real patient versions of their forthcoming guidelines. Discussions are advanced with the Scottish Dental Clinical Effectiveness Program with regard to their periodontal care guideline due for publication in June 2014. A draft patient version using DECIDE strategies is

due at the end of January 2014. The European Renal Association is developing a patient guideline for its forthcoming guideline on kidney donor and recipient evaluation and perioperative care. Both SIGN and NICE also plan to use DECIDE strategies in real guidelines.

3.1.5 Explanations of terms

We are contributing to the development of a glossary in collaboration with WP5, which will be used by all WPs. The glossary aims to address the problems of jargon and inconsistent use of language which can act as a barrier to understanding of research evidence for non-specialists.

The glossary is an open access database that can facilitate the understanding and use of a variety of resources, including:

- plain language summaries
- summaries of findings
- evidence to decision frameworks
- databases of systematic reviews, recommendations or patient information

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
- technical definitions

The glossary is intended for use by guideline producers, health technology assessment agencies, and others providing support for evidence-informed decisions at all levels in healthcare systems.

3.1.6 Future plans

Revised versions of the draft guidelines taking into account the main issues identified from the user testing will be further tested in a randomised survey of a sample of guideline users prior to final testing with real guidelines.

Patient versions designed to take account of the lessons learned to date will be tested with actual guidelines produced by a number of DECIDE participants. Different

participants will be asked to test variations on the design, and to obtain feedback on user views of the format. Results will be collated and an attempt made to establish the design or designs most acceptable to users.

The issue of how to express 'confidence' will be further explored in conjunction with other WPs at the annual DECIDE meeting to be held in Barcelona in January 2014, and in a workshop during the DECIDE conference in June 2014.

A toolkit for the production of patient versions of guidelines has already been produced by GIN. We will work with the GIN group to produce an updated version incorporating the learning from our work into their tool.

We have opened discussions with WP6 regarding the incorporation of appropriately designed patient versions into the Guideline Development Tool, DECIDE's main tool to package project results.

3.2 Duodecim

3.2.1 Methods

Duodecim has followed the methods as described in section 4.1.1 putting emphasis on topics and development issues that are especially important in the Finnish context.

For Duodecim, DECIDE provides an opportunity to assess, improve and share its current practices with guidelines and their patient versions. Duodecim publishes two health portals: one for health professionals and another for all citizens. The health portal of patient information, Terveyskirjasto (Health Library) is the most important channel of guidelines information for the public in Finland.

3.2.2 Strategy development.

Following the first discussions and brainstorming within the WP3 group in DECIDE and in Duodecim, a four step strategy was formed:

1. Study patients' views on patient information and guidelines in particular. Try to integrate new ideas derived from the DECIDE collaboration and test them with the end users, the public and patients.
2. Since health professionals often deliver patient versions of guidelines, we wanted to study the role of guidelines as a tool to communicate with patients.
3. In Finland it is possible to study web-portal log files to see what the actual use of guidelines and patient information based is delivered via the portal. Since there are separate portals for health professionals and citizens, it is also possible to compare what is the actual use of guidelines in these groups. This information might be useful for guideline producers. We planned a register based log file study to assess the frequency of opening and printing the patient versions of guidelines by both health professionals and citizens.
4. Since the plan in DECIDE is to compare the most effective strategies to disseminate guidelines and to compare them in randomized trials, a method for that was developed in Duodecim. A link randomizer was developed, which can randomize one presentation format or a detail of a guideline and then present

the randomly selected format to the user. We can then survey the outcomes from the end users, health professionals or patients.

Study protocols for all these projects were approved by the relevant Finnish Ethics Committee.

3.2.3 Results

Patients, health information and guidelines: a focus group study

We ran 5 focus groups in 2012 with a total of 23 participants representing Finnish citizens and with one group with patient organisation activists. A topic guide was developed in collaboration with the DECIDE group.

Main results were that patients were mostly unfamiliar with the concept of guidelines. Less than one third of the interviewees had heard about guidelines. They linked guidelines to recommendations by a physician, standards of care and resourcing. Patients felt that health information on the Internet was abundant and its quality was sometimes difficult to assess. They appreciated conciseness, clarity, better use of subheadings and using specialists or well-known organizations as authors of health information. Most patients would like health professionals to deliver and clarify written materials to them or direct them to the relevant Internet sites.

These results were presented in a paper to the Nordic congress of General Practice in Tampere in 2013. It will soon be submitted for publication in the Scandinavian Journal of Primary Health Care.

In 2013, this topic was further studied in individual interviews with journalists. The interview guide was planned in cooperation with Professor Shaun Treweek. These interviews have not yet been fully analysed but the findings will be summarised in 2014.

Health professionals and patient information.

Two pilot focus groups were held in 2012. Since one of the main results from the patient study was that patients receive little written information from health

professionals and certainly less than they wished, this area deserved further attention.

Portal log file study.

In Finland, Duodecim produces guidelines. Two guidelines systems cooperate: Current Care publishes selected, comprehensive national guidelines, and Evidence-Based Medicine Guidelines updates a thorough collection of about thousand short guidelines. Duodecim disseminates guidelines and other health information through two portals: Terveystietä (Health Gate), which is a portal for health professionals purchased by practically all health care employers in Finland, and Terveystietä (Health Library), which is an open access health portal for citizens

Both portals contain a database of patient information articles that are based on guidelines. In this study we wanted to find out which guidelines are accessed most often so as to enable guideline producers to be respond to the needs of the public and professionals for patient information. We studied the log files from the beginning of 2010 in both portal systems in the database of patient information.

Main results from this study include that the use of patient information database is growing fast in the citizens' health portal (1.5 million articles opened monthly in 2010, rising to over 3 million per month in 2013) but remains constant in the professionals' health portal at around 100,000 articles per month. Citizens most often search for information on sexually transmitted diseases, infectious diseases, those reported in the media, and severe diseases. Professionals most often open and print articles where self-management is of great importance. There is seasonal variation in the searches and epidemics cause peaks in searches (norovirus, influenza etc).

It appears that a subgroup of health professionals has adopted the habit of printing out patient information. This practice has not been specifically promoted, but printing out patient information is a practice that patients like and could be endorsed (e.g. by Medical Associations) to encourage more widespread practice.

A paper reporting on this study is under development and will be submitted for publication in 2014.

Link Randomizer

The technical department at Duodecim has developed a method to enable us to conduct a randomized controlled trial in live circumstances using real guidelines. When a user opens a guideline, part of the text containing a link to an evidence summary is randomly selected from two (or more) alternatives. The user can only see the one (randomly selected) version of the contents.

Users reading the evidence summary are then requested to answer a questionnaire to assess the selected outcomes.

The method was tested with two clinical examples in a technical test with physicians using electronic guidelines. The examples concerned PSA-screening and treatment of urinary tract infection (UTI). Two types of evidence summaries were tested, the ordinary one, and an improved one with a recommendation. In the UTI example the users found the example with a recommendation more useful.

This study was presented to the Cochrane Colloquium in Auckland in 2012 and also at the yearly meeting of Finnish general practice. A paper based on the pilot study with link randomizer will be submitted in the form of a short communication to one of the health information technology journals in 2014.

Other results.

We have published two editorials concerning DECIDE:

1. *Liira H. Patient information for better health outcomes in primary care. Scand J Prim Health Care. 2011 Jun;29(2):65-6.*
2. *Jousimaa J, Liira H. Hoitosuositusten kehittämisen uusi aikakausi - potilas ja kansalainen aktiivisena toimijana. (The new era of developing guidelines – patient and citizen as active participants) Duodecim 2013;129(6):642-3.*

In addition, three abstracts related to DECIDE were presented in the Nordic GP congress in Tampere in 2013:

1. *Patients, health information and clinical guidelines: a focus group study* Helena Liira; Jukkapekka Jousimaa; Osmo Saarelma; Ilkka Kunnamo
2. *Guidelines go mobile – a focus group study on ultra-short guidelines with mobile interface* H Alenius; J Jousimaa; M Teikari
3. *McMaster Duodecim service – automated literature retrieval system for guideline developers* Jukkapekka Jousimaa; Heidi Alenius; Ilkka Kunnamo

3.2.4 Future plans.

We plan to improve the forms of guidelines with what has been learnt in DECIDE and continue testing the improvements with the link randomizer method, which is a tool we will use to test other WP3 presentation formats coming from other partners. We also plan to test patient versions of guidelines with the link randomizer.

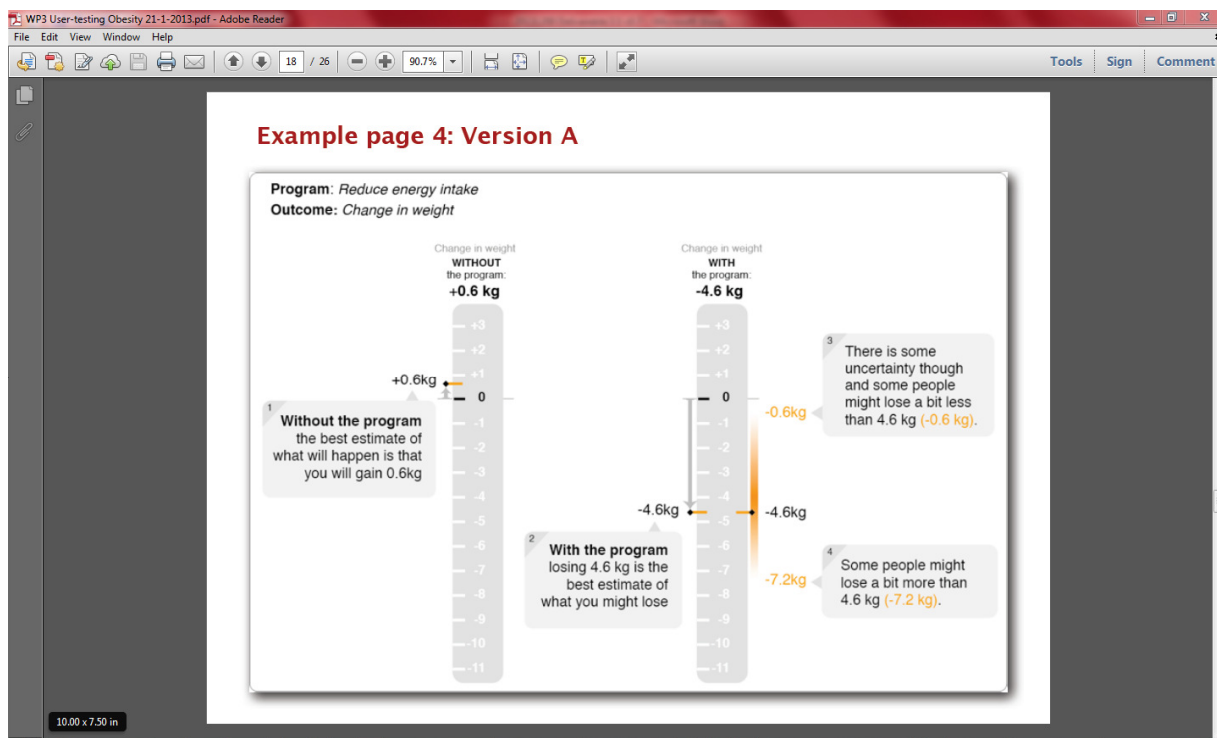
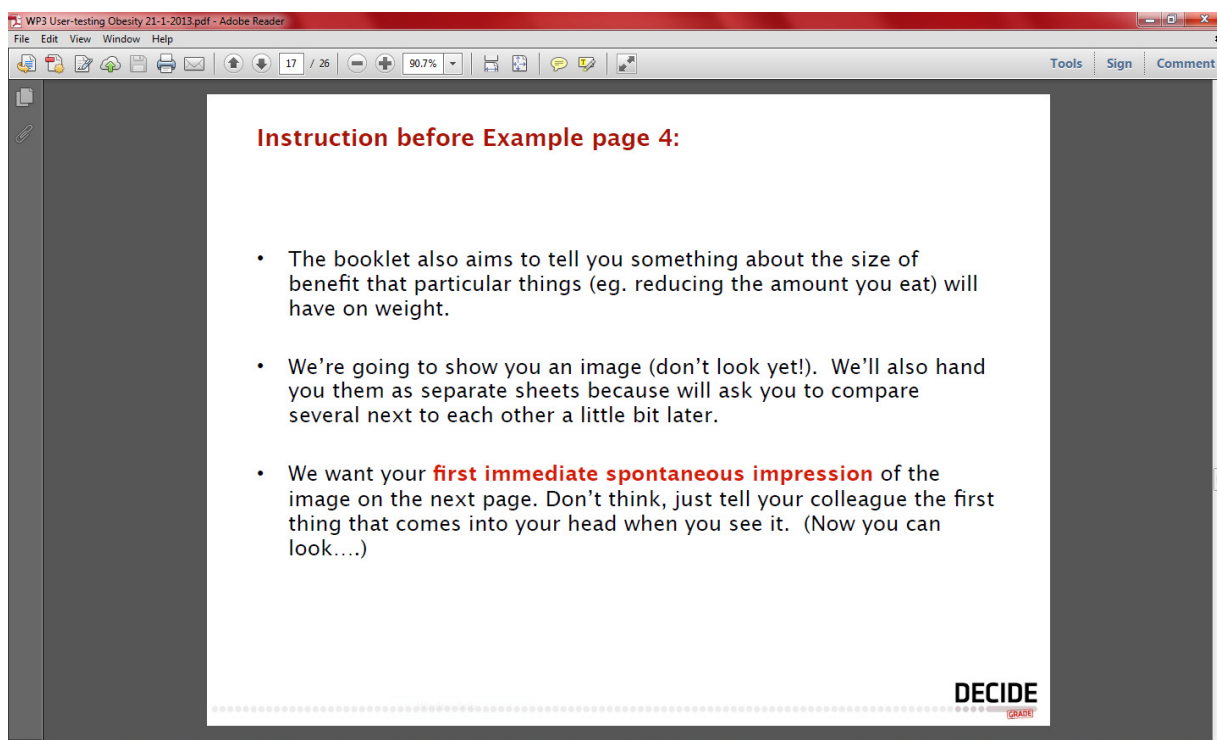
One conclusion so far is that patients wish to have written materials from their health professionals and they also wish to discuss what they have themselves found in the Internet. It is worth continuing to study what helps or hinders health professionals to actively disseminate and discuss guidelines material with patients. We plan to continue qualitative studies with focus groups and brainstorming on these issues.

Section 3 - Annexes

Annex 3.1 – WP3 Advisory Group membership

Ms. Amanda Burls	Oxford University
Ms Anna Sayburn	BMJ Publishing
Dr. Astrid Austvoll-Dahlgren	Kunnskapssenteret (Norway)
Dr. Corinna Schaeffer	G-I-N Public
Ms Eleanor Bradford	BBC Scotland
Sir Iain Chalmers	James Lind Alliance
Jukkapekka Jousimaa	Finland
Dr. Karen Facey	University of Glasgow
Ms Marjory Inglis	DC Thomson (newspaper publisher)
Mark Duman	Patient Information Forum
Merja Aaltonen	Finland
Ms. Nancy Greig	Health and Social Care Alliance
Paivi Pyykkola	Finland
Pertti Mustajoki	Finland
Dr. Ray Moynihan	Journalist and researcher
Ms Rosemary Hill	Scottish Health Council
Professor Sasha Shepherd	Oxford University
Ms Sine Jensen	Graphic Designer
Dr. Sophie Hill	Cochrane Consumers and Communication Review Group
Tarja Sampo	Finland
Professor Vikki Entwistle	University of Aberdeen

Annex 3.2: Example pages from user testing material



WP3 User-testing Obesity 21-1-2013.pdf - Adobe Reader

File Edit View Window Help

19 / 26 90.7%

Tools Sign Comment

Question 8

What are your first spontaneous reactions?

Answer:

DECIDE

10.00 x 7.50 in

WP3 User-testing Obesity 21-1-2013.pdf - Adobe Reader

File Edit View Window Help

20 / 26 90.7%

Tools Sign Comment

Question 9

a. Does it contain enough information for you to understand what is likely to happen with and without the program?

b. If you wanted to know how much weight you would expect to lose, would this sort of image be useful? Is anything missing?

Answer (a):

Answer (b):

DECIDE

10.00 x 7.50 in

Annex 3.3: Focus group script – depression

Questions for Depression Guideline

First page Instructions

If you are paired with a colleague, please discuss the questions together and fill out one form. If you disagree then please indicate this, reporting your answers and your points of discussion.

Please remember that we are not testing you but testing the material. If there is anything you do not understand or feel could be made clearer then please say. You can be as critical as you like.

You can write what you think on the document and make sketches if you like.

Second page (before contents)

Imagine that you or a member of your family have been told by a doctor or other health care professional that you are suffering from mild to moderate depression. You want to find out what sort of things might help you to cope with this. What information would you want to know first of all?

(a box here for the answers)

Now please turn over (to content page)

Page after contents page

What is your first impression of the page that you saw?

Is there anything that you would like to know that is not in the contents list?
[boxes for answer]

Page after 'what is depression' 'levels of depression'
Could you please take some time to read the text above?

Is this information clear? If it helpful? Do you have any other thoughts about this text (for example how to make it clearer or what you think of the language)

Page after 'How will this guide help you?' Are we sure things recommended in this guideline will work?

What do you think this section is trying to tell you about evidence?

How do you feel about getting information on the research evidence for treatment that you might have? Is this interesting for you or do you feel that it is too much information?

How do you feel about the information on confidence in research evidence? Do you understand what this means? Do you think that it is useful?

(after cognitive behavioural therapy)

What do you think the symbol is telling you about cognitive behavioural therapy?

Do you think that you would try this if you were depressed?

(after self-help)

What do you think the symbol is telling you about self-help groups?

Do you think that you would try this if you were depressed?

(exercise)

What do you think the symbol is telling you about exercise?

Do you think that you would try this if you were depressed?

(diet and lifestyle)

What do you think the symbol is telling you about diet and lifestyle?

Do you think that you would try this if you were depressed?

(nutritional supplements and herbal remedies)

What do you think the symbol is telling you about nutritional supplements and herbal remedies?

Do you think that you would try this if you were depressed?

(complementary therapies)

What do you think the symbol is telling you about complementary therapies?

Do you think that you would try this if you were depressed?

Last page

What do you think about using symbols to show how good the evidence is for different treatment? Do you understand this? Do you think this could be done in a clearer way? Do you think it is useful to have this kind of information?

Is there anything else that you would like to add?

Annex 3.4: Key themes from focus groups

(Note that these are raw results from focus group discussions. A structured report is in preparation).

Strong desire for context.

- Am I getting this at my GP surgery or somewhere else?
- Will I then have the opportunity to go back and ask the GP or not and have enough time to discuss it?
- Is this a web based document or a paper based one?
- All of these factors will influence participants' views on the guideline.

Accessibility

- People with disabilities can find it harder to exercise.
- Language can be difficult for some.
- May find it hard to afford complementary treatments etc.
- Many people don't have easy access to the web.
- Shouldn't have a web page on a written document and if it is meant to be displayed on the web should be tested on the web.

Graphics.

More graphics but they need to be more meaningful (people talking to each other and facing out etc).

Amount of information

Need to direct them to places for more information.

Evidence

- Scepticism about medical evidence. Often still trumped by anecdotal experience or studies they are aware of that would not meet our evidence criteria.

- Still not personalised enough.
- Not clear who it is written for. Another clinician or the person (e.g. weight management rather than losing weight).
- Evidence synthesis – difficult language

Specific to depression.

- Traffic lights symbol were felt to have merit but these could be made clearer - confusion because of the extra colour (blue), the fact that they are on the front page before they are explained and the fact that there is a tick when sometimes the advice is not to do something.
- People with depression in particular have an even greater need for simple explanations and may find it very hard to make changes, such as exercising more.
- Participants in this stage had a greater understanding of what evidence is but many still felt that it wasn't necessary for patients to know this.
- People would like to know what you would expect at different stages, how long will it last.

Specific to obesity

- Weight and diet issues so often discussed in society and so many other programmes addressing them that this isn't adding anything to what people already know.
- Need a sense of what your ideal weight should be for your height and whether other factors are important (like your age).
- Red and black colours are depressing / intimidating.
- Not a great deal of interest from participants in how guidelines are created.
- Felt there were too many logos (and for some this was true of all of the guides).
- Told to weigh yourself regularly and avoid certain foods without knowing whether you do this already.
- Side effects referred to without further discussion of what these are.

Specific to diabetes.

(More complex results as more complex disease- advice- probably more evidence in this area).

- Participants were interested in how they got diabetes and whether they could reverse this once they had it and how it would affect their lives.
- Was quite frightening – many people can live with diabetes without all the problems mentioned and this should be highlighted.
- Seemed to be a long list of things that could go wrong with little insight into how to prevent this.
- Refers to things without explaining what they are – such as diabetes team and care pathway.
- A lot of the information was felt to be written in a very clear way.
- Colours very unattractive and script too small. Needs to stand out better.
- Concern that Scotland wasn't mentioned (example used was based on the NICE guideline).

4. Conclusion

All three WPs represented in this report are on target with regard to their strategies for effectively presenting research to users of guidelines. DECIDE strategies are already being used in real guidelines while the iterative nature of DECIDE means that further user-testing and trials are also running in parallel.

A challenge for all WPs is the need to present enough information while not overwhelming the user, which has led to the idea of layering information. This is being used in all WPs to a greater or lesser extent. For patients and the public, presenting information about the quality of evidence has been of limited use as most people assume all research is of the same quality, ie. high. Efforts are now focused on presenting confidence linked to a recommendation without getting into detail at the top layer about what influences that confidence. Testing of iSoFs will provide information for where in the layer hierarchy they should appear. Work with policymakers has benefited from an earlier FP7 project, SUPPORT, and tools to support them are making promising progress. WPs 1 and 2 have developed frameworks (as have WPs 4 and 5), which are receiving positive feedback, although there is room for improvement. They do provide structure and transparency for a process, moving from evidence to recommendation or decision that can often be opaque.

Future plans are listed above under each WP summary but in short all three WPs will continue to refine their strategies while at the same time putting them into real guidelines and getting feedback from users as to how they compare with alternative presentations. All three WPs are working with WP6 to package their results into the Guideline Development Tool, the main DECIDE tool. This tool is covered by Deliverable D8.0, due at Month 50.

Dissemination of DECIDE work is very strong; DECIDE was a dominant theme at the 2013 Guidelines International Conference in San Francisco and several papers either have, or are about to be submitted. Registrations for the 2014 DECIDE conference to be held in Edinburgh, Scotland, are strong, reflecting interest in the project.