DECIDE

Developing and Evaluating Communication strategies to support Informed Decisions and practice based on Evidence

GRADE

Communicating evidence-based recommendations to health professionals

Work package 1

This project has received funding from the European Union's Seventh Framework Programme for research, technological development and demonstration under grant agreement n° 258583

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IMPLEMENTATION SCIENCE

STUDY PROTOCOL Open Access

Developing and evaluating communication strategies to support informed decisions and practice based on evidence (DECIDE): protocol and preliminary results

Shaun Treweek[1*], Andrew D Oxman[2], Philip Alderson[3], Patrick M Bossuyt[4], Linn Brandt[2], Jan Brożek[5], Marina Davoli[6], Signe Flottorp[2], Robin Harbour[7], Suzanne Hill[8], Alessandro Liberati[9], Helena Liira[10], Holger J Schünemann[5,11], Sarah Rosenbaum[2], Judith Thornton[3], Per Olav Vandvik[2], Pablo Alonso-Coello[12] and the DECIDE Consortium

Health care professionals (WP1)

- Strategies-formats developed
  - Need to be based on GRADE
  - Should be organized as multilayered
    - Different needs, different layers
  - Need to be electronic
    - » Static presentation (e.g. pdf)
    - » Interactive moving from layer to layer (e.g. PC, smartphone,…)

1. **A top layer format**
2. **A decision aid template**
3. An evidence to recommendation framework

DECIDE Developing and Evaluating Communication strategies to support Informed Decisions and practice based on Evidence GRADE

MAGIC Making GRADE the Irresistible Choice

IDE GRADE

TOP LAYER

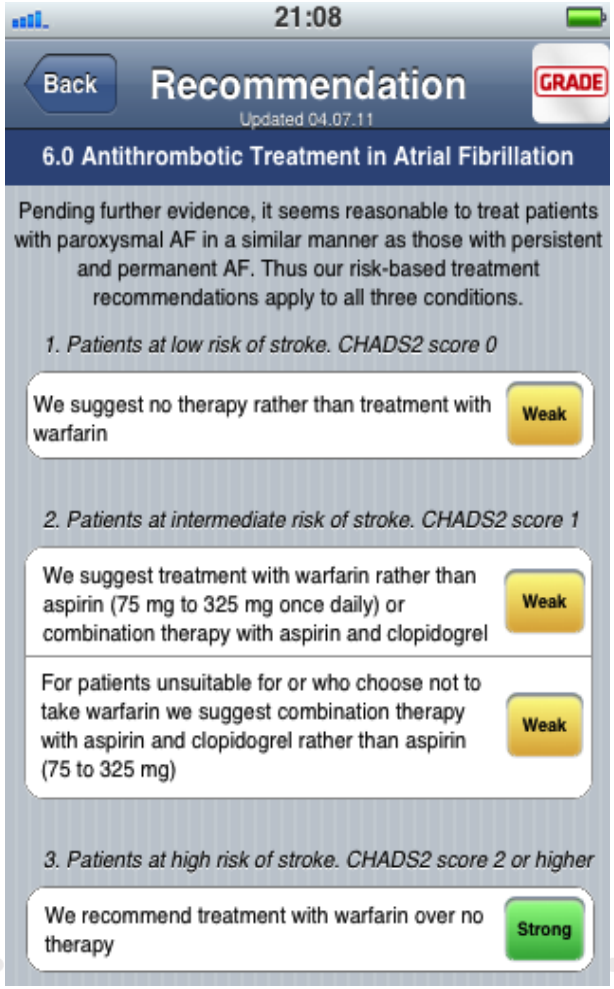
Top layer: development of a prototype

Top layer format: what clinicians would want to see next to understand the recommendation (entrance).

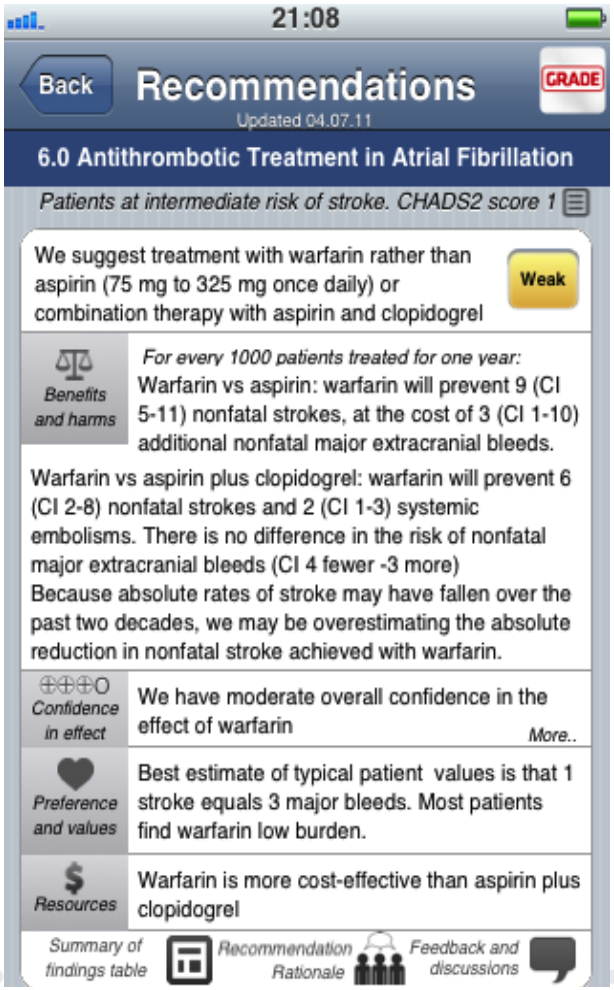
- **Rationale/Justification**
- **Key information (grade factors)**
  - The balance between benefits and harms
  - The confidence/certainty in the estimates of effect (quality)
  - Values and preferences
  - Resource considerations
  - Other factors

Top layer: template version 1

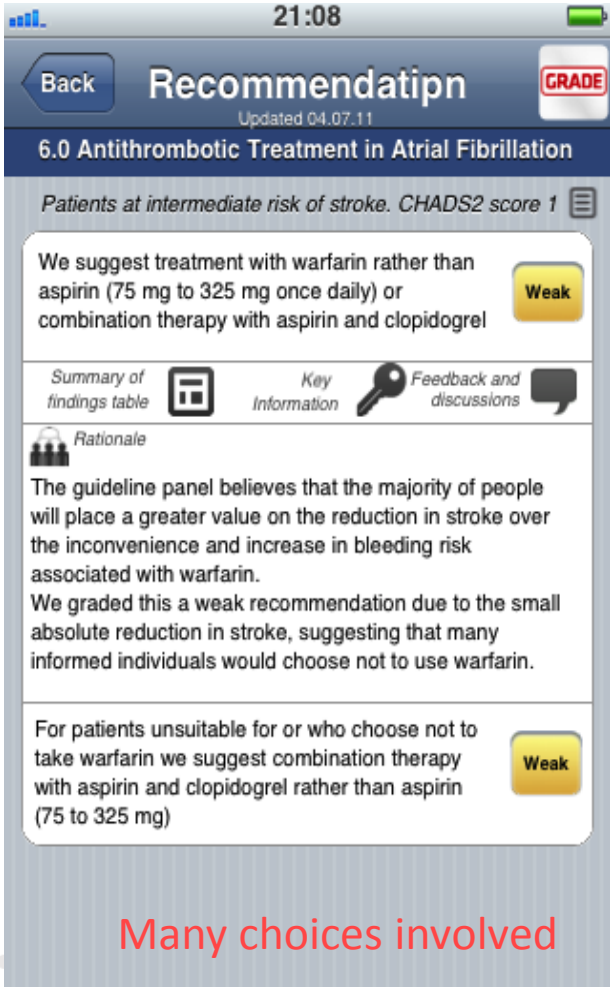
Recommendation



Key information



Rationale



Many choices involved

TL: Stakeholder feedback/user testing

- 35 individual user tests across 7 countries in 3 iterations:
  - Liked interactive multilayer approach
  - Too crowded, too complex (i.e. out with 95%CIs)
  - Symbols were confusing
  - Colors promising.
- Subsequent refined templates received improved feedback

Choice of oral anticoagulation

Weak recommendation

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

View More Details

Choice of oral anticoagulation

Weak recommendation

It is less clear whether the benefits outweigh the drawbacks. We believe there will be variation in patients preferences

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

View Less Details

Effect estimates | **Key info** | Rationale | Practical advice | A

The new oral anticoagulants have equal effect to warfarin with regards to stroke reduction, they lower the incidence of intracranial bleeds and are more convenient to use. We therefore suggest the new oral anticoagulants over warfarin as first treatment of choice.
For patients that are already on warfarin therapy with stable INR values the cost/benefit ratio is similar to treatment with NOACs. We therefore suggest that patients well-established on warfarin therapy continue with this if they wish.

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Benefits and harms

New oral anticoagulants versus warfarin per 1,000 patients treated for 1 year:

Death and stroke: No significant difference

Major bleeding: Overall no relevant difference, but the number of intracranial bleeds was halved with dabigatran, resulting in a absolute risk reduction of 2 fewer per 1000 patients

Myocardial infarction: No significant difference. The exception is dabigatran, which increased the risk compared to warfarin. The absolute risk, however, is generally very low: 5/1000 with warfarin, 6/1000 with dabigatran.

Treatment discontinuation (e.g. due to side effects): 31 interrupted with warfarin, 39 with NOAC.

Practical consequences: Daily medication with all. Regular INR controls and dietary restrictions with warfarin.

Quality of evidence

Moderate. The expected effects of NOAC compared with warfarin is taken from a systematic review with heterogeneity, and imprecise results (wide confidence intervals) for death and bleeding. Dabigatran was associated with an increase in myocardial infarction and treatment discontinuation in a reliable subgroup analysis.

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

Puntuación CHA2DS2-VASc de 2 o más

Débil

No está tan claro si los beneficios superan claramente los inconvenientes. Esto significa que la mayoría de los pacientes elegirían el tratamiento recomendado. Sin embargo, hay una elevada posibilidad de variabilidad en las preferencias individuales.

Se sugiere el tratamiento con dabigatran, rivaroxaban o apixaban (nuevos anticoagulantes orales) frente a antagonistas de la Vitamina K (warfarina o acenocumarol)

View Less Details

PICO | **Información clave** | Justificación | Consejo práctico | Adaptación | Resumen | Discusión (0)

Población	Intervención	Comparador	Desenlaces
Fibrilación auricular y alto riesgo de ictus (puntuación CHA2DS2-VASc de 2 o más)	Nuevos anticoagulantes orales (inhibidires directos de la trombina)	Antagonista de la Vitamina K (warfarina, acenocuma	Mortalidad, ictus, sangrados mayores

Desenlaces | Resumen | Referencias

Desenlaces	Calidad De La Evidencia	Efecto Relativo	Antagonistas De La Vitamina K (Warfarina, Acenocumar	Nuevos Anticoagular Orales (Inhibidires Directos De La Trombina)	Diferencia Absoluta	Participantes (Estudios), Seguimiento
Mortalidad por cualquier causa (a 1 año)	Alta	RR 0.88 *(CI 0.82 - 0.96)*	63 *per 1000*	55 *per 1000*	8 menos *Por 1000* *(CI 11 menos - 3 menos)*	44.442 (3), 2 años
Ictus isquémico (a 1 año)	Alta	RR 0.89 *(CI 0.78 - 1.02)*	21 *per 1000*	19 *per 1000*	2 menos *Por 1000* *(CI 5 menos - 0 menos)*	44.442 (3), 2 años
Sangrados mayores (a 1 año)	Moderada *debido a heterogeneidad*	RR 0.88 *(CI 0.71 - 1.1)*	57 *per 1000*	50 *per 1000*	7 menos *Por 1000* *(CI 17 menos - 6 más)*	44.501(3), 2 years

Trials and surveys

- **Multicenter RCT 1:**
  - A randomized trial comparing evidence summaries with and without evidence based recommendations.
- **Survey / RCT 2:**
  - To determine physicians´understanding, attitudes and preferences concerning trustworthy guidelines in traditional and new presentation formats (using clickers)

DECISION AIDS

Implications of weak recommendations

- Many recommendations are weak
  - Patients: The majority of people in this situation would want the recommended course of action, but *many would not*.
  - Clinicians: Be more prepared to *help patients to make a decision* that is consistent with their own values

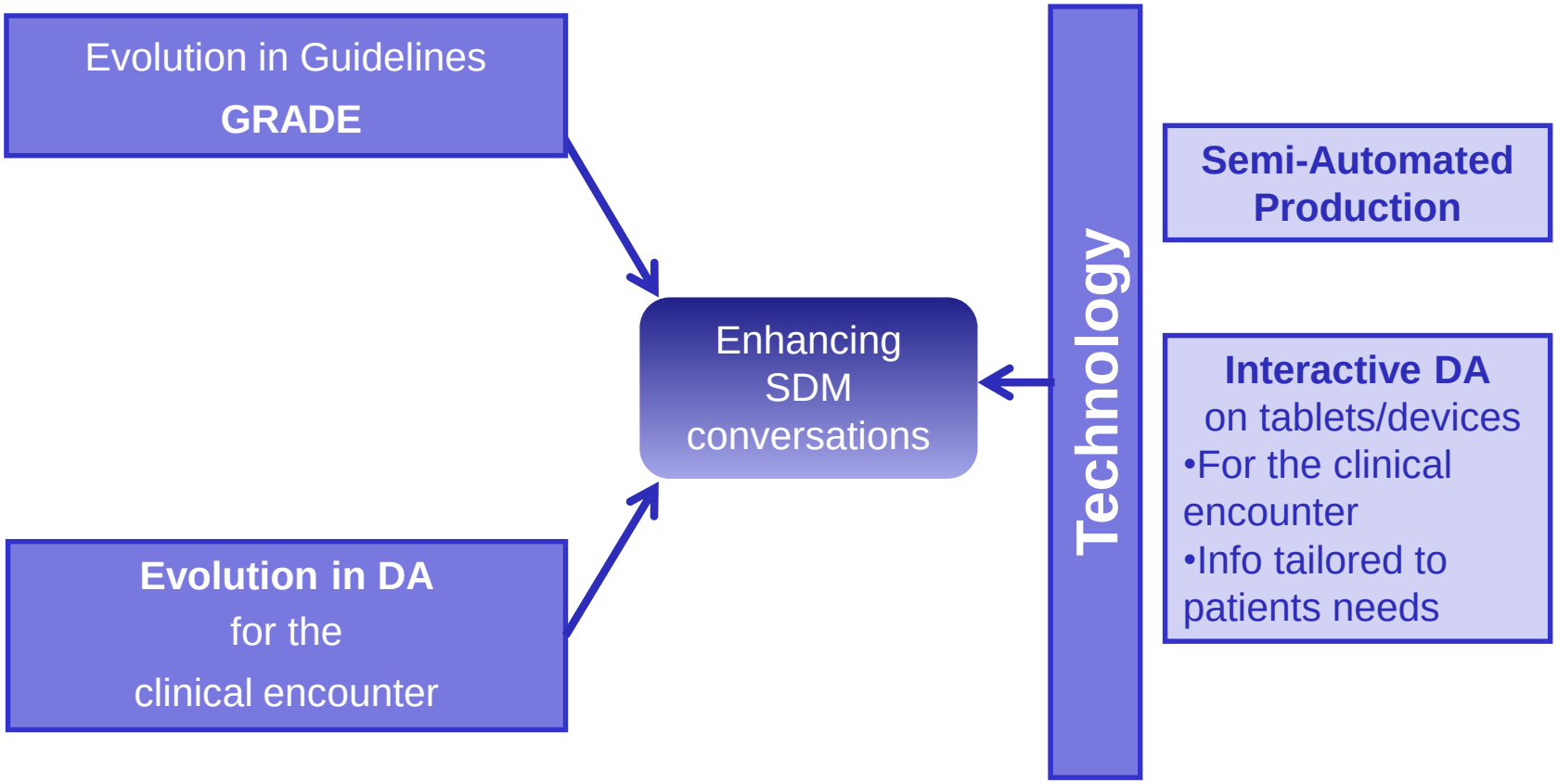
Decision aids (SHARE-IT)

- Weak recommendations warrant shared-decision making, but how?

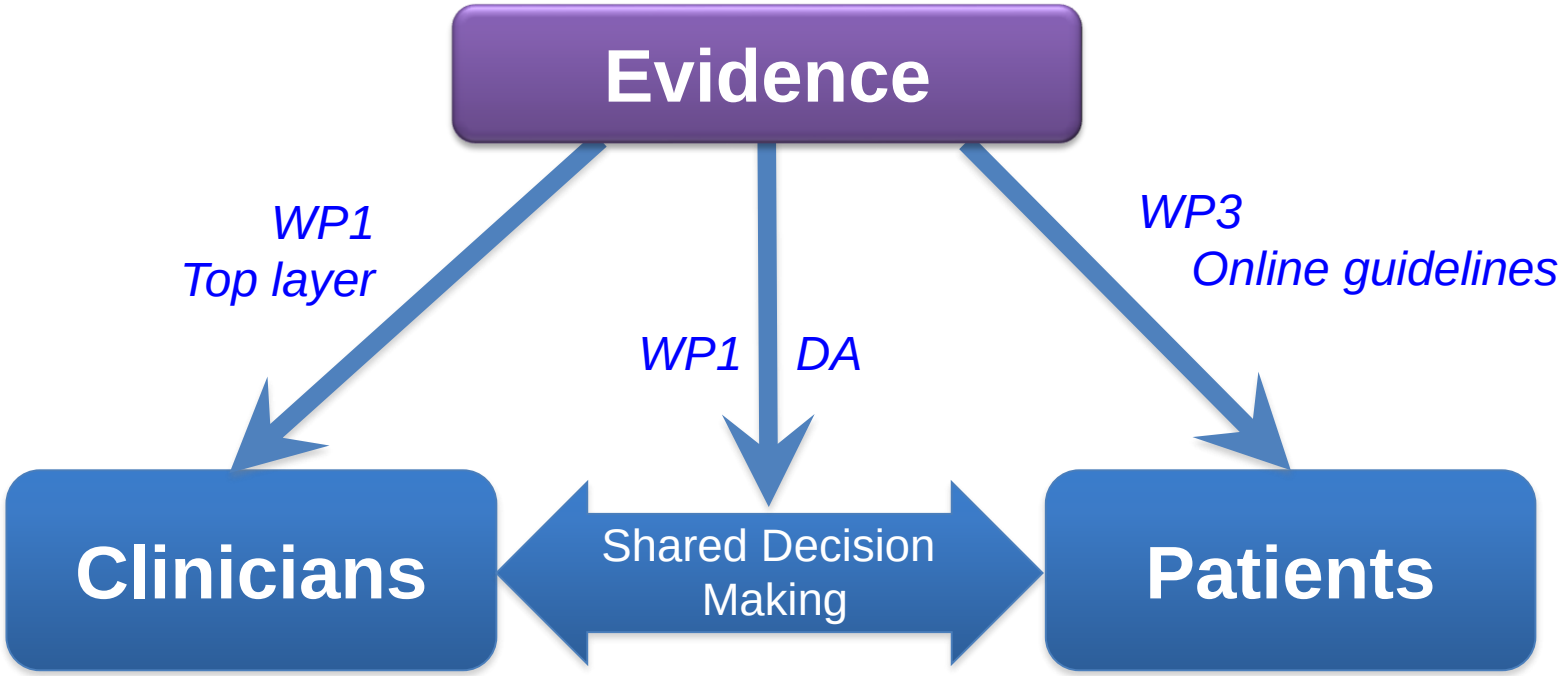
✓Decision aids linked to GRADE Guidelines

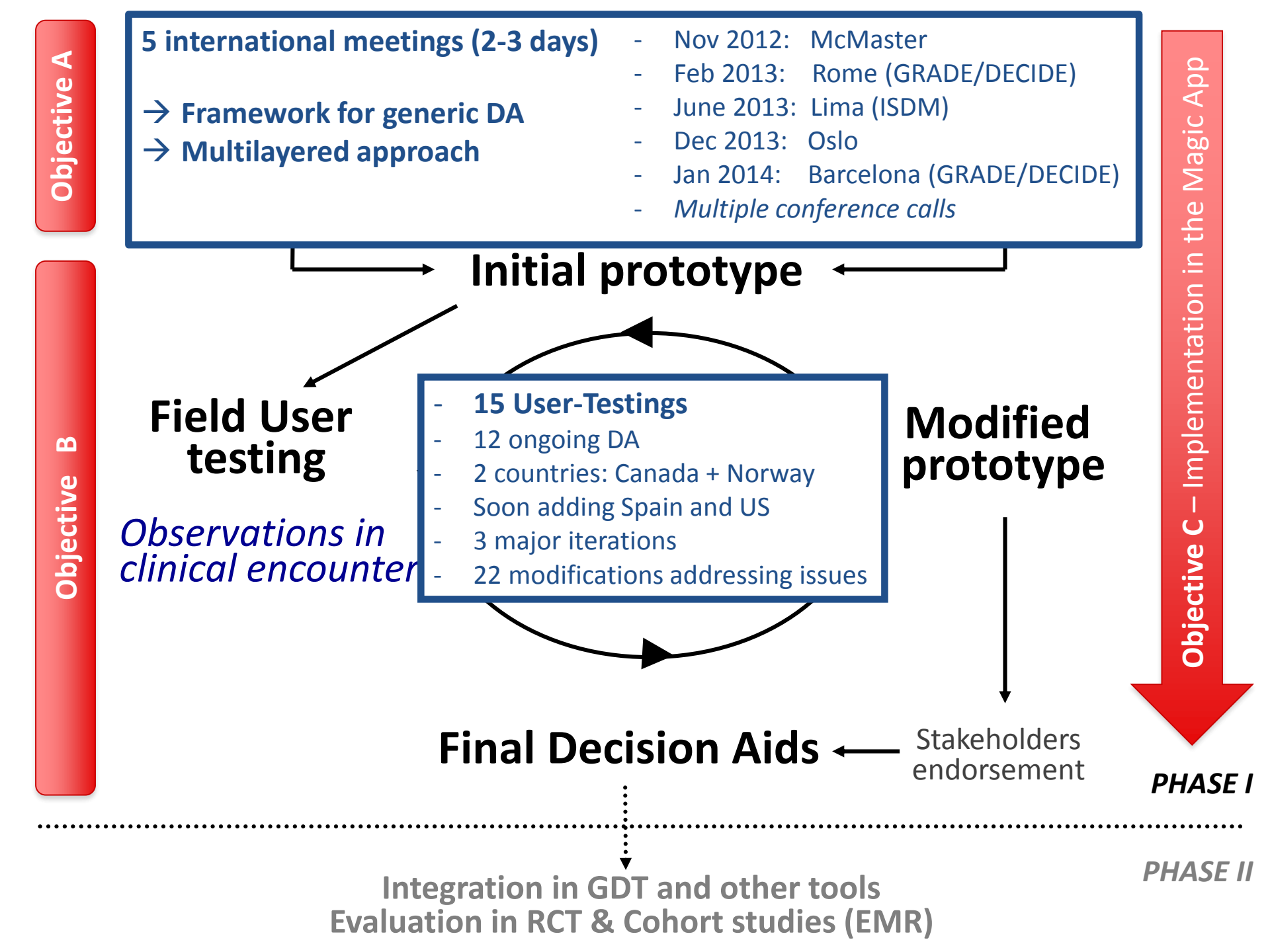
✓Designed to enhance the conversation during the clinical encounter

Decision aids

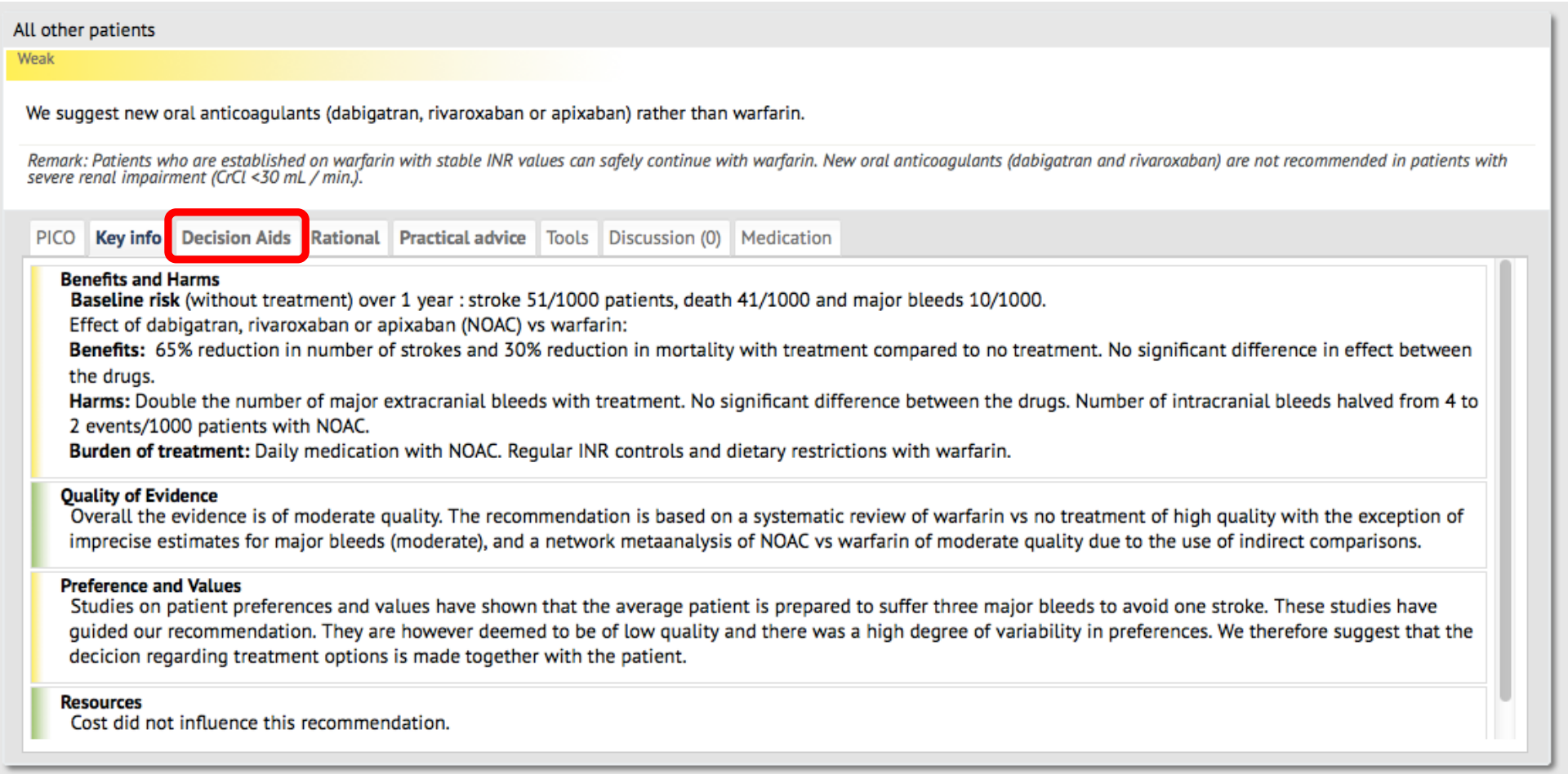


Evidence & SDM the point of care




Objective A
5 international meetings (2-3 days)
→ Framework for generic DA
→ Multilayered approach
- Nov 2012: McMaster
- Feb 2013: Rome (GRADE/DECIDE)
- June 2013: Lima (ISDM)
- Dec 2013: Oslo
- Jan 2014: Barcelona (GRADE/DECIDE)
- Multiple conference calls
Objective C – Implementation in the Magic App
Initial prototype
Objective B
Field User testing
Observations in clinical encounter
- 15 User-Testings
- 12 ongoing DA
- 2 countries: Canada + Norway
- Soon adding Spain and US
- 3 major iterations
- 22 modifications addressing issues
Modified prototype
Final Decision Aids
Stakeholders endorsement
PHASE I
PHASE II
Integration in GDT and other tools
Evaluation in RCT & Cohort studies (EMR)

Information one click away



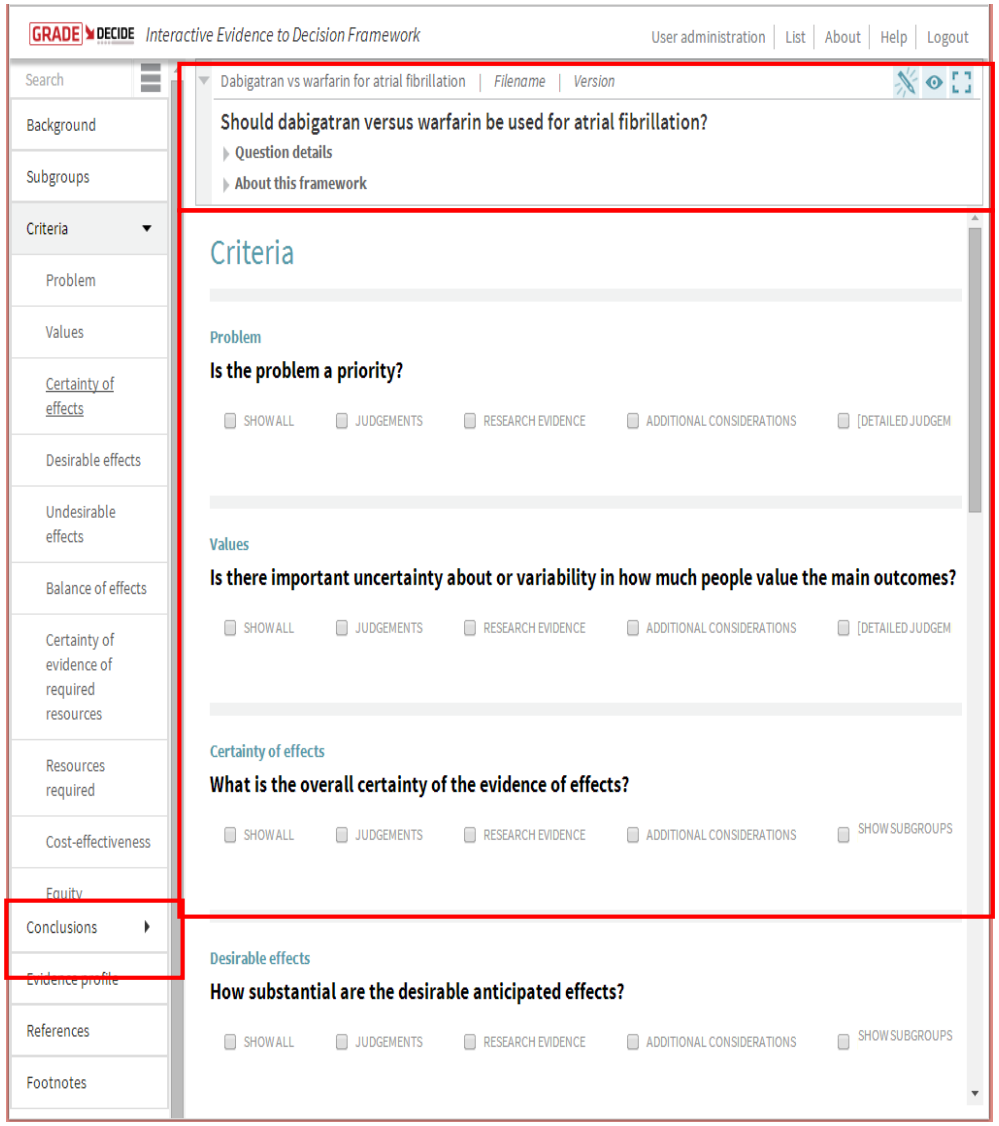
DECIDE GRADE

EVIDENCE TO DECISION FRAMEWORKS

EtD frameworks

- To help guideline panels (and decision makers) move from evidence to a recommendation or decision.
- Builds on previous work from GRADE
- Different frameworks for different types of decisions
  - Clinical, Health system, Coverage, Diagnostic
  - Worked coordinated across WPs
- Interactive and integrated in GDT
- Working on a series

EtD frameworks



DECIDE GRADE

Next steps

- Further refinement of top layer
  - User testing
  - Implementation and evaluation in guidelines
  - Decision aid template
  - User testing
  - Implementation in GDTs and guidelines
  - Test in RCTs / other designs
  - Evidence to decision framework
  - Further evaluation in guideline panels
    - Compare with standard less structured processes

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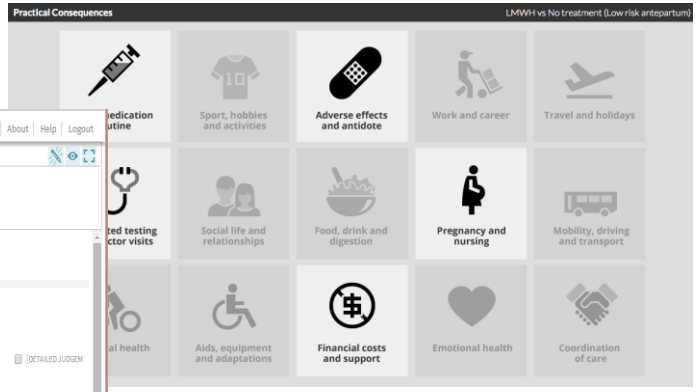

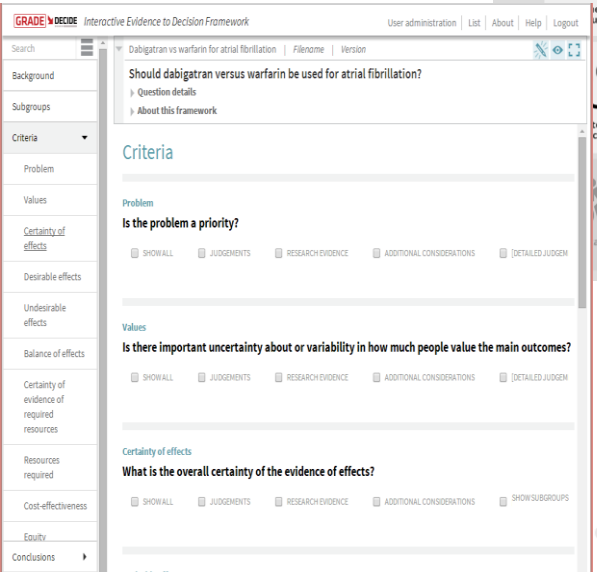

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