

DECIDE



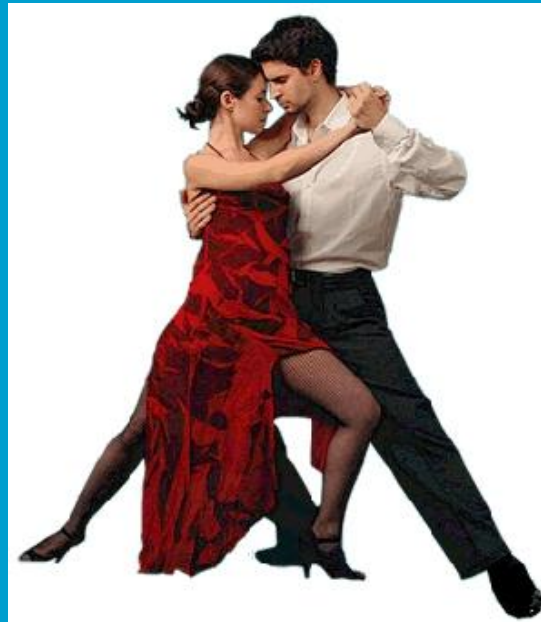
Developing and Evaluating
Communication strategies to support
Informed Decisions and practice
based on Evidence

GRADE

magic

making **GRADE**
the irresistible choice

Relating clinical decisions to evidence



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

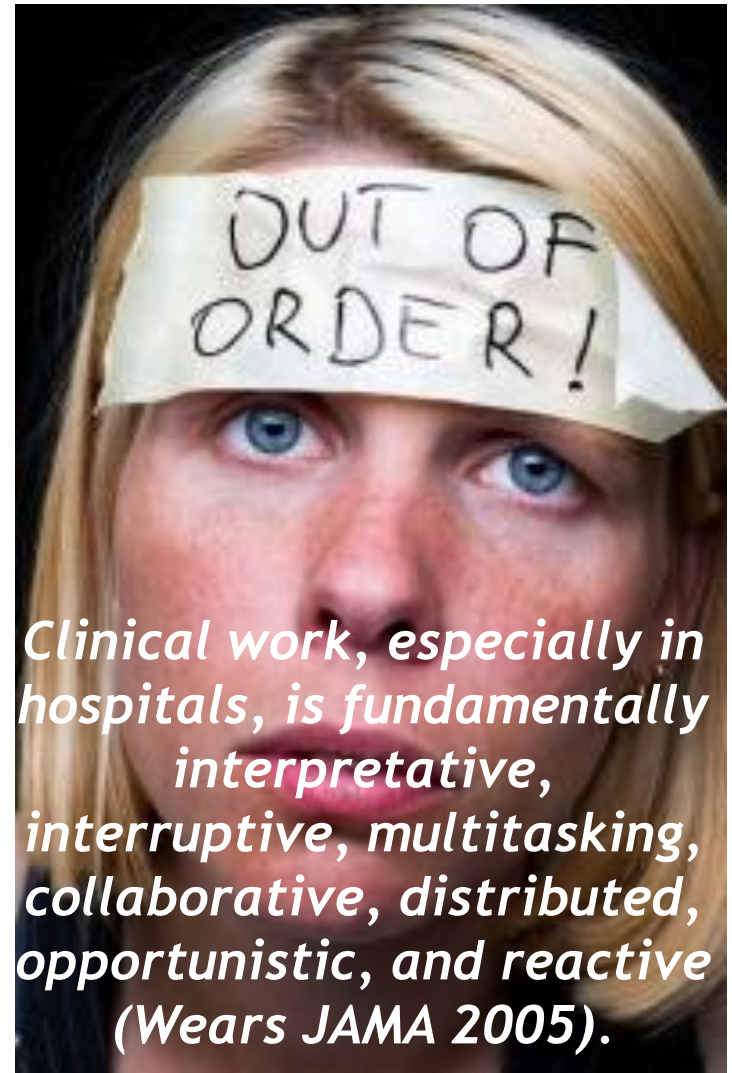


Sykehuset Innlandet HF

Relating clinical decisions to evidence

Scope of this talk:

- ✓ Clinical questions at the point of care, why bother?
- ✓ Evidence-based practice and trustworthy guidelines
- ✓ What are the problems with current guidelines?
- ✓ Real life implementation of DECIDE strategies through MAGIC
- ✓ Remaining challenges, solutions



Meet Anne, with abdominal complaints...

- 53 yrs, account manager
- DM II, hyperlipidemia and HT (high cardiovascular risk)
- Aspirin, statins, ACE-inhibitor
- Stomach pain past 6 months
- Upper endoscopy: Normal
- Diagnosis: Functional dyspepsia

Anne: ”*Do I really need aspirin? What is it good for?*”



How good are we at answering our questions?

Original Investigation

Clinical Questions Raised by Clinicians at the Point of Care A Systematic Review

Guilherme Del Fiol, MD, PhD; T. Elizabeth Workman, PhD, MLIS; Paul N. Gorman, MD

RESULTS In 11 studies, 7012 questions were elicited through short interviews with clinicians after each patient visit. The mean frequency of questions raised was 0.57 (95% CI, 0.38-0.77) per patient seen, and clinicians pursued 51% (36%-66%) of questions and found answers to 78% (67%-88%) of those they pursued. Overall, 34% of questions concerned drug treatment, and 24% concerned potential causes of a symptom, physical finding, or diagnostic test finding. Clinicians' lack of time and doubt that a useful answer exists were the main barriers to information seeking.

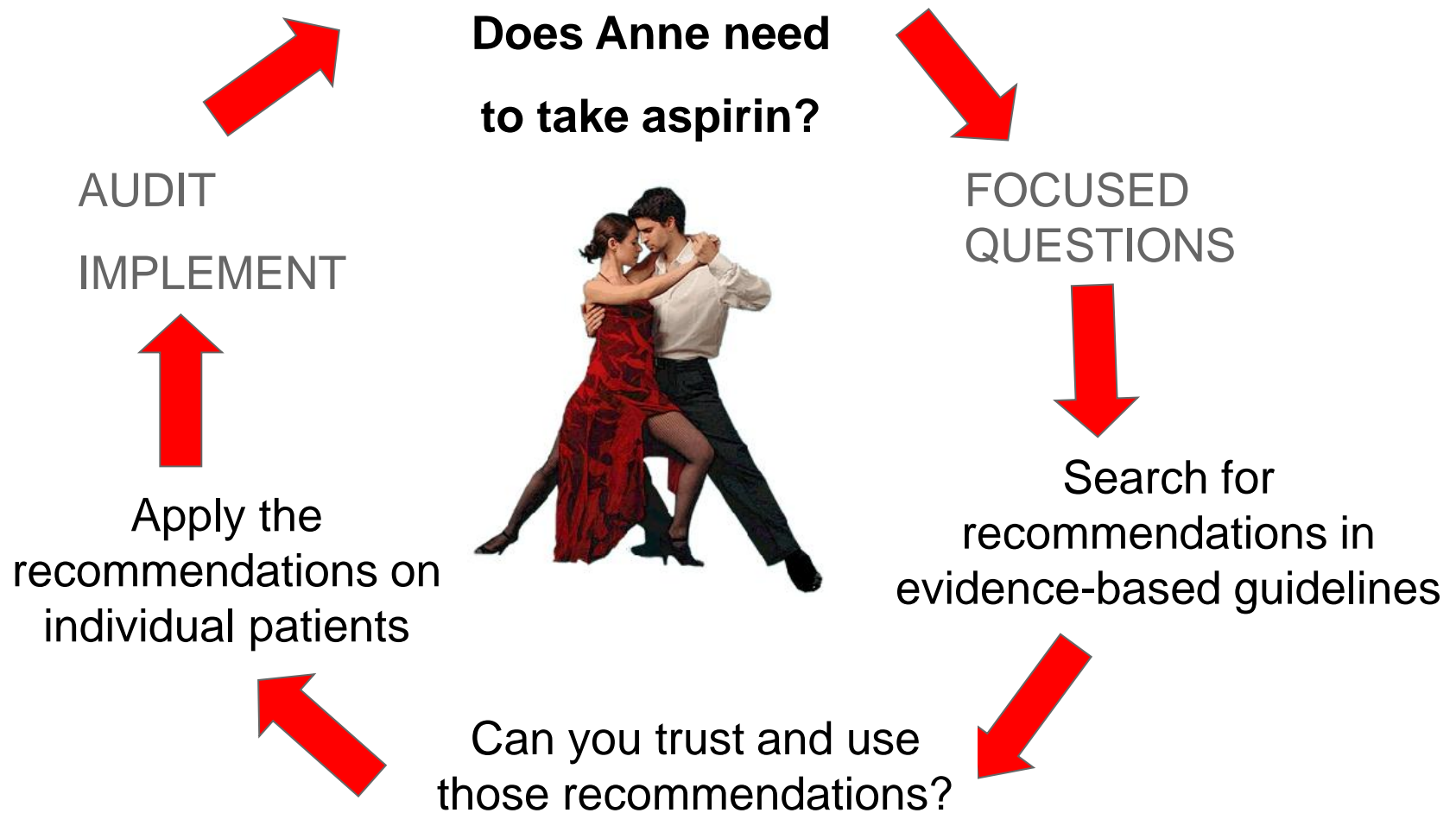
CONCLUSIONS AND RELEVANCE Clinicians frequently raise questions about patient care in their practice. Although they are effective at finding answers to questions they pursue, roughly half of the questions are never pursued. This picture has been fairly stable over time despite the broad availability of online evidence resources that can answer these questions. Technology-based solutions should enable clinicians to track their questions and provide just-in-time access to high-quality evidence in the context of patient care decision making. Opportunities for improvement include the recent adoption of electronic health record systems and maintenance of certification requirements.

studies with similar methods.

← Invited Commentary

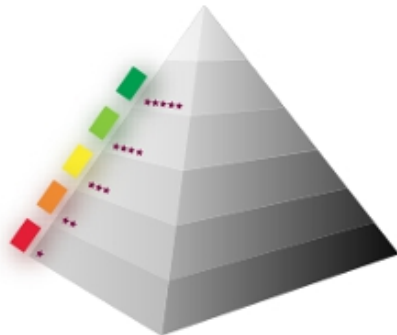


Walking steps of evidence-based practice 2014



How do we get to the evidence in Norway?

- Pyramid-search through Norwegian Electronic Health Library
- 6 S model: A hierarchy of information resources for clinical questions



6S model explained
Criteria for articles in **PLUS**

Oppslagsverk ★★★★★

UpToDate

Best Practice

Oppsummerte oversikter ★★★★★

ACP Journal Club (via PLUS)

DARE

Systematiske oversikter ★★★★★

PLUS Syntheses

Oppsummerte enkeltstudier ★★★★★

ACP Journal Club (via PLUS)

Enkeltstudier ★★★★★

PLUS Studies

Oppslagsverk ★★★★★

UpToDate

Benefits and risks of aspirin in secondary and primary prevention of cardiovascular disease

Where are the national or local guidelines?

Oppsummerte oversikter ★★★★★

ACP Journal Club (selected via PLUS)

Review: Daily aspirin reduces short-term risk for cancer and cancer mortality

Review: Aspirin does not reduce CHD or cancer mortality but increases bleeding

More Results...

Systematiske oversikter ★★★★★

PLUS Syntheses

Oral 5-aminosalicylic acid for maintenance of remission in ulcerative colitis. *(Systematic Review)*

Safety, effectiveness, and cost-effectiveness of new oral anticoagulants compared with warfarin in preventing stroke and other cardiovascular events in patients with atrial fibrillation. *(Systematic Review)*

More Results...

Oppsummerte Enkeltstudier ★★★★★

ACP Journal Club (selected via PLUS)

Aspirin in the primary prevention of cardiovascular disease and cancer

www.uptodate.com/contents/aspirin-in-the-primary-prevention-of-cardiovascular-disease-and-cancer?source=see_link#H1761645

aspirin primary prevention

All Topics Contents Patient Info What's New PCUs Calculators Drug Interactions

Aspirin in the primary prevention of cardiovascular disease and cancer

Find Patient Print Email

Topic Outline

SUMMARY & RECOMMENDATIONS

INTRODUCTION

MECHANISM OF ACTION

PRIMARY PREVENTION OF CARDIOVASCULAR DISEASE

PRIMARY PREVENTION OF CANCER

- Aspirin and cancer incidence
 - Colorectal cancer
 - Other cancers
- Aspirin and cancer mortality

TOTAL MORTALITY

ADVERSE EFFECTS OF ASPIRIN

- Bleeding
 - Rates
 - Risk factors for aspirin-associated bleeding
 - Primary prevention of aspirin-induced GI bleeding
- Aspirin sensitivity

DOSING

- Prevention of cardiovascular events
- Prevention of cancer events
- Bleeding

disease and cancer (Beyond the Basics).)

SUMMARY AND RECOMMENDATIONS

- [Aspirin](#) modestly decreases the risk of non-fatal myocardial infarction, cancer incidence, and overall mortality in patients without underlying cardiovascular disease and at average cancer risk, but increases the risk of major bleeding. (See '[Primary prevention of cardiovascular disease](#)' above and '[Primary prevention of cancer](#)' above and '[Total mortality](#)' above and '[Bleeding](#)' above.)
- Estimates of the very small absolute benefits and risks of [aspirin](#) in primary prevention are provided in a table ([table 1](#)). Clinicians can use these estimates as a starting point for discussions with individual patients. Not all informed patients will choose to use aspirin and individual discussion is imperative. (See '[Estimating benefits and risks](#)' above.)
- Factors to be considered in this discussion include assessment of the individual's risk for each outcome (cardiovascular events, cancer, bleeding, and total mortality); assessment of the relative value the individual places on preventing specific outcomes; assessment of the patient's attitude to inconvenience of long-term daily therapy; and value placed on immediate increase in risk of bleeding versus delayed potential benefit on cancer and death. (See '[Individualizing decisions for aspirin prophylaxis](#)' above.)
- In many adults, the benefits of [aspirin](#) exceed the risks (principally bleeding). For individuals age ≥ 50 years without excess bleeding risk, we suggest low-dose daily aspirin (75 to 100 mg) (**Grade 2B**). Patients who are more concerned about the bleeding risks than the potential benefits (prevention of cardiovascular events and cancer) may reasonably choose to not take aspirin for primary prevention. (See '[Recommendations for primary prevention](#)' above.)

Topic Feedback

Doctor 56 yrs old: "Aspirin to everyone above 50? Are you kidding me?"

Discuss with your neighbour: What does GRADE 2B mean?

National guidelines, what do they say?

NEL | Norsk Elektronisk Legehåndbok

primærforebygging

SØK

Avdeling For Kunnskaps
Allmenlege

Håndboken

Favoritter

Ordliste

Hjelp

Om NEL

Fagmedarbeidere

Kontakt

Innstillinger

Logg ut

Forside › Hjerte/kar › Tilstander og sykdommer › Koronarsykdom › Primærforebygging hjer...

Kliniske kapitler

Medisinske

Recommendation translated to Scottish:
Aspirin 75 mg recommended only to persons with high to very high cardiovascular risk, and for women only to those older than 65 yrs

Endokrinologi

Fysmed og rehab

Generelt

Geriatric

Gynekologi

Helsestasjon/skole

Hjerte/kar

› Symptomer og tegn

› Tilstander og sykdommer

• Det er ikke vist effekt av acetylsalisylsyre for å forebygge hjerte-kar-sykdom hos pasienter med diabetes¹⁴

• Blodtrykk må være under kontroll (< 160 mmHg systolisk)

• ASA bør brukes med forsiktighet hos personer med tidligere gastrointestinale blødninger og er kontraindisert ved acetylsalisylsyreutløst allergi/astma

• I følge en metaanalyse er ASA effektiv både i den primære og sekundære forebyggingen av vaskulære hendelser, men i primærforebyggingen oppveier nesten blødningskomplikasjoner de gunstige effektene (1a)¹⁵

• Anbefalinger fra Storbritannia (2009): ASA bør ikke rutinemessig benyttes som

Clinical practice guidelines: The good, the bad and the ugly

ORIGINAL INVESTIGATION

ONLINE FIRST | HEALTH CARE REFORM

Failure of Clinical Practice Guidelines to Meet Institute of Medicine Standards

Two More Decades

Justin Kung, MD; Ram F

Background: In March 2002, the Institute of Medicine (IOM) issued a new set of standards for guideline development. Guidelines intended to be produced. To our view of adherence to standards taken since one published.

Methods: Two review guidelines selected at random from the National Guidelines Clearinghouse (NHC) against 18 of 25 IOM standards.

Results: The overall methodological standards satisfied (out of 18) had an interquartile range of 6 to 10, less than half of the guidelines met the IOM standards. Bias was reduced by subspecialty standards of the IOM standards. Conflicts of interest (COIs) were found in the guidelines surveyed. Such information, COIs, and other information should

INVITED COMMENTARY

ONLINE FIRST

In Guidelines We Cannot Trust

The Institute of Medicine (IOM) recently updated its standards for guideline development.¹ If adhered to, trustworthy guidelines should follow. Trustworthiness connotes integrity, dependability, and reliability. Unfortunately, in guidelines we cannot trust.

In the late 1990s, 2 colleagues and I critically appraised a broad set of published guidelines and found that guidelines adhered to less than half of the methodological standards for guideline development.² We opined that since the guideline industry was in its infancy, over time developers would adhere to recommended standards of guideline development. As demonstrated by Kung et al³ in this issue of the *Archives*, guidelines are still not following guidelines.

Kung et al³ scrutinized 114 guidelines published in the National Guidelines Clearinghouse against 18 of the standards recently set forth by the IOM.¹ Despite some methodological limitations, Kung et al³ found that the overall

should have no COIs.¹ While I laud this ideal we have little evidence regarding the impact on guideline quality and the resulting recommendations by policies prohibiting relations with industry, and there is the potential cost of the loss of subject expertise on guideline panels. Disclosure alone is insufficient to protect against COIs. I favor an approach championed by the American College of Chest Physicians' Antithrombotic Guidelines, in which panel members with significant COIs do not participate in discussions or voting on recommendations for which they have COIs but may offer written input so that clinical and research expertise is maintained.³

A closely related topic that limits guideline trustworthiness is the often single subspecialty panel composition. Members of a clinical specialty are likely to recommend interventions for which their specialty serves a role. One needs to look no further than prostate cancer screening guidelines for evidence of this. Groups without mul-

Trustworthy guidelines: New standards and definitions

New definition

“Clinical Practice Guidelines are statements that include recommendations intended to optimize patient care. They are informed by a systematic review of evidence and an assessment of the benefits and harms of alternative care options”

Wide consensus



Imagine you found a trustworthy guideline for Anne

- Are these guidelines
- ✓ Created efficiently?
- ✓ Available, useful and understandable for clinicians?
- ✓ Suited for integration into EMRs, EBM textbooks and adaptation?
- ✓ Sufficiently up to date?
- ✓ Facilitating shared decisions?
- We need to do better!

Table 3—[Section 2.1.4.1.5] Aspirin Plus Clopidogrel vs Aspirin in the Secondary Prevention of Cardiovascular Events

Outcomes	Participants (Studies), Follow-up	Quality of the Evidence (GRADE)	Relative Effect (95% CI)		Anticipated Absolute Effects Over 5 y	
			Risk With Aspirin	Risk Difference With Clopidogrel (95% CI)	Risk With Aspirin	Risk Difference With Clopidogrel (95% CI)
Total mortality ^a	15,603 (1 RCT), 28 mo	Moderate due to imprecision	RR 0.69 (0.46–1.04)		No significant difference; 1 fewer per 1,000 (from 17 fewer to 17 more)	
MI and fatal events	15,603 (1 RCT), 28 mo	Moderate due to imprecision	RR 0.94 (0.75–1.38)		No significant difference; 5 fewer per 1,000 (from 20 fewer to 14 more)	
Stroke includes nonfatal ischemic and hemorrhagic stroke ^b	15,603 (1 RCT), 28 mo	Moderate due to imprecision	RR 0.81 (0.64–1.02)		No significant difference; 21 fewer per 1,000 (from 43 fewer to 1 more)	
Major cardiovascular benefit ^c	15,603 (1 RCT), 28 mo	Moderate due to imprecision	RR 1.05 (0.92–1.63)		No significant difference; 10 more per 1,000 (from 3 fewer to 24 more)	

See Table 1 through 3 for details for estimation of absolute risks.

^aOf the deaths in the CHARISMA (Clopidogrel for High Atherothrombotic Risk and Ischemic Stroke) trial, 17 of 271 (6%) with aspirin were fatal bleeds, and 26 of 274 (4.9%) with clopidogrel and aspirin were fatal bleeds.

^bUpdated down for imprecision because of wide CIs for absolute effects, suggesting important benefit, no benefit, or important harm with clopidogrel for all outcomes. Not rated down for inconsistency, although subgroup analysis found no significant effect of clopidogrel on vascular mortality in patients with established cardiovascular disease in contrast with increased mortality in asymptomatic patients. We judged claim of subgroup effect to be not credible. High number of subgroup hypotheses tested, and/or whether appropriate test for interaction used.

^cControl group risk estimates for total mortality come from the aspirin arm of the CHARISMA trial. Estimation for MI and stroke come from observed events in a meta-analysis of 16 RCTs in secondary prevention of cardiovascular disease.

^dOf the strokes in CHARISMA, 27 of 180 (15%) with aspirin were intracranial hemorrhages, and 26 of 179 (17%) with clopidogrel were intracranial hemorrhages.

^eWe included fatal bleeding and intracranial hemorrhage to avoid the double counting of events in the CHARISMA trial. Proportion of severe GI bleeds in CHARISMA was 0.65% (not reported separately for each treatment arm).

^fControl group risk estimates come from observed major bleeding events in the CAPRIE (Clopidogrel Versus Aspirin in Patients at Risk of Ischemic Events) trial, adjusted to a 5-y time frame, and not from the 10 studies included in the meta-analysis or from CHARISMA because these studies did not report major bleeds consistently.

DECIDE WP1: health professional focussed strategies



[Home](#)

DECIDE

Developing and Evaluating Communication Strategies to Support Informed Decisions and Practice Based on Evidence



[Home](#)

[Queries & Staying Informed](#)

[Project Partners & Coordinating Person](#)

[Work Packages & Strategies](#)

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[Work Package 2](#)

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[Member login](#)

Work Packages & Strategies

- WP 1: [Health professional focussed strategies](#) for communicating evidence-based recommendations
- WP 2: [Policymaker and manager focussed strategies](#) for communicating evidence-based recommendations
- WP 3: [Patient and public focussed strategies](#) for communicating evidence-based recommendations
- WP 4: Strategies for communicating evidence based recommendations about [diagnostic tests](#)
- WP 5: Strategies for communicating evidence to inform decisions about [health system and public health interventions](#)
- WP 6: Strategies for **collaboration** among European guideline developers and health technology assessment agencies in Europe
- WP 7: [Dissemination and exploitation](#)
- WP 8: [Management](#)

Related Resources

[Grade Working Group](#)

[Cochrane Applicability and Recommendations Methods Group](#)

Search

Search this site:

Our news

[Professor Bruce Guthrie - DECIDE conference opening speaker](#)

[DECIDE workshop sessions confirmed](#)

[DECIDE Conference workshops](#)

GDT will implement DECIDE dissemination strategies

The image shows a web browser window at the top with the URL www.guidelinedevelopment.org. The browser's address bar and tabs are visible. Below the browser, a banner for the GDT website features the GDT logo, the text "A new quality in guideline development", and "Brought to you by the creators of GRADEpro (GRADE Working Group)". A diagonal banner on the right says "Contact support".

In the foreground, a laptop displays the GRADE software interface. The interface shows a table of evidence with columns for "Study design", "Risk of bias", "Inconsistency", "Indirectness", "Imprecision", "Other considerations", "Summary of findings", "Effect", "Relative 95% CI", "Absolute 95% CI", "Quality", and "Importance". The table contains data for "Should Chronic daily headache (SDH) be treated for preventing migraine and tension-type headaches?".

Overlaid on the right side of the laptop are two blue buttons: "Login" with a right-pointing arrow, and "Create bookmark to launch offline". Below these buttons, the text "it's FREE" is displayed in green.

MAGIC research and innovation program performs research in collaboration with DECIDE

MAGIC – Making GRADE the irresistible choice. Creating guidelines we can trust, use and share

Mozilla Firefox Start Page x MagicApp – Making GRADE the ... x MAGIC – Making GRADE the irre... x

www.magicproject.org

Most Visited Getting Started Apple Disney Yahoo! Google MAGIC BMJ Quality and ... G-I-N 2013 – Sa... Centres for Rese... Magic website

magic
making **GRADE**
the irresistible choice

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Creating trustworthy medical guidelines that we can all use and share

MAGIC is a **non-profit initiative** working to improve the creation, dissemination and dynamic updating of GRADE guidelines. We accomplish this through good methodology and international collaboration combined with the latest technology and clean design.

With your help, we can bring medical guidelines into the 21st Century! Visit our authoring and publication platform, **MAGICapp**, and learn how easy it is to start making high quality medical guidelines today.

Sign Up for Email Updates

Stay up to date with the latest from Magic.

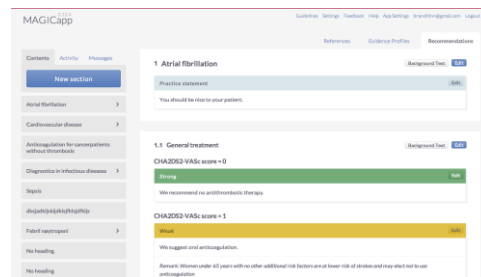
We respect your privacy and won't share your email address.

EMAIL ADDRESS... →

magic app authoring and publication platform



Guideline panel using MAGICapp



Guideline authoring tool and publication platform (MAGICapp)

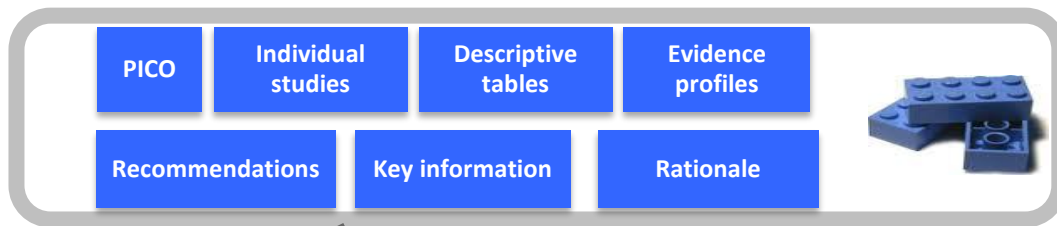
New evidence

THE LANCET



Compression stockings to prevent post-thrombotic syndrome: a randomised placebo-controlled trial

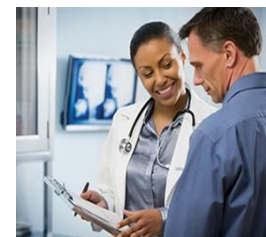
Dynamic updating



Database structured and tagged content



Decision aids for patients and clinicians



Multilayered Guideline outputs

Web + App



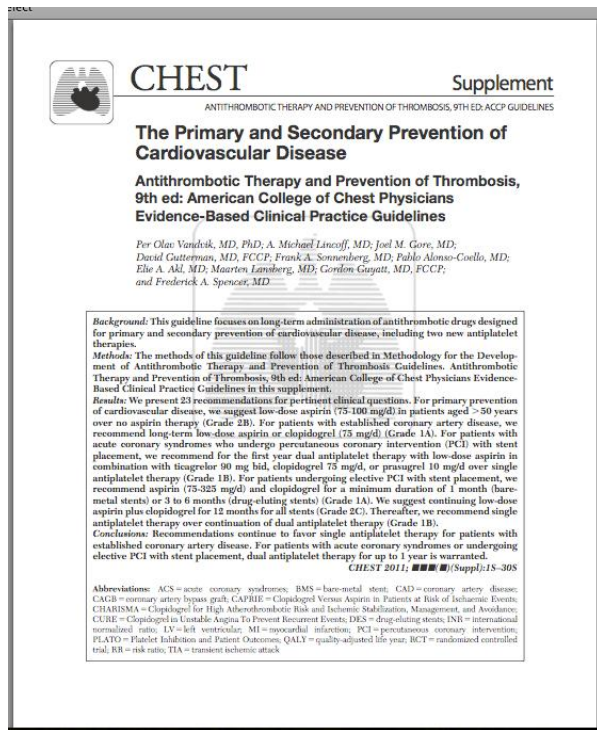
Integrated in the EMR



Adaptation National/ local or EBM Textbooks



Developing and testing DECIDE WP1 strategies through MAGICapp and national adaptation of guidelines




Authoring of multilayered guideline formats, insights so far:

- Feasible to create and publish, difficult to write
- Transparent and systematic adaptation process was painful

Kristiansen A, Brandt L, Alonso P, et al. CHEST 2014-online

DECIDE phase 3: Implementing and testing multilayered guideline formats in Norway

 Norsk Selskap for Trombose og Hemostase

Home Settings Feedback Help Account Logout ONLINE

Primary prevention of CAD

Sections Activity Messages

Add New Section

Disease

Antithrombotic Therapy for Atrial Fibrillation

Antithrombotic and Thrombolytic Therapy for Ischemic Stroke

Primary and Secondary Prevention of Cardiovascular Disease

Antithrombotic Therapy in Peripheral Artery Disease

VTE, Thrombophilia, Antithrombotic Therapy, and Pregnancy

References Evidence Profiles Recommendations

10.1 Primary prevention

Background Text Add Recommendation

Cardiovascular risk score (NORRISK)

Weak recommendation Options

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

We suggest aspirin 75 mg daily to patients at high cardiovascular risk (10 year risk of cardiovascular death > 10%).

Effect estimates Key info Rationale Practical advice Adaptation References Discussion (0)

Show selected Show section Show all

Selected	Title	Pubmed Link	Journal Link
<input checked="" type="checkbox"/>	Vandvik et al. Primary and secondary prevention of cardiovascular disease: Antithrombotic Therapy and Prevention of Thrombosis, 9th ed: American College of Chest Physicians Evidence-Based Clinical Practice Guidelines. Chest 2012;141:e637S-e668S	22315274	10.1378/chest.11-2306
<input checked="" type="checkbox"/>	Baigent C, Blackwell L, Collins R, et al. Collaborative meta-analysis of randomised trials of antiplatelet therapy for prevention of death, myocardial infarction, and stroke in high risk patients. BMJ.	11786451	10.1136/bmj.324.7329.71

Insights from DECIDE WP1 research so far

From user-testing, surveys/ trials and real life observations

- Multilayered formats
 - ✓ Well accepted, useful, preferred
 - ✓ Conceptual (mis) understanding
 - ✓ Further improvements necessary
 - ✓ Ready to be applied in your guidelines
- Optimised formats not enough!
Are guidelines:
 - Possible to find, navigate and use?
 - ✓ Integrated in EMR, localized?
 - ✓ Kept up to date?

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 Adaptation

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

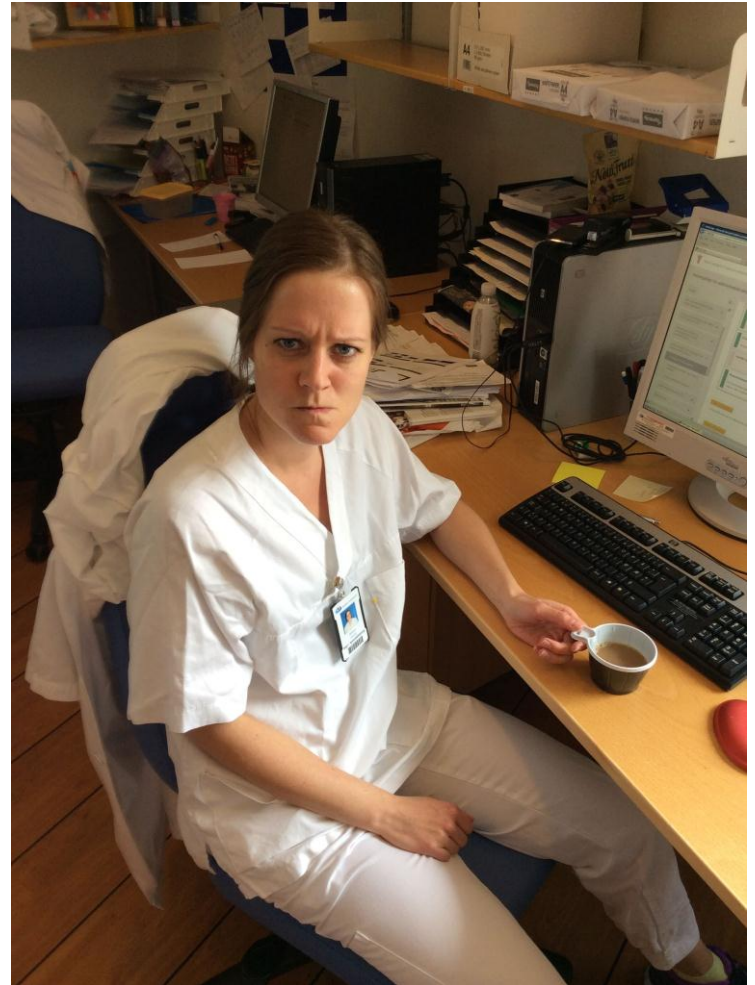
Moderate. The expected effects of NOAC compared with warfarin is taken from a systematic review with heterogeneity, and imprecise results (wide confidence intervals) for death and bleeding. Dabigatran was associated with an increase in myocardial infarction and treatment discontinuation in a reliable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

Preference and values

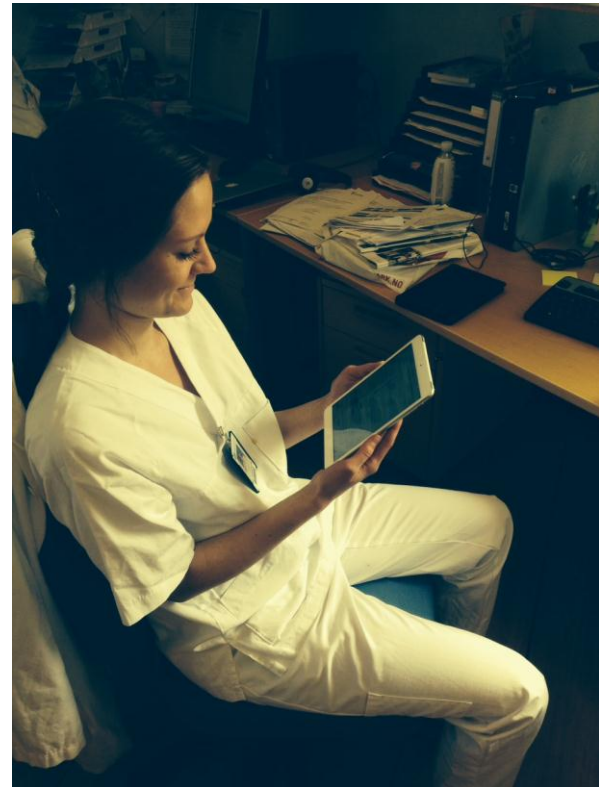
Studies on patient preferences and values have shown that the average patient is prepared to suffer three major bleeds to avoid one stroke. These studies have guided our recommendation. They are however deemed to be of low quality and there was a high degree of variability in preferences. We therefore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

Remaining challenges: The long and winding road

- Clinical question: *Should my bedridden patient with pneumonia get thromboprophylaxis?*
- *"Oh, there is a new guideline for this? That 's nice..."*
- 3 minutes, still no answer
- Showstopper, angry doc..
- Thanks Internet Explorer 8



Solutions: Answer in 17 seconds on tablet
(happy doctor, strong recommendation for
thromboprophylaxis, patient got the right treatment ;-)





SHARE IT

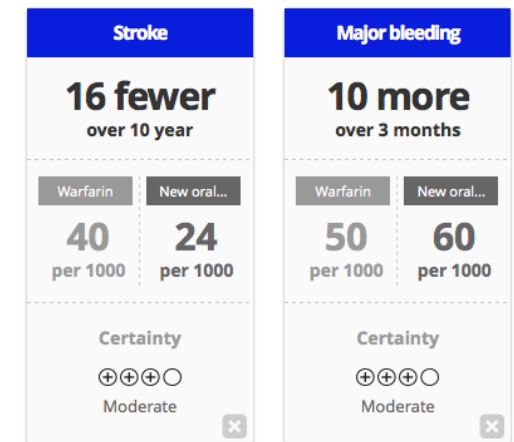
(Sharing Evidence to Inform Treatment decisions)



DECISION AIDS LINKED TO RECOMMENDATIONS IN
GRADE GUIDELINES TO IMPROVE SHARED DECISION
MAKING IN CLINICAL CONSULTATIONS

- Weak recommendations: Shared decisions becomes key but how?
- We develop decision aids that
 - ✓ *Display benefits, harms, burdens to clinicians and patients, to **create discussions***
 - ✓ *Based on best current published research evidence*
- Research ongoing with development (user-testing) optimal presentation formats in consultations

Among a 1000 patients like you, with new oral anticoagulants



Choose and compare outcomes

Mortality

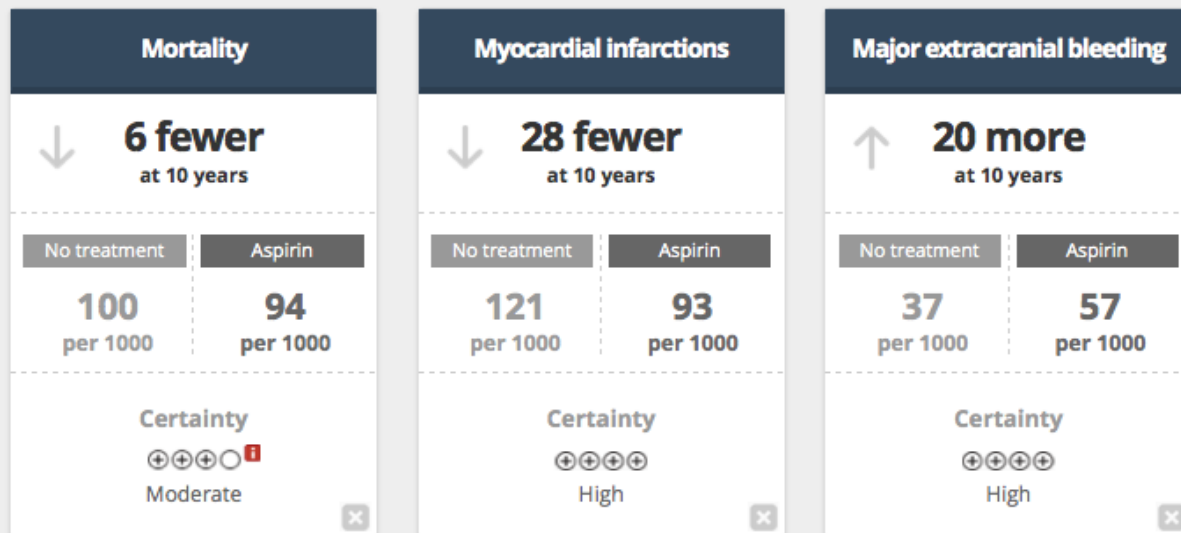
Stroke

Major bleeding

Practical consequences

Low dose aspirin vs. no treatment for primary prevention ▼

Among a 1000 patients like you, with aspirin



Choose and compare outcomes

Mortality

Myocardial infarctions

Non-fatal stroke

Major extracranial bleeding

Practical consequences



Walking steps of evidence-based practice 2014

**Does Anne need
to take aspirin?**

Focused clinical question in
PICO format

Search for
recommendations in
evidence-based guidelines

Weak recommendation
for aspirin in trustworthy
guideline, answer within 2
minutes

Share evidence with Anne,
she decided not to take
aspirin

How do we implement these
guidelines in practice?



In summary

- Trustworthy guidelines answer questions by relating best current evidence to clinical decisions. They need to
 - ✓ Be easy to find, use and understand point of care
 - ✓ Facilitate shared decision making
- DECIDE WP1 strategies show promise
- Conceptual understanding one main challenge
- Real life testing yields additional insights
- Implementation in your guidelines would be great!



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

