W14: Practical interpretation of research evidence for shared decision making

Workshop Chair: Marco Blanker, Netherlands
28 August 2018 13:30 - 15:00

Start	End	Topic	Speakers
13:30	13:35	Introduction	Marco Blanker
13:35	13:55	Quality of evidence in RCTs	Kari Tikkinen
13:55	14:10	Interpretation of OR for common conditions	Marco Blanker
14:10	14:30	Statistical significance vs. Clinical relevance vs. Patient importance?	Kari Tikkinen Philippe Violette
14:30	14:50	Decision aids - how to use it in clinical practice	Philippe Violette
14:50	15:00	Discussion	Marco Blanker Kari Tikkinen Philippe Violette

Aims of Workshop

In the 21st century a clinician must be adept at facilitating shared decision making with patients. The evidence for competing interventions in the field of LUTS and prolapse is increasingly complex. Furthermore, clinicians must master the skill of presenting this evidence for patients. A sound interpretation of estimates of harms and benefits is therefore vital. This workshop aims to provide ICS members with important principles of evidence based medicine (EBM) to enhance a better interpretation of evidence and enable shared decision-making.

Learning Objectives

Workshop attendees will learn:

A. How the GRADE approach can be used to summarise and rate a body of evidence.
B. How to judge the risk of bias in randomised trials and observational studies.
C. How to assess inconsistency of results as well as indirectness and imprecision of evidence.
D. How to compare and present different measures of effect size and understand the difference between patient importance and statistically significance.
E. How to interpret odds ratios for common conditions.
F. How to use decision aids to enable shared decision making for complex clinical choices.

Learning Outcomes

After the course, attendees will be able to

- Apply information from randomised controlled trial to the individual patient in the consultation room.
- Correctly interpret odds ratios for common conditions.
- Explain the difference between statistical significance and clinical relevance of study outcomes.
- Apply decision aids in clinical practice for shared decision making.

Target Audience

All members invited.

Advanced/Basic

Basic

Conditions for Learning

This is an interactive workshop in which the speakers will invite you to respond to questions and share your thoughts and opinions.

Suggested Reading

GRADE:
http://help.magicapp.org/knowledgebase/articles/191848-what-is-grade
http://help.magicapp.org/knowledgebase/articles/294932-how-to-rate-risk-of-bias-in-randomized-controlled
http://help.magicapp.org/knowledgebase/articles/294933-how-to-rate-risk-of-bias-in-observational-studies

Quality of evidence in RCTs
Kari Tikkinen, Finland

Randomized controlled trials (RCT) can provide the most reliable evidence for questions of efficacy, but do they always? The quality of evidence is based on more than study design alone. Many grading systems consider "study limitations" as a reason to reduce our certainty in evidence for RCTs. However, what does this really mean?
The Grading of Recommendations Assessment, Development and Evaluation (GRADE) working group has developed a systematic approach to assessing the evidence we use for clinical decision-making and guideline development. We will review the key concepts within this framework that are used to evaluate quality of RCTs, and observational studies.
Five factors can lower our certainty about this evidence:

1. Risk of bias (randomization, allocation concealment, blinding, Intention to treat),
2. Inconsistency
3. Indirectness
4. Imprecision
5. Publication bias

Occasionally there are factors that can increase our certainty as well

1. Large effect
2. Dose response
3. Residual confounding supports inferences about effect.

We will give and overview of these factors and how they apply to understanding and interpreting evidence.

Interpretation of OR for common conditions
Marco Blanker, The Netherlands

Epidemiological studies often present large odds ratios (ORs), or at least large ORs get much attention. Many physicians regard such high ORs as relevant for their patients. Mostly, ORs are interpreted as relative risks. So an OR of 4 is "translated" in to a four times higher risk for having the outcome. Physicians tend to regard higher risks as more relevant for patients. As a consequence, advises may enter guidelines.
When interpreting ORs, two questions need to be answered. First from what kind of study were the ORs derived? What is the baseline risk in these studies. In other words, what was the chance of having the outcome.
Both OR and RR can be calculated from the same 2x2 Table. Still, the interpretation may differ. We will show that OR and RR are nearly the same in case of low prevalence, and that OR and RR strongly differ in case of high prevalences.

Statistical significance Clinical relevance vs patient importance?
Kari Tikkinen, Finland & Phillippe Violette, Canada

High quality studies sometime identify "significant" results, but when to these matter? With sufficient number of patients in a study even very small differences can be statistically significant. A more important consideration is when we believe that these differences have a clinical meaning and impact an important aspect of patient care. The concept of clinical significance distinguishes mere mathematics from findings that can actually inform our practice. In the era of patient-centred medicine, it is also important to realize that we consider clinically relevant may not be the most important consideration for our patients. We will engage in an overview of these key concepts for modern evidence based urological care.

Decision aids - how to use it in clinical practice
Phillippe Violette, Canada

Some decisions in urology are straightforward and most patients would agree to one course of action. However, possibly more situations in urology are not so clear. Often there are two, three or more reasonable options for our patients, with different pros and cons. How do we help our patients to make the best decision when we don't know which one is "right"? These situations call for shared decision making. Unfortunately, its not so clear what that is and how to do it. We will explore the practical aspects of shared decision-making and how decision aids can be helpful in doing more than simply informing our patients.

Marco H. Blanker, MD PhD

ICS 2018 PHILADELPHIA

Affiliations to disclose†:

None

† All financial ties (over the last year) that you may have with any business organisation with respect to the subjects mentioned during your presentation

Funding for speaker to attend:

- [x] Self-funded
- [ ] Institution (non-industry) funded
- [ ] Sponsored by:

W14 – Schedule

ICS 2018 PHILADELPHIA

13:30	Introduction	Marco Blanker
13:35	Quality of evidence	Kari Tikkinen
13:55	Interpretation of OR for common conditions	Marco Blanker
14:10	Statistical significance vs. Clinical relevance vs. Patient importance	Kari Tikkinen
14:30	Decision aids - how to use it in clinical practice	Philippe Violette
14:50	Discussion	Marco Blanker Kari Tikkinen Philippe Violette

ICS 2018 PHILADELPHIA

- A shortened version of the handout has been provided on entrance to the hall
- A full handout for all workshops is available via the ICS website
- Please silence all mobile phones
- Please refrain from taking video and pictures of the speakers and their slides. PDF versions of the slides (where approved) will be made available after the meeting via the ICS website.

General introduction

ICS 2018 PHILADELPHIA

Shared decision making (SDM) is key in clinical practice

SDM involves applying scientific evidence about diagnostics and treatments to individual patients

EBM-triad

General introduction

ICS 2018 PHILADELPHIA

Shared decision making (SDM) is key in clinical practice

SDM involves applying scientific evidence about diagnostics and treatments to individual patients

Clinicians must master the skill of presenting this evidence for patients

Sound interpretation of estimates of harms & benefits is vital

Before afternoon tea you will be able to:

- How to interpret quality of evidence in RCTs
- Interpret Odds Ratios for common conditions
- Discuss the differences between statistical significance and clinical relevance of treatment outcomes
- Know how to use decision aids in clinical practice

Faculty

Kari Tikkinen, MD PhD, urologist & adjunct professor of clinical epidemiology, University of Helsinki, Finland

Philippe Violette, MSc. MD CM, urologist & assistant professor health research methods evidence and impact, McMaster University, Canada

Marco Blanker, MD PhD, general practitioner & epidemiologist, University of Groningen, the Netherlands

Who are you?

Personal introduction impossible, but please rise if you are a:

nurse

resident

urologist

GP

researcher

(pelvic) physiotherapist

(uro)gynaecologist

other:...

Who are you?

How do you rate your epidemiological knowledge/skills?

(please provide honest answer....)

Less than average

Average

Better than average

(What's average?)

Who are you?

Your input is more than welcome in this workshop

so feel free to interrupt, ask questions, or even correct us

Quality of evidence

Kari Tikkinen
Depts. of Urology and Public Health, Helsinki University Hospital and University of Helsinki, and Academy of Finland, Helsinki, Finland
www.clueworkinggroup.com
kari.tikkinen@gmail.com KariTikkinen

W14: Practical interpretation of research evidence for shared decision making
48th Annual Scientific Meeting of the International Continence Society
August 28, 2018 – Philadelphia, PA, USA

Kari Tikkinen

ICS 2018 PHILADELPHIA

Affiliations to disclose†:

None

† All financial ties (over the last year) that you may have with any business organisation with respect to the subjects mentioned during your presentation

Funding for speaker to attend:

- [ ] Self-funded
- [X] Institution (non-industry) funded
- [ ] Sponsored by:

Guidelines and clinicians

- increasingly, clinicians rely on formal guidelines
- strong recommendations
  - strong methods
  - large precise effect
  - few down sides of therapy
- weak recommendations
  - weak methods
  - imprecise estimate
  - small effect
  - substantial down sides

Proliferation of systems ☹
Common international grading ☺

- GRADE (*G*rades of *r*ecommendation, *a*ssessment, *d*evelopment and *e*valuation)
- international group
  - Australian NMRC, SIGN, USPSTF, WHO, NICE, Oxford CEBM, CDC, CC
- ~ 35 meetings over last 14 years
  - (~10 – 80 attendants – now 300 contributors)

THE COCHRANE COLLABORATION® World Health Organization UpToDate ACP American College of Physicians Internal Medicine | Doctors for Adults

>100 organizations have adopted GRADE

What are we grading?

two components

strength of recommendation:
strong and weak

Grading system – for what?

- interventions
  - management strategy 1 versus 2
- what grade is **not** about
  - individual studies (body of evidence)

What GRADE is not primarily about

- diagnostic accuracy questions
  - in patients with a sore leg, what is the accuracy of a blood test (D-Dimer) in sorting out whether a deep venous thrombosis is the cause of the pain
- prognosis
- what it is about: diagnostic impact
  - are patients better off (improved outcomes) when doctors use the d-dimer test

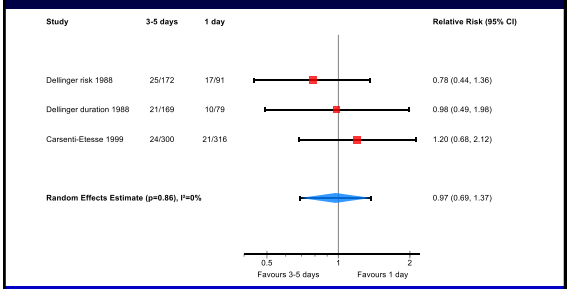
Determinants of quality

- RCTs start high
- observational studies start low
- what can lower confidence?

What can lower confidence?

- clue 1
  - lack of blinding in an RCT
- clue 2
  - RCT loses ½ patients to follow-up
- high risk of bias in RCTs lowers confidence

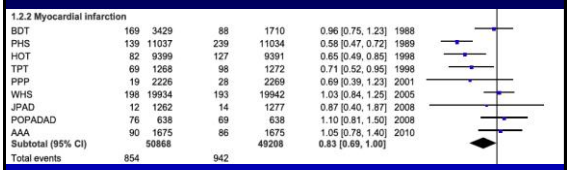
Clue: Have a look at the forest plot below –
Infections with short and long term antibiotics after open fractures



Any concerns?

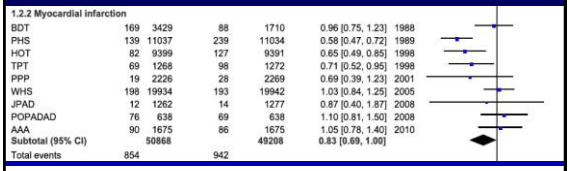
Another reason for rating down: imprecision

Clue: Have a look at the forest plot below
Aspirin in primary prophylaxis



Any concerns?

Another reason for rating down: inconsistency



More reasons to lose confidence

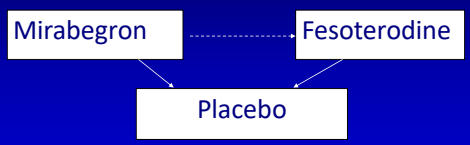
- RCTs show less UI after new intervention
  - patients in RCTs 40 to 70
  - your patient 90
- are you confident?
- indirectness of population
  - older, sicker or more co-morbidity

More reasons to lose confidence

- operation for lap mesh prolapse repair
- technically challenging
  - frequent complications
- RCTs: lap surgery decreases recurrence
  - only top surgeons participate in the RCTs
- are you confident?
- indirectness of intervention

Directness

interested in A versus B
available data A vs C, B vs C



Another reason to lose confidence

- some trials never get published
- "negative" studies more likely
- biased sample of studies
  - overestimates of treatment effect

Positive results more likely to get published

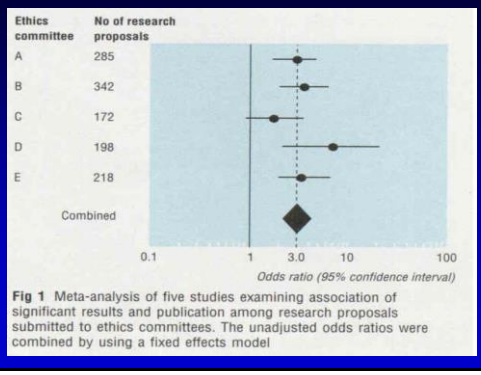
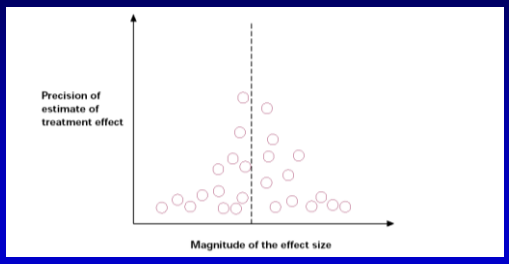


Fig 1 Meta-analysis of five studies examining association of significant results and publication among research proposals submitted to ethics committees. The unadjusted odds ratios were combined by using a fixed effects model

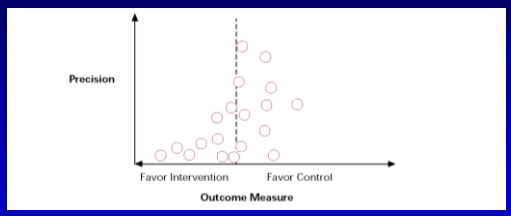
How to demonstrate?

Funnel plot



How to demonstrate?

Publication bias



Confidence assessment criteria

Study Design	Confidence in estimates	Lower if	Higher if
Randomised trial →	High	Risk of bias -1 Serious -2 Very serious Inconsistency -1 Serious -2 Very serious Indirectness -1 Serious -2 Very serious Imprecision -1 Serious -2 Very serious Publication bias -1 Likely -2 Very likely	Large effect +1 Large +2 Very large Dose response +1 Evidence of a gradient All plausible confounding +1 Would reduce a demonstrated effect or +1 Would suggest a spurious effect when results show no effect
	Moderate		
Observational study →	Low		
	Very low		

Strength of Recommendation

- strong recommendation
  - benefits clearly outweigh risks/hassle/cost
  - risk/hassle/cost clearly outweighs benefit

- what can downgrade strength?
- low confidence in estimates
- close balance between up and downsides

Risk/Benefit tradeoff

- aspirin after myocardial infarction
  - 25% reduction in relative risk
  - side effects minimal, cost minimal
  - benefit obviously much greater than risk/cost
- warfarin in low risk atrial fibrillation
  - warfarin reduces stroke vs ASA by 50%
  - but if risk only 1% per year, ARR 0.5%
  - increased bleeds by 1% per year

Conclusion

- clinicians, policy makers need summaries
  - quality of evidence
  - strength of recommendations
- explicit rules
  - transparent, informative
- GRADE
  - simple, transparent, systematic
  - increasing wide adoption
  - great opportunity for teaching evidence-based healthcare

ICS 2018 PHILADELPHIA

W14 Practical interpretation of research evidence for shared decision making

THE INTERPRETATION OF ODDS RATIOS FOR COMMON CONDITIONS

Marco Blanker

Marco H. Blanker, MD PhD

ICS 2018 PHILADELPHIA

Affiliations to disclose†:

None

† All financial ties (over the last year) that you may have with any business organisation with respect to the subjects mentioned during your presentation

Funding for speaker to attend:

- [x] Self-funded
- [ ] Institution (non-industry) funded
- [ ] Sponsored by:

Measures of association

ICS 2018 PHILADELPHIA

Odds ratio's (OR) are commonly used to describe associations between two characteristics

Other measures for this are

- relative risks
- hazard ratios
- correlation coefficients

These measures in itself don't inform you about statistical significance

Odds ratio's

ICS 2018 PHILADELPHIA

Result from logistic regression analyses

but also from simple 2x2 Tables

How familiar are you with the interpretation of odds ratios?

LUTS & CVD – an example

ICS 2018 PHILADELPHIA

Association between lower urinary tract symptoms (LUTS) and Cardiovascular Disease (CVD)

Described by Russo et al (BJU Int 2015)


BJUI Functional Urology

Increase of Framingham cardiovascular disease risk score is associated with severity of lower urinary tract symptoms

Giorgio I. Russo, Tommaso Castelli, Salvatore Privitera, Eugenia Fragalà, Vincenzo Favilla, Giulio Reale, Daniele Urzì, Sandro La Vignera*, Rosita A. Condorelli*, Aldo E. Calogero*, Sebastiano Cimino and Giuseppe Morgia

Department of Urology, and *Department of Medical and Paediatric Sciences, Section of Endocrinology, Andrology and Internal Medicine, University of Catania, Catania, Italy

BJU Int 2015; 116: 791–6

LUTS & CVD – an example

ICS 2018 PHILADELPHIA

Main outcome: Risk of having moderate/severe LUTS for high CVD-risk group: OR 5.9 (95% CI 1.3– 28.0)

How do you interpret this outcome?

A. Men in high CVD group have approximately 6 times higher chance of having moderate/severe LUTS
B. Undecided (missing information)
C. Don't know

LUTS & CVD – an example

Main outcome: Risk of having moderate/severe LUTS for high CVD-risk group: OR 5.9 (95% CI 1.3– 28.0)

How do you interpret this association?

A. Strong association
B. Moderate association
C. Weak association
D. Don't know

LUTS & CVD – an example

Main outcome: Risk of having moderate/severe LUTS for high CVD-risk group: OR 5.9 (95% CI 1.3– 28.0)

How do you interpret this outcome?

A. Men in high CVD group ha… higher chan…
B.
C.

In general, many healthcare professionals tend to interpret OR's as Relative Risks (RR)

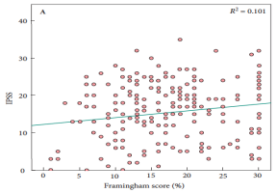
LUTS & CVD – an example

If you see an OR (or other measure of association)

please look what's behind the numbers

In the Russo article it was
IPSS scores and
Framingham heart scores

(BJU Int 2015; 116: 791–6)



LUTS & CVD – an example

Main outcome: Risk of having moderate/severe LUTS for high CVD-risk group: OR 5.9 (95% CI 1.3– 28.0)

How do you interpret this association?

A. Strong association
B. Moderate association
C. Weak association
D. Don't know

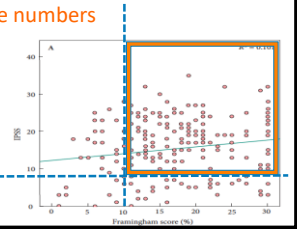
LUTS & CVD – an example

If you see an OR (or other measure of association)

please look what's behind the numbers

In the Russo article it was
IPSS scores and
Framingham heart scores

(BJU Int 2015; 116: 791–6)



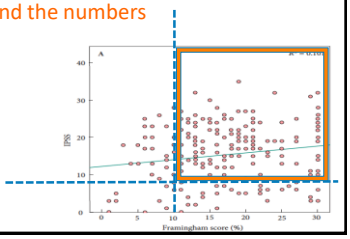
LUTS & CVD – an example

If you see an OR (or other measure of association)

please look what's behind the numbers

What is your main comment on this categorisation?

(BJU Int 2015; 116: 791–6)



LUTS & CVD – an example

If you see an OR (or other measure of association) please look what's behind the numbers

In the Russo article it was IPSS scores and Framingham heart scores

Categorisation lead to high prevalence of

- moderate/severe LUTS (81.5%)
- increased CVD risk (82.1%)

Odds ratio's

May be interpreted as relative risks

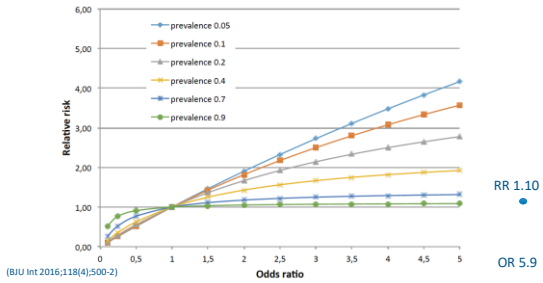
only if the prevalence of the outcome is low

(rule of thumb < 10%)

RR can be calculated based on OR and prevalence (p)

$$RR = \frac{OR}{(1-p) + (p \times OR)}$$

Odds ratio's



(BJU Int 2016;118(4);500-2)

LUTS & CVD – an example

Main outcome: Risk of having moderate/severe LUTS for high CVD-risk group: OR 5.9 (95%CI 1.3-28.0)

How do you interpret this outcome?

With known high prevalence the OR with 95%CI corresponds to:

Relative Risk 1.10 (95% CI 1.08– 1.22)

Take home message

Odds ratio's are no Relative Risks

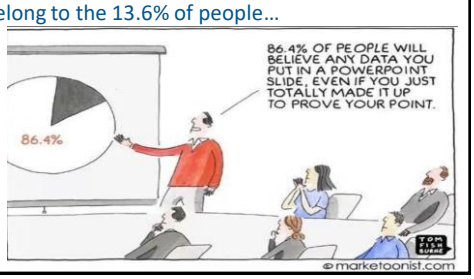
Odds ratio's may be interpreted as Relative Risks only if prevalence of outcome is low

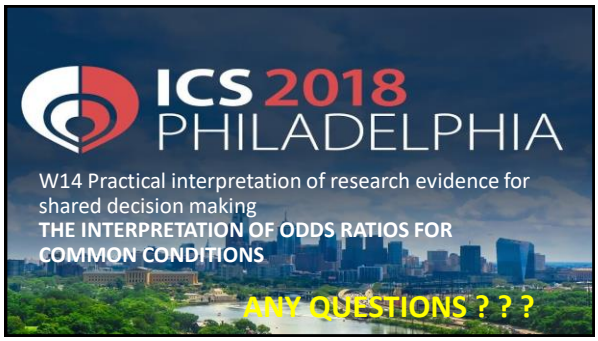
So for sound interpretation of Odds Ratio's:

- check prevalence of outcome
- check how data were handled

Take home message

You'll belong to the 13.6% of people…




ICS 2018
PHILADELPHIA
W14 Practical interpretation of research evidence for shared decision making
THE INTERPRETATION OF ODDS RATIOS FOR COMMON CONDITIONS
ANY QUESTIONS ? ? ?

Clinical Urology and Epidemiology Working Group
www.clueworkinggroup.com

Statistical significance vs. Clinical relevance vs. Patient-importance

Kari Tikkinen (@KariTikkinen)

Departments of Urology and Public Health,
Helsinki University Hospital, Academy of Finland and University of Helsinki, Finland

W14: Practical interpretation of research evidence for shared decision making
48th Annual Scientific Meeting of the International Continence Society
August 28, 2018 – Philadelphia, PA, USA

Kari Tikkinen

ICS 2018 PHILADELPHIA

Affiliations to disclose†:

None

† All financial ties (over the last year) that you may have with any business organisation with respect to the subjects mentioned during your presentation

Funding for speaker to attend:

- ☐ Self-funded
- ☒ Institution (non-industry) funded
- ☐ Sponsored by:

Calibrating Your Enthusiasm

Your flight is cancelled due to bad weather

Your flight will arrive earlier than scheduled due to very good weather and nice tailwind

Interpreting the Evidence

Willingness to fund mammography screening

- *program A* reduces the rate of dying from breast cancer by 33% (p=0.001)
- *program B* increases the rate of patients not dying from breast cancer from 99.82% to 99.88% (p=0.001)
- *program C* means that 1,667 women needed to be screened yearly for 7 years to prevent one death from breast cancer (p=0.001)

Breast Cancer Screening

Breast cancer death rates (p=0.001)

- unscreened 0.18% (18 out of 10,000)
- screened 0.12% (12 out of 10,000)

Relative risk reduction: (0.18% - 0.12%) / 0.18% = 33%

Breast cancer death rates

- unscreened 0.18% means 99.82% don't die
- screened 0.12% means 99.88% don't die

Absolute risk reduction: 0.18% - 0.12% = 0.06%

Number needed to screen: 100/0.06 = 1,667

P-value same, tells nothing about magnitude

Example: VA hypertension study

Mortality after 5 years of treatment

	Controls	Treated	RRR
DBP (90 – 104)	0.074	0.059	0.074 - 0.059 / 0.074
			20%

DBP, diastolic blood pressure

Relative risk reduction (RRR)

	Control	Treat-ment	RRR
TOD+	0.20	0.16	20%
TOD-	0.057	0.045	21%

TOD, target organ damage

Absolute risk reduction (ARR)

	Control	Treat-ment	RRR	ARR
TOD+	0.20	0.16	20%	4%
TOD-	0.057	0.045	21%	1.2%

TOD, target organ damage

Number needed to treat (NNT)

	Control	Treat-ment	RRR	ARR	NNT
TOD+	0.20	0.16	20%	4%	25
TOD-	0.057	0.045	21%	1.2%	83

TOD, target organ damage

Patient with DVT

Completes 6 months prophylaxis

Question: continue or not?

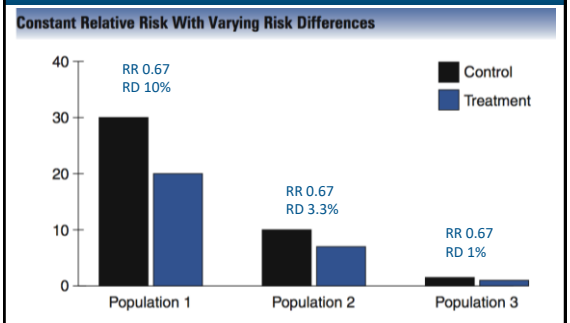
Doctor: continuing reduces risk of recurrence by 33%

- chance unlikely to explain the difference (p=0.001)

What does patient understand?

Is there something missing?

Patient with DVT



Patients with atrial fibrillation

$CHADS_2$: congestive heart failure; hypertension; age >75; diabetes; prior stroke

Risk of stroke varies

- $CHADS_2$ 0: 8 per 1,000 per year
- $CHADS_2$ 1: 22 per 1,000 per year
- $CHADS_2$ 2: 45 per 1,000 per year
- $CHADS_2$ 3: 96 per 1,000 per year

Warfarin constant 2/3 relative risk reduction

- $CHADS_2$ 0: 5 per 1,000 per year
- $CHADS_2$ 1: 14 per 1,000 per year
- $CHADS_2$ 2: 30 per 1,000 per year
- $CHADS_2$ 3: 64 per 1,000 per year

Measures of Relative Effect

- Relative risk
- Relative risk reduction
- Odds ratio
- Relative odds reduction
- Hazard ratio

Small, medium or large?

VTE prophylaxis in 65 year old man, COPD exacerbation, anticipated walking in hall day 3, hospitalization

RRR	50%	
Baseline risk	4/1,000	
Risk difference	2/1,000	so, NNT 500

Balance in favour of treatment?

VTE, venous thromboembolism

Small, medium or large?

VTE prophylaxis in 65 year old man, disseminated cancer, severe pneumonia, likely bed-bound for at least 3 days

RRR	50%	
Baseline risk	100/1,000	
Risk difference	50/1,000	so, NNT 20

Balance in favour of treatment?

Summary

Relative estimates: RR, OR, HR

Absolute estimates: RD (ARR), NNT

Ultimately patients interested in absolute risk (reductions)

Patients not interested in p-values or relative estimates

Relative risk reductions constant across patients, absolute risk reductions not

So, to get absolute risk reductions, need baseline risk and relative risk reductions

Extra slides

Risk	Odds
0.8	

Risk	Odds
0.8	0.8/0.2 = 4.0

Risk	Odds
0.8	0.8/0.2 = 4.0
0.66	

Risk	Odds
0.8	0.8/0.2 = 4.0
0.66	0.66/0.33 = 2.0

Risk	Odds
0.8	0.8/0.2 = 4.0
0.66	0.66/0.33 = 2.0
0.6	

Risk	Odds
0.8	0.8/0.2 = 4.0
0.66	0.66/0.33 = 2.0
0.6	0.6/0.4 = 1.5

Risk	Odds
0.8	0.8/0.2 = 4.0
0.66	0.66/0.33 = 2.0
0.6	0.6/0.4 = 1.5
0.4	

Risk	Odds
0.8	0.8/0.2 = 4.0
0.66	0.66/0.33 = 2.0
0.6	0.6/0.4 = 1.5
0.4	0.4/0.6 = 0.66

Risk	Odds
0.8	0.8/0.2 = 4.0
0.66	0.66/0.33 = 2.0
0.6	0.6/0.4 = 1.5
0.4	0.4/0.6 = 0.66
0.33	

Risk	Odds
0.8	0.8/0.2 = 4.0
0.66	0.66/0.33 = 2.0
0.6	0.6/0.4 = 1.5
0.4	0.4/0.6 = 0.66
0.33	0.33/0.66 = 0.5

Risk	Odds
0.8	0.8/0.2 = 4.0
0.66	0.66/0.33 = 2.0
0.6	0.6/0.4 = 1.5
0.4	0.4/0.6 = 0.66
0.33	0.33/0.66 = 0.5
0.25	

Risk	Odds
0.8	0.8/0.2 = 4.0
0.66	0.66/0.33 = 2.0
0.6	0.6/0.4 = 1.5
0.4	0.4/0.6 = 0.66
0.33	0.33/0.66 = 0.5
0.25	0.25/0.75 = 0.33

Risk	Odds
0.8	0.8/0.2 = 4.0
0.66	0.66/0.33 = 2.0
0.6	0.6/0.4 = 1.5
0.4	0.4/0.6 = 0.66
0.33	0.33/0.66 = 0.5
0.25	0.25/0.75 = 0.33
0.20	

Risk	Odds
0.8	0.8/0.2 = 4.0
0.66	0.66/0.33 = 2.0
0.6	0.6/0.4 = 1.5
0.4	0.4/0.6 = 0.66
0.33	0.33/0.66 = 0.5
0.25	0.25/0.75 = 0.33
0.20	0.20/0.80 = 0.25

Risk	Odds
0.8	0.8/0.2 = 4.0
0.66	0.66/0.33 = 2.0
0.6	0.6/0.4 = 1.5
0.4	0.4/0.6 = 0.66
0.33	0.33/0.66 = 0.5
0.25	0.25/0.75 = 0.33
0.20	0.20/0.80 = 0.25
0.10	0.1/0.9 = 0.11

	Dead	Alive
Treatment	20	80
Control	40	60

Risk in treatment:

	Dead	Alive
Treatment	20	80
Control	40	60

Risk in treatment: 20%

	Dead	Alive
Treatment	20	80
Control	40	60

Risk in treatment: 20%
Risk in control:

	Dead	Alive
Treatment	20	80
Control	40	60

Risk in treatment: 20%
Risk in control: 40%
Risk ratio:

	Dead	Alive
Treatment	20	80
Control	40	60

Risk in treatment: 20%
Risk in control: 40%
Risk ratio: 0.5 (50%)

	Dead	Alive
Treatment	20	80
Control	40	60

Risk in treatment: 20%
Risk in control: 40%
Risk ratio: 0.5 (50%)

Odds in treatment: 25%

	Dead	Alive
Treatment	20	80
Control	40	60

Risk in treatment: 20%
Risk in control: 40%
Risk ratio: 0.5 (50%)

Odds in treatment: 25%

	Dead	Alive
Treatment	20	80
Control	40	60

Risk in treatment: 20%
Risk in control: 40%
Risk ratio: 0.5 (50%)

Odds in treatment: 25%
Odds in control:

	Dead	Alive
Treatment	20	80
Control	40	60

Risk in treatment: 20%
Risk in control: 40%
Risk ratio: 0.5 (50%)

Odds in treatment: 25%
Odds in control: 67%

	Dead	Alive
Treatment	20	80
Control	40	60

Risk in treatment: 20%
Risk in control: 40%
Risk ratio: 0.5 (50%)

Odds in treatment: 25%
Odds in control: 67%
Odds ratio:

	Dead	Alive
Treatment	20	80
Control	40	60

Risk in treatment: 20%
Risk in control: 40%
Risk ratio: 0.5 (50%)

Odds in treatment: 25%
Odds in control: 67%
Odds ratio: 0.37 (37%)

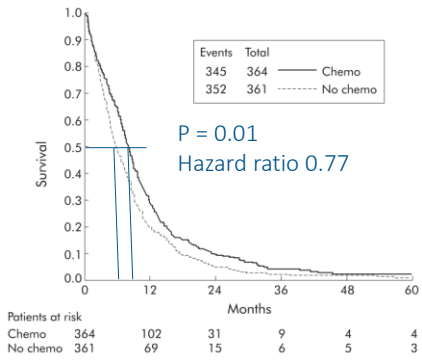
Absolute effect?

Time to event

Ultimately everyone will die
- ultimate RRR 0

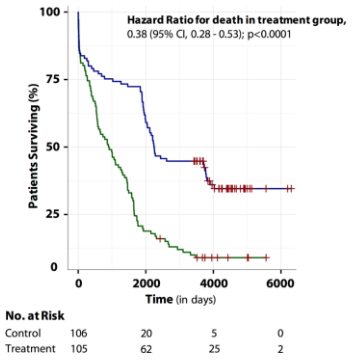
Actually interested in <u>when</u> people die

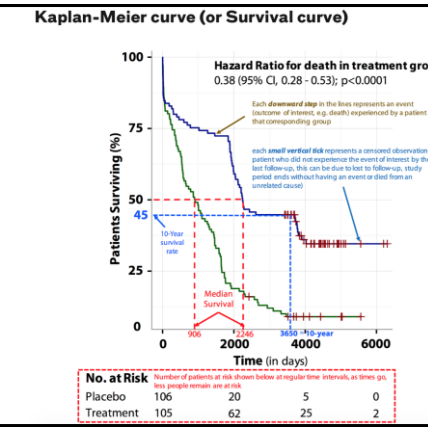
time to event (survival) analysis



Median survival 8.0 vs 5.7 months (9 wk difference)

https://www.students4bestevidence.net/tutorial-hazard-ratios/





ICS 2018 PHILADELPHIA

W14 Decision aids - how to use it in clinical practice

Philippe Violette

Assistant Professor, Depts. of Surgery and Health Research Methods Evidence and Impact, McMaster University

Philippe D. Violette, Msc. MD CM

ICS 2018 PHILADELPHIA

Affiliations to disclose†:

None

† All financial ties (over the last year) that you may have with any business organisation with respect to the subjects mentioned during your presentation

Funding for speaker to attend:

- [X] Self-funded
- [ ] Institution (non-industry) funded
- [ ] Sponsored by:

Overview

ICS 2018 PHILADELPHIA

- How do we make clinical decisions?
- What is Shared Decision making?
- How decisions aids help bring everything together

ICS 2018 PHILADELPHIA

ICS 2018 PHILADELPHIA

← Option 1 (Buffalo)

Option 2 → (Rome)

ICS 2018 PHILADELPHIA

clean

quiet

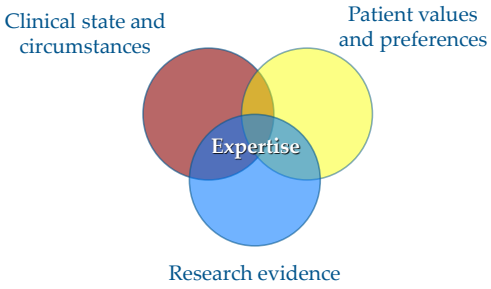
great work situation

dirty

noisy

work situation problematic

Clinical decision-making 2018



Case 1- Values and Preferences

40 year old man with minimal medical co-morbidities, diagnosed with symptomatic urethral stricture disease.

What is important to making a clinical decision to treat?

What are the relevant tradeoffs?

Which outcomes are most important?

Do physicians know best?

Comprehensive Qualitative Assessment of Urethral Stricture Disease: Toward the Development of a Patient Centered Outcome Measure

Benjamin N. Breyer,* Todd C. Edwards, Donald L. Patrick and Bryan B. Voelzke

53% agreement between physician and patient

- ie: physicians are wrong about patient priorities half the time

J Urol 2017;198: 113-118

Alternative models of clinical decision making

Physician Perception-Reality Gap

Many health care practitioners believe they practice SDM but may not be

BMJ 2012;344: e256
BMJ 2015;350: g7624

SDM: why, when, how?

- What would be your own definition of SDM?
- When should it, could it, or shouldn't it be done?
- How much SDM is needed in you view?

Shared Decision Making

is a process by which
a **patient** and a **clinician**
work together,
have a **conversation**,
partner with each other
to identify the **best course of action**,
the best treatment or test
at this point in time.

Not just throwing numbers!

It is a about **sharing what matters**

Clinicians share information about the alternatives, benefits, harms
Patients share prior experience, goals, expectations, values.

Victor Montori

Need for relevant evidence summaries

- A key component of doing SDM well requires
  - a detailed knowledge of the key evidence
  - shared in a manner that is accessible and supportive of the deliberation process
- Clinicians often
  - lack detailed knowledge of the evidence
  - Are unable to produce accurately and efficiently relevant evidence summaries on the fly

GRADE

Strong recommendations	*Weak recommendations*
1. Clear balance ➢ benefits clearly outweigh risks/hassle/cost ➢ risk/hassle/cost clearly outweighs benefits	1. Close balance ➢ Close call between benefits and risks/hassle/cost ➢ Therefore more preference-sensitive
2. Sufficient confidence in estimates (high or moderate)	2. Low confidence in estimates
3. Patients values & preferences: ➢ almost all **same** choice	3. Patients values & preferences: ➢ choice **varies** appreciably (or is very uncertain)

GRADE

ICS 2018 PHILADELPHIA

Strong recommendations

1. Clear ba[illegible]e
   - ➢ benefit[illegible]early outweigh risks/[illegible]cost
   - ➢ risk/hassle/cost clearly

Just do it

3. Patients values & preferences:
   - ➢ almost all **same** choice

Weak recommendations

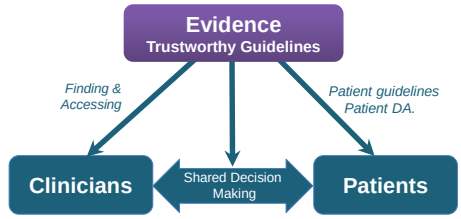
1. Close bala[illegible]e
   - ➢ Close ca[illegible]tween benefits and ris[illegible]e/cost
   - ➢ Therefore more preference-

Shared decision making

3. Patients values & preferences:
   - ➢ choice **varies** appreciably (or is very uncertain)

ICS 2018 PHILADELPHIA

Evidence Dissemination & Shared Decision Making (SDM)



Decision Aids

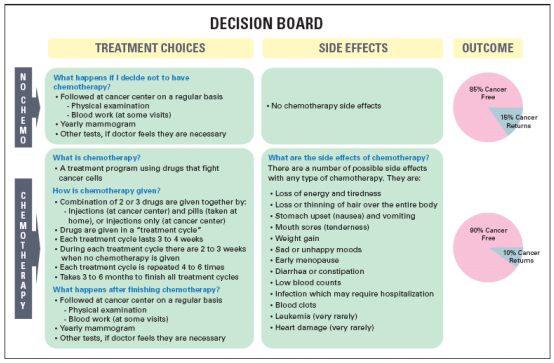
ICS 2018 PHILADELPHIA

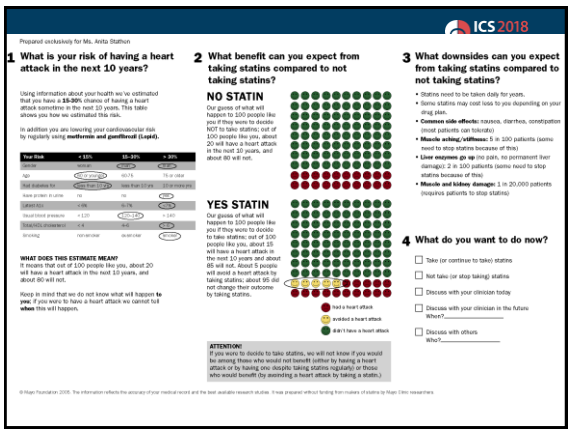
International Patient Decision Aids Standards (IPDAS) Collaboration

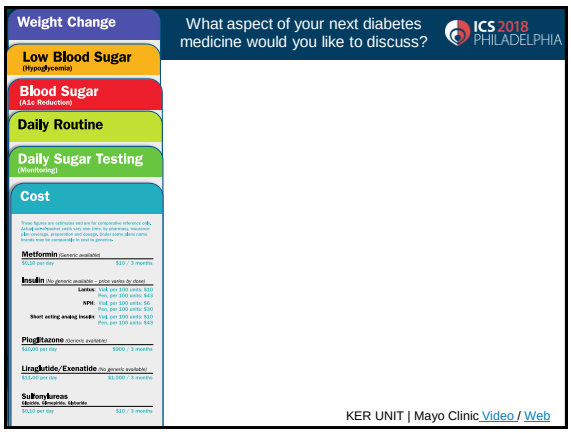
> "Decision aids are evidence-based tools designed to help patients make specific and deliberated choices among health-care options."

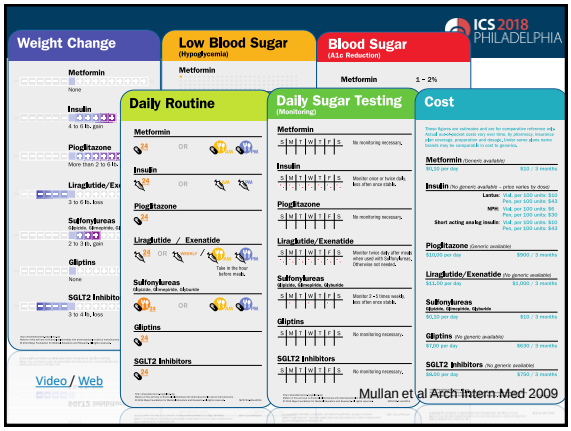
Traditional decision aids

- decision boards
- decision booklets
- flip charts
- videos
- audiotapes
- computerized decision instruments









Do decision aids work?

ICS 2018 PHILADELPHIA

>500 existing DA, 115 included in recent Cochrane review (Stacey et al.)

compared to usual care, decision aids:

- consistently improve patients' knowledge & provide more accurate expectations of possible benefits and harm
- Show inconsistent effects on clinical outcomes, adherence, and healthcare utilization

ICS 2018 PHILADELPHIA

Traditional DA: limitations

- Majority are meant to be used by patients outside the clinical encounter
  - goal: patient empowerment
  - to prepare for the consultation
- Production time-consuming
- Often not based on current best evidence
- Have not had the desired uptake in practice

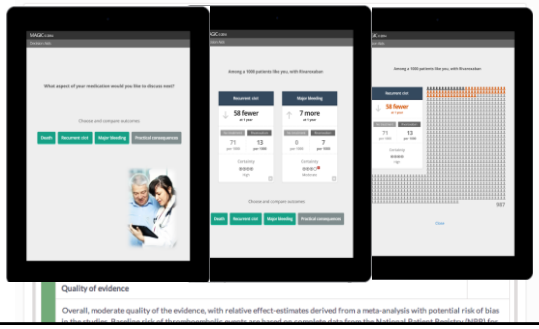
Motivation for SHARE-IT: necessity for alternative models:

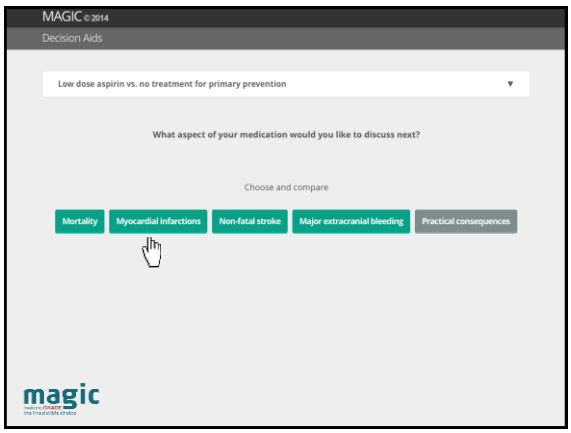
→ **Link with evidence summaries in SR and Guidelines**

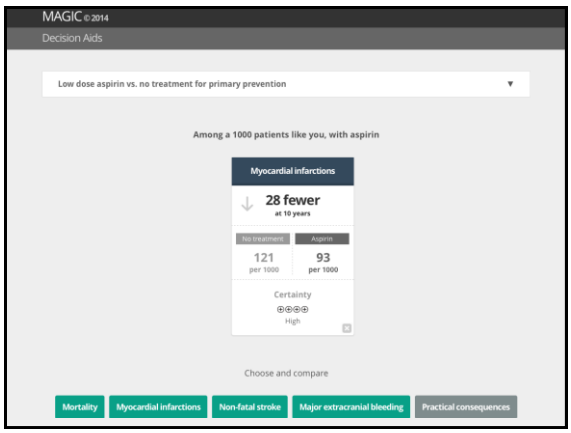
→ **Generic approach = opportunities for wider dissemination**

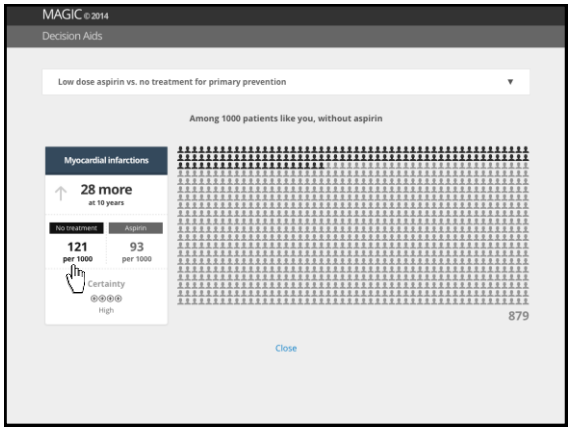
ICS 2018 PHILADELPHIA

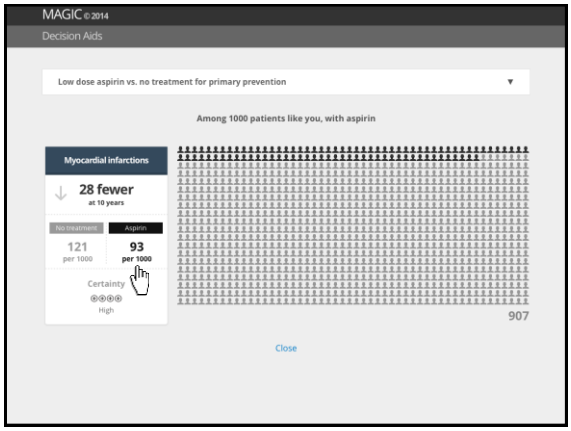
The SHARE-IT project

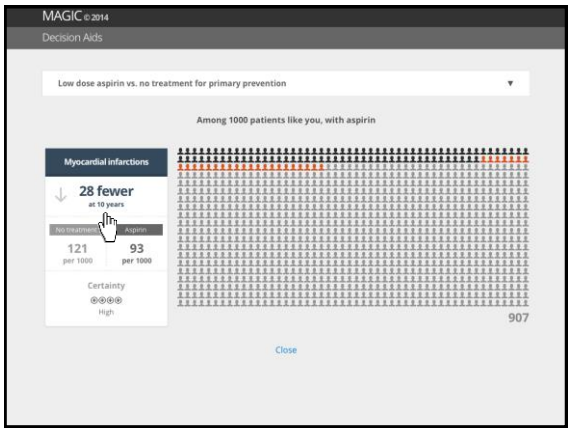


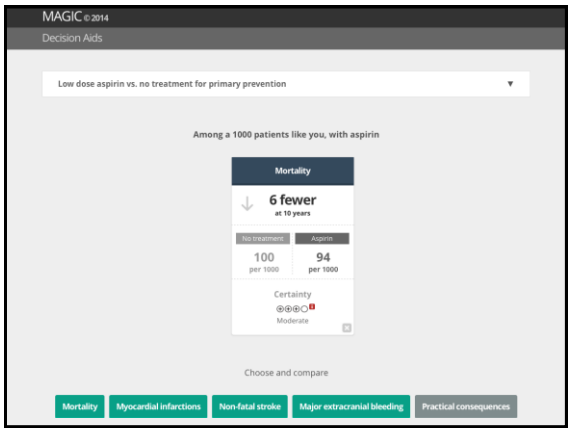


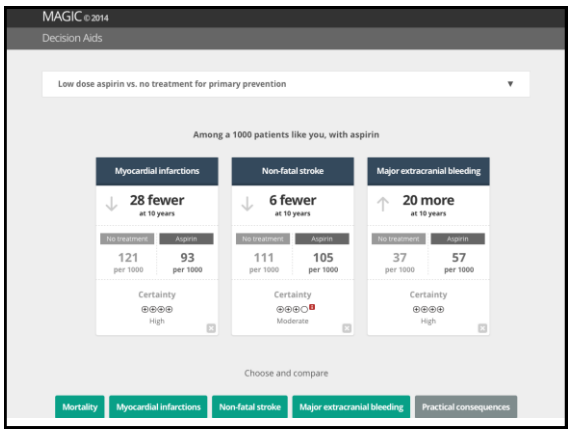


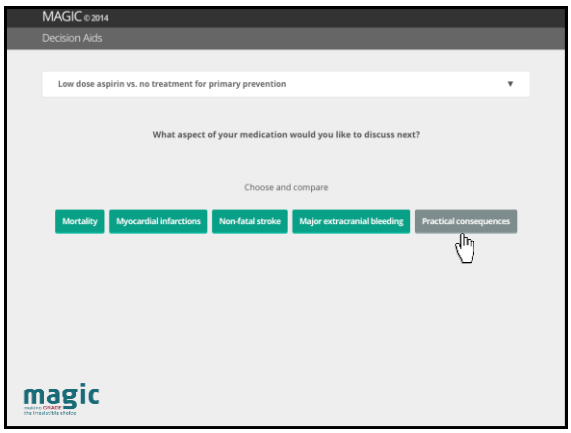

MAGIC © 2014
Decision Aids
Low dose aspirin vs. no treatment for primary prevention
Among 1000 patients like you, without aspirin
Myocardial infarctions
28 more
at 10 years
No treatment
Aspirin
121
per 1000
93
per 1000
Certainty
High
879
Close

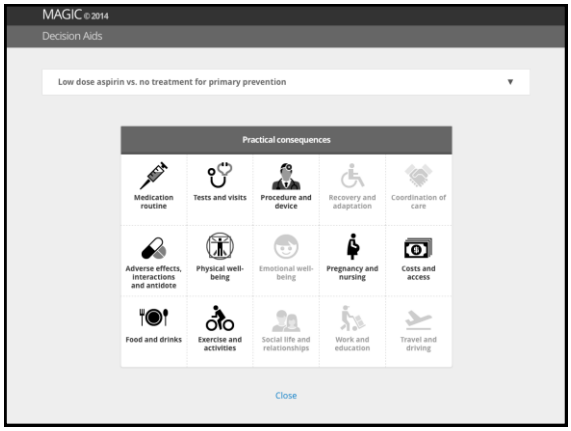

MAGIC © 2014
Decision Aids
Low dose aspirin vs. no treatment for primary prevention
Among 1000 patients like you, with aspirin
Myocardial infarctions
28 fewer
at 10 years
No treatment
Aspirin
121
per 1000
93
per 1000
Certainty
High
907
Close


MAGIC © 2014
Decision Aids
Low dose aspirin vs. no treatment for primary prevention
Among 1000 patients like you, with aspirin
Myocardial infarctions
28 fewer
at 10 years
No treatment
Aspirin
121
per 1000
93
per 1000
Certainty
High
907
Close


MAGIC © 2014
Decision Aids
Low dose aspirin vs. no treatment for primary prevention
Among a 1000 patients like you, with aspirin
Mortality
6 fewer
at 10 years
No treatment
Aspirin
100
per 1000
94
per 1000
Certainty
Moderate
Choose and compare
Mortality
Myocardial infarctions
Non-fatal stroke
Major extracranial bleeding
Practical consequences


MAGIC © 2014
Decision Aids
Low dose aspirin vs. no treatment for primary prevention
Among a 1000 patients like you, with aspirin
Myocardial infarctions
28 fewer
at 10 years
No treatment
Aspirin
121
per 1000
93
per 1000
Certainty
High
Non-fatal stroke
6 fewer
at 10 years
No treatment
Aspirin
111
per 1000
105
per 1000
Certainty
Moderate
Major extracranial bleeding
20 more
at 10 years
No treatment
Aspirin
37
per 1000
57
per 1000
Certainty
High
Choose and compare
Mortality
Myocardial infarctions
Non-fatal stroke
Major extracranial bleeding
Practical consequences


MAGIC © 2014
Decision Aids
Low dose aspirin vs. no treatment for primary prevention
What aspect of your medication would you like to discuss next?
Choose and compare
Mortality
Myocardial infarctions
Non-fatal stroke
Major extracranial bleeding
Practical consequences
magic



Summary

ICS 2018 PHILADELPHIA

SDM involves a patient and clinician discussing what matters

- Values and Preferences
- Evidence (trustworthy guidelines)
- Context (clinical state and circumstances)

Decision Aids

- Present knowledge in an accessible form
- Help clarify patient values
- provide more accurate expectations of possible benefits and harm
- Should be used dynamically to enrich the clinical encounter tailored to each patient (MAGICapp)