

How to develop and publish a digital, living and trustworthy evidence summary and recommendation through the MAGIC authoring and publication platform

Workshop EBHC Conference Taormina 2017

Per Olav Vandvik, on behalf of colleagues in the non-profit MAGIC research and innovation program



11/8/2017



UiO • University of Oslo



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Objectives

- To understand how MAGICapp works for clinicians and patients, with trustworthy recommendations, evidence summaries and decision aids, exemplified through the BMJ-RapidRecs project for practice-changing evidence
- To be introduced to the process of developing **and dynamically updating** a trustworthy evidence summary and recommendation with MAGICapp
- To get hands-on experience with use of the MAGICapp in the updating of an evidence summary and treatment recommendation

2016: Time for a post-guidelines era in health care?

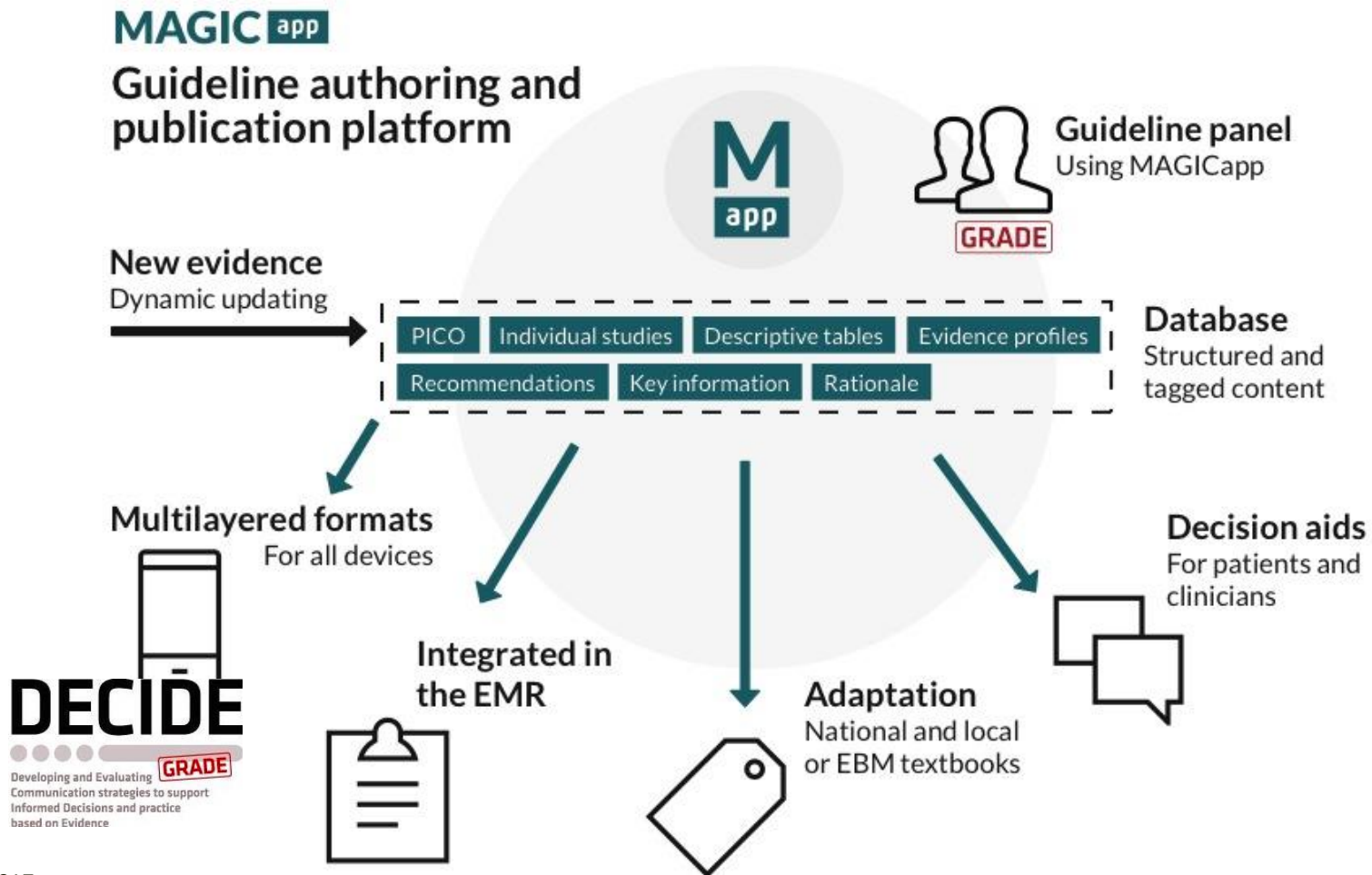
Major limitations EBM and guidelines

- Developers
 - Not trustworthy, ignore other knowledge
 - Resource-demanding, extreme duplication
- Clinicians and patients
 - Available, useful, understandable?
 - Allow shared, personalized decisions?
 - Up to date?
 - Integrated in the electronic health record?

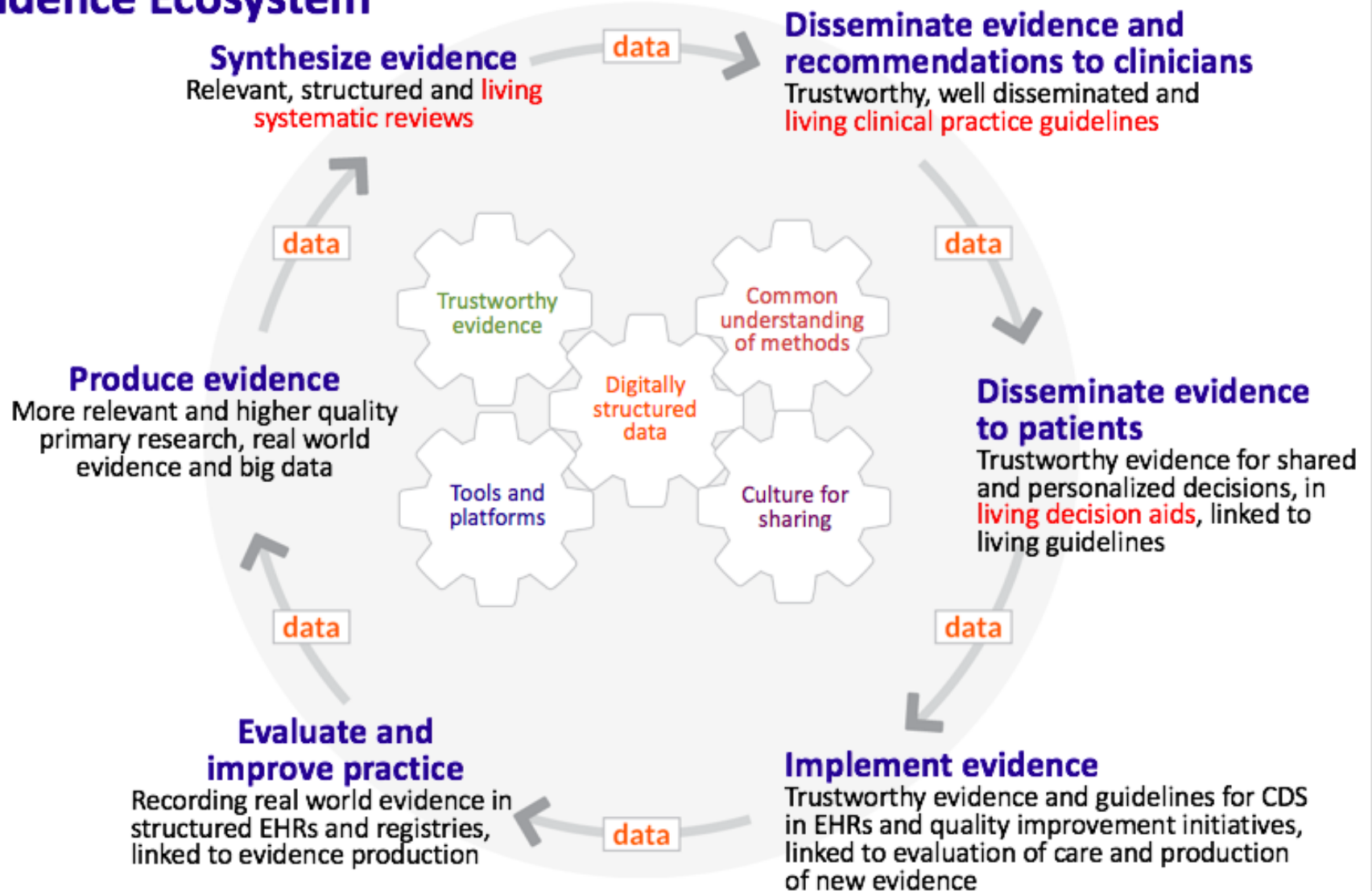


Time to respond to calls from the opponents?

Creating, publishing and dynamically updating trustworthy recommendations, evidence summaries and decision aids in digitally structured formats



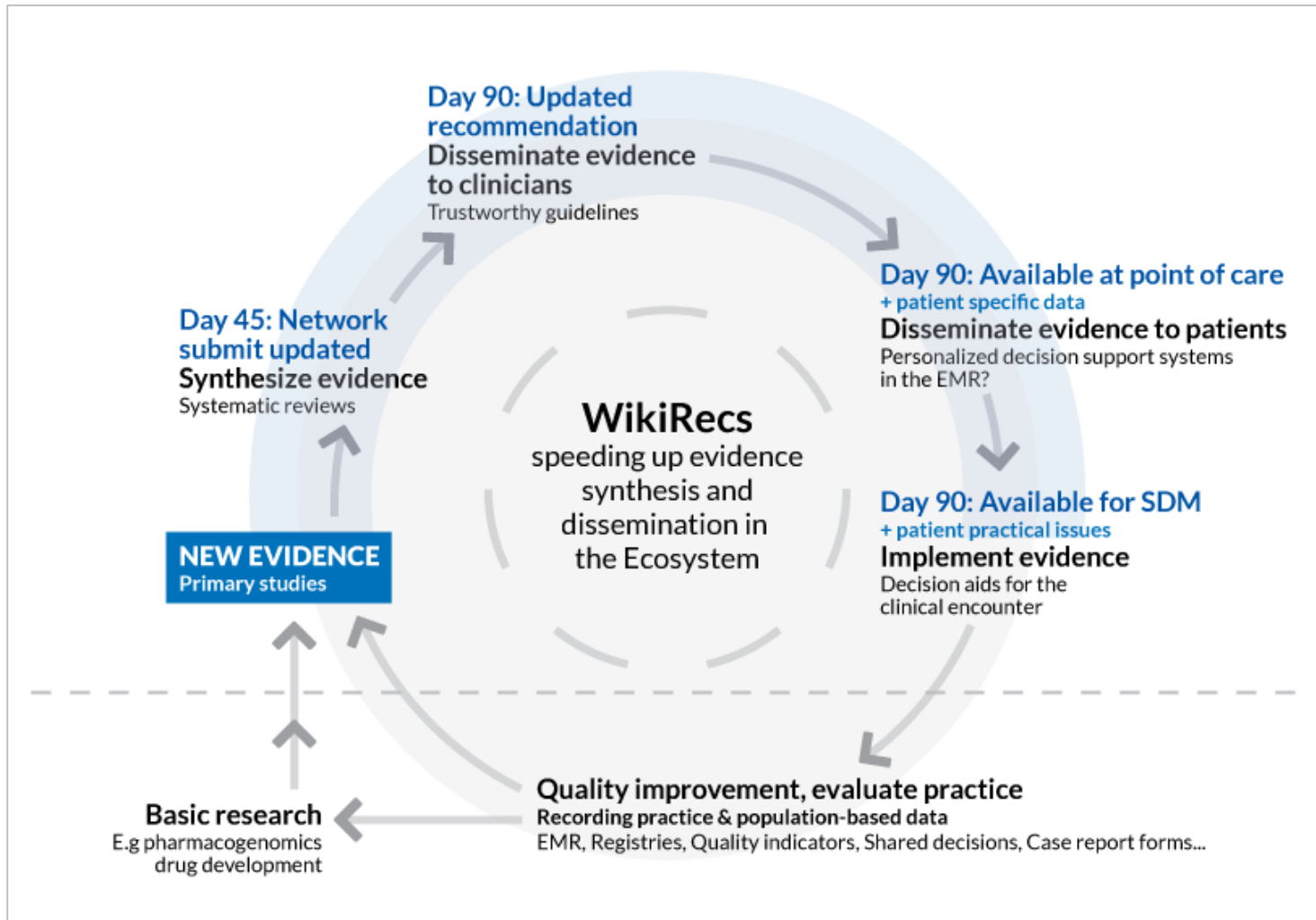
The Digital and Trustworthy and living Evidence Ecosystem



Some hurdles to overcome: Organizations fit for purpose?

How can we rapidly get potentially practice-changing evidence into practice?

Collaborative network approach, partnering with innovative medical journal?



The BMJ-RapidRecs project: methods and process

- Guideline panel, network of the right people
 - ✓ Trustworthy guideline standards, GRADE
 - ✓ Focus on conflict of interest, patient involvement....
- Linked high quality systematic reviews
 - ✓ effects, prognosis, values and preferences
 - ✓ Separate teams, closely interacting with guideline panel



Rapid Recommendations process step by step (with target times)

Step 1: Monitor and identify potentially practice changing evidence

Step 2: Executive + chair triggers process and RapidRecs panel (day 7)

Step 3: Systematic reviews created by separate teams (day 45)

Step 4: RapidRecs created in MAGICapp and as synopsis paper (day 60)

Step 5: RapidRecs + reviews submitted for peer review (day 60)

Step 6: RapidRecs and reviews disseminated globally (day 90)

Potentially practice-changing evidence for Daniel?

Triggering our first BMJ- RapidRecs, published September 28 2016



- Daniel, 69 years old
- Heart failure, not feeling well..
- Severe aortic stenosis, all set up for open heart surgery in Norway
- Read newspaper, questions if he could have “TAVI”...

The **NEW ENGLAND**
JOURNAL of MEDICINE

ESTABLISHED IN 1812 APRIL 28, 2016 VOL. 374 NO. 17

**Transcatheter or Surgical Aortic-Valve Replacement
in Intermediate-Risk Patients**

Martin B. Leon, M.D., Craig R. Smith, M.D., Michael J. Mack, M.D., Raj R. Makkar, M.D.,
Lars G. Svensson, M.D., Ph.D., Susheel K. Kodali, M.D., Vinod H. Thourani, M.D., E. Murat Tuzcu, M.D.,
D. Craig Miller, M.D., Howard C. Herrmann, M.D., Darshan Doshi, M.D., David J. Cohen, M.D.,
Augusto D. Pichard, M.D., Samir Kapadia, M.D., Todd Dewey, M.D., Vasilis Babaliaros, M.D.,
Wilson Y. Szeto, M.D., Mathew R. Williams, M.D., Dean Kereiakes, M.D., Alan Zajarias, M.D.,
Kevin L. Greason, M.D., Brian K. Whisenant, M.D., Robert W. Hodson, M.D., Jeffrey W. Moses, M.D.,
Alfredo Trento, M.D., David L. Brown, M.D., William F. Fearon, M.D., Philippe Pibarot, D.V.M., Ph.D.,
Rebecca T. Hahn, M.D., Wael A. Jaber, M.D., William N. Anderson, Ph.D., Maria C. Alu, M.M.,
and John G. Webb, M.D., for the PARTNER 2 Investigators*

ABSTRACT

BACKGROUND
Previous trials have shown that among high-risk patients with aortic stenosis, survival rates are similar with transcatheter aortic-valve replacement (TAVR) and surgical aortic-valve replacement. We evaluated the two procedures in a randomized trial involving intermediate-risk patients.

METHODS
We randomly assigned 2052 intermediate-risk patients with severe aortic stenosis, at 57 centers, to undergo either TAVR or surgical replacement. The primary end point was death from any cause or disabling stroke at 2 years. The primary hypothesis was that TAVR would not be inferior to surgical replacement. Before randomization, patients were entered into one of two cohorts on the basis of clinical and imaging findings; 76.5% of the patients were included in the transfemoral-access cohort and 23.7% in the transhoracic-access cohort.

RESULTS
The rate of death from any cause or disabling stroke was similar in the TAVR group and the surgery group (P=0.001 for noninferiority). At 2 years, the Kaplan–Meier event rates were 19.3% in the TAVR group and 21.1% in the surgery group (hazard ratio in the TAVR group, 0.89; 95% confidence interval [CI], 0.73 to 1.09; P=0.25). In the transfemoral-access cohort, TAVR resulted in a lower rate of death or disabling stroke than surgery (hazard ratio, 0.79; 95% CI, 0.62 to 1.00; P=0.05), whereas in the transhoracic-access cohort, outcomes were similar in the two groups. TAVR resulted in larger aortic-valve areas than did surgery and also resulted in lower rates of acute kidney injury, severe bleeding, and new-onset atrial fibrillation; surgery resulted in fewer major vascular complications and less paravalvular aortic regurgitation.

CONCLUSIONS
In intermediate-risk patients, TAVR was similar to surgical aortic-valve replacement with respect to the primary end point of death or disabling stroke. (Funded by Edwards LifeSciences; PARTNER 2 ClinicalTrials.gov number: NCT01314312.)

The authors' affiliations are listed in the Appendix. Address reprint requests to Dr. Leon at Columbia University Medical Center, 611 Ft. Washington Ave., 6th Floor, New York, NY 10032, or at mleon@columbia.edu.

*A complete list of investigators in the Placement of Aortic Transcatheter Valves (PARTNER) 2 trial is provided in the Supplementary Appendix, available at NEJM.org.

This article was published on April 2, 2016, at NEJM.org.

N Engl J Med 2016;374:e1609-20.
DOI: 10.1056/NEJMoa1514516
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BMJ-RapidRecs for TAVI , let us have a look before you explore it together...*

* All papers open access and for you to scrutinize, adapt and use for your purposes

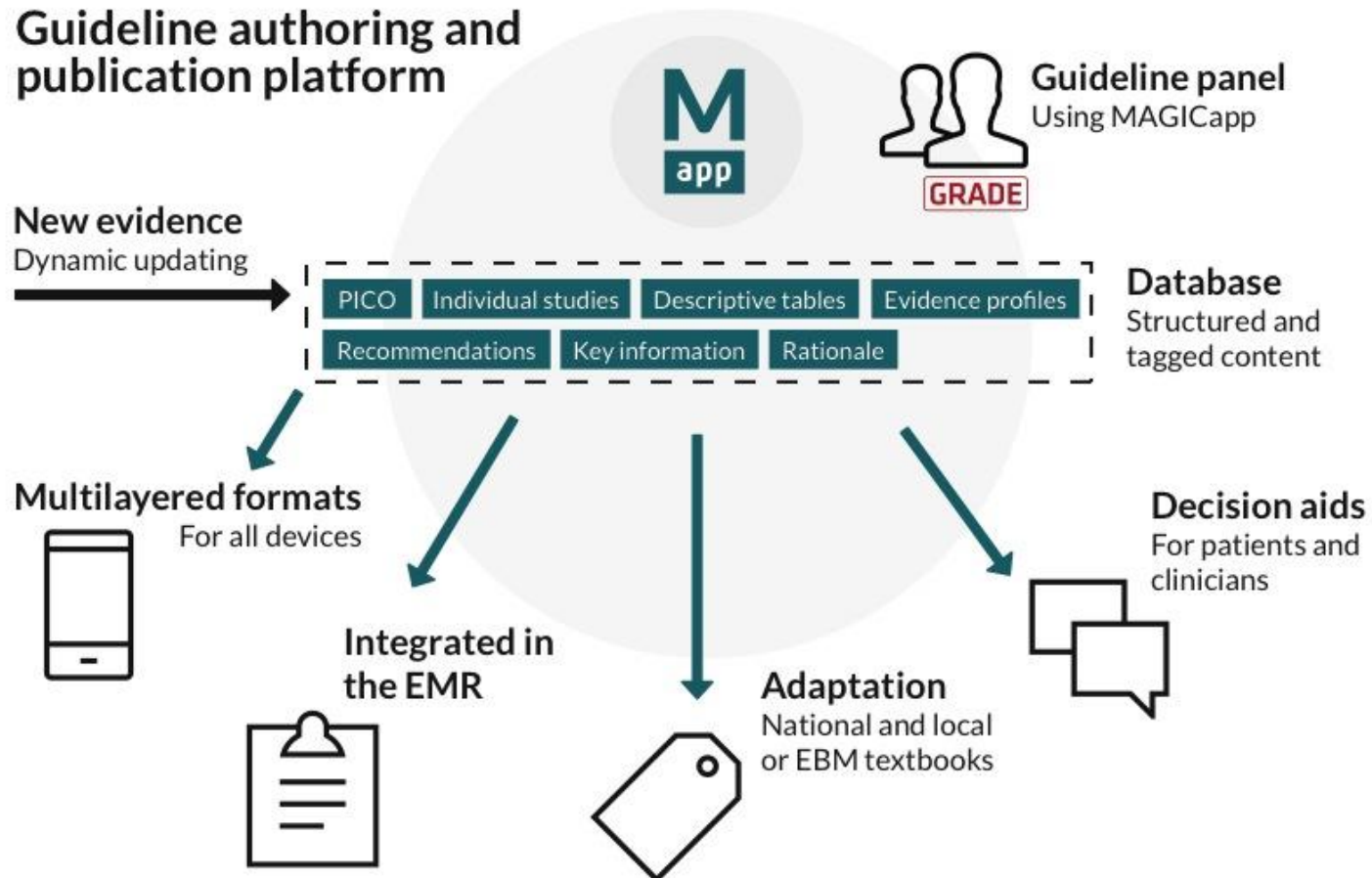
Plenary discussion

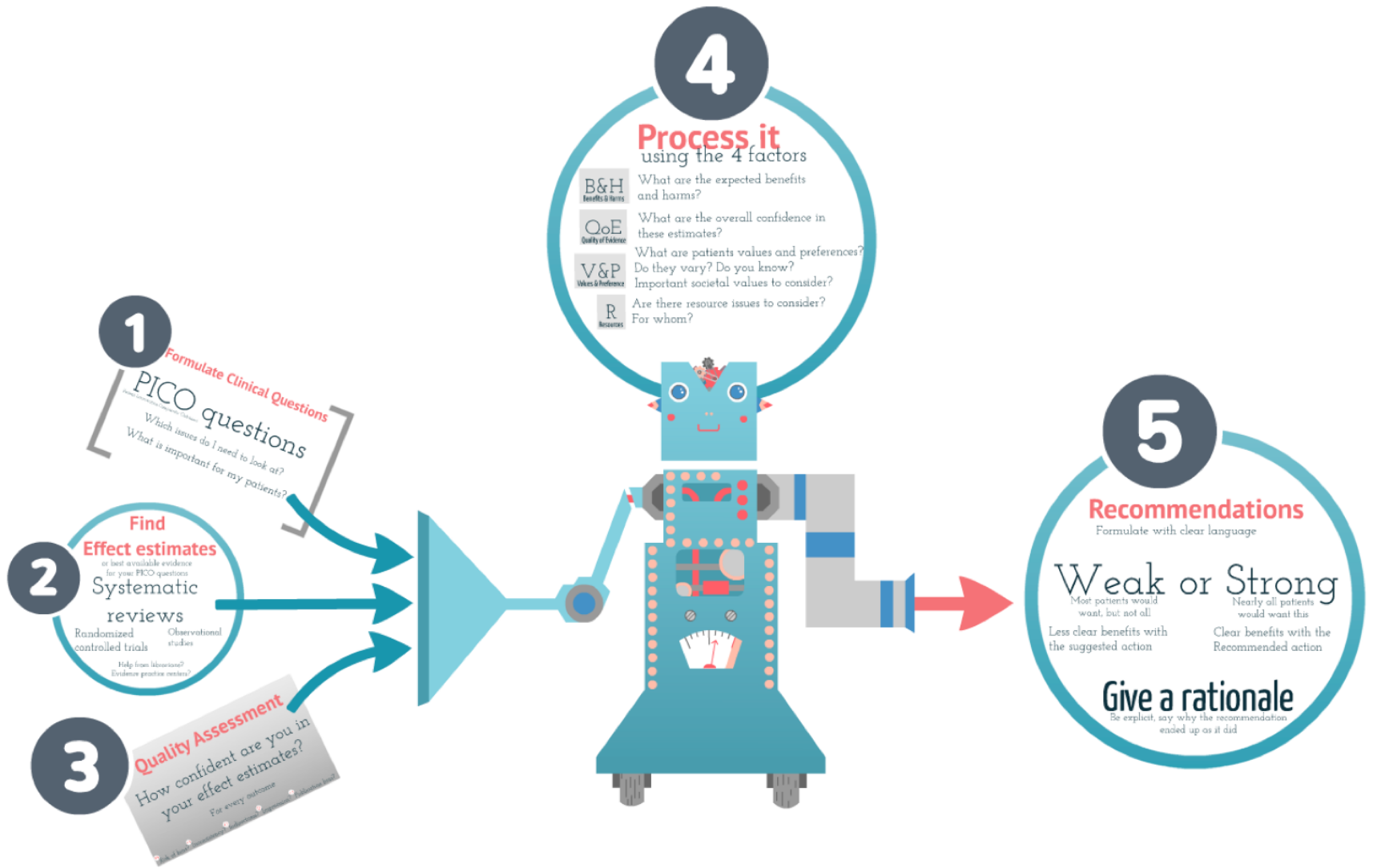
- How does this way of displaying evidence and recommendations work for clinicians, you, people?
- How can we further improve MAGICapp?

How to develop and update an evidence summary and a trustworthy recommendation in MAGICapp

MAGIC app

Guideline authoring and publication platform





BASICs of making **GRADE** guidelines

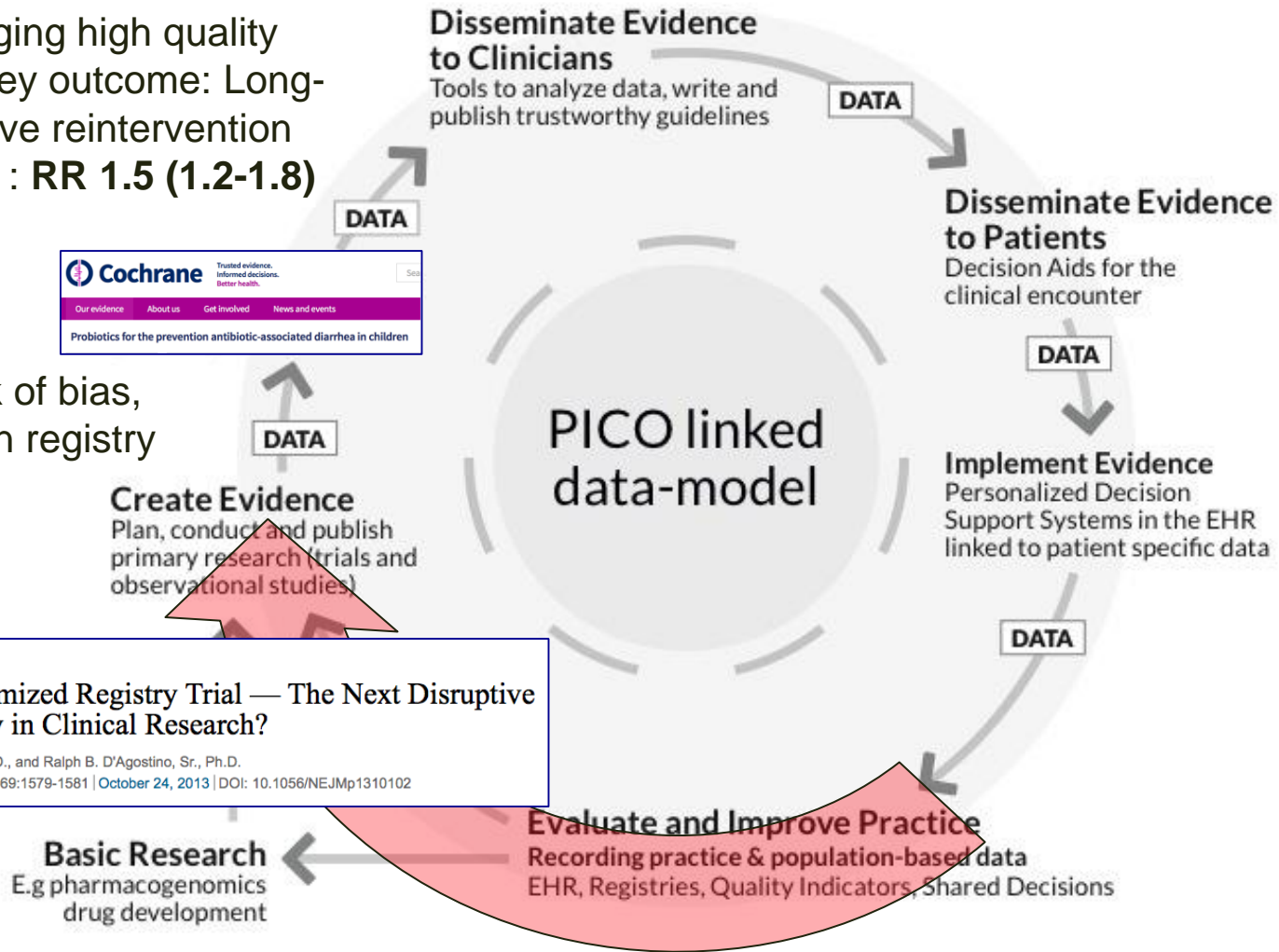
FAKE NEWS: Imagine such a new trial on TAVI was published rapidly synthesized into a Cochrane review in the Evidence Ecosystem

Practice-changing high quality evidence for key outcome: Long-term aortic valve reintervention
TAVI vs SAVR : RR 1.5 (1.2-1.8)



RCT at low risk of bias,
 5000 patients in registry

PERSPECTIVE
The Randomized Registry Trial — The Next Disruptive Technology in Clinical Research?
 Michael S. Lauer, M.D., and Ralph B. D'Agostino, Sr., Ph.D.
 N Engl J Med 2013; 369:1579-1581 | October 24, 2013 | DOI: 10.1056/NEJMp1310102



✓ **Transfemoral Transcatheter aortic valve insertion (TAVI) vs Surgical aortic valve replacement (SAVR)**

Patients 65-75 years with severe symptomatic aortic stenosis who are at low or intermediate perioperative risk

15 Outcomes [Summary](#)

Outcome Timeframe	Study results and measurements	Absolute effect estimates		Certainty in effect estimates (Quality of evidence)	Plain text summary
		SAVR	Transfemoral TAVI		
Mortality, age adjusted 2 years	Hazard Ratio 0.79 (CI 95% 0.66 - 0.94) Based on data from 2576 patients in 3 studies Follow up: 2 years.	92 per 1000	73 per 1000	Moderate Due to serious imprecision	TAVI probably reduces the risk of death.
Stroke (includes perioperative events) 2 years	Relative risk 0.8 (CI 95% 0.63 - 1.01) Based on data from 2576 patients in 3 studies Follow up: 2 years.	70 per 1000	56 per 1000	Moderate Due to serious imprecision	TAVI probably reduces the risk of stroke.
Aortic valve reintervention 2 years	Relative risk 1.5 (CI 95% 1.2 - 1.8) Based on data from 3058 patients in 3 studies Follow up: 2 years.	3 per 1000	5 per 1000	High	TAVI probably increases the risk of aortic valve reintervention.
Aortic valve reintervention - long term 10 years	Relative risk 1.5 (CI 95% 1.2 - 1.8) Based on data from 3058 patients in 3 studies Follow up: 2 years.	61 per 1000	92 per 1000	High	TAVI may increase need for aortic reintervention due to structural valve deterioration

www.magicapp.org

Improving patient care through guidelines, evidence summaries and decision aids that we can all trust, use and share

Recently published guidelines

[View all](#)

Wiki Recs

Adjunctive corticosteroid therapy for adults hospitalized with community-acquired pneumonia

Reed Siemiemiuk - WikiRecs Group



Retningslinjer for antitrombotisk behandling og profylakse

Per Olav Vandvik - Norsk Selskap for Trombose og Hemostase



Behandlingsretningslinjer for håndleddsbrudd hos voksne

Hebe Désirée Kvermmo. Medforfattere: Leiv Magne Hove, Adalsteinn Odinson, Katrine Bjørnebek Frønsdal, Ingrid Harboe, Yngvar Krukhaug - Norsk Ortopedisk forening



National klinisk retningslinje for analinkontinens hos voksne - konservativ behandling og utredning af nyopstået

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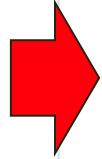
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☑ **Transfemoral Transcatheter aortic valve insertion (TAVI) vs Surgical aortic valve replacement (SAVR)**

Patients 65-75 years with severe symptomatic aortic stenosis who are at low or intermediate perioperative risk

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Aortic valve reintervention - long term 10 years	Relative risk 1.5 (CI 95% 1.2 - 1.8) Based on data from 3058 patients in 3 studies Follow up: 2 years.	61 per 1000	92 per 1000	High	TAVI may increase need for aortic reintervention due to structural valve deterioration





1 TAVI versus SAVR for patients with severe symptomatic aortic stenosis at low to intermediate perioperative risk

[View Section Text](#)[Add PICO](#)

1.1

[Options](#)

POPULATION

Patients 65-75 years with severe symptomatic aortic stenosis who are at low or intermediate perioperative risk

INTERVENTION

Transfemoral transcatheter aortic valve insertion (TAVI)

COMPARATOR

Surgical aortic valve replacement (SAVR)

OUTCOMES

Under development

Mortality, age adjusted

Stroke (includes perioperative events)

Aortic valve reintervention

Aortic

valve reintervention - long term

Permanent pacemaker insertion

Life threatening bleeding

Atrial fibrillation (includes

transient postoperative)

Moderate/severe heart failure symptoms (NYHA \geq III)

Myocardial infarction

Acute kidney injury

(includes transient events)

something

Health-related quality of life

Length of index

hospitalization

Pain

Recovery time

[VIEW MORE DETAILS](#) 

Outcome
TimeframeStudy results and
measurements

Absolute effect estimates

SAVR

Transfemoral TAVI

Certainty in effect
estimates

(Quality of evidence)

Plain text summary

+ Outcome

Dichotomous Outcome

Outcome Timeframe	Study results and measurements	Absolute effect estimates SAVR	Absolute effect estimates Transfemoral TAVI	Certainty in effect estimates (Quality of evidence)	Plain text summary	
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Aortic valve reintervention 2 years	Relative risk 3.25 (CI 95% 1.29 - 8.14) Based on data from 3058 patients in 3 studies Follow up: 2 years.	3 per 1000	10 per 1000	High	TAVI probably increases the risk of aortic valve reintervention.	Development ⚙️ ↑ ↓
Aortic valve reintervention - long term 10 years	Relative risk 3.25 (CI 95% 1.29 - 8.14) Based on data from 3058 patients in 3 studies Follow up: 2 years.	61 per 1000	198 per 1000	High	TAVI may increase need for aortic reintervention due to structural valve deterioration	Development ⚙️ ↑ ↓

Aortic valve reintervention 2 years

Relative risk 3.25
(CI 95% 1.29 - 8.14)
Based on data from 3058
patients in 3 studies
Follow up: 2 years.

3 per 1000
10 per 1000
Difference: 7 more per 1000
(CI 95% 1 more - 21 more)

High

TAVI probably
increases the risk
of aortic valve
reintervention.

Development



← Outcome

Save

Close

Certainty in effect estimates →

Changed fields | Undo all changes

1 Relative effect of intervention vs. comparator ?

SOURCE OF EVIDENCE

Systematic review/ meta-

Systematic review:
Studies: 0

Add and show evidence

DATA FROM INCLUDED STUDIES Autofill from added studies ?

3,058 patients in 3 Studies.

Randomized controlled

Follow up (in studies)

2 years

RELATIVE EFFECT (FROM STUDIES)

Relative risk 3.25

CI 95% (1.29 - 8.14)

2 Baseline risk (result of the outcome in the comparison group): SAVR ?

SOURCE OF EVIDENCE

Control arm of reference

Studies: 0

Add and show evidence

BASELINE RISK/ EFFECT WITH COMPARATOR

3

per 1000

3 Expected difference and best estimate of effect with intervention: Transfemoral TAVI ?

Calculate
estimates

CALCULATED ESTIMATE WITH INTERVENTION

10

per 100

ESTIMATED ABSOLUTE DIFFERENCE OF INTERVENTION VS. COMPARATOR (CALCULATED)

Difference: 7 more per 1000

CI 95% (1 more - 21 more)



Updating the recommendation: What would the panel recommend be for patients 65-75 years old? (screenshot current)

Patients aged 65 to < 75 years and eligible for transfemoral TAVI or SAVR

Weak recommendation

We suggest SAVR rather than TAVI

This recommendation considers benefits and harms of treatment alternatives with a particular weight on the uncertainty regarding the long-term durability of TAVI valves for those under 75. The age thresholds reflect the key issue, which is expected life span; clinicians need to also consider other factors such as comorbidity.

[VIEW MORE DETAILS](#) ▼

<p>Aortic valve reintervention - long term 10 years</p>	<p>Relative risk 3.25 (CI 95% 1.29 - 8.14) Based on data from 3,058 patients in 3 studies. (Randomized controlled) Follow up 2 years</p>	<p>61 per 1000 198 per 1000</p> <p>Difference: 137 more per 1000 (CI 95% 436 more - 18 more)</p>	<p>Very Low Due to inconsistency, indirectness and imprecision</p>	<p>TAVI may increase need for aortic reintervention due to structural valve deterioration</p>
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Updating the recommendation: What would the panel recommend be for patients 65-75 years old? (screenshot new)

Patients aged 65 to < 75 years and eligible for transfemoral TAVI or SAVR

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<p>Aortic valve reintervention 2 years</p>	<p>Relative risk 1.5 (CI 95% 1.2 - 1.8) Based on data from 3058 patients in 3 studies Follow up: 2 years.</p>	<p>3 per 1000 5 per 1000 Difference: 2 more per 1000 (CI 95% 1 more - 2 more)</p>	<p>High</p>	<p>TAVI probably increases the risk of aortic valve reintervention.</p>
<p>Aortic valve reintervention - long term 10 years</p>	<p>Relative risk 1.5 (CI 95% 1.2 - 1.8) Based on data from 3058 patients in 3 studies Follow up: 2 years.</p>	<p>61 per 1000 92 per 1000 Difference: 31 more per 1000 (CI 95% 12 more - 49 more)</p>	<p>High</p>	<p>TAVI may increase need for aortic reintervention due to structural valve deterioration</p>

Patients aged 65 to < 75 years and eligible for


Weak recommendation · Set ▼

Benefits outweigh harms for the majority, but not for every
[Learn more](#)

We suggest SAVR rather than TAVI

 This recommendation considers benefits and harms of treatment and uncertainty regarding the long-term durability of TAVI valve, life expectancy issue, which is expected life span; clinicians need to also consider

VIEW LESS


 Search evidence

Key info

Rationale

Pr

Benefits and harms

 Benefits of TAVI include reduced deaths, strokes, major bleeds, new onset atrial fibrillations and days in hospital over 2 year follow-up. Harms include increased need for aortic reinterventions in the short term over 2 year follow-up. Long term durability of TAVI valves is likely to be reduced compared to SAVR biological valves which suggests increased need for aortic valve reinterventions within the first 10 years.

Quality of evidence

Benefits and harms

▼ Small net benefit, or little difference between alternatives



Benefits of TAVI include reduced deaths, strokes, major bleeds, new onset atrial fibrillations and days in hospital over 2 year follow-up. Harms include increased heart failure, need for pacemaker insertions and aortic reinterventions in the short term over 2 year follow-up. Long term durability of TAVI valves is likely to be reduced compared to SAVR biological valves which suggests increased need for aortic valve reinterventions within the first 10 years.

Quality of evidence

▼ Moderate



For transfemoral TAVI versus SAVR, high certainty for decrease in acute kidney injury, bleeding, atrial fibrillation, and hospital length of stay; moderate certainty for decrease in mortality, stroke, recovery time and increase in short term (2 year) aortic valve reintervention, permanent pacemaker, and moderate/severe heart failure; low certainty for decrease in postoperative pain and very low certainty for increase in long term (10 year) aortic valve reintervention.

Preference and values

▼ Substantial variability is expected or uncertain



Patients are likely to place different value on benefits and harms associated with TAVI. Patients aged 75 or younger - with a life expectancy well beyond 10 years - are likely to place a particularly high value on avoiding need for a second aortic valve replacement and are likely to choose surgery. Patients who place a high value on avoiding initial open heart surgery and are willing to accept an increased risk for aortic valve reintervention are likely to choose TAVI. A systematic review of values and preferences provided limited evidence to inform our judgements. One study showed that patients have high risk willingness for mortality in exchange for perfect health (someone of equal age without aortic stenosis) [14].

Resources and other considerations

▼ Important issues, or potential issues not investigated



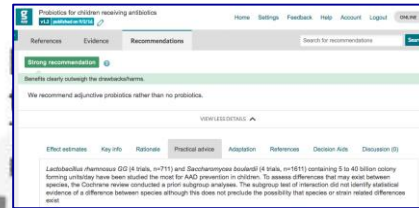
TAVI should be considered only in centres with sufficient expertise utilizing specialized TAVI teams consisting of interventional cardiologists, general cardiologists, cardiac surgeons, and appropriate nursing and adjunctive personnel. Cost-effectiveness of SAVR versus TAVI in low to intermediate risk patients remains uncertain in the absence of available cost-benefit analyses.

Plenary discussion

- Digital authoring of evidence summaries, recommendations and decision aids: Feasible or too big of a leap for you?
- How could MAGICapp work for you, in creating, publishing and updating evidence summaries for systematic reviews?
- Want to be part of the Evidence Ecosystem?

Digital and Trustworthy Evidence Ecosystem

From RapidRecs pilot to closing the loop in Finland and Belgium

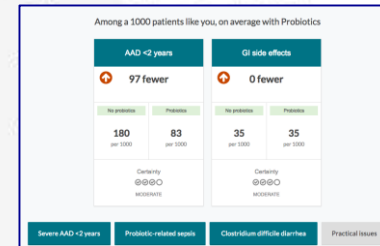


DATA

DATA

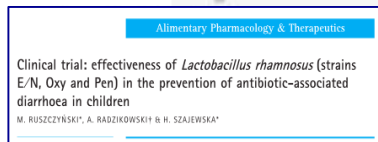


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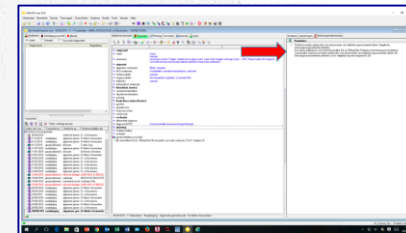


PICO linked data-model

DATA



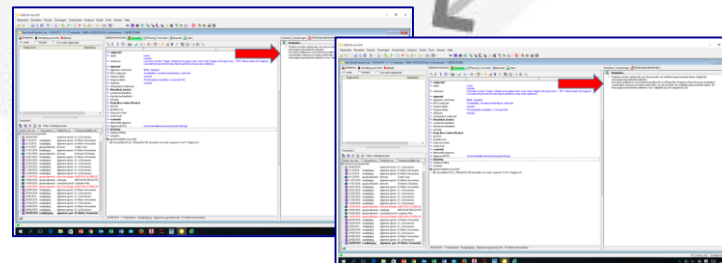
23 trials
n=4000



Offer probiotics

DATA

Basic Research
E.g pharmacogenomics
drug development



Baseline:
3 of 100
offered
probiotics

In summary

- MAGICapp allows creation, dissemination and dynamic updating of evidence summaries, recommendations and decision aids
- Within an emerging evidence ecosystem, the BMJ-RapidRecs provide a model for rapidly responding to potentially practice-changing evidence through systematic reviews and trustworthy recommendations: Organizations fit for purpose?
- Authoring, publishing and updating of evidence summaries for systematic reviews an emerging opportunity: Will Cochrane and other review groups benefit from our services?



Per Olav Vandvik, MD PhD

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Linn Brandt, MD

PLUGGED-IN, technology and collaboration

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Annette Kristiansen, MD

SNAP-IT, methodology

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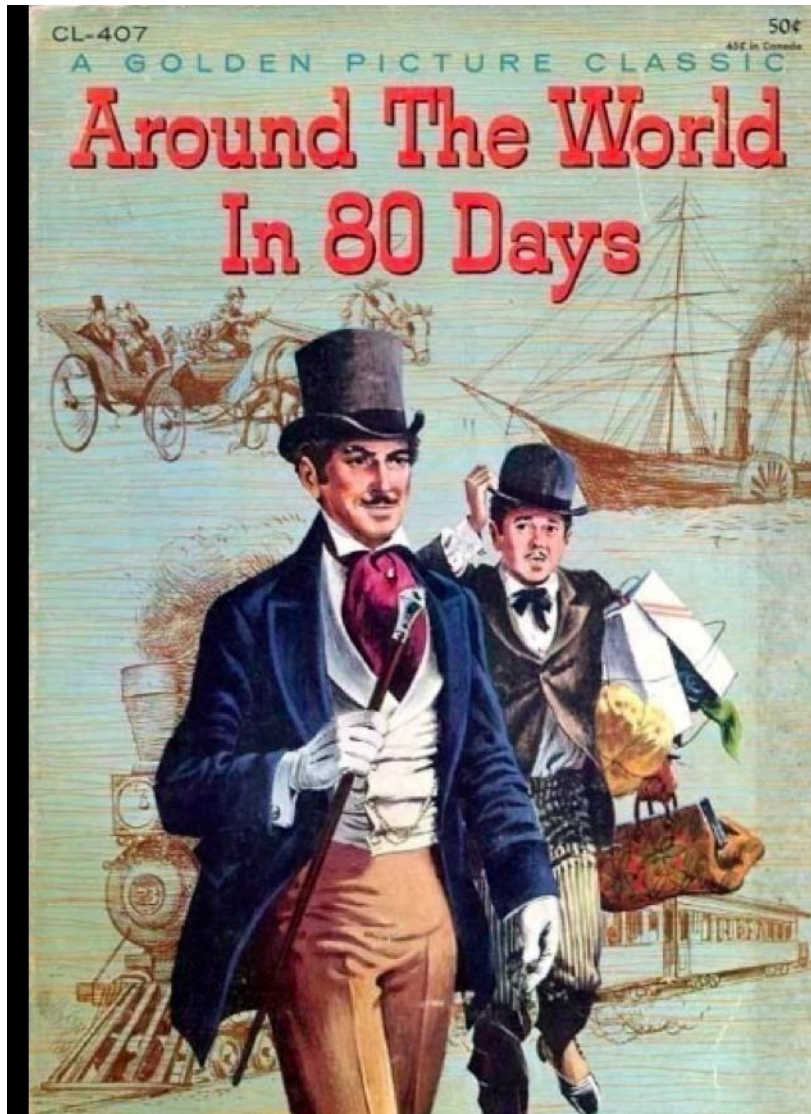


Lyubov Lytvyn, MSc

WikiRecs

Medical Researcher, Oslo University Hospital, Norway

Ilkka Kunnamo 2016:



Jules Verne imagined that you could travel around the world in 80 days

The Evidence Ecosystem summarized, circulated and implemented the evidence in 85 days

One day evidence can be circulated as quickly as you travel today

Want to join the journey?