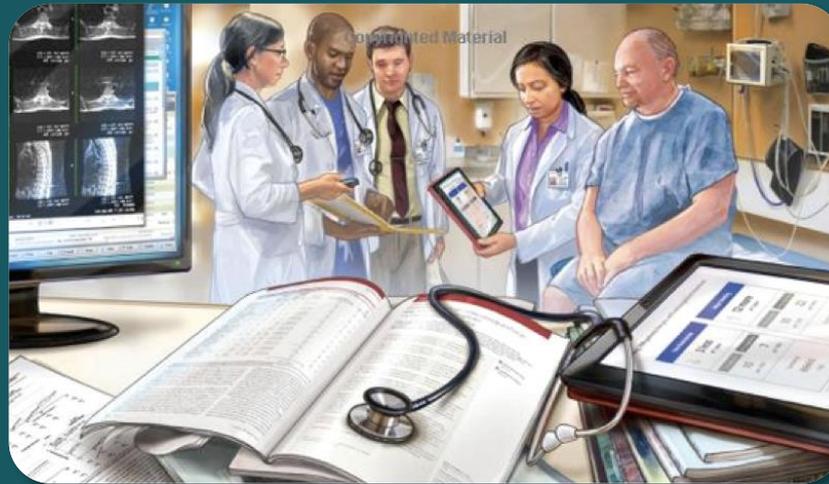


# Health data and Real World Evidence to inform policy and practice – through a digital and trustworthy evidence ecosystem

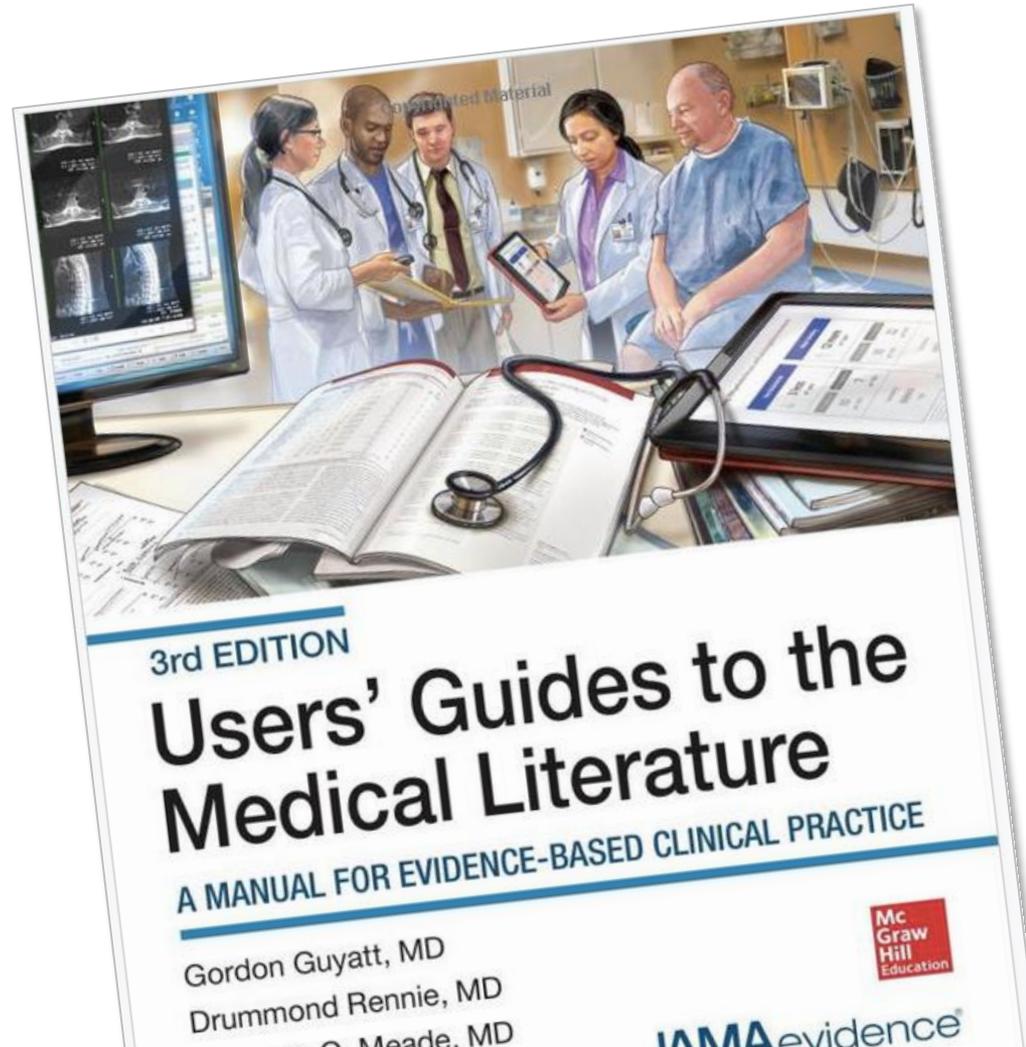


**Per Olav Vandvik**, Professor of Medicine, University of Oslo and Norwegian Institute of Public Health

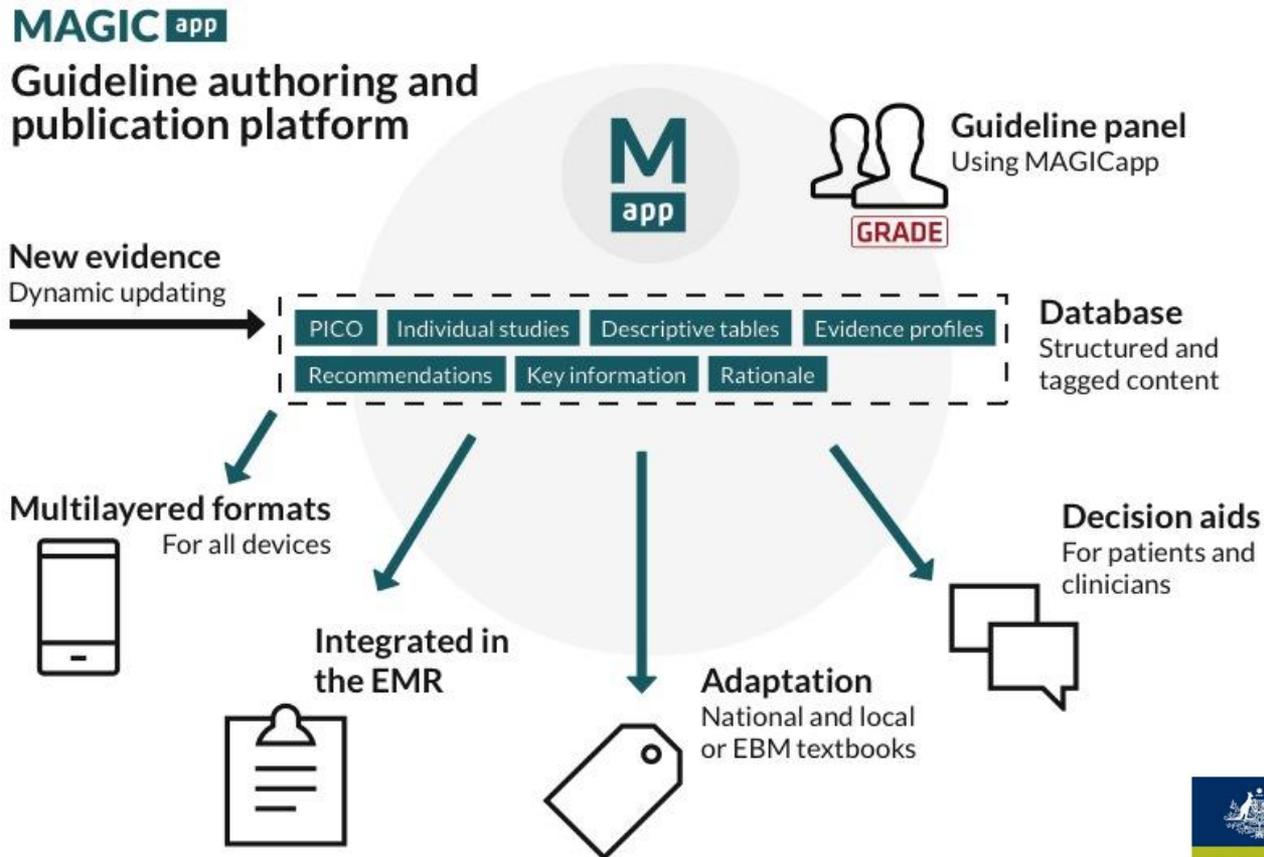
**Disclosures:** Head of MAGIC (non-profit), BMJ Rapid Recommendations and the Evidence Ecosystem project



**Major challenges with EBM, systematic reviews, HTA and guidelines** but also great advances in standards, methods and tools



# Can technology help? Platforms and tools ready for use (e.g., [www.magicapp.org](http://www.magicapp.org))



# Multilayered formats of guidelines

The screenshot displays a web browser window with the URL `magicapp.org/app#/guideline/2178`. The page title is "The 2017 Canadian Guideline for Opioids for Chronic Non-Cancer Pain" (v4.8, published on 9/28/17). The navigation menu includes Home, Help, Resources, Log in, and language options (EN). A search bar is present with the placeholder text "Search for recommendations".

The main content area is organized into a list of sections on the left and a corresponding list of section cards on the right. Each card includes a "View Section Text" button.

- 1 About this guideline** (View Section Text)
- 2 Scope of the Guideline and How To Use the Guideline** (View Section Text)
- 3 Background and methods** (View Section Text)
- 4 Initiation and Dosing of Opioids in Patients with Chronic Noncancer Pain** (View Section Text)

Section 4 is expanded to show a recommendation:

**Recommendation 1: When considering therapy for patients with chronic non-cancer pain** (View Section Text)

**Strong recommendation**

We recommend optimization of non-opioid pharmacotherapy and non-pharmacological therapy, rather than a trial of opioids

# Challenges beyond guidelines, for patients and society

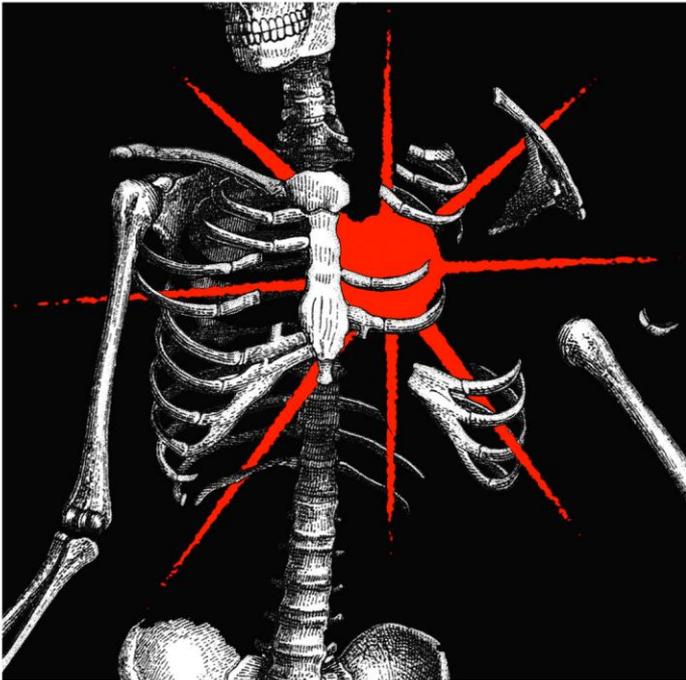


# eHealth is blooming with new devices, personalized medicine through genomics and Big Data : Are we creating value?

## The New York Times

OPINION

### Can Your Hip Replacement Kill You?

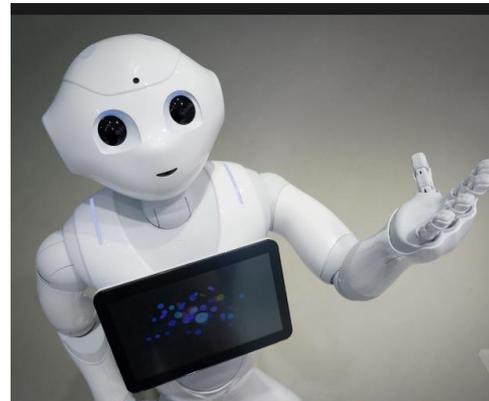


## JAMA The Journal of the American Medical Association

VIEWPOINT

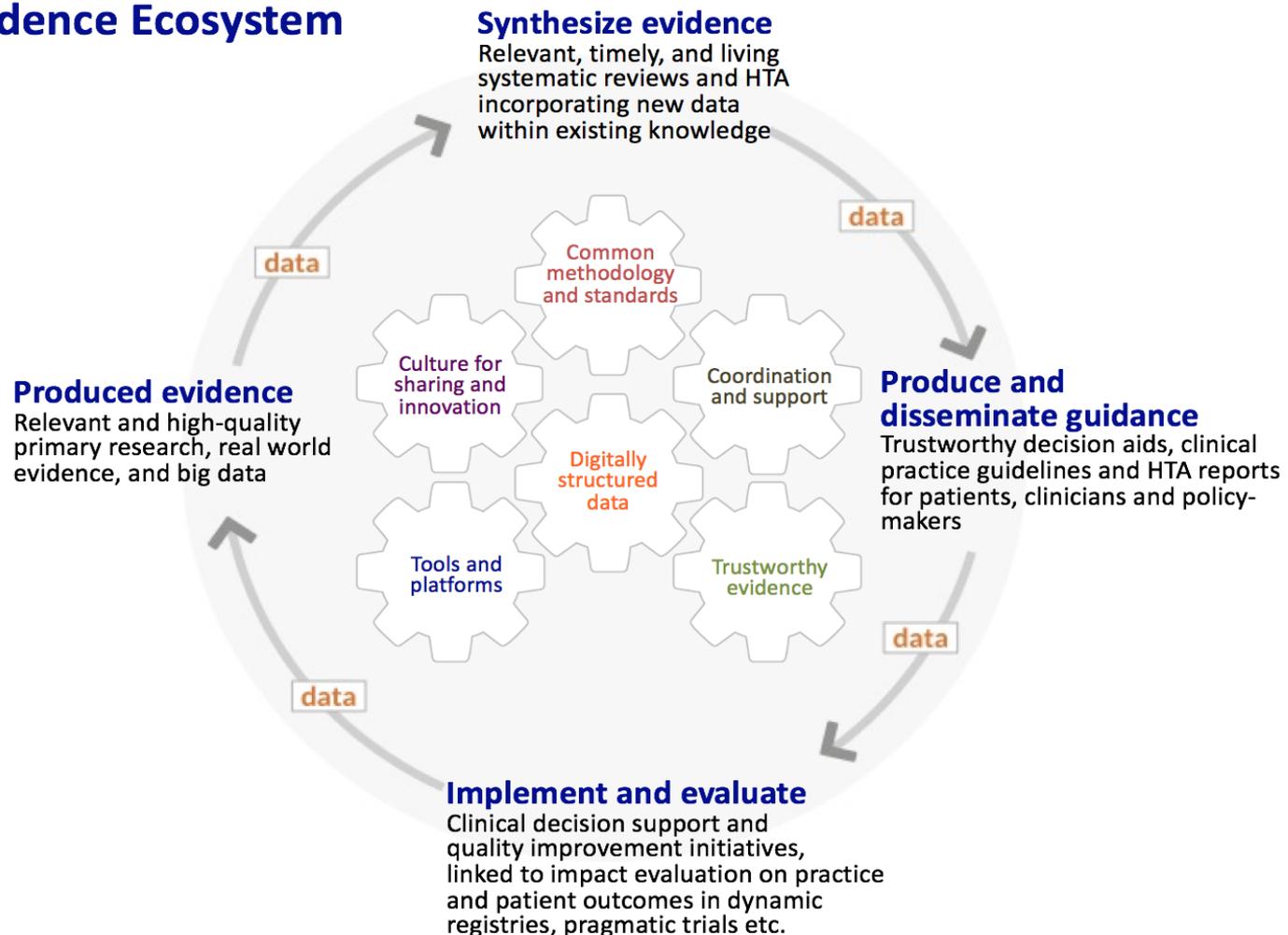
### No Shortcuts on the Long Road to Evidence-Based Genomic Medicine

With the recent proliferation of direct-to-consumer genetic testing, the need for evidence in genomic medicine is more important than ever.



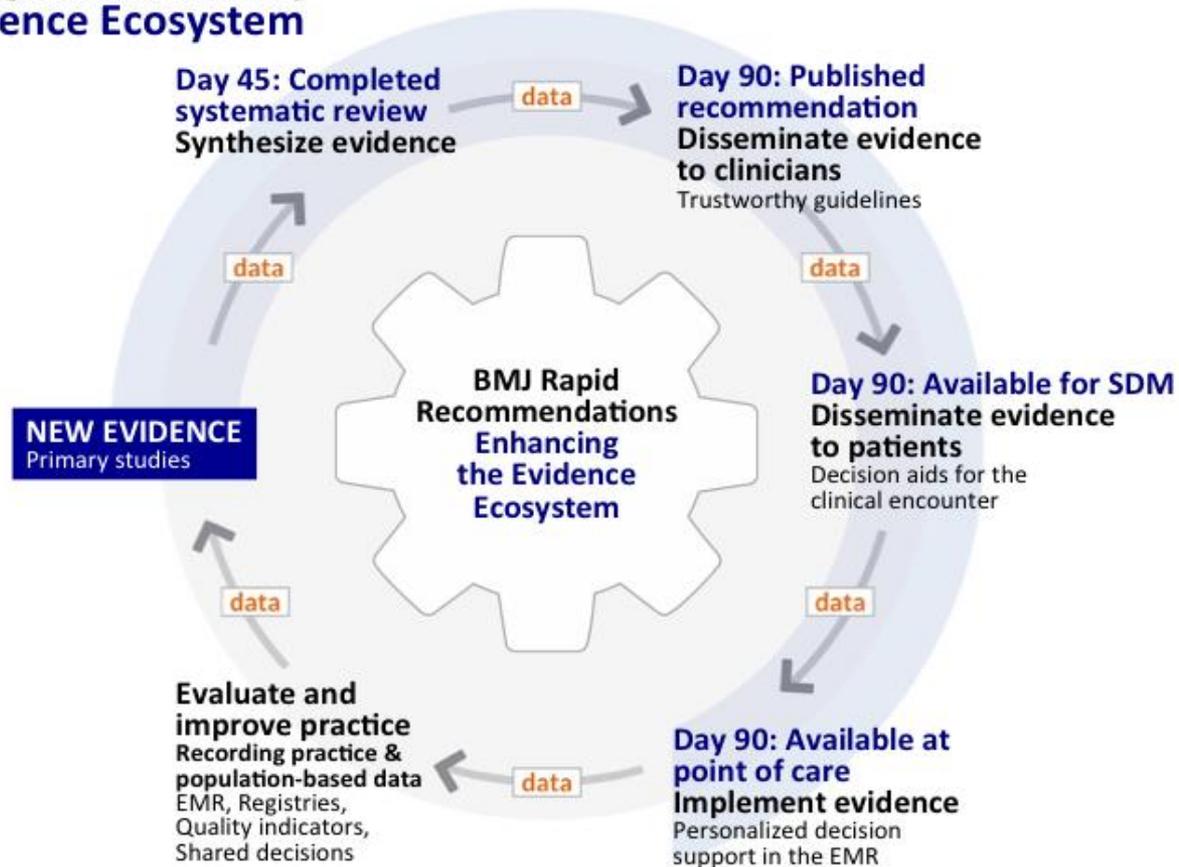
# Solutions, to increase value and reduce waste in health care and research

## Trustworthy, efficient and integrated Evidence Ecosystem



# Some hurdles to overcome: Organizations fit for purpose? BMJ Rapid Recommendations, a disruptive innovation?

## The Digital and Trustworthy Evidence Ecosystem



# Evidence Ecosystem: Fact or fiction?

3 case studies

# Potentially practice-changing evidence for Daniel?



- Daniel, 69 years old
- Heart failure, dizzy, not feeling well, sees his cardiologist
- 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**

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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; 76.3% 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 Life-sciences; NCT01323452.)

The authors' affiliations are listed in the Appendix. Address reprint requests to Dr. Leon at Columbia University Medical Center, 161 Ft. Washington Ave, 6th Floor, New York, NY 10032, or at mleon@crf.org.

\*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.

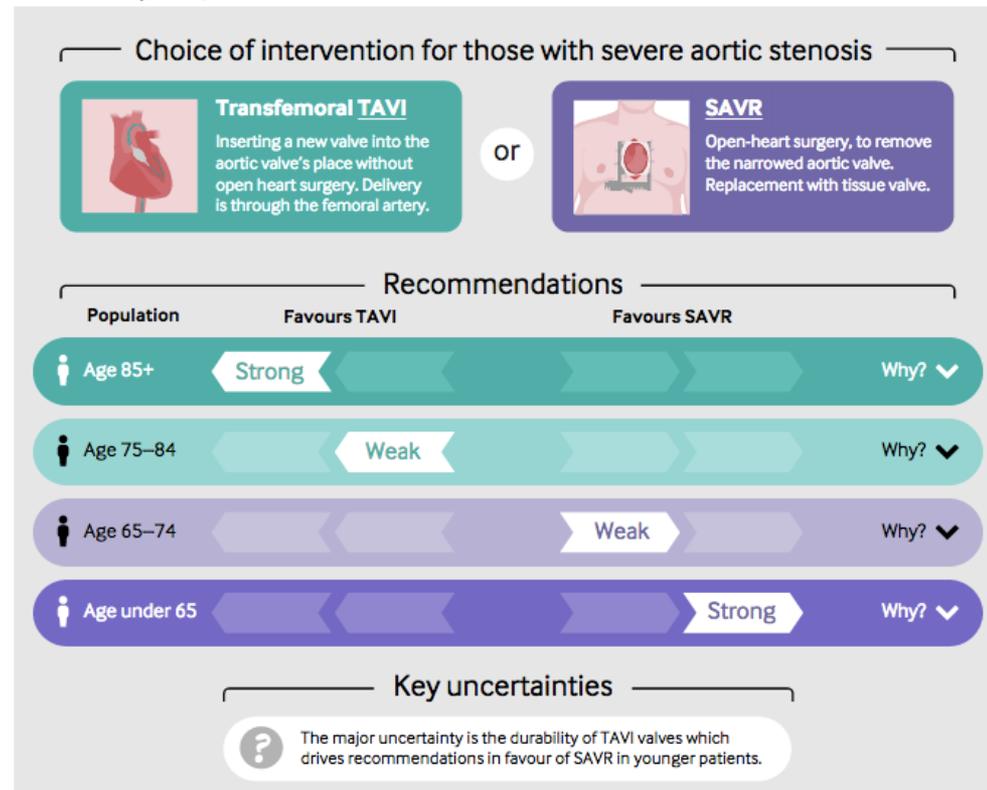
This article was published on April 2, 2016, at NEJM.org.

N Engl J Med 2016;374:1609-20.  
DOI: 10.1056/NEJMoa1514616  
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# BMJ Rapid Recommendations, let's have a look

## Transcatheter or surgical aortic valve replacement for patients with severe, symptomatic, aortic stenosis at low to intermediate surgical risk: a clinical practice guideline

BMJ 2016 ; 354 doi: <http://dx.doi.org/10.1136/bmj.i5085> (Published 28 September 2016)  
Cite this as: BMJ 2016;354:i5085

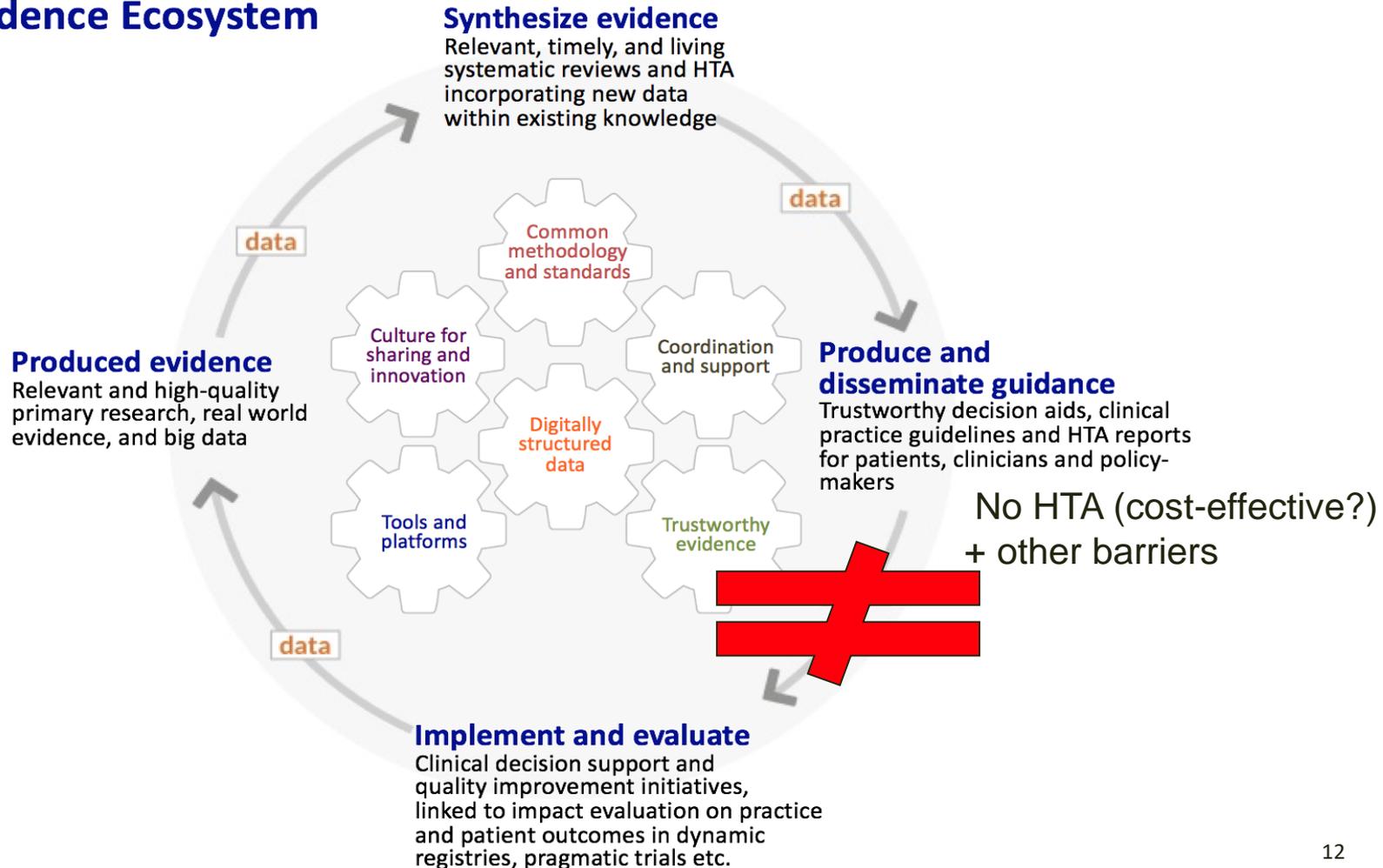


# Rapid and well-informed decisions for new health technologies, in a digital and trustworthy evidence ecosystem

Increasing value and reducing waste in Norwegian specialist health care



## Trustworthy, efficient and integrated Evidence Ecosystem



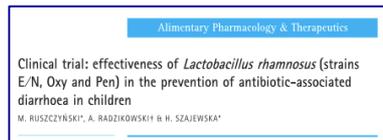
# Evidence Ecosystem increasing value

## Probiotics in children taking antibiotics?

### Trustworthy, efficient and integrated Evidence Ecosystem

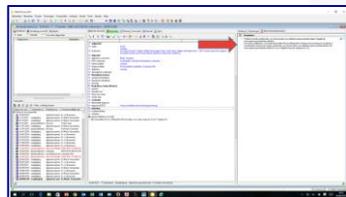
#### Synthesize evidence

Relevant, timely, and living systematic reviews and HTA incorporating new data within existing knowledge



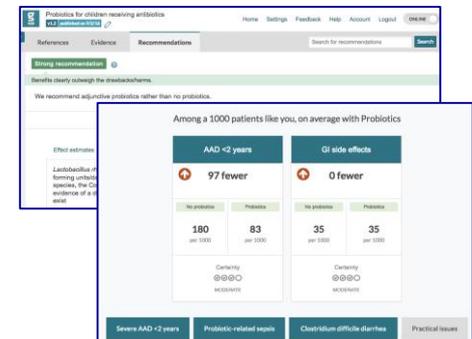
#### Produced evidence

Relevant and high-quality primary research, real world evidence, and big data



#### Produce and disseminate guidance

Trustworthy decision aids, clinical practice guidelines and HTA reports for patients, clinicians and policy-makers



#### Implement and evaluate

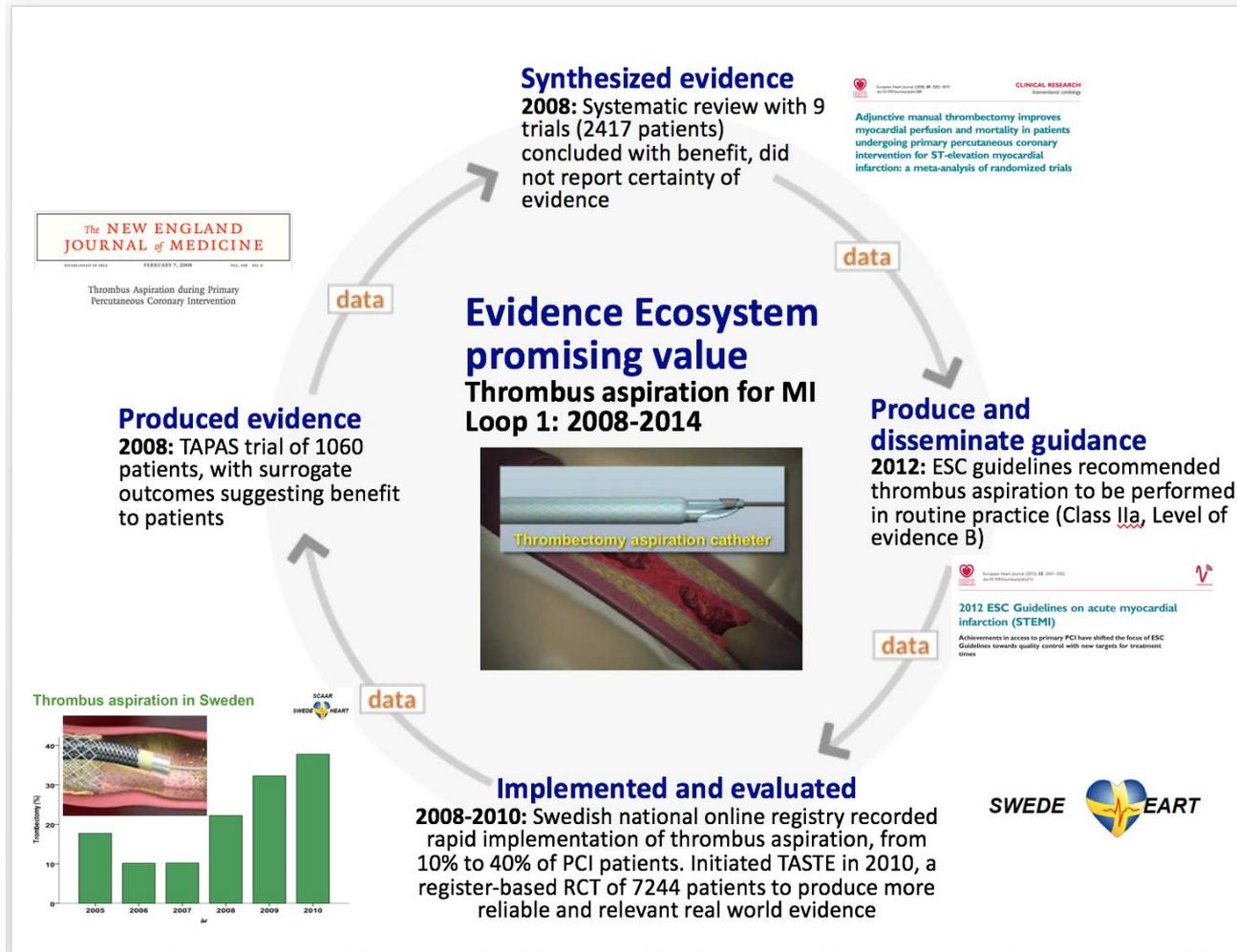
Clinical decision support and quality improvement initiatives, linked to impact evaluation on practice and patient outcomes in dynamic registries, pragmatic trials etc.

#### Baseline:

3 of 100 offered probiotics

# Evidence Ecosystem reducing waste

## Sweden using real-world evidence in SwedeHeart registry





## In summary and for discussion

- **Digital and Trustworthy Evidence Ecosystem to create value and reduce waste in health care**
  - Great advances in EBM, with decision support at the point of care, including shared decision-making and ready for CDS in the EHR
  - Rapid HTA for new health technologies in the Ecosystem?
  - Online registries harvesting real world evidence, with integrated evaluation of impact and generation of new and more trustworthy evidence to feed the Ecosystem loop
  - Norway to close the loop using real world evidence and health data?
- What do we need to get this in place, sooner than later?