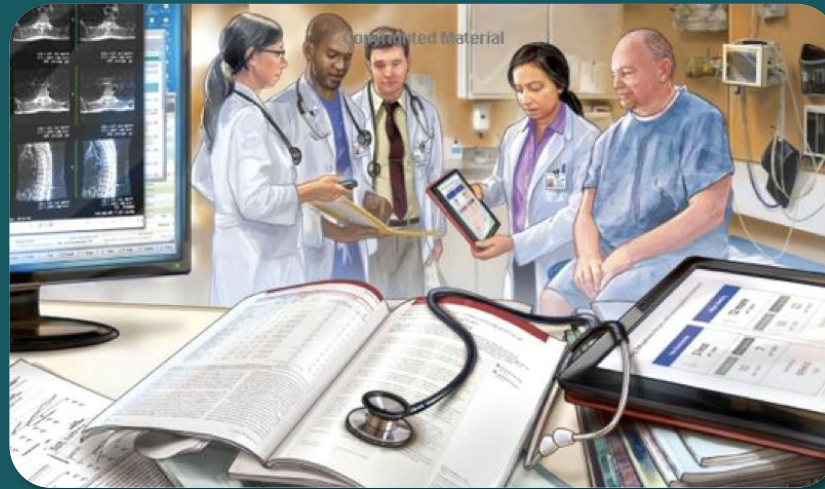


The digital and trustworthy evidence ecosystem: how can health industry players join to increase value in health care and capture a global market?



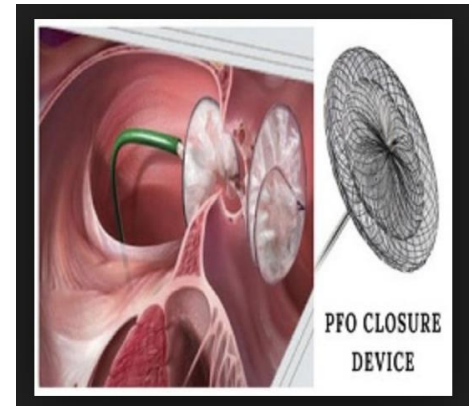
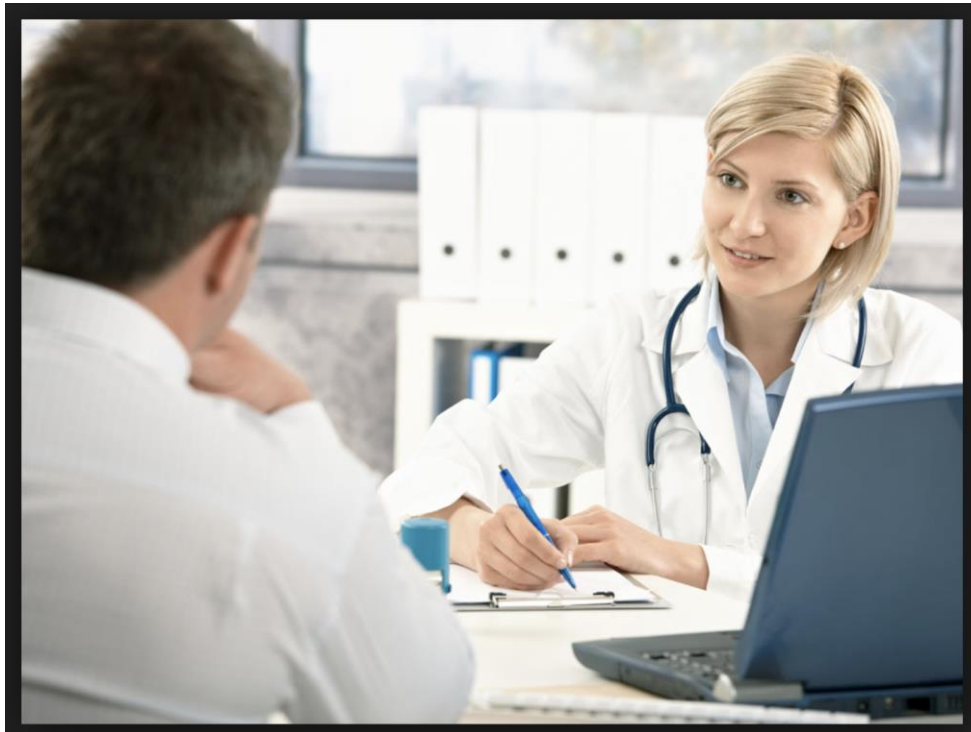
Per Olav Vandvik, Professor of Medicine, University of Oslo and Norwegian Institute of Public Health

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



Meet Jon with cryptogenic stroke, in need of a new device?

How can these two make a well- informed decision?

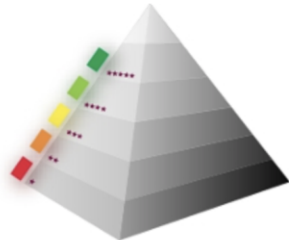


Doc: Should I close the hole in my heart?

How can clinicians find best current evidence < 2 minutes?

McMaster **PLUS** // helsebiblioteket.no
gir deg fri tilgang til denne tjenesten

Utvalgte nye studier



6S model explained
Criteria for articles in PLUS

Oppslagsverk ★★★★★

UpToDate
Best Practice
EBM Guidelines

Oppsummerte oversikter ★★★★★

ACP Journal Club (via PLUS)

Systematiske oversikter ★★★★★

PLUS Syntheses

Oppsummerte enkeltstudier ★★★★★

ACP Journal Club (via PLUS)

Enkeltstudier ★★★★★

PLUS Studies

Non-Appraised ★★★★★

PubMed Clinical Queries
PubMed

Historikk
cryptogenic stroke pfo closure
Current PLUS Database: Lege
Søk
Avansert søk

Oppslagsverk ★★★★★

UpToDate

Treatment of patent foramen ovale (PFO) f
Cryptogenic stroke
More Results...

Best Practice

Patent foramen ovale - Guidelines
Patent foramen ovale - Treatment algorithm
More Results...

EBM Guidelines

Closure vs. medical therapy for preventing
cryptogenic stroke or TIA



HelseDirektoratet



< Nasjonale faglige retningslinjer

Hjerneslag

Nasjonal faglig retningslinje for behandling og rehabilitering ved hjerneslag

OM RETNINGSLINJEN LAST NED PDF



Innholdsfortegnelse

Oppsummerte oversikter ★★★★★

ACP Journal Club (selected via PLUS)

Review: In cryptogenic stroke with PFO, adding PFO closure to medical therapy reduces recurrence

Systematiske oversikter ★★★★★

PLUS Syntheses

Patent foramen ovale closure, antiplatelet therapy or anticoagulation in patients with patent foramen ovale and cryptogenic stroke: a systematic review and network meta-analysis incorporating complementary external evidence. (Systematic Review)

Percutaneous patent foramen ovale closure for secondary stroke prevention: Network meta-analysis. (Systematic Review)

More Results...

Oppsummerte Enkeltstudier ★★★★★

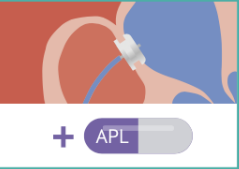
ACP Journal Club (selected via PLUS)

Adding patent foramen ovale closure to antiplatelet drugs reduced ischemic stroke after cryptogenic stroke

Adding patent foramen ovale closure to antiplatelet therapy reduced stroke after cryptogenic stroke

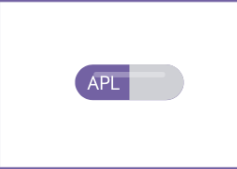
Trustworthy recommendation just published

PFO closure
Percutaneous closure of PFO followed by antiplatelet therapy



OR

Antiplatelets
Antiplatelet therapy alone



PFO closure **Antiplatelets**

Strong ⁱ Weak ⁱ Weak ⁱ Strong ⁱ

We recommend PFO closure followed by antiplatelet therapy over antiplatelet therapy alone.

[More details](#) ▼

Comparison of benefits and harms

Favours PFO closure No important difference ⁱ Favours antiplatelets

	Events per 1000 people		Evidence quality
Within 5 years			
Ischaemic stroke	13	87 fewer	★★★★ Moderate More ▼
Death	9	No important difference	★★★★ Moderate More ▼
Major bleeding	7	No important difference	★★★★ Moderate More ▼
Within 1 year			
Persistent AF ⁱ flutter	23	18 fewer	★★★★ Moderate More ▼
Device-related adverse events	36	36 fewer	★★★★ High More ▼

[▶ See all outcomes](#) **MAGIC app** [▶ See patient decision aids](#) **MAGIC app**

Key practical issues

<p>PFO closure</p> <ul style="list-style-type: none"> Procedure takes under 2 hours In-hospital stay is usually one day Most activities can be resumed within a few days Full recovery within a few weeks 	<p>Antiplatelets</p> <p>No key practical issues</p>
--	--

Preferences and values

Applicability

Take home messages/ objectives for this talk

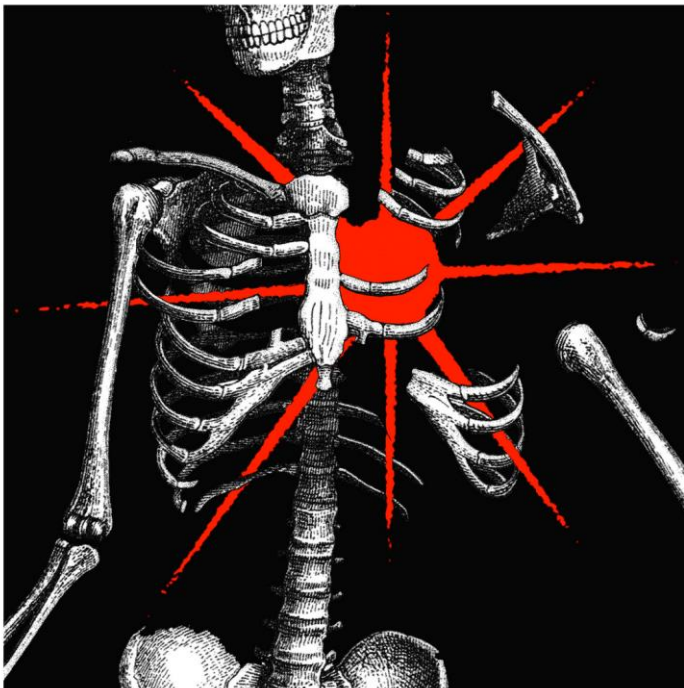
- PFO closure device companies got it right!
- How can you succeed in demonstrating benefits of devices and drugs to increase value in health care, while reaching the global market?
 - Get the question right, and make sure it's a good one
 - Perform the research to demonstrate value and to fully inform downstream decisions by policy-makers, clinicians and patients
 - Understand advances in standards, methods, processes and tools within an emerging digital and trustworthy evidence ecosystem for health care
 - Help improve the evidence ecosystem for mutual benefits

Health industry is blooming with new devices and drugs, personalized medicine through genomics and Big Data : Are we creating value?

The New York Times

OPINION

Can Your Hip Replacement Kill You?

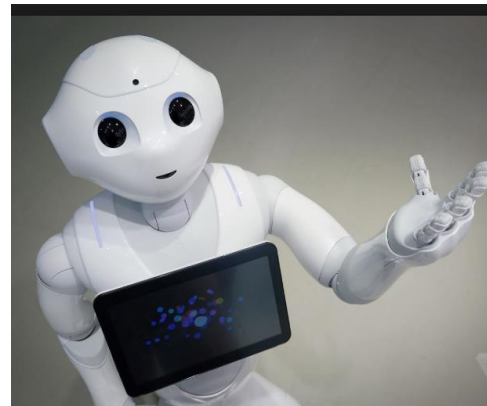


JAMA The Journal of the American Medical Association

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.



Reasons to be concerned (about the \$ 400 billion medical device industry)?



All good for drugs?

RESEARCH



OPEN ACCESS

Availability of evidence of benefits on overall survival and quality of life of cancer drugs approved by European Medicines Agency: retrospective cohort study of drug approvals 2009-13

Courtney Davis,¹ Huseyin Naci,² Evrim Gurpinar,² Elita Poplavska,³ Ashlyn Pinto,² Ajay Aggarwal^{4,5}

WHAT THIS STUDY ADDS

Most new oncology drugs authorised by the EMA in 2009-13 came onto the market without clear evidence that they improved the quality or quantity of patients' lives

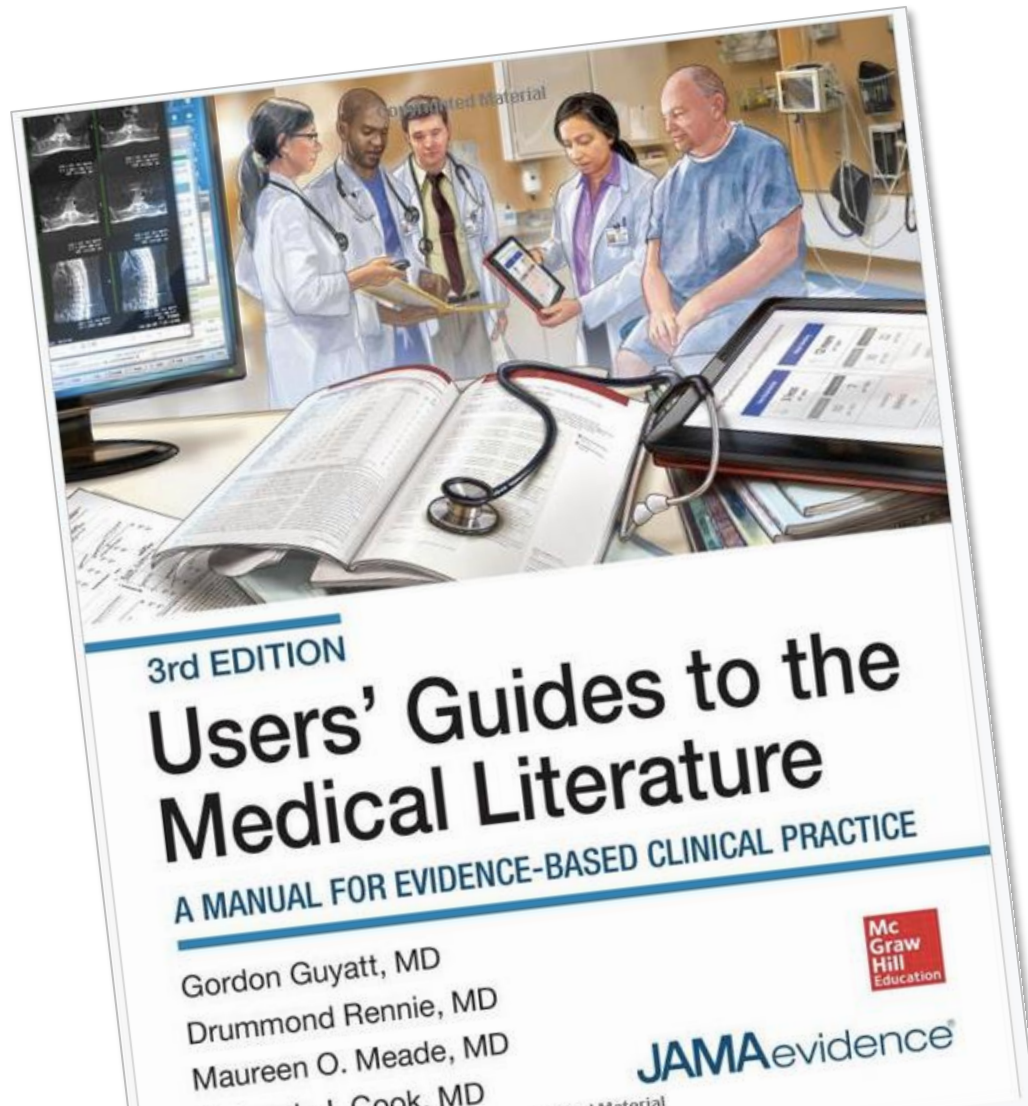
After market entry, cancer drugs rarely show benefits on overall survival or quality of life in randomised trials

When survival gains over available treatment alternatives are shown, they are not always clinically meaningful

Major advances for EBM, systematic reviews and guidelines in standards, methods and tools, but what about technology?

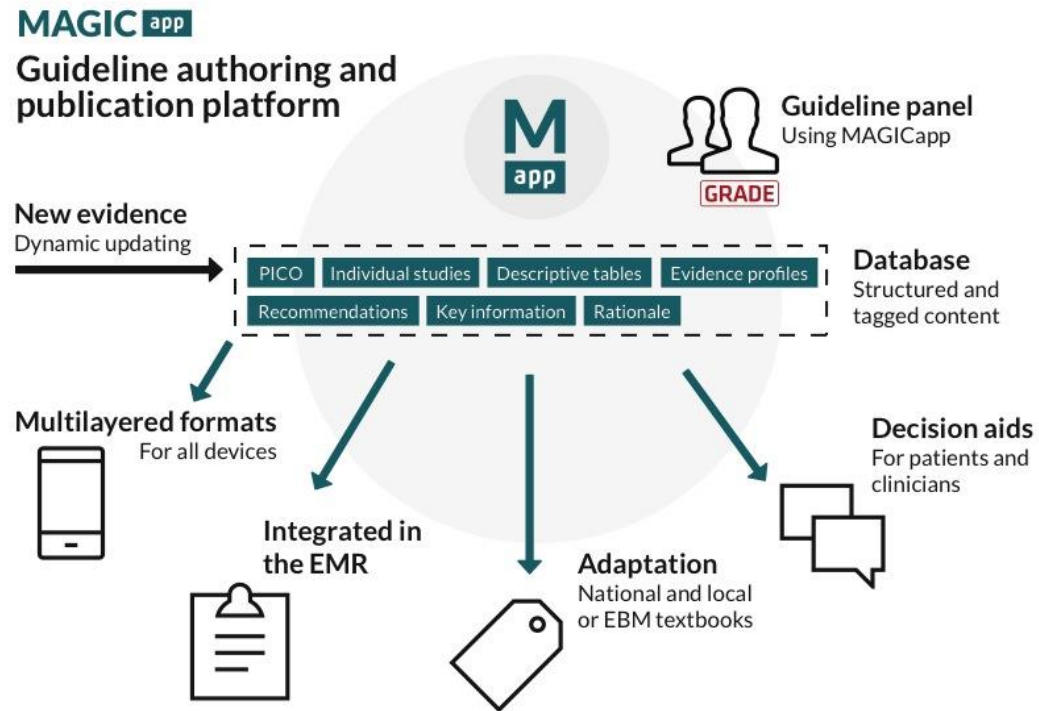


CLINICAL PRACTICE
GUIDELINES
WE CAN TRUST



Problems with guidelines: Can technology help?

Platforms and tools ready for use (e.g., www.magicapp.org)



Multilayered guidelines in digitally structured formats plugged into any information resource, ready for adaptation

The screenshot displays a web browser window with the URL `magicapp.org/app#/guideline/2178`. The page header includes the logo for SUNDHEDSSTYRELSEN (Danish Health Authorities) and navigation links for Home, Help, Resources, and Log in. A search bar is present with the text "Search for recommendations". The main content area is titled "Guidelines for Chronic Non-Cancer Pain" and is organized into a table of contents with four sections:

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

Section 4 is expanded to show a recommendation:

Recommendation 1: When considering therapy for patients with chronic non-cancer pain

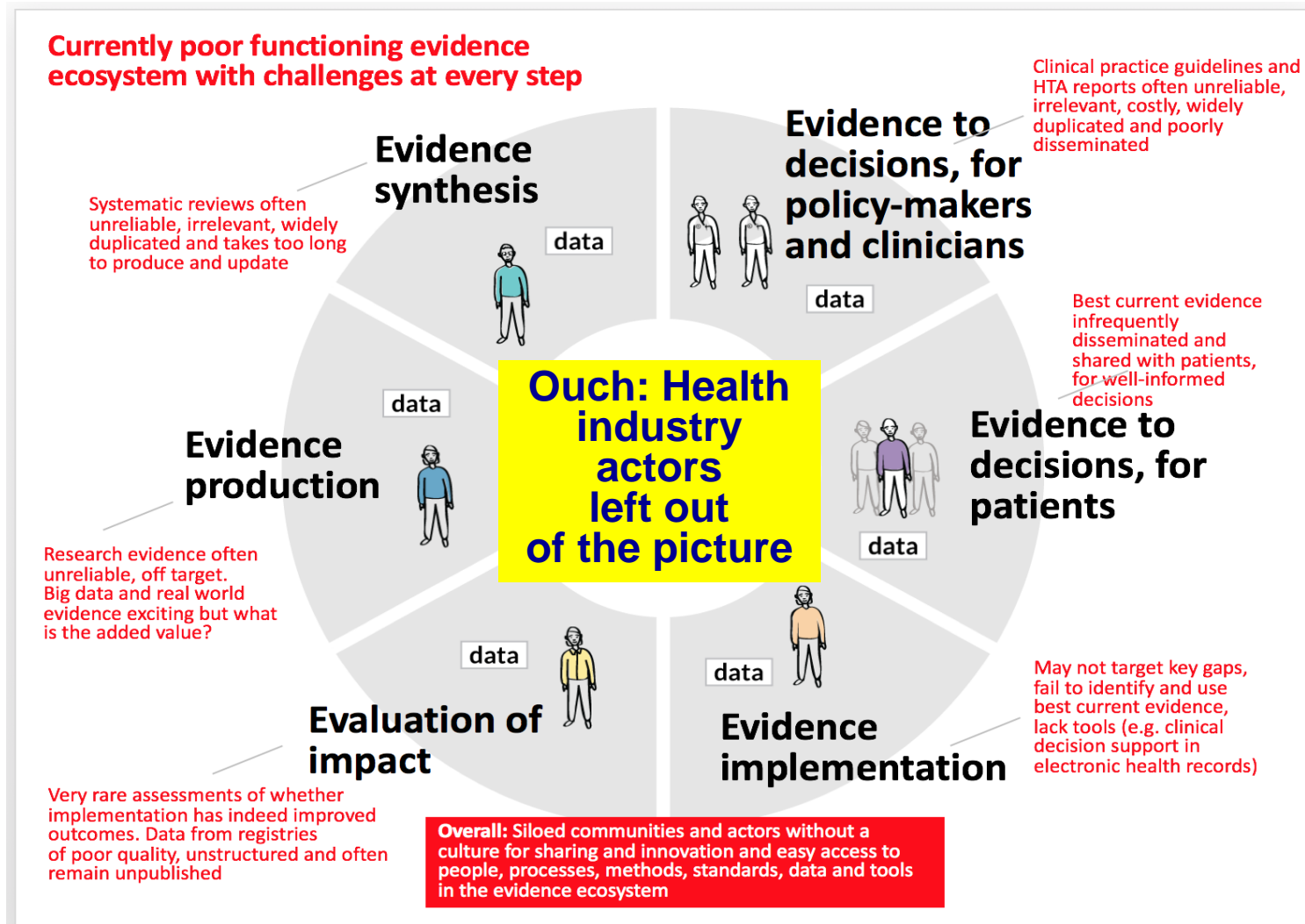
Strong recommendation

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

Challenges beyond guidelines, for patients and society



Problems in current Evidence Ecosystem, spelled out





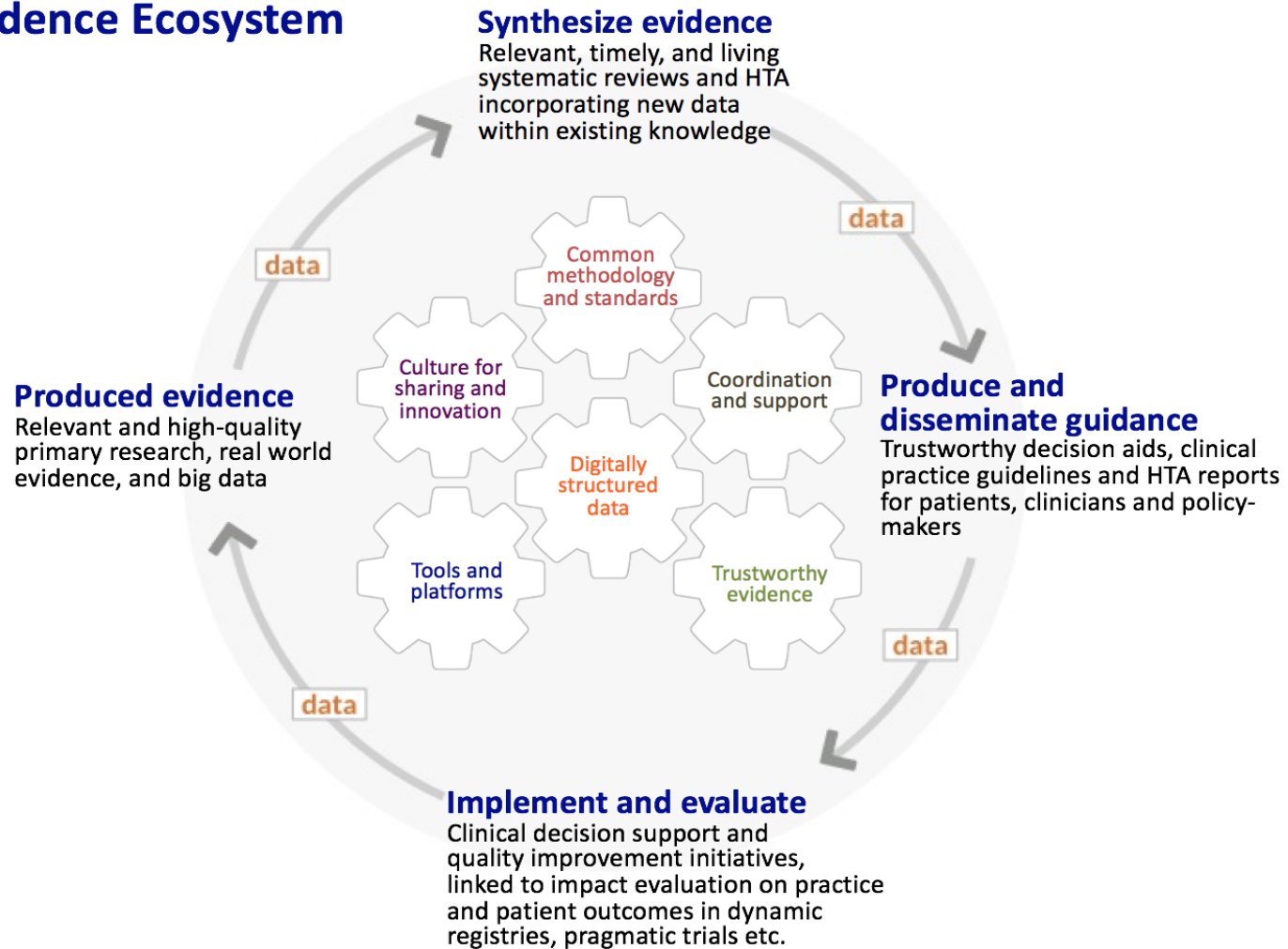
Driving innovations for faster uptake of new technologies in the Nordic and global healthcare

Health industry blooming but struggling to create valuable products and take the market

How can we accelerate product development, evaluation and implementation in health care at the global level?

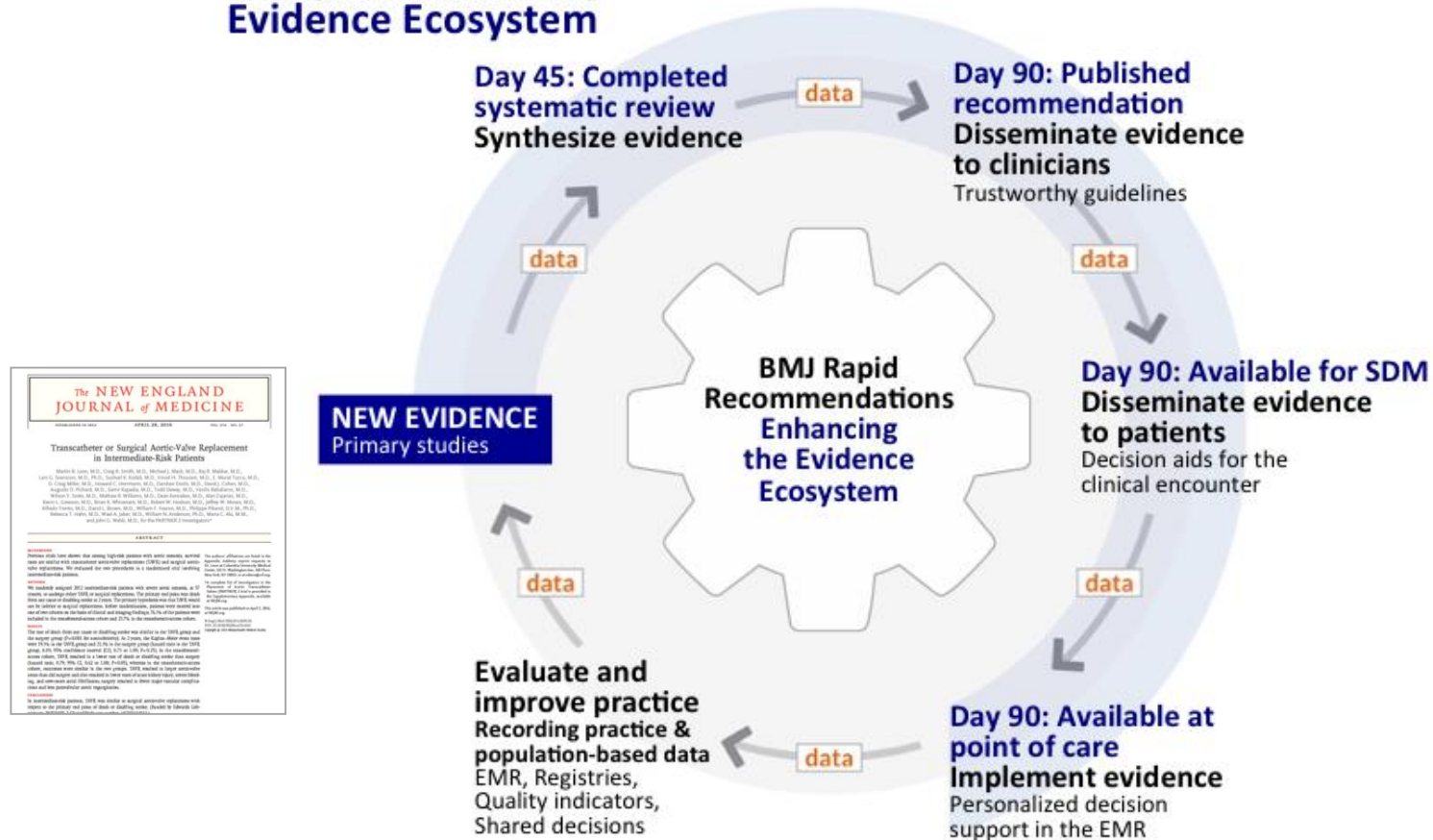
Solutions, to increase value and reduce waste in health care and research

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



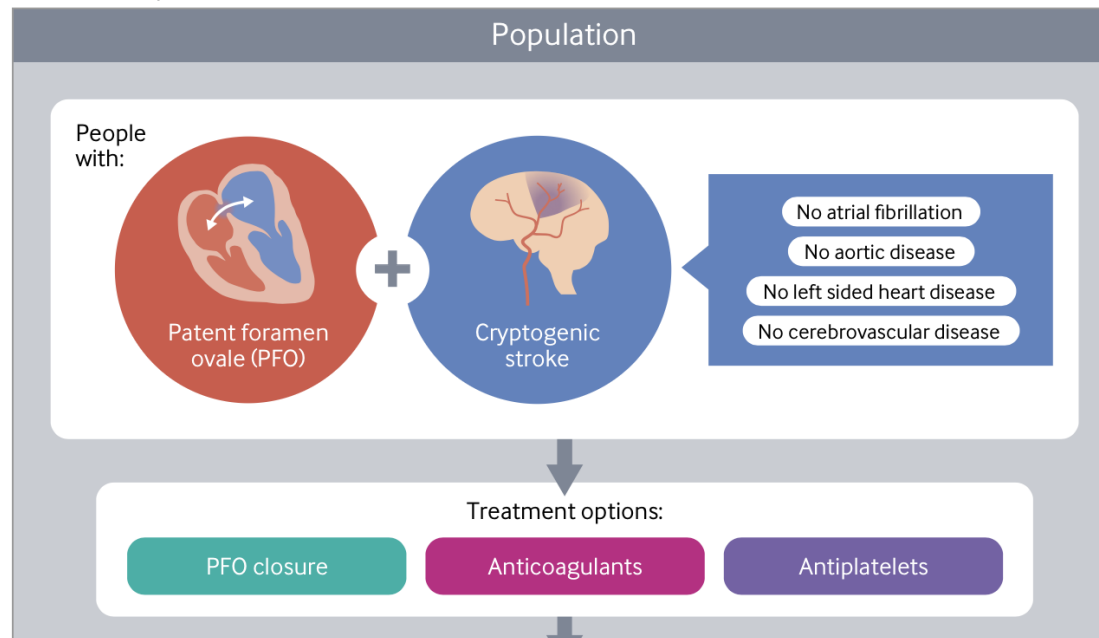
BMJ Rapid Recommendations, speeding up evidence synthesis and guidance dissemination

Practice » Rapid Recommendations

Patent foramen ovale closure, antiplatelet therapy or anticoagulation therapy alone for management of cryptogenic stroke? A clinical practice guideline

BMJ 2018 ; 362 doi: <https://doi.org/10.1136/bmj.k2515> (Published 25 July 2018)

Cite this as: BMJ 2018;362:k2515



What can we learn from the PFO closure device story?

The NEW ENGLAND JOURNAL of MEDICINE

ORIGINAL ARTICLE

Patent Foramen Ovale Closure or Antiplatelet Therapy for Cryptogenic Stroke

Lars Søndergaard, M.D., Scott E. Kasner, M.D., John F. Rhodes, M.D.,
Grethe Andersen, M.D., D.M.Sc., Helle K. Iversen, M.D., D.M.Sc.,
Jens E. Nielsen-Kudsk, M.D., D.M.Sc., Magnus Settergren, M.D., Ph.D.,
Christina Sjöstrand, M.D., Ph.D., Risto O. Roine, M.D.,
David Hildick-Smith, M.D., J. David Spence, M.D., and Lars Thomassen, M.D.,
for the Gore REDUCE Clinical Study Investigators*

The NEW ENGLAND JOURNAL of MEDICINE

EDITORIAL

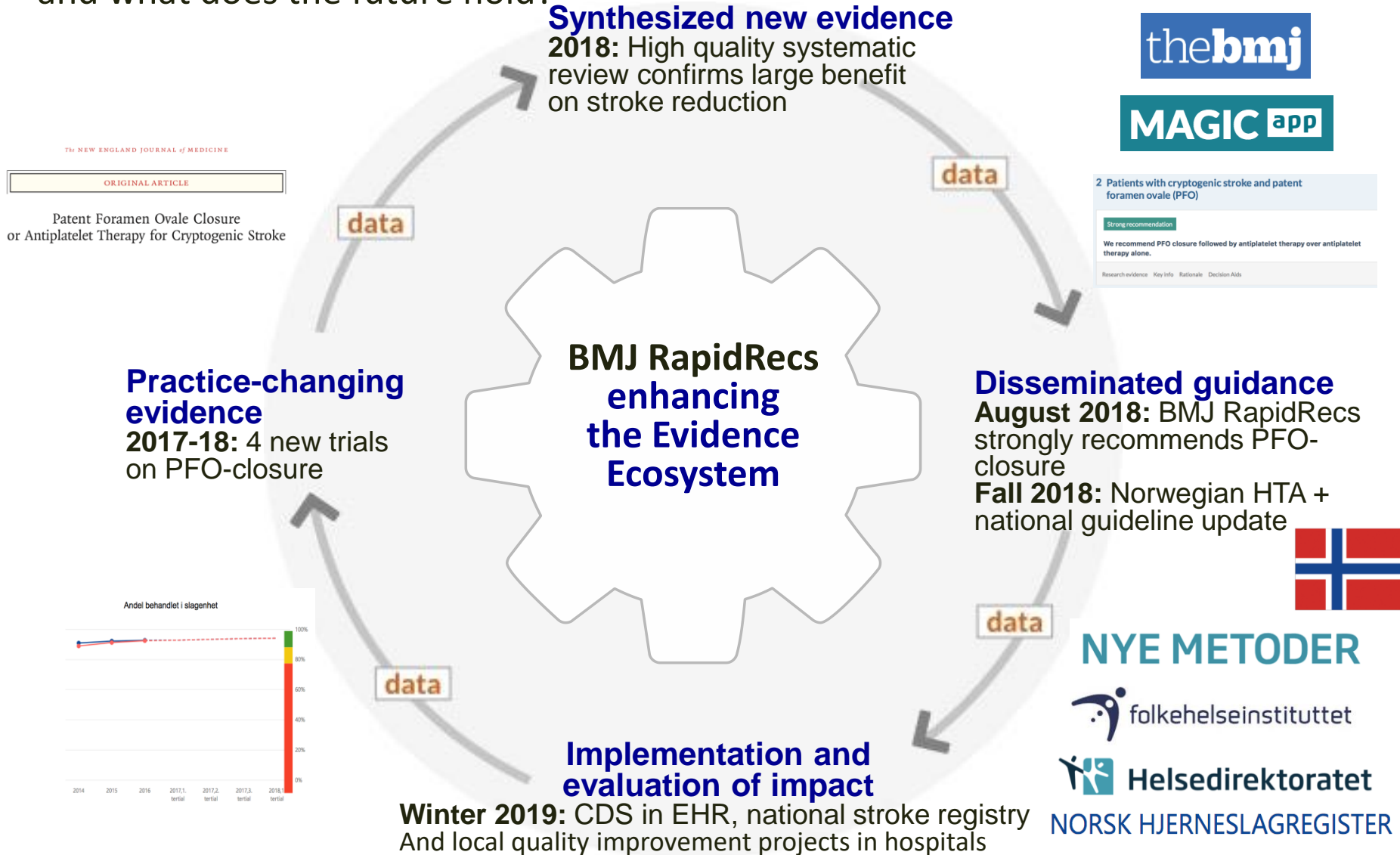


Tipping Point for Patent Foramen Ovale Closure

Allan H. Ropper, M.D.

How can we help in the Evidence Ecosystem?

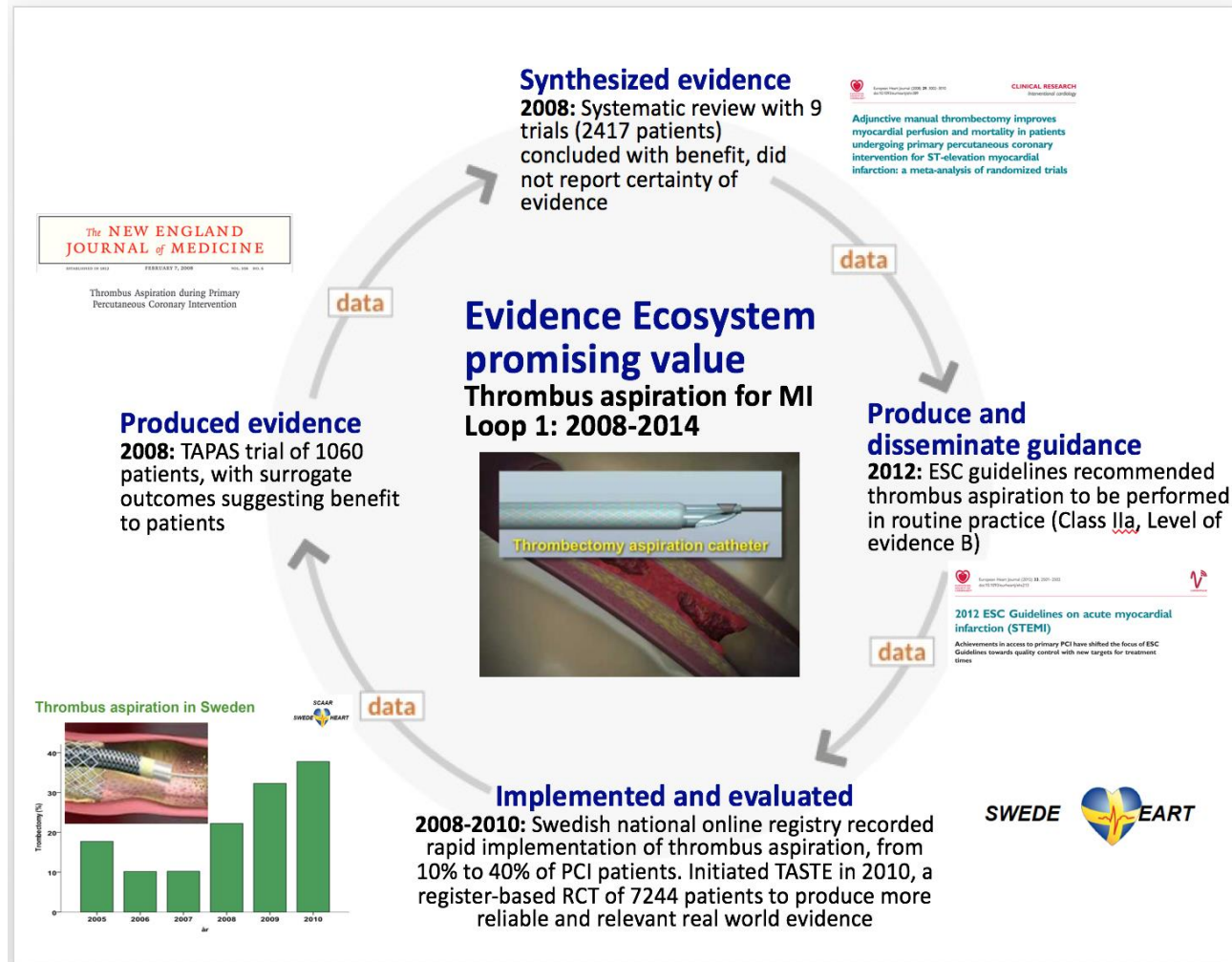
and what does the future hold?



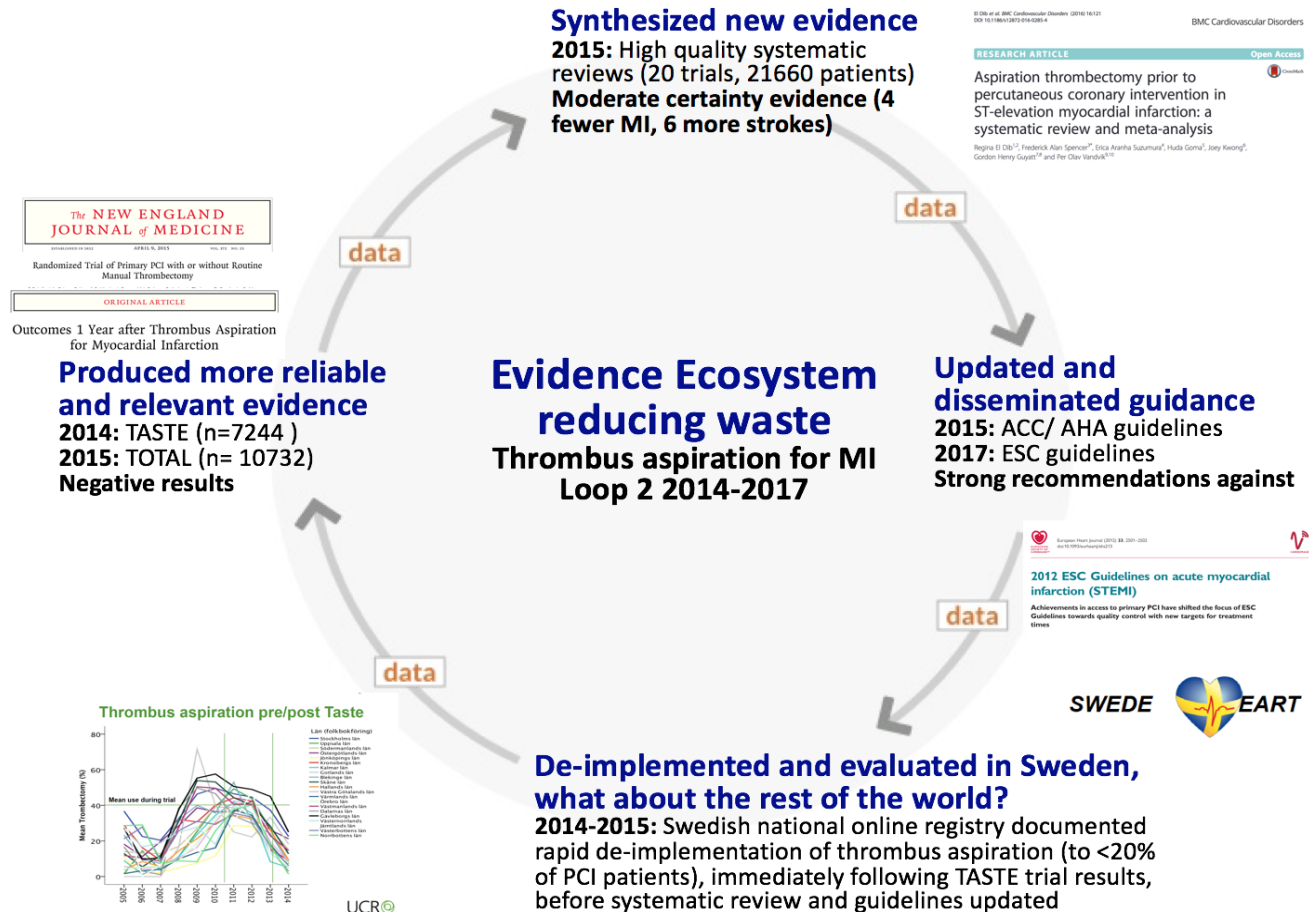
What do we do with new technologies who got it wrong?

Evidence Ecosystem reducing waste

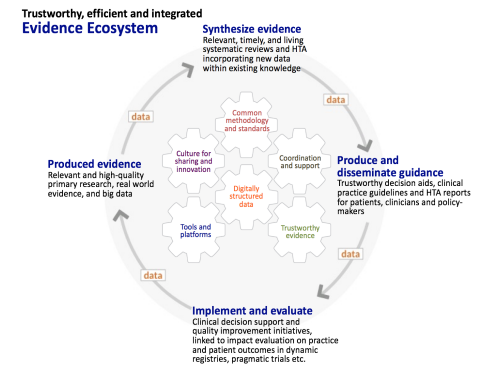
Sweden using real-world evidence in SwedeHeart registry



Registry-based trial closing the loop, with real world evidence changing practice worldwide



In summary and for discussion



- Health industry blooming but struggling to demonstrate benefits of devices and drugs to increase value in health care while reaching the global market
- You can succeed if you:
 - Get the question right, and make sure it's a good one
 - Perform the research to demonstrate value and to fully inform downstream decisions by policy-makers, clinicians and patients
 - Understand advances in standards, methods, processes and tools within an emerging evidence ecosystem for health care
 - Are better supported by health care actors in a joint effort to improve the evidence ecosystem, for mutual benefits