

Knowledge synthesis and implementation - the huge challenges of today and tomorrow

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European JBI symposium of
Evidence-Based Healthcare in the Czech Republic
Brno 13 December 2018

Conflicts of interest

- Till 31 Oct 2018
- 50% Cochrane Germany Foundation (tax-based charity)
- 50% Institute for Evidence in Medicine (for Cochrane Germany Foundation)
- Potential intellectual conflict:
Long-lasting commitment to Evidence and Systematic Reviews

Contents

- Inflation of unnecessary trials and SRs
- Growing problem in the publication process: predatory journals
- Soft science?
Real World Data (RWD), Big Data and Artificial Intelligence (AI)
- One world? Knowledge in English – implementation in ? language
- New science or better old science?

**What is the optimal decision
for the selection of the right
diagnostic procedure or the
best therapy?**



Neumann





trials - trials - trials - trials

System

Information from similar persons under same conditions

Neumann

The path to the truth

Counterfactual thinking: What would happen if . . .

Two crucial targets

1. Minimization of systematic errors (risk of bias)
2. Control of random errors (play of chance)

Gold standard is
not the randomized controlled trial but
the criteria to control error and to maximize benefit

Transfer of Research into Practice

Knowledge Translation

Answers to medical questions

- Clinical (randomised / controlled) studies
- Epidemiological (observational -) studies

....

Body of Evidence



- Practicing physicians
- Health authorities, sickness funds, insurances, institutions
- Clinical research
- Patients

1968 McMaster Univ.
Hamilton, Canada
1971 Archie Cochrane, UK
1996 EBM in Germany
1998 Cochrane Germany
2018 Cochrane Czech Rep

Evidence
production

Implementation

Transfer of research results into practice

Patients / healthy persons

Research / studies / data

Literature based
synthesis
(SR; Cochrane
classic)

Individual-
patient-
based
synthesis
(IPD SR)

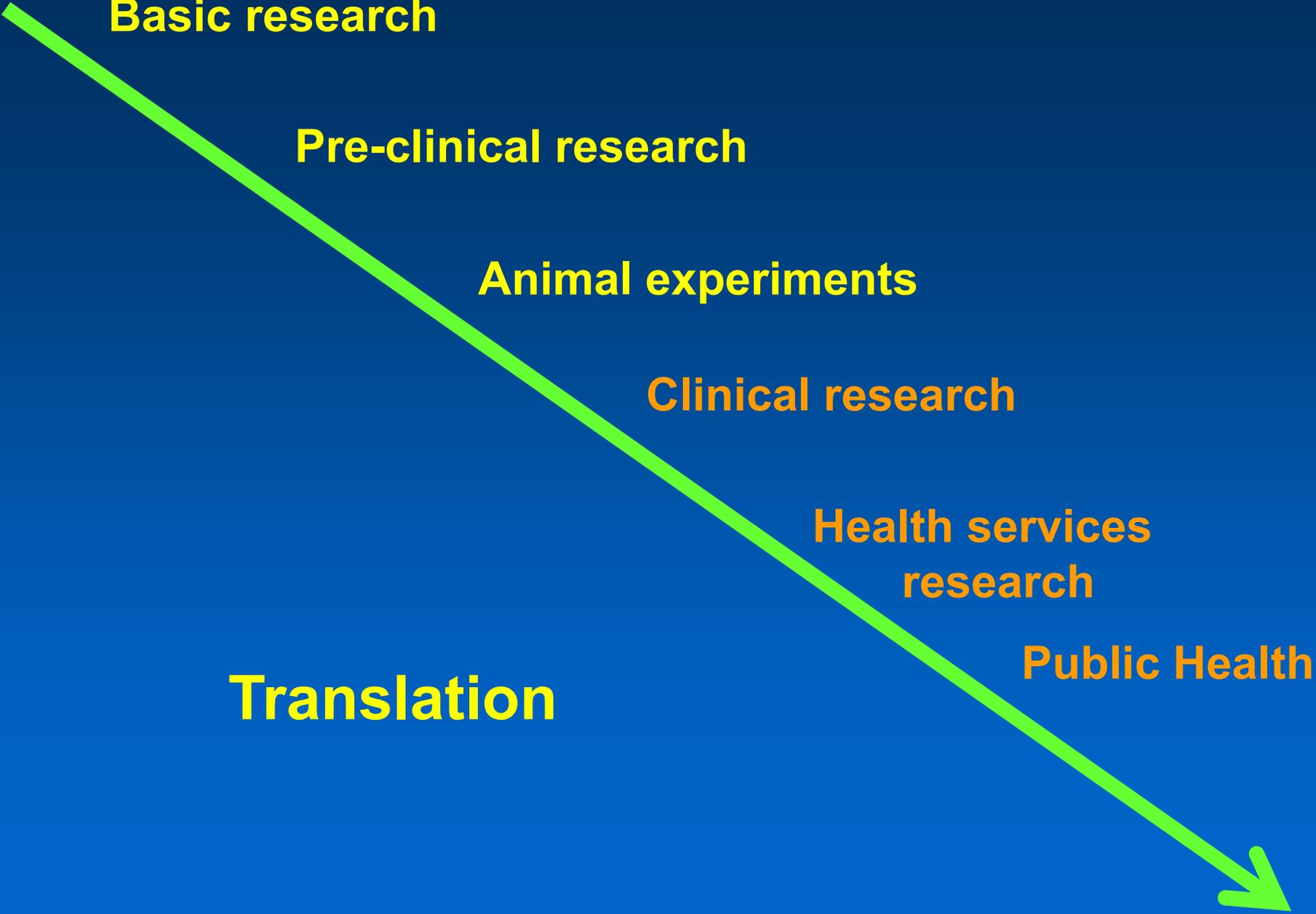
Trustworthy?

Access to
individual data
(SR from
authority data)

Access to trial
reports
(SR from
authority data)

Patients / healthy persons

Application / benefit / harm / costs



Basic research

Pre-clinical research

Animal experiments

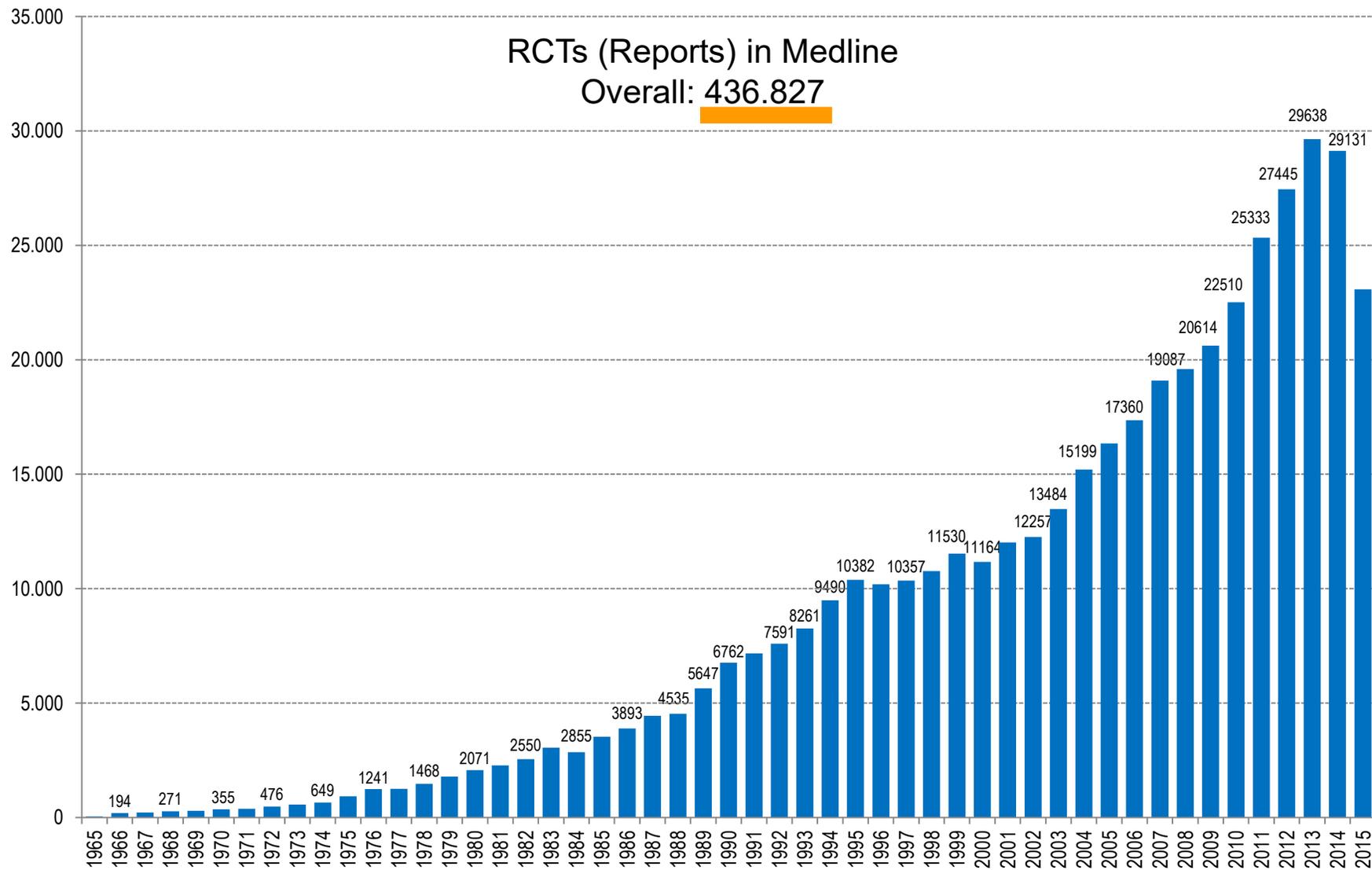
Clinical research

**Health services
research**

Public Health

Translation

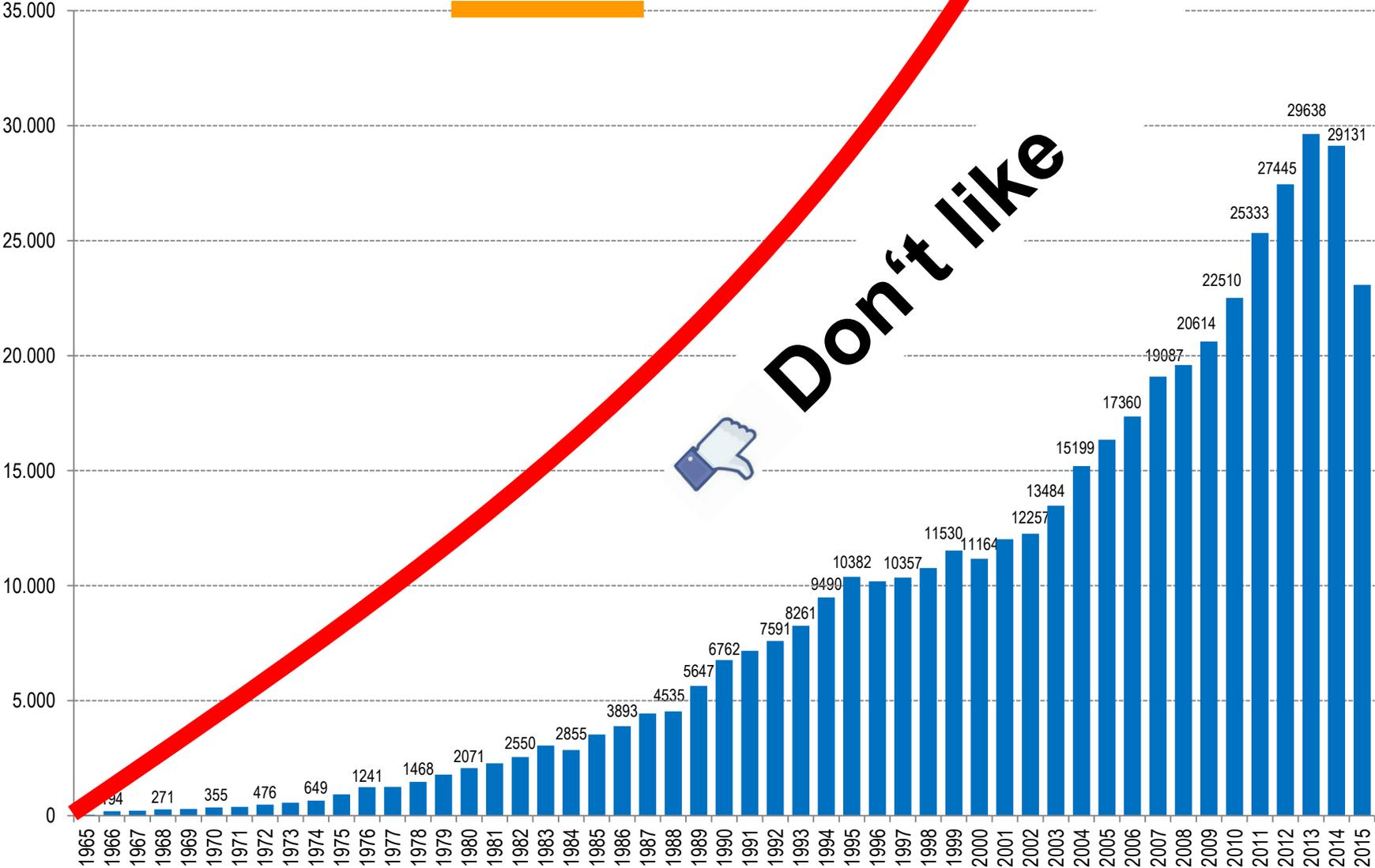
The trial deluge



The truth

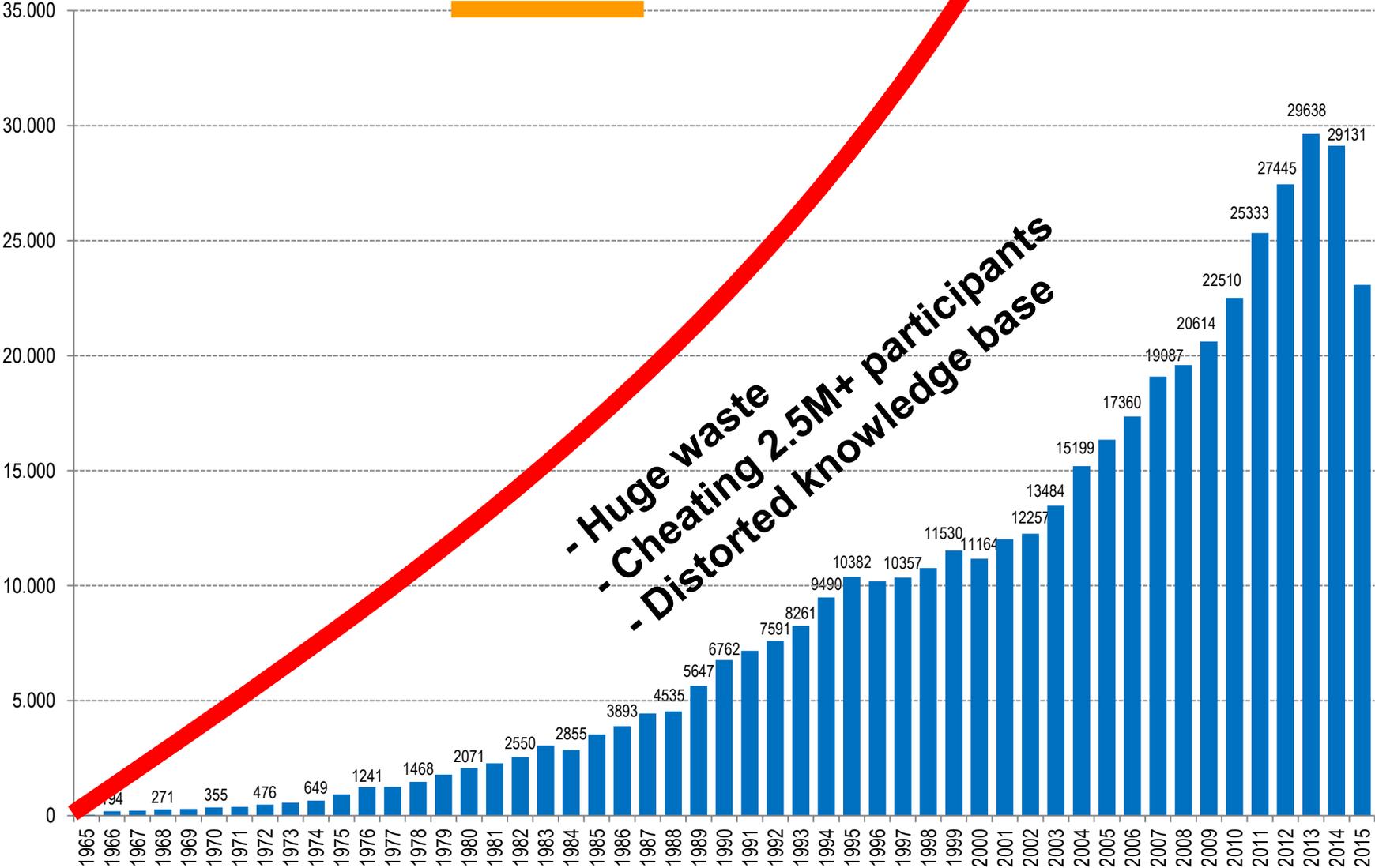
RCTs (Reports) in Medline (PubMed)

Overall: **436.827**



RCTs (Reports) in Medline (PubMed)

Overall: 436.827

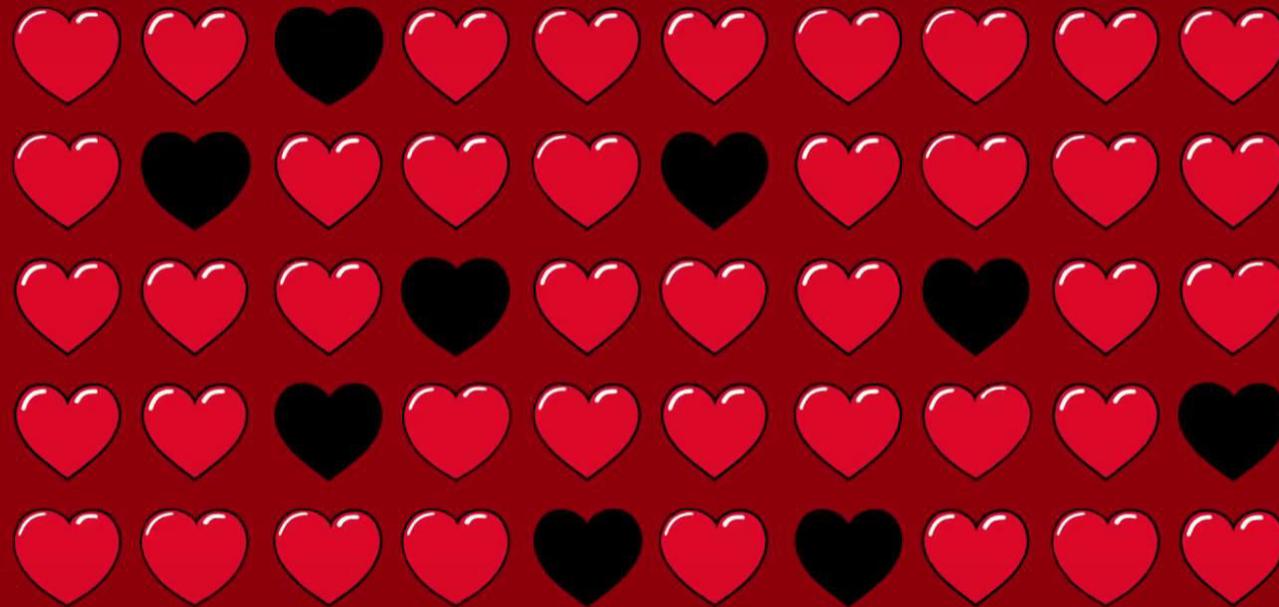


- Huge waste
- Cheating 2.5M+ participants
- Distorted knowledge base

AllTrials: Withholding results costs lives



On Lorcainide

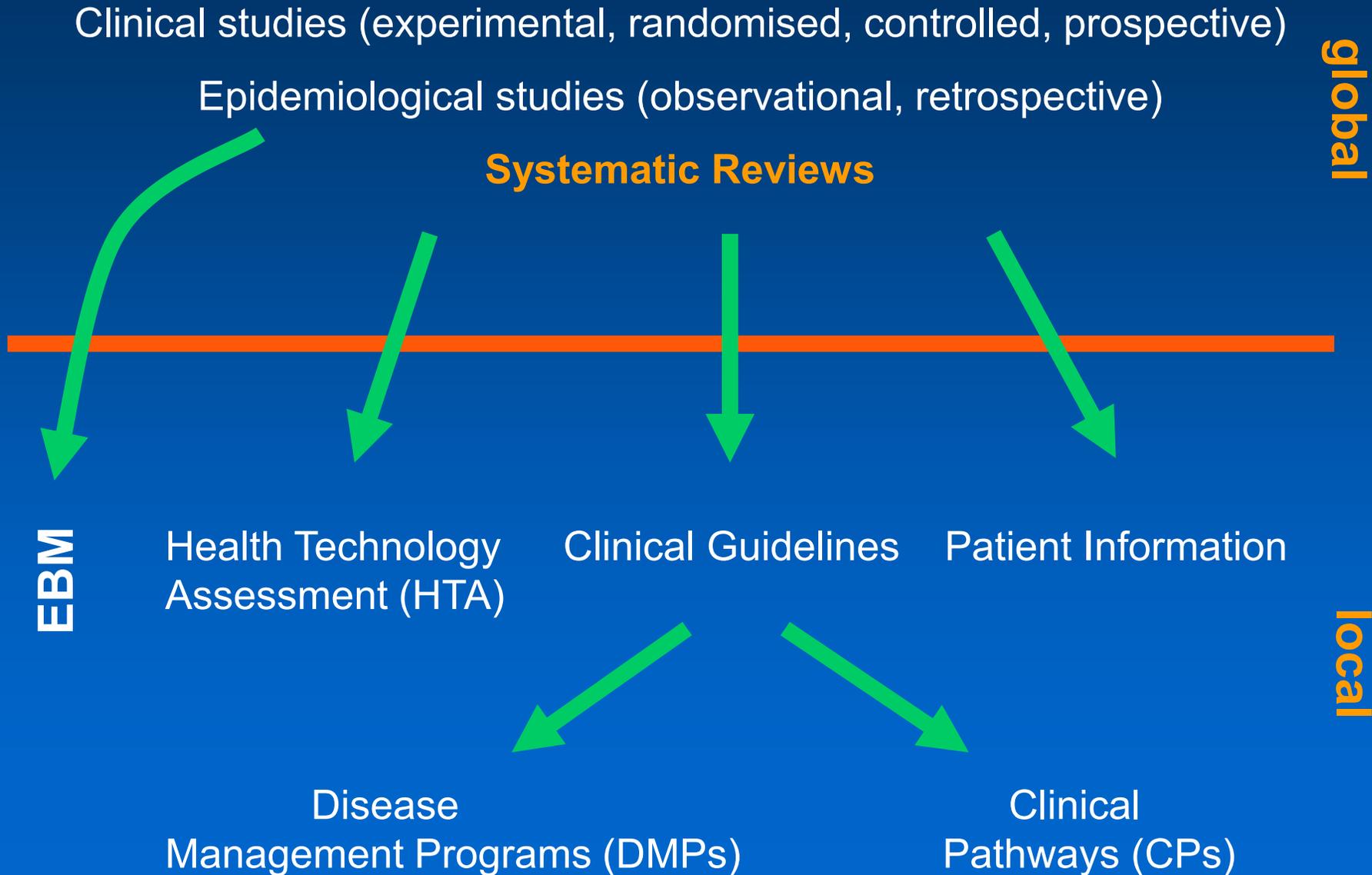


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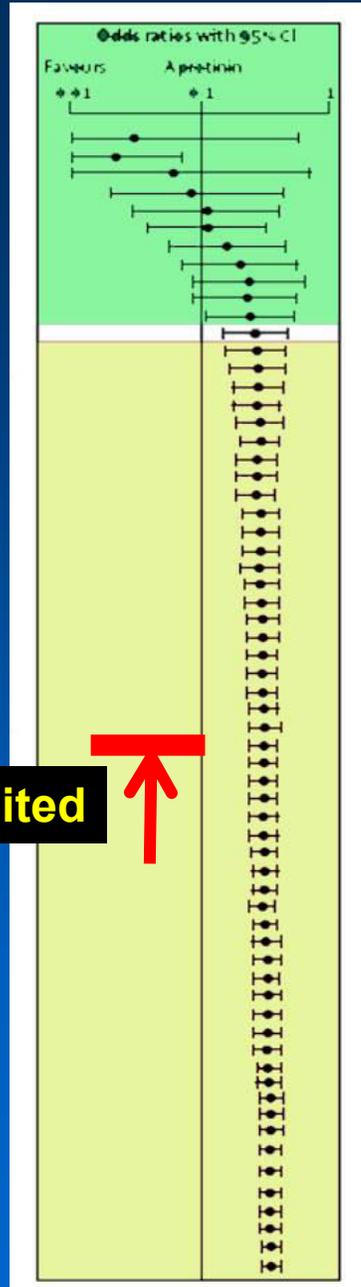
Youtube (now)

Transfer of Research into Practice



Unnecessary Trials and SRs

1987



2002

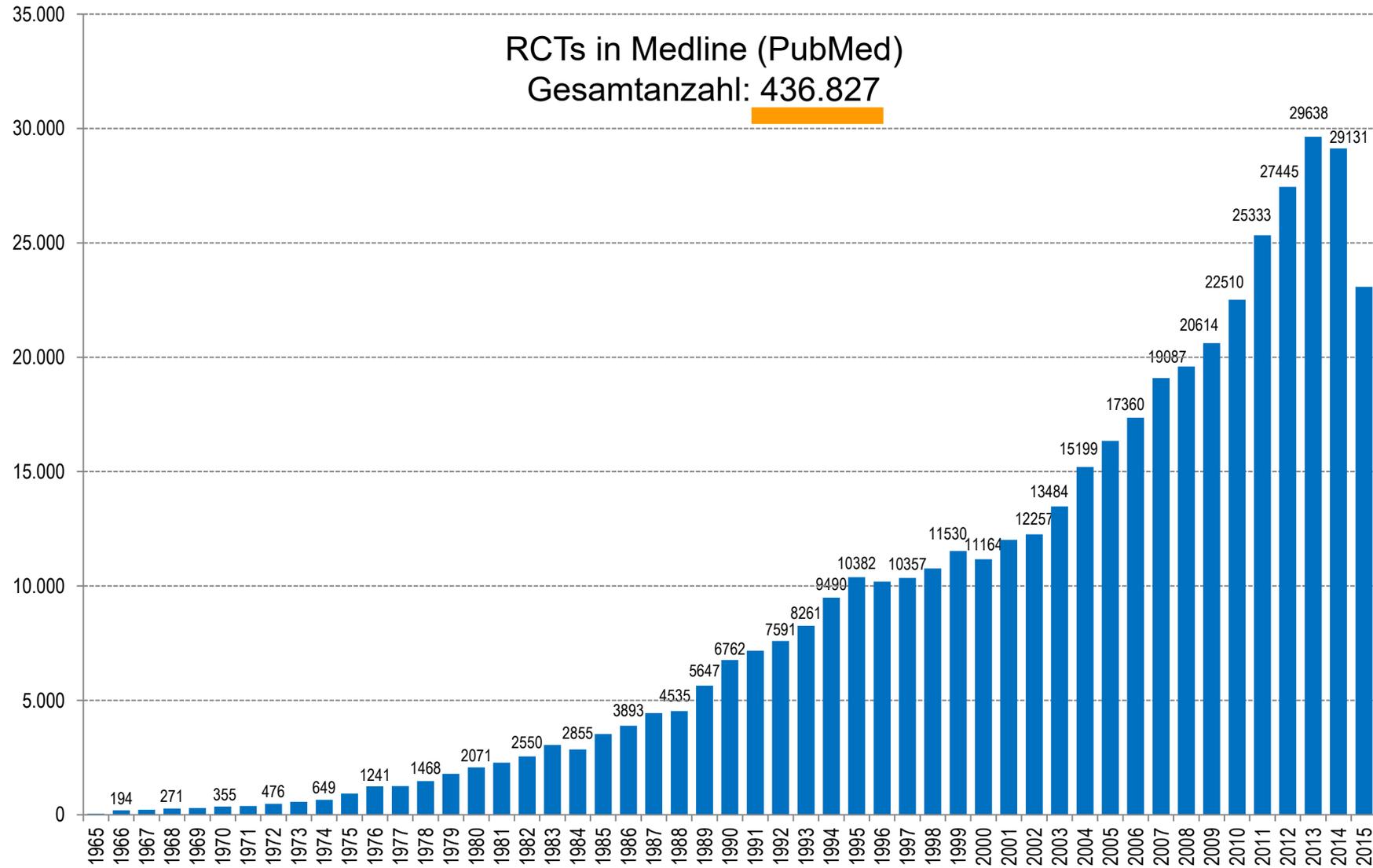
RCTs of aprotinin in cardiac surgery to stop bleeding

Lancet 2005
Clinical Trials 2005

2018 No stopping rule for trials

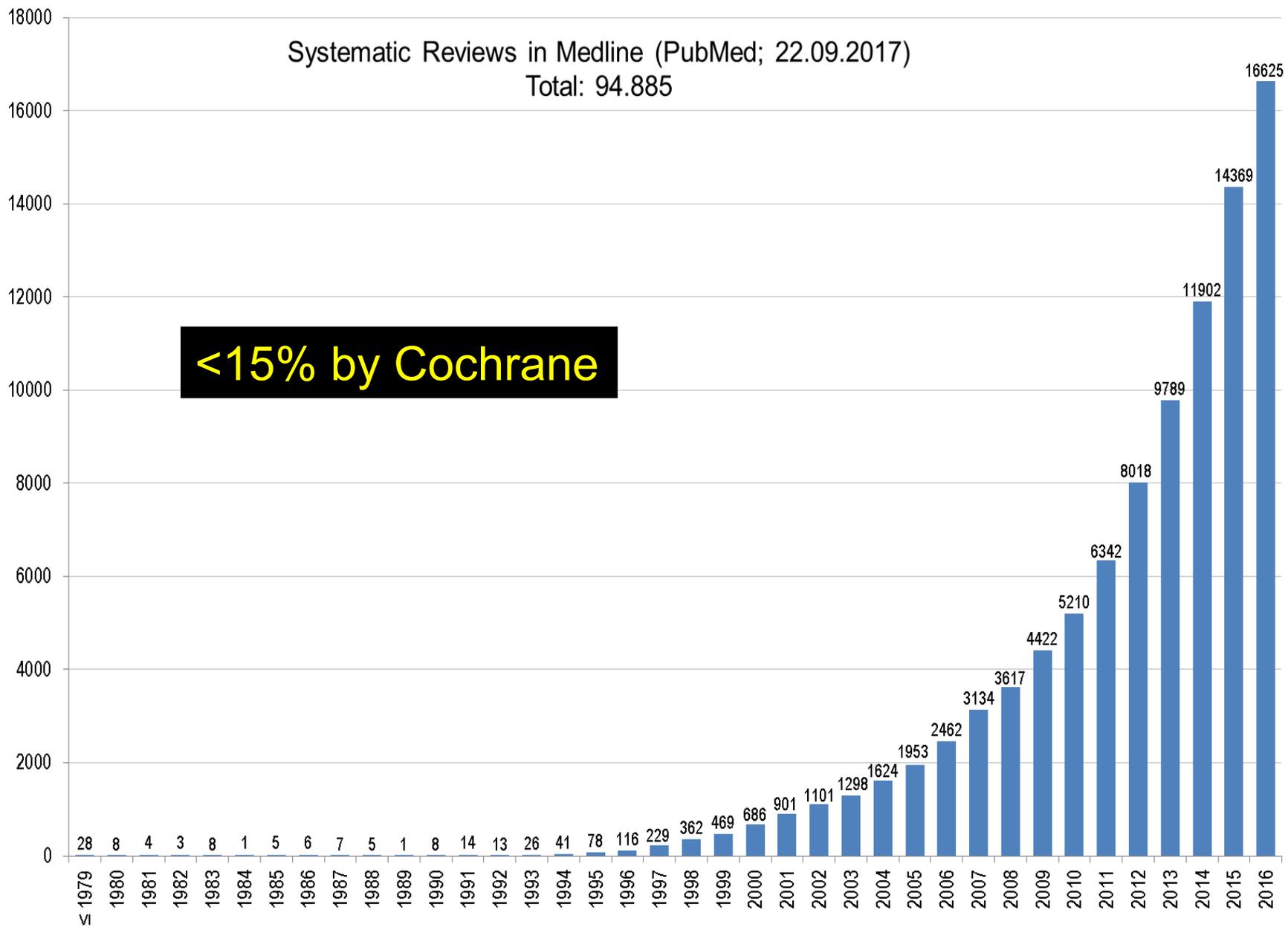
Ethics approval for unnecessary trials

**Knowledge accumulation:
A good principle failing**



Systematic Reviews in Medline (PubMed; 22.09.2017)
Total: 94.885

<15% by Cochrane



[Archive Search](#) > [Volume 94, Issue 3, 2016](#) > The Mass Production of Redundant, Misleading, and ...

Original Investigation

THE MASS PRODUCTION OF REDUNDANT, MISLEADING, AND CONFLICTED SYSTEMATIC REVIEWS AND META-ANALYSES

Policy Points:

- Currently, there is massive production of unnecessary, misleading, and conflicted systematic reviews and meta-analyses. Instead of promoting evidence-based medicine and health care, these instruments often serve mostly as easily produced publishable units or marketing tools.
- Suboptimal systematic reviews and meta-analyses can be harmful given the major prestige and influence these types of studies have acquired.
- The publication of systematic reviews and meta-analyses should be realigned to remove biases and vested interests and to integrate them better with the primary production of evidence.

Systems of wrong incentives, agendas driven by science and scientists' careers, maldevelopment of journals . . .

EDITORIALS

The problem of duplicate systematic reviews

Systematic reviewers should identify existing reviews as a compulsory first step

David Moher *senior scientist*

Clinical Epidemiology Program, Ottawa Hospital Research Institute, Ottawa Hospital, Ottawa, Canada ON K1H 8L6

Systematic reviews occupy a central position in evidence based medicine. They are the starting point of a well developed practice guideline. Some funders of randomised trials ask investigators for a strong rationale for their proposed trial, indicating that the best evidence is likely to be a well conducted and completely reported systematic review.¹ These reasons, and others, probably explain the popularity and publication trajectory of systematic reviews.² Does this translate into duplication of effort and waste? In a linked paper (doi:10.1136/bmj.f4501), using sound methodology and complete and transparent reporting, Siontis and colleagues examined this question.³

Having selected 73 meta-analyses published during 2010, the authors identified two thirds of them as having at least one overlapping meta-analysis. The good news is that duplication does not seem to have been a major problem. The authors report a median of two overlapping meta-analyses per topic. However,

protocols of ongoing systematic reviews. However, an international prospective register for systematic review protocols now exists (**PROSPERO**; www.crd.york.ac.uk/PROSPERO/), funded by the National Institute of Health Research and administered through the Centre for Reviews and Dissemination. The database contains 18 mandatory items and 22 discretionary ones.^{7,8} This information can be used to search for existing systematic review protocols. At the time of writing, 1871 records of review protocols exist from 65 countries and duplication seems to be rare. This number will probably increase substantially later this summer when Cochrane protocols are added to the register. With increasing international endorsement of the register by journals and funders,⁹ it is likely to help reduce unnecessary duplication.

Another factor contributing to duplication is the relentless

**Open access, data sharing . . .
A new enemy?**

List of Predatory Publishers 2014

By Jeffrey Beall

Released January 2, 2014

The gold (author pays) open-access model has given rise to a great many new online publishers. Many of these publishers are corrupt and exist only to make money off the author processing charges that are billed to authors upon acceptance of their scientific manuscripts.

There are two lists below. The first includes questionable, scholarly open-access publishers. Each of these publishers has a portfolio that ranges from just a few to hundreds of individual journal titles.

The second list includes individual journals that do not publish under the platform of any publisher — they are essentially standalone, questionable journals.

**Old: The poor can't read
New: The poor can't write**



Publishers	
Year	Number of publishers
2011	18
2012	23
2013	225
2014	477
2015	693
2016	923

Number of predatory publishers, 2011-2016.

Open-Access

- Author fees are business model for new journals
- Immediate consequence:
growth, equivalent to loss of quality in a limited market

Tangled web. The location of a journal's publisher, editor, and bank account are often continents apart.



John Bohannon *Science* 2013;342:60-65





Predatory journals: Ban predators from the scientific record

Jeffrey Beall

Nature 534, 326 (16 June 2016) | doi:10.1038/534326a

Published online 15 June 2016

PDF Citation Reprints Rights & permissions Article metrics

Subject terms: [Publishing](#) · [Peer review](#)

Predatory journals are threatening the credibility of science. By faking or neglecting peer review, they pollute the scholarly record with fringe or junk science and activist research. I suggest that every publishing stakeholder could contribute to reining in these journals.

Universities and colleges should stop using the quantity of published articles as a measure of academic performance. Researchers and respectable journals should not cite articles from predatory journals, and academic library databases should exclude metadata for such publications.

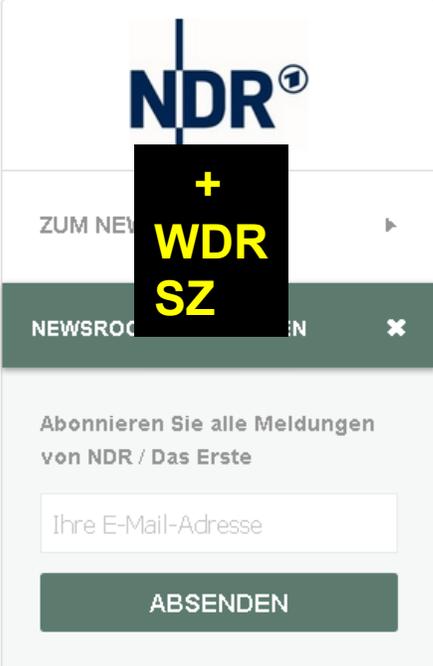
Mehr als 5000 deutsche Wissenschaftler haben in scheinwissenschaftlichen Zeitschriften publiziert

More than 5000 German scientists published in predatory journals

Including directors of institutions, the rector of a university . . .

Hamburg (ots) - Mehr als 5000 deutsche Wissenschaftler haben in scheinwissenschaftlichen Zeitschriften publiziert. Das ergaben Recherchen von NDR, WDR und dem Süddeutsche Zeitung Magazin zusammen mit weiteren nationalen und internationalen Medien. Demnach haben Forscherinnen und Forscher deutscher Hochschulen, Institute und Bundesbehörden oft mit öffentlichen Geldern finanzierte Beiträge in wertlosen Online-Fachzeitschriften scheinwissenschaftlicher Verlage veröffentlicht, die grundlegende Regeln der wissenschaftlichen Qualitätssicherung nicht beachten. Weltweit sind den Recherchen zufolge 400.000 Forscherinnen und Forscher betroffen. Das Phänomen der pseudowissenschaftlichen Verlage ist zwar seit einigen Jahren bekannt. Deutsche Hochschulen und Forschungsgesellschaften hatten bereits mehrfach davor gewarnt. Neu sind jedoch das Ausmaß und die rasant gestiegenen Zahlen. Die Zahl solcher Publikationen bei fünf der wichtigsten Verlage hat sich den Recherchen zufolge seit 2013 weltweit verdreifacht, in Deutschland gar verfünffacht.

Die Recherchen zeigen: Pseudowissenschaftliche Verlage nutzen den Publikationsdruck, der auf Wissenschaftlerinnen und Wissenschaftlern lastet, und sprechen sie per E-Mail an. Die



The image shows a mobile application interface for news. At the top, there is a logo for NDR with a registered trademark symbol. Below it, a search bar contains the text 'ZUM NEWS'. A large black overlay with a white plus sign and the text 'WDR SZ' is positioned over the search bar. Below the search bar, there is a green bar with the text 'NEWSROOM' and a close button (X). Underneath, there is a section for subscribing to all news from NDR / Das Erste. It includes a text input field for 'Ihre E-Mail-Adresse' and a green button labeled 'ABSENDEN'.

Closely linked to “Presentations at World Congress for Urology”



Leopoldina
Nationale Akademie
der Wissenschaften



Über uns Mitglieder Wissenschaft Publikationen Politikberatung International F&E

Startseite _ Presse _ Pressemitteilungen _

Pressemitteilung | Mittwoch, 25. Juli 2018

Stellungnahme von neun Partnern der Allianz der Wissenschaftsorganisationen zur Qualitätssicherung von wissenschaftlichen Veröffentlichungen

Fortschritt und gesellschaftlicher Wohlstand beruhen zu einem großen Teil auf den Ergebnissen von Forschung und Wissenschaft und dem Vertrauen, das von der Gesellschaft in sie gesetzt werden. Die Einhaltung der hohen Standards der Qualitätssicherung als Element der guten wissenschaftlichen Praxis ist eine unverzichtbare Voraussetzung, um dieses Vertrauen aufrechtzuerhalten.

Joint statement of

v.-Humboldt-St

DFG

Fraunhofer

HRK

Dt. Akad. Naturf.

DAAD

Helmholtz

(25 July 2018)

- Complaints: scientists deceived, damaged trust into science
- Self-repair of science is sufficient
- Emphasis that articles in those journals may be high quality

Surprised and downplaying the issue

- No statement before July 2018
- Who focusses on “Fake Science“ ignores the real problems
- Storm in a teacup: predatory journals are irrelevant
- Presentations and texts from G. Antes describing Predatory Journals since October 2015

PERSPECTIVE

Current Incentives for Scientists Lead to Underpowered Studies with Erroneous Conclusions

Andrew D. Higginson^{1*}, Marcus R. Munafò^{2,3*}

1 Centre for Research in Animal Behaviour, College of Life and Environmental Sciences, University of Exeter, Exeter, United Kingdom, **2** MRC Integrative Epidemiology Unit (IEU) at the University of Bristol, Bristol, United Kingdom, **3** UK Centre for Tobacco and Alcohol Studies, School of Experimental Psychology, University of Bristol, Bristol, United Kingdom

* a.higginson@exeter.ac.uk (ADH); marcus.munafò@bristol.ac.uk (MRM)



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click for updates

Abstract

We can regard the wider incentive structures that operate across science, such as the priority given to novel findings, as an ecosystem within which scientists strive to maximise their fitness (i.e., publication record and career success). Here, we develop an optimality model that predicts the most rational research strategy, in terms of the proportion of research effort spent on seeking novel results rather than on confirmatory studies, and the amount of research effort per exploratory study. We show that, for parameter values derived from the scientific literature, researchers acting to maximise their fitness should spend most of their effort seeking novel results and conduct small studies that have only 10%–40% statistical power. As a result, half of the studies they publish will report erroneous conclusions. Current incentive structures are in conflict with maximising the scientific value of research; we suggest ways that the scientific ecosystem could be improved.

OPEN ACCESS

Citation: Higginson AD, Munafò MR (2016) Current Incentives for Scientists Lead to Underpowered Studies with Erroneous Conclusions. PLoS Biol 14(11): e2000995. doi:10.1371/journal.pbio.2000995

Published: November 10, 2016

Copyright: © 2016 Higginson, Munafò. This is an open access article distributed under the terms of the [Creative Commons Attribution License](https://creativecommons.org/licenses/by/4.0/), which



richard horton @richardhorton1 · 4d

Medical and scientific publishers have lost their moral voice. Do they have the courage to reclaim it? There is little sign of it as yet.



1



7



8



richard horton @richardhorton1 · 4d

Today's medical/scientific publishing industry operates in a moral vacuum. It has betrayed its Enlightenment values. Time to remoralise.



3



22



29



**Richard Horton, Editor of The Lancet
Jan 2017**



SCIENTIFIC PUBLISHING

German researchers start 2017 without Elsevier journals

More than 60 institutions lose online subscriptions after negotiations over price and open access stall

The main library at the University of Göttingen, which says it will hold firm in negotiations with Elsevier.

about prices included in most contracts.

Formal talks with Elsevier began in August to draft a contract that would take effect on 1 January. To increase pressure on the publisher, more than 60 participating organizations canceled their online subscriptions effective 31 December. After DEAL rejected Elsevier's offer in early December, several universities warned staff that access could be disrupted starting 1 January. Though some German universities had subscriptions allowing them to continue to access papers published through the end of 2016, others, such as Braunschweig University of Technology, have been cut off completely. "Despite the loss of immediate full-text access, our scientists are supportive and have welcomed the measures" to push for more open access, says Katrin Stump, director of the university's library.

Officials at the University of Göttingen said in December that they are committed to holding firm; the university would work with researchers to obtain papers through an interlibrary loan and other online sources, they said. (Researchers also have an illegal option: downloading papers from Sci-Hub, a site hosting pirated papers that is becoming increasingly popular.) Waiters

ce.sciencemag.org/ on January 6, 2017

1 Jan 2017

A further obstacle: The language

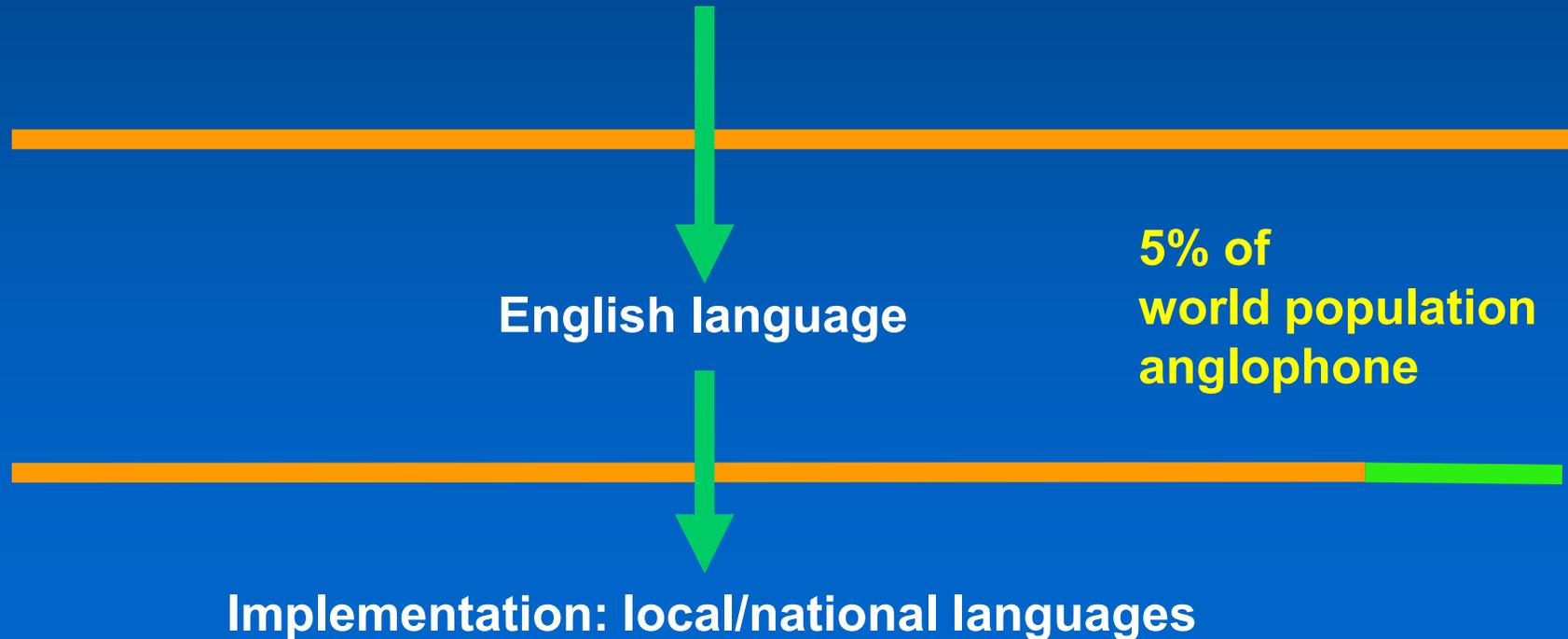
Transfer of Research into Practice

Answers to medical questions

- Clinical (randomised / controlled) studies
- Epidemiological (observational -) studies

.....

Knowledge Translation





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Wie kann ein Cochrane Review weiterhelfen?

Seriously underfunded

Am häufigsten besuchte Themen:

- 1 Oral verabreichtes Misoprostol zur Einleitung der Wehentätigkeit
- 2 Die Behandlung des Thoracic Outlet Syndroms (Schultergürtelkompressionssyndrom)
- 3 Manuelle Therapie und Übungen bei Frozen Shoulder (Adhäsive Kapsulitis, Schultersteife)
- 4 Kontinuierliche passive Bewegungsbehandlung
- 11 Impfstoffe zur Vorbeugung gegen Grippe bei Erwachsenen
- 12 Homöopathisches Oscillococcinum® zur Vorbeugung und Behandlung von Grippe und grippeähnlichen Erkrankungen
- 13 Rehabilitation für Menschen mit Demenz nach der Operation eines Oberschenkelhalsbruchs



Turning Research Into Practice

SEARCH

PICO

ADVANCED

PRO

RECENT

PRO

search terms



Language Settings

My query is: English Français Deutsch Čeština Español Magyar Svenska

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**Observational studies “sufficient”:
Real world data**

Risk of Bias tools 

ROBINS-I

RoB 2.0

ROBINS-E

Risk of bias assessment tools

Welcome to our pages about risk of bias tools for use in systematic reviews.

- Go to [ROBINS-I tool](#) (Risk Of Bias in Non-randomized Studies - of Interventions)
- Go to [RoB 2.0 tool](#) (revised tool for Risk of Bias in randomized trials)
- Go to [ROBINS-E tool](#) (Risk Of Bias in Non-randomized Studies - of Exposures)

Feedback is welcome to julian.higgins@bristol.ac.uk



Relevant for Real-World-Data (RWD)

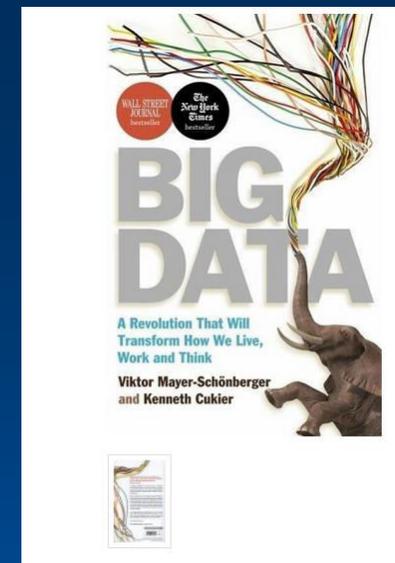
**The new competitor:
Big data, artificial intelligence, personalized medicine .**

..

Big Data:

**A Revolution That Will
Transform How We Live, Work
and Think**

**Kenneth Cukier
Viktor Mayer-Schönberger**



Big Data Hype: The Mantras

Big Data

- can analyze unstructured data
- can easily solve every problem by using more data
- needs ownership moving from owner to user
- cannot reproduce results because everything is changing every second: real-time results
- The era of causality is over, now is the era of correlation (enabled by unlimited access to data)

**Chris Anderson
16/2007 Wired Magazine:**

**The End of Theory. The Data Deluge
Makes the Scientific Method Obsolete**

Science in megalomania

Wissenschaft im Grössenwahn

Algorithmen sind objektiv, und die Daten sprechen für sich selbst. Das behaupten die Big-Data-Anhänger. Ihr Glaubensbekenntnis beruht aber auf naiven und fragwürdigen Annahmen,



Neue Züricher Zeitung 11 Jan. 2015

Das Ende des Zufalls

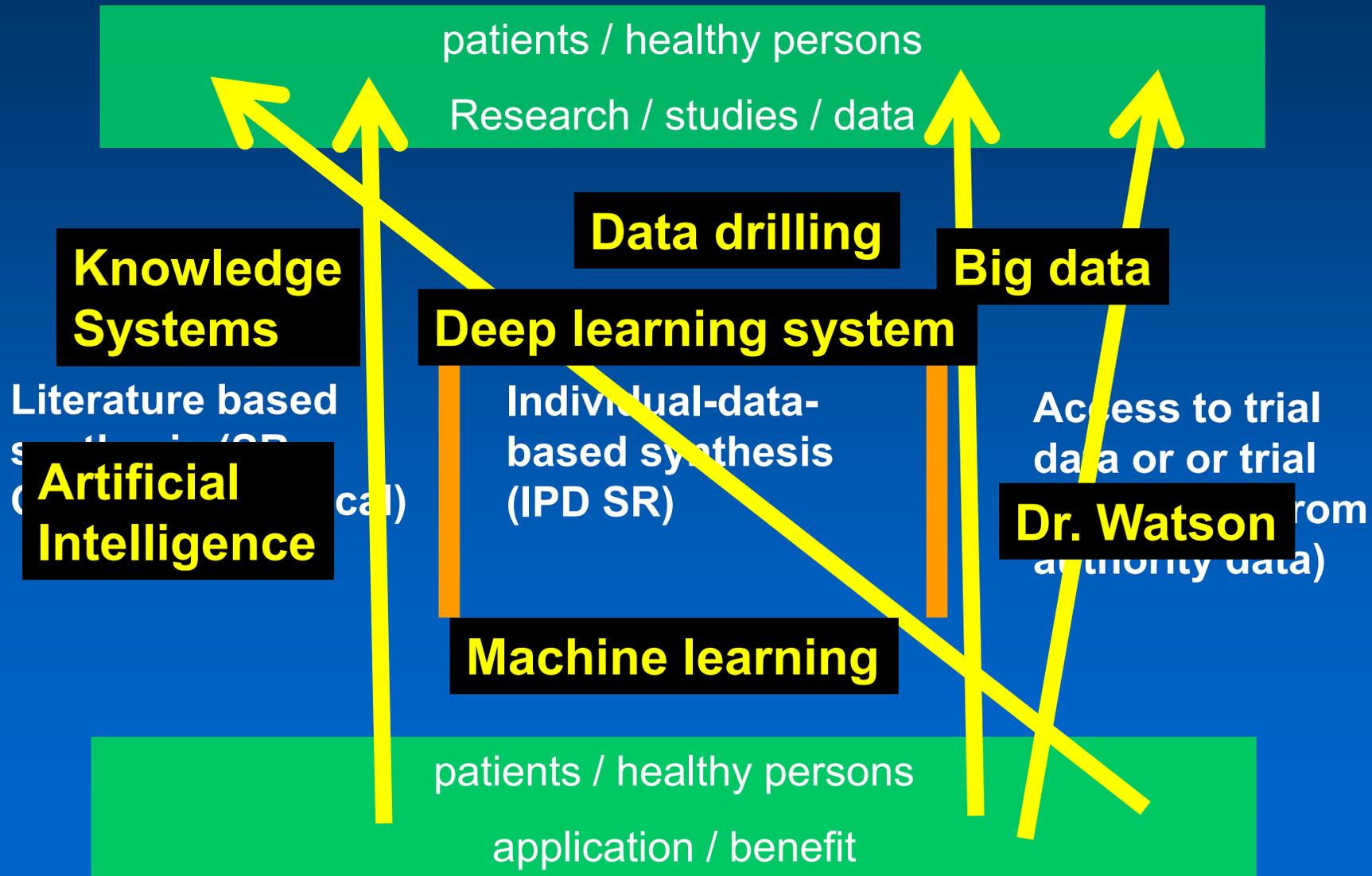
[Über das Buch](#) [Über den Autor](#) [Über den Verlag](#) [Blog](#) [Kontakt](#)

Wie Big Data uns und
unser Leben
vorhersagbar macht !
DAS BUCH ZU BIG DATA !

**How Big Data makes us and
our life predictable**



Transfer of research results into practice



A STAT INVESTIGATION

IBM pitched its Watson supercomputer as a revolution in cancer care. It's nowhere close

By CASEY ROSS [@byCaseyRoss](#) and IKE SWETLITZ [@ikeswetlitz](#) / **SEPTEMBER 5, 2017**

Why Everyone Is Hating on IBM Watson —Including the People Who Helped Make It



“Their marketing and PR has run amok—to everyone’s detriment.”

Large amounts of electronic patient records . . . will help to avoid any wrong diagnosis and treatment

Investment at MD Anderson Houston: \$62 million

FEBRUARY 23, 2017

MD Anderson Cancer Center's IBM Watson project fails, and so did the journalism related to it

POSTED BY



CATEGORIES

[Business of health](#), [Cancer](#)

TAGS

[MD Anderson Cancer Center](#)

Mary Chris Jaklevic is a freelance health reporter who joined our review team in April 2016. She tweets as [@mcjaklevic](#)

We often call out overly optimistic news coverage of drugs and devices. But information technology is another healthcare arena where uncritical media narratives can cause harm by raising false hopes and allowing costly and unproven investments to proceed without scrutiny.

A case in point is the recent collapse of M.D. Anderson Cancer Center's ambitious venture to use IBM's Watson cognitive computing system to expedite clinical decision-making around the globe and match patients to clinical trials.

Launched in 2013, the project initially received glowing mainstream media coverage that suggested Watson was already being deployed to revolutionize cancer care—or soon would be.

But that was premature. By all accounts, the electronic brain was never used to treat patients at M.D. Anderson. A University of Texas [audit](#)

"IBM **spun** a story about how Watson could improve cancer treatment that was superficially plausible."

A new Science(ability)?

(November 2nd, 2015) Big Data, Innovation, Personalised Medicine and co. – Are these the hallmarks of a new science(ability) in medicine? An essay by Gerd Antes, Freiburg.



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If one is to believe what one reads in editorials, comments or opinion articles in scientific journals then we are at the beginning of a golden age for patients and healthy people. Patients will be diagnosed much earlier and more correctly, and then treated accurately, efficiently and free of side effects by personalised medicine. Healthy people aren't at all at risk because they will be protected from becoming sick in the first place by perfect preventative healthcare.

THEMEN

Golden future or empty promises?

BIG DATA UND PERSONALISIERTE MEDIZIN

Goldene Zukunft oder leere Versprechungen?

Es erscheint überfällig, die Versprechungen für die Zukunft auf den Prüfstand der Qualitätsdiskussion (Good Scientific Practice) zu stellen.

Die Medizin scheint auf dem Marsch in eine goldene Zukunft zu sein. Die Forschung liefert eine stetig schneller wachsende Menge immer hochwertigerer Ergebnisse. Diese müssen nur noch in die Gesundheitsversorgung umgesetzt werden, was durch Translation der Forschungsergebnisse in die Praxis ein Leichtes sei. Alles, was man für den Sprung in die Zukunft braucht, sind der uneingeschränkte Zugang zu allen Daten und eine unbegrenzte Rechnerkapazität, um aus den ungeheuren Datenmengen in Echtzeit die gewünschten Regeln

Durchführung und Publikation von Studien wie auch die systematische Zusammenfassung von Wissen und dessen Implementierung.

An zentraler Stelle ist die weltweit wie eine Naturkonstante herrschende Publikationsrate von 50 Prozent zu nennen. Das heißt, 50 Prozent der durchgeführten Forschung verschwindet und wird der Welt nicht präsentiert, was dem wissenschaftlichen Grundprinzip der Wissenskommunikation fundamental entgegensteht. Erstaunlich dabei ist, dass diese enorme Lücke seit Jahren beharrlich ist, jedoch weit

und Organisationen, so zum Beispiel von Nature und Science (2), zum Thema Nichtreproduzierbarkeit wissenschaftlicher Experimente. Hintergrund ist die seit Jahren zunehmende Erkenntnis über die mangelhafte Reproduzierbarkeit und Verifizierbarkeit eines Großteils der Ergebnisse aus dem Wissenschaftsprozess, die in der Folge zu Irrwegen, Fehlentwicklungen und -investitionen führt. Dass dies aus ethisch-moralischer Perspektive wegen der unmittelbar folgenden Schädigung von Menschen nicht zu verantworten ist, lässt auf den Hand

Solutions?



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EQUATOR Network resources now available in German

12/12/2018

Sprechen Sie Deutsch?

The EQUATOR Network is proud to launch its [German pages](#) this week. Now, German-speaking researchers around the world will find resources for better research reporting more easily and quickly, says [Shona Kirtley](#), EQUATOR's Information Manager, who coordinated the effort: "When we were approached about translating our resource pages to German, we were delighted to help and felt that it built well on previous work".

The previous work she mentions are the EQUATOR web pages in Spanish and Portuguese, which were made available in 2015 and 2016, through the support of PAHO (Pan American Health Organization). These are among the most accessed pages in the EQUATOR website. The EQUATOR Network hopes the same success will happen with the [German pages](#).

"Full and transparent reporting is key to make research usable. Providing more resources to those whose first language is not English is vital in the campaign (spearheaded by the REWARD initiative) to reduce waste in research", said [Gary Collins](#), director of the UK EQUATOR Centre. "The EQUATOR website has become a reference resource about research integrity around the world. Following translations of the website into Spanish and Portuguese, this new German translation is another important milestone to provide information to authors whose first language is not English."

EQUATOR in German is composed of a set of 26 pages with information on reporting guidelines, guidance on scientific writing, ethics and good practice guidelines and toolkits.

News archive

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13 Dec 2018

Orthodox

- clearly defined question
- prospective
- based on protocol
- good scientific practice
- quality
- overarching principle: risk-of-bias
- rigid methodology
- reproducibility
- transparency, data sharing
- crisis of science

- Basic model: incremental progress, research in context

The new world

- unplanned, unintended
- **quality** of results?
- reproducibility?
- principles of modeling?
- significance, clinical relevance
- results under **uncertainty**?
- non-transparent!
- **clinical outcome**?
- renaissance of surrogates

Basic model:
disruptiv

From Experiment to Real World Data XXL



<i>Level der Evidenz</i>	Systematic Reviews
I	Experimental studies
II	
III	Observational studies
IV	
V	Big Data (AI)

Summary

- Enormous progress to use knowledge from trials and studies:
Global knowledge – local implementation
- Evidence world based on systematic reviews as key technology for
knowledge synthesis and translation
- Erosion and damage of key concepts in current development: serious
confrontation with the old quality world of EBM clinical epidemiology
- Return to quality and quality assessment as leading principle



WO IST DER BEWEIS?

Plädoyer für eine
evidenzbasierte Medizin



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