# Bestandsaufnahme zur klinischen Forschung in Deutschland

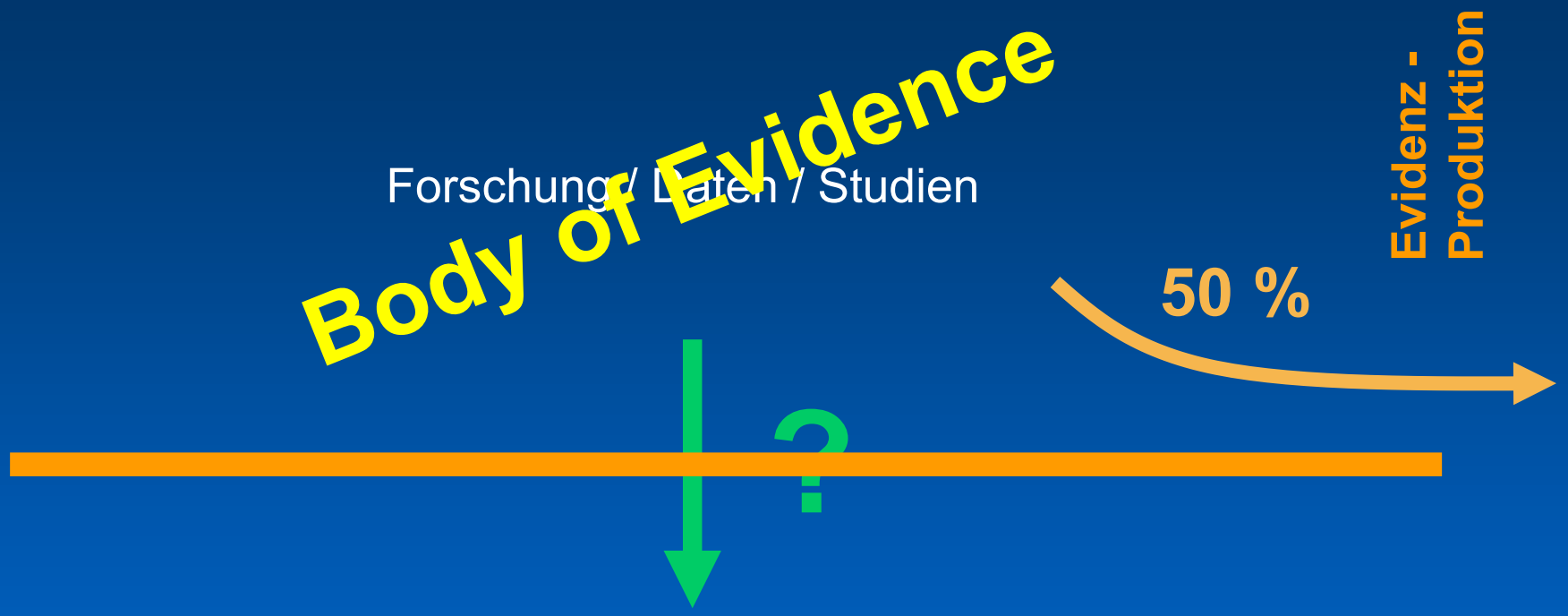
Gerd Antes
(antes@cochrane.de, @gerdantes)

39. Jahrestagung des Arbeitskreises Medizinischer Ethik-Kommissionen in der Bundesrepublik Deutschland e.V.
11. Nov. 2021

# Inhalt

- Durchführung und Nutzbarmachung von klinischen Studien in der Architektur systematischer Übersichtsarbeiten
- Chronisches Problem: Das Verschwinden von Studien
- Blick auf internationale Entwicklungen
- Perspektiven

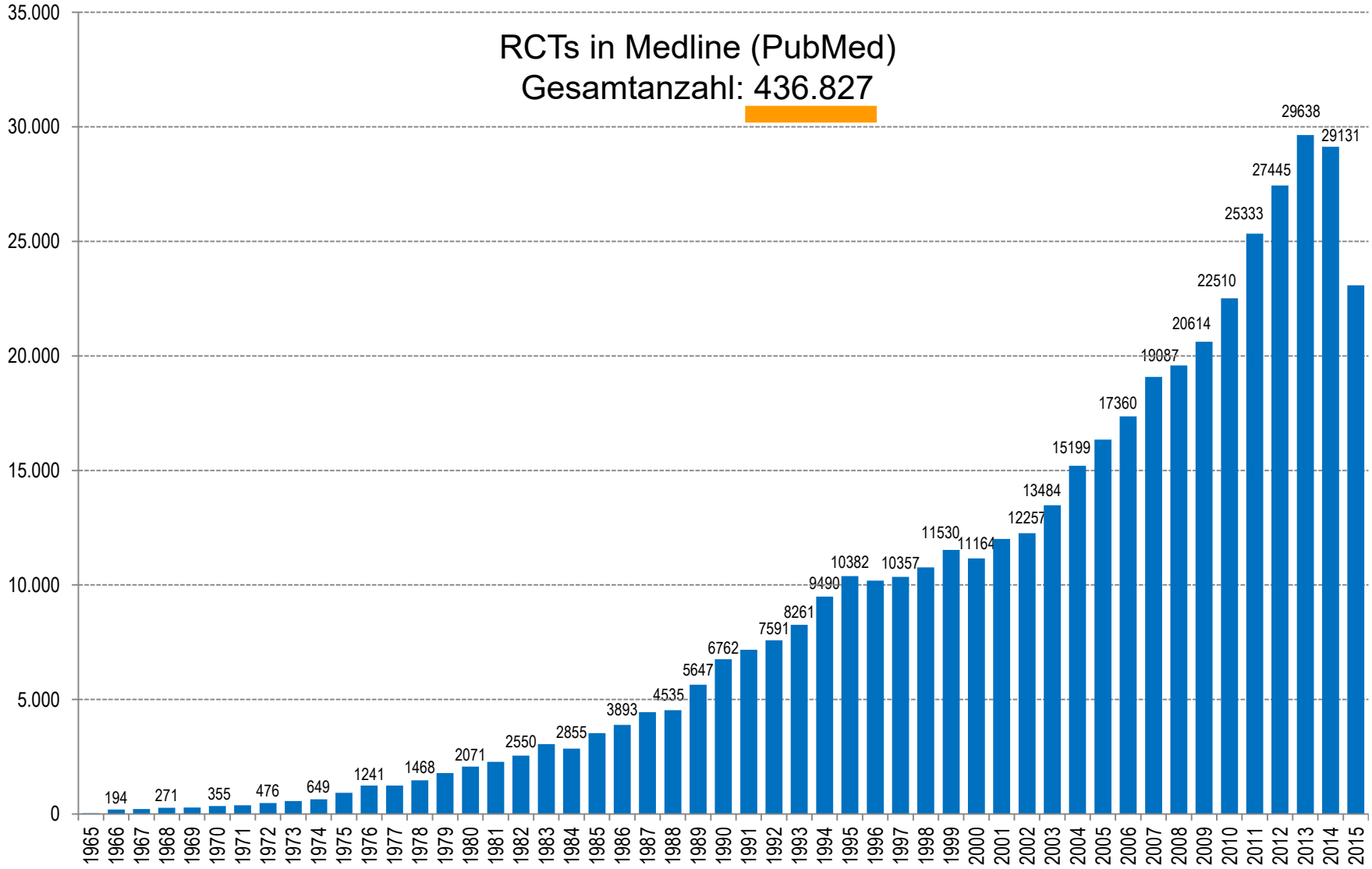
# Transfer von Forschung in die Praxis




- Behandelnde Ärzte
- Gesundheitsbehörden, Krankenkassen, Institutionen
- Klinische Forschung
- Patienten

Evidenz - Nutzung

Stand 22. 9. 2017



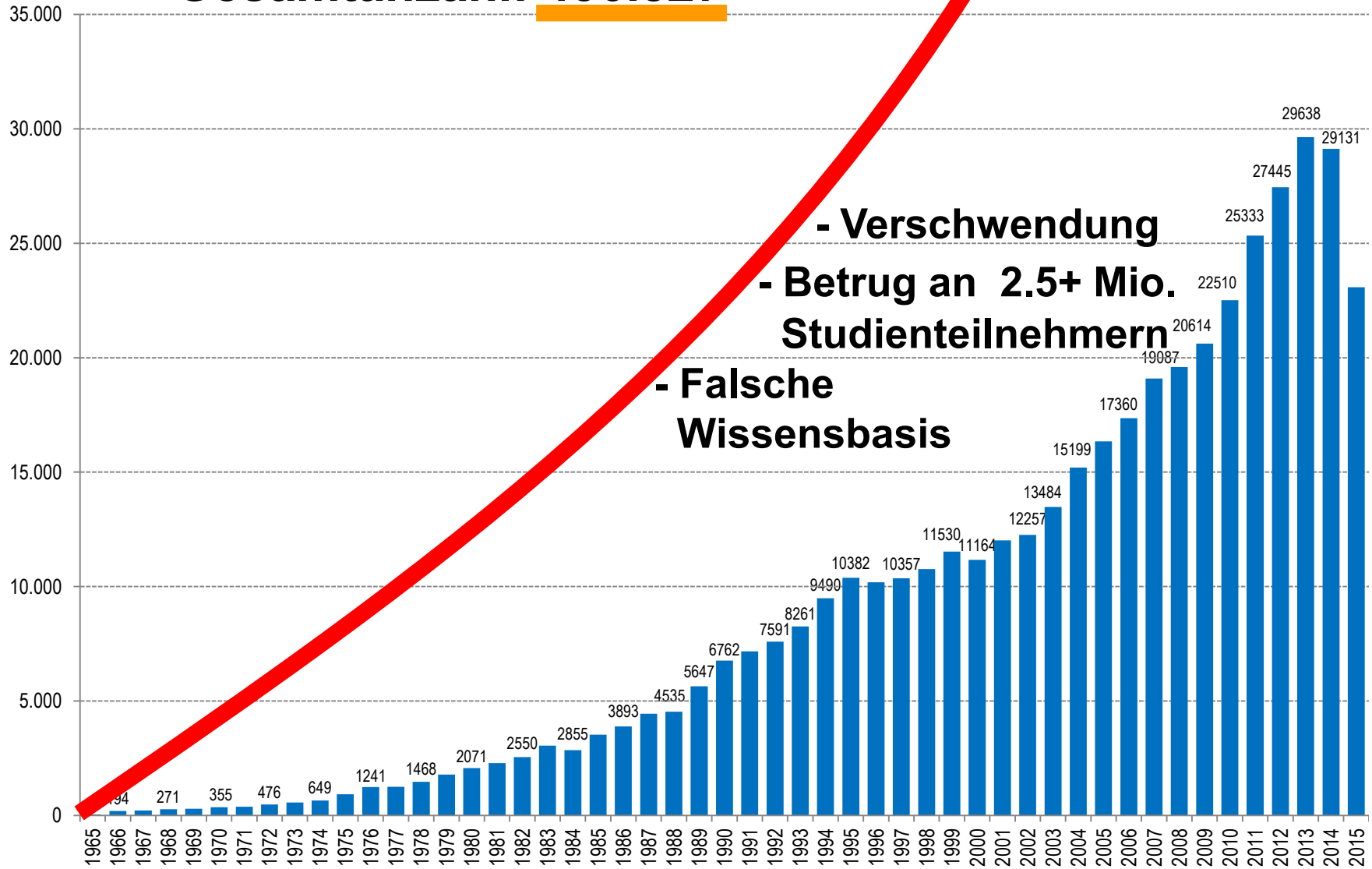
# Die Wahrheit

Stand 22. 9. 2017

# RCTs in Medline (PubMed)
# Gesamtanzahl: 436.827

Stand 16. 9. 2015

# RCTs in Medline (PubMed)
# Gesamtanzahl: 436.827



# Transfer von Forschung in die Praxis

global

Klinische Studien (randomisiert, kontrolliert, prospektiv)

Epidemiologische Studien (prospektiv, retrospektiv, . . .)

**Systematische Reviews**

**50 %**

**EBM**

Health Technology Assessment (HTA)

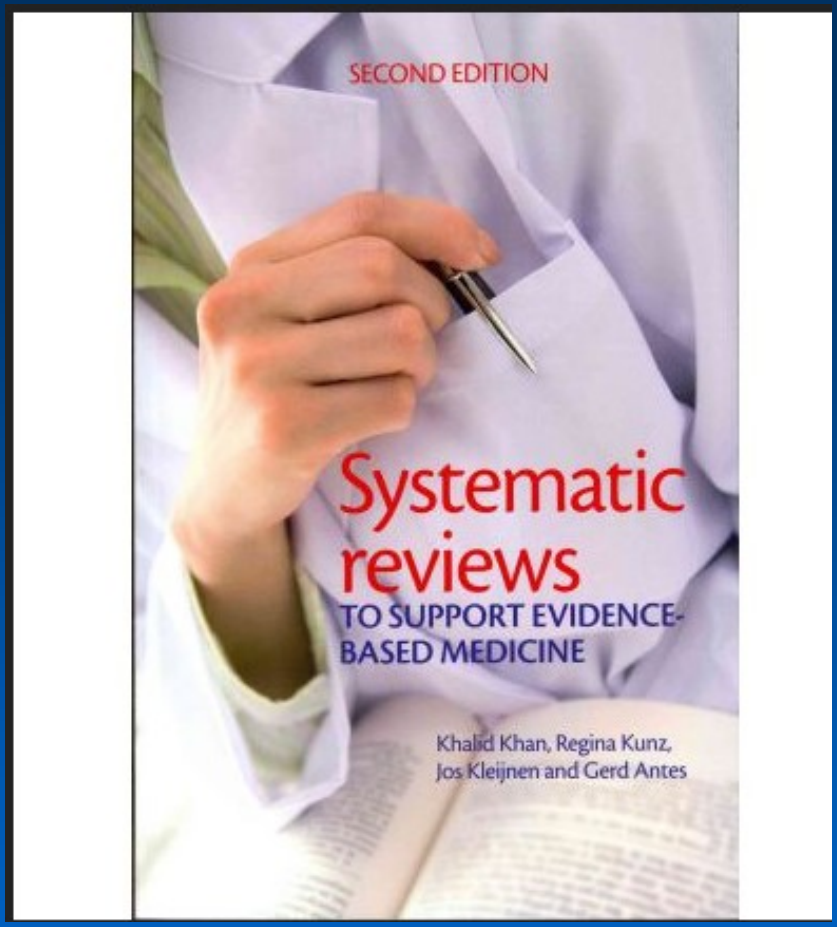
Klinische Leitlinien

Patienteninformation

lokal

# Eine Studie ist keine Studie:
# Die Wissensraffinerie

1. Formulieren der Fragestellung
2. Systematische Suche in der Literatur
3. Qualitätsbewertung der Funde
4. Zusammenfassung der Evidenz
5. Interpretation der Ergebnisse



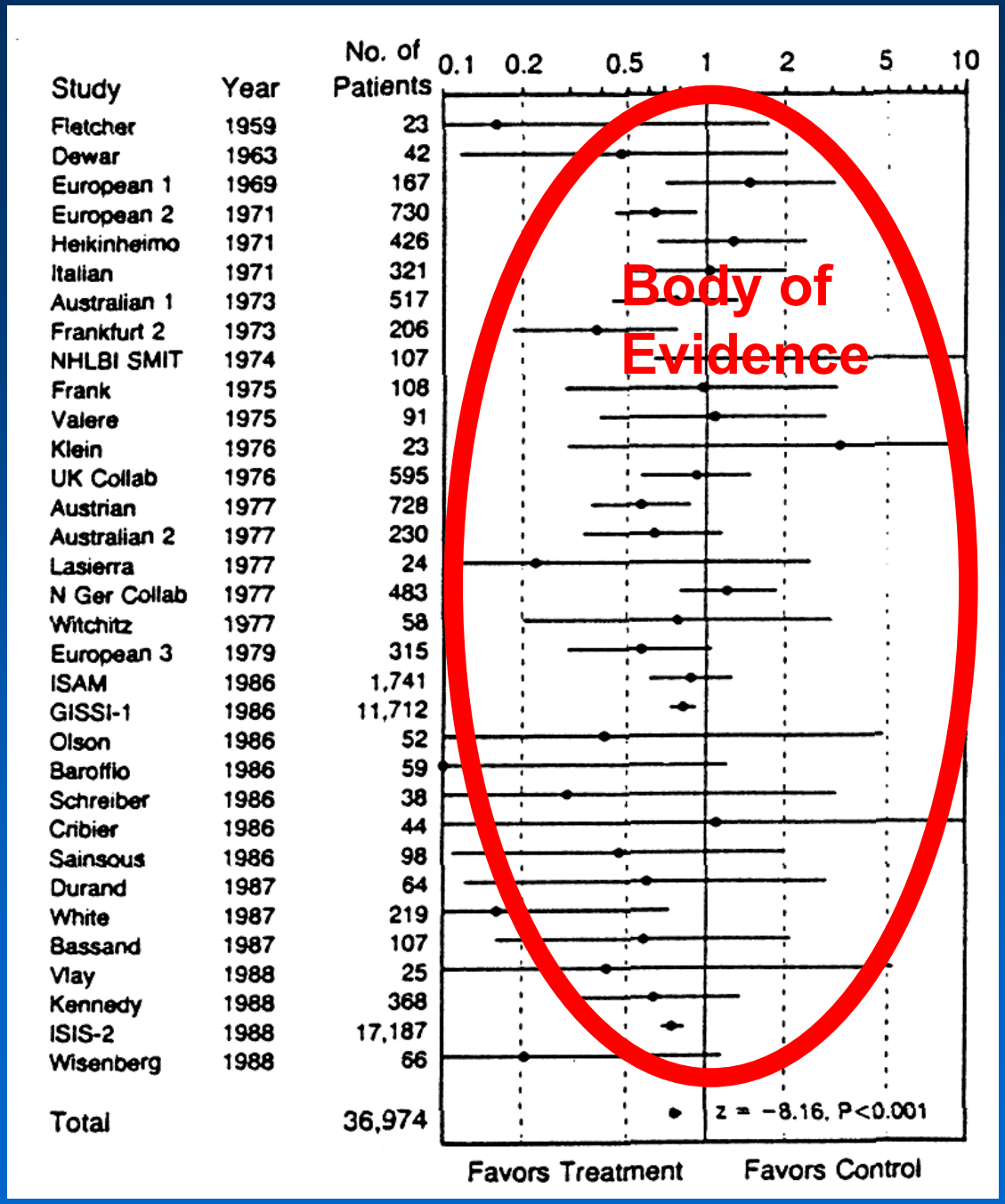

*Juli 2011*

**Aktualisierung!!**

*Auch in Deutsch*

# Example Thrombolyse nach akutem Herzinfarkt

*NEJM 1992*

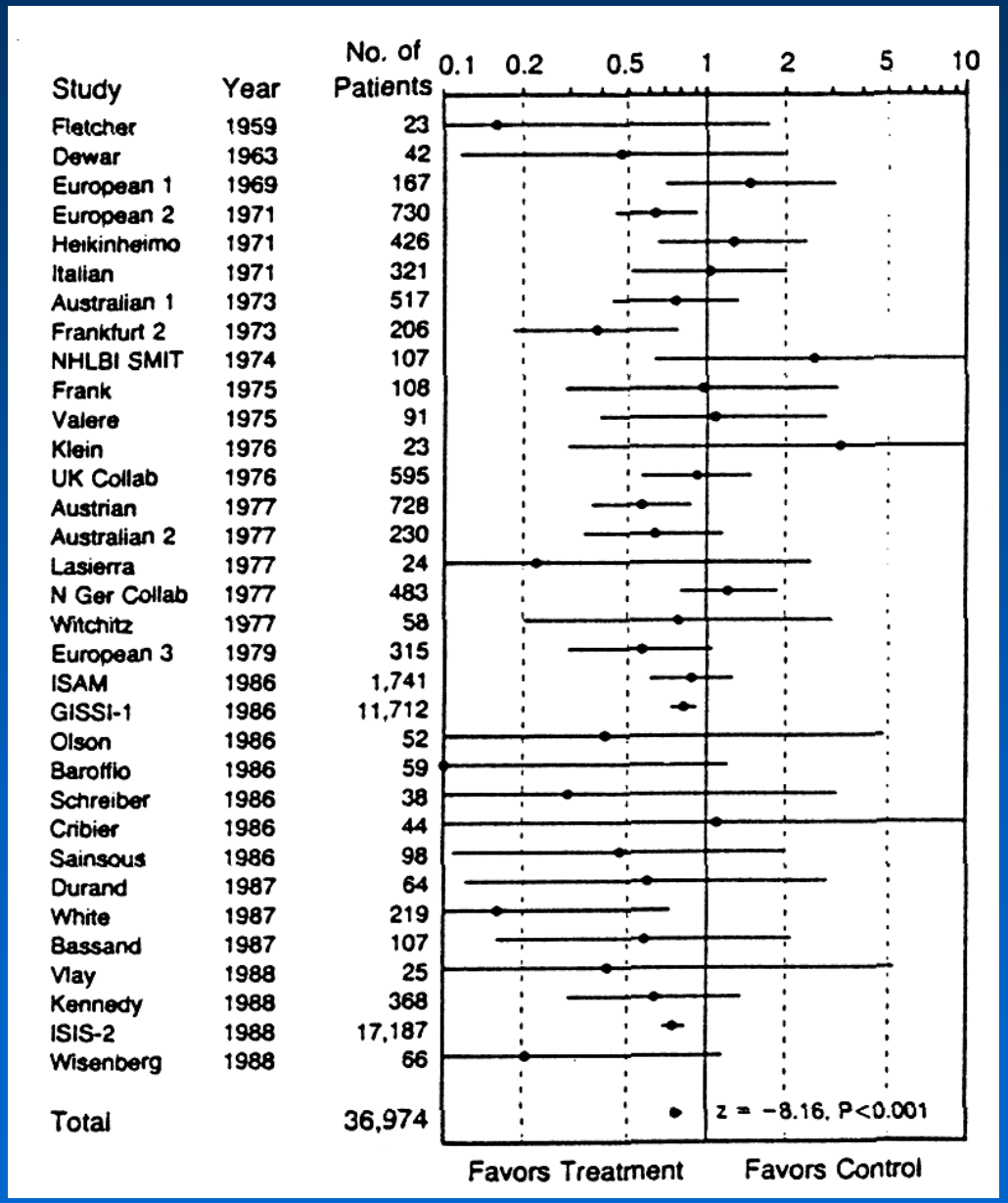



# Forest Plot

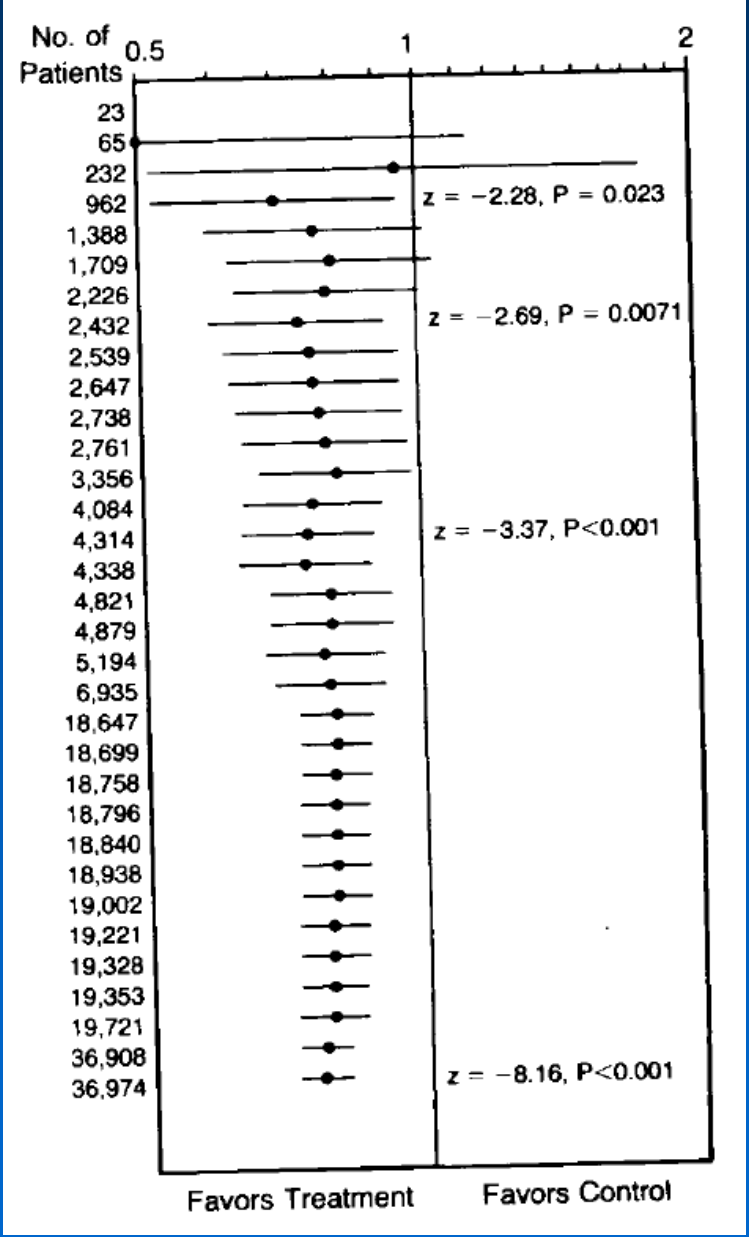
# Thrombolyse (Streptokinase) nach akutem Herzinfarkt

*NEJM 1992*

## Forest Plot:




## Cumulative Forest Plot:

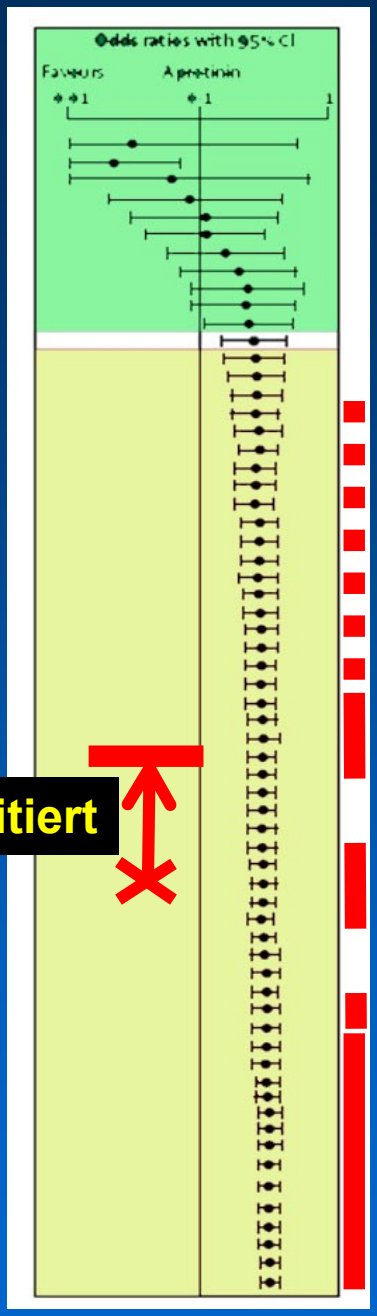


## Ungelöste Probleme

- Keine akzeptierte und praktizierte Stop – Regel
- Sind alle relevanten Studien gefunden und berücksichtigt?

**Auch November 2021 keine auch nur annähernd sichere Methode zur Identifikation der vorhandenen Evidenz**

1987




Zitiert

unethisch

2002

# RCTs of aprotinin in cardiac surgery to stop bleeding

*Lancet 2005*
*Clinical Trials 2005*

*Annals of Internal Medicine 2011*

# „Alle“ Studien ?

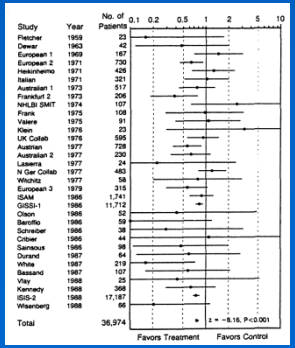
gefunden

Nicht gefunden

Nicht publiziert

?

Qualität?




laufend

# Studien nicht verschwinden lassen

COMMENTARY | VOLUME 361, ISSUE 9362, P978-979, MARCH 22, 2003

## Under-reporting of clinical trials is unethical

Gerd Antes • Iain Chalmers

Published: March 22, 2003 • DOI: https://doi.org/10.1016/S0140-6736(03)12838-3

6 years ago the Danish Research Ethics Committee System, after considering what influence the results of existing research should have on the ethical evaluation of proposals for new clinical trials, declared that researchers should review all relevant evidence before they submitted a new protocol for ethical assessment. [1] This injunction asks no more of researchers than respect for the principle that science is cumulative. Patients being invited to participate in a clinical trial have a right to expect that its design has been informed by a scientifically defensible review of what is known already.

JAMA. 2003 Jul 23;290(4):516-23. doi: 10.1001/jama.290.4.516.

## Registering clinical trials

Kay Dickersin [1], Drummond Rennie

Affiliations + expand

PMID: 12876095 DOI: 10.1001/jama.290.4.516

Home
About
E-mail alert
Submissions

Bulletin of the World Health Organization

Bull World Health Organ. 2004 May; 82(5): 321.

PMCID: PMC2622841
PMID: 15298220

## Registering clinical trials is necessary for ethical, scientific and economic reasons.

Gerd Antes

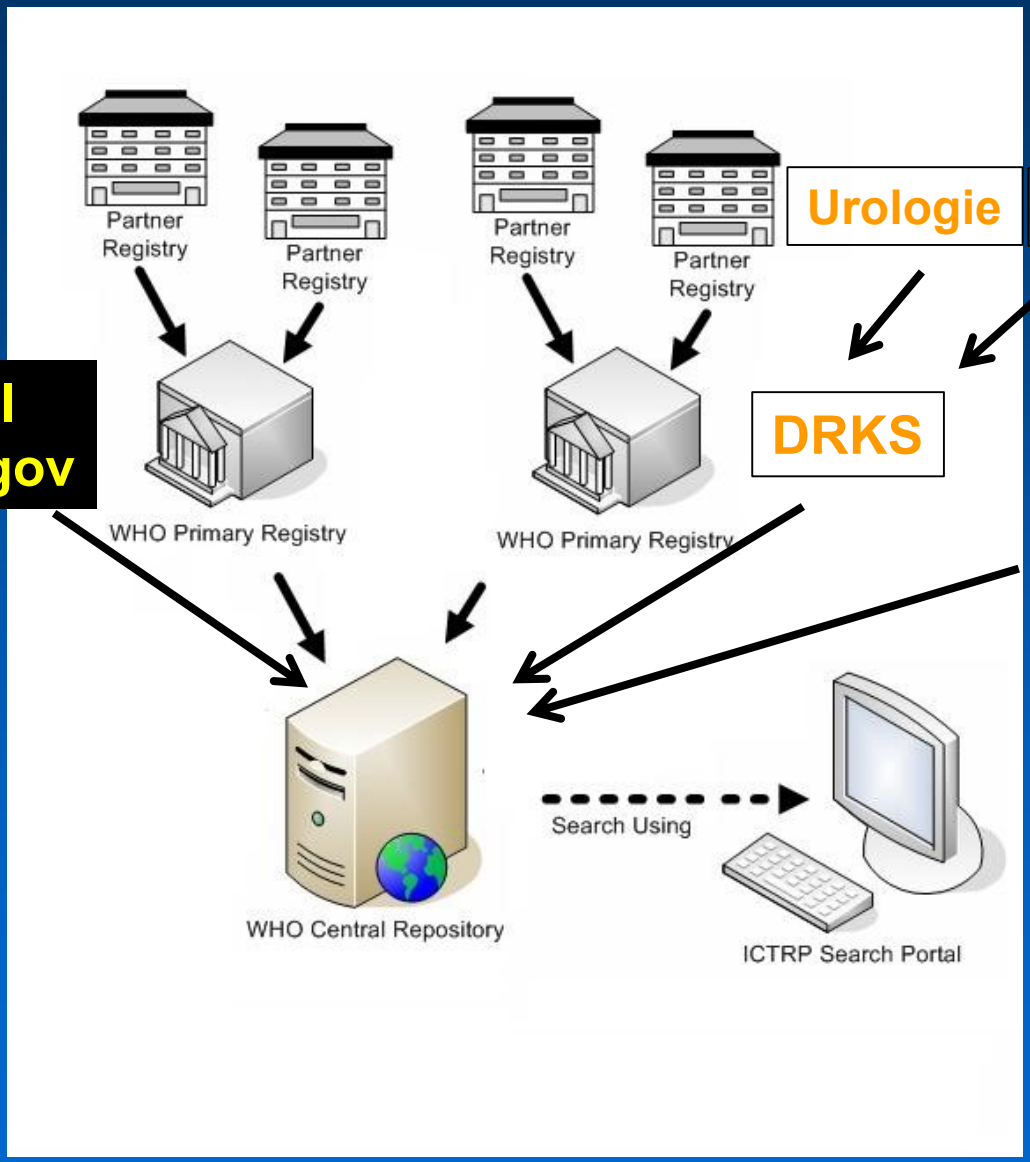
# Inkonsistente Bedingungen

| Land | Registrierung | Publikation |
|---|---|---|
| USA (2007) | Gesetz | Gesetz |
| Germany (2011) | - | Gesetz<br>(nur Arzneimittel) |
| Schweiz(2013)<br>(Humanforschungsgesetz) | Gesetz | - |

In Deklaration von Helsinki 2013

# WHO Register Netzwerk ICTRP

www.who.int/ictrp




Clinical Trials.gov

EU Clinical Trials Register

CT kein WHO Primary Registry

# Entwicklung der Studienregistrierung in Deutschland

- 2003 – 2007 WHO Arbeitsgruppe zum Aufbau eines globalen Netzwerks von Registern klinischer Studien (Convenor Richard Horton, Kay Dickersin)
- 8. 8. 2008 Deutsches Register klinischer Studien: www.drks.de
- 2017 Aufnahme ins DIMDI nach 2 Förderphasen+Verlängerung durch das BMBF
- 2020 DIMDI ins BfArM integriert
- Neukonstruktion des DRKS; Juni 2021 Registrierungsplficht am Uniklinikum Freiburg

**TranspariMED** @TranspariMED · 17 Std.

"While in the UK 1/7 hospitalised Covid patients participated in a clinical trial, in Germany it was just 1/100" - @iqwig

observer-gesundheit.de/traurige-forsc... @MartinLandray @matt_westmore @CommonsSTC @NIHRresearch @ABPI_UK

observer-gesundheit.de

Traurige Forschungskultur und fehlender politische...

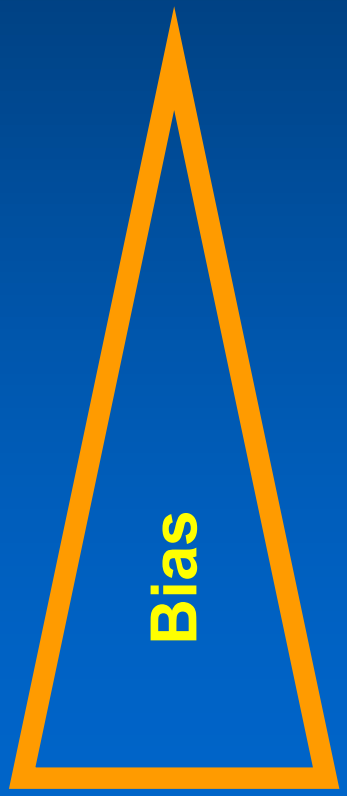
Eine Krise wie die Corona-Pandemie schärft die Kontraste, lässt die Probleme deutlicher werden. S...

# Level der Evidenz

| ***Level der Evidenz*** | Systematische Übersichtsarbeiten (Reviews) |
|---|---|
| I | Random.-kontrollierte Studien |
| II | Kohortenstudien |
| III | Fall-Kontroll-Studien |
| IV | Fall-Serien |
| V | Experten |

http://www.cebm.net

# Level der Evidenz

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| IV | Fall-Serien |
| V | Experten |

http://www.cebm.net

# Kein Ersatz für randomisierte Studien

Patientenregister-Daten sind für die Klärung von Ursache-Wirkungs-Zusammenhängen und somit für die Nutzenbewertung ungeeignet. Ihre sonst unstrittigen Potenziale erfüllen sich nur bei Ausschöpfung anspruchsvoller Qualitätsanforderungen.

Jürgen Windeler, Jörg Lauterberg, Beate Wieseler, Stefan Sauerland, Stefan Lange

Verbreitet wird in letzter Zeit der Eindruck erweckt, dass mithilfe von Analysen sogenannter „real world data“ aus Routinedatenbeständen und medizinischen Registern Fragen nach Nutzen und Schaden von Arzneimitteln, Medizinprodukten und anderen medizinischen Interventionen schneller, kostengünstiger oder gar glaubwürdiger beantwortet werden können als mit klinischen Studien. Im gesundheitspolitischen Raum scheint entsprechend die Zahl der Befür-

Dabei würde bereits ein Blick in die jüngere Geschichte der internationalen Gesundheitsforschung – beispielsweise die der gescheiterten „Outcomes-Forschung“ in den USA (1, 2) – zeigen, dass hier kein allzu großer Optimismus angebracht ist.

## Was sind Register?

Frei übersetzt definieren die Autoren des ersten Standard-Handbuchs dazu (3) ein Patientenregister als ein organisiertes System, das mit der Methodik einer Beobachtu

wissenschaftliche, klinische oder programmatische Zwecke verfolgt. Genauer betrachtet handelt es sich bei Registern nicht um Studien, sondern um patientenbezogene Datensammlungen unterschiedlichster Art und Zweckbestimmung. Entsprechend vielgestaltig sind Patientenregister und ihre Auswertungen in der Praxis. Sie lassen sich nach Haupttypus grob unterscheiden, auch wenn fallweise Überlappungen existieren. So können krankheitsbe-

Deutsches Ärzteblatt, April 2017

# The Magic of Randomization versus the Myth of Real-World Evidence

Rory Collins, F.R.S., Louise Bowman, M.D., F.R.C.P., Martin Landray, Ph.D., F.R.C.P., and Richard Peto, F.R.S.

Nonrandomized observational analyses have been promoted as alternatives to randomized clinical trials. However, randomization ensures balance between groups, whereas nonrandomized studies are often biased by between-group differences. Efforts to reduce the cost and complexity of clinical trials are preferable to relying on observational studies.

February 13, 2020
N Engl J Med 2020; 382:674-678
DOI: 10.1056/NEJMsb1901642



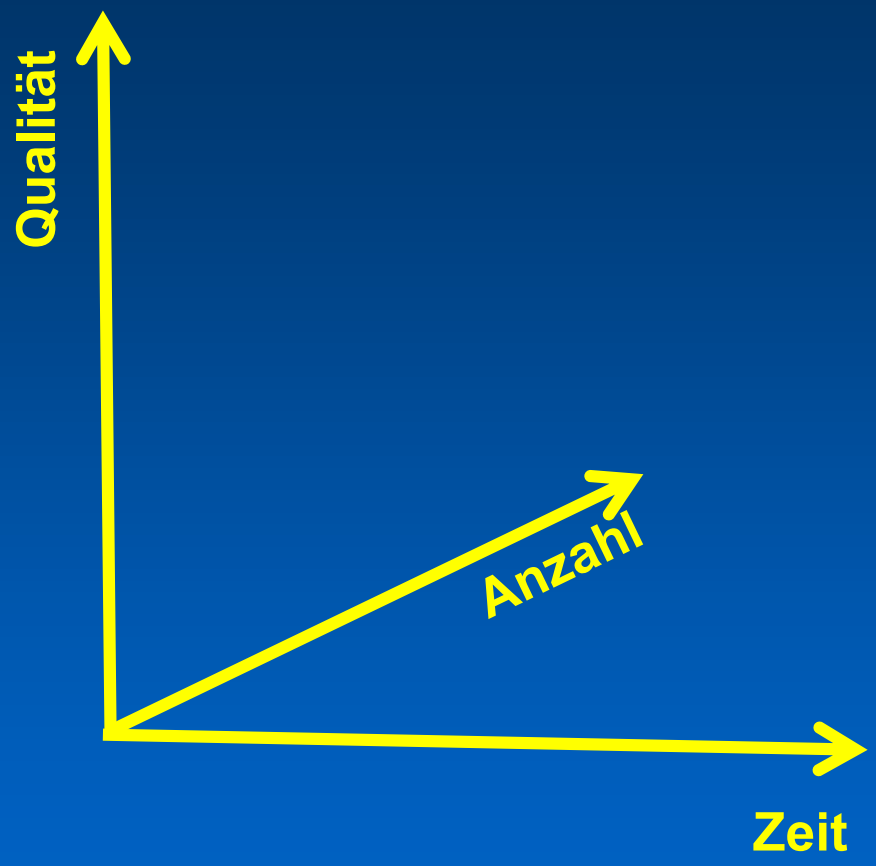
**However, because of the potential biases inherent in observational studies, such studies cannot generally be trusted when – as is often the case – the effects of the treatment of interest are actually null or only moderate.**

# Evidenz/Evidence in Corona-Zeiten

Studien:
Tausende+

<Dutzende

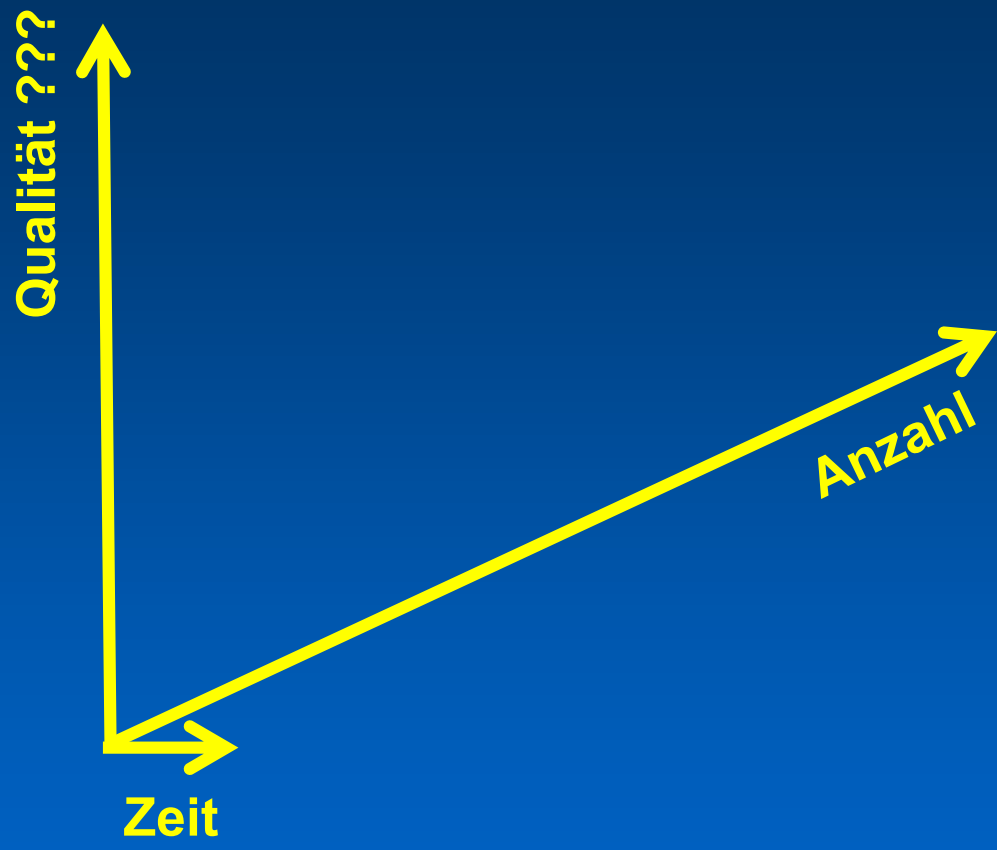
Normale Zeiten



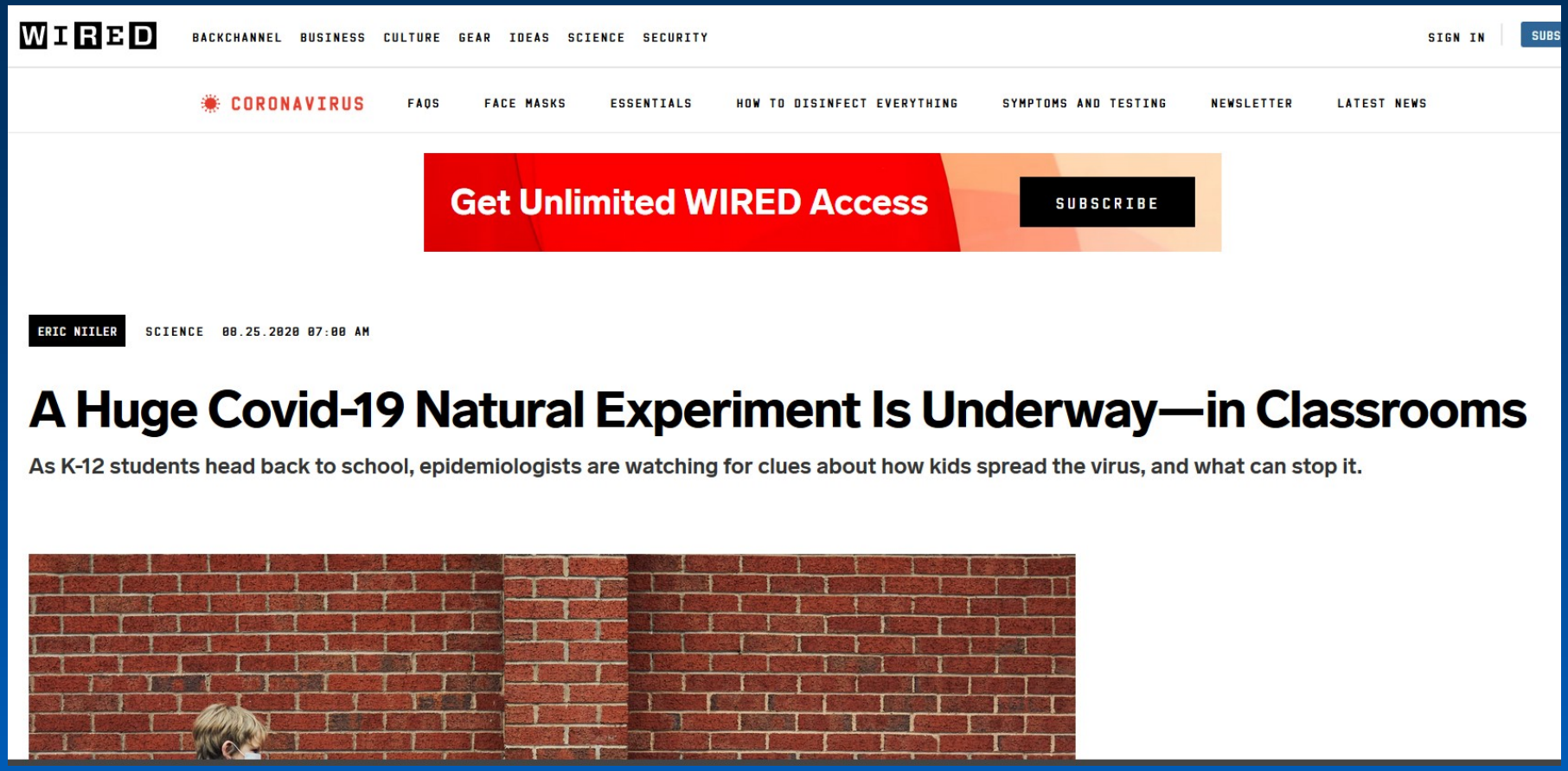
Studien:
Tausende+

<Dutzende

Corona - Zeiten



# Mitten in einer gigantischen Beobachtungsstudie



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CORONAVIRUS FAQS FACE MASKS ESSENTIALS HOW TO DISINFECT EVERYTHING SYMPTOMS AND TESTING NEWSLETTER LATEST NEWS

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ERIC NIILER SCIENCE 08.25.2020 07:00 AM

A Huge Covid-19 Natural Experiment Is Underway—in Classrooms

As K-12 students head back to school, epidemiologists are watching for clues about how kids spread the virus, and what can stop it.

- Gleichzeitig Versuchstiere und Wissenschaftler
- Notwendig: Vergleich von **Strukturen**, die sich durch eine Maßnahme unterscheiden

BMC
Part of Springer Nature

ISRCTN registry

View all studies | Why register? | Register your study | Update your rec

ISRCTN44152751 https://doi.org/10.1186/ISRCTN44152751

School opening in Norway during the COVID-19 pandemic

**"Estimate the relative effect of keeping schools partially closed versus fully reopening schools on community transmission . . . ."**

**Our Minister of Health said at a press conference May 7 2020 that he thought a trial was a good idea, but in their assessment it would be too difficult to get popular support for it. There were some other objections too, but this was the main stated reason.**


- Nutzung der Datenbestände erweitern
- Routinedaten der Kassen nutzen
- Datenverknüpfung schafft Transparenz
- Verknüpfung ohne viel Aufwand

# Daten bündeln gegen Corona

Infektionszahlen, Impfgeschehen, Kassen-Abrechnungen: Zur Covid-19-Pandemie gibt es zahlreiche Daten – aber in getrennten Pools. Es ist an der Zeit, die Datentöpfe zu verknüpfen. Das schafft mehr Transparenz und erhöht das Vertrauen der Bevölkerung. Von Helmut Schröder, Uwe Repschläger und Jochen Walker

**Gesundheit und Gesellschaft**
**Mai 2021 (AOK Bundesverb.)**

TASKFORCE

# Caring for people with COVID-19

Supporting Australia's healthcare professionals with continually updated, evidence-based clinical guidelines

05/11/20: Weekly Communique from the National Steering Committee »

## LATEST GUIDANCE

05 NOVEMBER 2020

Updates this week include:

- Bromhexine hydrochloride

Subscribe here for updates

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LIVING GUIDELINES

CLINICAL FLOWCHARTS

EVIDENCE UNDER REVIEW

DO YOU HAVE A CLINICAL QUESTION?

## LIVING GUIDELINES

We have developed rec

> Definition of disease sev

Definition of disease s

## QUICK STATISTICS

**COVID-19 research pipeline**

- 28,153 studies published or registered in Cochrane COVID-19 Study Register, **1,232 added this week**
- 1,979 randomised controlled trials registered (data from Covid-nma site), **39 added this week**
- 2,475 systematic reviews registered in PROSPERO, **40 added this week**
- 112 randomised controlled trials published (data from Covid-nma site), **6 added this week**

## LIVING GUIDELINES

**Australian guidelines for the clinical care of people with COVID-19: Version 28.0**

**NEW RECOMMENDATIONS**

- **Bromhexine hydrochloride**

Melbourne

The **National COVID-19 Clinical Evidence Taskforce** tracks new and updated global COVID-19 research. As at 19 November 2020, the global research pipeline includes:

NATIONAL COVID-19 CLINICAL EVIDENCE TASKFORCE

| | |
|---|---|
| **29,948 STUDIES**<br>**838** added this week<br>(Cochrane COVID-19 Study Register) | **2,098 REGISTERED RCTs**<br>**47** added this week<br>(Covid-nma site) |
| **2,564 SYSTEMATIC REVIEWS**<br>**40** added this week<br>(PROSPERO) | **121 PUBLISHED RCTs**<br>**6** added this week<br>(Covid-nma site) |

covid19evidence.net.au

6:10 vorm. · 25. Nov. 2020 · Hootsuite Inc.

# Professionelles Krisenmanagement?

Clarke M, Hopewell S, Chalmers I. Reports of clinical trials should begin and end with up-to-date systematic reviews of other relevant evidence: a status report. Journal of the Royal Society of Medicine 2007;100: 187-190.

# Reports of clinical trials should begin and end with up-to-date systematic reviews of other relevant evidence: a status report

Mike Clarke[1] Sally Hopewell[1] Iain Chalmers[2]

*J R Soc Med* 2007;**100**:187–190

RESEARCH

**SUMMARY**

**Objective** Scientific and ethical justification for new clinical trials requires them to have been designed in the light of scientifically defensible assessments of relevant previous research. Reliable interpretation of the results of new clinical trials entails setting them in the context of updates of the reviews upon which they were deemed scientifically and ethically justifiable. We have shown previously that most reports of randomized trials published

qualitative—of the results of the new trials in an update of these reviews. In the remaining ten reports there was no evidence that any systematic attempt had been made to set the new results in the context of previous trials.

**Conclusions** There is no evidence of progress between 1997 and 2005 in the proportion of reports of trials published in general medical journals which discussed new results within the context of up-to-date systematic reviews of relevant evidence from other

*Table 1* **Classification of Discussion sections in reports of RCTs published in May 1997, May 2001 and May 2005 in five general medical journals**

| *Classification* | *May 1997 (n=26)* | *May 2001 (n=33)* | *May 2005 (n=18)* |
|---|---|---|---|
| First trial addressing the question | 1 | 3 | 3 |
| Contained an updated systematic review integrating the new results | 2 | 0 | 0 |
| Discussed a previous review but did not attempt to integrate their results | 4 | 3 | 5 |
| No apparent systematic attempt to set the results in the context of other trials | 19 | 27 | 10 |

ISSN 1682-6833 Erscheinungsort: Wien; Verlagspostamt: A-8600 Bruck/Mur
Jahrgang 25, Ausgabe 4/2021

INTENSIV-NEWS
Forum für Intensiv- und Notfallmedizin

Verband der intensivmedizinischen Gesellschaften Österreichs (FASIM)
Österr. Gesellschaft f. Internistische & Allgemeine Intensivmedizin & Notfallmedizin (ÖGIAIN)
Deutsche Gesellschaft für Internistische Intensivmedizin und Notfallmedizin (DGIIN)
Deutsche Sepsis-Gesellschaft e.V. (DSG)

DGIIN | DSG
ÖGIAIN
FASIM
Federation of Austrian Societies of Intensive Care Medicine

# Therapieforschung bei COVID-19: Masse statt Klasse

In einer jüngsten Analyse der *US Food and Drug Administration (FDA)* wurden 2.024 registrierte Studien mit insgesamt 2.895 Studienarmen untersucht, welche angaben, insgesamt mehr als 500.000 Patienten rekrutieren zu wollen *(Bugin K; Nat Rev Drug Discov 2021; 20:254)*. Dabei konnten nur 5% der geplanten Studienarme als ausreichend gepowert angesehen werden, um verlässliche Aussagen über die Wirksamkeit der experimentellen Intervention nachweisen zu können. Nur 26% der rekrutierten Patienten würden zu angemessen gepowerten kontrollierten Studien beitragen; d. h., zwei Drittel der Patienten wer-

einzige randomisierte klinische Studie. Die COVID-19 Pandemie stellt eine Herausforderung an die Therapieforschung dar, denn die Forschungsergebnisse müssen schnell verfügbar sein. Die klassische Wertschöpfungskette der pharmazeutischen Industrie von der Phase I-III stößt hier an ihre Grenzen. Daher werden bereits zugelassene Medikamente mit potentieller Wirksamkeit bei COVID-19 untersucht.
Der Vorteil dieser „*repurposed drugs*“ ist, dass deren Nebenwirkungen bekannt und die Kosten relativ niedrig sind, was deren Verfügbarkeit auch in Low-Income Countries ermöglicht.

schungsaktivitäten integriert.

## Durchbrüche in der Therapieforschung bei COVID-19

Klinische Studien, welche neue Standards in der Therapie von hospitalisierten Patienten mit COVID-19 gesetzt haben, sind maßgeblich drei großen Studiengruppen zu verdanken, welche in einer in der Geschichte der klinischen Forschung bisher einzigartigen Weise kooperative nationale bzw. internationale Studienplattformen in Rekordzeit aufgebaut haben: RECOVERY, SOLIDARITY und REMAP-CAP.

**Global Commission on Evidence** @EvidenceComm · 9. Nov.

Join us in an hour for our webinar on systematizing best evidence use in routine times and to address future global crises. Register now! ow.ly/rasJ50GEGCs #EE21 @jhjelliott @ALeighMP @nhmrc @McMasterForum @CochraneAus

ENGAGING EVIDENCE 2021: Evolving Approaches
Australia & New Zealand presents:

Global Commission on Evidence
to Address Societal Challenges

# Systematizing best evidence use in routine times and to address future global crises

Jenn Thornhill Verma
Executive Lead, Secretariat

Julian Elliott
Commissioner

**Free Webinar**

Andrew Leigh
Commissioner

Davina Ghersi
Discussant

**WEDNESDAY, NOVEMBER 10, 2021**
**9:00-10:00AM AEDT***

PREVIEWING THE WORK OF THE GLOBAL COMMISSION ON EVIDENCE TO ADDRESS SOCIETAL CHALLENGES

*TUESDAY, NOVEMBER 9, 2021
5:00-6:00PM EST

# The James Lind Library

Illustrating the development of fair tests of treatments in health care



## RECOVERY Trial team (2020)

Randomized Evaluation of COVID019 Therapy (RECOVERY). RECOVERY Central Coordinating Office, Oxford. www.recoverytrial.net

RECOVERY
Randomised Evaluation of COVID-19 Therapy

**RANDOMISED EVALUATION OF COVID-19 THERAPY (RECOVERY)**

**Background:** In early 2020, as this protocol was being developed, there were no approved treatments for COVID-19, a disease induced by the novel coronavirus SARS-CoV-2 that emerged in China in late 2019. The UK New and Emerging Respiratory Virus Threats Advisory Group (NERVTAG) advised that several possible treatments should be evaluated, including Lopinavir-Ritonavir, low-dose corticosteroids, and Hydroxychloroquine. These groups also advised that other treatments will soon emerge that require evaluation. A World Health Organization (WHO) expert group issued broadly similar advice.

### Whole article

Download the full article as a PDF

RELEVANT TOPICS

The need to address treatment uncertainties

Principles of Testing

Treatment comparisons are essential

Treatment comparisons must be fair

Bringing it all together for the benefit of patients and the public

Improving reports of research

Using the results of research

KEY ARTICLES

Glasziou PP, Tikkinen KAO (2021).
The RECOVERY trial platform: a milestone in the development and execution of treatment evaluation during an epidemic.

# Glasziou PP, Tikkinen KAO (2021). The RECOVERY trial platform: a milestone in the development and execution of treatment evaluation during an epidemic.

© Paul Glasziou, Centre for Research in Evidence-Based Practice, Faculty of Health Sciences and Medicine, Bond University, Gold Coast, Queensland 4229, Australia. Email: pglaszio@bond.ac.uk

**Cite as:** Glasziou PP, Tikkinen KAO (2021). The RECOVERY trial platform: a milestone in the development and execution of treatment evaluation during an epidemic. JLL Bulletin: Commentaries on the history of treatment evaluation (https://www.jameslindlibrary.org/articles/the-recovery-trial-platform-a-milestone-in-the-development-and-execution-of-treatment-evaluation-during-an-epidemic/)

> *"Any treatment given for coronavirus other than general supportive care, treatment for underlying conditions, and antibiotics for secondary bacterial complications, should currently be as part of a trial, where that is possible."*

Letter from Chief Medical Officers of Wales, Scotland, Northern Ireland, England to NHS Staff

Journal of the Royal Society of Medicine; 0(0) 1–6
DOI: 10.1177/01410768211051720

# Protecting the public from the adverse effects of confused research ethics

**2021**

**Iain Chalmers[1] and Paul Glasziou[2]**
[1]Centre for Evidence-Based Medicine, Department of Primary Care, University of Oxford, Oxford OX2 6GG, UK
[2]Institute for Evidence-Based Healthcare, Faculty of Health Sciences and Medicine, Bond University, Gold Coast QLD 4229, Australia
**Corresponding author:** Paul Glasziou. Email: pglaszio@bond.edu.au

*This is an article in our series on the theme of 'More efficient ethics review could improve health'*

## Neglecting treatment uncertainties leads to avoidable suffering

Healthcare abounds with uncertainties about the effects of treatments. When therapeutic uncertainties have not been addressed, subsequent research has unaccountably abandoned it in the 2013 edition of *Good Medical Practice*.[5,6]

## Obstacles facing proposed research to reduce treatment uncertainties

The RECOVERY trial, which randomised 20,000 patients to several different COVID-19 treatments, illustrates the potential1: the **National Institute for Health Research provided emergency funding to address priority questions** and to support a trials network infrastructure. Significantly, the Chief Medical Officers of England, Scotland, Wales and Northern Ireland wrote to clinicians to urge them to **treat patients within the RECOVERY trial platform rather than use medications 'off-label'**.

Journal of the Royal Society of Medicine; 0(0) 1–7
DOI: 10.1177/01410768211051711

# Improving research ethics review and governance can improve human health

**2021**

**Paul Glasziou[1], Anna Mae Scott[1], Iain Chalmers[2], Simon E Kolstoe[3] and Hugh T Davies[4]**
[1]Institute for Evidence-Based Healthcare, Faculty of Health Sciences and Medicine, Bond University, Gold Coast, QLD 4229, Australia
[2]Centre for Evidence-Based Medicine, Department of Primary Care, University of Oxford, Oxford OX2 6GG, UK
[3]School of Health Sciences and Social Work, University of Portsmouth, Portsmouth PO1 2UP, UK
[4]Health Research Authority, London SE1 6LH, UK
**Corresponding author:** Paul Glasziou. Email: pglaszio@bond.edu.au

*This is an article in our series on the theme of 'More efficient ethics review could improve health'*

While research oversight is necessary and desirable for some types and elements of research, we must also recognise that **research review is itself a healthcare intervention** and should therefore be subject to the same evidence-based requirements demanded of other healthcare interventions. Inefficiencies in any part of the research process – including its regulation, governance and ethics review – are harmful to human health.

**EBM → EBHC → EBPH → EBResearch (Towards Evidence based research; BMJ 2016)**

# Inferring the effectiveness of government interventions against COVID-19

**Jan M. Brauner[1,2*†], Sören Mindermann[1*†], Mrinank Sharma[2,3,4*†], David Johnston[5,6], John Salvatier[6], Tomáš Gavenčiak[7], Anna B. Stephenson[8], Gavin Leech[9], George Altman[10], Vladimir Mikulik[11], Alexander John Norman[12], Joshua Teperowski Monrad[2,13,14], Tamay Besiroglu[15], Hong Ge[16], Meghan A. Hartwick[17], Yee Whye Teh[3], Leonid Chindelevitch[18,19‡], Yarin Gal[1‡], Jan Kulveit[2‡]**

[1]Oxford Applied and Theoretical Machine Learning (OATML) Group, Department of Computer Science, University of Oxford, Oxford, UK. [2]Future of Humanity Institute, University of Oxford, Oxford, UK. [3]Department of Statistics, University of Oxford, Oxford, UK. [4]Department of Engineering Science, University of Oxford, Oxford, UK. [5]College of Engineering and Computer Science, Australian National University, Canberra, Australia. [6]Quantified Uncertainty Research Institute, San Francisco, CA, USA. [7]Independent scholar, Prague, Czech Republic. [8]Harvard John A. Paulson School of Engineering and Applied Sciences, Harvard University, Cambridge, MA, USA. [9]School of Computer Science, University of Bristol, Bristol, UK. [10]School of Medical Sciences, University of Manchester, Manchester, UK. [11]Indepdendent scholar, London, UK. [12]Mathematical, Physical and Life Sciences (MPLS) Doctoral Training Centre, University of Oxford, Oxford, UK. [13]Faculty of Public Health and Policy, London School of Hygiene and Tropical Medicine, London, UK. [14]Department of Health Policy, London School of Economics and Political Science, London, UK. [15]Faculty of Economics, University of Cambridge, Cambridge, UK. [16]Engineering Department, University of Cambridge, Cambridge, UK. [17]Tufts Initiative for the Forecasting and Modeling of Infectious Diseases, Tufts University, Boston, MA, USA. [18]Medical Research Council (MRC) Centre for Global Infectious Disease Analysis, School of Public Health, Imperial College London, London, UK. [19]Abdul Latif Jameel Institute for Disease and Emergency Analytics (J-IDEA), School of Public Health, Imperial College London, London, UK.

***Corresponding author. Email: jan.brauner@cs.ox.ac.uk (J.M.B.); soren.mindermann@cs.ox.ac.uk (S.M.); mrinank@robots.ox.ac.uk (M.S.)**

†These authors contributed equally to this work. ‡These authors contributed equally to this work.

Governments are attempting to control the COVID-19 pandemic with nonpharmaceutical interventions (NPIs). However, the effectiveness of different NPIs at reducing transmission is poorly understood. We gathered chronological data on the implementation of NPIs for several European, and other, countries between January and the end of May 2020. We estimate the effectiveness of NPIs, ranging from limiting gathering sizes, business closures, and closure of educational institutions to stay-at-home orders. To do so, we used a Bayesian hierarchical model that links NPI implementation dates to national case and death counts and supported the results with extensive empirical validation. Closing all educational institutions, limiting gatherings to 10 people or less, and closing face-to-face businesses each reduced transmission considerably. The additional effect of stay-at-home orders was comparatively small.

**Science 15 Dec 2020**

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# CEIR – Centre for Epidemic Interventions Research

The Centre for Epidemic Interventions Research aims to advance our understanding of epidemic control measures and enable us to conduct research on different measures in the future.

**2 Sept 2021**

## Fazit

- Das Brennglas Pandemie macht die Strukturmängel überdeutlich sichtbar
- Die Situation ist außerordentlich komplex: Keine leichten Lösungen. Aber: zurück zur Wissenschaftlichkeit
- Systematische Überprüfung der organisatorischen und prozeduralen Strukturen notwendig
- Enquete – Kommission für die Bewertung des Geschehens
- Den Ethikkommissionen kommt eine wichtige Rolle zu: Für die eigene Weiterentwicklung und für die Gesamtstruktur