Medizinische Forschung: Mehr Wert, weniger Verschwendung – was ist zu tun?

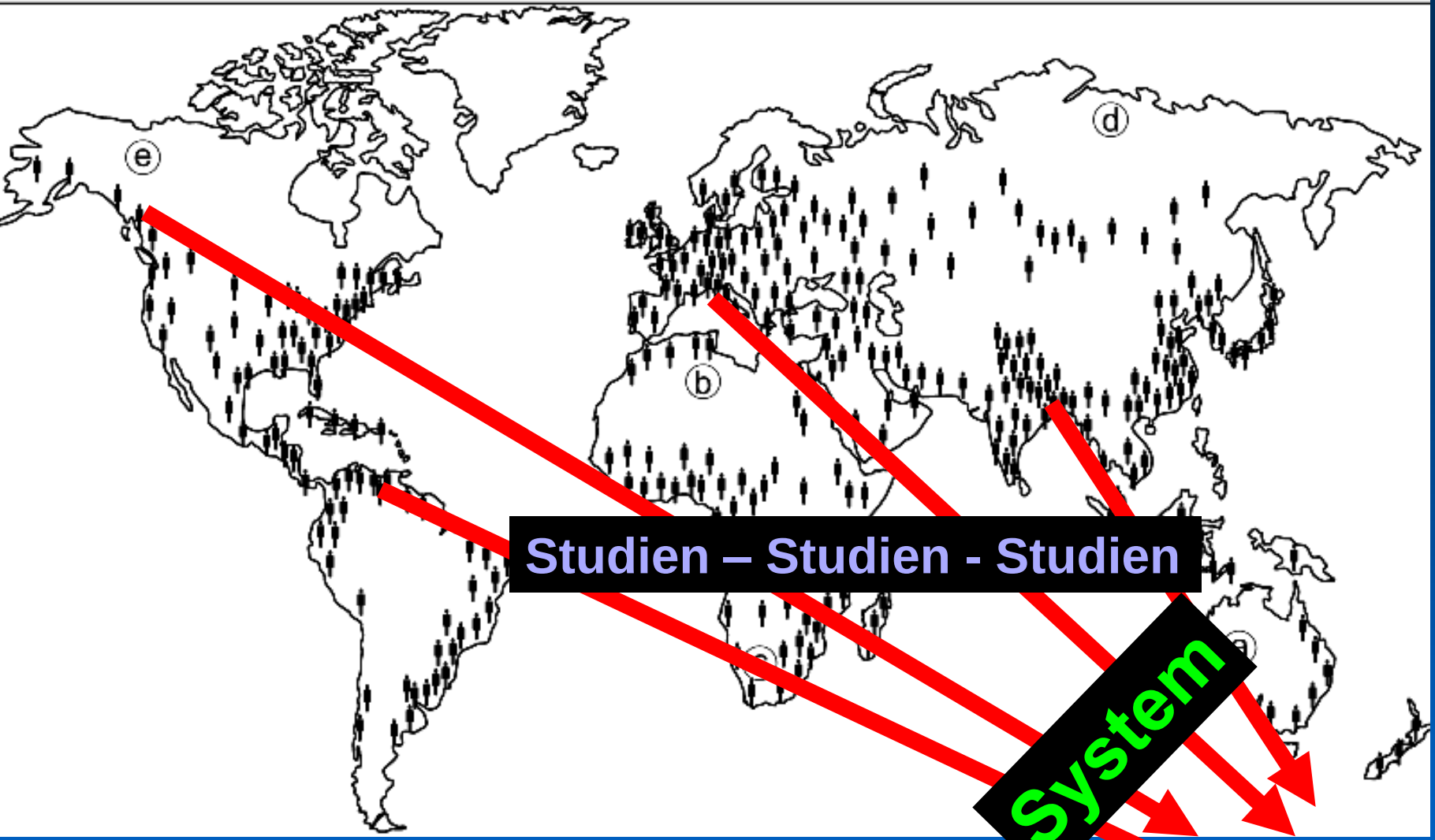
Gerd Antes

Cochrane Germany
University Medical Center Freiburg

Gemeinsames Symposium TMF & CC
Berlin 24. September 2015

Inhalt

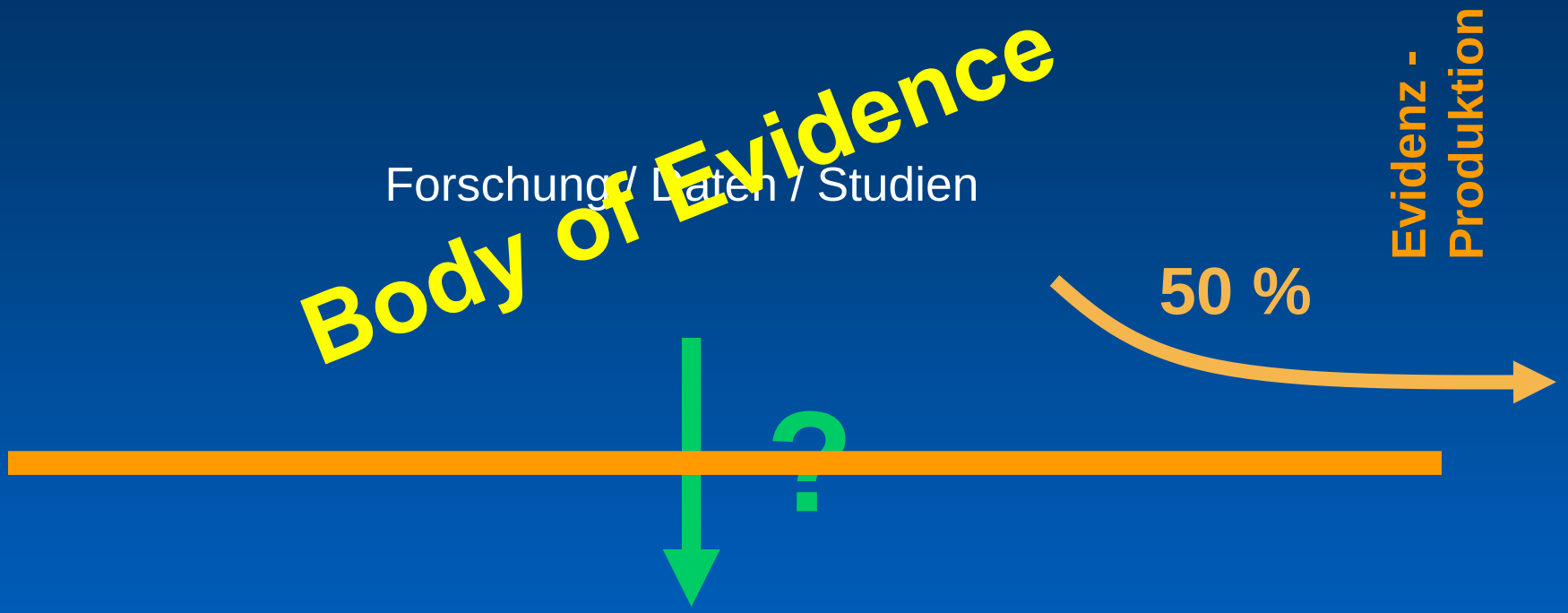
- Mehr Qualität in medizinischer Forschung und Wissensanwendung: Warum das Ganze?
- Defizite bei allen Interessengruppen: Beispiele
- Defizite in jeder Forschungsphase und in der Translation
- Die REWARD/EQUATOR – Konferenz 28.-30. Sept. in Edinburgh: Vorgeschichte und Stand der Dinge



Information von ähnlichen Menschen mit gleicher Diagnostik oder Therapie

Neumann

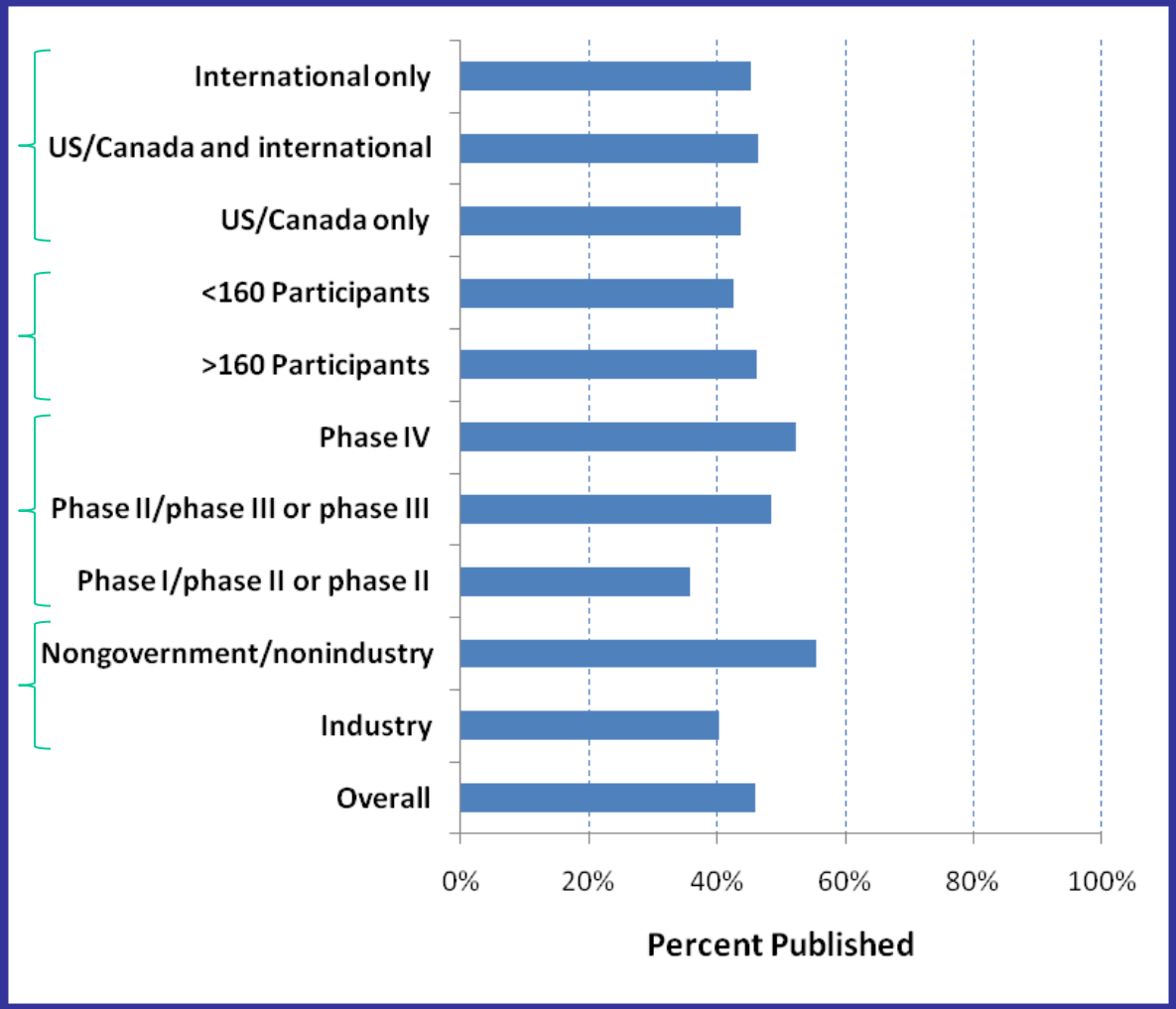
Transfer von Forschung in die Praxis



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

2009

Publication (2007) after registration (1999)



Ross JS, Mulvey GK, Hines EM, Nissen SE, Krumholz HM (2009). Trial publication after registration in ClinicalTrials.Gov: a cross-sectional analysis. PLoS Med 6(9): e1000144.

Example 2

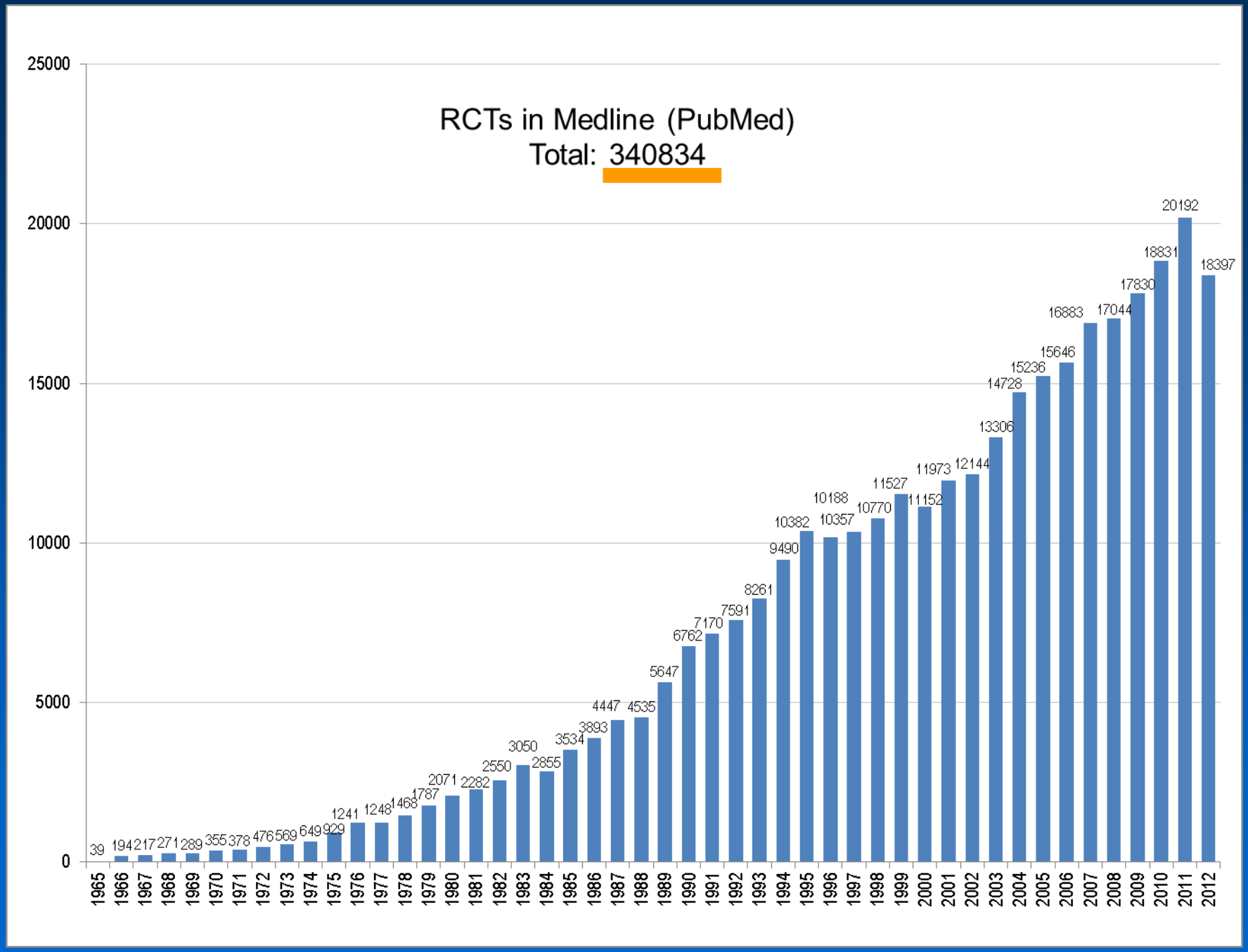
One million children were included in a deworming trial from India with mortality as the primary outcome. This was completed in 2005 but has not been published.

DISCUSSION

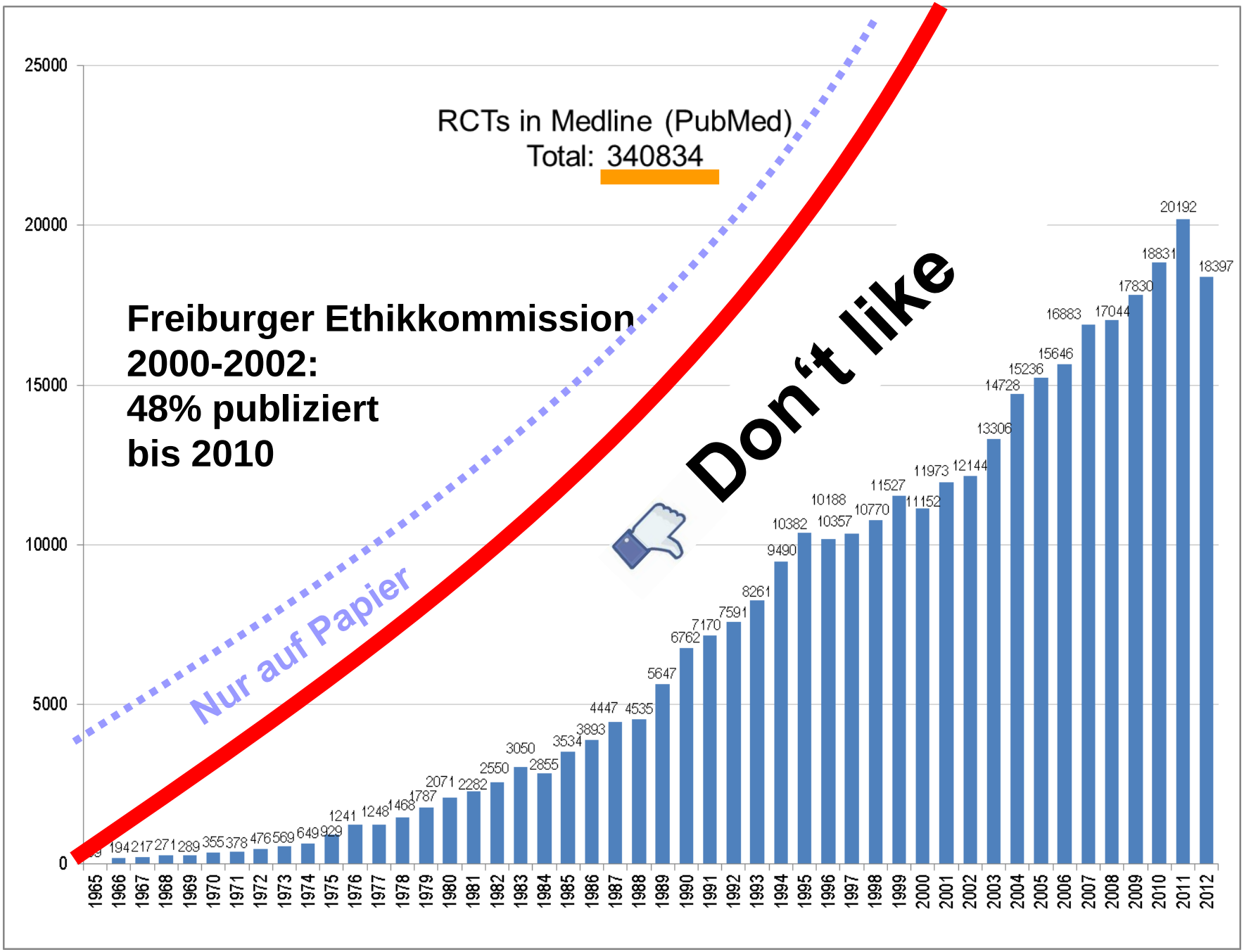
(SECTION ON BIAS)

Publication bias: We are uncertain about the number of unpublished trials in this area. We know of two unpublished trials: **1.** Hall 2006 (Cluster) is unpublished. This large trial from Vietnam, with 2 years follow-up, kindly provided by one of the authors, did not demonstrate a significant difference in weight gain. Clustering was not taken into account in the analysis, which artificially narrows the confidence intervals. In this update we included the results of this trial in meta-analysis by imputing an intra-cluster correlation coefficient, calculated from the adjusted data from Alderman 2006 (Cluster). **2. The DEVTA trial** (deworming and vitamin A; http://www.ctsu.ox.ac.uk/projects/devta), the world's largest ever RCT, which includes over a million children randomised in a cluster design with mortality as the primary outcome, remains unpublished 6 years after completion.We have corresponded with the senior author, on several occasions. We also wrote a letter to the Lancet, asking for publication of this important study. When this letter was accepted, the authors submitted the manuscript to the Lancet within a week, and we withdrew our letter. However, at the time of writing (April 2012) the paper is still not published, for unknown reasons.

Letter to the Lancet (April 2012)


RCTs in Medline (PubMed)
Total: 340834
25000
20000
15000
10000
5000
0
39 194 217 271 289 355 378 476 569 649 929 1241 1248 1468 1787 2071 2282 2550 3050 2855 3534 3893 4447 4535 5647 6762 7170 7591 8261 9490 10382 10357 10188 10770 11527 11152 11973 12144 13306 14728 15236 15646 16883 17044 17830 18831 20192 18397
1965 1966 1967 1968 1969 1970 1971 1972 1973 1974 1975 1976 1977 1978 1979 1980 1981 1982 1983 1984 1985 1986 1987 1988 1989 1990 1991 1992 1993 1994 1995 1996 1997 1998 1999 2000 2001 2002 2003 2004 2005 2006 2007 2008 2009 2010 2011 2012

Die Wahrheit


RCTs in Medline (PubMed)
Total: 340834
Freiburger Ethikkommission
2000-2002:
48% publiziert
bis 2010
Don‘t like
Nur auf Papier
25000
20000
15000
10000
5000
0
1965 1966 1967 1968 1969 1970 1971 1972 1973 1974 1975 1976 1977 1978 1979 1980 1981 1982 1983 1984 1985 1986 1987 1988 1989 1990 1991 1992 1993 1994 1995 1996 1997 1998 1999 2000 2001 2002 2003 2004 2005 2006 2007 2008 2009 2010 2011 2012
194 217 271 289 355 378 476 569 649 929 1241 1248 1468 1787 2071 2282 2550 3050 2855 3534 3893 4447 4535 5647 6762 7170 7591 8261 9490 10382 10357 10188 10770 11527 11152 11973 12144 13306 14728 15236 15646 16883 17044 17830 18831 20192 18397

Clinical research projects at a German medical faculty: follow-up from ethical approval to publication and citation by others

J Med Ethics 2008

A Blümle,[1] G Antes,[1] M Schumacher,[1] H Just,[2] E von Elm[1,3]

ABSTRACT

Background: Only data of published study results are available to the scientific community for further use such

likely to give an over-optimistic effect of treatment.[4] This can lead to inappropriate or even detrimental treatment recommendations.[5]

Publication rate 48%; 2010 52%

Wo finde ich als Arzt vertrauenswürdige Aussagen zu diagnostischen und therapeutischen Verfahren?

Wie glaubwürdig ist die Evidenz?

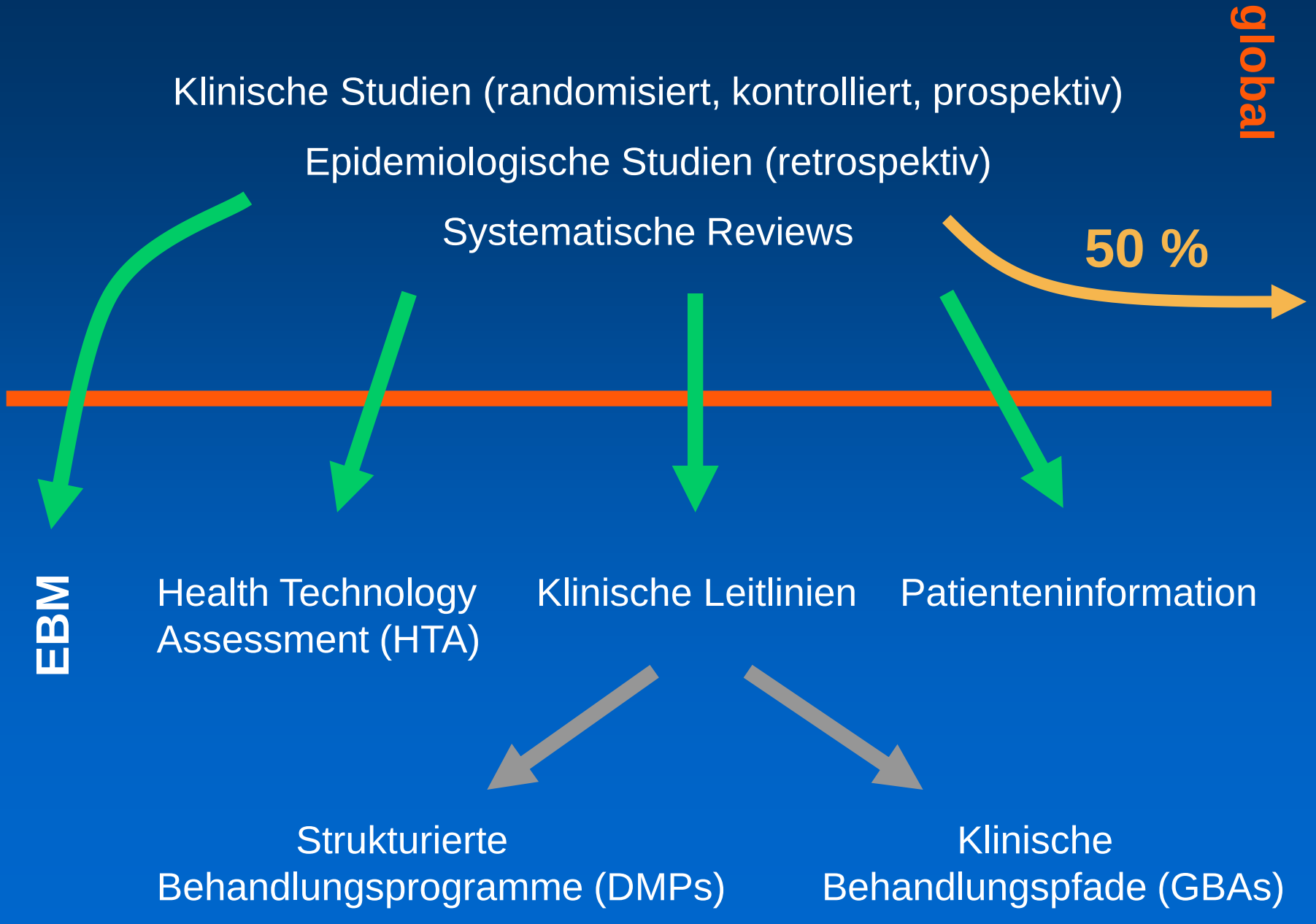
Ingrid Töws, Gerd Antes

Cochrane Deutschland, Universitätsklinikum Freiburg, Freiburg im Breisgau, Deutschland

Schweizerisches Medizin-Forum (SMF) Sept 2015

Jährlich werden weit mehr als 20 000 kontrollierte Studien publiziert. Doch nutzen wir dieses Wissen überhaupt? Und wie können wir es noch überblicken und für unsere Entscheidungen in die Praxis transferieren? Unsere Möglichkeiten, Forschungsergebnisse für die Entscheidungsfindung einfach und praxisbezogen zu nutzen, hängen ganz wesentlich von ihrer Qualität und Verfügbarkeit ab.

Transfer von Forschung in die Praxis

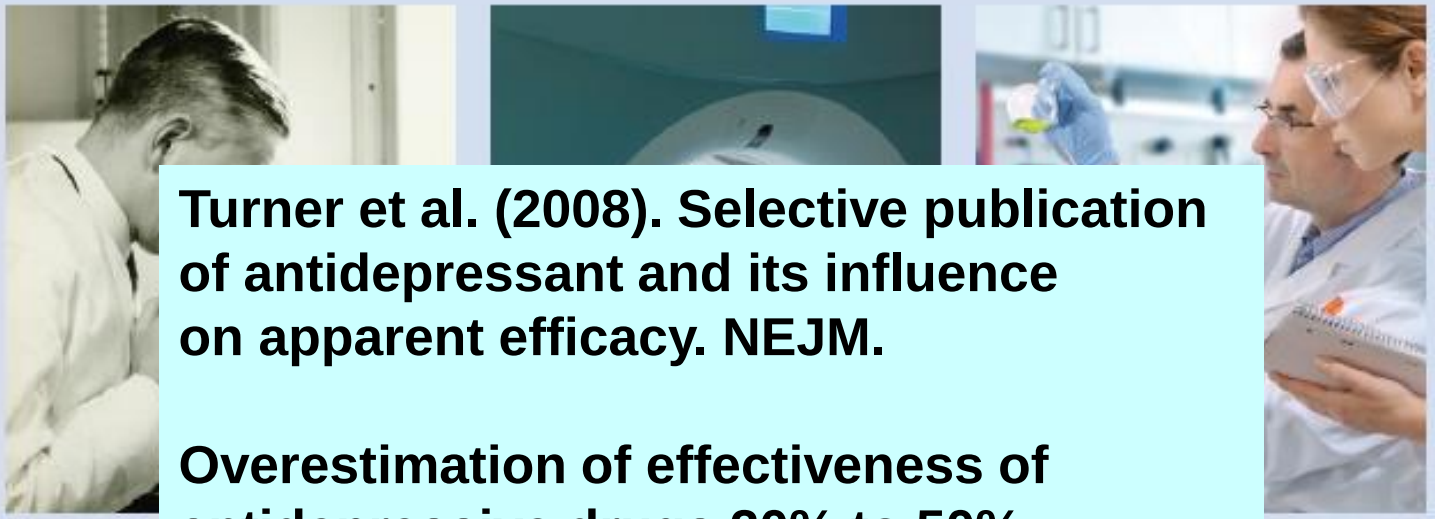


EUROPEAN SCIENCE FOUNDATION

SETTING SCIENCE AGENDAS FOR EUROPE

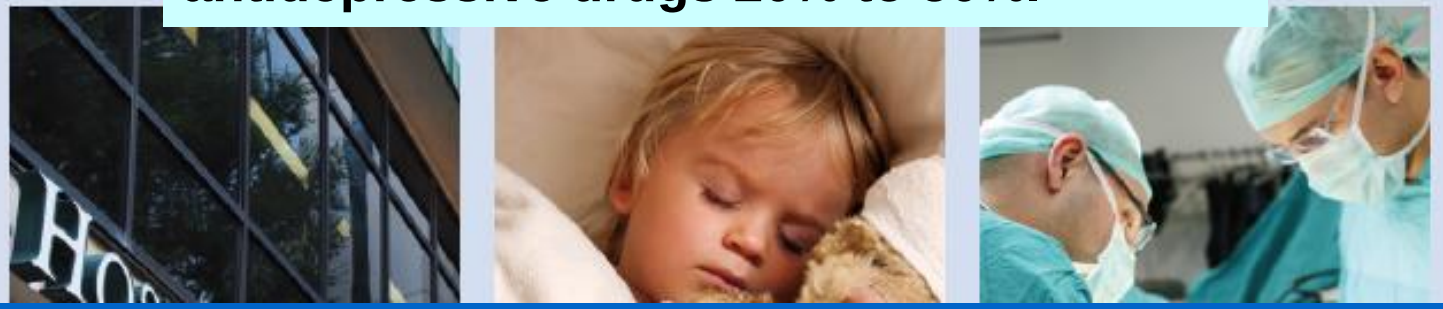
FORWARD LOOK

Implementation of Medical Research in Clinical Practice



Turner et al. (2008). Selective publication of antidepressant and its influence on apparent efficacy. NEJM.

Overestimation of effectiveness of antidepressive drugs 20% to 50%.



Berlin, 11. Mai 2011

Selective Reporting

1. Hiding whole trials (classical publication bias)
2. Incomplete or biased information within published trials
3. Discrepancies between quantitative results and interpretation (spin)

Ist Selective Reporting schädlich?

Ja, denn es führt zu einer falschen Wissensbasis für

- Systematische Übersichtsarbeiten und alle Folgeprodukte und wissensbasierten Derivate:
  nutzerspezifische Zusammenfassungen wie HTA Reports, klinische Leitlinien, patient Patienteninformation etc.

- Alle darauf aufbauenden Entscheidungen und Handlungen:
  Partizipative Entscheidungsfindung/Shared decision making

Durch diese systematische Fehlinformation leiden oder sterben Patienten unnötigerweise und vermeidbar.

Gegenmaßnahmen

Gegenwärtige Aktivitäten gegen selektives Berichten

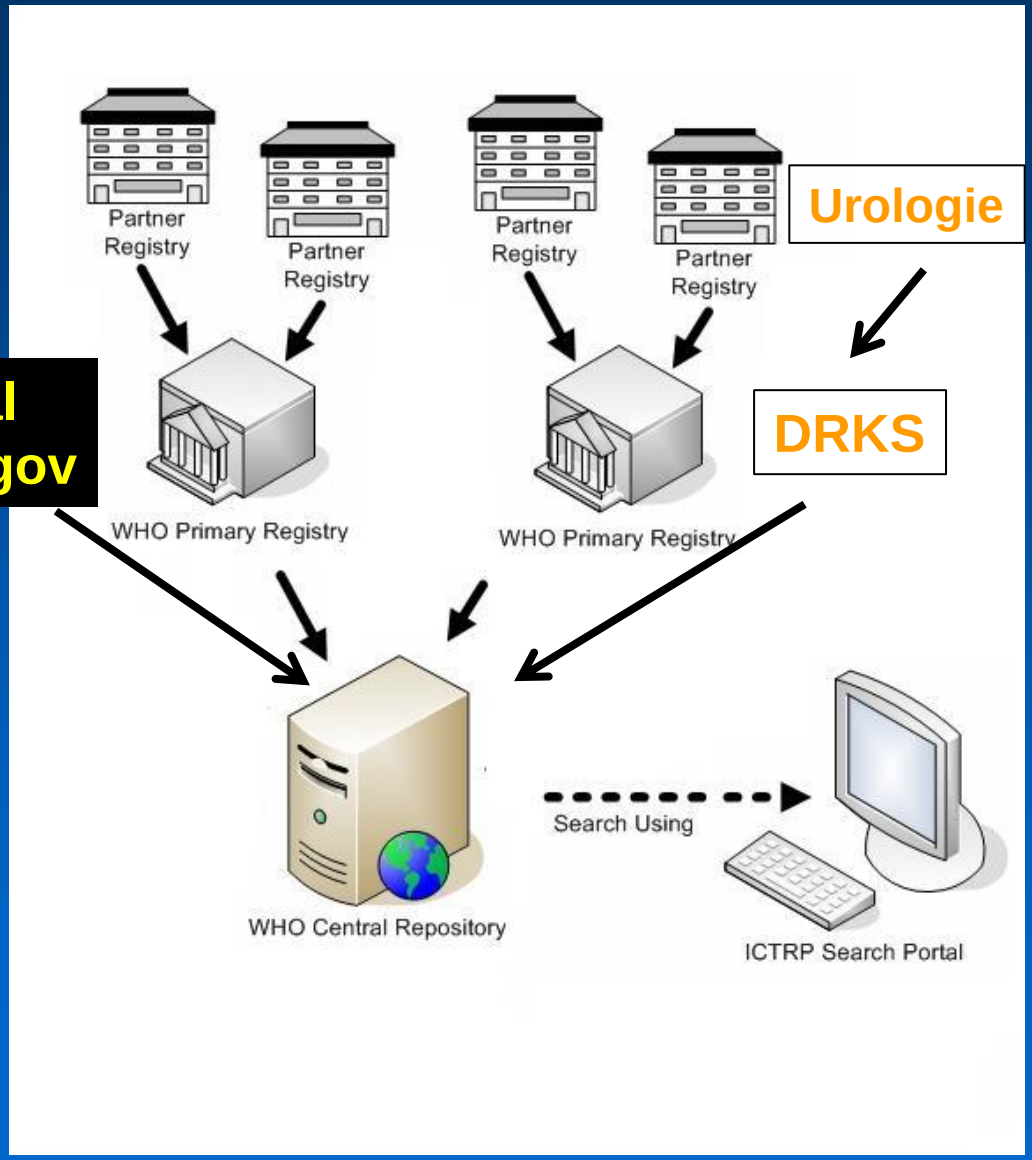
I Studienregistrierung (Geburtsurkunde)

II Publikationspflicht (nur möglich in Registern)

III Vollen Zugang zu Studienberichten und Studiendaten bei Behörden (gegenwärtiger politischer Prozess)

WHO Register Netzwerk ICTRP

www.who.int/ictrp



CT kein WHO Primary Registry

Das Deutsche Register Klinischer Studien (drks.de)

- Qualitätssicherung der Studieneinträge
- Zweisprachig
- Verständlich, nutzbar für Ärzte und Patienten
- Wesentlicher Beitrag zur deutschen Studienkultur

Studienregistrierung und Publikationspflicht

- Internationales Netzwerk von Studienregistern:
  20 Parameter erfasst: Portal bei WHO: www.who.org/ictrp
- Registrierung notwendig für Publikation (ICMJE.org)
- Deutsches Register: www.drks.de
- Öffnung des EMA – Registers EuDraCT in Sept. 2010
  https://eudract.ema.europa.eu/
- Zukunft: Ergebnisse in Register (bereits in www.clinicaltrials.gov)

AllTrials

All Trials Registered | All Results Reported

Home | Find out more | Get involved | Supporters | News | **Sign the petition** | **Donate** | Q

All trials registered and results reported

5th August 2013

Sign the petition

Donate to the campaign

All trials registered and results reported

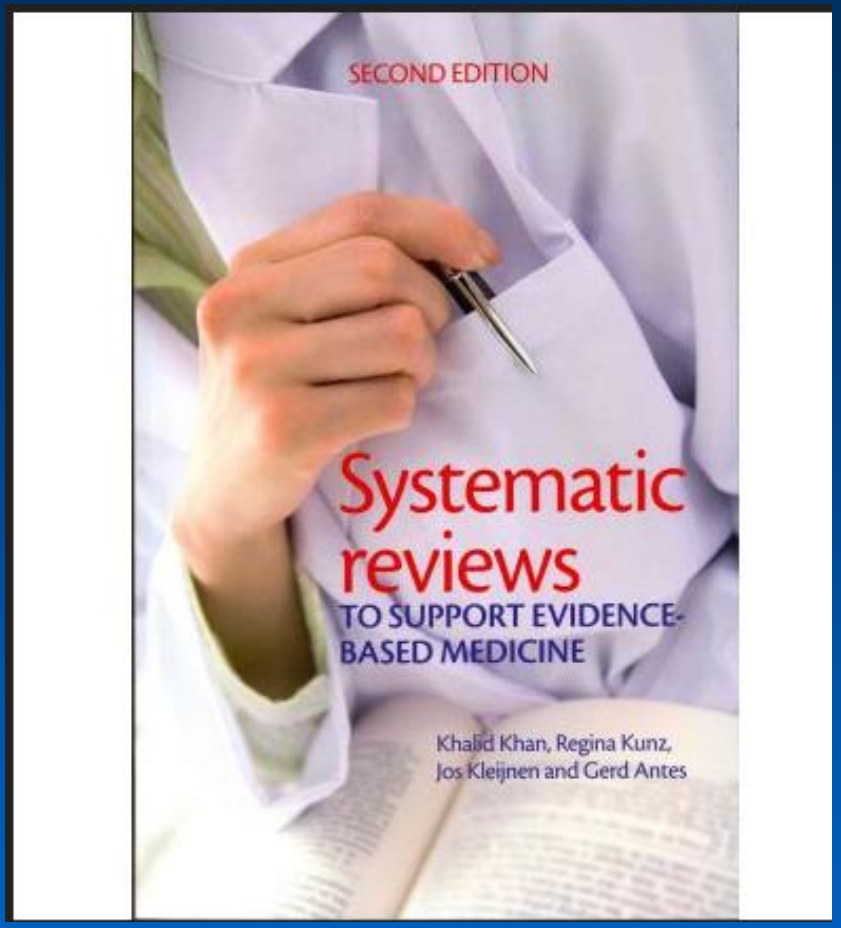
The AllTrials campaign has published a detailed plan on how all clinical trials can be registered and all results reported. This document sets out more information about achieving a situation globally where all trials are registered and results reported. It is an achievement that will involve regulators and registries, clinical trial funders, universities and institutes, professional and learned societies and medical journals, patients and researchers.

The document sets out four levels of information in clinical trial reporting: (1) knowledge that a trial has been conducted, from a clinical trials register; (2) a brief summary of the trial's results; (3) full details about the trial's methods and results; (4) individual patient data from the trial, and discusses the first three in detail. The AllTrials campaign is not calling for individual patient data to be made publicly available

This document is part of a continuing discussion which many different organisations are working on elaborating further over coming weeks and months. Please email views and contributions to: alltrials@senseaboutscience.org

Eine Studie ist keine Studie:
Die Wissensraffinerie als zentraler Qualitätstreiber

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



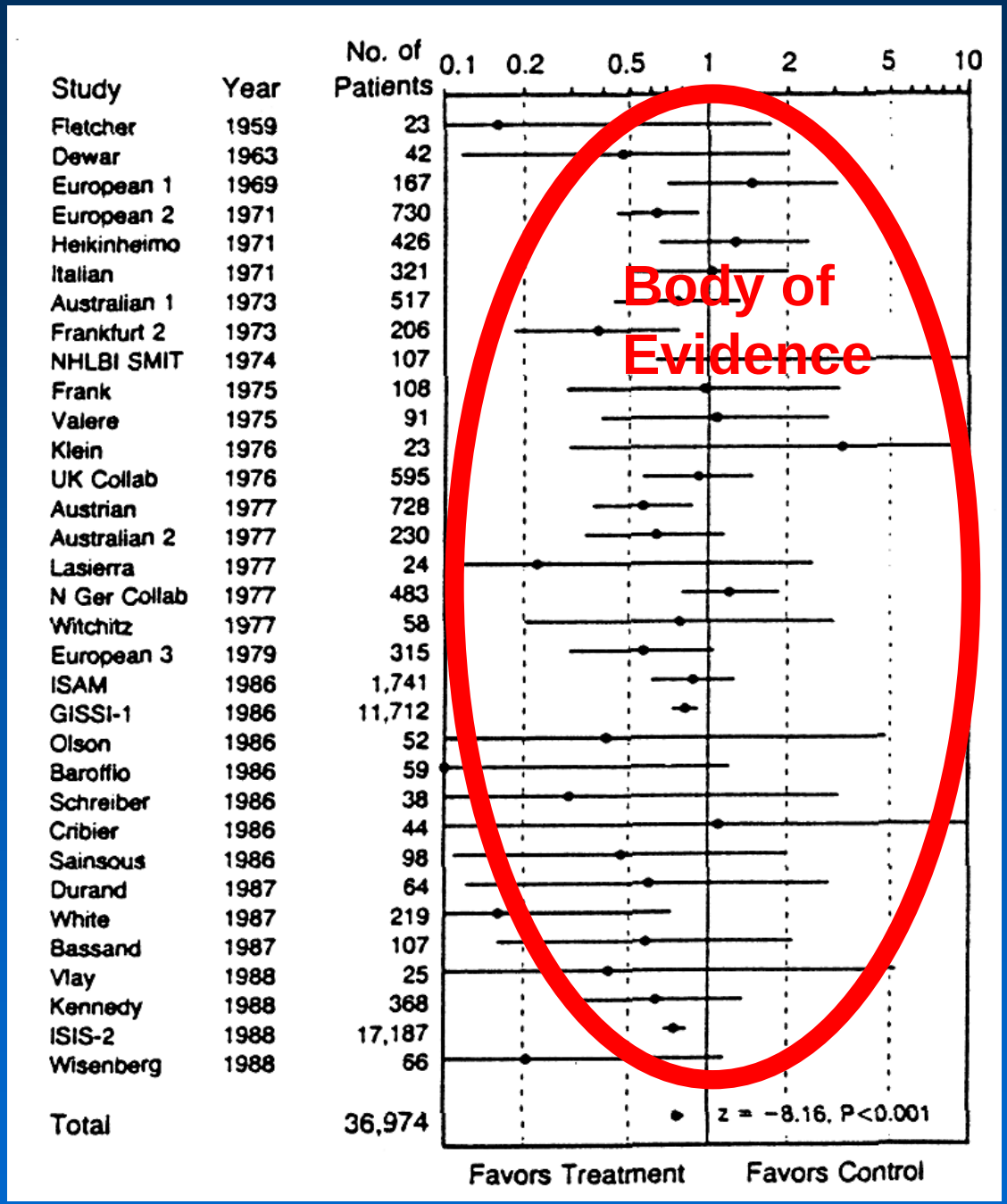
Juli 2011

Aktualisierung!!

Auch in Deutsch

Example
Thrombolyse nach akutem Herzinfarkt

NEJM 1992

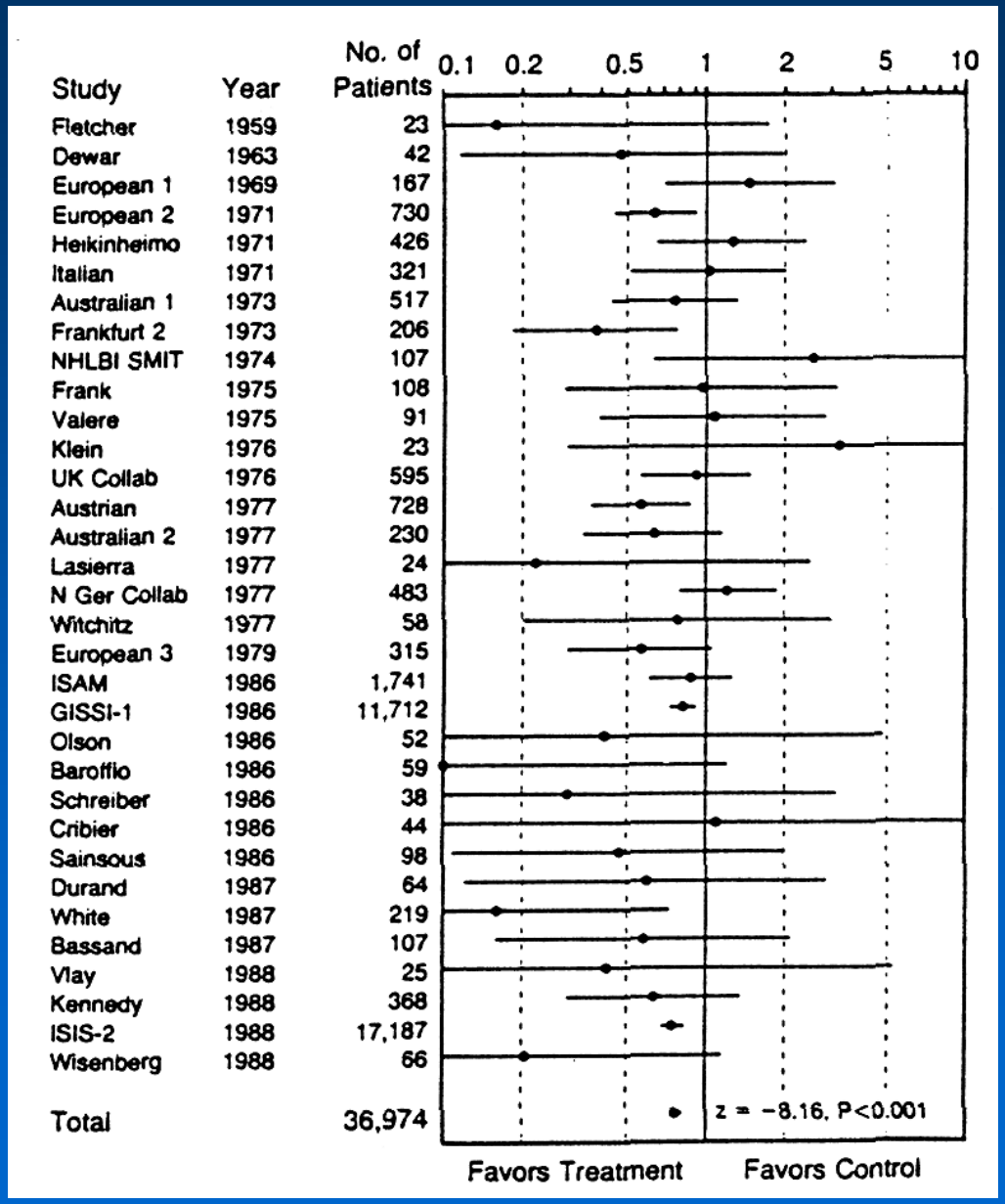


Forest Plot

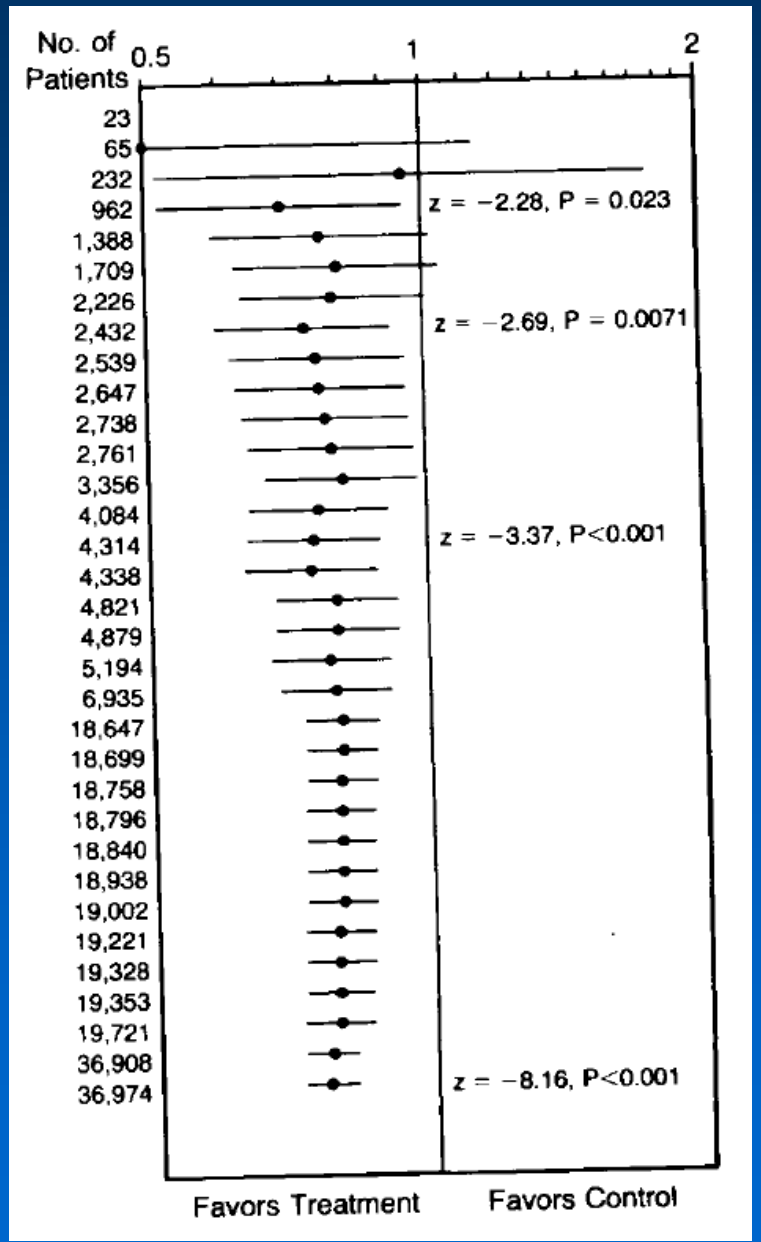
Thrombolyse (Streptokinase) nach akutem Herzinfarkt

NEJM 1992

Forest Plot:



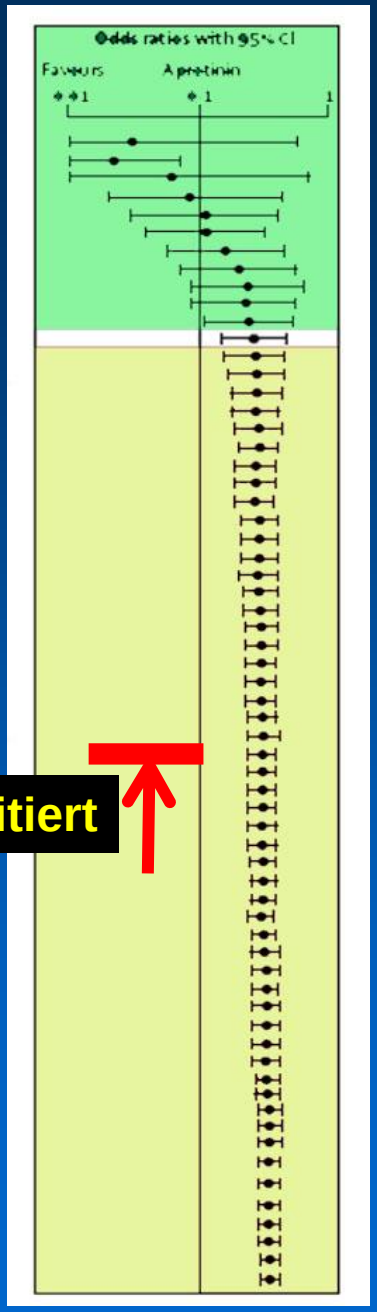
Cumulative Forest Plot:



Ungelöste Probleme

- Keine akzeptierte Stop – Regel
- Sind alle relevanten Studien gefunden und berücksichtigt?
- Ziel: “Alle“
- Auch 2015 keine auch nur annähernd sichere Methode zur Identifikation der vorhandenen Evidenz

1987



2002

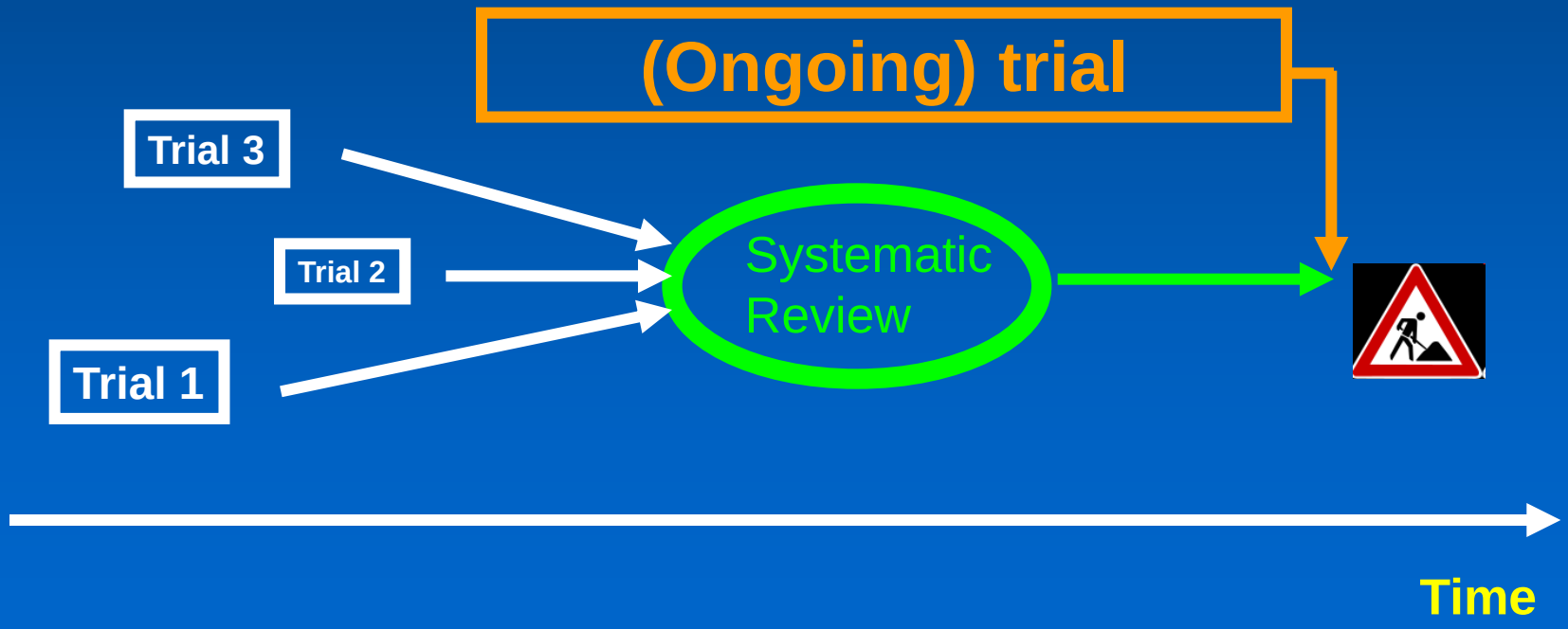
RCTs of aprotinin in cardiac surgery to stop bleeding

Lancet 2005

Clinical Trials 2005

Annals of Internal Medicine 2011

Including ongoing trials into systematic reviews?



Potential für Verbesserungen? Schuld?

April 2012 | Nr. 106

HTA-Newsletter

Evaluation medizinischer Intervention

Intransparenz in der medizinischen Forschung

Viele Opfer, viele Täter

Forschung dient dem Erwerb neuen Wissens. Ein zentrales Ziel des gesamten Wissenschaftsprozesses ist, das neue Wissen zu bestätigen oder zu verwerfen. Grundvoraussetzung dafür ist, dass Forschungsergebnisse schnell, vollständig und unverfälscht veröffentlicht werden. Implizit erfolgt das durch Lehre (deswegen Forschung und Lehre, F&L), vor allem jedoch durch den Publikationsprozess. Kommunikation ist deswegen ein unteilbarer Baustein des Wissenschafts- und Erkenntnisbetriebs.

Regelmäßig in den Medien auftauchende Berichte über frei erfundene oder verfälschte Ergebnisse zeigen deutlich, dass die für den Weg zur Wahrheit notwendige Integrität von etlichen Seiten – vor allem auch aus der Wissenschaft selbst – ständig bedroht wird. Die Auswirkungen können dramatisch sein,

schlägt damit voll durch auf die anderen zielgruppenspezifischen Produkte wie HTA-Reports, klinische Leitlinien und Patienteninformation.

Alle auf Studienergebnisse aufbauenden – evidenzbasiert erzeugten also – Produkte sind den inhärenten Fehlern des Publikationsprozesses schutzlos ausgeliefert. Auch die noch so sorgfältige Arbeit einer Leitlinien- oder HTA-Gruppe kann ein perfekt erscheinendes Gebäude erzeugen, dass jedoch – bildlich gesprochen – aufgrund des morastigen Untergrunds beliebig schief stehen kann. Tiefe Einsicht in diese systematischen Schieflagen liefern Arbeiten aus jüngster Zeit, die Zusammenfassungen vergleichen, die die Bewertung bestimmter therapeutischer Verfahren einerseits auf der Basis publizierter Daten und anderseits aufgrund von Daten der Zulassungsbehörden vergleichen. Die Unterschiede sind oft dramatisch und führen oft zu qualitativ unterschiedlichen Aussagen [2]. Nicht überraschend kommen vieler dieser methodischen Beiträge zum großen Teil aus der Cochrane Collaboration, da deren literaturbasierten systematischen Übersichtsarbeiten chronisch von verzerrten Publikationen bedroht sind.

Die herstellende Industrie wird für die Folgen dieses Publikationsbias – meistens zu Recht – heftig kritisiert. Nur ist die Ausschließlichkeit auch hier wiederum kontraproduktiv. Alle Beteiligten am Studiengeschehen tragen aktiv zu den Verwerfungen bei, von medizinischen Fakultäten über Ethikkommissionen, Ärzte und ihre Organisationen, Institutionen des Forschungs- und Versorgungssystems, wissenschaftlichen Zeitschriften, Zulassungsbehörden und Förderer von Studien bis hin zu Parlamenten, Gesetzgebern und WHO. Da alle Mitspieler gleichermaßen Täter und Opfer sind, fällt es aufgrund der Komplexität des Geschehens

Wer ist schuldig? – Die Achse des Bösen

- Industrie
- Forscher und Wissenschaftler
- Fakultäten und Universitäten
- Ethikkommissionen
- Ärzte(schaft)
- Zeitschriften und Verlage
- Forschungsförderer, Ministerien
- Regulatoren, Behörden
- HTA-Agenturen, Leitliniengruppen etc.
- WHO
- Parlamente, Regierungen
- Patienten

Deutsche Ethikkommission

- Weniger als 10 Ethikkommissionen haben einen klaren Hinweis zur Notwendigkeit der Studienregistrierung auf Webseiten

- Registrierungsproblem wäre sofort vollständig mit EKs gelöst (wenn es ein Gesetz gäbe)

Global inkonsistente Bedingungen

Land	Registrierung	Publikation
USA (2007)	Gesetz	Gesetz
Germany (AMNOG 2011)	-	Gesetz (Arzneimittel)
Schweiz (2013) (Humanforschungsgesetz)	Gesetz	-

Declaration of Helsinki 2013

"Research Registration and Publication and Dissemination of Results

35. Every research study involving human subjects must be registered in a publicly accessible database before recruitment of the first subject.

36. Researchers, authors, sponsors, editors and publishers all have ethical obligations with regard to the publication and dissemination of the results of research. Researchers have a duty . . . . . .

Die Rolle des Lancet

The Lancet: Treiber methodischer Qualität

- 1990er Jahre: Wer das Protokoll einer klinischen Studie hinterlegt, erhält bevorzugte Behandlung beim Studienreport
- 2002: Diskussion in Studienreports sollen Vorwissen darstellen
- 2007: Reports of clinical trials should begin and end with up-to-date systematic reviews of other relevant evidence: a status report
- 2010: Putting research into context—revisited
- 8. Januar 2014: Sonderband mit 5 Artikeln
  Research: increasing value, reducing waste
  (vorgestellt von The Lancet und dem Department of Health, DoH)

The Lancet: Aber auch . . .

- Zeitschrift des Elsevier Verlags
- Stolz auf seine Ablehnungsrate (>90%, Qualitätsmaß!)
- Hohe Einnahmen durch Sonderdrucke (frei verteilt auf Kongressen)
- Im Mittelpunkt allen negativen Geschehens um Impaktfaktoren, Peer Review und anderer Verwerfungen des Publikationsprozesses

THE LANCET

Research: increasing value, reducing waste

Published January 8, 2014

Executive summary

The Lancet presents a Series of five papers about research. In the first report Iain Chalmers *et al* discuss how decisions about which research to fund should be based on issues relevant to users of research. Next, John Ioannidis *et al* consider improvements in the appropriateness of research design, methods, and analysis. Rustam Al-Shahi Salman *et al* then turn to issues of efficient research regulation and management. Next, An-Wen Chan *et al* examine the role of fully accessible research information. Finally, Paul Glasziou *et al* discuss the importance of unbiased and usable research reports. These papers set out some of the most pressing issues, recommend how to increase value and reduce waste in biomedical research, and propose metrics for stakeholders to monitor the implementation of these recommendations.

Comments

How should medical science change?

Sabine Kleinert, Richard Horton

Jährlich für bio-medizinische Forschung:

240 Milliarden US$ (2010)

THE LANCET

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< Previous Article Volume 384, No. 9961, p2176–2177, 20 December 2014 Next Article >

Comment

Further emphasis on research in context

Sabine Kleinert, Laura Benham, David Collingridge, William Summe

Panel: **Research in context**

Evidence before this study

This section should include a description of all the evidence that the authors considered before undertaking this study. Authors should state: the sources (databases, journal or book reference lists, etc) searched; the criteria used to include or exclude studies (including the exact start and end dates of the search), which should not be limited to English language publications; the search terms used; the quality (risk of bias) of that evidence; and the pooled estimate derived from meta-analysis of the evidence, if appropriate.

Added value of this study

Authors should describe here how their findings add value to the existing evidence (including an updated meta-analysis, if appropriate).

Implications of all the available evidence

Authors should state the implications for practice or policy and future research of their study combined with existing evidence.

findings? How can we improve the accessibility and usability of research findings, and data availability? And, finally, how can we further raise awareness and continue discussions on the topic of research productivity?

As a first step, we are strengthening our requirement to put research into context. Knowing and rigorously assessing the context and value of research will help editors make decisions about whether to publish a paper, and will help readers to interpret the importance of published research in addressing unanswered questions and building an evidence base. From Jan 1, 2015, all research papers, apart from systematic reviews and meta-analyses, submitted to any journal in *The Lancet* family must include a Research in context panel with an enhanced structure and subheadings (panel). Editors will use this information at the first assessment stage and

researchwaste.net

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search here ... Go

Research Waste/EQUATOR Conference

REWARD

REduce research **WA**ste and **R**eward **D**iligence

http://researchwaste.net/

equator network

Enhancing the **QUA**lity and **T**ransparency **O**f health **R**esearch

www.equator-network.org/

Increasing value and reducing waste in biomedical research conference

28th – 30th September 2015, Edinburgh

Recent Posts

- Rigour mortis: How bad research is killing science
- The Need for Randomisation in Animal Trials
- Waste in medical academia must be addressed, Chalmers urges in The BMJ Awards acceptance speech
- Reducing waste in preclinical research through better mouse studies
- Videos from symposium on the Lancet series online

REWARD
REduce research Waste
And Reward Diligence

THE LANCET

Antje Schuett
Technology, Methods and Infrastructure for Networked Medical Research

By email – Antje.Schuett@tmf-ev.de

15 September 2015

Invitation to support *The Lancet*'s REduce research Waste And Reward Diligence (REWARD) campaign

We are writing to ask you to seek the support of Technology, Methods and Infrastructure for Networked Medical Research for *The Lancet*'s REWARD campaign. REWARD will become the third of *The Lancet* campaigns, alongside the 'cancer' and 'liver' campaigns that you can see on the journal's homepage www.thelancet.com. These campaigns have supporting partners (for example, the liver campaign's society partners include The Royal College of Physicians, the Royal College of General Practitioners, The Foundation for Liver Research etc.). We hope to obtain your organisation's support for the REWARD campaign.

Editorial
The Lancet

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London, EC2Y 5AS
United Kingdom

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editorial@lancet.com
www.the lancet.com

The REWARD campaign follows the 2014 series in *The Lancet* on *Research: increasing value, reducing waste* (www.thelancet.com/series/research). The series set out some of the most pressing issues, recommended how to increase value and reduce waste in biomedical research, and proposed metrics for stakeholders to monitor the implementation of these recommendations. Progress since the series will be celebrated at the first REWARD conference, held jointly with EQUATOR Network, in Edinburgh on 28-30 September 2015, where an action plan for the future will be developed (see the 'Events' section of http://researchwaste.net).

First we would like your organisation to become a supporting partner for this campaign by doing the following:

1. Endorse the REWARD statement:
   We recognise that, while we strive for excellence in biomedical research, there is much that needs to be done to reduce waste and increase the value of our contributions. We maximise our research potential when we set the right research priorities; when we use robust research design, conduct and analysis; when regulation and management are proportionate to risks; when all information on research methods and findings are accessible; and when reports of research are complete and usable. We believe we have a responsibility not just to seek to advance knowledge, but

REWARD
REduce research Waste
And Reward Diligence

THE LANCET
RICHARD HORTON EDITOR
ASTRID JAMES DEPUTY EDITOR

Second, we would like your organisation to consider these four other possible supportive actions:

3. Provide content for the campaign pages to give examples of the measures your organisation has taken, is taking, and will take to increase value and reduce waste in research.

4. Consider endorsing the REWARD action plan announced after the conference in September.

5. Consider supporting the REWARD observatory, which will systematically monitor efforts to increase value and reduce waste in biomedical research.

6. Consider providing financial support for the REWARD observatory and campaign.

Editorial
The Lancet

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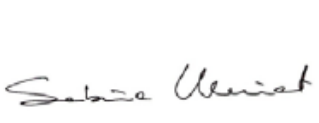
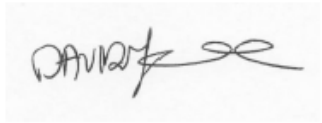
www.the lancet.com

***The Lancet*'s REWARD campaign will be launched** at the conference in Edinburgh on 29 September, so **please respond to us by 22 September**. In the meantime, we will be very happy to answer questions by email.

Yours sincerely,





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Media centre

WHO calls for increased transparency in medical research

Note for the media

14 APRIL 2015 | GENEVA - WHO today issued a public statement calling for the disclosure of results from clinical trials for medical products, whatever the result. The move aims to ensure that decisions related to the safety and efficacy of vaccines, drugs and medical devices for use by populations are supported by the best available evidence.

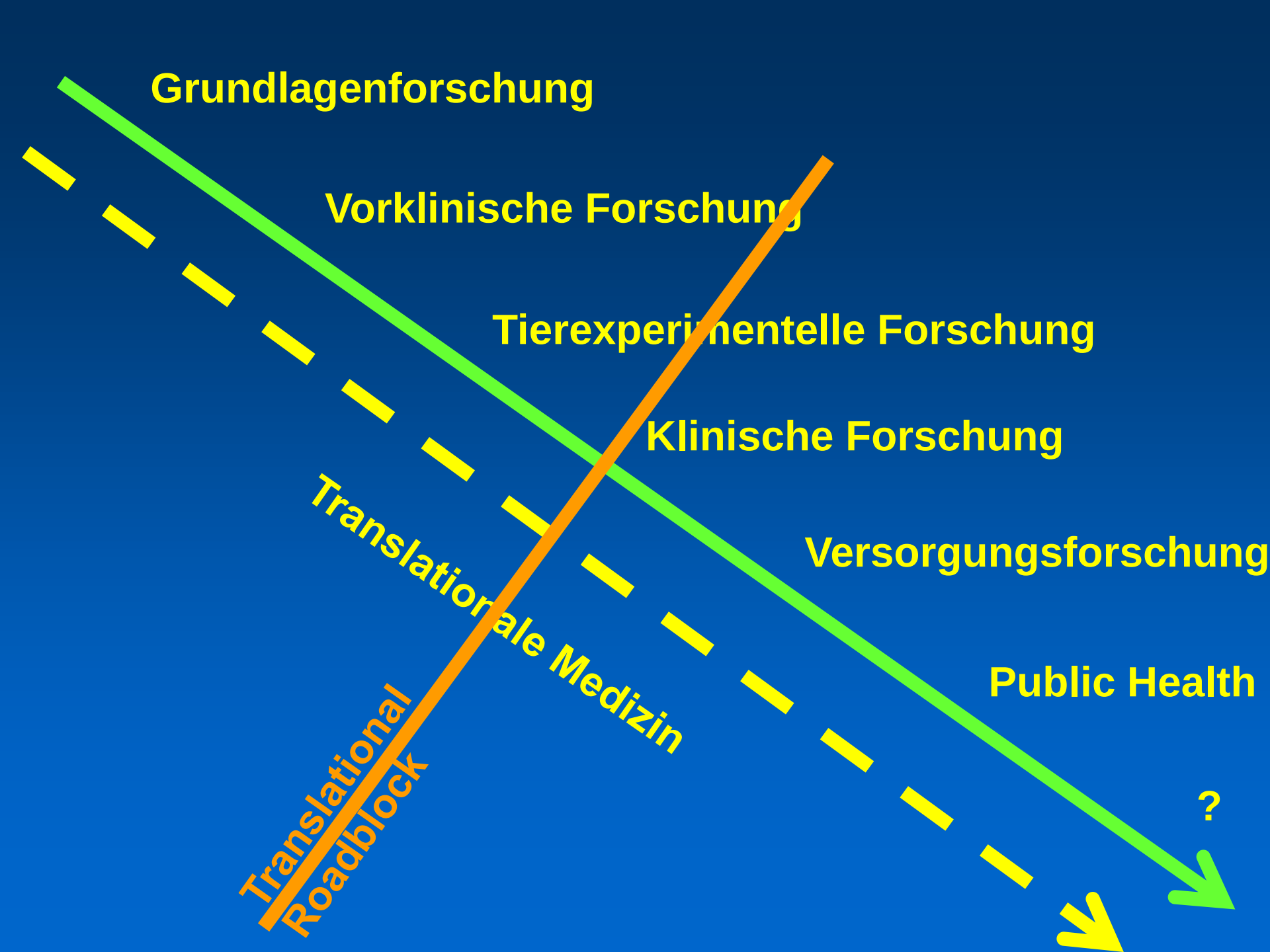
"Our intention is to promote the sharing of scientific knowledge in order to advance public health," said Dr Marie-Paule Kieny, WHO Assistant Director-General for Health Systems and Innovation. "It underpins the principal goal of medical research: to serve the betterment of humanity."

"Failure to publicly disclose trial results engenders misinformation, leading to skewed priorities for both R&D and public health interventions," said Dr Kieny. "It creates indirect costs for public and private entities, including patients themselves, who pay for suboptimal or harmful treatments."

Unreported trials lead to misinformation

For example, in a study that analysed reporting from large clinical trials (more than 500 participants) registered on ClinicalTrials.gov and completed by 2009, 23% had no results reported. These unreported trials included nearly 300 000 participants.

Das ganze Spektrum


Grundlagenforschung
Vorklinische Forschung
Tierexperimentelle Forschung
Klinische Forschung
Translationale Medizin
Versorgungsforschung
Public Health
Translational Roadblock
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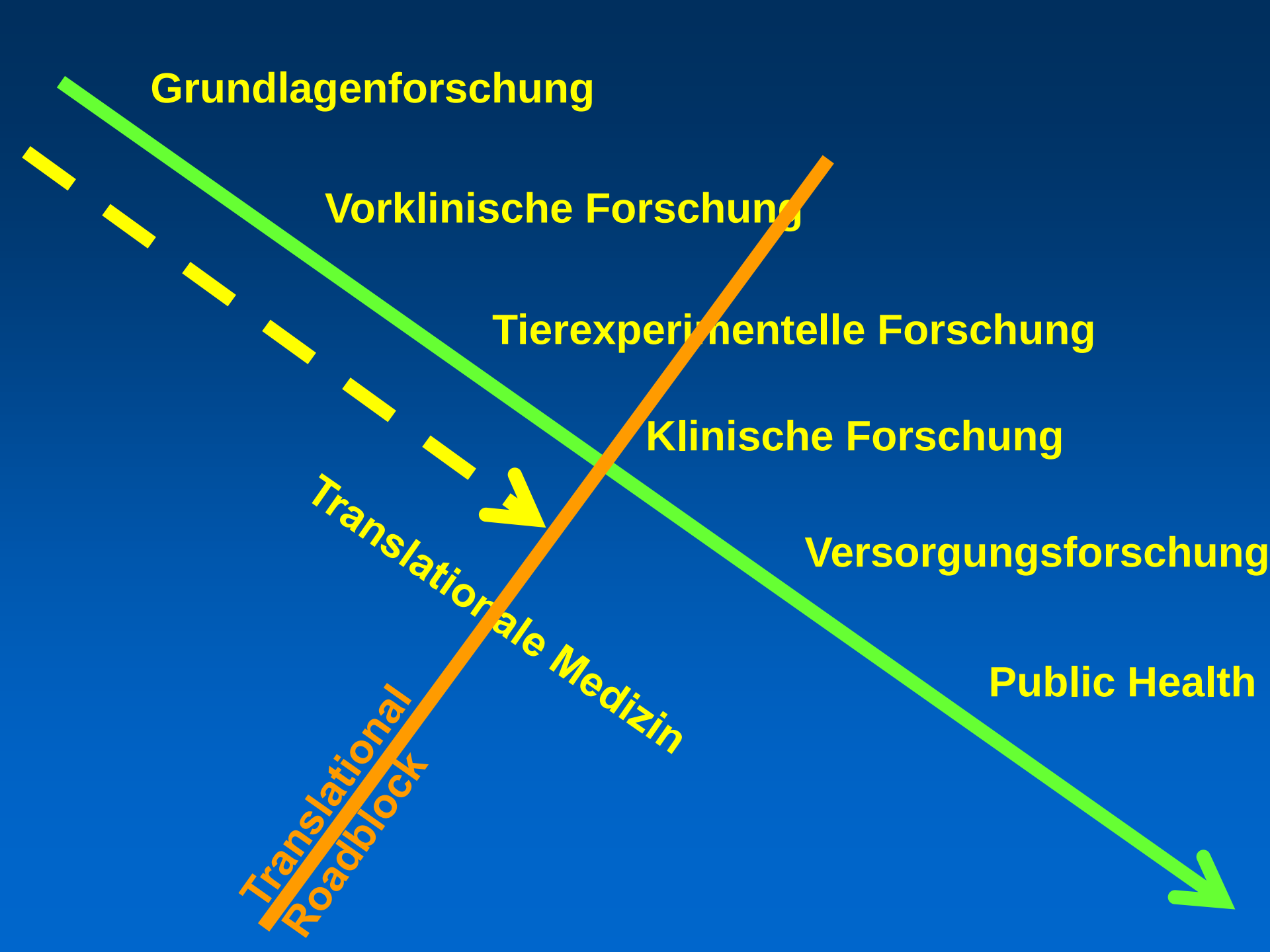
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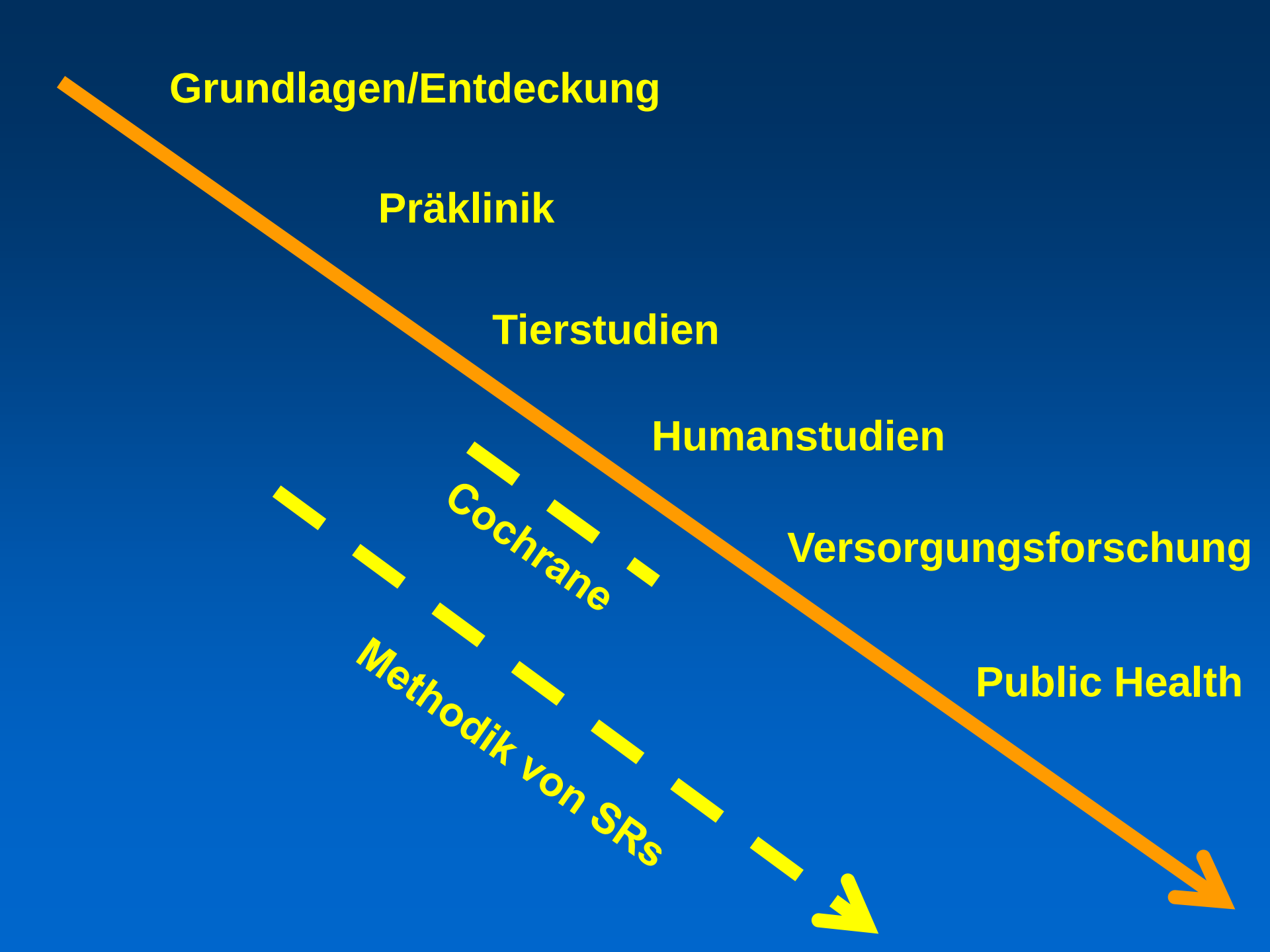

Grundlagen/Entdeckung
Präklinik
Tierstudien
Humanstudien
Versorgungsforschung
Public Health
Cochrane
Methodik von SRs

Reproducibility of research results: the tip of the iceberg

February 27, 2014 10:35 am , 1 Comment , SciELO

Print

Image: Osccarr

A previous post on this blog addressed the question of the reproducibility of research results and how this topic is attracting increasing attention in the scientific community and society at large. The reliability of scientific research can be measured by the number of subsequent retractions of previously published articles when it is determined that they are fraudulent or they contain errors of experimentation or interpretation of the results. The number of retractions has gone up tenfold since 1975, but the greater proportion of these is due to fraud. As already mentioned, irreproducibility is, however, underestimated, since repeating an experiment requires time, human and material resources and a strong reason to be suspicious about the results.

The development of new drugs for the treatment of diseases mostly have their beginnings in scientific studies carried out in research institutions working in the particular clinical field concerned. It is therefore pharmaceutical companies which are amongst the most interested parties in the reliability of these results, since it is on the basis of these that they will develop projects to test and possibly produce these drugs which have considerable costs attached to them.

However, studies carried out by the pharmaceutical companies Bayer (Germany) and Amgen (USA) concluded that between 60% and 70% of studies in the field of biomedicine may include non-reproducible results. A study carried out on clinical trials for drugs under development for certain diseases which took place in 2011 showed that the success rate for new drugs in phase II clinical trials fell from 28% to 18% over the last few years. The most frequent cause of this lack of success is the low-level of efficacy of the drugs tested. This points to the limited predictability of new drugs in combatting diseases when there were previous indications that these drugs would be

Why Most Published Research Findings Are False

John P.A. Ioannidis

PLoS Medicine August 2005

Session 3 — 4th EQUATOR Annual Lecture

Session Chair: Prof Doug Altman, Director, Centre for Statistics in Medicine, Oxford, UK

Reporting and reproducible research: salvaging the self-correction principle of science [Slides] [Video]

John Ioannidis, Professor of Medicine, Health Research and Policy, and Statistics, Stanford University, USA

In YouTube

Freiburg, 12 Oct 2012

EDITORIAL

7 Nov 2014

Journals unite for reproducibility

Reproducibility, rigor, transparency, and independent verification are cornerstones of the scientific method. Of course, just because a result is reproducible does not necessarily make it right, and just because it is not reproducible does not necessarily make it wrong. A transparent and rigorous approach, however, can almost always shine a light on issues of reproducibility. This light ensures that science moves forward, through independent verifications as well as the course corrections that come from refutations and the objective examination of the resulting data.

menters were blind to the conduct of the experiment, how the sample size was determined, and what criteria were used to include or exclude any data. Journals should recommend the deposition of data in public repositories where available and link data bidirectionally to the published paper. Journals should strongly encourage, as appropriate, that all materials used in the experiment be shared with those who wish to replicate the experiment. Once a journal publishes a paper, it assumes the obligation to consider publication of a refutation of that paper, subject to its usual standards of quality.

The more open-ended por-

Marcia McNutt
Editor-in-Chief
Science *Journals*

The gathering was convened by the U.S. National Institutes of Health, *Nature*,* and *Science*.

The discussion ranged from what journals were already doing to address reproducibility and the effectiveness of those measures, to the magnitude of the problem and the cost of solutions. The attendees agreed on a common set of Principles and Guidelines in Reporting Preclinical Research (www.nih.gov/about/reporting-preclinical-research.htm) that list proposed journal policies

"...scientific journals are standing together in their conviction that reproducibility and transparency are important..."

strain characteristics, or transgenic animals, etc. For cell lines, one might report the source, authentication, and mycoplasma contamination status. The existence of these guidelines does not obviate the need for replication or independent verification of research results, but should make it easier to perform such replication.

Some of the journals at the meeting already had implemented all or most of these principles and guidelines. But the important point is that a

Collaborative Approach to Meta Analysis and

·C·A·M·A·R·A·D·E·S·

Review of Animal Data from Experimental Studies

OPEN ACCESS Freely available online

PLoS BIOLOGY

Publication Bias in Reports of Animal Stroke Studies Leads to Major Overstatement of Efficacy

Emily S. Sena[1,2,3], H. Bart van der Worp[4], Philip M. W. Bath[5], David W. Howells[2,3], Malcolm R. Macleod[1,6]*

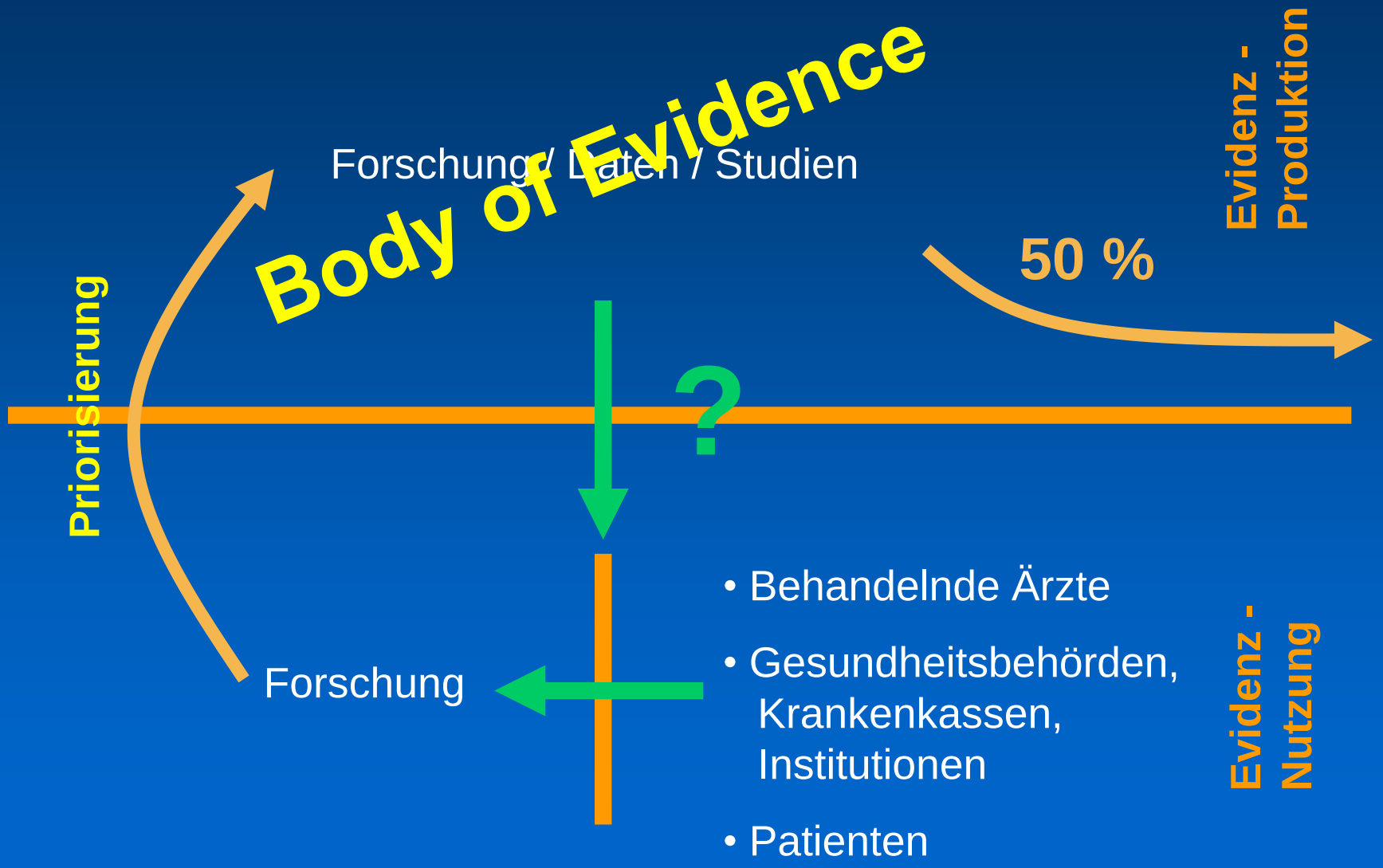
2nd International Symposium on
Systematic Reviews in Laboratory Animal Science
7th and 8th March 2013

Join us on twitter!

Edinburgh

Und Deutschland . . .

Transfer von Forschung in die Praxis



"Das Register trägt dazu bei, dass das Vertrauen der Bevölkerung in die klinische Forschung gestärkt wird."

(Bundesforschungsministerin Annette Schavan)

Pressemitteilung des BMBF zum Aufbau des Deutschen Registers Klinischer Studien in Freiburg, 14.09.2007

Zukünftige Finanzierung des DRKS

- BMBF: Keine Verantwortung nach 2 Förderphasen
- BMG: Schriftliche Mitteilung, dass die öffentlich zugängliche Registrierung doch durch BfArM und DIMDI gesichert sei

D. h. das Register als integraler Bestandteil deutscher Studienkultur wird 2016 verschwinden?

Kein Geld für gute Gesundheits-Infos

Ist das Geschäft mit der Gesundheit einflussreicher als eine vernünftige Medizin?

Sonntag, 20.09.2015, 17:39 · von FOCUS-Online-Experte Frank Frick

Das Deutsche Cochrane Zentrum will Entscheidungen in der Gesundheitsversorgung verbessern. dpa/Jens Wolf

Ist Medikament XY wirksam? Welche Patienten werden besser nach Methode A behandelt als nach Methode B? Das Deutsche Cochrane Zentrum bewertet klinische Studien zu solchen Fragen und liefert unabhängige Gesundheitsinformationen. Doch jedes Jahr muss es erneut für seine Finanzierung kämpfen.

- **Das deutsche Cochrane Zentrum besteht aus Wissenschaftlern und Ärzten.**
- **Das Team erstellt systematische Übersichtsartikel auf dem neuesten Forschungsstand.**
- **Im Jahr 2015 erhielt das Zentrum rund 230.000 Euro vom Bund.**

ZUM THEMA

Von Osteopathie bis TCM
Humbug oder Heilung? Das kann sanfte Medizin wirklich

Jeder vierte Verdacht

Eine **Medizin, die auf gesichertem und überprüfbarem Wissen beruht, ist Deutschland nicht viel wert**. Zu diesem Schluss kann jedenfalls kommen, wer einen Blick auf die Finanzierung des **Deutschen Cochrane Zentrums** richtet. Benannt ist es nach dem britischen Arzt Archibald Leman Cochrane (1909 bis 1993).

Das Zentrum ist die nationale Vertretung der Cochrane Collaboration. Dieses globale Netzwerk besteht aus Wissenschaftlern, Gesundheitsfachleuten und Patienten, die Entscheidungen in der Gesundheitsversorgung verbessern wollen. Dafür stellt die Organisation systematisch unter anderem

Wissenstransfer in Deutschland

Fast keine relevanten Studien in Deutschland durchgeführt

Fast alle Studien in Englisch publiziert (gegen 100%)

„Keine“ Investitionen in Knowledge Translation

Totale Abhängigkeit von ausländischen Quellen
(IQWiG - Berichte 95+ % internationale Studien)

Keine Bewertungskultur; große methodische Schwächen

80% der Ärzteschaft und 98% (?) der Patienten lesen kein Englisch

Fazit

- Kollektive Anstrengung notwendig, um Wissensgenerierung und –nutzung zum Wohl des Patienten entscheidend zu verbessern
- Markante Schritte nur in enger internationaler Einbindung möglich
- Substantielle strukturelle Verbesserung auf nationaler Ebene und im globalen Kontext notwendig, um markante Verbesserungen zu erreichen
- Mehr Forschung an den Prozessen (Research on Research)
- Anschluss an die REWARD/EQUATOR – Initiative ist Eingangstür für substantielle Verbesserungen