

Hype versus evidence

Fiona Godlee

Warwick Medical School

January 23, 2008

What I'm going to talk about

- What is hype
- Why does it matter?
- A toolkit for hype-sters
- Can hype be a good thing?
- What can we do to guard against hype?

What is hype?

Why does hype matter?

Because it impedes the search for the “truth” and damages the integrity of the biomedical literature, causing:

- Loss of public trust in science
- Pursuit of wrong avenues of research
- Puts participants and patients at risk
- Wastes time and resources

A toolkit for hype-sters

- The media anecdote – MMR, Alzheimers
- The press conference (MMR)
- Data manipulation (Vioxx)
- Composite end points (Rosaglitazone/NAO)
- Publication bias (olanzapine)
- Absolute and relative risk (preosteoporosis)
- Disease mongering (Indolobant)
- Spinning the conclusions (BMJ)

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http://www.mmrthefacts.nhs.uk/ Go Link

The overwhelming weight of evidence proves that MMR is safe, and the number of studies demonstrating this is growing.

- [Go to a list of the key studies looking at MMR](#)
- [Go to a detailed list in the research timeline](#)

MMR basics
Answers to the questions parents often ask, such as when to take your child for their MMR jab.
[Go the the MMR basics section](#)

MMR resources
Leaflets, factsheets, information sheets and more.
[Go the the MMR resources section](#)

MMR library
Read through a topic - for example MMR and choice - or search the list of resources.
[Go the the MMR library section](#)

MMR world map
An interactive world map showing how MMR is used across the globe.
[Go the the MMR world map section](#)

Your questions answered
The most frequently asked questions submitted to the MMR The facts website are compiled into a list which is updated weekly. If your question isn't here, send it in to our expert panel.
[Go the Your questions answered section](#)

Analysis of the 1998 Lancet Wakefield paper
12-Mar-04
[Protecting Women Against Rubella: Switch From Rubella Vaccine To MMR](#)

**11-Mar-04
Researchers issue retraction**

**11-Mar-04
Lancet editor praises MMR The facts website**

**08-Mar-04
Sunday Times Article**

**24-Feb-04
Continuing increase in MMR uptake rates in Scotland**

[More news...](#)

 **immunisation**
the safest way to protect your child

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http://www.mmrthefacts.nhs.uk/news/newsitem.php?id=70

Internet

dose, route, duration, condition etc – without this detail, can't disentangle the patterns
A database of stories would have to be flexible to evolve to things we don't know about yet.



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Immunisation Information

Monday May 17 2004

MMR The facts

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- World map
- Your questions
- The team

Welcome to MMR The facts

This website has been put together to answer any questions you might have about MMR. You can look for information and resources in the [MMR library](#), ask our expert panel a question, and read up on the [latest news stories](#) relating to MMR.



MMR Research

The overwhelming weight of evidence proves that MMR is safe, and the number of studies demonstrating this is growing.

- Go to a list of the key studies looking at MMR
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MMR basics

Answers to the questions parents often ask, such as when to take your child for their MMR jab.

[Go to the MMR basics section](#)

MMR resources

MMR news



29-Apr-04
[Analysis of the 1998 Lancet Wakefield paper](#)

12-Mar-04
[Protecting Women Against Rubella: Switch From Rubella Vaccine To MMR](#)

11-Mar-04
[Researchers issue retraction](#)

11-Mar-04
[Lancet editor praises MMR The facts website](#)

08-Mar-04

GOOD

HE HAS been mocked, denounced and driven from his job. To the medical and political establishment, he is an outcast and an enemy. But Andrew Wakefield, the doctor at the heart of the furor over the MMR vaccination, believes he is on the brink of vindication.

It was Mr Wakefield, a gastroenterologist then working at the Royal Free hospital in London, who first made the devastating claim that the triple jab for measles, mumps and rubella can provoke both autism and bowel disease in a small proportion of children. His theory, which exploded into the public arena in 1998, spread alarm among parents everywhere.

The British and international medical authorities tried to dismiss it, securing his research as worthless and insisting the vaccination was perfectly safe. Report after report was published to rebut his findings, with MPs and ministers — including Prime Minister Tony Blair — joining the chorus that there was no cause for concern.

According to Mr Wakefield, his life was made impossible. His funding started to dry up, professional collaborations were broken off and researchers were allegedly belittled or threatened not to have anything to do with him.

Reading his work was impeded, he felt obliged to leave the Royal Free and move to America. Now, however, Mr Wakefield has evidence that he thinks will prove he was right all along.

His new research — which has yet to be published in a medical journal — focuses on booster MMR jabs, which are given to children around the age of four, to reinforce the original injection given at around 15 months.

Among the children in Wakefield's study, those given the booster jabs suffered a dramatic deterioration in both behavioural problems and bowel symptoms.

After the booster, he claims, one child stopped growing for 18 months and another failed to develop at all for five years. There was also a significant increase in acute bowel inflammation in the majority of children who received the second jab.

Such evidence from re-vaccination is potentially explosive,



by MELANIE PHILLIPS

not common among classically autistic children, but indicates a more catastrophic disintegration.

The whole row has been fuelled by an apparent huge rise in the incidence of autism across the Western world.

Yet this, too, is the object of the most intense controversy, with experts in violent dispute over whether there really are more children with autism, or whether the diagnostic guidelines have simply been moved.

These are profoundly important arguments, but the whole debate has been tainted by the extraordinary behaviour of some of MMR's key supporters, and the sheer recklessness with which dissenting voices have been ignored.

MMMR THE TRUTH

For three months, a top Mail writer has investigated the MMR controversy. Her findings, revealed in this major new series, are vital to every parent.

dose, route, duration, condition etc — without this detail, can't disentangle the patterns
A database of stories would have to be flexible to evolve to things we don't know about yet.

Raymond Tallis

Anecdotes, data, and the curse of the media anecdote
Healthwatch Newsletter 2007

- The media love anecdotes because readers love them
- Unlike data, they have a human face, they are closer to gossip
- MMR and Jackie Fletcher

What did Wakefield et al report in the Lancet?

- 12 children referred to a paediatric gastro clinic with bowel symptoms and loss of acquired skills
- Lots of tests done. Several were abnormal, though none was consistently abnormal in all children
- 11/12 had evidence of inflammatory reaction in their bowel
- Parents asked to say whether they suspected a link with MMR vaccine. In 8 children, parents said onset of developmental delay occurred within 2 weeks of MMR vaccination. In 3 children within 48 hours.

Raymond Tallis

Anecdotes, data, and the curse of the media anecdote
Healthwatch Newsletter 2007

- Anecdotes, however multiplied, don't point the way to reliable knowledge
- The plural of anecdote is not data
- An anecdote is not even a datum, though it may drive the search for data

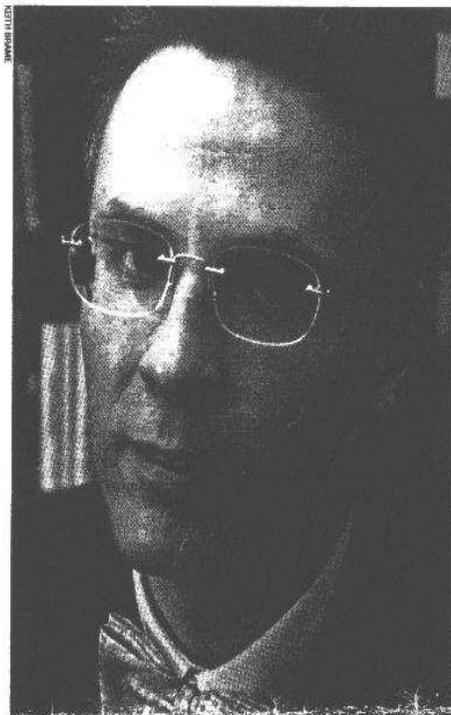


Single vaccine is better than none

Dr Jean Knowles 'has no concerns' over the safety of either MMR or a single alternative, but many of her patients do. She has given single vaccines for measles and mumps to 15 children on the remote island of Islay, Inner Hebrides, where she practises.

Dr Knowles gets the vaccines from London and parents pay the cost.

'I support the single-jab option, as I would rather those parents consent to some form of immunisation,' she said.



Trying to pressure parents is unethical

Dr Wolfgang Walter believes it is unethical to persuade parents on the MMR vaccine. 'The Government is trying to follow one party line, which it is forcing on parents and doctors, and a number of my colleagues feel that parents must be able to choose,' said Dr Walter, a GP in Edinburgh.

He added: 'Parental choice is paramount in this important issue. It is unethical to persuade parents in this matter - the jury is still out.'



Prohibiting single vaccines illogical

Dr Stephen Novick says he only had both of his children immunised with the triple vaccine because monovalent vaccines were not available.

Dr Novick, a GP in Wolverhampton, West Midlands, told Pulse: 'There is no satisfactory or logical explanation why they can't be given separately.'

'I've seen lots of kids made poorly by the MMR vaccine. My own daughter was vaccinated at 14 months and was ill for about three weeks.'



Government stance on MMR is right

Dr Deirdre O'Gallagher supports the Government's strong stance on the triple MMR vaccine and believes it is right to restrict the availability of monovalent vaccines on the NHS.

But Dr O'Gallagher, who practises in west London, has seen her own target pay affected by the MMR scare.

'It's a struggle to hit targets due to the numbers of articulate patients who refuse the MMR jab,' she said. 'Patient resent being railroaded.'

Vaccine crisis grows

Health boss warns of outbreak

By Zoe Morris and Maxine Frith

LONDON'S MMR crisis intensified today as the capital's director of public health, Dr Sue Atkinson, gave a stark warning that plummeting immunisation levels could lead to a devastating measles outbreak.

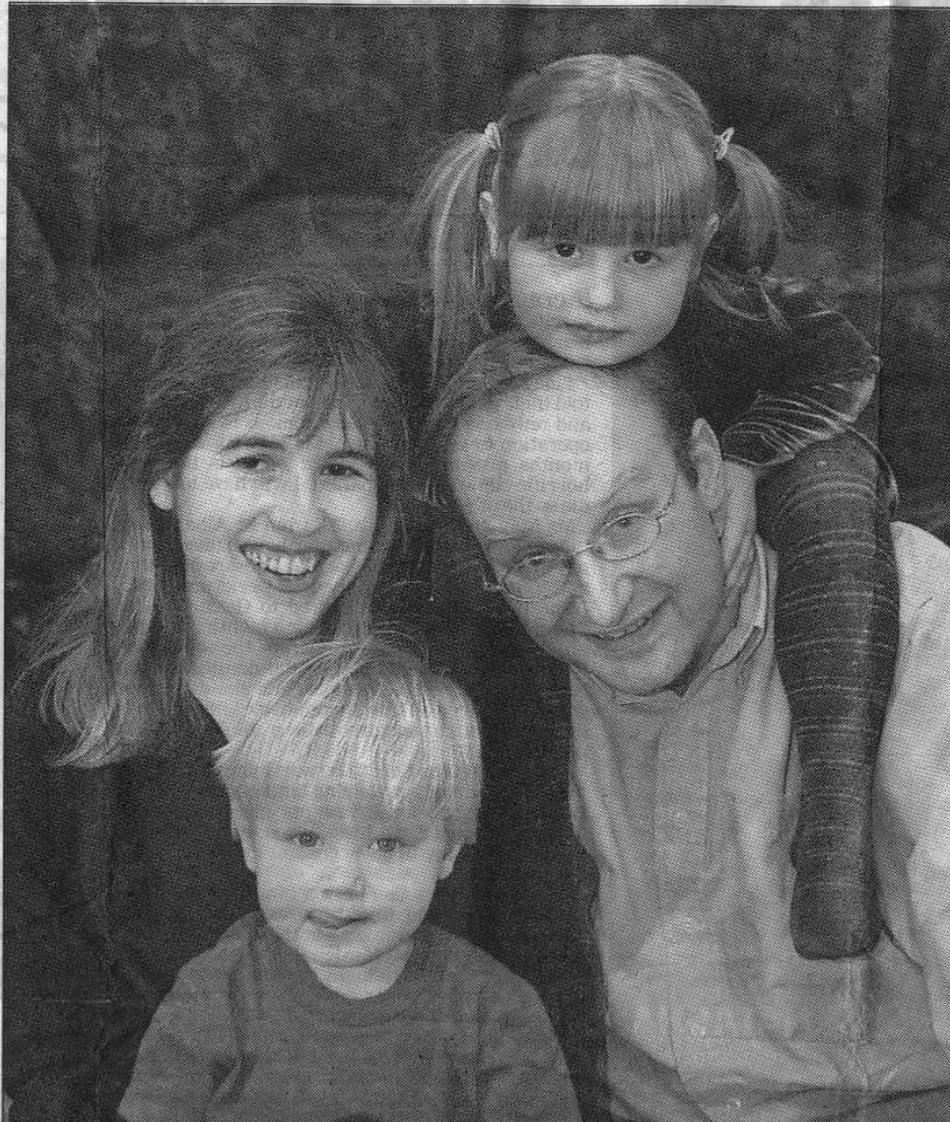
As new figures showed that half of the capital's parents are refusing to allow their children to have the MMR booster jab, Dr Atkinson admitted: "We have not managed to get the message across that this vaccine is safe."

Take-up of the first MMR jab has fallen to 73.4 per cent in London, while immunisation levels of the second booster injection are as low as 45 per cent in some boroughs. The World Health Organisation says that 95 per cent of people need to be vaccinated to ensure the success of the immunisation programme. The uptake of MMR2 is just 45 per cent in Croydon, Kensington, Chelsea and Westminster and Merton, Sutton and Wandsworth health authority areas.

Vaccination levels in London are now lower than they were in Dublin two years

WORRIED Government ministers are planning a hard-hitting television advertising campaign to persuade mothers to give their children the MMR jab. A previous set of television adverts, screened last summer, were a re-run of an old immunisation campaign. An insider said today: "These new ads will be harder-hitting, and a lot of research has been done on how to win over mothers who are hesitant about receiving the triple-dose."

ago, when a measles outbreak left two babies dead, 100 children in hospital and



'We simply don't trust Government'

By Colin Freeman

KATE and Mark Fazakerley's four-year-old daughter Isobel caught measles two weeks ago while attending the White House Preparatory School in Clapham Park. Isobel then passed it on to her brother Dominic, who will be two next month.

Mrs Fazakerley, 36, said: "I know they keep telling us that it is dangerous and there has been one little girl who was in hospital, but when I spoke to my doctor they said there was nothing unduly dangerous — they said just keep an eye on them. There is the chance of complications, but it is something like one in 100,000 cases.

"As it happens, we were just about to get the individual injections for Isobel. Neither she nor her brother has had the MMR vaccine as we are just not confident about it all.

"Friends have a child who had the jab who later contracted a mild form of autism. You can see it is a very strong combination of injections for a young child.

"We are basing our decision about the vaccine on what has happened to parents I know. We discovered Isobel was diabetic when she was two and a half, which was another reason for not getting it done."

Mrs Fazakerley, a part-time marketing manager, added that many of her neighbours are questioning the validity of the vaccine. "Only about a third of people in Isobel's class have had the MMR jab," she said. "It is a constant subject of conversation in our local playgroups as to whether or

Raymond Tallis

Anecdotes, data, and the curse of the media anecdote
Healthwatch Newsletter 2007

- The media has a “habit of giving appealing individuals with their moving stories at least as much credence and coverage as unappealing data, of preferring faces to graphs, and vox pops to statistics”
- Anecdote based discussion is characterised by “the domination of the visible over the invisible. The millions of children who had been saved from harm by the vaccine were given little foreground.”

The press conference

MMR and autism: what the published article said

“We did not prove an association between measles, mumps and rubella vaccine and the syndrome described.”

MMR and autism: at the press conference

“There is sufficient doubt in my own mind for a case to be made for the vaccines to be given individually at not less than one year intervals” - Andrew Wakefield

Some lessons

Hargreaves et al BMJ 2003

- Research questioning the safety of something that is widely used should be approached with caution
- Legal definitions of impartiality in broadcast journalism cannot be applied simplistically to this sort of question

The Cox-2 story

Suppression and distortion of data

BMJ

Lessons from VIOXX



Participating in a trial and learning
Knowledge for all
The essential update
BMJ MEDICAL HISTORY

Vioxx (rofecoxib)

- Introduced by Merck in 1999 as an effective safer alternative to non-steroidal anti-inflammatory drugs for pain in osteoarthritis
- Merck now faces claims from ~ 30 000 people who suffered cardiovascular events while taking Vioxx

Vioxx – the story

- Early concerns that rofecoxib increased thrombus formation
- 1996-7 – a study sponsored by Merck found signs that the drug altered the balance between thromboxane and prostacyclin
- Merck officials persuaded the academic authors to soften their interpretation

Vioxx – licensing and promotion

FDA application for Vioxx (1998) was not designed to pick up cardiovascular risk

- 9 intervention studies
- small, short treatment periods
- enrolled patients at low risk of CV disease
- no standard procedures for collecting cardiovascular outcomes

Merck pooled data from these studies and used the results to promote rofecoxib's cardiovascular safety

Vioxx – the VIGOR study

- Started in 1999
- Intended to show that Vioxx had fewer GI side effects than naproxen for treatment of rheumatoid arthritis – would mean a new indication \$\$\$\$\$
- Over 8000 patients
- No standard operating procedure for collecting information on CV events
- No cardiologist on the safety monitoring board

Vioxx – the VIGOR study

- Interim analyses showed higher CV risk in one group, but decision to continue
- Undisclosed conflicts of interest among board members – head of VIGOR board awarded a two year consulting contract two weeks before the trial ended, and as the trial was concluding disclosed family ownership of Merck shares worth \$70 000



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ORIGINAL ARTICLE

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Volume 343:1520-1528

November 23, 2000

Number 21

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Comparison of Upper Gastrointestinal Toxicity of Rofecoxib and Naproxen in Patients with Rheumatoid Arthritis

Claire Bombardier, M.D., Loren Laine, M.D., Alise Reicin, M.D., Deborah Shapiro, Dr.P.H., Ruben Burgos-Vargas, M.D., Barry Davis, M.D., Ph.D., Richard Day, M.D., Marcos Bosi Ferraz, M.D., Ph.D., Christopher J. Hawkey, M.D., Marc C. Hochberg, M.D., Tore K. Kvien, M.D., Thomas J. Schnitzer, M.D., Ph.D., for The VIGOR Study Group

ABSTRACT

Background Each year, clinical upper gastrointestinal events occur in 2 to 4 percent of patients who are taking nonselective nonsteroidal antiinflammatory drugs (NSAIDs). We assessed whether rofecoxib, a selective inhibitor of cyclooxygenase-2, would be associated with a lower incidence of clinically important upper gastrointestinal events than is the nonselective NSAID naproxen among patients with rheumatoid arthritis.

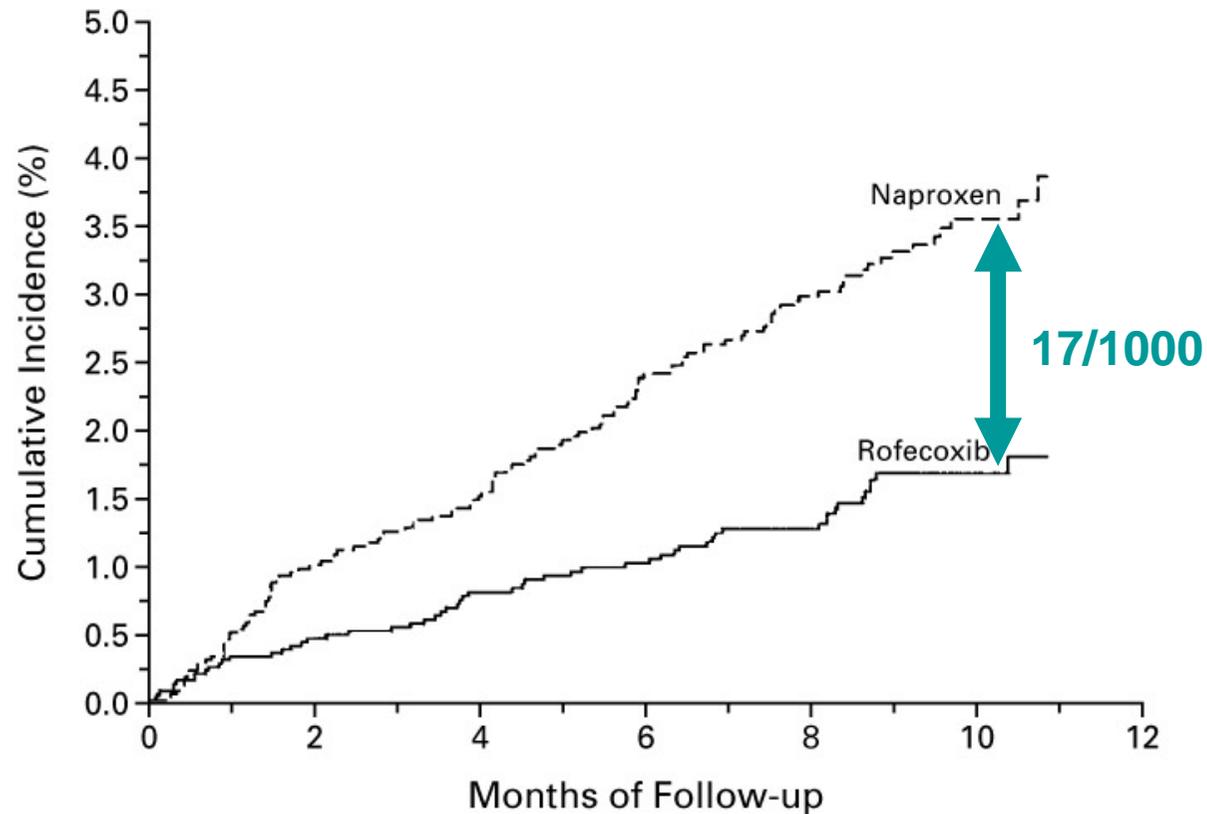
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COMMENTARY

- ▶ Editorial
by Curfman, G. D.

GI outcomes VIGOR



No. AT RISK							
Rofecoxib	4047	3641	3402	3180	2806	1073	533
Naproxen	4029	3644	3389	3163	2796	1071	513

Figure 1. Cumulative Incidence of the Primary End Point of a Confirmed Upper Gastrointestinal Event among All Randomized Patients.

Vioxx – VIGOR study

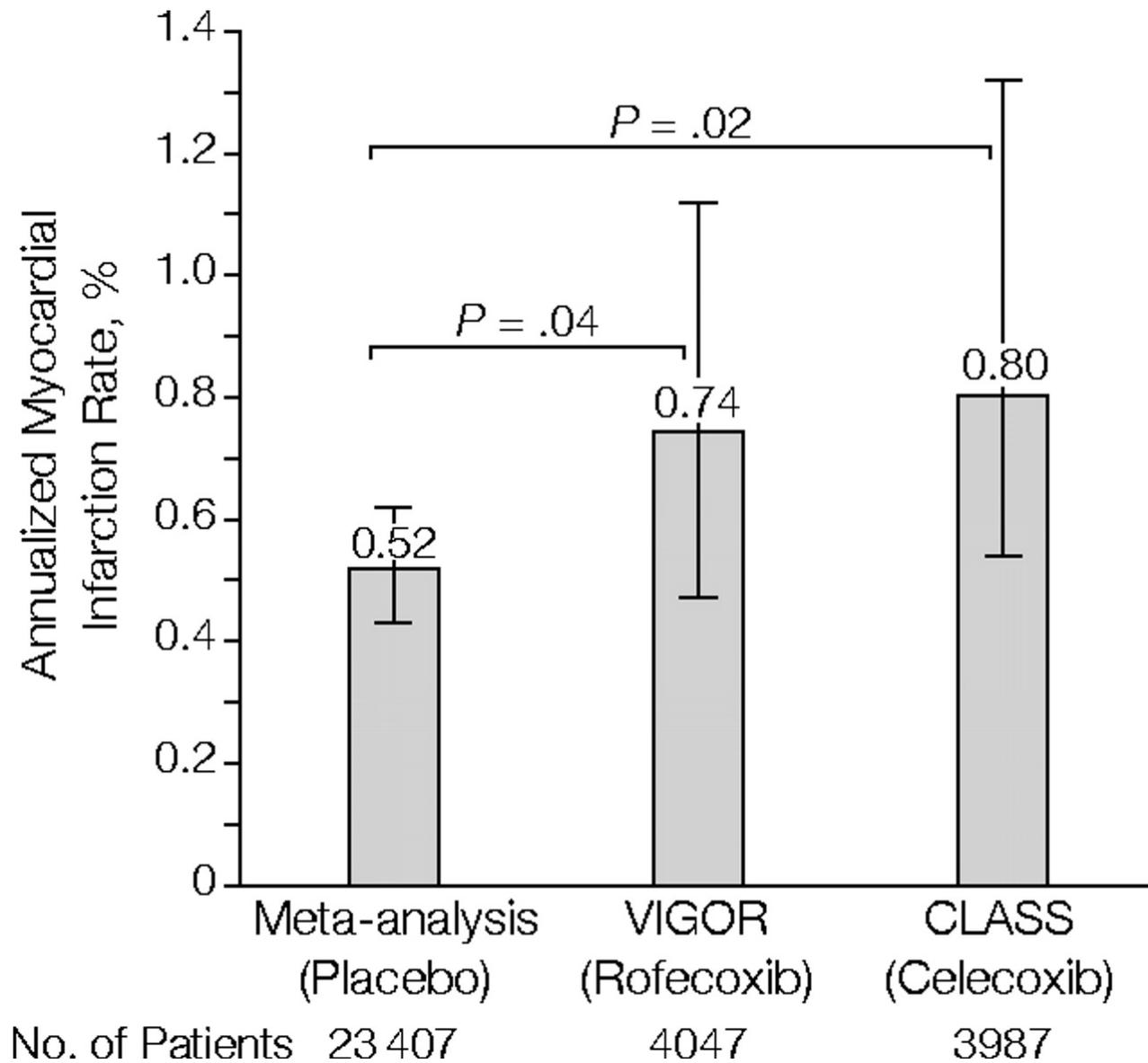
- CV events obscured
- Report was of interim analysis
- Different end points for GI and CV events (GI events counted for one month longer than CV events) – not described in the publication in NEJM – favoured GI benefits and understated CV risks
- 3 additional myocardial infarctions in treatment group occurred in the missing month
- Authors dismissed any additional CV risk by suggesting that the difference between the two drugs was because naproxen had a cardio-protective effect

Promotion

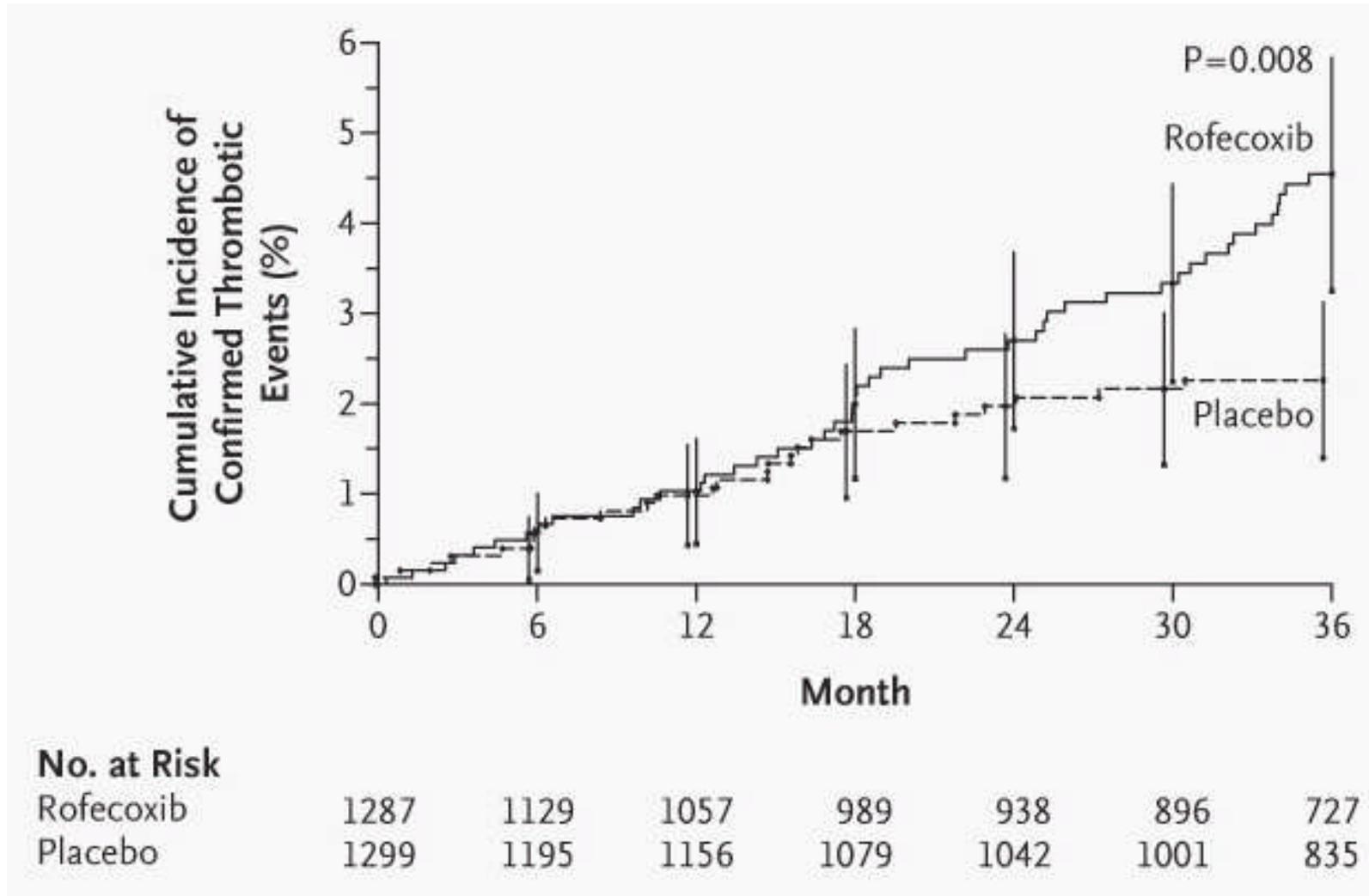
- Merck bought nearly 1 million reprints of the NEJM paper

- Evidence emerges of increased rates of cardiovascular adverse events

Comparison of MI Rates Among Subjects Receiving Placebo vs Rofecoxib or Celecoxib



Thrombotic events



Approve study NEJM 2004

Vioxx withdrawn

Lessons from Vioxx

Harlan Krumholz et al, BMJ 20 January 2007

- Bad news for industry, academics, journals, and the public
- Merck has lost vast sums of money, shareholder value, and reputation
- Merck conducted the trials, stored and analysed the data internally, paid academic researchers as consultants to the investigative teams and safety boards, and maintained heavy involvement in the writing and presentation of the findings

Undeclared competing interest/ghosts and guests

- RCT of Vioxx versus Naproxen Lisse et al. Ann Intern Med 2003; 139: 539-46
- New York Times, 24 April 2005
“Merck designed the trial, paid for the trial, ran the trial...Merck came to me after the study was completed and said, ‘We want your help to work on the paper.’ The initial paper was written at Merck, and then sent to me for editing.”

Lessons from Vioxx

- Define a set of principles – code of conduct
- Insist data are stored in academic sites, analysed by non-company investigators, and eventually made accessible to the public for scrutiny
- Independent audits
- Independent data and safety monitoring boards, governance not in control of the company
- Industry should not be allowed to select who serves on these boards or allowed to compensate members after their service

Lessons from Vioxx

- More intense scrutiny of such studies by journals
- Ghost writing must be exposed and the academic authors who take part must be penalised

The perils of composite outcomes - Rosiglitazone

Rosiglitazone – the perils of composite outcomes

DREAM (diabetes reduction assessment with ramipril and rosiglitazone medication)

Lancet 2006;368: 1096-105.

- 5269 people with impaired fasting glucose or impaired glucose tolerance
- Rosiglitazone versus placebo
- Primary outcome: composite of incidence of diabetes or death over three years
- Results: diabetes occurred in 306 (11.6%) of patients on rosiglitazone compared with 686 (26%) on placebo (HR 0.40, 95% CI 0.35 to 0.46, $P < 0.0001$)

Rosiglitazone – the perils of composite outcomes

Editorial, Carl Heneghan and colleagues

BMJ 2006;333:764-765 (14 October)

Prevention of diabetes

*Drug trials show promising results, but have
limitations*

Rosiglitazone – interpret with caution

- **Diabetes incidence was reduced on rosiglitazone compared with placebo**
- **Composite outcome showed benefit, but death rates were similar on both groups**
- **Rates of heart failure were higher on rosiglitazone (NNH 250)**
- **Not sure whether preventing onset of diabetes or lowering blood sugar in people with new onset diabetes**
- **Risk of medicalising a life style issue**

Rosiglitazone – the perils of composite outcomes

Editorial, Nick Freemantle, Mel Calvert

BMJ 2007;334:756-757 (14 April)

Composite and surrogate outcomes in randomised controlled trials

*Composite end points may mislead—and
regulators allow it to happen*



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ORIGINAL ARTICLE

Published at www.nejm.org May 21, 2007 (10.1056/NEJMoa072761)

Effect of Rosiglitazone on the Risk of Myocardial Infarction and Death from Cardiovascular Causes

Steven E. Nissen, M.D., and Kathy Wolski, M.P.H.

ABSTRACT

Background Rosiglitazone is widely used to treat patients with type 2 diabetes mellitus, but its effect on cardiovascular morbidity and mortality has not been determined.

Methods We conducted searches of the published literature, the Web site of the Food and Drug Administration, and a clinical-trials registry maintained by the drug manufacturer

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Rosiglitazone and Cardiovascular Risk

Bruce M. Psaty, Curt D. Furberg

“On the basis of this meta-analysis...the possibility of cardiovascular benefit associated with the use of rosiglitazone seems remote.”

“For a drug approved in 1999, the delay in obtaining information about health outcomes has already been considerable.”

“During the market life of rosiglitazone, tens of millions of prescriptions for the drug have been written for patients with type 2 diabetes.”

“Insofar as the findings of Nissen and Wolski represent a valid estimate of the risk of cardiovascular events, rosiglitazone represents a major failure of the drug-use and drug-approval processes in the United States.”

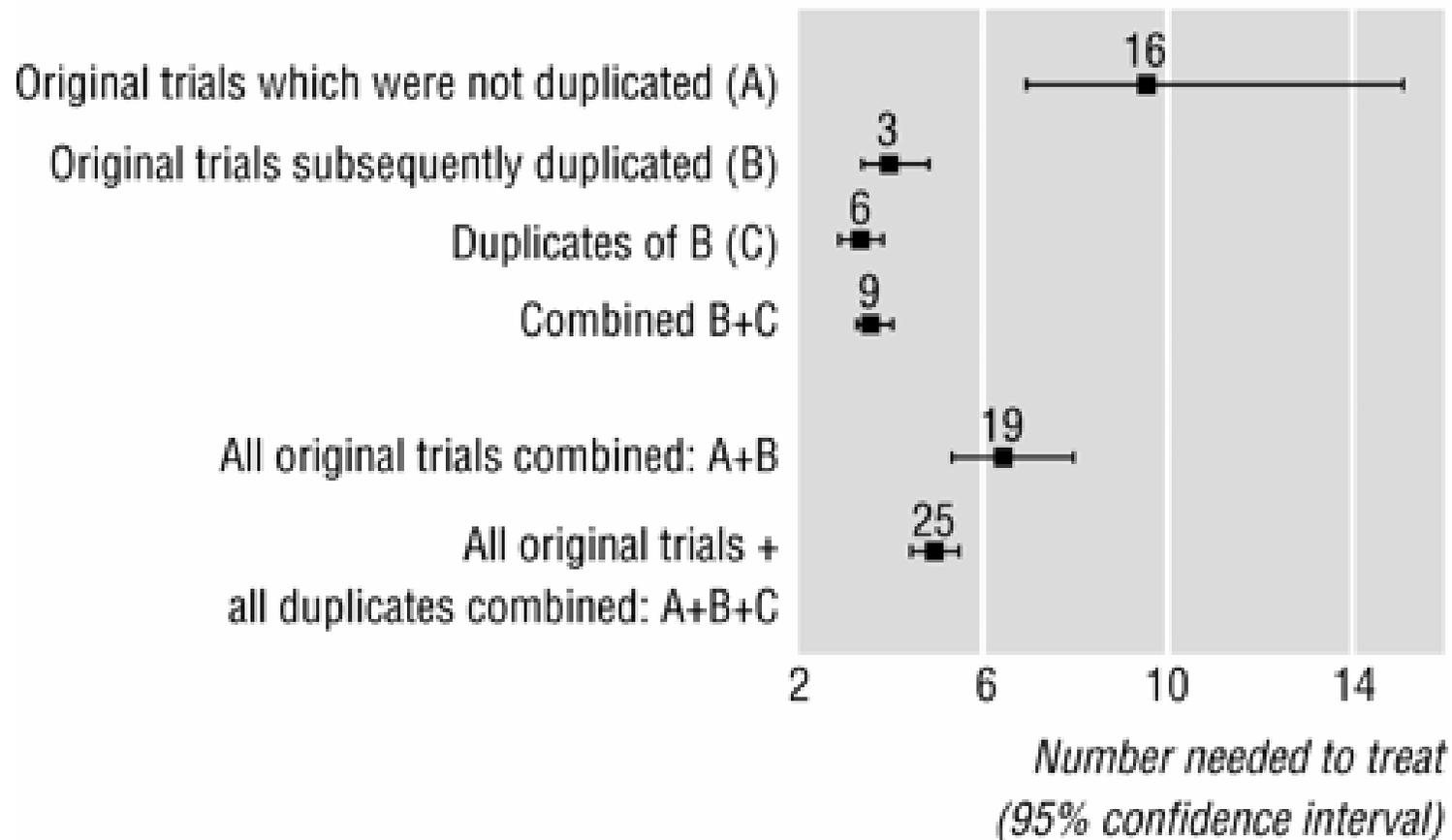
Other perils of composite outcomes

- Warlow et al, Lancet 1999 on stroke unit care found a 9% RRR for death and dependency
- NAO report on stroke put this into its economic assumptions as 9% RRR in death and a 9% RRR in dependency, magnifying the benefits of acute stroke unit care
- BMJ news item and editorial

The odansetron story – duplicate publication and salami slicing

- 84 trials that included information on 11 980 patients
- In reality only 70 trials and 8645 patients (17% of the studies had been published more than once and the number of patients had been inflated by 28%)
- Impossible to tell from published studies
- Four pairs of identical trials were published by completely different authors without any common authorship (Misconduct)

Effectiveness of odansetron



Publication bias in medical research

Positive studies are more likely to be:

- **Published** Stern and Simes, BMJ 1997
- **Published faster** Ioannides, JAMA 1998
- **Published in higher impact journals**
Easterbrook et al, Lancet 1991: Tierney and Stewart, 1997
- **Cited** old style narrative review articles

Publication bias - Who's to blame?

- Editors/peer reviewers?
- Researchers?
- Both?

There's some evidence that journals are partial to positive results

Mahoney 1977

- Submitted different versions of the same manuscript to 75 referees
- Introduction and methods sections were the same but different results and discussion sections
- Referees favoured the ones with positive findings, rating them higher in methodological quality

Epstein 1990

- Submitted two versions of the same paper
- Positive version had higher acceptance rates

But...

Most of the “blame” seems to rest with researchers

Olson et al, JAMA 2002

- 745 submitted manuscripts
- About half had positive results
- 17.9% published
- 20.4% positive, 15.0% negative (OR 1.30 (95% CI 0.87 – 1.96))

Dickersin et al, Controlled Clinical Trials 1987

- Surveyed 318 authors of published trials to see if they had any in their bottom draw
- Of the completed but unpublished trials, 15% were positive, 55% negative

Hype using relative rather than absolute risk in the medicalisation of risk factors

Alonso-Coello et al, BMJ 2008

- Looked at four post hoc analyses of trials of drug treatment for osteoporosis, which claimed benefit from treatment in low risk women (with osteopenia)
- In relative terms, benefits of treatment the same as in women with osteoporosis and fractures
- We know that relative risk reductions are more or less constant across wide range of baseline risk
- Impressive sounding reductions in relative risk can mask much smaller reductions in absolute risk
- But much lower baseline risk means much smaller absolute benefits and therefore much higher risk to benefit and cost to benefit ratios

Disease mongering/Medicalisation

BMJ 2006;332:f45 (1 April), doi:10.1136/bmj.332.f44.f45-a

News

Scientists find new disease: motivational deficiency disorder

Ray Moynihan

Sydney

Extreme laziness may have a medical basis, say a group of high profile Australian scientists, describing a new condition called motivational deficiency disorder (MoDeD).

The condition is claimed to affect up to one in five Australians and is characterised by overwhelming and debilitating apathy. Neuroscientists at the University of Newcastle in Australia say that in severe cases motivational deficiency disorder can be fatal, because the condition reduces the motivation to breathe.

Neurologist **Leth Argos** is part of the team that has identified the disorder,

- “We discovered this disease a few years ago but couldn’t be bothered to write it up”

Spinning the conclusions

Yank, Rennie, Bero, BMJ 2007

- Compared results and conclusions in industry and non-industry funded meta-analyses of anti-hypertensive drugs
- Financial ties to a single drug company were not associated with favourable results, but were associated with favourable conclusions

Spinning the conclusions

Hewitt, Mitchell, Torgerson, BMJ 2008

- Interpretive bias in RCTs published in BMJ
- In trials that come up with surprising result that is not statistically significant, some authors seem to support interventions despite evidence that they might be ineffective

Some solutions?

What are journals doing about all this?

- Peer review
- But peer review is imperfect

Problems with peer review

- Slow
- Expensive
- Biased
- Unaccountable
- Bad at detecting error

What are journals doing?

Improving and extending peer review

- Additional statistical review for drug industry trials (JAMA)
- Active post-publication review (rapid responses)
- Space on the web (ELPS)
- Emphasis on harms as well as benefits of treatments
- Education and training, authors and peer reviewers
- Penalties for misconduct
- Trial registration
- Protocols

Effect of ICMJE deadline on weekly trial registrations at clinicaltrials.gov 2005

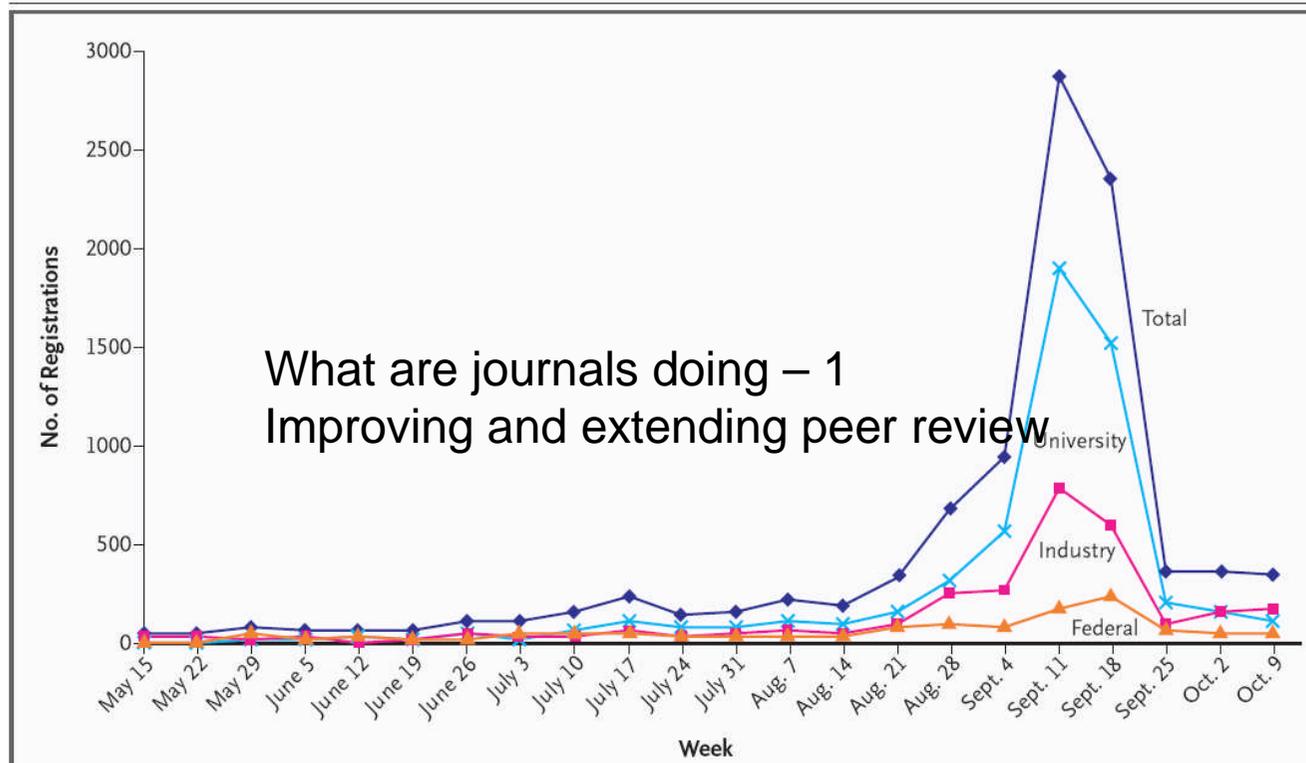


Figure 2. New Trials Registered in ClinicalTrials.gov, According to Week.

The figure shows the number of new registrations per week (beginning on the date indicated) from mid-May through early October 2005. The “Industry” category includes all commercial data providers; the “Federal” category includes the National Institutes of Health and other U.S. federal data providers; and the “University” category includes universities, foundations, and other providers.

New FDA rules

What are journals doing?

Working with the media to improve quality of information

- Ongoing RCT comparing structured guide to results of studies versus normal press release
- Outcomes will be extent to which journalists can extract relevant information on absolute effects, and give appropriate caveats

What are journals doing?

Open access to peer reviewed
research

BMJ Today



Research

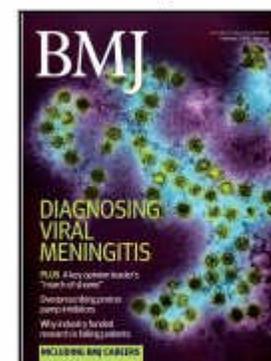
Occupational therapy for dementia patients and their care givers

Maud J L Graff and colleagues - 2 January 2008

In a single blind randomised controlled trial, providing training in the use of aids to compensate for cognitive decline to 135 people aged 65 or older with mild to moderate dementia and training in coping behaviours and supervision to carers was cost effective, with the main savings in informal care.

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Poverty and blindness in Pakistan

Clare E Gilbert and colleagues - 17 December 2007

Household and local poverty were significantly associated with blindness and visual impairment in more than 16 000 adults, and was partly explained by poor access to eye care services. Clare E Gilbert and colleagues report results from the Pakistan national blindness and visual impairment survey.

Effect of European Clinical Trials Directive on academic drug trials in Denmark

Louise Berendt and colleagues - 6 December 2007

Applications for drug trials showed an identical steady decline from 1993 to 2006, with no noticeable change after 2004, when good clinical practice became mandatory for academic trials. Louise Berendt and colleagues report a retrospective study of applications to the Danish Medicines Agency.

Paolo Bruzzi, in an accompanying [editorial](#), concludes that the high cost and poor availability of drugs mean that important clinical questions remain unanswered.

BMJ Blogs

Read entries and post your comments.



Listen to BMJ interview with health minister Lord Darzi



What's the future?

- Further attempts to understand and improve peer review
- Training for authors and peer reviewers
- Further pressure towards transparency about conflicts of interest
- Further extensions of trial registration
- Better education of journalists and the public
- Regular critical review of press coverage

Conclusions

- Hype is important because it distorts our understanding and impedes the search for “truth”
- It’s not something other people do or believe, but something we are all at risk of doing and believing
- The group effort to maintain organised scepticism – through pre- and post publication peer review - is crucial in keeping the influence of hype to a minimum

Thank you

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