

Science for precautionary decision-making

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Eur. J. Oncol. - Library Vol. 2

THE PRECAUTIONARY PRINCIPLE

IMPLICATIONS FOR RESEARCH
AND PREVENTION IN ENVIRONMENTAL
AND OCCUPATIONAL HEALTH



EUROPEAN RAMAZZINI FOUNDATION

Editors

**Philippe Grandjean, Morando Soffritti,
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European Journal of Oncology

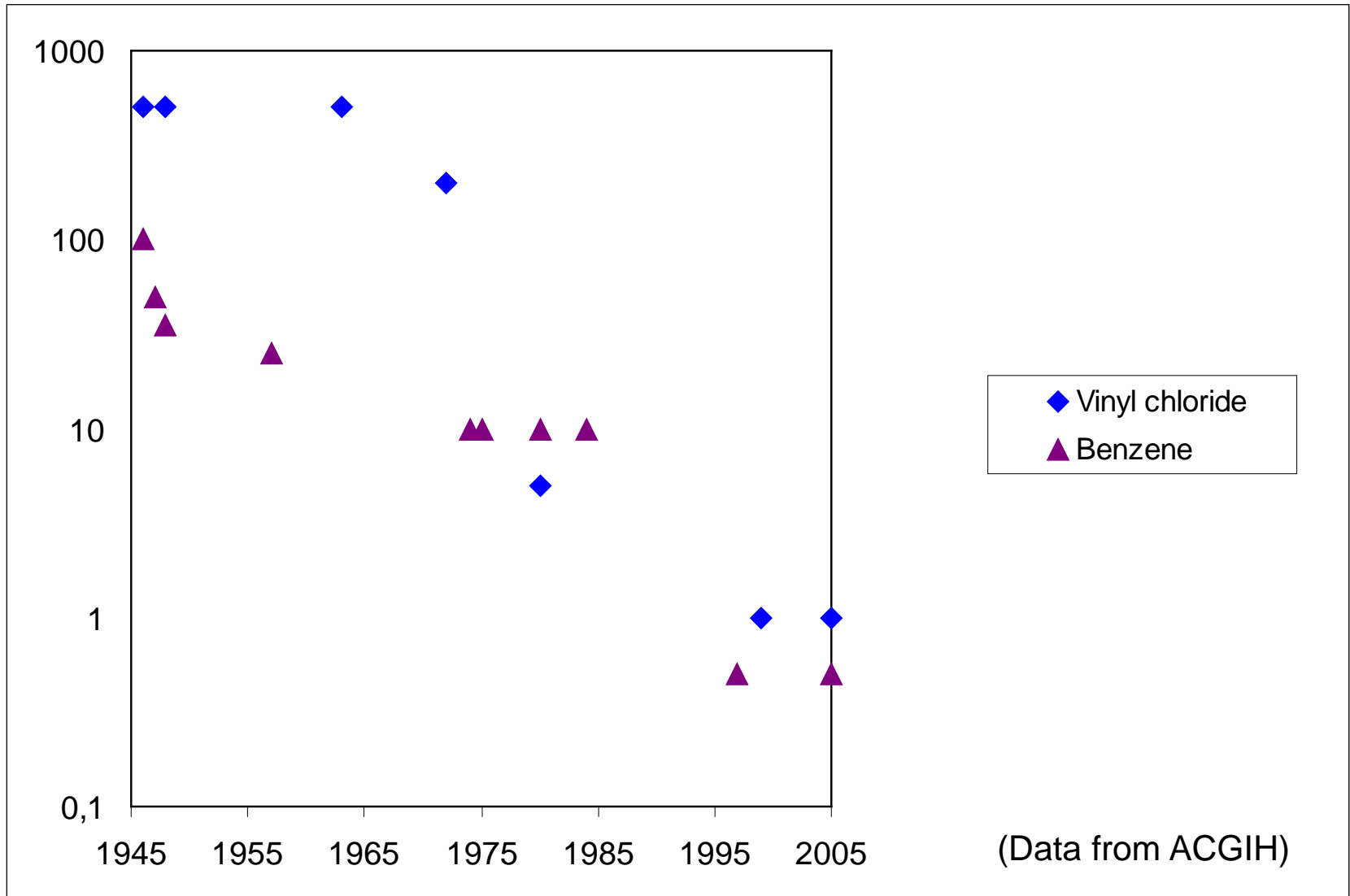
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European Foundation of Oncology and Environmental Sciences "B. Ramazzini"

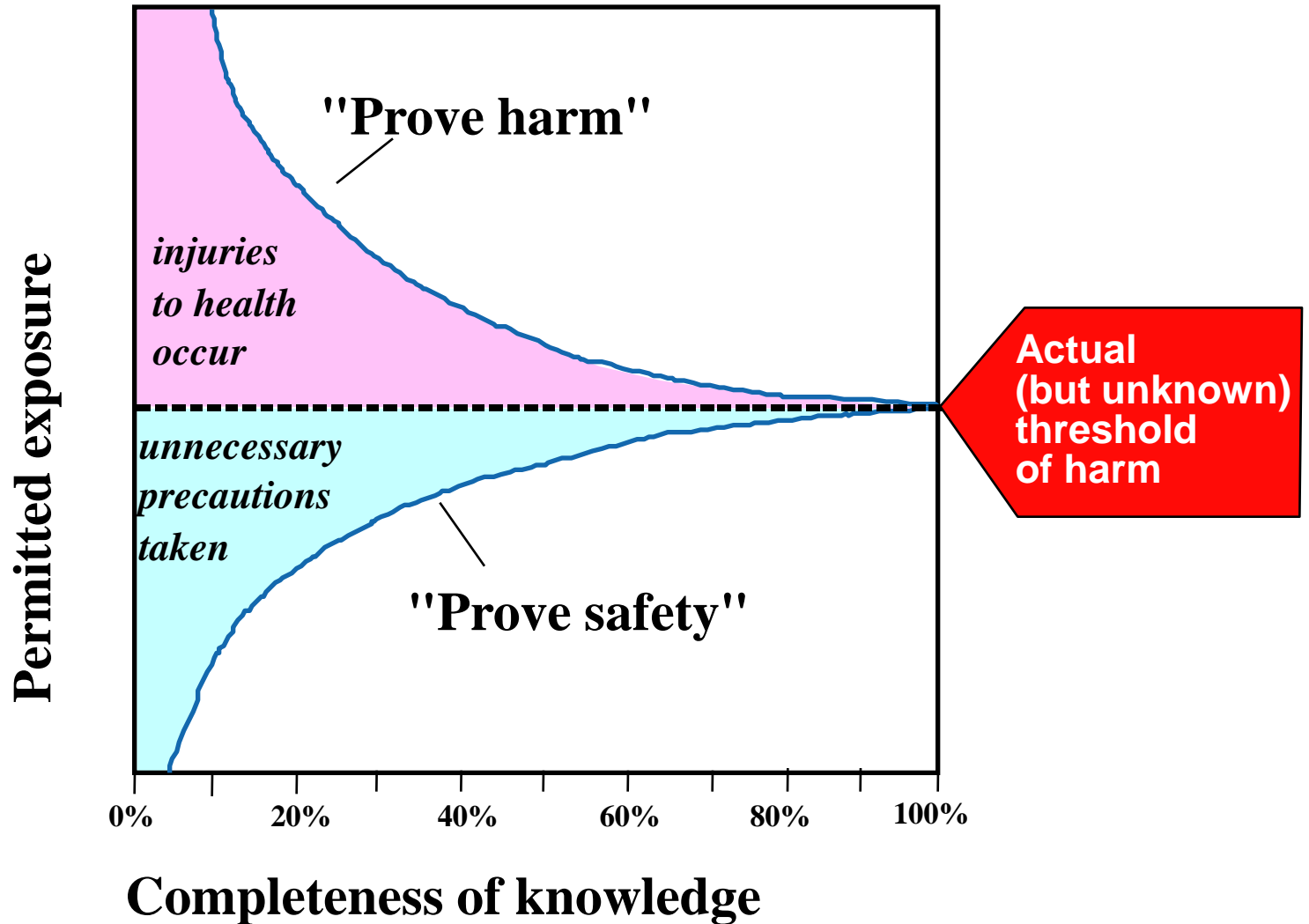
PP-related research challenges

- 1) Coverage of the **societal needs** for data on known and **potential** hazards
- 2) Exploration of new and emerging hazards and serving as an **early warning system**
- 3) **Reporting** of results appropriate as evidence **for PP-based decisions**
- 4) Publicly **available, reliable and independent** of vested interests

Threshold Limit Values (ppm)



Exposure limits and the burden of proof



The initial assumptions were wrong

- Presence of environmental chemicals in the body is 'safe' as long as no evidence on toxicity exists
- Absence of harm in adult male workers means absence of risk to the general public
- Biological effects may not necessarily be adverse
- Dose-response relationships are consistent (and 'monotonic'), and thresholds exist
- The placenta and the blood-brain barrier amply protect sensitive life-stages and organs from toxic chemicals
- Average findings in exposed subjects indicate the potential for harm to the exposed population

The traditional science paradigm was wrong

Have we reliably proven

through meticulous study and replication

that this substance is mechanistically

and causally linked

to this biological change?

● PALAZZO DEL GOVERNO ●



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Bibliometry: Research coverage of environmental chemicals

- Web of Science journals within *“Toxicology”*, *“Environmental Science”*, and/or *“Public, Environmental and Occupational Health”*
- Also in PubMed Medline database
- At least half of articles linked to at least one Chemical Abstracts Service (CAS) number
- Total of 78 journals – all articles in 2000-2009
- SciFinder to download all CAS numbers

Top-20 substances in environmental journals 2000-2009

metals, PAHs, PCBs, ethanol and benzene

1. Copper

2. Lead

3. Zinc

4. Cadmium

5. Iron

6. Nickel

7. Chromium

8. Arsenic

9. Mercury

10. Manganese

11. Aluminum

12. Benzo[a]pyrene

13. 1,1'-Biphenyl (PCBs)

14. Phenanthrene

15. Pyrene

16. Naphthalene

17. Ethanol

18. Cobalt

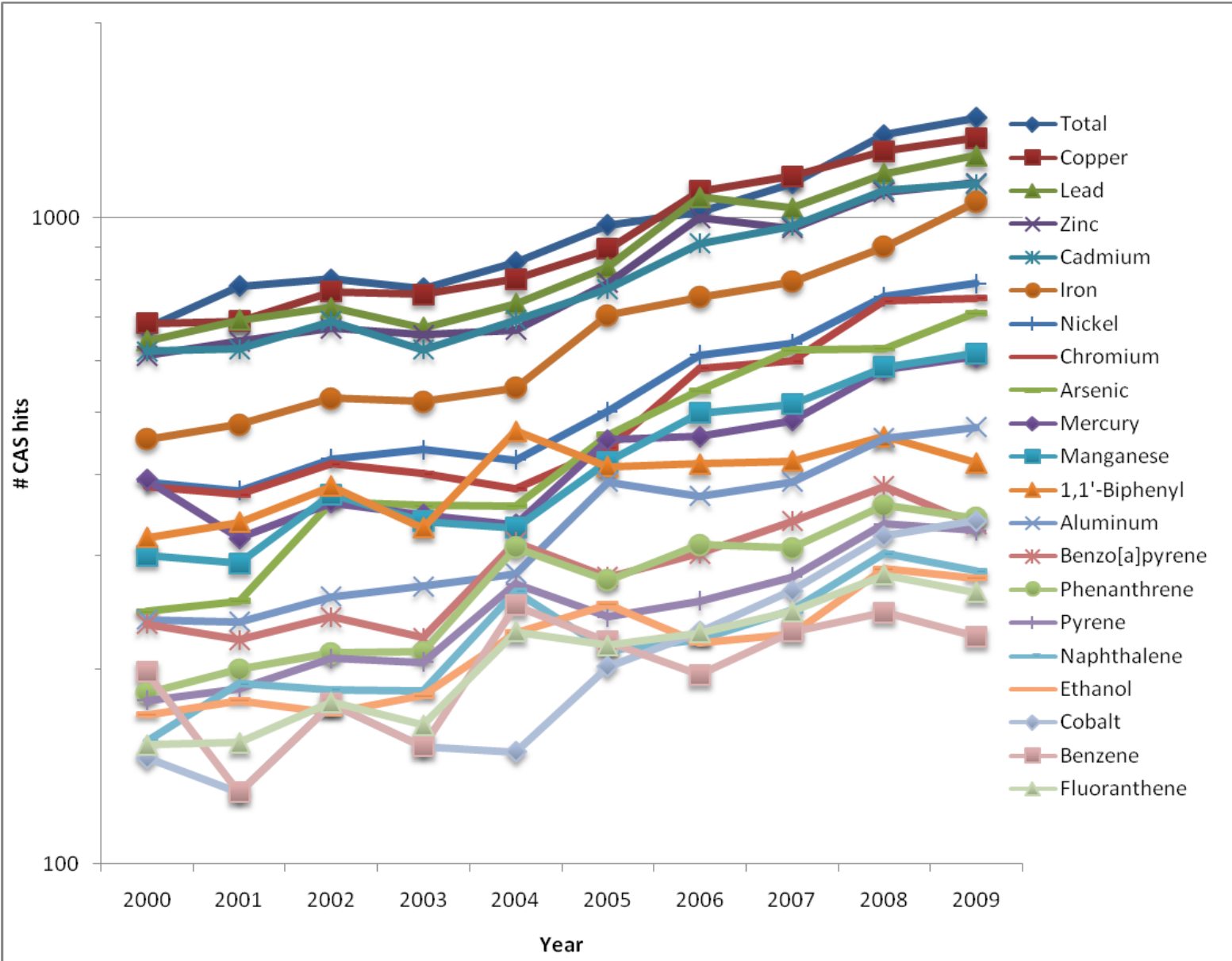
19. Benzene

20. Fluoranthene

Top-20 had
90,620 links,
each >2,000
(out of
760,056 total)

Grandjean et al., 2011

Annual number of CAS links for top-20 substances

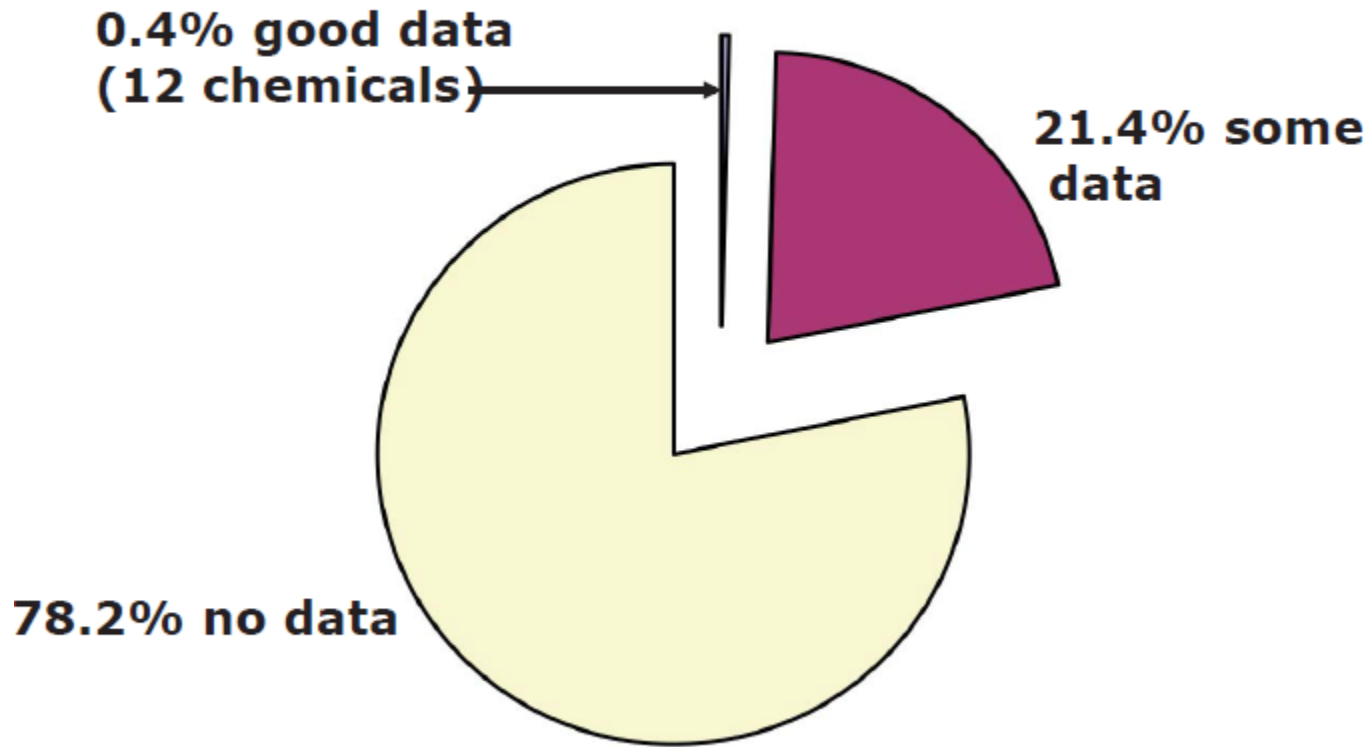


Matthew 25:29

For unto every one that hath shall be given, and he shall have abundance: but from him that hath not shall be taken away even that which he hath.

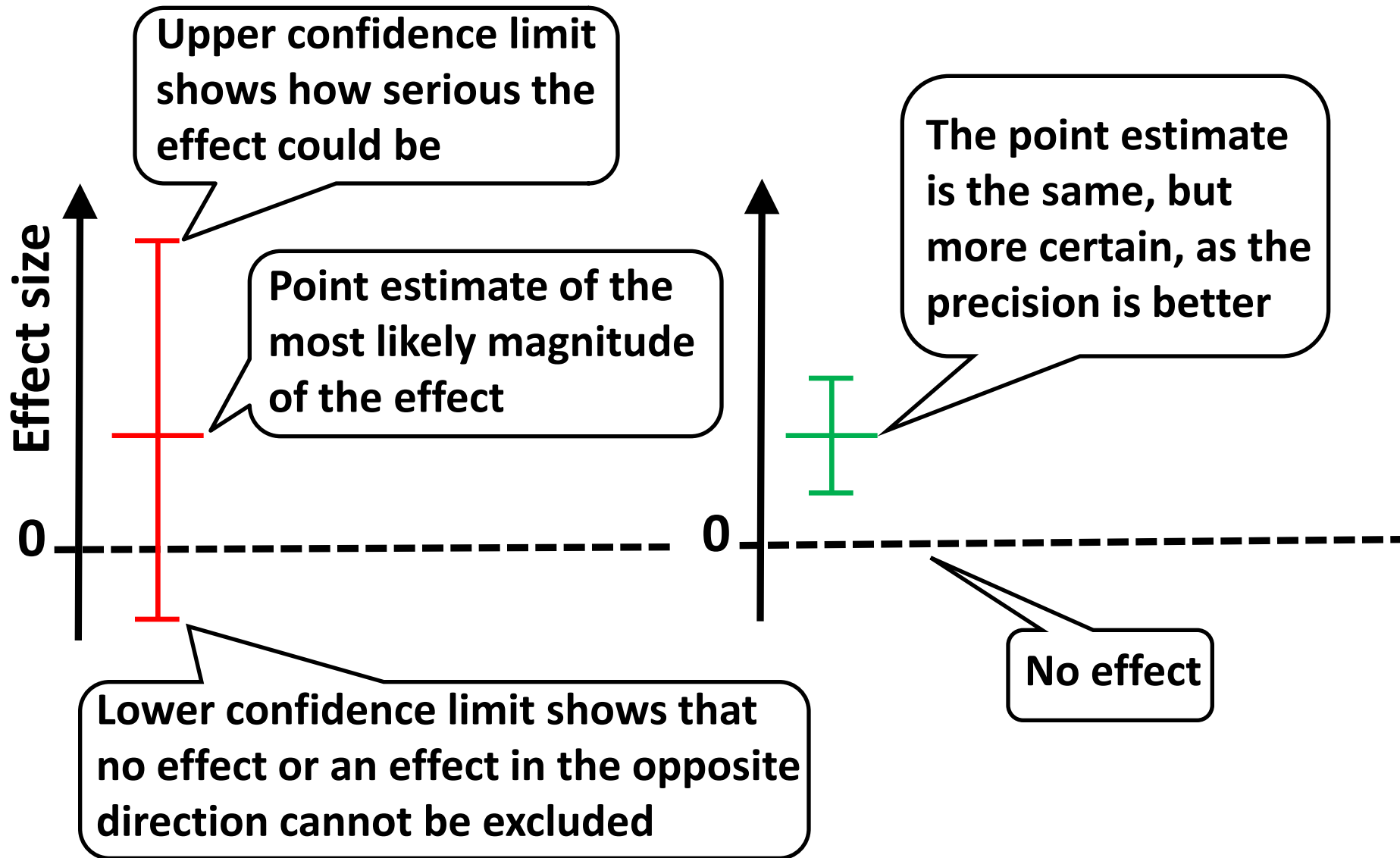
Documentation on High-Production Volume chemicals

2863 above 1 Million pounds

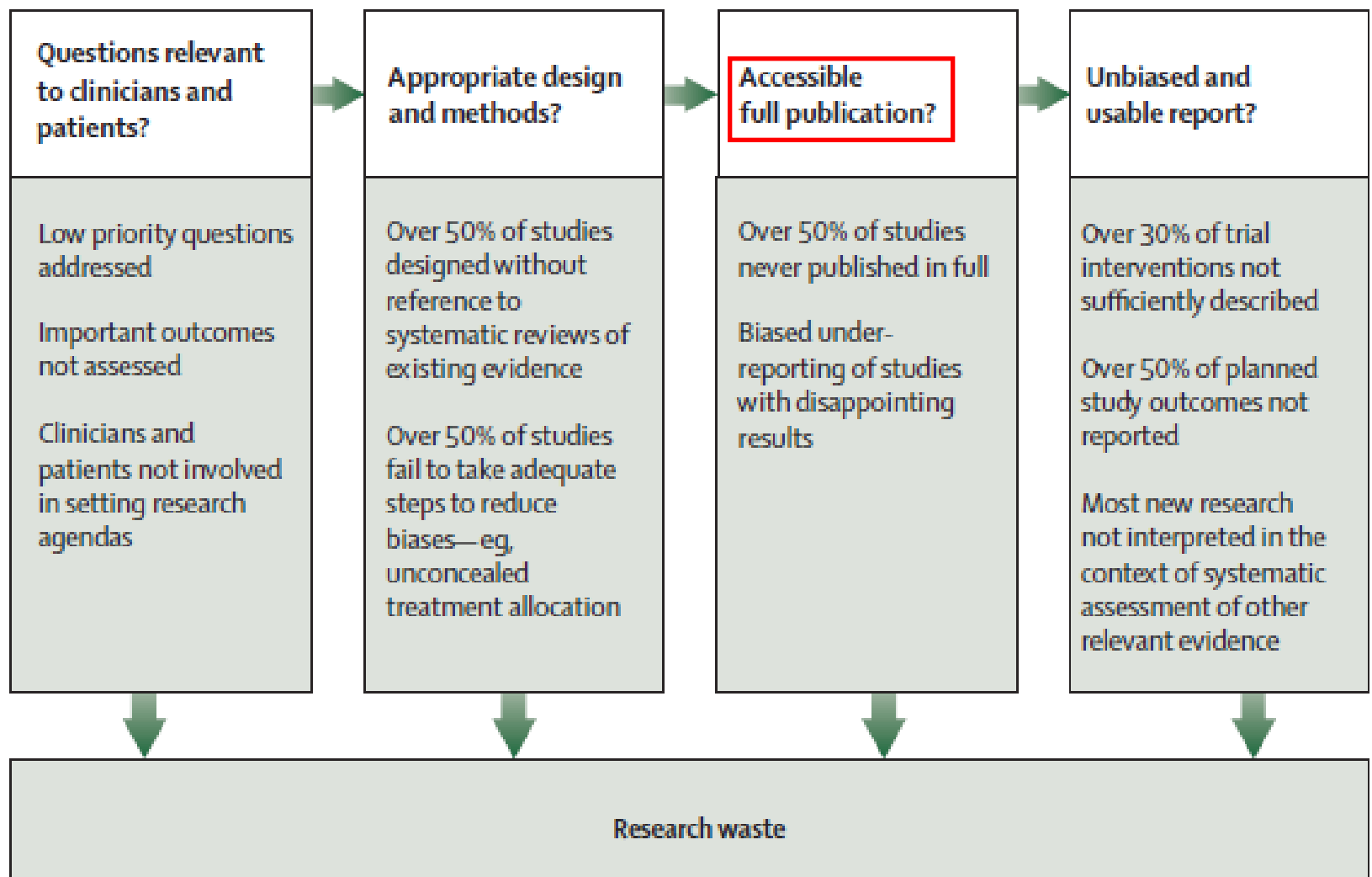


Overlooked causes of false negatives

- Inadequate statistical power
- Lost cases and inadequate follow-up
- Exposure misclassification
- Insensitive or imprecise outcome measures
- Failure to adjust for confounders with effects in the opposite direction
- Disregarding vulnerable subgroups
- Type I error: $p < 0.05$ to minimize risk of false positives (and Bonferroni adjustment)



Lack of availability leads to "Research waste"



Environmental health research in Europe – bibliometric analysis

S. M. Tarkowski

Background: This article describes a bibliometric review of the environmental health research literature in Europe for a period of 10 years. The work, within the study *SPHERE* (Strengthening Public Health Research in Europe) aimed to provide an overview of the extent of published environmental health research in Europe and to assess recent output in this research field and future research direction. **Methods:** Medline was used via the PubMed online service of the US National Library of Medicine. Only original, peer-reviewed research journal articles were retrieved, which were published from mid-1995 to mid-2005 and by authors from the 28 (then) countries in Europe of the European Economic Area plus Switzerland. **Results:** In the PubMed database, 6329 references were located and were allocated to 11 pre-defined topic areas and 31 subtopic areas. The largest number of articles was in the topic area of work environment and health (2339) followed by environmental exposures (1314) and environmental illnesses (952) and these were the primary foci of 73% of the published articles. There were marked differences between countries in the number of published articles. Ten countries contributed 81% of all publications. It is apparent that economic factors have a major role for research outputs of countries in environmental health. **Conclusions:** Major advances have been made during recent years in the understanding of associations between health and environment, and of biological, environmental and social mechanisms involved in this association. More emphasis should be placed on investigations of complex environmental health problems such as complex exposures to different pollutants at different levels and their combined health impact in different populations.

Articles published in 711 scientific journals!!!

Is science anti-precautionary?

- Verification *ad nauseam*
- Indirect support for hazards being innocuous until proven otherwise
- Scientific scepticism that can be misinterpreted
- Ignored tendency toward false negatives
- Type three errors
- Publication not aimed at the public
- ...

The traditional scientist's question:

Have we reliably proven
through meticulous study and replication
that this substance is mechanistically
and causally linked
to this biological change?

Precautionary risk manager's question:

Are we sufficiently confident
that this exposure to a potential hazard
leads to doses of a magnitude
that can result in adverse effects
that are serious enough
to initiate transparent and democratic procedures
to decide on appropriate intervention?

PP-directed change in research paradigm

Academic (normal)
CUDOS
Communalism
Universalism
Disinterestedness
Originality
Skepticism
<i>Merton (1973)</i>

Is lack of precaution culpable?

22 October 2012: Six scientists and a government official were sentenced to six years in prison for manslaughter by an Italian court for failing to give adequate warning of an earthquake that killed more than 300 people in L'Aquila in 2009.

