

Centro Cochrane Italiano



*Con il patrocinio della Regione
Umbria*

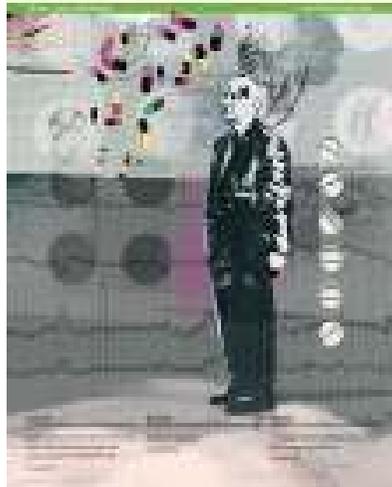
**XIV Riunione Annuale
Network Cochrane
Italiano
e Workshop satelliti**

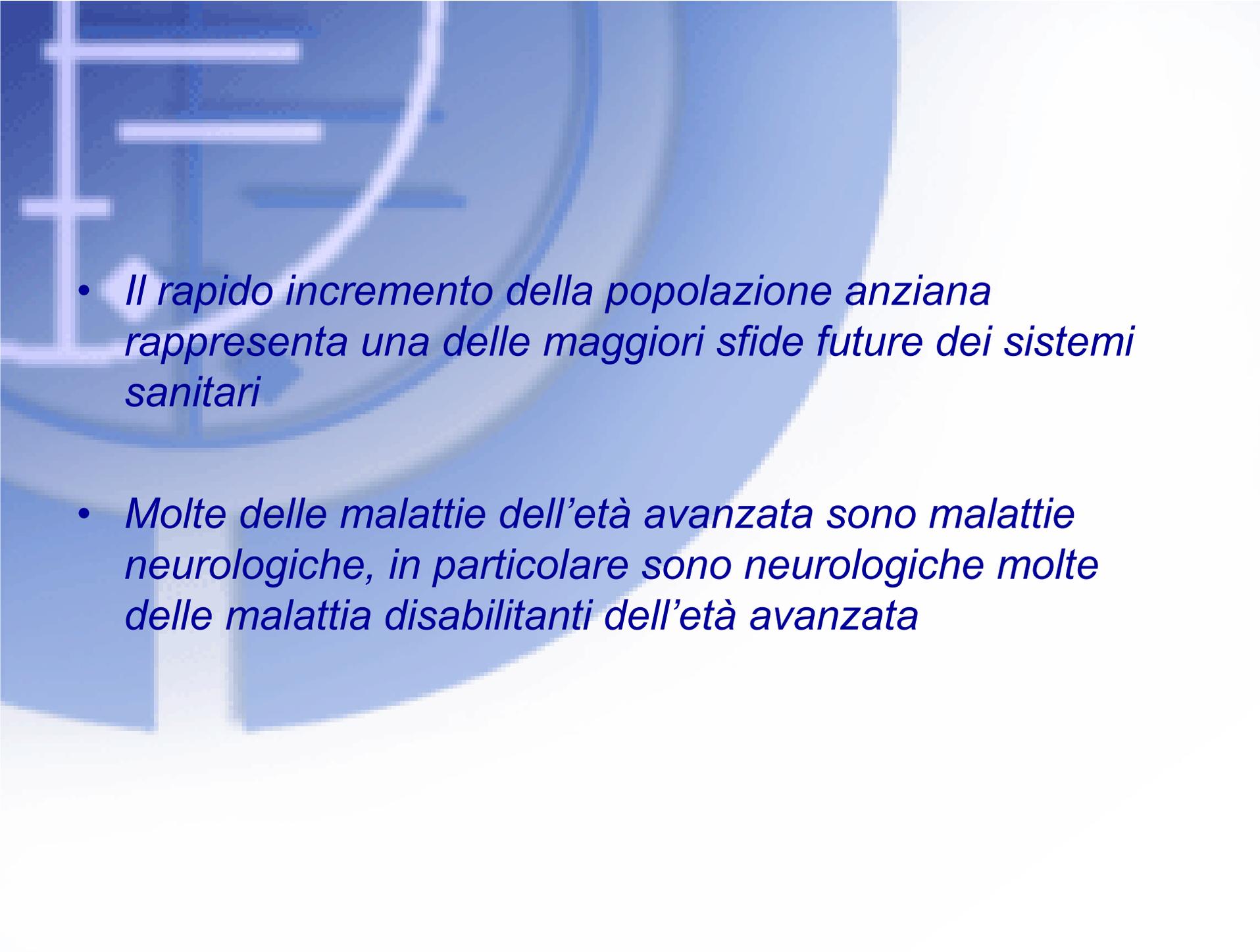


**LE PRIORITÀ DELLA RICERCA
NEI SISTEMI SANITARI
Perugia, 20-21 Novembre 2009**

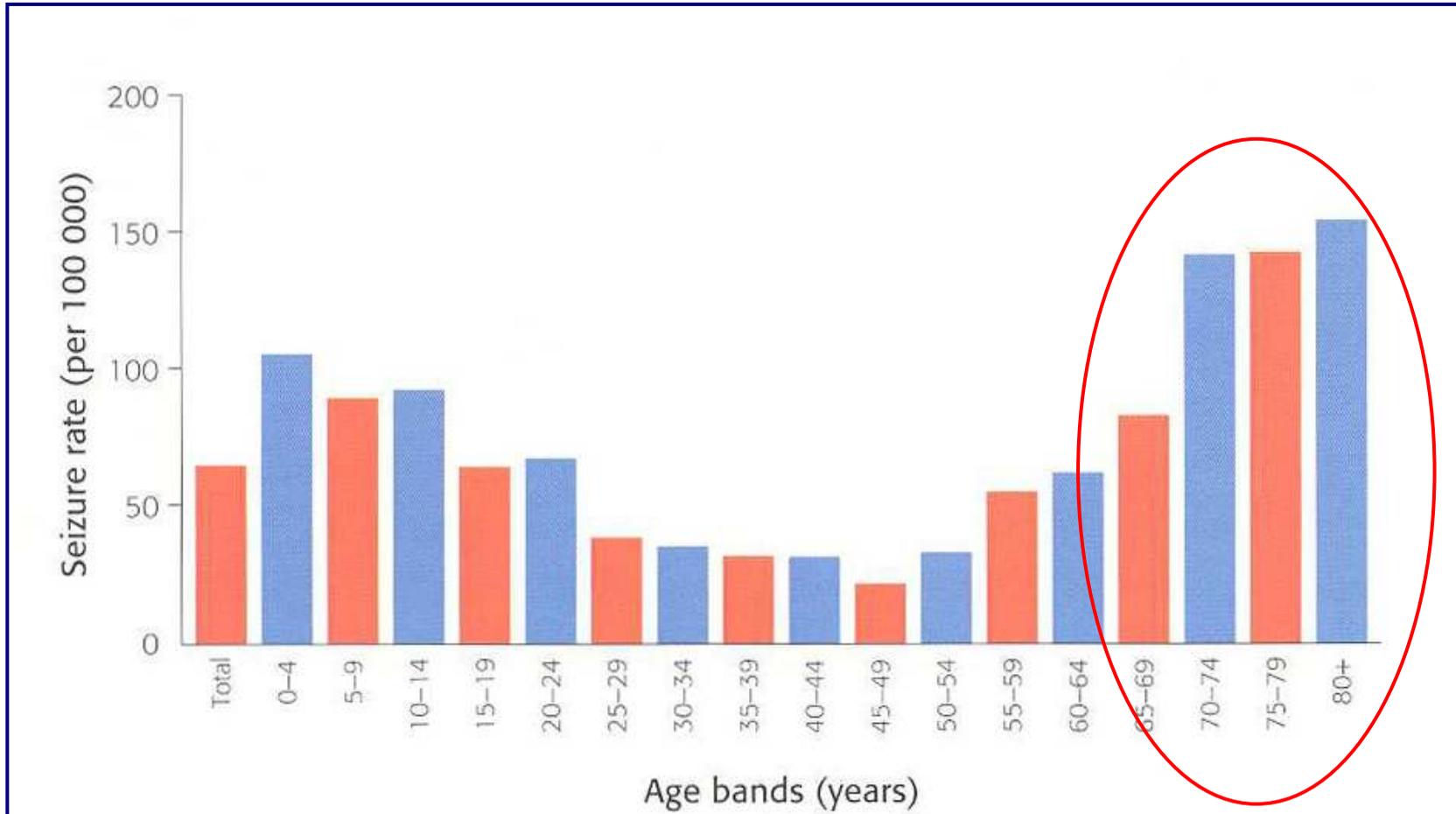


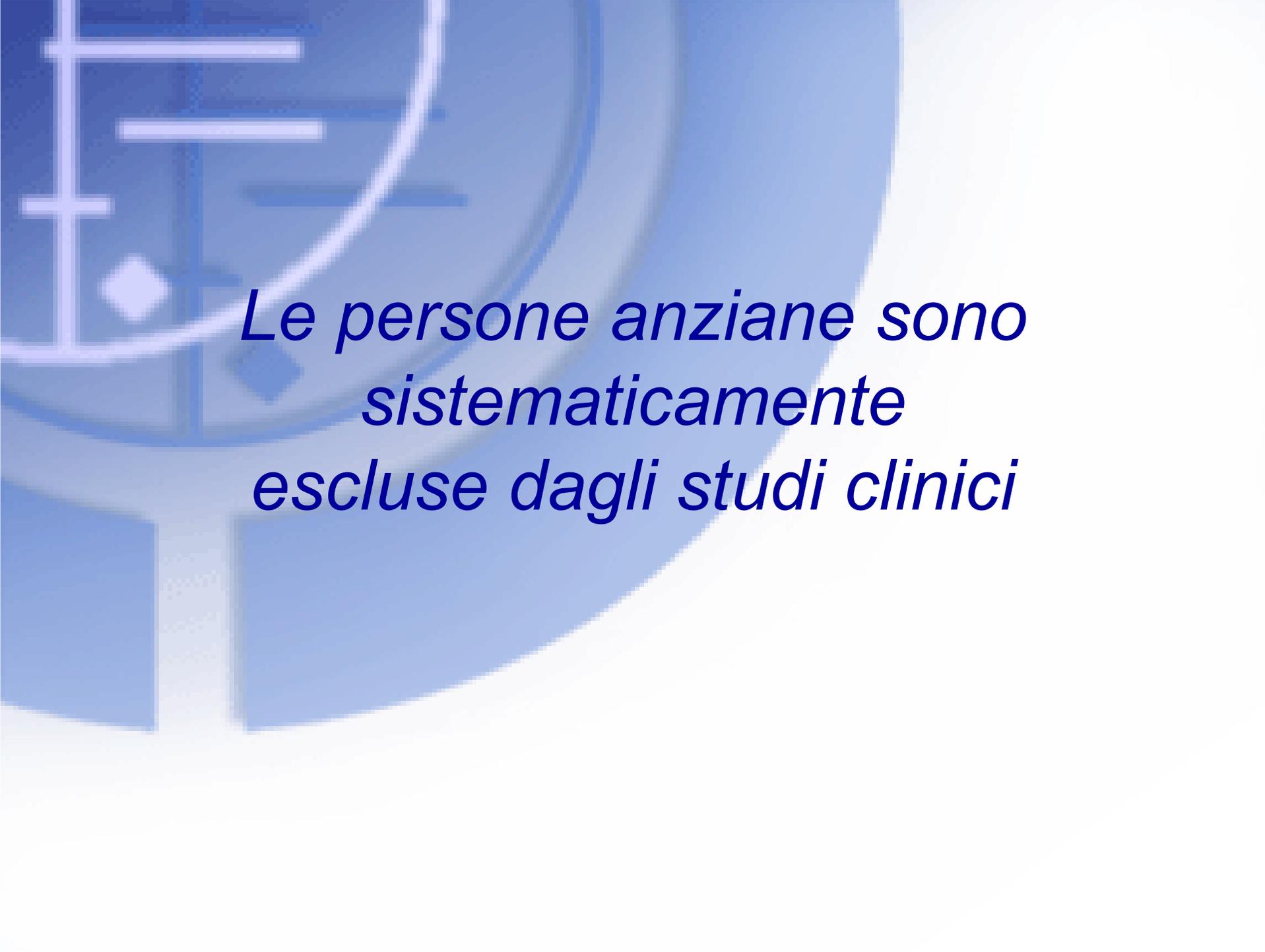
THE LANCET *Neurology*



- 
- *Il rapido incremento della popolazione anziana rappresenta una delle maggiori sfide future dei sistemi sanitari*
 - *Molte delle malattie dell'età avanzata sono malattie neurologiche, in particolare sono neurologiche molte delle malattie disabilitanti dell'età avanzata*

Incidenza dell'epilessia





*Le persone anziane sono
sistematicamente
escluse dagli studi clinici*

I pazienti anziani...

- Hanno con più probabilità patologie concomitanti che possono favorire ed incrementare eventi inattesi
- Assumono spesso molti farmaci che possono incrementare le potenziali interazioni tra loro
- Hanno una farmacocinetica che può essere diversa da quella dei più giovani e può portare ad una maggiore frequenza ed intensità di eventi avversi

Neurology in the elderly: more trials urgently needed
R. Lindley, The Lancet Neurology, November 2009

Fattori che possono costituire una barriera alla partecipazione agli studi clinici dei pazienti anziani:

- Complessità nelle procedure di informazione e consenso
- Deficit cognitivi
- Dipendenza dalla volontà di familiari o assistenti
- Problemi di mobilità e di trasporto

Neurology in the elderly: more trials urgently needed
R. Lindley, The Lancet Neurology, November 2009





☞ *efficacy* trials or “*explanatory*” trials

☞ *effectiveness* trials or “*pragmatic*” trials

Key domains that distinguish *pragmatic* from *explanatory* trials

- *The eligibility criteria for trial participants.*
- *The flexibility with which the experimental intervention is applied.*
- *The degree of practitioner expertise in applying and monitoring the experimental intervention*
- *The flexibility with which the comparison intervention is applied.*
- *The degree of practitioner expertise in applying and monitoring the comparison intervention*

A pragmatic–explanatory continuum indicator summary (PRECIS): a tool to help trial designers. Thorpe et al. Can. Med. Assoc. J., May 2009; 180: E47 - E57

Key domains that distinguish *pragmatic* from *explanatory* trials

- *The intensity of follow-up of trial participants.*
- *The nature of the trial's primary outcome.*
- *The intensity of measuring participants' compliance with the prescribed intervention, and whether compliance-improving strategies are used.*
- *The intensity of measuring practitioners' adherence to the study protocol, and whether adherence-improving strategies are used.*
- *The specification and scope of the analysis of the primary outcome.*

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The eligibility criteria for trial participants

- *As one moves toward a more explanatory attitude additional restrictions will be placed on the study population applying various exclusion criteria to filter out participants thought least likely to respond to the intervention*

A pragmatic–explanatory continuum indicator summary (PRECIS): a tool to help trial designers. Thorpe et al. Can. Med. Assoc. J., May 2009; 180: E47 - E57

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The nature of the trial's primary outcome

☞ Choice of clinically relevant outcomes measures

Outcomes as mortality might not be relevant to very elderly patients, more relevant endpoints could include physical handicap, cognitive function or quality of life

Neurology in the elderly: more trials urgently needed
R. Lindley, The Lancet Neurology, November 2009

Federal Coordinating Council for Comparative Effectiveness Research
Report to the President and the Congress

June 30, 2009



Rationale for Comparative Effectiveness Research

- *When patients ask clinicians about the evidence supporting one treatment choice, diagnostic plan, or prevention modality over another, the answer too often is that the evidence is unclear.*
- *Even when evidence exists, it is often from a trial that may not apply to the specific patient and/or situation under consideration, such as an elderly African-American woman with multiple comorbidities.*
- *When specific evidence is lacking, clinicians have to rely on their clinical experience to make the best treatment decisions possible. Nevertheless, these decisions can result in less than optimal, and sometimes inappropriate, treatment choices.*

***Recommendations for research
priorities in breast cancer by the
Coalition of Cancer Cooperative Groups
Scientific Leadership Council: systemic
therapy and therapeutic
individualization***

***Sparano JA, Hortobagyi GN, Gralow JR,
Perez EA, Comis RL***

Breast Cancer Res Treat. 2009 Jun 14

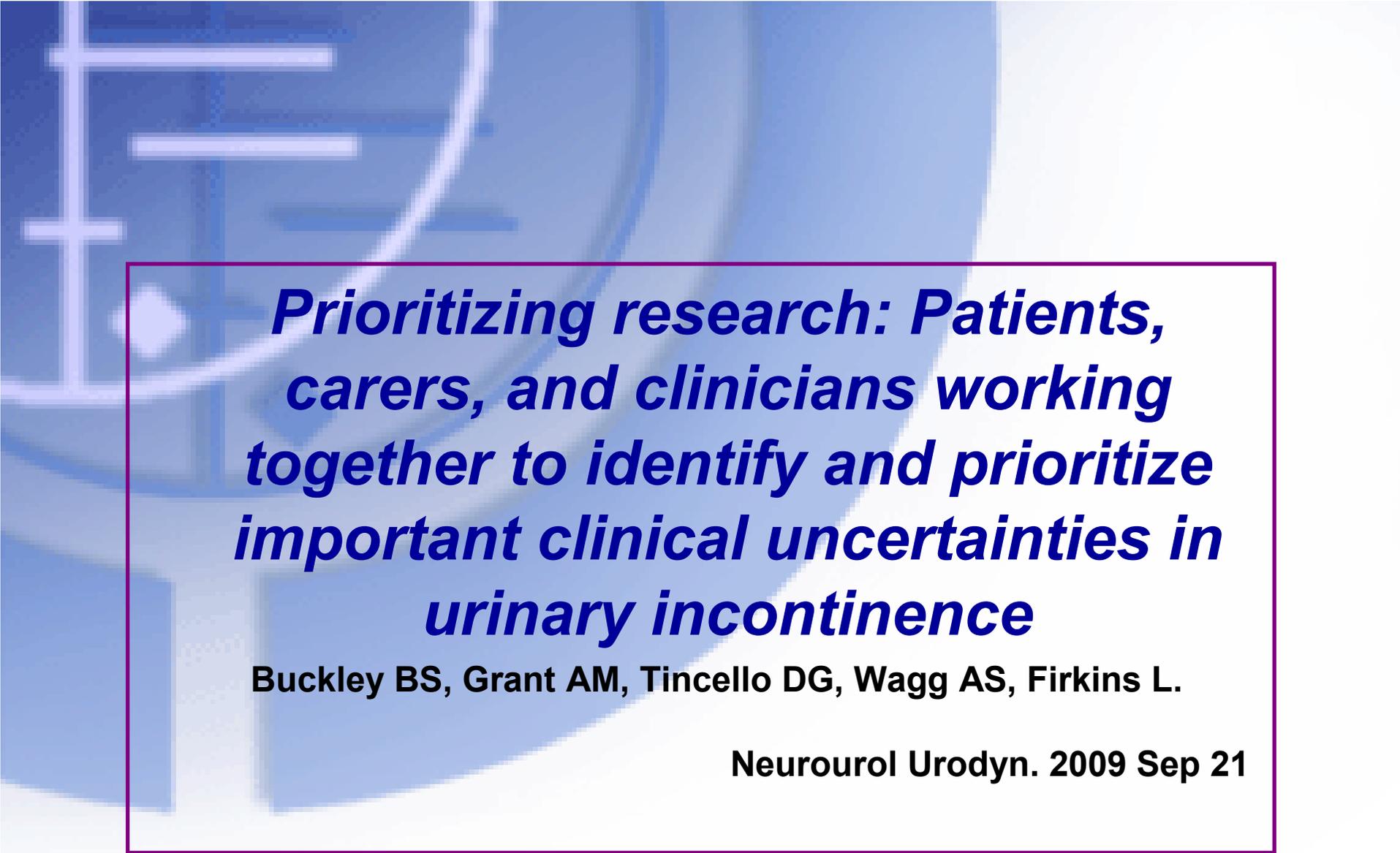
Workshop Reports

***Research priorities in epilepsy for the
next decade—A representative view of
the European scientific community:***

***Summary of the ILAE Epilepsy
Research Workshop, Brussels,
17–18 January 2008***

Michel Baulac and Asla Pitkänen

Epilepsia 2009, 50:571-583



***Prioritizing research: Patients,
carers, and clinicians working
together to identify and prioritize
important clinical uncertainties in
urinary incontinence***

Buckley BS, Grant AM, Tincello DG, Wagg AS, Firkins L.

Neurourol Urodyn. 2009 Sep 21



Welcome to the James Lind Alliance website

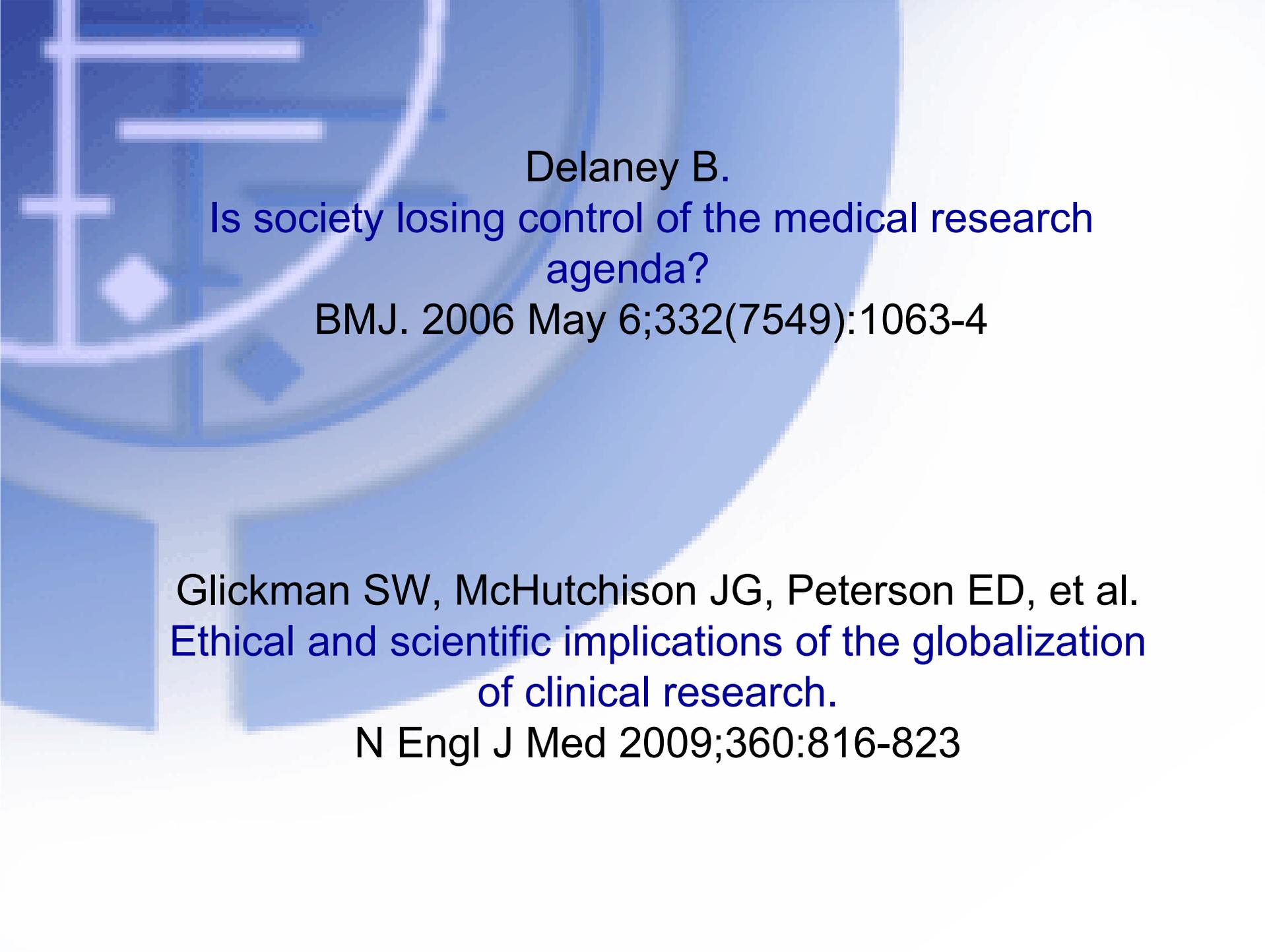
- Despite the vast amount of research on the effects of treatments in health care, many uncertainties remain. The **James Lind Alliance** aims to identify the most important gaps in knowledge about the effects of treatments, and has been established to bring patients and clinicians together in '**Priority Setting Partnerships**' to identify and prioritise the unanswered questions that they agree are most important. This information will help ensure that those who fund health research are aware of what matters to patients and clinicians.
- The James Lind Alliance is a non-profit making initiative, being developed under the direction of a broadly-based **Strategy and Development Group**. Its Secretariat is funded by **the Medical Research Council** and the **Department of Health**

Ed ancora...

- Sproporzione degli investimenti nella ricerca medica a favore di quella farmacologica

Necessità di studi su...

- Procedure chirurgiche
- Interventi complessi
- Cambiamenti degli stili di vita
- Accuratezza diagnostica



Delaney B.

Is society losing control of the medical research
agenda?

BMJ. 2006 May 6;332(7549):1063-4

Glickman SW, McHutchison JG, Peterson ED, et al.
Ethical and scientific implications of the globalization
of clinical research.

N Engl J Med 2009;360:816-823

The Cochrane Collaboration
The reliable source of evidence in health care



**THE COCHRANE
COLLABORATION®**

Quali sono i limiti?

- Mancanza di un esplicito processo di prioritarizzazione
- Quesiti talora troppo “atomizzati”
- “Qualità” non sempre ottimale
- Formato di presentazione “ostico”

Alessandro Liberati
Centro Cochrane Italiano
Convegno AIE di Primavera
Roma, Maggio 2009

Grazie per essere intervenuti!

anche a nome del

Cochrane Neurological Network

Teresa Anna Cantisani

Maria Grazia Celani

Alfonso Ciccone

Mariolina Congedo

Cristina Cusi

Kathrin Mahan

Cristina Motto

Enrico Righetti

Rudolf Schonoeuber



Regione Umbria