



Use of Cochrane review results in designing new studies

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Acknowledgements to: David Jones, Alex Sutton

CONTEXT

- The importance of systematic review & meta-analysis is widely acknowledged for identifying gaps in the evidence base & providing a quantitative basis for informing new research initiatives.
- BUT little is known about what actually happens in practice.

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MRC Medical Research Council

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Grants for Trials (Including Clinical Trials) and Intervention Studies

To provide support for trials to provide high quality evidence on the efficacy and effectiveness of interventions in medicine and health services.

Objectives

The MRC recognises the importance of trials as tools to provide high quality evidence on efficacy and effectiveness of interventions in medicine and the health services. It also recognises the complexity of designing, co-ordinating and monitoring trials and the importance of incorporating their results into practice. The focus of the MRC's support is based primarily on:

- trials that break new ground in terms of research questions or methodologies.
- trials that add significantly to our understanding of biological or behavioural mechanisms and processes in humans

The MRC's focus is **not** in:

- confirmatory studies or trials of interest to existing health technologies.
- trials focused on efficacy or management

Key features

An underlying principle behind the MRC approach to funding trials is that they should be fully developed and costed (as far as is reasonably practicable) before they are allowed to start, and that progress should be monitored and evaluated throughout the lifetime of the trial.

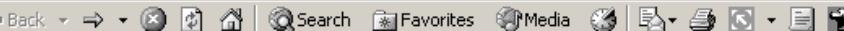
Potential applicants are encouraged to conduct a systematic review of the available evidence (where a recent such review does not already exist); and also preferably a pilot or feasibility study before applying for a grant for a full trial.

The MRC recognises the importance of maintaining rigorous standards of trial management in order to ensure patient safety and maximise the chances of a trial finishing on time and to budget.

EAA Electronic Application & Assessment

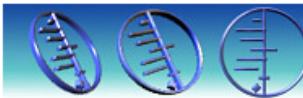
OBJECTIVE

- To assess how the results of systematic reviews are used in the designing of new studies.
- In particular, the use of Cochrane systematic reviews of randomised controlled trials of medical interventions.

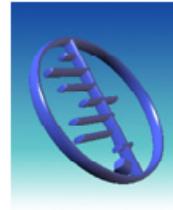


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* Comprises 2170 Complete Reviews and 1500 Protocols

In-hospital care pathways for stroke

J Kwan and P Sandercock

The Cochrane Database of Systematic Reviews 2004 Issue 4 (Status: *Updated*)
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Background Stroke care pathways have the potential to promote organised and efficient patient care that is based on best evidence and guidelines, but evidence to support their use is unclear.

Objectives We aimed to assess the effects of care pathways, compared with standard medical care, among patients with acute stroke who had been admitted to hospital.

Search strategy We searched the Cochrane Stroke Group Trials Register (last searched in June 2003), the Cochrane Central Register of Controlled Trials (The Cochrane Library, Issue 2, 2003), MEDLINE (1975 to June 2003), EMBASE (1980 to June 2003), CINAHL (1982 to June 2003), ISI Proceedings: Science & Technology (1990 to November 2003), and HealthSTAR (1994 to May 2001). We also handsearched the Journal of Integrated Care Pathways (2001 to 2003), formerly Journal of Managed Care (1997 to 1998) and Journal of Integrated Care (1998 to 2001). Reference lists of articles were searched.

Selection criteria We compared care pathways with standard medical care.

Data collection and analysis All studies were independently assessed.

Main results Three randomised controlled trials (RCTs) were included. There was no statistical heterogeneity between the trials in terms of death or disability at 3 months. (a) patients who suffered a stroke and were admitted to hospital (n = 111) had a 3-month mortality of 0.03 to 0.39); and (d) mortality, quality of life, patient satisfaction and quality of care.

Reviewers' conclusions Use of stroke care pathways may be associated with positive and negative outcomes. As the trials were derived from non-randomised studies, they are likely to be influenced by potential biases and confounding factors. There is currently insufficient supporting evidence to justify the routine implementation of care pathways for acute stroke management or care.

Synopsis The effects of using care pathways to manage people admitted to hospital with stroke are not clear.

Care in a hospital stroke unit can reduce the risks of death and disability after stroke. Care pathways aim to promote organised and efficient patient care based on the best evidence and guidelines. The review found that patients treated within a care pathway may be less likely to experience complications (e.g. urine infections), and more likely to have certain tests (e.g. brain scans). However, the use of care pathways may also reduce the patient's likelihood of functioning independently when discharged from hospital, their quality of life, and their satisfaction with hospital care. Currently, there is not enough evidence to justify introducing care pathways for the routine care of all patients with stroke. Further research is needed to find out if care pathways for stroke do more good than harm.

“Currently, there is not enough evidence to justify introducing care pathways for the routine care of all patients with stroke. Further research is needed to find out if care pathways for stroke do more good than harm.”

Current evidence is currently insufficient

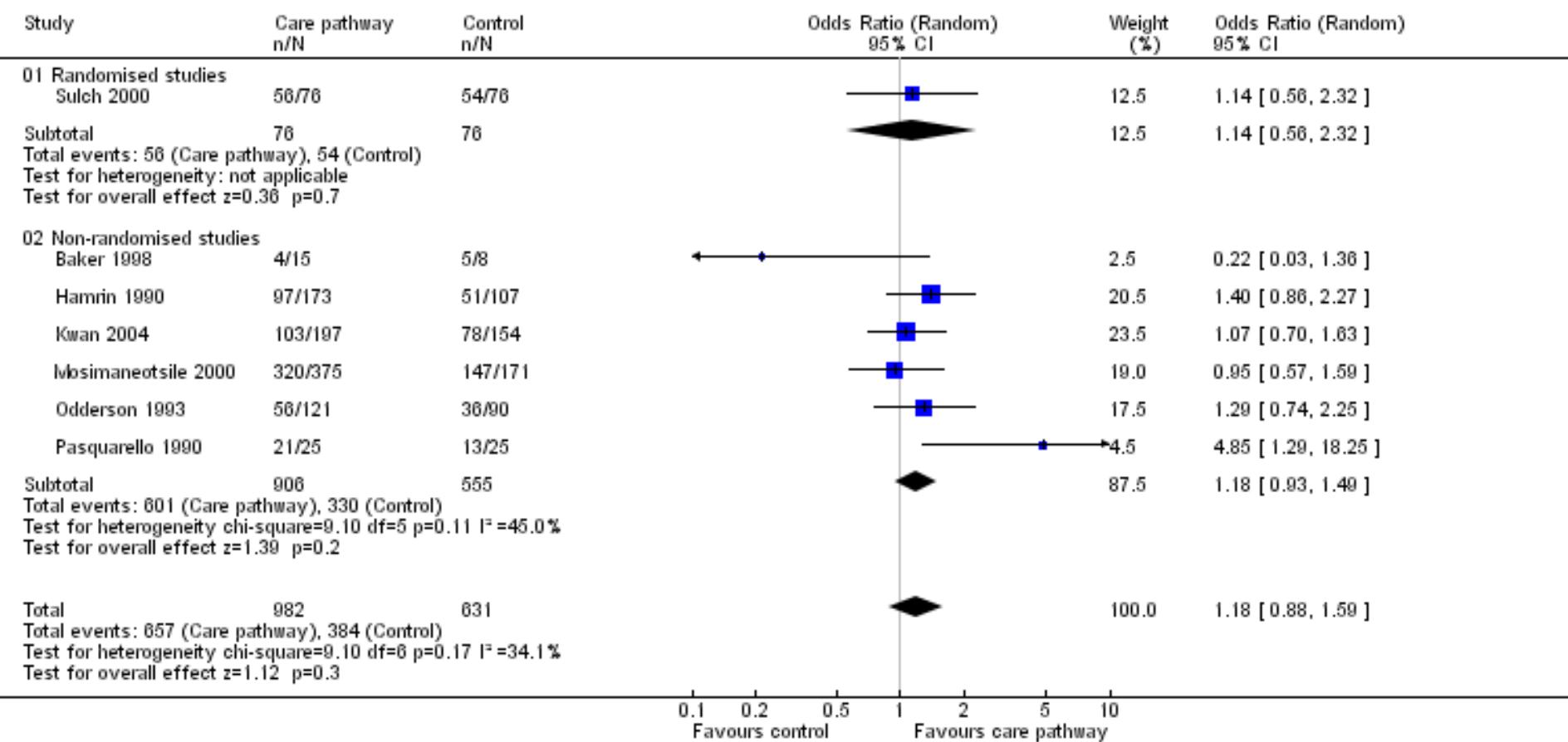
efficient patient

care pathways offer some

benefits but have been

In-hospital care pathways for stroke (cont.)

Review: In-hospital care pathways for stroke
 Comparison: 01 Care pathway care versus standard care
 Outcome: 07 Discharged to home



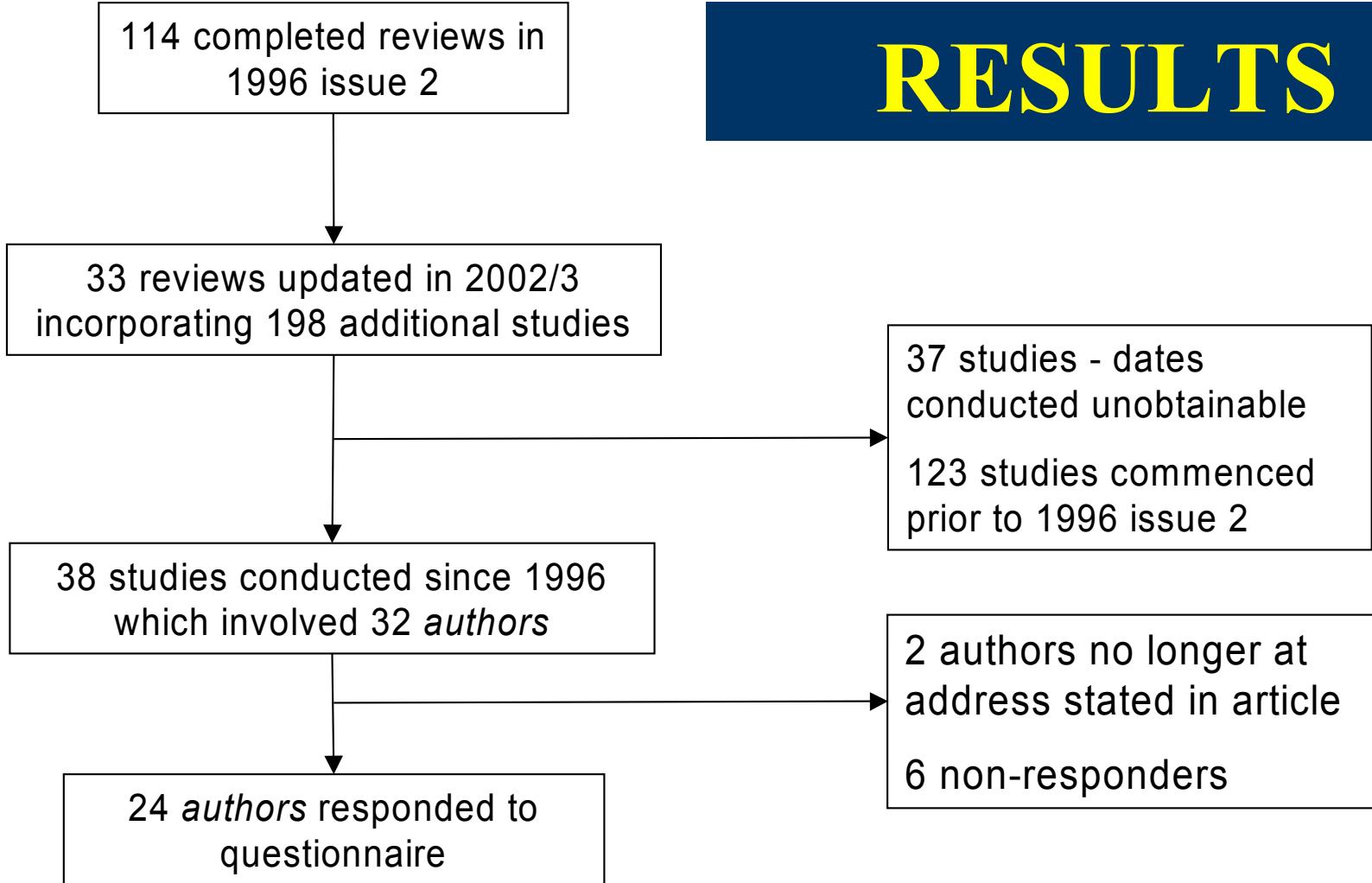
METHODS

- Of all Cochrane reviews published in 1996, those *updated* in 2002 or 2003 were identified.
- Authors of trials added in the *updated* systematic reviews, and conducted *after* 1996, were contacted via e-mail or post & asked the following 2 questions:

METHODS

- 1) When you were writing the protocol for the above trial, was the study design influenced by a published review of the current evidence at the time (for example, a meta-analysis)? If yes, please provide a reference(s) to the published review used.
- 2) At the time of designing the above study were you aware of the review in this area on the Cochrane Database of Systematic Reviews?

RESULTS



RESULTS

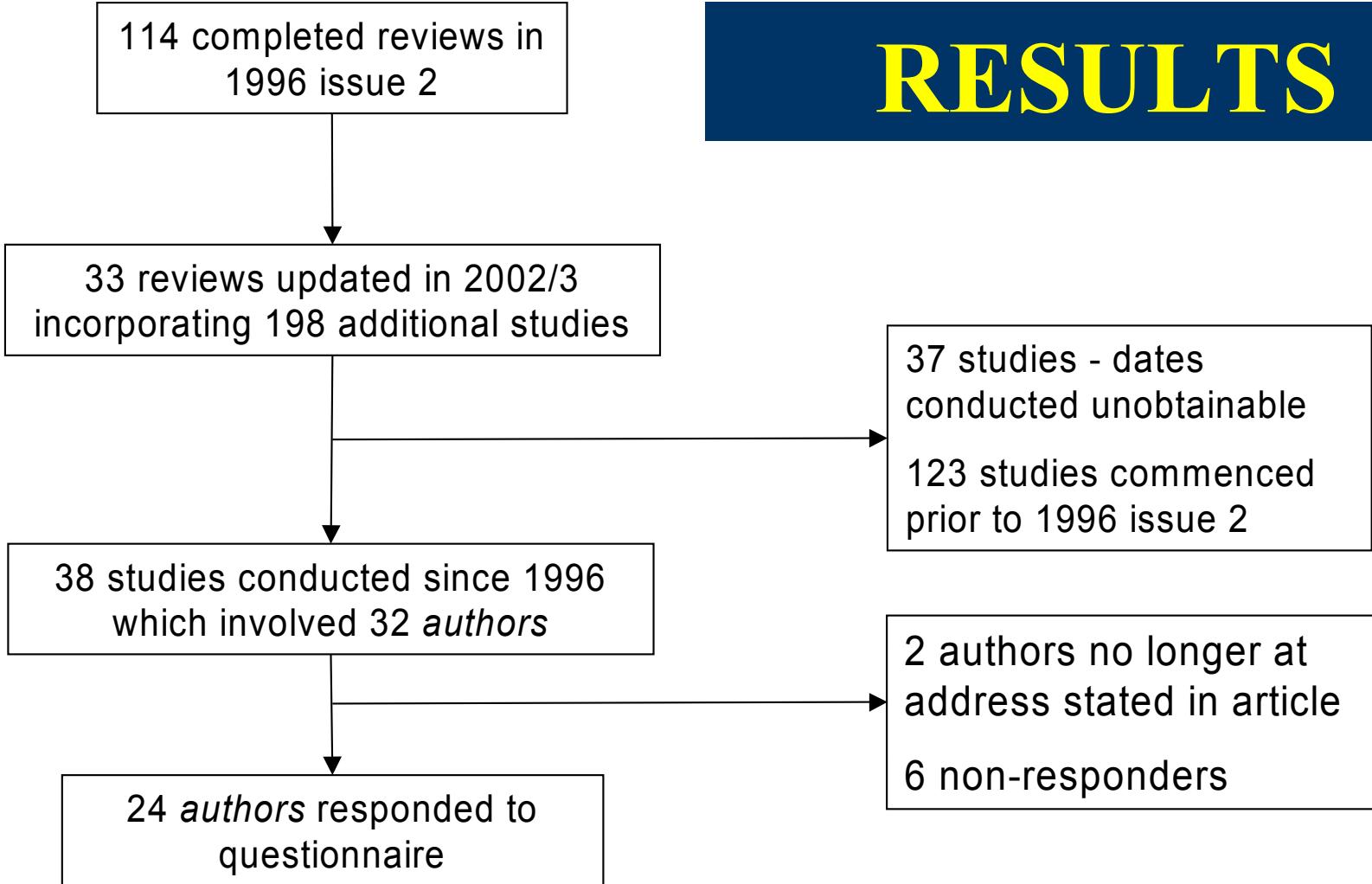
Question 1: Was design of the new study influenced by a review?

Yes	No	No, but trial results used	Other
8 (33%)	6 (25%)	7 (29%)	3 (13%)

Question 2: Was the investigator aware of a relevant Cochrane review?

Yes	No	No, design stage pre-dated review	Other
11 (46%)	7 (29%)	2 (8%)	4 (17%)

RESULTS



CONCLUSION

- Proportion of study investigators using Cochrane or other systematic reviews in designing their new studies was very limited.
- Inclusion of encouragement in publication or application guidelines to consider and cite review results is desirable (MRC already request this).

CRITIQUE OF OUR STUDY

- Life cycle of conception, development, conduct & reporting of a trial often extends over several years, therefore possible that trials that commenced after 1996 were designed prior to the Cochrane review of 1996.
 - Although, by concentrating on updates in the most recent reviews, we allowed a minimum of more than 5 years between publication of the 1996 review & the critical date for inclusion of a new trial in the later reviews considered.
- Early versions of the Cochrane library (including 1996 issue 2) may be atypical of more recent versions due to, for example, a higher proportion of reviews from the Pregnancy & Childbirth group.

FURTHER WORK

- Little formal methodology developed on how to use previous evidence when designing a new study.
- Is the updated systematic review/meta-analysis of more interest than the new individual study results?
- Methods to estimate study power based on the updated meta-analysis in development