

# Applied HealthCare Research: How to Get Started

## 10 components of effective clinical epidemiology



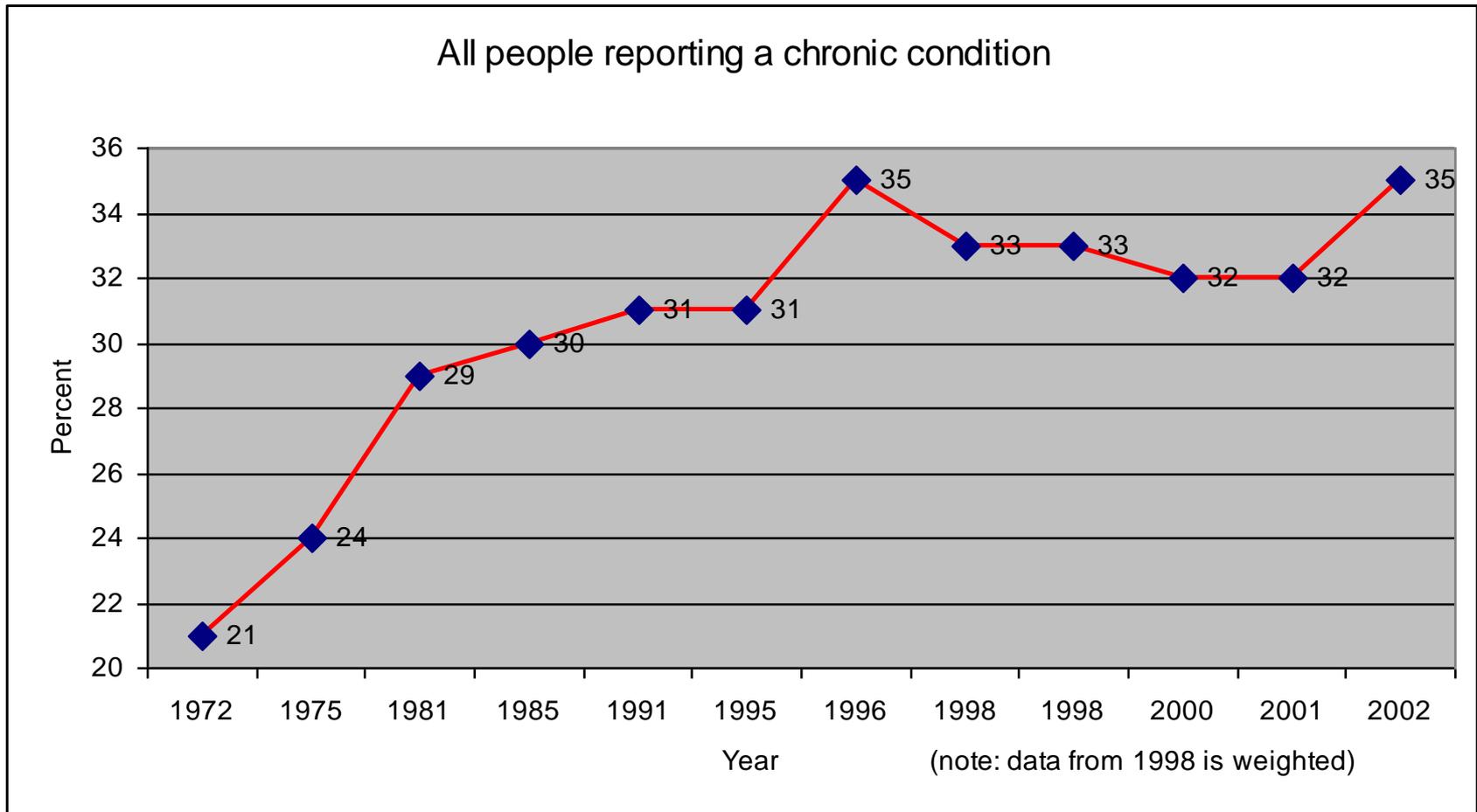
Carl Heneghan

Professor of Evidence-Based Medicine &  
Director CEBM

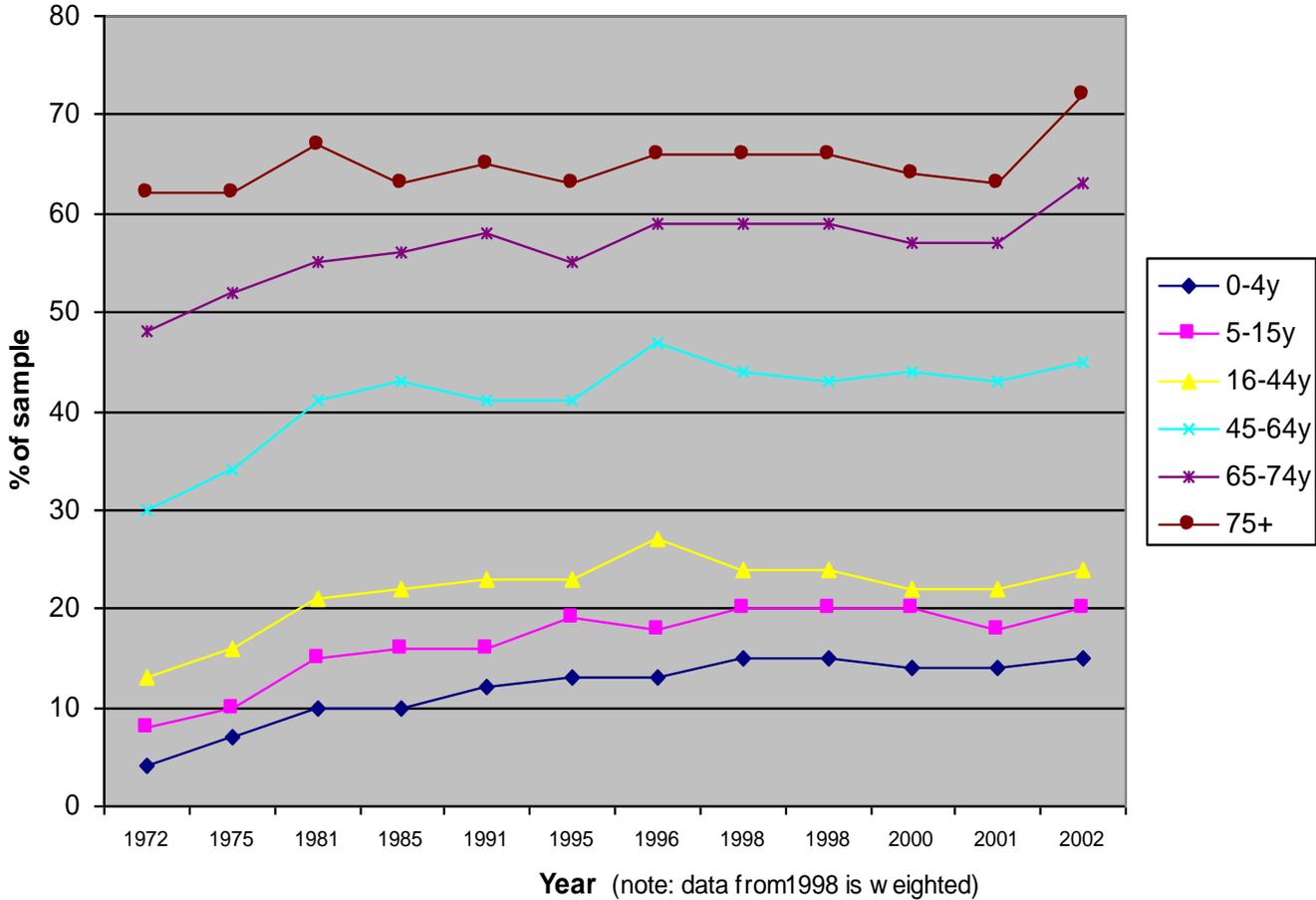
University of Oxford

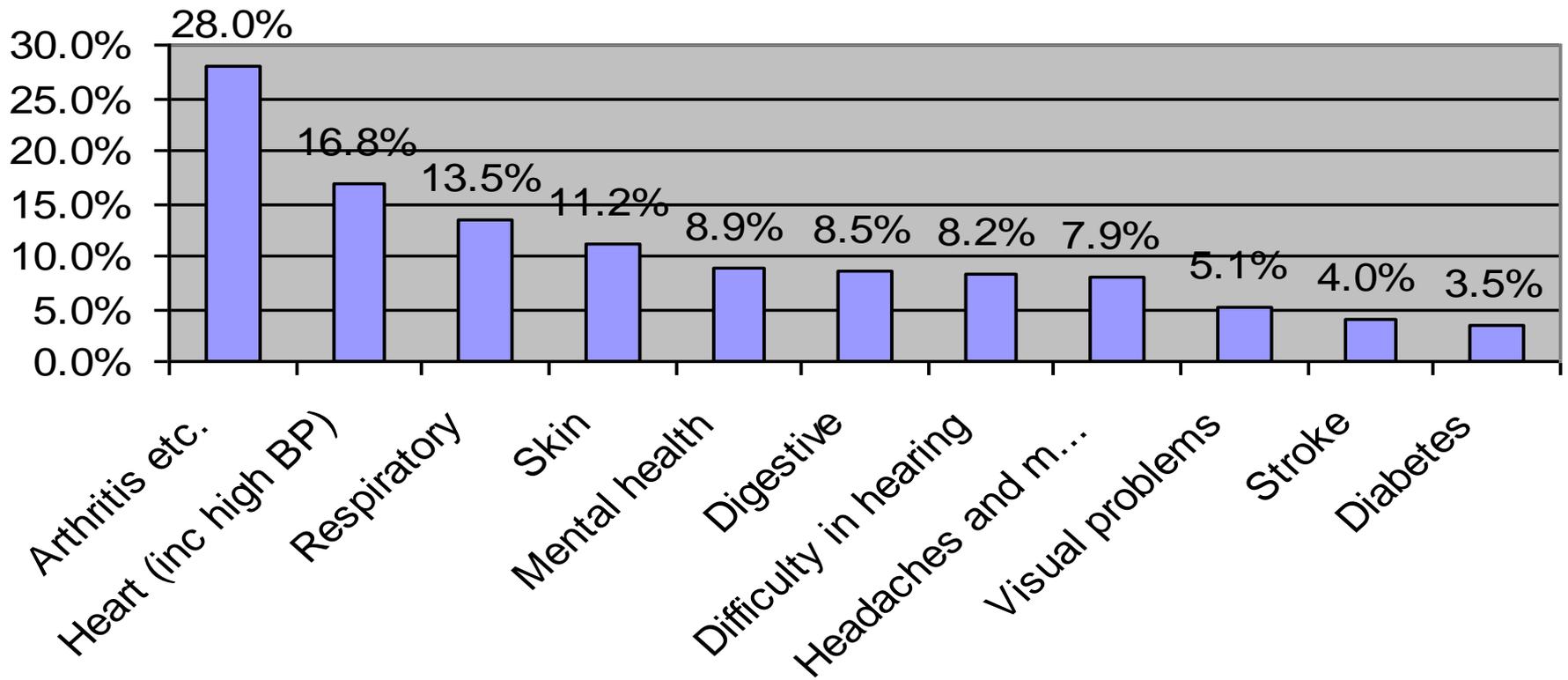


# 1. What's the problem that interests you?



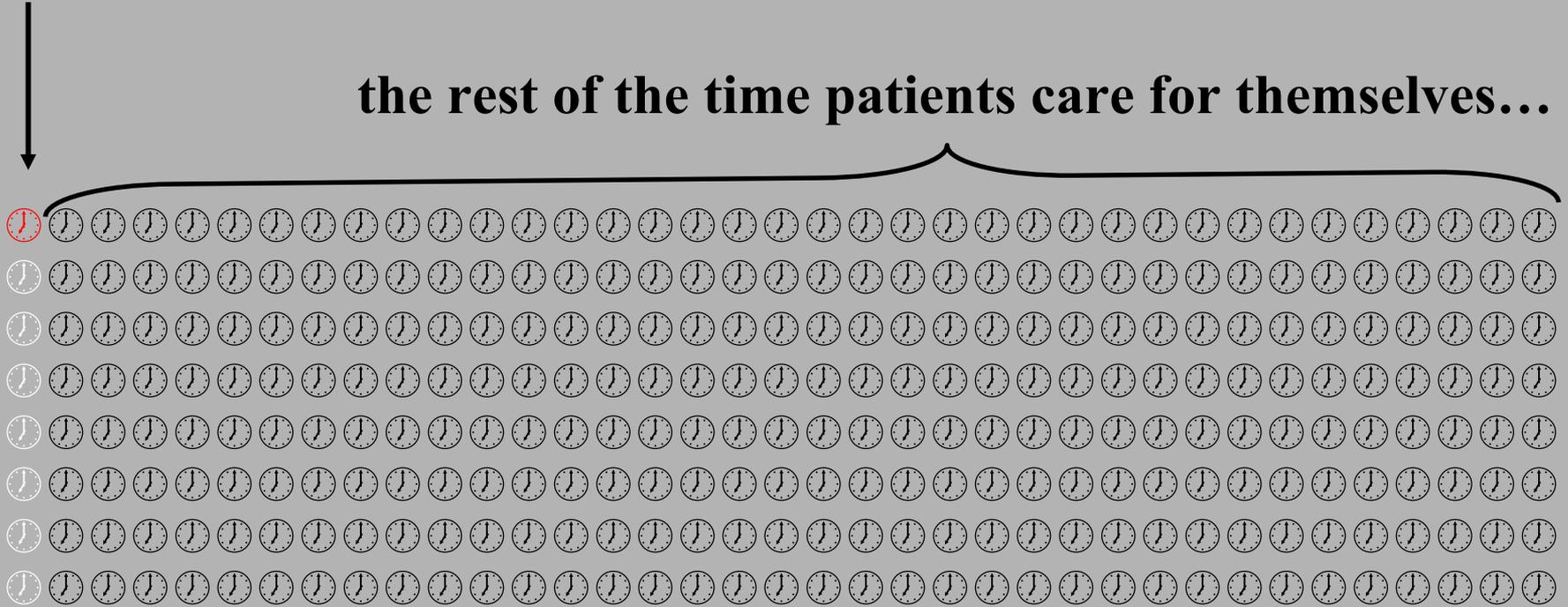
# People reporting a chronic condition (by age)



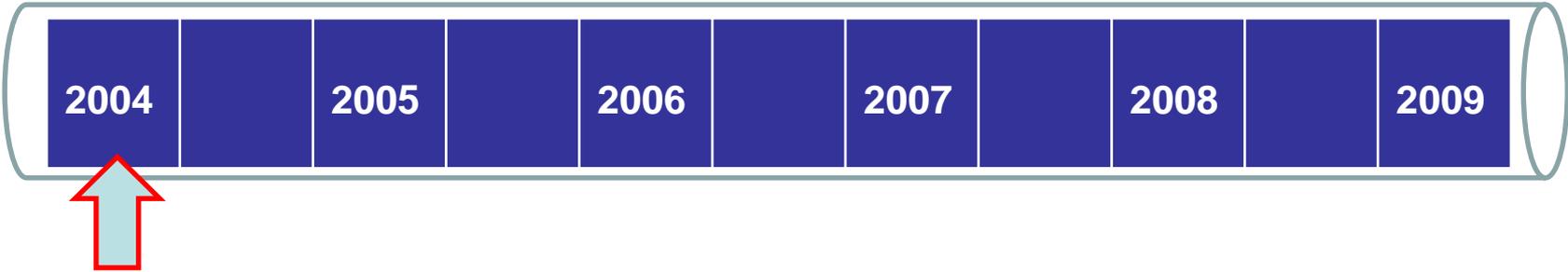


**Health care professionals may only interact with people with a chronic disease for a few hours a year...**

**the rest of the time patients care for themselves...**



# How to get started



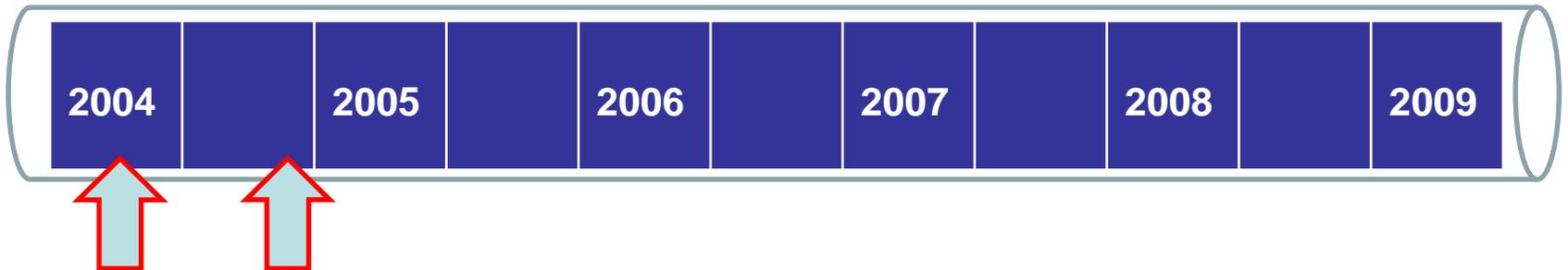


## 2. Systematic overview of the field

### **ROYAL COLLEGE OF GENERAL PRACTITIONERS SCIENTIFIC FOUNDATION BOARD**

**Title of Project: What is the impact of self-monitoring in chronic disease management? A systematic overview**

The aim is to identify the effects and components of currently evaluated self-monitoring methods relevant to general practice. We will undertake a systematic overview of current research.



heart-failure-workbook1 [Compatibility Mode] - Microsoft Excel

Home Insert Page Layout Formulas Data Review View Developer

Clipboard Font Alignment Number Styles Cells Editing

K5 Regular

Heart failure management programmes and component interventions														
Study	Sample size	Population	Mean age	Key components of Intervention	Monitoring components									
					Weight	oedema	BP	HR	Signs & Symptoms	Telephone contact	Telemonitoring	Video-monitoring	Self management strategy	Other
Hanchett 1967	239	Patients with HF attending specialty clinic US	60-69 median	Nurse-led patient education, regular telephone contact, regular home/clinic visits							Regular			
Rich 1993	98	> 70 yrs with HF discharged from hospital, moderate or high risk for readmission US	79	Nurse-led patient education, dietary and social services consultation, review of medications by geriatric cardiologist, and intensive follow-up at home by study team	Daily				education	Regular			To contact personnel if weight gain greater than 3-5 lbs	Compliance recommendations, Sodium restriction, discharge card written instruction and medication schedules
Naylor 1994	276 (142 with CHD or HF)	Patients > 70 yrs discharged from a tertiary care hospital with either CHD or HF US	76	Discharge planning protocol with gerontologic nurse providing education, coordinating care, and maintaining telephone contact. APN, in collaboration with the patient's physician, to individualize					education	maintained contact 2 weeks after discharge				
Kostis 1994	60	Patients with CHF NYHA-II or III, US		Non-pharmacologic treatment program: (1) graduated exercise training; (2) structured cognitive therapy and stress management; (3) dietary intervention aimed at salt reduction and weight										
Rich 1995	282	> 70 yrs with HF discharged from hospital at high risk for readmission US	79	Nurse-led patient education, dietary and social services consultation, review of medications by geriatric cardiologist, and intensive follow-up at home by study team										Dietary assesment
Weinberger 1996	1396 (504 with HF)	Patients discharged from the general medicine service with HF, diabetes mellitus, or COPD	63	Primary care nurse provided educational materials and coordinated care between discharge and outpatient clinics, regular telephone follow-up, primary care physician follow-up within 7 days of						regular contact				Patient card with telephone numbers, reminders of appt
Oddone 1996	443	443 from the 504 patients in the Weinberger study CHF and LVEF < 40%	65(10)	Measurements of daily weight, diuretic adjustment, medication review, increased communication between providers, prescheduled clinic appointments during 6mo after discharge	Daily				Education				Individual guidelines for weight change that triggered a phone call to their physician or nurse	

Page 1

Sheet1 Sheet2 Sheet3

Ready 80%

## Review Article

# Overview of Systematic Reviews: Yoga as a Therapeutic Intervention for Adults with Acute and Chronic Health Conditions

Marcy C. M

<sup>1</sup> Department of

<sup>2</sup> Department of

<sup>3</sup> Bodleian Hea

Corresponden

Received 20 D

Google Scholar

Overview of systematic reviews: Yoga as a therapeutic intervention for adults with acute and chronic health conditions [PDF] from hindawi.com Find it @ Oxford

Authors: Marcy C McCall, Alison Ward, Nia W Roberts, Carl Heneghan  
Downloaded from <http://bmjopen.bmj.com/> on January 7, 2016 - Published by [group.bmj.com](http://group.bmj.com)

Publication date: 2013/5/11

Journal: Evidence-Based Complementary and Alternative Medicine

Volume: 2013

Publisher: Hindawi Publishing Corporation

Description: Objective treatment searched searches as a prim The AMS

Total citations: Cited by: 1



Year	Citations
2013	1
2014	2

Open Access

Protocol

## BMJ Open Protocol for an overview of systematic reviews of interventions to reduce unscheduled hospital admissions among adults

Niklas Bobrovitz,<sup>1</sup> Igho Onakpoya,<sup>1</sup> Nia Roberts,<sup>2</sup> Carl Heneghan,<sup>1</sup> Kamal R Mahtani<sup>1</sup>

**To cite:** Bobrovitz N, Onakpoya I, Roberts N, *et al.* Protocol for an overview of systematic reviews of interventions to reduce unscheduled hospital

### ABSTRACT

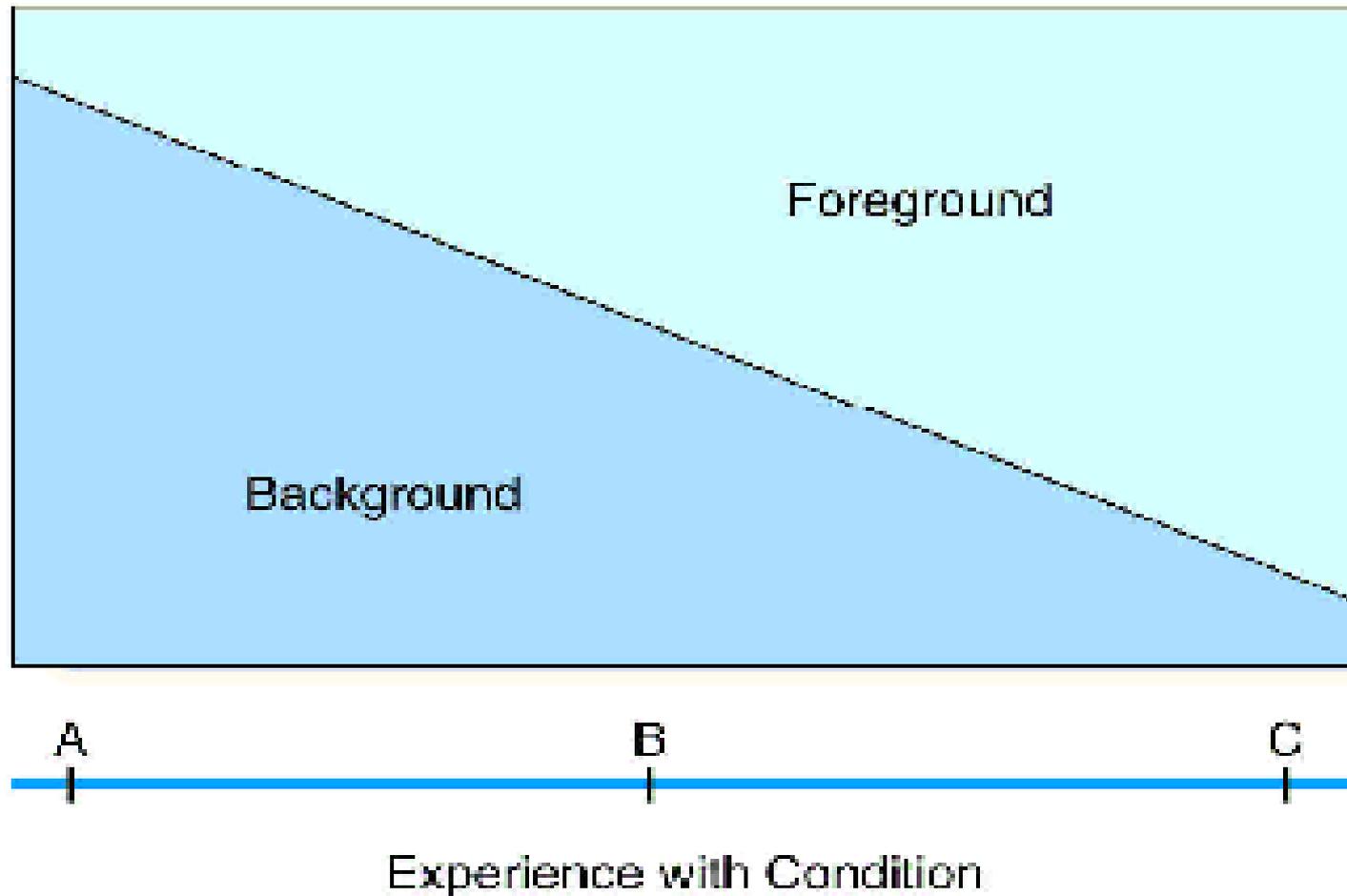
**Introduction:** Unscheduled hospital admissions are an increasing burden on health systems worldwide. To date, initiatives to reduce admissions have had limited success as it is unclear which strategies

### Strengths and limitations of this study

- We are using a novel methodology to hierarchically rank interventions to reduce unscheduled admissions.

### 3. Defining the question – the hardest bit

Figure 1.1 Background and foreground questions.



# Patient presenting with MI

## Foreground' Questions

About actual patient care decisions and actions

For treatment

4 (or 3) components:

In **P**atients on oral anticoagulation

Does (**I**) self testing

**C**ompared to usual care

reduce thrombosis (**O**)

# (7 Types of questions)

1. How common is the problem	Prevalence	<b>PO</b>
2. Is early detection worthwhile	Screening	<b>PICO</b>
3. Is the diagnostic test accurate	Diagnosis	<b>PICO</b>
4. What will happen if we do nothing	Prognosis	<b>PO</b>
<b>5. Does this intervention help</b>	<b>Treatment</b>	<b>PICO</b>
6. What are the common harms of an intervention		<b>PICO</b>
7. What are the rare harms of an intervention		<b>PICO</b>

## Box 1

### FINER criteria for a good research question

#### F Feasible

- Adequate number of subjects
- Adequate technical expertise
- Affordable in time and money
- Manageable in scope

#### I Interesting

- Getting the answer intrigues investigator, peers and community

#### N Novel

- Confirms, refutes or extends previous findings

#### E Ethical

- Amenable to a study that institutional review board will approve

#### R Relevant

- To scientific knowledge
- To clinical and health policy
- To future research

Adapted with permission from Wolters Kluwer Health.<sup>2</sup>

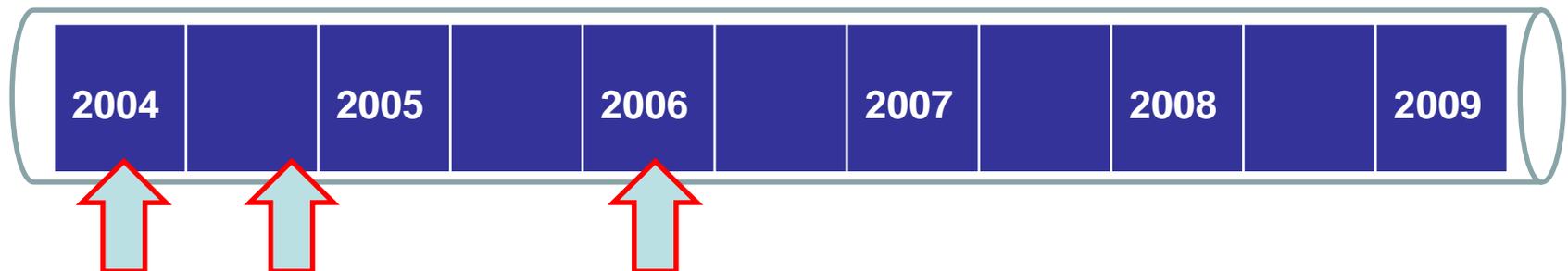
## 4. Start and end with a systematic review



NIHR DRF 2015 Guidance Notes

### Points to consider when preparing an NIHR TCC Training Fellowship Application

NIHR will only fund primary research\* where the proposed research is informed by a review of the existing evidence.



## Articles

# Self-monitoring of oral anticoagulation: a systematic review and meta-analysis

Dr [C Heneghan](#), MRCGP  , [P Alonso-Coello](#), MD, [JM Garcia-Alamino](#), RN, [R Perera](#), PhD, [E Meats](#), BSc, Prof [P Glasziou](#), FRACGP

Altmetric  7

DOI: [http://dx.doi.org/10.1016/S0140-6736\(06\)68139-7](http://dx.doi.org/10.1016/S0140-6736(06)68139-7)



### Article Info

© 2006 Elsevier Ltd. All rights reserved.

This article can be found in the following collections: [Cardiology & vascular-other](#)

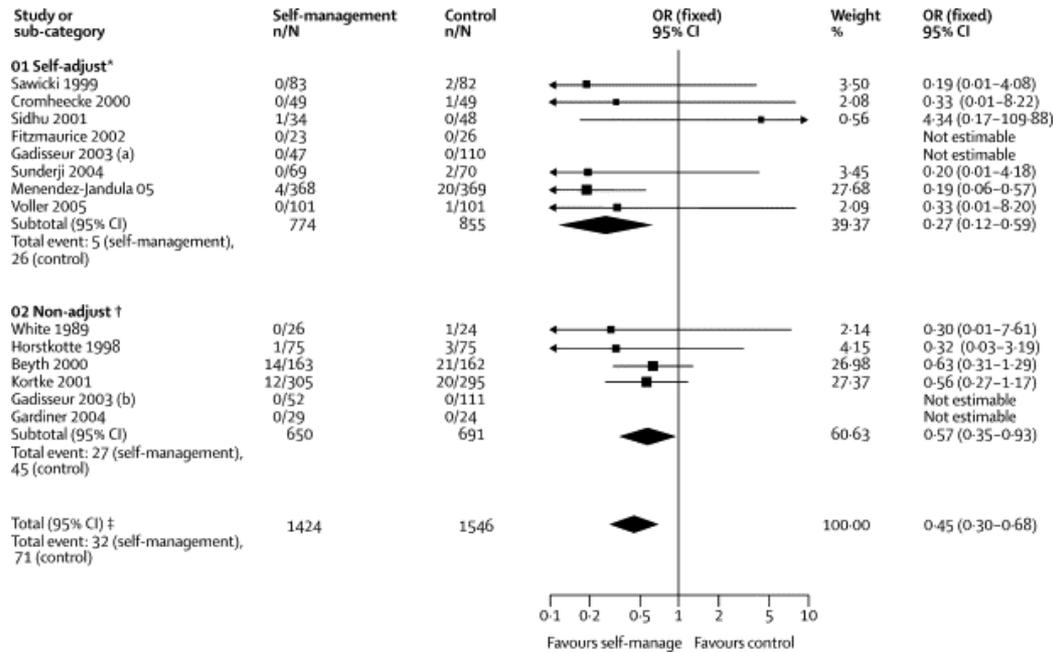
Summary

Full Text

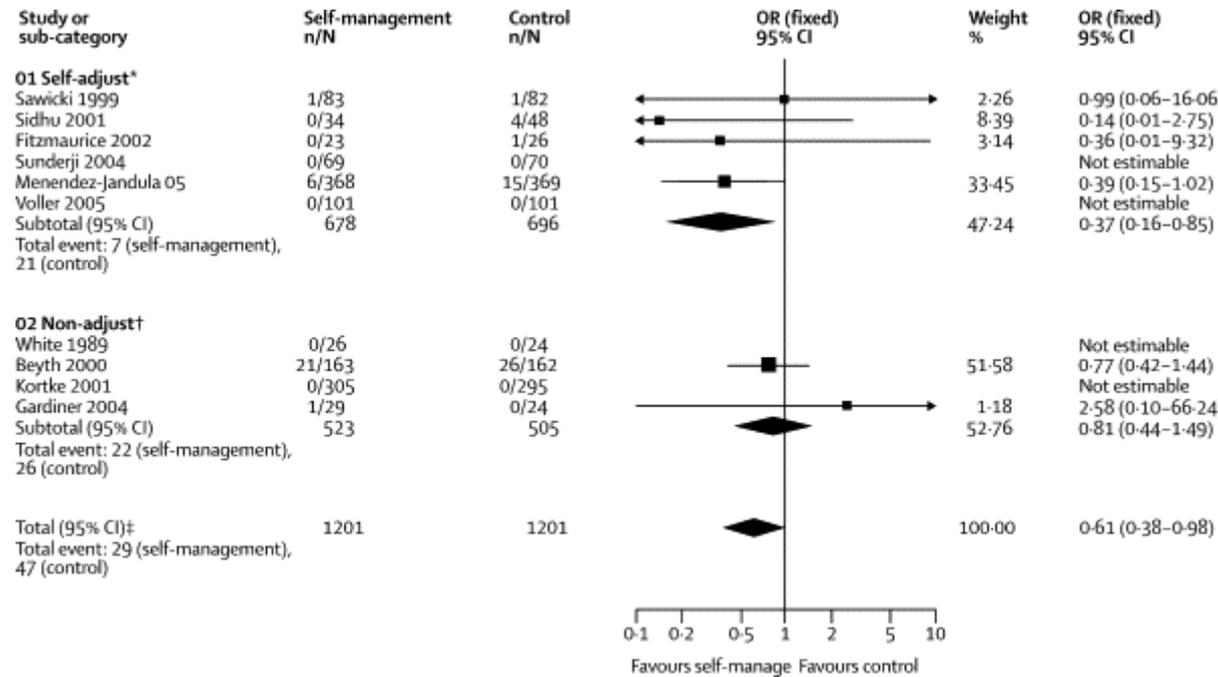
Tables and Figures

References

## Summary



Self-monitoring & thromboembolic events  
OR 0.45 (0.30-0.68)



Self-monitoring & death  
OR 0.61 (0.38 to 0.98)

# 5. Identify gaps in your skills

## Clinical Epidemiology for the uninitiated

Skills Level	Score
No idea of the skill	1
Heard of the skill and would be able to undertake basics	2
Could undertake the skill but would require considerable help	3
Could undertake the skill requiring input only for the most difficult tasks	4
Can teach the skill	5

## 6. Develop further research questions –

### **Delivering safe and effective anticoagulation for patients – further questions**

1. Which subgroups benefit from self-monitoring?
2. Can you replicate trial results in practice?
3. How useful is time in range as a predictor of adverse events?
4. Can we predict successful self monitoring of anticoagulation at the outset?

# Which subgroups benefit from self-monitoring?

## Executive Summary Prevention of Thromboembolic Events: The Role of Point of Care Management

David Fitzmaurice<sup>1</sup>, Dieter Horstkotte<sup>2</sup>

<sup>1</sup>Department of Primary Care and General Practice, The University of Birmingham, Birmingham, UK, <sup>2</sup>Department of Cardiology, Heart and Diabetes Center North Rhine-Westphalia, Ruhr University Bochum, Bad Oeynhausen, Germany

The Journal of Heart Valve Disease 2007;16:184-186

The Infection, Thrombosis, Embolism and Bleeding Working Group of the Society for Heart Valve Disease (SHVD) held an International Symposium and Workshop, in Berlin, from 28th to 30th September 2006. A total of 80 participants was involved, with attendees from around Europe, Israel and the United States. A range of topics were discussed, from the organization of oral anticoagulation clinics in different countries to

*Sessions II and III* were interactive workshops on the development of registries for valvar patients receiving oral anticoagulation and patient training for self-management of oral anticoagulation. Data were presented from the UK training model, with points of contention discussed between agreement regarding with most countr

the introduction of these devices for patients at high risk of valve failure, for example, in the first few months following surgery, or in pregnant women.

*Sessions IX and X* focused on the developments of new POC devices for oral anticoagulation management, including the INRatio (S. Testa, Cremona, Italy), PROTIME (U. Taborski, Ludwigshafen, Germany), SmartCheck (H. Kamlah, Dannenfels, Germany), and the CoaguChek XS (B. Piso, Vienna, Austria). Two reports were made from Oxford, UK, providing data on a meta-analysis of published data for self-testing and management of oral anticoagulation (C. Heneghan), with a call for trialists to collaborate in an individual patient-level meta-analysis (R. Perera).

# 7. Look for methodological issues

## Can you replicate the trial results in practice?

BMJ 2008;336:1472-1474 (28 June), doi:10.1136/bmj.39590.732037.47

### Analysis

#### What is missing from descriptions of treatment in trials and reviews?

Paul Glasziou, professor of evidence based medicine<sup>1</sup>, Emma Meats, research assistant<sup>1</sup>, Carl Heneghan, senior clinical research fellow<sup>1</sup>, Sasha Shepperd, NIHR research scientist in evidence synthesis<sup>2</sup>

<sup>1</sup> Centre for Evidence-Based Medicine, Department of Primary Health Care, University of Oxford, Oxford OX3 7LF, <sup>2</sup> Department of Public Health, University of Oxford

#### What is missing from descriptions of treatment in trials and reviews?

Replicating non-pharmacological treatments in practice depends on how well they have been described in research studies, say Paul Glasziou and colleagues

Have you ever read a trial or review and wondered exactly how to carry out treatments such as a "behavioural intervention," "salt reduction," or "exercise programme"? Although CONSORT and related initiatives have focused on the assessment of validity and presentation of results,<sup>1 2</sup> less attention has been given to the adequacy of the description of the treatment used. For pharmacological treatments the description would need to include the dose, titration, route, timing, duration, and any monitoring used. For complex treatments the problems are even greater.

##### Why are full descriptions of treatment

receiving numerous requests for additional details from doctors and patients, the author of a randomised trial on graded exercise for chronic fatigue syndrome<sup>3</sup> subsequently published a supplementary article with a more detailed "prescription."<sup>4</sup> Similarly, it is not possible to set up a stroke unit, offer low fat diets, or give smoking cessation advice without sufficient details on the components that were planned and delivered.<sup>5</sup>

##### Extent of the problem

To assess the extent of problems with descriptions of treatment we prospectively assessed 80 consecutive studies selected for abstraction in the journal *Evidence-Based Medicine*

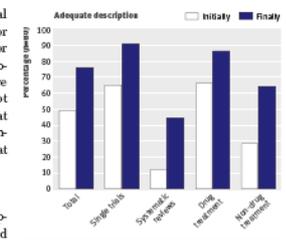


Fig 2 | Percentage of studies with sufficient description of treatment initially (based only on



# COMPARE

TRACKING SWITCHED OUTCOMES IN CLINICAL TRIALS

Outcome switching in clinical trials is a serious problem ([read why](#)). We are systematically checking every trial published in the top five medical journals, to see if they have misreported their findings.

First, we compare each clinical trial report against its registry entry. Some trials report their outcomes perfectly. For the others, we count how many of the outcomes specified in the registry were never reported. And we count how many outcomes were silently added.

Second, whenever we detect unreported or added outcomes, we write a letter to the journal pointing them out, so that readers are aware of the problems. We are tracking which journals have published our letters after 4 weeks - and which haven't (see [our approach](#)).

Here's what we've found so far. Our project is ongoing since October 2015, and these numbers are updated live.

66

TRIALS CHECKED TO  
DATE

9

TRIALS WERE PERFECT

355

OUTCOMES NOT  
REPORTED

336

NEW OUTCOMES  
SILENTLY ADDED

# How useful is time in range as a predictor of adverse events?



## Circulation

### Circulation: C Quality and

Anticoagulation control and prediction of adverse events in patients with atrial fibrillation a systematic review  
Yi Wan, Carl Heneghan, Rafael Perera, Nia Roberts, Jennifer Hollowell, Paul Glasziou, Clare Bankhead, and  
CIRCULATIONAHA



Carl Heneghan

Anticoagulation control and prediction of adverse events in patients with atrial fibrillation a systematic review

[\[HTML\]](#) from [ahajournals.org](#)  
Find it @ [Oxford](#)

Authors Yi Wan, Carl Heneghan, Rafael Perera, Nia Roberts, Jennifer Hollowell, Paul Glasziou, Clare Bankhead, Yongyong Xu

Publication date 2008/11/1

Journal Circulation: Cardiovascular Quality and Outcomes

Volume 1

Issue 2

Pages 84-91

Publisher Lippincott Williams & Wilkins

Description Methods and Results— We searched MEDLINE, EMBASE, and Cochrane through January 2008 for studies of atrial fibrillation patients receiving vitamin-K antagonists that reported INR control measures (percentage of time in therapeutic range [TTR] and percentage of INRs in range) and major hemorrhage and thromboembolic events. In total, 47 studies were included from 38 published articles. TTR ranged from 29% to 75%; percentage of INRs ranged from 34% to 84%. From studies reporting both measures, TTR significantly correlated with percentage of INRs in range ...

Total citations [Cited by 242](#)



# 8. Look for effects in real world populations

**School for Primary Care Research** Increasing the evidence base for primary care practice

National Health Service

Home News Who We Are Research Events Publications Our Staff Contact Us Links

**Individual patient meta-analysis of self-monitoring of oral anticoagulation: a systematic review protocol**

Theme: **Prevention, diagnosis, and management of haemorrhagic events**

Lead Contact(s): **Dr Carl Heneghan**

Other NIGPC staff participating: **Professor Paul Glasziou, FRACGP, MRCGP; Dr Alison Ward; Dr David Fitzmaurice; Professor David Fitzmaurice; Professor Jim Doust**

Collaborator(s): **P. Alonso-Castro, Centre Catalana d'Investigacio Biomèdica, Barcelona; J. Ayané, Department of Medicine, Boston University Medical Center; P. Byth, Cook Investigator, Shooka QUERI Center, University of Florida; Thomas Decker Christensen, Dept of Cardio Thoracic and Vascular Surgery, Aarhus University, Denmark; U. Dörflinger, Institute for Evidence Based Medicine, Cologne, Germany; J.M Garcia-Alamo.**

Date:

**Individual Patient Meta-Analysis of Self-Monitoring of an Oral Anticoagulation Protocol**

Rafael Perera<sup>1</sup>, Carl Heneghan<sup>1</sup>, David Fitzmaurice<sup>2</sup> and the IPD Working Group

<sup>1</sup>Department of Primary Health Care, University of Oxford, <sup>2</sup>Department of Primary Care and General Practice, University of Birmingham, UK

Background and aims of the study Oral anticoagulation with vitamin K antagonists is effective for the prevention and treatment of thromboembolic events. Recent systematic reviews have shown that self-monitoring improves the quality of oral anticoagulation therapy (OAT), with patients spending more time in the therapeutic range than traditionally treated patients, and with a concomitant decrease in the incidence of adverse events. However, methodological and reporting heterogeneity has limited the

include data from randomized trials that have compared self-monitoring (including in self-management (SMT) versus a control group, and also measured adverse events defined as major haemorrhage, thromboembolism, and death. The data to be captured for each trial will include outcomes demographic and psychosocial (e.g. quality of life) data. The primary outcomes of interest will be time to next haemorrhage, thromboembolism, and death. The secondary outcomes will be minor haemorrhage.

**Executive Summary**  
**Prevention of Thromboembolic Events: The Role of Point of Care Management**  
 David Fitzmaurice<sup>1</sup>, Dieter Horstkotte<sup>2</sup>

<sup>1</sup>Department of Primary Care and General Practice, The University of Birmingham, Birmingham, UK, <sup>2</sup>Department of Cardiology, Heart and Diabetes Center North Rhine-Westphalia, Ruhr University Bochum, Bad Oeynhausen, Germany

The Journal of Heart Valve Disease 2007;16:184-186

BMJ 2008;336:1472-1474 (28 June), doi:10.1136/bmj.39590.732037.47

**Analysis**  
**What is missing from descriptions of treatment in trials and reviews?**

Paul Glasziou, professor of evidence based medicine<sup>1</sup>, Emma Meats, research assistant<sup>2</sup>, Carl Heneghan, senior clinical research fellow<sup>3</sup>, Sasha Shepperd, NIHR research academic in evidence synthesis<sup>2</sup>

<sup>1</sup> American Heart Association  
 Learn and Live.

**Circulation**  
 Circulation: Cardiovascular Quality and Outcomes



**Articles**

**Self monitoring of oral anticoagulation: a systematic review and meta-analysis**

Background: Self monitoring may be used to improve the quality of oral anticoagulation therapy (OAT) and reduce the risk of adverse events. We conducted a systematic review and meta-analysis to assess the effectiveness of self monitoring compared with traditional OAT. Methods: We searched Medline, Embase, and Cochrane databases for randomised controlled trials comparing self monitoring with traditional OAT. Results: Self monitoring was associated with a higher proportion of patients in the therapeutic range (OR 1.48, 95% CI 1.28 to 1.71) and a lower risk of major haemorrhage (OR 0.58, 95% CI 0.41 to 0.81). Conclusion: Self monitoring improves the quality and safety of OAT. Self monitoring should be considered as an option for patients with OAT. Registration: PROSPERO 2007012542.

**BMC Medical Research Methodology**

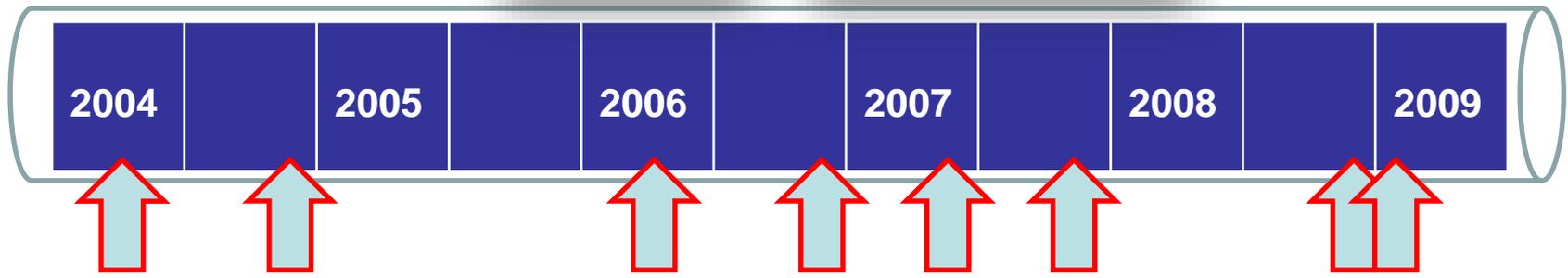
Research article

**Assessing differential attrition in clinical trials: self-monitoring of oral anticoagulation**

Paul Glasziou<sup>1</sup>, Rafael Perera<sup>1</sup>, Alison Ward<sup>1</sup>, David Fitzmaurice<sup>2</sup>

<sup>1</sup> Department of Primary Health Care, University of Oxford, Oxford, UK; <sup>2</sup> Department of Primary Health Care, University of Birmingham, Birmingham, UK

Received: 13 November 2006  
 Accepted: 2 May 2007  
 Published: 2 May 2007



Br J Gen Pract. 2015 Jul; 65(636): e428–e437.

Published online 2015 Jun 29. doi: [10.3399/bjgp15X685633](https://doi.org/10.3399/bjgp15X685633)

## **Cohort study of Anticoagulation Self-Monitoring (CASM): a prospective study of its effectiveness in the community**

### **Aim**

**To estimate the current levels of control and adverse events in patients self-monitoring OAT, explore the factors that predict success, and determine whether the level of side effects reported from randomised controlled trials are translated to a non-selected population.**

### **Design and setting**

Prospective cohort study in the UK.

### **Method**

Participants were aged  $\geq 18$  years and registered with a GP. Main outcomes were the proportion of participants, over 12 months, who were still self-monitoring, had not experienced adverse events, and had achieved  $>80\%$  of time in therapeutic range (TTR).

## Results

- In total, 296 participants were recruited (median age 61 yrs, 55% male).
- **Predominately professional or held a university qualification (83%).**
- At 12 months, 267 (90%) were still self-monitoring.
- Mean TTR was 75% (SD 16.9).
- Six serious and two minor adverse events were reported by GPs.
- **Only 46% of participants received any in-person training at the outset.**
- Increased age ( $P = 0.027$ ), general wellbeing (EQ-5D visual score,  $P = 0.020$ ), and lower target INR ( $P = 0.032$ ) were all associated with high (>80% TTR) levels of control.

## Conclusion

**The findings show that, even with little training, people on OAT can successfully self-monitor, and even self-manage, their INR.** TTR was shown to improve with age. However, widespread use of self-monitoring of INR may be limited by the initial costs, as well as a lack of training and support at the outset.

# 9. It takes at least two people to do applied health research

1. [Cohort study of Anticoagulation Self-Monitoring \(CASM\): a prospective study of its effectiveness in the community.](#) Ward A, Tompson A, Fitzmaurice D, Sutton S, Perera R, **Heneghan C**. Br J Gen Pract. 2015

2. [Supporting patients to self-monitor their oral anticoagulation therapy: recommendations based on a qualitative study of patients' experiences.](#) Tompson A, **Heneghan C**, Fitzmaurice D, Ward A. Br J Gen Pract. 2015 Jun 7; Review.

3. [Current practice of venous thromboembolism prophylaxis in the community.](#) McFarland L, Murray E, Harrison S, **Heneghan C**. Br J Gen Pract. 2015 Jun 7; Review.

4. [ExPeKT--Exploring prevention and management of venous thromboembolism in the community.](#) McFarland L, **Ward A**, Greenfield S, Murray E, **Heneghan C**. BMJ Open. 2013 Apr 2;3(4). pii: e002727. doi: 10.1136/bmjopen-2012-002727.

5. [Optimal loading dose of warfarin in the community.](#) Mahtani KR, **Heneghan CJ**, Nijman R, **Heneghan C**. Cochrane Database Syst Rev. 2012 Dec 12; CD009792. doi: 10.1002/14651858.cd009792.pub3.

6. [Self-monitoring of oral anticoagulation in the community.](#) **Heneghan C**, **Ward A**, Perera R; Self-Monitoring Trialists (SMT) collaboration. Lancet. 2011 Nov 30. Review. Erratum in: Lancet. 2012 Jun 16;379(9827):1033-4.

7. [Optimal loading dose for the initiation of warfarin in the community.](#) **Heneghan C**, Tyndel S, Bankhead C, **Heneghan C**. BMC Cardiovasc Disord. 2010 Apr 19; 10:12. doi: 10.1186/1471-2268-10-12.

8. [Self-monitoring and self-management of oral anticoagulation in the community.](#) Garcia-Alamino JM, **Ward AM**, Alonso-Coello P, **Heneghan C**, Perera R, Meats E, Glasziou P. Lancet. 2006 Feb 4;367(9508):404-11. Review.

9. [Individual patient meta-analysis of self-monitoring of oral anticoagulation in the community.](#) Perera R, **Heneghan C**, Fitzmaurice D, Sutton S, **Heneghan C**, Ward A, Tompson A, Fitzmaurice D, Sutton S, Perera R, **Heneghan C**. Br J Gen Pract. 2015 Jun 7; Review.

10. [Self-monitoring of oral anticoagulation: a systematic review and meta-analysis.](#) **Heneghan C**, Alonso-Coello P, Garcia-Alamino JM, Perera R, Meats E, Glasziou P. Lancet. 2006 Feb 4;367(9508):404-11. Review.

The screenshot shows a PubMed search results page for the query 'heneghan and perera'. The page is from the NCBI (National Center for Biotechnology Information) website. The search results are displayed in a list format, showing the first four results. Each result includes the title, authors, journal name, year, and a link to the full text. The search results are sorted by 'Most Recent' and are displayed in a grid layout. The page also includes a search bar, a 'Search' button, and various filters and options for the search results.

NCBI Resources How To

PubMed.gov US National Library of Medicine National Institutes of Health

Search heneghan and perera

Create RSS Create alert Advanced

Article types Summary 20 per page Sort by Most Recent Send to: Filters: Manage Filters

Clinical Trial Review Customize ...

Text availability Abstract Free full text Full text

PubMed Commons Reader comments Trending articles

Publication dates 5 years 10 years Custom range...

Species Humans Other Animals

Clear all

Show additional filters

**Search results**

Items: 1 to 20 of 53

<< First < Prev Page 1 of 3 Next > Last >>

[Corticosteroids for the common cold.](#)

1. Hayward G, Thompson MJ, Perera R, Del Mar CB, Glasziou PP, Heneghan CJ. Cochrane Database Syst Rev. 2015 Oct 13;10:CD008116. doi: 10.1002/14651858.CD008116.pub3. Review. PMID: 26461493 [Similar articles](#)

[Cohort study of Anticoagulation Self-Monitoring \(CASM\): a prospective study of its effectiveness in the community.](#)

2. Ward A, Tompson A, Fitzmaurice D, Sutton S, Perera R, Heneghan C. Br J Gen Pract. 2015 Jul;65(636):e428-37. doi: 10.3399/bjgp15X685633. Epub 2015 Jun 15. PMID: 26077267 **Free PMC Article** [Similar articles](#)

[Relationship between altitude and the prevalence of hypertension in Tibet: a systematic review.](#)

3. Mingji C, Onakpoya IJ, Perera R, Ward AM, Heneghan CJ. Heart. 2015 Jul;101(13):1054-60. doi: 10.1136/heartjnl-2014-307158. Epub 2015 May 7. Review. PMID: 25953970 **Free PMC Article** [Similar articles](#)

[Accuracy of self-monitored blood pressure for diagnosing hypertension in primary care.](#)

4. Nunan D, Thompson M, Heneghan CJ, Perera R, McManus RJ, Ward A. Self-monitoring Trialists (SMT) collaboration. J Heart Valve Dis. 2008 Mar;17(2):255-8.

**New feature**  
Try the new Display Settings  
**Sort by Relevance**

**Find related data**  
Database: Select

**Search details**  
heneghan[All Fields] A  
perera[All Fields]

**Recent Activity**  
heneghan and perera (53)  
Endometrial injury in wom

# 10. Get organized and then get organized a bit more

## TEAM

Interpersonal

Talk

Evaluate

Assist

Motivate

## FOCUS

Analytic

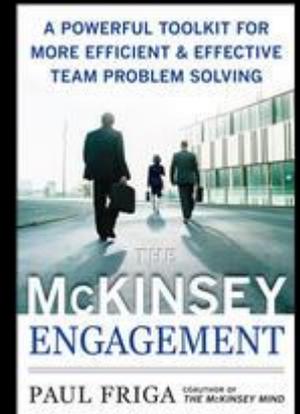
Frame

Organize

Collect

Understand

Synthesize



# What does impact look like?

## NIHR Dissemination Centre



### NIHR Signal Self-monitoring of warfarin

Published on 21 August 2015

Cost effectiveness

Expert commentary

The NIHR Health Technology assessment adds to a substantial body of evidence supporting the use of self-monitoring of anticoagulation.

This review is supplemented by a recent NIHR-funded study which has reported that self-monitoring was effective in the long term for patients who successfully self-monitor, and even self-manage, in the context of warfarin therapy.

Therefore the evidence clearly supports the adoption of self-monitoring of anticoagulation. This review supports effective strategies to reduce thromboembolic events in patients on warfarin. **Professor Carl Heneghan, Professor of Evidence-Based Health Sciences University of Oxford**

## WHO Collaborating Centre for Self-Care

+44 (0)1865 289322  
cebm@phc.ox.ac.uk



The Nuffield Department of Primary Care Health Sciences has been designated a World Health Organization (WHO) Collaborating Centre for Self-Care in recognition of its international reputation in patient self-monitoring and self-management of cancer, cardiovascular disease and other non-communicable disease (NCD).

The research, training and education undertaken in collaboration with the WHO aims to embed primary care practice to support NCD patient self-care in low and middle income countries.

Over the next four years, the WHO Collaborating Centre for Self-Care will coordinate a network of research centres to promote implementation

### OUR TEAM

**Carl Heneghan**

Professor of  
Evidence-Based Medicine



**Alison Ward**

Director of Postgraduate Studies

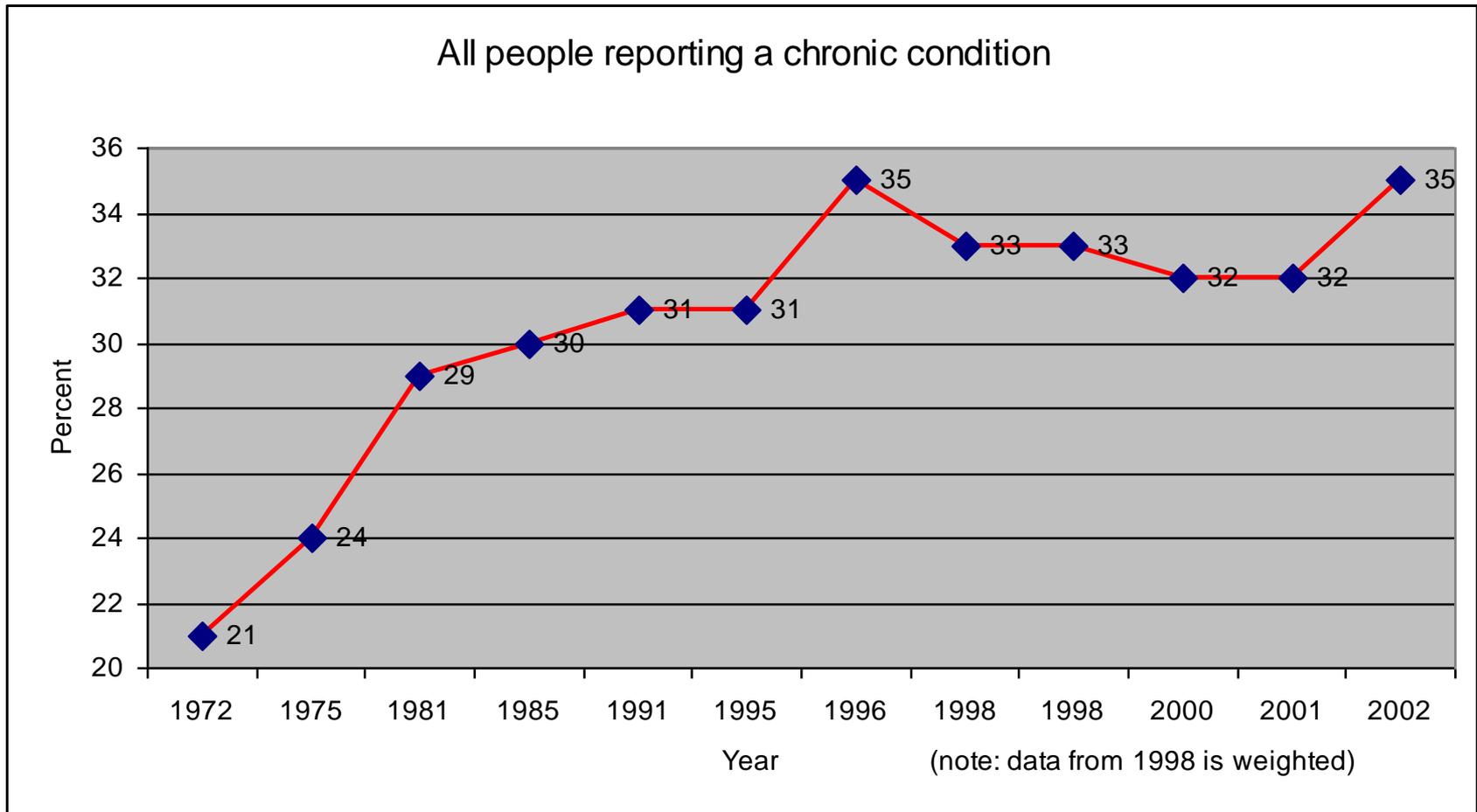
KEEP INFO

For the latest  
newsletter.

Sign up

# Recap

# 1. What's the problem that interests you?





## 2. Systematic overview of the field

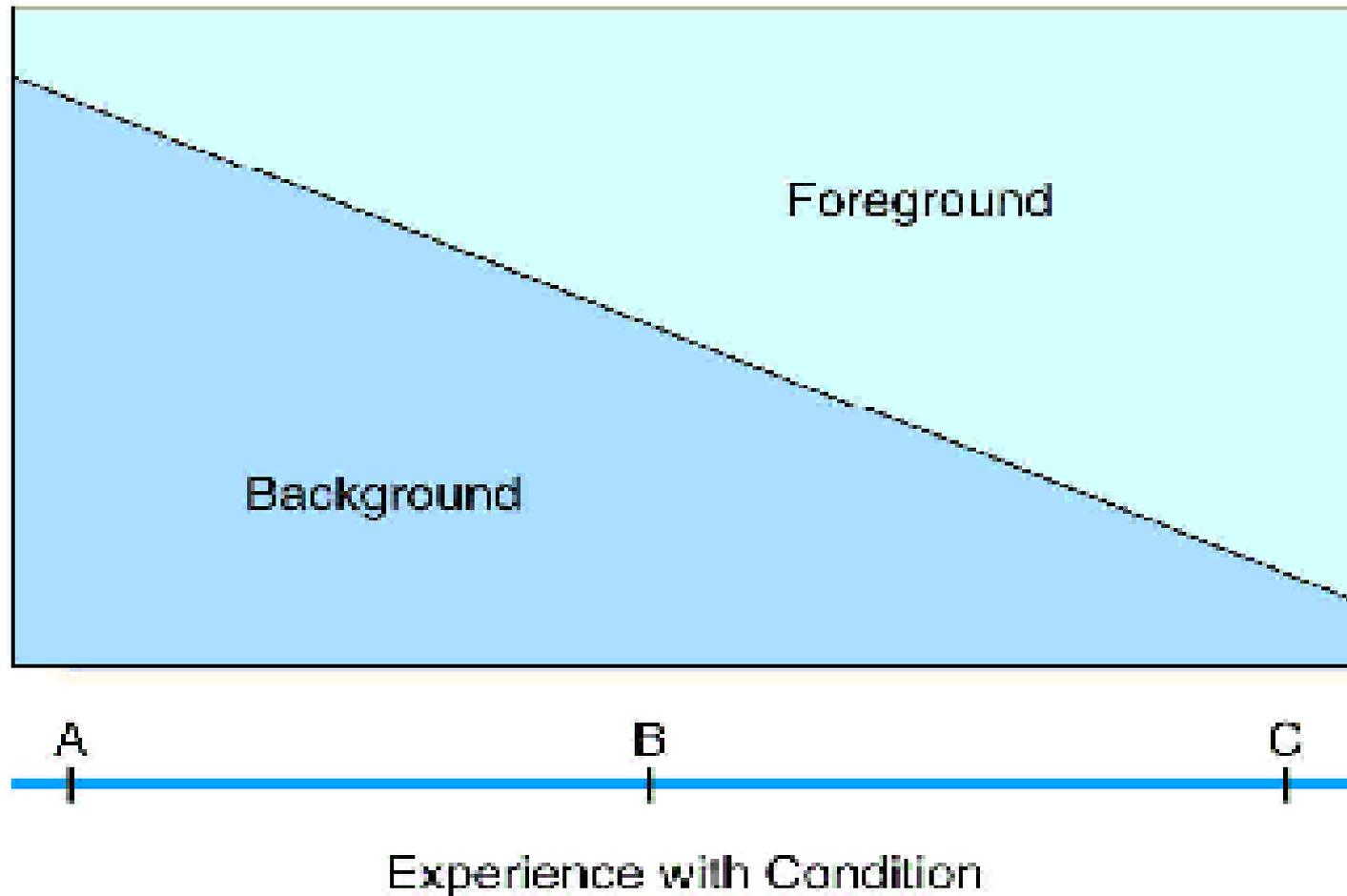
### **ROYAL COLLEGE OF GENERAL PRACTITIONERS SCIENTIFIC FOUNDATION BOARD**

**Title of Project: What is the impact of self-monitoring in chronic disease management? A systematic overview**

The aim is to identify the effects and components of currently evaluated self-monitoring methods relevant to general practice. We will undertake a systematic overview of current research.

### 3. Defining the question – the hardest bit

Figure 1.1 Background and foreground questions.



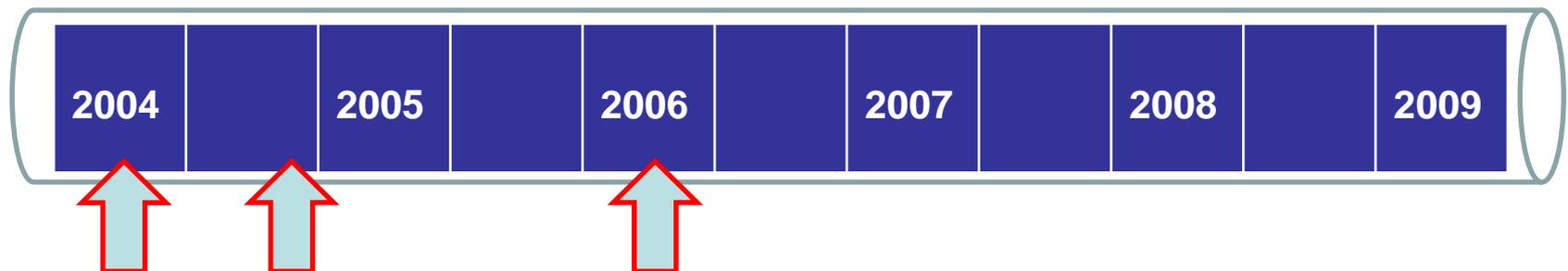
## 4. Start and end with a systematic review



NIHR DRF 2015 Guidance Notes

### Points to consider when preparing an NIHR TCC Training Fellowship Application

NIHR will only fund primary research\* where the proposed research is informed by a review of the existing evidence.



# 5. Identify gaps in your skills

## Clinical Epidemiology for the uninitiated

Skills Level	Score
No idea of the skill	1
Heard of the skill and would be able to undertake basics	2
Could undertake the skill but would require considerable help	3
Could undertake the skill requiring input only for the most difficult tasks	4
Can teach the skill	5

## 6. Develop further research questions –

### **Delivering safe and effective anticoagulation for patients – further questions**

1. Which subgroups benefit from self-monitoring?
2. Can you replicate trial results in practice?
3. How useful is time in range as a predictor of adverse events?
4. Can we predict successful self monitoring of anticoagulation at the outset?

# 7. Look for methodological issues

## Can you replicate the trial results in practice?

BMJ 2008;336:1472-1474 (28 June), doi:10.1136/bmj.39590.732037.47

### Analysis

#### What is missing from descriptions of treatment in trials and reviews?

Paul Glasziou, professor of evidence based medicine<sup>1</sup>, Emma Meats, research assistant<sup>1</sup>, Carl Heneghan, senior clinical research fellow<sup>1</sup>, Sasha Shepperd, NIHR research scientist in evidence synthesis<sup>2</sup>

<sup>1</sup> Centre for Evidence-Based Medicine, Department of Primary Health Care, University of Oxford, Oxford OX3 7LF, <sup>2</sup> Department of Public Health, University of Oxford

#### What is missing from descriptions of treatment in trials and reviews?

Replicating non-pharmacological treatments in practice depends on how well they have been described in research studies, say Paul Glasziou and colleagues

Have you ever read a trial or review and wondered exactly how to carry out treatments such as a "behavioural intervention," "salt reduction," or "exercise programme"? Although CONSORT and related initiatives have focused on the assessment of validity and presentation of results,<sup>1,2</sup> less attention has been given to the adequacy of the description of the treatment used. For pharmacological treatments the description would need to include the dose, titration, route, timing, duration, and any monitoring used. For complex treatments the problems are even greater.

##### Why are full descriptions of treatment

receiving numerous requests for additional details from doctors and patients, the author of a randomised trial on graded exercise for chronic fatigue syndrome<sup>3</sup> subsequently published a supplementary article with a more detailed "prescription."<sup>4</sup> Similarly, it is not possible to set up a stroke unit, offer low fat diets, or give smoking cessation advice without sufficient details on the components that were planned and delivered.<sup>5</sup>

##### Extent of the problem

To assess the extent of problems with descriptions of treatment we prospectively assessed 80 consecutive studies selected for abstraction in the journal *Evidence-Based Medicine*

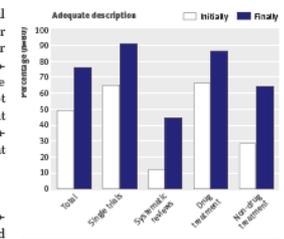


Fig 2 | Percentage of studies with sufficient description of treatment initially (based only on

# 8. Look for effects in real world populations

**School for Primary Care Research** Increasing the evidence base for primary care practice

National Health Service

Home News Who We Are Research Events Publications Our Staff Contact Us Links

**Individual patient meta-analysis of self-monitoring of oral anticoagulation: a systematic review protocol**

Theme: **Prevention, diagnosis, and management of haemorrhagic events**

Lead Contact(s): **Dr Carl Heneghan**

Other NIGPCF staff participating: **Professor Paul Glasziou, FRACGP, MRCGP; Dr Alison Ward; Dr David Fitzmaurice; Professor David Fitzmaurice; Professor Jim Doukatz**

Collaborator(s): **P. Alonso-Castro, Centre Cochrane, Barcelona; J. Ayané, Department of Medicine, Boston University Medical Center; P. Byth, Cook Investigator, Stoker QUERI Center, University of Florida; Thomas Decker Christensen, Dept of Cardio-Thoracic and Vascular Surgery, Aarhus University, Denmark; U. Dörflinger, Institute for Evidence Based Medicine, Cologne, Germany; J.M. Garcia-Alamo.**

Date:

**Individual Patient Meta-Analysis of Self-Monitoring of an Oral Anticoagulation Protocol**

Rafael Perera<sup>1</sup>, Carl Heneghan<sup>1</sup>, David Fitzmaurice<sup>2</sup> and the IPD Working Group

<sup>1</sup>Department of Primary Health Care, University of Oxford, <sup>2</sup>Department of Primary Care and General Practice, University of Birmingham, UK

**Background and aims of the study** Oral anticoagulation with vitamin K antagonists is effective for the prevention and treatment of thromboembolic events. Recent systematic reviews have shown that self-monitoring improved the quality of oral anticoagulation therapy (OAT), with patients spending more time in the therapeutic range than traditionally treated patients, and with a concomitant decrease in the incidence of adverse events. However, methodological and reporting heterogeneity has limited the

include data from randomized trials that have compared self-monitoring (including in self-management (SMT) versus a control group, and also measured adverse events defined as major haemorrhage, thromboembolism, and death. The data to be compared for each trial will include outcomes demographic and psychosocial (e.g. quality of life) data. The primary outcomes of interest will be time to next haemorrhage, thromboembolism, and death. The secondary outcomes will be minor haemorrhage.

**Executive Summary**  
**Prevention of Thromboembolic Events: The Role of Point of Care Management**  
 David Fitzmaurice<sup>1</sup>, Dieter Horstkotte<sup>2</sup>

<sup>1</sup>Department of Primary Care and General Practice, The University of Birmingham, Birmingham, UK, <sup>2</sup>Department of Cardiology, Heart and Diabetes Center North Rhine-Westphalia, Ruhr University Bochum, Bad Oeynhausen, Germany

The Journal of Heart Valve Disease 2007;16:184-186

BMJ 2008;336:1472-1474 (28 June), doi:10.1136/bmj.39590.732037.47

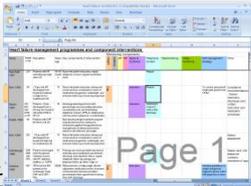
**Analysis**

**What is missing from descriptions of treatment in trials and reviews?**

Paul Glasziou, professor of evidence based medicine<sup>1</sup>, Emma Meats, research assistant<sup>2</sup>, Carl Heneghan, senior clinical research fellow<sup>3</sup>, Sasha Shepperd, NIHR research academic in evidence synthesis<sup>2</sup>

<sup>1</sup> American Heart Association  
 Learn and Live.

**Circulation**  
 Circulation: Cardiovascular Quality and Outcomes



**Articles**

**Self monitoring of oral anticoagulation: a systematic review and meta-analysis**

**Background** Oral anticoagulation therapy to avoid thrombosis of cardiovascular risk factors, and avoid thromboembolic events, is effective for the prevention and treatment of thromboembolic events. Recent systematic reviews have shown that self-monitoring improved the quality of oral anticoagulation therapy (OAT), with patients spending more time in the therapeutic range than traditionally treated patients, and with a concomitant decrease in the incidence of adverse events. However, methodological and reporting heterogeneity has limited the

**BMC Medical Research Methodology**

**Assessing differential attrition in clinical trials: self-monitoring of oral anticoagulation**

**Background** Assessing differential attrition in clinical trials: self-monitoring of oral anticoagulation

**Methods**

**Results**

**Conclusions**

**Author's contributions**

**Competing interests**

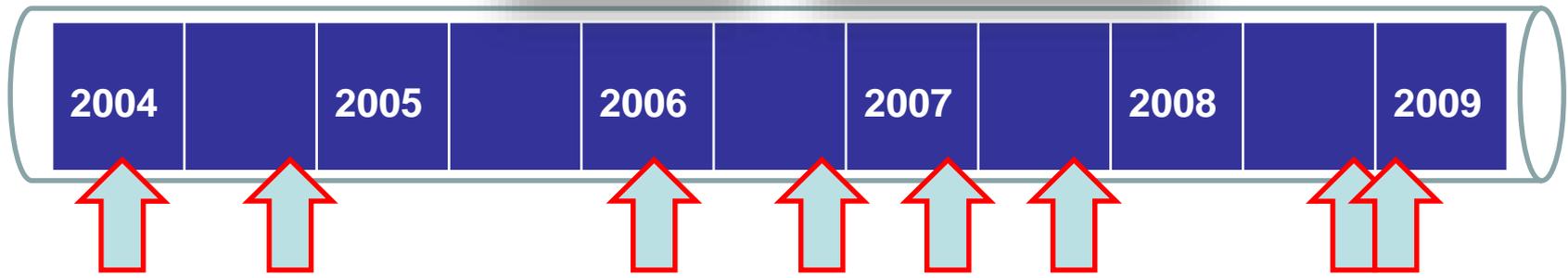
**Received** 13 November 2006

**Accepted** 2 May 2007

**Published** 2 May 2007

**References**

© 2007 Heneghan et al; licensee BioMed Central Ltd. This is an Open Access article distributed under the terms of the Creative Commons Attribution License



# 9. It takes at least two people to do applied health research

[1. Cohort study of Anticoagulation Self-Monitoring \(CASM\): a prospective study of its effectiveness in the community.](#) Ward A, Tompson A, Fitzmaurice D, Sutton S, Perera R, **Heneghan C**. Br J Gen Pract. 2015

[2. Supporting patients to self-monitor their oral anticoagulation therapy: recommendations based on a qualitative study of patients' experiences.](#) Tompson A, **Heneghan C**, Fitzmaurice D, Sutton S, Harrison S, **Ward A**. Br J Gen Pract. 2015

[3. Current practice of venous thromboembolism prevention in acute trusts: a qualitative study.](#) McFarland L, Murray E, Harrison S, **Heneghan C**, **Ward A**, Fitzmaurice D, Greenfield S. BMJ Open. 2014

[4. ExPeKT--Exploring prevention and knowledge of venous thromboembolism: a two-stage, mixed-method study protocol.](#) McFarland L, **Ward A**, Greenfield S, Murray E, **Heneghan C**, Harrison S, Fitzmaurice D. BMJ Open. 2013 Apr 2;3(4). pii: e002766. doi: 10.1136/bmjopen-2013-002766. Print 2013.

[5. Optimal loading dose of warf](#)  
Mahtani KR, **Heneghan CJ**, Ni  
Cochrane Database Syst Rev. 2012 Dec 12;12:CD008685. doi: 10.1002/14651858.CD008685.pub2.

[6. Self-monitoring of oral anticoagulation: systematic review and meta-analysis of individual patient data.](#) **Heneghan C**, **Ward A**, Perera R; Self-Monitoring Trialist Collaboration. Lancet. 2012 Jan 28;379(9813):322-34. doi: 10.1016/S0140-6736(11)61294-4. Epub 2011 Nov 30. Review. Erratum in: Lancet. 2012 Mar 24;379(9821):1102.

[7. Optimal loading dose for the initiation of warfarin: a systematic review.](#) **Heneghan C**, Tyndel S, Bankhead C, Wan Y, Keeling D, Perera R, **Ward A**. BMC Cardiovasc Disord. 2010 Apr 19;10:18. doi: 10.1186/1471-2261-10-18. Review.

[8. Self-monitoring and self-management of oral anticoagulation.](#) Garcia-Alamino JM, **Ward AM**, Alonso-Coello P, Perera R, Bankhead C, Fitzmaurice D, **Heneghan CJ**. Cochrane Database Syst Rev. 2010

[9. Individual patient meta-analysis of self-monitoring of an oral anticoagulation protocol.](#) Perera R, **Heneghan C**, Fitzmaurice D; Self Monitoring Trialists (SMT) collaboration. J Heart Valve Dis. 2008 Mar;17(2):233-8.

[10. Self-monitoring of oral anticoagulation: a systematic review and meta-analysis.](#) **Heneghan C**, Alonso-Coello P, Garcia-Alamino JM, Perera R, Meats E, Glasziou P. **Lancet**. 2006 Feb 4;367(9508):404-11. Review.

Get organized and then  
get organized a bit more, and then  
get organized a bit more, and then get organized a bit more  
and then get organized a bit more and then get organized a bit more and then get organized a bit more and

then get organized a bit more and then get organized a bit more oh and Get

organized

# Applied HealthCare Research: How to Get Started

## 10 components of effective clinical epidemiology

Thank You



Carl Heneghan

Professor of Evidence-Based Medicine &  
Director CEBM

University of Oxford

