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?

All people reporting a chronic condition

<table>
<thead>
<tr>
<th>Year</th>
<th>Percent</th>
</tr>
</thead>
<tbody>
<tr>
<td>1972</td>
<td>21</td>
</tr>
<tr>
<td>1975</td>
<td>24</td>
</tr>
<tr>
<td>1981</td>
<td>29</td>
</tr>
<tr>
<td>1985</td>
<td>30</td>
</tr>
<tr>
<td>1991</td>
<td>31</td>
</tr>
<tr>
<td>1995</td>
<td>31</td>
</tr>
<tr>
<td>1996</td>
<td>35</td>
</tr>
<tr>
<td>1998</td>
<td>33</td>
</tr>
<tr>
<td>1998</td>
<td>33</td>
</tr>
<tr>
<td>2000</td>
<td>32</td>
</tr>
<tr>
<td>2001</td>
<td>32</td>
</tr>
<tr>
<td>2002</td>
<td>35</td>
</tr>
</tbody>
</table>

(note: data from 1998 is weighted)

Department of Health: Chronic Diseases management; the growing challenge and the strategic response
Department of Health: Chronic Diseases management; the growing challenge and the strategic response
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
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.
<table>
<thead>
<tr>
<th>Study</th>
<th>Sample size</th>
<th>Population</th>
<th>Mean Age</th>
<th>Key components of Intervention</th>
<th>Monitoring components</th>
<th>Self management strategy</th>
<th>Other</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hancock</td>
<td>239</td>
<td>Patients with HF attending specialty clinic US</td>
<td>60-81</td>
<td>Nurse-led patient education, regular telephone contact, regular home/clinic visits</td>
<td>Regular</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Rich 1993</td>
<td></td>
<td>Patients &gt;70 yrs discharged from hospital, moderate or high risk for readmission US</td>
<td>79</td>
<td>Nurse-led patient education, dietary and social services, consultation, review of medications by geriatrician, and intensive follow-up at home by study team</td>
<td>Daily education</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Naylor 1994</td>
<td>276</td>
<td>Patients &gt;70 yrs discharged from a tertiary care hospital with either CHD or HF US</td>
<td>76</td>
<td>Discharge planning protocol, providing education, coordinating care, and maintaining telephone contact. Potential, in collaboration with the patient's physician, to individualize care</td>
<td>Education, maintained contact 2 weeks after discharge</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Kostis 1994</td>
<td>60</td>
<td>Patients with CHF NYHA-II or III, US</td>
<td></td>
<td>Non-pharmacological treatment program: (1) graduated exercise training; (2) structured cognitive therapy and stress management; (3) dietary intervention aimed at salt reduction and weight</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Rich 1995</td>
<td>202</td>
<td>Patients &gt;70 yrs discharged from hospital at high risk for readmission US</td>
<td>79</td>
<td>Nurse-led patient education, dietary and social services consultation, review of medications by geriatrician, and intensive follow-up at home by study team</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Weinberger 1996</td>
<td>1386</td>
<td>Patients discharged from the general medicine service with HF, diabetes mellitus, or COPD</td>
<td>83</td>
<td>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 discharge</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Oddone 1996</td>
<td>443</td>
<td>441 from the 504 patients in the Weinberger study CHF and LVEF &lt; 40</td>
<td>69(1)</td>
<td>Measurements of daily weight, diuretic adjustment, medication review, increased communication between providers, pre-scheduled clinic appointments during 30 days after discharge</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Overview of Systematic Reviews: Yoga as a Therapeutic Intervention for Adults with Acute and Chronic Health Conditions
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 Patients on oral anticoagulation
Does (I) self testing
Compared to usual care
reduce thrombosis (O)
(7 Types of questions)

1. How common is the problem
   - Prevalence
   - PO

2. Is early detection worthwhile
   - Screening
   - PICO

3. Is the diagnostic test accurate
   - Diagnosis
   - PICO

4. What will happen if we do nothing
   - Prognosis
   - PO

5. Does this intervention help
   - Treatment
   - PICO

6. What are the common harms of an intervention
   - PICO

7. What are the rare harms of an intervention
   - PICO
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.²
4. Start and end with a systematic review

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.
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

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

Summary

This article can be found in the following collections: Cardiology & vascular-other
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

<table>
<thead>
<tr>
<th>Skills Level</th>
<th>Score</th>
</tr>
</thead>
<tbody>
<tr>
<td>No idea of the skill</td>
<td>1</td>
</tr>
<tr>
<td>Heard of the skill and would be able to undertake basics</td>
<td>2</td>
</tr>
<tr>
<td>Could undertake the skill but would require considerable help</td>
<td>3</td>
</tr>
<tr>
<td>Could undertake the skill requiring input only for the most difficult tasks</td>
<td>4</td>
</tr>
<tr>
<td>Can teach the skill</td>
<td>5</td>
</tr>
</tbody>
</table>
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 Fitzmaurice¹, Dieter Horstkotte²

¹Department of Primary Care and General Practice, The University of Birmingham, Birmingham, UK. ²Department of Cardiology, Heart and Diabetes Centre 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 those present and agreement reached with most countries.

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 INRratio (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 (23 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, Emma Meats, research assistant, Carl Heneghan, senior clinical research fellow, Sasha Shepperd, NIHR research scientist in evidence synthesis

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

<table>
<thead>
<tr>
<th>Trials Checked to Date</th>
<th>Trials Were Perfect</th>
<th>Outcomes Not Reported</th>
<th>New Outcomes Silently Added</th>
</tr>
</thead>
<tbody>
<tr>
<td>66</td>
<td>9</td>
<td>355</td>
<td>336</td>
</tr>
</tbody>
</table>
How useful is time in range as a predictor of adverse events?
8. Look for effects in real world populations
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 ≥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


10. Get organized and then get organized a bit more

TEAM
Interpersonal

FOCUS
Analytics

Talk
Evaluate
Assist
Motivate

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 that self-monitoring of anticoagulation is effective in reducing thromboembolic events. This review is supplemented by a recent NIHR-funded study that showed that patients who were able to successfully self-monitor, and even self-manage, in the complex anticoagulation environment at home in the community, has reported that self-monitoring was effective in the long term.

Therefore the evidence clearly supports the adoption of self-monitoring as one strategy to reduce thromboembolic events and the costs associated with hospital admissions. 

Professor Carl Heneghan, Professor of Evidence-Based Sciences University of Oxford

WHO Collaborating Centre for Self-Care

The World Health Organization (WHO) Collaborating Centre for Self-Care 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 diseases (NCDs).

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.
Recap
1. What’s the problem that interests you?

Department of Health: Chronic Diseases management; the growing challenge and the strategic response
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.
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

<table>
<thead>
<tr>
<th>Skills Level</th>
<th>Score</th>
</tr>
</thead>
<tbody>
<tr>
<td>No idea of the skill</td>
<td>1</td>
</tr>
<tr>
<td>Heard of the skill and would be able to undertake basics</td>
<td>2</td>
</tr>
<tr>
<td>Could undertake the skill but would require considerable help</td>
<td>3</td>
</tr>
<tr>
<td>Could undertake the skill requiring input only for the most difficult tasks</td>
<td>4</td>
</tr>
<tr>
<td>Can teach the skill</td>
<td>5</td>
</tr>
</tbody>
</table>
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?
8. Look for effects in real world populations
9. It takes at least two people to do applied heath research
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, 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