“I numeri delle evidenze di cura: esclusione o inclusione con la scienza delle narrazioni?”

Milan – 28 October 2011

Lorenzo Moja, MD, MSc, Dr PH

University of Milan, Milan

Mario Negri Institute for Pharmacological Research, Milan

Italian Cochrane Network

Chi sono (disclosure)

- Medico
- Cochrane Effective Practice and Organisation of Care Group (EPOC), Università di Ottawa, Canada
- Centro Cochrane Italiano
- **UNIMI**
- Studi clinici randomizzati
- Revisioni sistematiche e meta-analisi in campo sanitario
- Diade medico-paziente: prendere decisioni informate

Disclosure

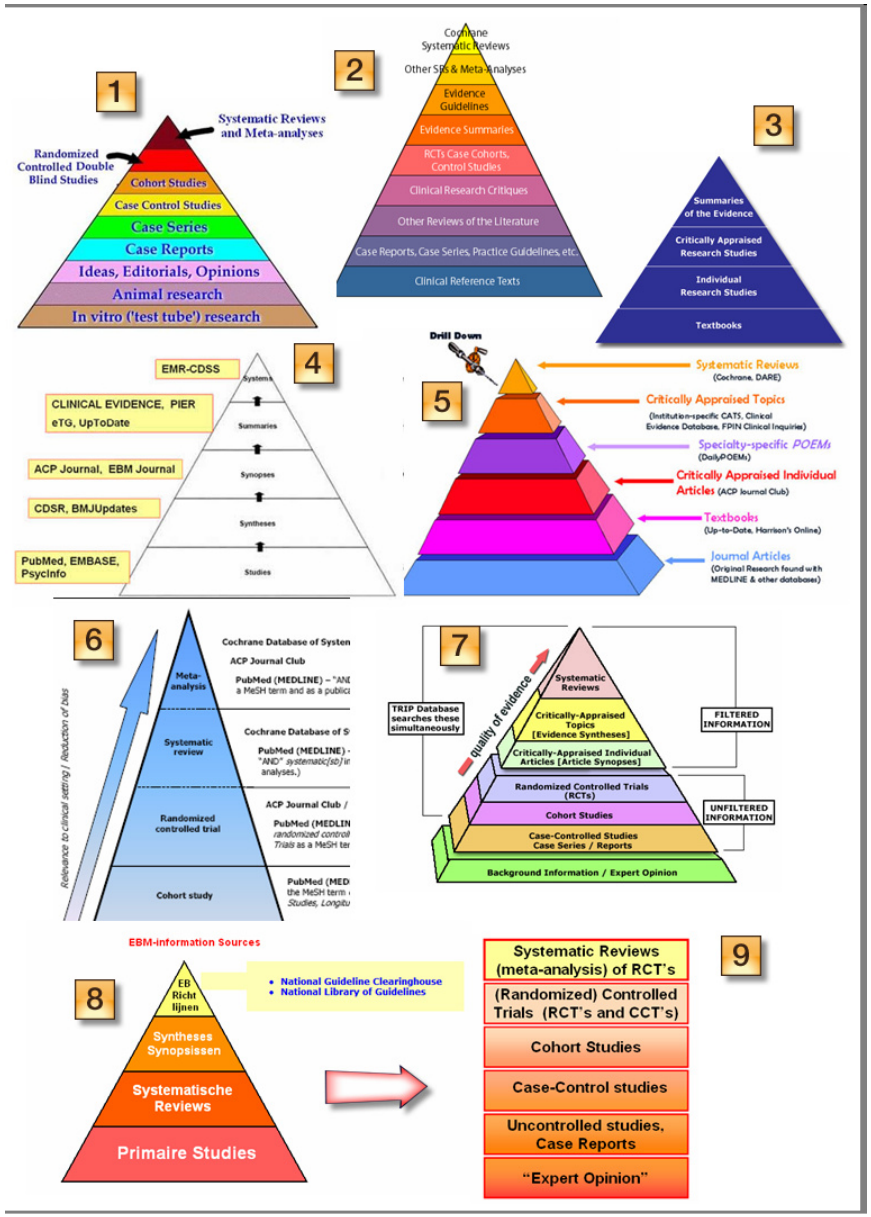
Tipo di conflitto

- Accademico

- Intellettuale

- Il conflitto d’interesse non è un comportamento, è una condizione.
- Per riconoscerlo non c’è bisogno che crei danni o disagi.
- Non può essere eliminato, ma deve essere reso palese.

Hierarchies of evidence



Laika Spoetnik

https://laikaspoetnik.wordpress.com/tag/evidence-piramide/

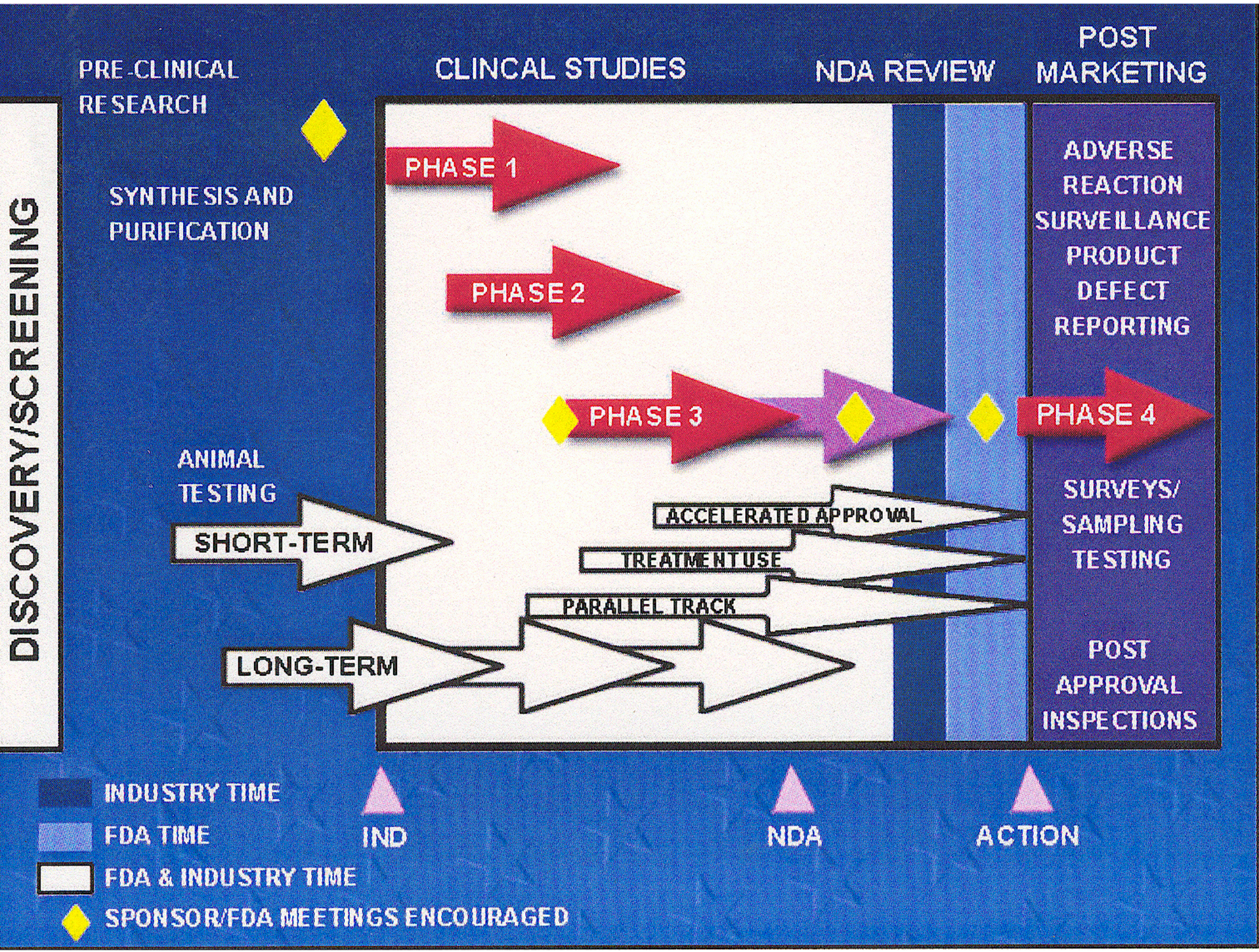
? Narrative medicine ?

In the pyramid diagram the least clinically relevant literature is at the bottom and the most clinically relevant is at the top.

Not even mentioned

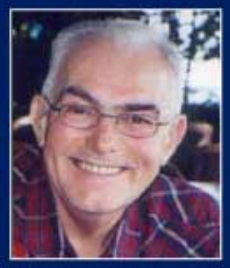
What I want to talk about

- Where and when narrative medicine is integrated with EBM: a personal view
- Reflections on whether evidence based practice is radical and does not honour NM
- Thoughts why NM is not questioned by EBM
- Thoughts why NM can be questioned by anyone eventually
- Conclusions


PRE-CLINICAL RESEARCH
CLINCAL STUDIES
NDA REVIEW
POST MARKETING
DISCOVERY/SCREENING
SYNTHESIS AND PURIFICATION
PHASE 1
PHASE 2
PHASE 3
PHASE 4
ADVERSE REACTION SURVEILLANCE PRODUCT DEFECT REPORTING
ANIMAL TESTING
SHORT-TERM
LONG-TERM
ACCELERATED APPROVAL
TREATMENT USE
PARALLEL TRACK
SURVEYS/ SAMPLING TESTING
POST APPROVAL INSPECTIONS
INDUSTRY TIME
FDA TIME
FDA & INDUSTRY TIME
SPONSOR/FDA MEETINGS ENCOURAGED
IND
NDA
ACTION

Phase 1

where exp and NM should be max audited



"Death is not a barrier to love."

ANONYMOUS

Lethal Dose — an emotionally gripping testament — an intense love story that, in turn, becomes a pulse-pounding suspense story; a medical misconduct drama; a gut-wrenching tragedy and a call to arms.

"Whew! And wow! Very powerful! I will have to restrain myself from hugging Pat Maddocks if I ever meet her."
Renate Preuss, copy editor

"... rabble-rousing ... malcontent ..."
Medical reporter for The Vancouver Sun, *Pamela Fatterman, expressed this opinion of the author on her blog,* Medicine Matters.

What do YOU think?

info@researchwithrespect.ca
www.researchwithrespect.ca

ISBN: 978-0-9868952-0-3
FOR PLACEMENT ONLY

LETHAL DOSE MADDOCKS

Research with Respect

LETHAL DOSE

ONE MAN'S JOURNEY THROUGH A PHASE 1 DRUG TRIAL

PAT MADDOCKS

How is the Phase 1 patient volunteer monitored?

The researchers pay keen attention to the **laboratory data** generated by the copious samples that are extracted from the Phase 1 study subject.

Their focus is the experimental treatment.

The patient volunteer is merely a means to an end – that end being the answer to the question, "**What is the MTD (maximum tolerated dosage)**?"

Patients do not have face.

Phase 3

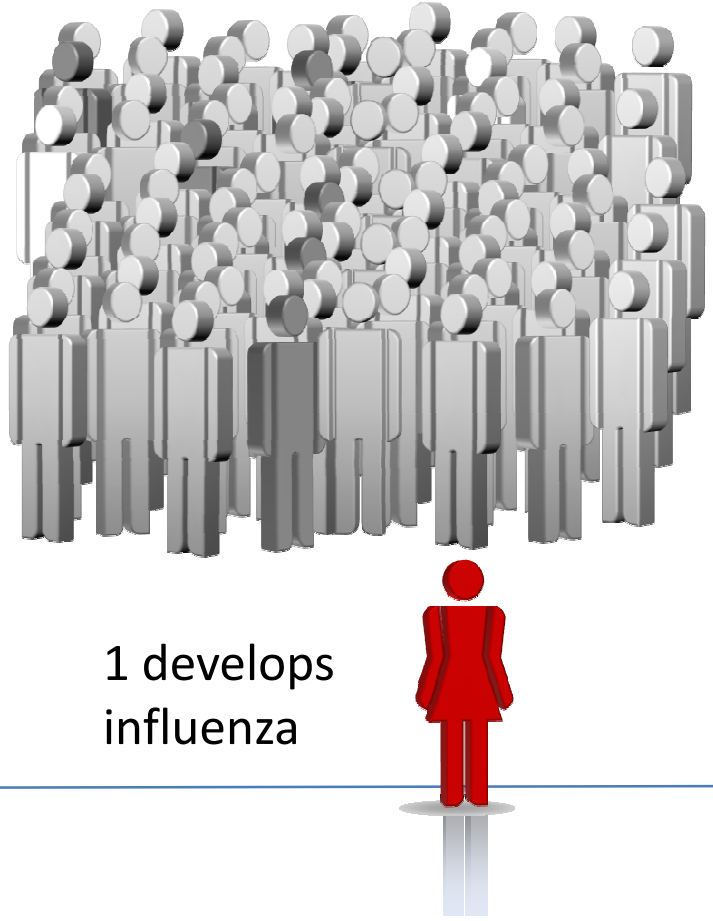
Where means start to get more attention – bloody hell!

Efficacy of influenza vaccine in healthy adults

(vaccine content incompletely matching circulating strain or not reported)

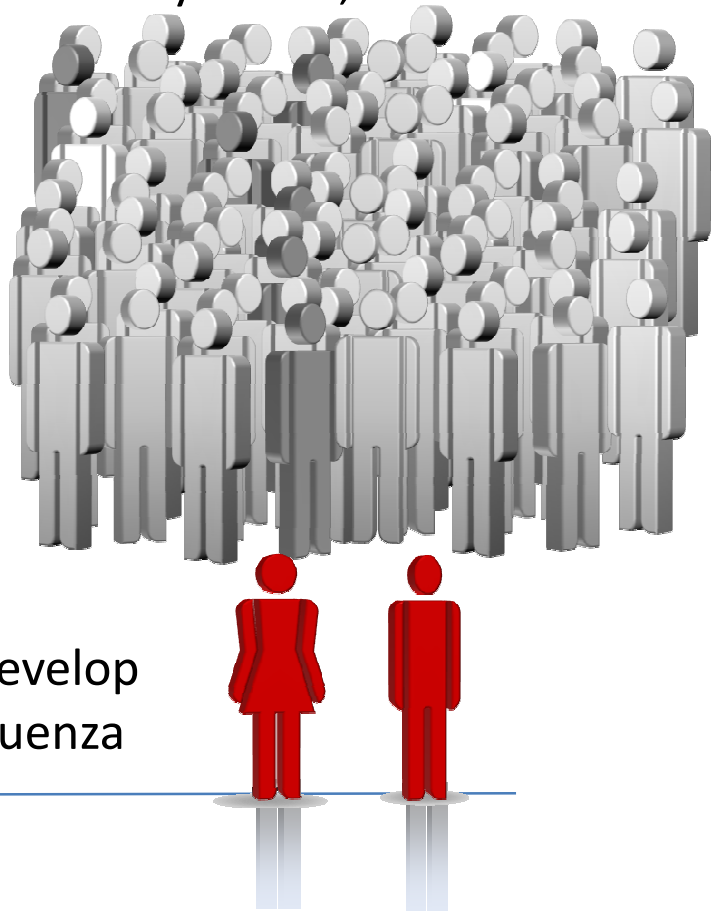
One clinical trial with 1000 participants

100 healthy adults, **vaccinated**



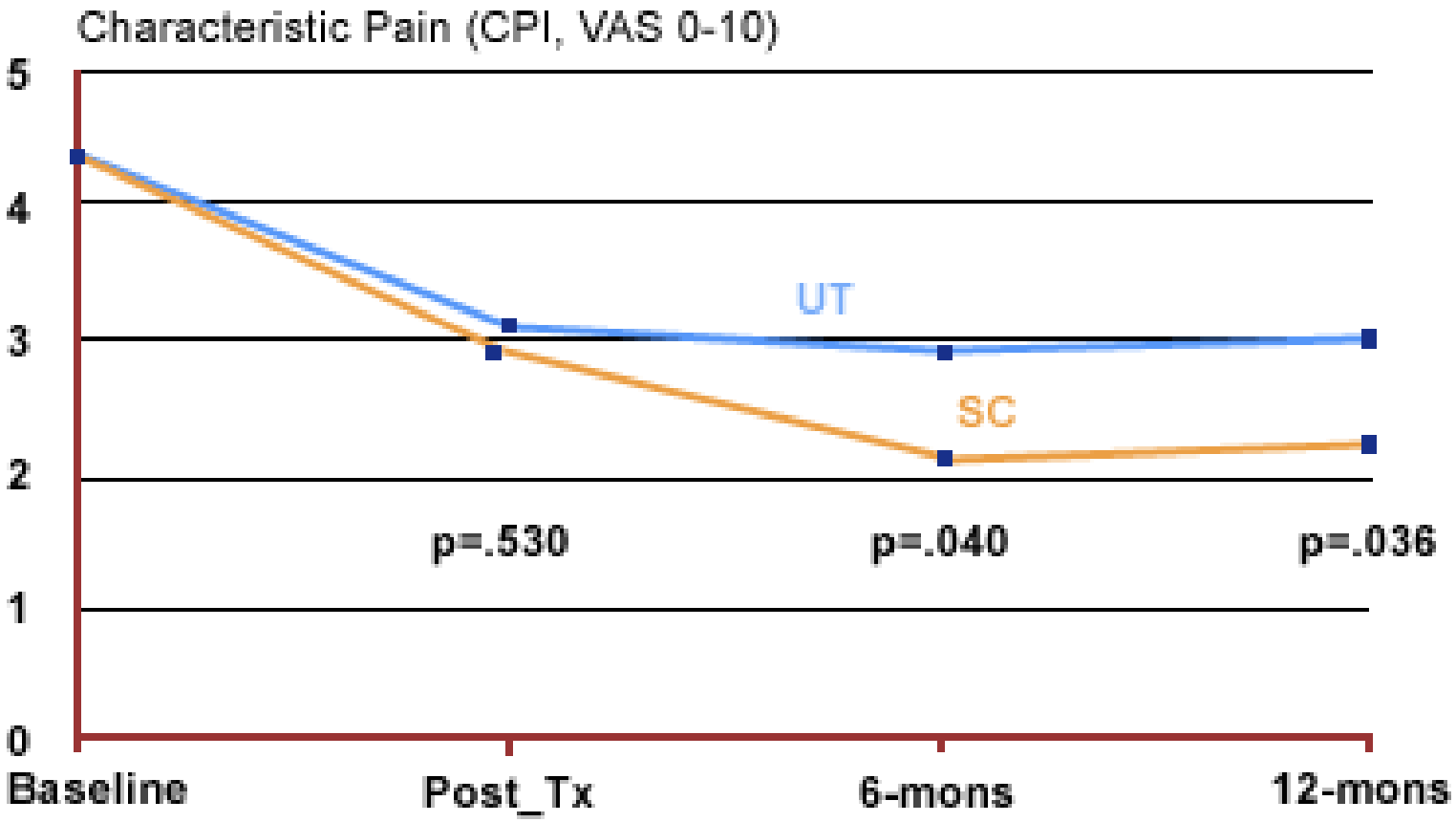
1 develops influenza

100 healthy adults, **not vaccinated**



2 develop influenza

Figure 12.1 RCT Results: Self-Care (SC) vs. Usual Treatment (UT) for TMD: Characteristic Pain (CPI)
ANCOVA (adjusted for baseline levels & education)



Materiale

- Scarpe Nike plus

- Sensore di movimento Nike

- iPod con cuffie

A.S.L. BI
Azienda Sanitaria Locale di Biella

MARIO NEGRI
ISTITUTO DI RICERCHE FARMACOLOGICHE

UNIVERSITAS STUDIORUM MEDIOLANENSIS

A randomized controlled trial evaluating the effects on gait of home independent rehabilitation with individual external rhythmical cueing

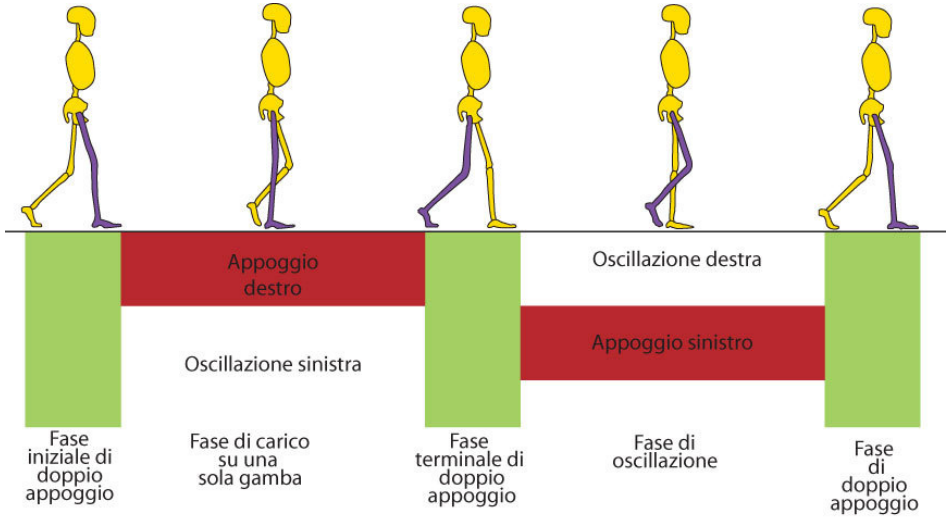
Nike for Health Knowledge

Il recente sviluppo e diffusione delle tecnologie promosse da Nike rende possibile monitorare non solo le prestazioni dei soggetti sani ma anche dei soggetti disabili.

Alcuni strumenti Nike potrebbero trovare un importante ruolo nel campo delle sperimentazioni cliniche.

Cosa ci dice la scienza

L’esercizio motorio finalizzato al miglioramento della deambulazione abbinato allo stimolo acustico migliora la lunghezza, la velocità e la stabilità del cammino nei pazienti affetti da Parkinson.



Camminare è fondamentale per l’essere umano

La riabilitazione a domicilio dei pazienti affetti da Parkinson

Nelle prime fasi della malattia i parkinsoniani possono condurre sessioni di esercizio a casa. E' un momento chiave della malattia.

L'obiettivo di questo studio è di dimostrare che i pazienti affetti da Parkinson, in grado di utilizzare autonomamente a domicilio il sistema Nike + iPod, dopo un training di 6 settimane, presentano un miglioramento della funzionalità del cammino.

Objective To evaluate the use of a computerised support system for decision making for implementing evidence based clinical guidelines for the management of asthma and angina in adults in primary care.

Effect of computerised evidence based g management of asthma and angina in a primary care: cluster randomised contr

Martin Eccles, Elaine McColl, Nick Steen, Nikki Rousseau, Jeremy Grimshaw, David Parkin, Ian Purves

Abstract

Objective To evaluate the use of a computerised support system for decision making for implementing evidence based clinical guidelines for the management of asthma and angina in adults in primary care.

Design A before and after pragmatic cluster randomised controlled trial utilising a two by two incomplete block design.

Setting 60 general practices in north east England.

Participants General practitioners and practice nurses in the study practices and their patients aged 18 or over with angina or asthma.

Main outcome measures Adherence to the guidelines, based on review of case notes and patient reported generic and condition specific outcome measures.

Results The computerised decision support system had no significant effect on consultation rates, process of care measures (including prescribing), or any patient reported outcomes for either condition. Levels of use of the software were low.

Conclusions No effect was found of computerised evidence based guidelines on the management of asthma or angina in adults in primary care. This was probably due to low levels of use of the software, despite the system being optimised as far as was technically possible. Even if the technical problems of producing a system that fully supports the management of chronic disease were solved, there remains the challenge of integrating the systems into clinical encounters where busy practitioners manage patients with complex, multiple conditions.

Introduction

Despite the current interest in clinical guidelines there remains uncertainty about how best to introduce them

recent systematic review of 68 controlled trials examined the effectiveness of such systems.[5] They were shown to be beneficial: nine of 15 trials of systems to improve drug dosing; one of five trials evaluating diagnostic aids; 14 of 19 trials evaluating systems to improve preventive care; and 19 of 26 trials evaluating "other" medical care such as the management of disease in hospital and ordering tests. Improvements were found in six of the 14 studies measuring patient outcomes. However, the authors reported that most of the studies had flaws in design or analysis so that the findings should be interpreted with caution. Moreover, no studies were identified in the management of chronic disease in primary care or in computerised decision support s
puter systems in p

We undertool
controlled trial o
system to imple
management of
primary care.

Methods

Our study metho
We chose as chro
adults; these disea
primary care and
bidity and morta
guidelines for th
approved by the appropriate multicentre research ethics committee.

Study general practices

We chose the study practices because their computer systems were extensively used. General practices in north east England were eligible to participate if at least 50% of the doctors reported using one of two computer systems to view clinical data and to issue

Centre for Health Services Research, University of Newcastle, Newcastle upon Tyne NE2 4AA

Martin Eccles
professor of clinical effectiveness

Elaine McColl
national primary care career scientist

Nick Steen
statistician

Nikki Rousseau
research associate

Health Services Research Unit,

Ian Purves
professor

Correspondence to:
M Eccles
martin.eccles@ncl.ac.uk

bmj.com 2002;325:941

Results The computerised decision support system had no significant effect on consultation rates, process of care measures (including prescribing), or any patient reported outcomes for either condition. Levels of use of the software were low.

Practice based, longitudinal, qualitative interview study of computerised evidence based guidelines in primary care

Nikki Rousseau, Elaine McColl, John Newton, Jeremy Grimshaw, Martin Eccles

Abstract

Objective To understand the factors influencing the adoption of a computerised clinical decision support system for two chronic diseases in general practice.
Design Practice based, longitudinal, qualitative interview study.
Setting Five general practices in north east England.
Participants 13 respondents (two practice managers, three nurses, and eight general practitioners) gave a total of 19 semistructured interviews. 40 people in practices included in the randomised controlled trial (34 doctors, three nurses) and interview study (three doctors, one previously interviewed) gave feedback.
Results Negative comments about the decision support system significantly outweighed the positive or neutral comments. Three main areas of concern among clinicians emerged: timing of the guideline trigger, ease of use of the system, and helpfulness of the content. Respondents did not feel that the system fitted well within the general practice context. Experience of "on demand" information sources, which were generally more positively viewed, informed the comments about the system. Some general practitioners suggested that nurses might find the guideline content more clinically useful and might be more prepared to use a computerised decision support system, but lack of feedback from nurses who had experienced the system limited the ability to assess this.
Conclusions Significant barriers exist to the use of complex clinical decision support systems for chronic disease by general practitioners. Key issues include the relevance and accuracy of messages and the flexibility to respond to other factors influencing decision making in primary care.

Introduction

questions about why systems are or are not effective. Models of implementation of guidelines and other innovations emphasise the importance of pre-existing attitudes and the context of the intervention, as well as the nature of the intervention itself, in the successful adoption of an intervention.[6,7] We conducted a randomised controlled trial of a computerised decision support system for the primary care management of two common chronic diseases, which is reported in detail elsewhere and summarised in box 1.[8,9] In this paper we report a qualitative interview study conducted in parallel in order to illuminate trial findings.[11,12]

Methods

Design

Box 1: Details of associated randomised controlled trial

Design—Before and after pragmatic cluster randomised controlled trial with a two by two incomplete block design
Setting—Sixty general practices in the north of England. Practices were eligible to participate if at least 50% of the doctors reported that they used one of two computer systems to view clinical data and to issue prescriptions during consultations

Box 2: Triggering mechanism

"That's the one point it does get a little bit annoying when that comes up and you think 'well I'm seeing them for their big toe' … It's actually come up a few times and I've thought 'they haven't got asthma' [laughing] … it's obviously been labelled wrongly … so that's actually quite helpful in some ways … No, no it's not acting as a prompt to review … if a patient had come in with an unrelated topic, it's very unlikely, I haven't done it yet, I think it's unlikely that I would go to the asthma guideline" (General practitioner, interview study)
"They're off [patient has left], I turn back and go back into this and then select the problem title, and then I say right well I've looked at ischaemic heart disease and then this comes up—and there [system has activated] and the patient's already gone by this stage" (General practitioner, interview study)
"The [guideline trigger] came up too soon to be useful—before you have even defined the problem" (General practitioner, trial practice, feedback)

"The [guideline trigger] came up too soon to be useful—before you have even defined the problem" (General practitioner, trial practice, feedback)

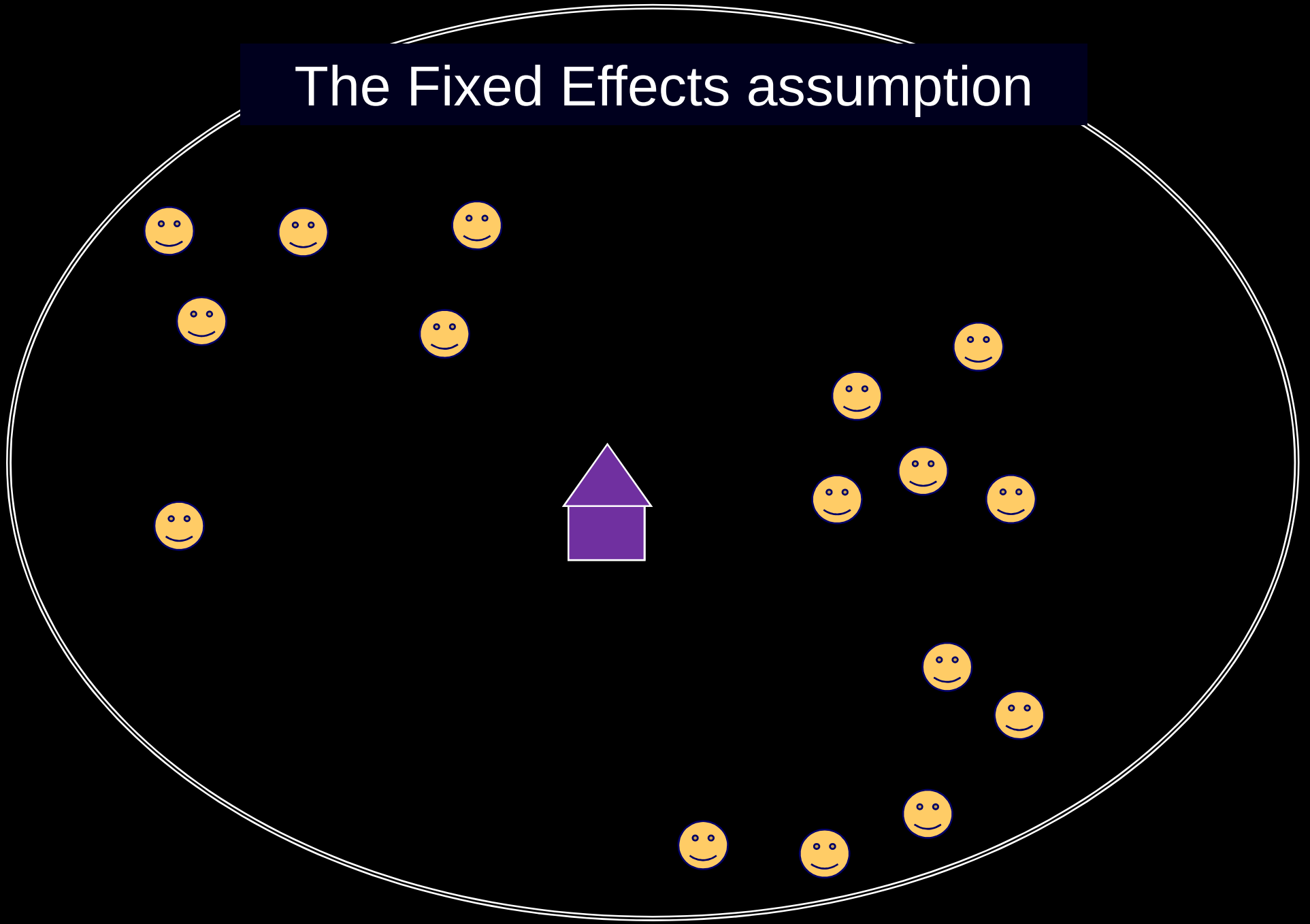
bmj.com 2003;326:314

Conclusions No effect was found of computerised evidence based guidelines on the management of asthma or angina in adults in primary care. This was probably due to low levels of use of the software, despite the system being optimised as far as was technically possible. Even if the technical problems of producing a system that fully supports the management of chronic disease were solved, there remains the challenge of integrating the systems into clinical encounters where busy practitioners manage patients with complex, multiple conditions.

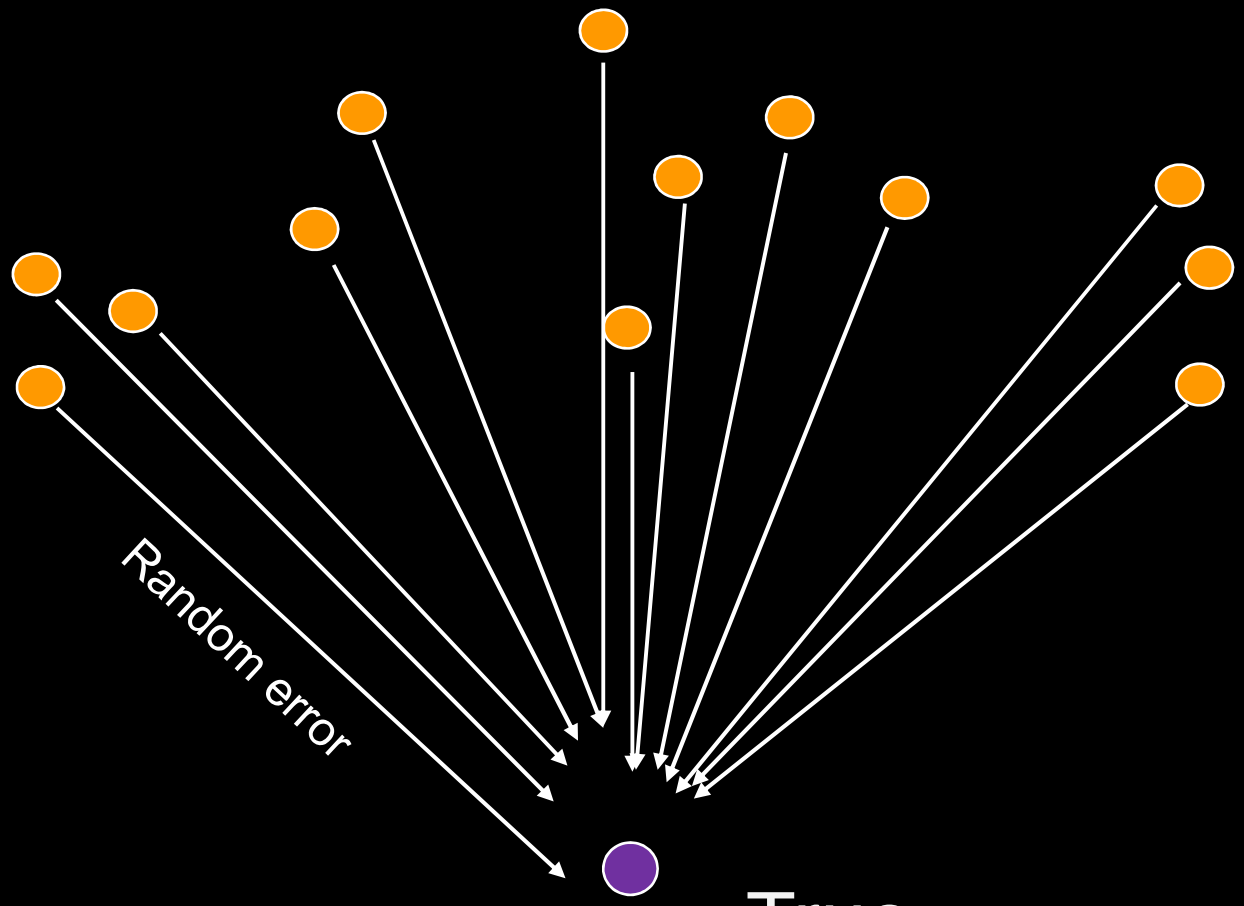
Meta-analysis

Kingdom of mean of means – NM banished

The Fixed Effects assumption



The Fixed Effects assumption



Meta-analyses

- Meta-analyses combine findings across studies addressing the same question
  - to summarise evidence ‘on a plate’ (e.g. Cochrane reviews)
  - or to make a specific decision (e.g. NICE, ASCO)

- Cochrane reviews evaluate the effects of healthcare interventions to provide essential information on the benefits of interventions at a population level.
- They can be used to guide individual patients in making well-informed decisions about their own health care.

EVIDENCE-BASED CHILD HEALTH: A COCHRANE REVIEW JOURNAL
Evid.-Based Child Health **5**: 1552–1554 (2010)
Published online in Wiley Online Library (onlinelibrary.wiley.com). **DOI:** 10.1002/ebch.612

Dr Cochrane

Chronic cough: a natural (and parental) disaster

Lorenzo Moja*
Italian Cochrane Centre, Mario Negri Institute for Pharmacological Research, Milan, Italy

The second in this series of Dr Cochrane clinical vignettes is based upon an overview of Cochrane Reviews that was published in the previous issue of *Evidence-Based Child Health*: Russell K, Chang AB, Foisy M, Thomson D and Williams K: ***The Cochrane Library* and the Treatment of Chronic Cough in Children: An Overview of Reviews**: *Evid.-Based Child Health* 2010, **5**: 1196–1205.

Dr Cochrane is a unique self-learning experience – the integration of Cochrane evidence with a quirky fictional story and multiple-choice questions provides readers with the opportunity to explore and understand the applicability of a Cochrane Review or Overview in a new way.

In this series of fictional clinical vignettes, Dr Cochrane travels across time from the past century to the present day, to solve clinical problems using evidence from Cochrane Reviews. Read the associated article and/or listen to the Evidence-Based Child-Health podcast available online at www.cochrane.org/podcasts/ and then test your knowledge with six multiple choice questions. You can find the answers to the questions in this issue on page 2007.

In the next issue of *Evidence-based Child Health*, Dr Cochrane explores the evidence for croup, based upon the Cochrane Overview available in this issue (Bjornson C, Russell K, Foisy M and Johnson DW: ***The Cochrane Library* and the Treatment of Croup in Children: An Overview of Reviews**. *Evid.-Based Child Health* 2010, **5**, 1555–1565).

On 6 April 2009 an earthquake measuring more than 6 on the Richter scale struck central Italy, killing 308 people. Twenty of the victims were children. Between 3,000 and 11,000 buildings in the medieval city of L'Aquila, the epicenter, were damaged. Around 65,000 people were made homeless. The name of this Baroque city means 'The Eagle'.

Nine months later, in November 2009, Dr Cochrane was directed early in the morning to the medical care centre. He was one of the volunteers from all over Europe joining the medical teams to provide help for those still living in the tent camp that provided temporary shelter. The immense tent sprawl was shaken were rarely acute. The majority of patients and families needed moral support and prescriptions for a few drugs, often the continuation of previous treatment for chronic illnesses.

Among the children, the illness which emerged most was chronic cough. Parents were often concerned about their child's health. Furthermore, although transmission of infection by a cough across tents was implausible, you can easily hear a cough through canvas walls in a tent camp so others in the camp also complained.

Why we should still pay attention to NM

- Permits discovery of new diseases and unexpected effects (adverse or beneficial)
- Clarifies the reasons behind successful/unsuccessful interventions
- Plays an important role in medical education
- Has a high sensitivity for detecting novelty and provides many new ideas in medicine
- Has implications in delivering better effective practice and organization of care
- Increases the attention paid to psychologically mediated effects of health care

- **Patient often is smarter**

Risks in receiving to much attention

- If NM is used to infer causality about efficacy (and association too)
- Medicalise patients (i.e. the process of making each patient a doctor)
- Forces promoting medicalisation: radical stories
- Misuse of stories (i.e., by funders, media, industry, etc.)
- NM demands a clear focus to make explicit to the community why a particular observation is important in the context of existing knowledge.

More respect for anecdotal information

Better integration of evidence and anecdotal information

- Iain Chalmers
- Brian Hurwitz
- Alex Jadad
- Alessandro Liberati
- Paola Mosconi
- David Sackett
- Richard Smith (BMJ)
- Jan Vandenbroucke

Thank you
for your kind attention

My contact

- lorenzo.moja@unimi.it

- Centro Cochrane Italiano – www.cochrane.it
- www.cochrane.org