Accelerating Knowledge to Practice: Evidence we can trust

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Thank you

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Disclosure

Director of Cochrane Rehabilitation

European Journal of Physical and Rehabilitation Medicine: congress expenses

ISICO (Italian Scientific Spine Institute): stock

Medtronic: consultant

Janssen Pharmaceutical: advisory board
Disclosure

I am a Juventus soccer fan
Disclosure

We are in Argentina, and soccer is relevant!
Disclosure

Today, in 45 minutes: Monaco-Juventus
Champions League – first semi-final

I will not be too long: promised!
In PRM there is no EVIDENCE

A constant boulder on PRM shoulders
Overview

Evidence Based Medicine (EBM)
- The origin and reason for EBM
- Cochrane: the Gold Standard of EBM

Physical and Rehabilitation Medicine (PRM) and EBM
- PRM vs other medical specialties
- Problems with evidence generation in PRM
- State of research in PRM

Implementation of EBM in PRM
- Knowledge Translation
- Cochrane Rehabilitation

Some solutions for EBM in PRM
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Some solutions for EBM in PRM
Charles II, King of England and Scotland (1685)

He had a stroke and was treated by the best physicians
• 16 ounces bloodletting
• Not allowed to sleep making him sitting
• Glass cups on the shoulders
• Shoulders scarification for 8 ounces more of bloodletting
• Emetics and laxative at high dosage, with repeated clysters
• Shaven and stucked needles in the head
• White-hot cautery

Luckily the king died without awakening

The so-called tradition-based official medicine
Dr. Lind and scarvy (1747)

Scarvy: cause of death in sea explorations

Treatments mandated by Dr Lind advisors and payers:
- Royal College of Physicians: sulfuric acid
- Admiralty: vinegar

The idea:
- 12 patients, same diet, 6 groups of 2
  - sulfuric acid,
  - vinegar,
  - cider,
  - sea water,
  - nutmeg,
  - 2 oranges and 1 lemon

First controlled study in history
Thalidomide (1961)

Drug for nausea during pregnancy
Proper studies were performed before marketing
First reports of phocomelias archived as “random events”
Reports increased, but the drug company did not disclose them until a scandal broke

Mandatory to collect data on adverse events and report to independent governmental agencies (like FDA)
Dr. Spock and Sudden Infant Death Syndrome

Renewed pediatrician, developer of a new educational model

Expert statement: “Do not let infants sleep on their back to avoid choking on the vomit and to avoid compression of the head always on the same side” (1956)

Studies about supine vs prone lying in infants:
• First small RCT (1965): no differences
• First serious RCT (1985): better supine
• Cochrane (2005): prone 4.15 (3.3-5.3) increased risk of SIDS

Importance of RCTs and metanalysis
«Official» Medicine today

- King Charles II
- Dr Lind
- Thalidomide
- Sudden Infant Death Syndrome

The methodology of “official medicine” comes from our history
Evidence Based Medicine

The explicit, conscientious, and judicious use of the current best evidence in making decisions about the care of individual patients (and populations)

Sackett DL et al. Evidence based medicine: what it is and what it isn't. BMJ 1996; 312:71. doi: https://doi.org/10.1136/bmj.312.7023.71
Growth of studies in PubMed

Number of papers per year in Medline from 1960 to 2015
Studies hierarchy
Evidence Based Clinical Practice

The integration of

• best research evidence
• with clinical expertise
• and patient values

EBM is the last methodological achievement in the young history of medicine
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Some solutions for EBM in PRM
Cochrane vision

A world of improved health where decisions about health and health care are informed by high-quality, relevant and up-to-date synthesized research evidence.
What does Cochrane do?

Cochrane gathers and summarizes the best evidence from research producing systematic reviews and meta-analysis including only Randomized Controlled Trials (RCTs).

Cochrane does not accept commercial or conflicted funding.
Cochrane Organization

**Review Groups**: systematic reviews

**Methods Groups**: development of methods for reviews

**Centres**: local knowledge translation

**Fields and Networks**: knowledge translation for a specific health community other than a condition
Why is Cochrane important? An example

A physiotherapist

Two very nice daughters with long, blond hair

Pediculosis – head lice got at school

They tried all known popular remedies, but no success

Last solution: totally cut their hair

Suddenly an IDEA – why not to try to check with Cochrane?
Problem solved

Cochrane Database of Systematic Reviews

Interventions for treating head lice

Johannes C van der Wouden, Tim Klootwijk, Laurence Le Cleach, Giao Do, Robert Vander Stichele, Arie Knuistingh Neven, Just AH Eekhof

First published: 5 October 2011
Editorial Group: Cochrane Infectious Diseases Group
DOI: 10.1002/14651858.CD009321 View/save citation
Cited by: 2 articles

Now he is the author of 2 systematic reviews in his field of competence
Cochrane and RCTs are the actual gold standard for a good EBM approach
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Some solutions for EBM in PRM
ICF biopsychosocial model (WHO)
Classical medical specialties

Health Condition (disorder/disease)

Body function & structure (Impairment)

Activities (Limitation)

Participation (Restriction)

Environmental Factors

Personal Factors
Physical and Rehabilitation Medicine

European Bodies Alliance. White Book of Physical and Rehabilitation Medicine in Europe
3rd Ed. To be published in 2018
## Core concepts of PRM

<table>
<thead>
<tr>
<th></th>
<th>Classical medicine</th>
<th>PRM specialty</th>
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</thead>
<tbody>
<tr>
<td><strong>Overall approach</strong></td>
<td>Disease oriented</td>
<td>Person/functioning oriented (holism)</td>
</tr>
<tr>
<td><strong>Diagnosis and prognosis</strong></td>
<td>Medical</td>
<td>Functional and medical</td>
</tr>
<tr>
<td><strong>Treatments</strong></td>
<td>One modality at a time</td>
<td>Multimodal</td>
</tr>
<tr>
<td><strong>Morbidities</strong></td>
<td>Single</td>
<td>Multiple</td>
</tr>
<tr>
<td><strong>Professional approach</strong></td>
<td>Individual</td>
<td>Multi-professional team</td>
</tr>
</tbody>
</table>

*European Bodies Alliance. White Book of Physical and Rehabilitation Medicine in Europe 3rd Ed. To be published in 2018*
Low and Middle Income Countries (LMIC)

Disability:
• Different epidemiology
• Bi-directional link to poverty

Professional rehabilitation capacity
• Few professionals
• Few facilities

Different therapy interventions due to reduced resources
PRM has specific challenges for EBM that must be faced
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Some solutions for EBM in PRM
Research problems in PRM

Conception of the study
- Ethical Committee Approval
- Randomised Controlled Trials
- Quasi Randomised Controlled Trials
- Benchmarking Controlled Trials
- Registries and clinical databases
- Community; Out-Inpatient
- Primary; Secondary; Tertiary
- Clinical; Research
- Environmental factors

Setting
- Functional diagnosis
- Multimorbidity

Population

Methods
- Outcomes
- Rehabilitation process
Research problems in PRM

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32 biases in research

1. Bias in concepts
2. Definition bias
3. Bias in design
4. Bias in selection of subjects
5. Bias due to concomitant medication or concurrent disease
6. Instruction bias
7. Length bias
8. Bias in detection of cases
9. ‘Lead-time’ bias
10. Bias due to confounder
11. Contamination in controls
12. Berkson’s bias
13. Bias in ascertainment or assessment
14. Interviewer bias or observer bias
15. Instrument bias
16. Hawthorne effect
17. Recall bias
18. Response bias
19. Repeat testing bias
20. Mid-course bias
21. Self-improvement effect
22. Digit preference
23. Bias due to nonresponse
24. Attrition bias
25. Bias in handling outliers
26. Recording bias
27. Bias in analysis
28. Bias due to lack of power
29. Interpretation bias
30. Reporting bias
31. Bias in presentation of results
32. Publication bias

Indrayan A. Basic Methods of Medical Research
3rd Ed. AITBS Publishers, Delhi
### Frequent biases in PRM: 13/32

1. Bias in concepts
2. Definition bias
3. Bias in design
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30. Reporting bias
31. Bias in presentation of results
32. Publication bias
Random sequence generation
Allocation concealment
Selection
Performance
Detection
Attrition
Reporting

Target Population
Allocation
Intervention
Control

Blinding of participants, personnel
Blinding of outcome assessment
Incomplete outcome data
Selective reporting

Outcome assessment
Publication of study outcomes

Cumpston M. Introduction to writing a Cochrane Review
http://training.cochrane.org/resource/introduction-writing-cochrane-review
Research problems in PRM

Conception of the study
- Ethical Committee Approval
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- Registries and clinical databases

Design

Setting
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Population
- Functional diagnosis
- Multimorbidity

Methods
- Outcomes

Rehabilitation process
Benchmarking Controlled Trials

An observational study aiming to provide non-biased estimates of differences in real-world circumstances due to:

• intervention(s)
• clinical pathways
• health care system(s)

among a well-defined group of patients.
Research problems in PRM

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Methods

Setting

Population

Outcomes
- Rehabilitation process
Rehabilitation process

Personal factors
- Team: multi-professional and interdisciplinary
- Therapists’ competency and convincement
- Patients’ convincement, compliance and adherence to treatment

Technical factors
- Low precision description (terminology and vocabulary)
- The Usual Therapy factor
- Multi-modal approach
Usual therapy (UT): the black box

Methods
• Systematic Review
• RCTs on rehabilitation for lower limb after stroke (2006-2016)

Results
• 79 papers (out of 1582)
• All treatments (13) checked only as «adjunctive» to UT
• 16 different treatments included in the UT groups
• Treatments in UT ranged from 1 treatment (19%) to 7 treatments (4%): mode 3 treatments (24%)
• No similar UT from different treating teams

Usual therapy (UT): the black hole

Methods
• Systematic Review
• RCTs on rehabilitation for lower limb after stroke (2006-2016)

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**Multimodal approach**

Different treatments provided together

Same treatments combined differently by different teams
Multimodal approach

Different treatments provided together

Treatments combined differently by different teams

Their combination gives the final result
Research problems in PRM

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Methods
Outcomes
Rehabilitation process
PRM research methodological problems requires better understanding
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Some solutions for EBM in PRM
Steady growth of research

<table>
<thead>
<tr>
<th>Population</th>
<th>2000</th>
<th>2011</th>
<th>Change</th>
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</thead>
<tbody>
<tr>
<td>PRM</td>
<td>PubMed</td>
<td>0.7%</td>
<td>1.5%</td>
</tr>
<tr>
<td>United States PRM</td>
<td>Country</td>
<td>1.7%</td>
<td>1.6%</td>
</tr>
<tr>
<td>United Kingdom PRM</td>
<td>Country</td>
<td>1.9%</td>
<td>1.7%</td>
</tr>
<tr>
<td>Germany PRM</td>
<td>Country</td>
<td>1.7%</td>
<td>1.1%</td>
</tr>
<tr>
<td>Canada PRM</td>
<td>Country</td>
<td>2.5%</td>
<td>1.9%</td>
</tr>
<tr>
<td>Australia PRM</td>
<td>Country</td>
<td>3.4%</td>
<td>1.8%</td>
</tr>
<tr>
<td>Italy PRM</td>
<td>Country</td>
<td>1.9%</td>
<td>0.9%</td>
</tr>
<tr>
<td>Netherlands PRM</td>
<td>Country</td>
<td>2.8%</td>
<td>1.8%</td>
</tr>
<tr>
<td>Japan PRM</td>
<td>Country</td>
<td>0.8%</td>
<td>0.6%</td>
</tr>
<tr>
<td>Sweden PRM</td>
<td>Country</td>
<td>3.4%</td>
<td>2.5%</td>
</tr>
<tr>
<td>France PRM</td>
<td>Country</td>
<td>1.2%</td>
<td>0.9%</td>
</tr>
</tbody>
</table>

Growth of studies in PubMed
Research interest in Rehabilitation is growing

Source: www.gopubmed.org
Growth of type of studies in Rehabilitation

Search: Rehabilitation [Mesh]

Filters: Randomized Controlled Trial, Systematic Reviews, Meta-Analysis

All studies in Rehabilitation

RCTs
Systematic Reviews
Meta-analysis
Relative research interest: SRs
Relative research interest: RCTs
What is Rehabilitation [Mesh]?
What is Rehabilitation [Mesh]?
What is Rehabilitation [Mesh]?
Relative research interest: RCTs

Exercise Therapy

PT modalities

Neurological rehabilitation

Rehabilitation

Drug Therapy
PRM is comparatively producing a lot of good research (RCTs and SRs)
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Some solutions for EBM in PRM
The Know-Do Gap

High quality evidence is not consistently applied in practice

Examples in clinical practice:
• Statins decrease mortality and morbidity in post-stroke, but they are under-prescribed
• Antibiotics are overprescribed in children with upper respiratory tract symptoms

Examples in health system policies:
• Evidence was not frequently used by WHO (not true for last rehabilitation guidelines)
• Out of 8 policymaking processes in Canada
  – Only 1 was fully based on research
  – Other 3 were partially based on research

Why there is the Know-Do Gap?

Evidence not focused on the end-users:

1. Epidemiologically and methodologically focused
2. Missing details on interventions and settings

Lack of knowledge management skills and infrastructure

1. Macro-level: health care system and organization (finance and equipments)
2. Meso-level: health care teams (standards of care)
   - Volume of, and access to research evidence
   - Time to read
   - Skills to appraise, understand and apply research evidence

Knowledge Translation

A dynamic and interactive process that includes the synthesis, dissemination, exchange, and ethically sound application of knowledge to improve health, provide more effective health services and products, and strengthen the health care system

Canadian Institute of Health Research¹

Dissemination and implementation, implementation science, research use, knowledge transfer and uptake/exchange²

Knowledge to action framework
Knowledge creation

Knowledge inquiry
• Primary research studies

Knowledge synthesis
• Secondary research studies (systematic reviews)

Knowledge tools/products
• Guidelines
• Algorithms
• Messages for end-users
The Action Cycle (application)

Identify problem
Identify, review, select knowledge
Adapt knowledge to local context
Access barriers – facilitation to knowledge use
Select, tailor, implement interventions
Monitor knowledge use
Evaluate outcomes
Sustain knowledge use

Implementation of evidence

Micro-level (individuals)
- Surrender to evidence
- Use facilitators (clinical charts)

Meso-level (organizations)
- EBM Continuous Quality Improvement groups
  - Human and financial resources
  - Specific thematic projects on a regular basis

Macro-level (Health Systems)
- National guidelines and flow-charts
- Data collection
- Rewarding system
When Evidence is known, a Knowledge Translation effort is required
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<table>
<thead>
<tr>
<th>Cochrane Review Groups</th>
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<tbody>
<tr>
<td>1. Acute Respiratory Infections Group</td>
</tr>
<tr>
<td>2. Airways Group</td>
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<tr>
<td>3. Anaesthesia, Critical and Emergency Care Group</td>
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<tr>
<td>4. Back and Neck Group</td>
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<tr>
<td>5. Bone, Joint and Muscle Trauma Group</td>
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<td>6. Breast Cancer Group</td>
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<td>7. Childhood Cancer Group</td>
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<td>8. Cochrane Response</td>
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<td>9. Colorectal Cancer Group</td>
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<td>10. Common Mental Disorders Group</td>
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<td>11. Consumers and Communication Group</td>
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<td>12. Covidence Review Group</td>
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<tr>
<td>13. Cystic Fibrosis and Genetic Disorders Group</td>
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<td>14. Dementia and Cognitive Improvement Group</td>
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<tr>
<td>15. Developmental, Psychosocial and Learning Problems Group</td>
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<td>16. Drugs and Alcohol Group</td>
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<td>17. Effective Practice and Organisation of Care Group</td>
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<td>18. ENT Group</td>
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<td>19. Epilepsy Group</td>
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<tr>
<td>20. Eyes and Vision Group</td>
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<tr>
<td>21. Fertility Regulation Group</td>
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<td>22. Gynaecological, Neuro-oncology and Orphan Cancer Group</td>
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<td>23. Gynaecology and Fertility Group</td>
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<td>24. Haematological Malignancies Group</td>
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<td>25. Heart Group</td>
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<td>26. Hepato-Biliary Group</td>
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<tr>
<td>27. HIV/AIDS Group</td>
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<td>28. Hypertension Group</td>
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<td>29. IBD Group</td>
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<td>30. Incontinence Group</td>
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<td>31. Infectious Diseases Group</td>
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<td>32. Injuries Group</td>
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<td>33. Kidney and Transplant Group</td>
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<td>34. Lung Cancer Group</td>
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<td>35. Metabolic and Endocrine Disorders Group</td>
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<td>37. Movement Disorders Group</td>
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<td>38. Multiple Sclerosis and Rare Diseases of the CNS Group</td>
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<td>39. Musculoskeletal Group</td>
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<td>40. Neonatal Group</td>
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<td>41. Neuromuscular Group</td>
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<td>42. Oral Health Group</td>
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<td>43. Pain, Palliative and Supportive Care Group</td>
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<td>44. Pregnancy and Childbirth Group</td>
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<td>45. Public Health Group</td>
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<td>46. Schizophrenia Group</td>
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<td>47. Skin Group</td>
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<td>48. STI Group</td>
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<td>49. Stroke Group</td>
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<td>50. Test CRG</td>
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<td>51. Tobacco Addiction Group</td>
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<td>52. Upper GI and Pancreatic Diseases Group</td>
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<td>53. Urology Group</td>
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<tr>
<td>54. Vascular Group</td>
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<td>55. Work Group</td>
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<tr>
<td>56. Wounds Group</td>
</tr>
</tbody>
</table>
4 with >20 reviews of PRM interest

1. Back and Neck
2. Bone, Joint and Muscle Trauma
3. Musculoskeletal
4. Stroke

28 with ≥ 1 reviews of PRM interest

1. Acute Respiratory Infections
2. Airways
3. Back and Neck
4. Bone, Joint and Muscle Trauma
5. Breast Cancer
6. Cystic Fibrosis and Genetic Disorders
7. Dementia and Cognitive Improvement
8. Developmental, Psychosocial and Learning Problems
9. Ear Nose and Throat disorders
10. Eyes and Vision
11. Gynaecological, Neuro-oncology and Orphan Cancer
12. Gynaecology and Fertility
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22. Neonatal
23. Neuromuscular
24. Pain, Palliative and Supportive Care
25. Pregnancy and Childbirth
26. Stroke
27. Vascular
28. Wounds
Role of Cochrane Fields
a bridge

-facilitate work of Cochrane Review Groups
-ensure that Cochrane reviews are both relevant and accessible to their fellow specialists and consumers

Rehabilitation stakeholders side

Cochrane Groups side
Vision

All rehabilitation professionals can apply Evidence Based Clinical Practice

Decision makers will be able to take decisions according to the best and most appropriate evidence
Mission

Allow all rehabilitation professionals to combine the best available evidence as gathered by high quality Cochrane systematic reviews, with their own clinical expertise and the values of patients.

Improve the methods for evidence synthesis, to make them coherent with the needs of disabled people and daily clinical practice in rehabilitation.
Goals

1. To connect stakeholders and individuals involved in production, dissemination, and implementation of evidence based clinical practice in rehabilitation, creating a global network.

2. To undertake knowledge translation for Cochrane on reviews relevant to rehabilitation, with dissemination to stakeholders, in line with Cochrane’s knowledge translation strategy.

3. To develop a register of Cochrane and non-Cochrane systematic reviews relevant to rehabilitation.
Goals

4. To **promote Evidence Based Clinical Practice** and provide education and training on it and on systematic review methods to stakeholders

5. To **review and strengthen methodology relevant to Evidence Based Clinical Practice** to inform both rehabilitation and other Cochrane work related to rehabilitation and stimulating methodological developments in other Cochrane groups

6. To **promote and advocate for Evidence Based Clinical Practice in rehabilitation** to other Cochrane groups and wider rehabilitation stakeholders
The Executive Committee

1. Stefano Negrini, MD (Italy) – Director; Publication Com
2. Carlotte Kiekens, MD (Belgium) – Coordinator; Communication Com
3. Francesca Gimigliano, MD, PhD (Italy) – Communication Com
4. Frane Grubisic, MD (Croatia) – Publication Com
5. Tracey Howe, PT (United Kingdom)
6. Elena Ilieva, MD, PhD (Bulgaria) – Education Com
7. William Levack, PT, PhD (New Zealand) – Review Com
8. Antti Malmivaara (Finland) – Method Com
9. Thorsten Meyer, Psy, PhD (Germany) – Method Com
10. Julia Patrick Engkasan, MD (Malaysia) – Education Com
11. Farooq Rathore, MD (Pakistan) – Review Com; LMIC representative
Committees

Methodology
- Stengthen methodology in Rehabilitation

Rehabilitation Reviews
- Reference database of Cochrane Reviews

Publication
- Cochrane Corners in scientific journals
- Cochrane Rehabilitation e-book

Communication
- Website, Newsletter, Social media

Education
- Courses, Workshops and Congresses
Advisory Board

3 Cochrane Groups
5 World Scientific Societies
4 Regional Scientific Societies
12 Journals
4 Experts
4 Representatives
Individual members and Cochrane Rehab Units

Members: individual tasks
Units: big tasks and actions
www.rehabilitation.cochrane.org

Cochrane News
- World Kidney Day
- Early bird registration and stipends now open for the Global Evidence Summit
- Anne Anderson Prize recognizing the enhancement and visibility of women in Cochrane
- New Cochrane Library Special Collection: Enabling breastfeeding for mothers and babies
- Breastfeeding: evidence on effective support and promotion

Latest News and Events
The Official Launch Event, December 16th, 2016
Overview

Evidence Based Medicine (EBM)
• The origin and reason for EBM
• Cochrane: the Gold Standard of EBM

Physical and Rehabilitation Medicine (PRM) and EBM
• PRM vs other medical specialties
• Problems with evidence generation in PRM
• State of research in PRM

Implementation of EBM in PRM
• Knowledge Translation
• Cochrane Rehabilitation

Some solutions for EBM in PRM
What can we do to face these challenges?

There is a general «agreement» that PRM has low evidence
• We are struggling to produce sound (and meaningful) research
• In reality, we are not missing methodologically sound research (RCTs)
• But this good research does not relieve us: we still feel that we are missing evidence

Probably we are stuck by the RCT gold standard, that is not the best methodological approach due to the intrinsic limitation of PRM:
• Rehabilitation process
• Black box
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It’s time to think out of the box!
The Parachute Systematic Review of RCTs

Objectives. To determine whether parachutes are effective in preventing major trauma related to gravitational challenge.

Material and Methods. Design: Systematic review of RCTs. Data sources: Medline, Web of Science, Embase, and the Cochrane Library databases; appropriate internet sites and citation lists. Study selection: Studies showing the effects of using a parachute during free fall. Main outcome measure: Death or major trauma, defined as an injury severity score > 15.

Results. We were unable to identify any randomised controlled trials of parachute intervention.

Conclusions. As with many interventions intended to prevent ill health, the effectiveness of parachutes has not been subjected to rigorous evaluation by using randomised controlled trials.
Equipoise

The ethics of clinical research requires equipoise – a state of genuine uncertainty … regarding the comparative therapeutic merits of each arm in a trial…

• Individual level
• Expert medical community
What the consequences in PRM?

Let’s imagine gait rehabilitation for stroke

Is an RCT about making the patient walk like a parachute RCT?

Would an ethical committee consider unethical a control group without treatment?
  • Yes!
  • Rehabilitation in this topic has evidence without RCTs

What are not parachutes (ethical committees would allow the studies)?
  • Who makes him walk?
  • How he/she makes him walk?
  • How we increase the recovery speed?
  • How we reduce inherent costs?
1. Parachute Evidence Based Ethical List in PRM

What is this?
• A proposal to systematically list all PRM treatments that:
  – are like parachutes,
  – would be unethical to stop providing,
  – do not need any scientific study to prove their evidence

Methods
• Consensus procedures
• Partners
  – ISPRM
  – Cochrane
  – others?

Limits
• Conflict of interest (?): but, who else if not us?
The Pyramid of Evidence
2. The Pyramids of Evidence in PRM

Task of Cochrane Rehabilitation

BCTs

RCTs

QRCTs

Cohort studies

Case-Control studies

Single Case studies
Take home messages

Evidence Based Medicine (EBM)
• EBM is the last methodological achievement of medicine
• Cochrane and RCTs are the gold standard for a good EBM approach

Physical and Rehabilitation Medicine (PRM) and EBM
• PRM has specific challenges for EBM that must be faced
• PRM research methodological problems requires better understanding
• PRM is comparatively producing a lot of good research

Implementation of EBM in PRM
• When Evidence is known, a Knowledge Translation (KT) effort is required
• Cochrane Rehabilitation is the KT organization for PRM

PRM needs new out of the box thinking about the Evidence that we have, and how to generate future better Evidence
In PRM there is no EVIDENCE

A constant boulder on PRM shoulders
In PRM there is no EVIDENCE

Perhaps it is only a pebble in the shoe of PRM
Thank you

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