Cochrane Rehabilitation

Methodological issues in rehabilitation research

Antti Malmivaara, MD, PhD, Chief Physician
Centre for Health and Social Economics.
National Institute for Health and Welfare

Trusted evidence.
Informed decisions.
Better health.

Potential conflicts of interests

Finnish Institute for Health and Welfare, Centre for Health and Social Economics, Chief Physician

Current Care Guidelines, Finnish Medical Association Duodecim, Editor

Ministry for Social Affairs and Health, Council for Choices in Health care in Finland, Expert

Hospital ORTON, Scientific Board, Member

European Academy of Rehabilitation Medicine

Cochrane Back and Neck Review Group, Editorial Board

Cochrane Rehabilitation Field: Member of the Executive Committee; Chair of the Methodology Committee

Cochrane Rehabilitation Methodology committee

Antti Malmivaara, Chair (Finland)

Thorsten Meyer, Co-chair (Germany)

William Levack (New Zealand)

Chiara Arienti (Italy)

Stefano Negrini (Italy)





Primary purpose of the Methodology Committee

To lead Cochrane Rehabilitation activities in the area of methodology, and to develop and disseminate rehabilitation methodology within and outside Cochrane Collaboration

Cochrane Rehabilitation Methodology Committee: an international survey of priorities for future work

William M. LEVACK, Thorsten MEYER Stefano NEGRINI, Antti MALMIVAARA

Eur J Phys Rehabil Med 2017;53:814-7

The survey findings indicated strongest interest in

- How reviewers have applied and interpreted Cochrane methods in reviews on rehabilitation topics in the past
- On gathering existing publications on review methods for undertaking systematic reviews relevant to rehabilitation

Cochrane Rehabilitation Methodology Committee: On-going activities

Study on Pros and cons of RCTs in rehabilitation

- To answer relevant research questions, an to provide internal validity (risk of bias) and generalizability of evidence
- To discuss future needs to advance methodology of effectiveness research in rehabilitation

Catalyst project and another collaboration project

- Supplement issues on rehabilitation methodology in the European Journal of Physical and Rehabilitation Medicine and in the Journal of Rehabilitation Medicine

J Rehabil Med 2017; 49: Epub ahead of print

SPECIAL REPORT

REHABILITATION: THE HEALTH STRATEGY OF THE 21ST CENTURY

Gerold STUCKI, MD, MS[1–3]* Jerome BICKENBACH, LLB, PhD[1–3]*, Christoph GUTENBRUNNER, MD[4] and John MELVIN, MD[2,5]

*From the [1]Department of Health Sciences and Health Policy, Faculty of Humanities and Social Sciences, University of Lucerne, Lucerne, [2]Swiss Paraplegic Research (SPF), Nottwil, [3]ICF Research Branch, a cooperation partner within the World Health Organization Collaborating Centre for the Family of International Classifications in Germany (at DIMDI), Nottwil, Switzerland, [4]Department of Rehabilitation Medicine, Hanover Medical School, Hanover, Germany, [5]Sidney Kimmel Medical College, Thomas Jefferson University, Philadelphia, PA, USA.*Both of these authors contributed equally to this paper.*

There is strong evidence that population ageing and the epidemiological transition to a higher incidence of chronic, non-communicable diseases will continue to profoundly impact societies worldwide, putting more pressure on healthcare systems to respond to the needs of the people they serve. These trends argue for the need to address what matters to people about their health: limitations in their functioning that affect their day-to-day actions and goals in life.

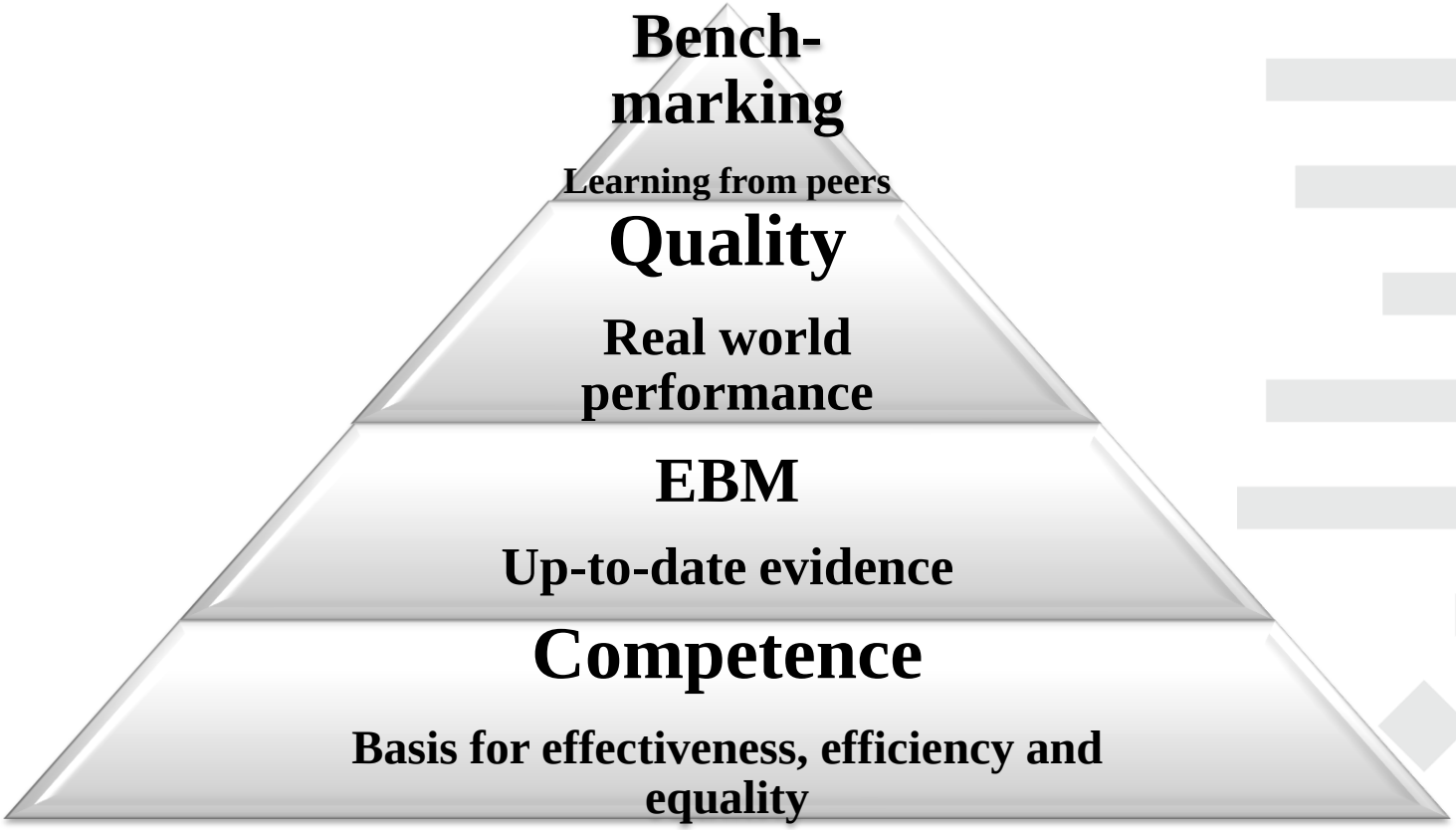
The objectives of this paper are to assemble the best demographic and epidemiological evidence about future trends, in order to build on the current conceptualization of the health strategy of rehabilitation, compared with other health strategies, and, utilizing the powerful notion of functioning as a health indicator, set out the best case for the proposition that rehabilitation is the key health strategy for the 21st century.

Real-effectiveness medicine - background

All activities within medicine (education, clinical work, leadership, research) have an ultimate aim to advance the health and wellbeing of everyday patients in ordinary health care settings.

Malmivaara A. Real-Effectiveness Medicine – pursuing the best effectiveness in the ordinary care of patients. Annals of Medicine 2013;45:103-106.

Real-Effectiveness Medicine



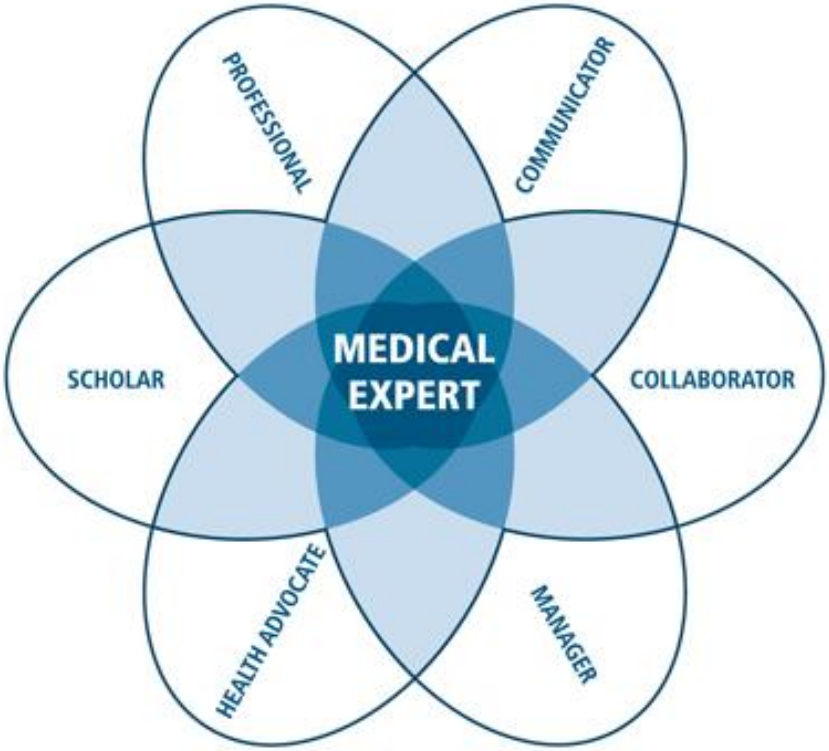
Malmivaara A. Real-Effectiveness Medicine – pursuing the best effectiveness in the ordinary care of patients. Annals of Medicine 2013;45:103-106.

Cochrane Rehabilitation

NATIONAL INSTITUTE FOR HEALTH AND WELFARE FINLAND

DUODECIM CURRENT CARE GUIDELINES

The Royal Collage of Physicians and Surgeons of Canada framework for competence



ROYAL COLLEGE OF PHYSICIANS AND SURGEONS OF CANADA | CANMEDS

The NEW ENGLAND JOURNAL of MEDICINE

SPECIAL ARTICLE

Surgical Skill and Complication Rates after Bariatric Surgery

John D. Birkmeyer, M.D., Jonathan F. Finks, M.D., Amanda O'Reilly, R.N., M.S., Mary Oerline, M.S., Arthur M. Carlin, M.D., Andre R. Nunn, M.D., Justin Dimick, M.D., M.P.H., Mousumi Banerjee, Ph.D., and Nancy J.O. Birkmeyer, Ph.D., for the Michigan Bariatric Surgery Collaborative

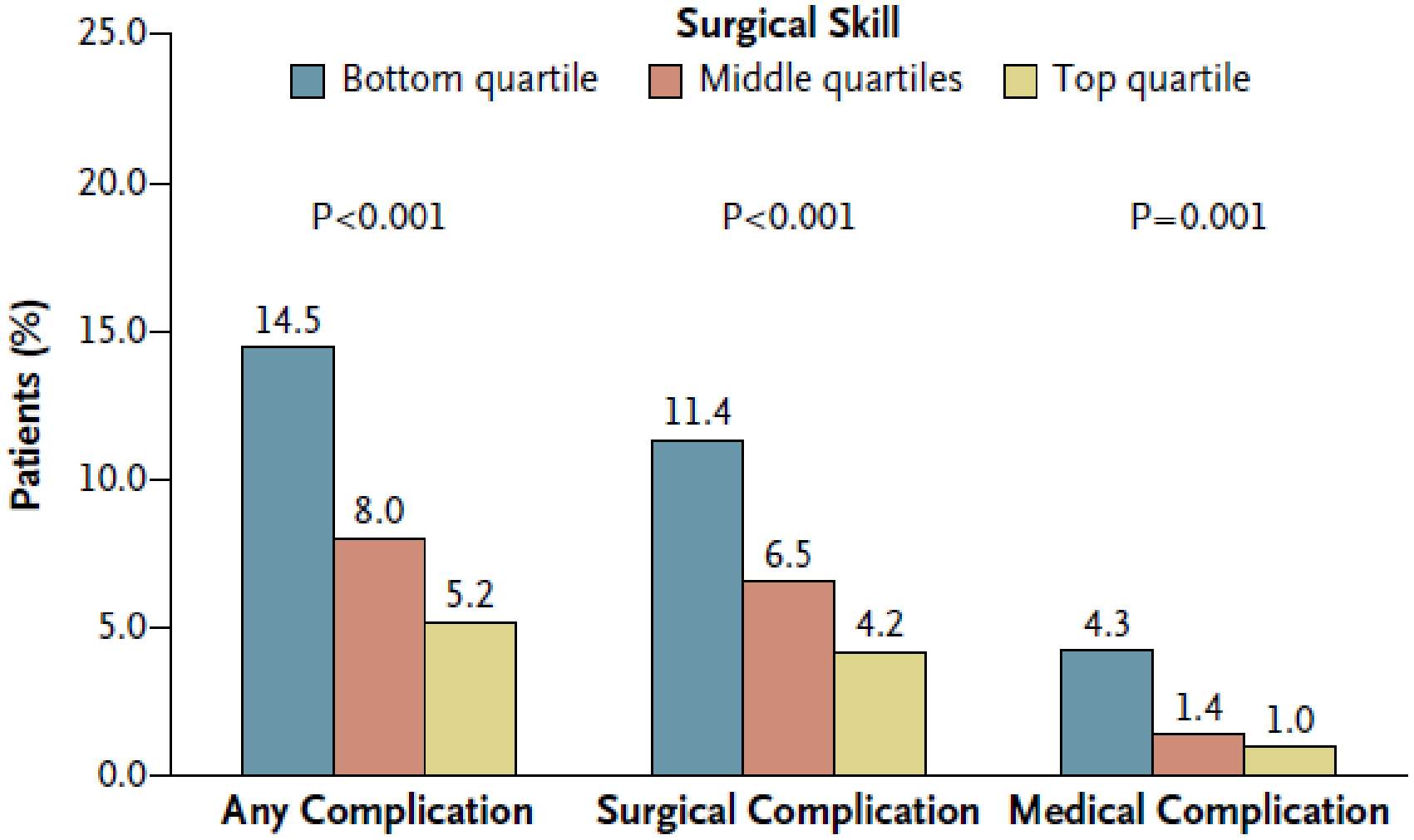


Figure 2. Risk-Adjusted Complication Rates with Laparoscopic Gastric Bypass, According to Quartile of Surgical Skill.

Cochrane Rehabilitation

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DUODECIM CURRENT CARE GUIDELINES

Competence of staff, an example

52-year old woman, have had breast cancer

The breast has been surgically removed

Previously active physically, particularly swimming

After operation slight depression, negative expectations of future

Weigth gain

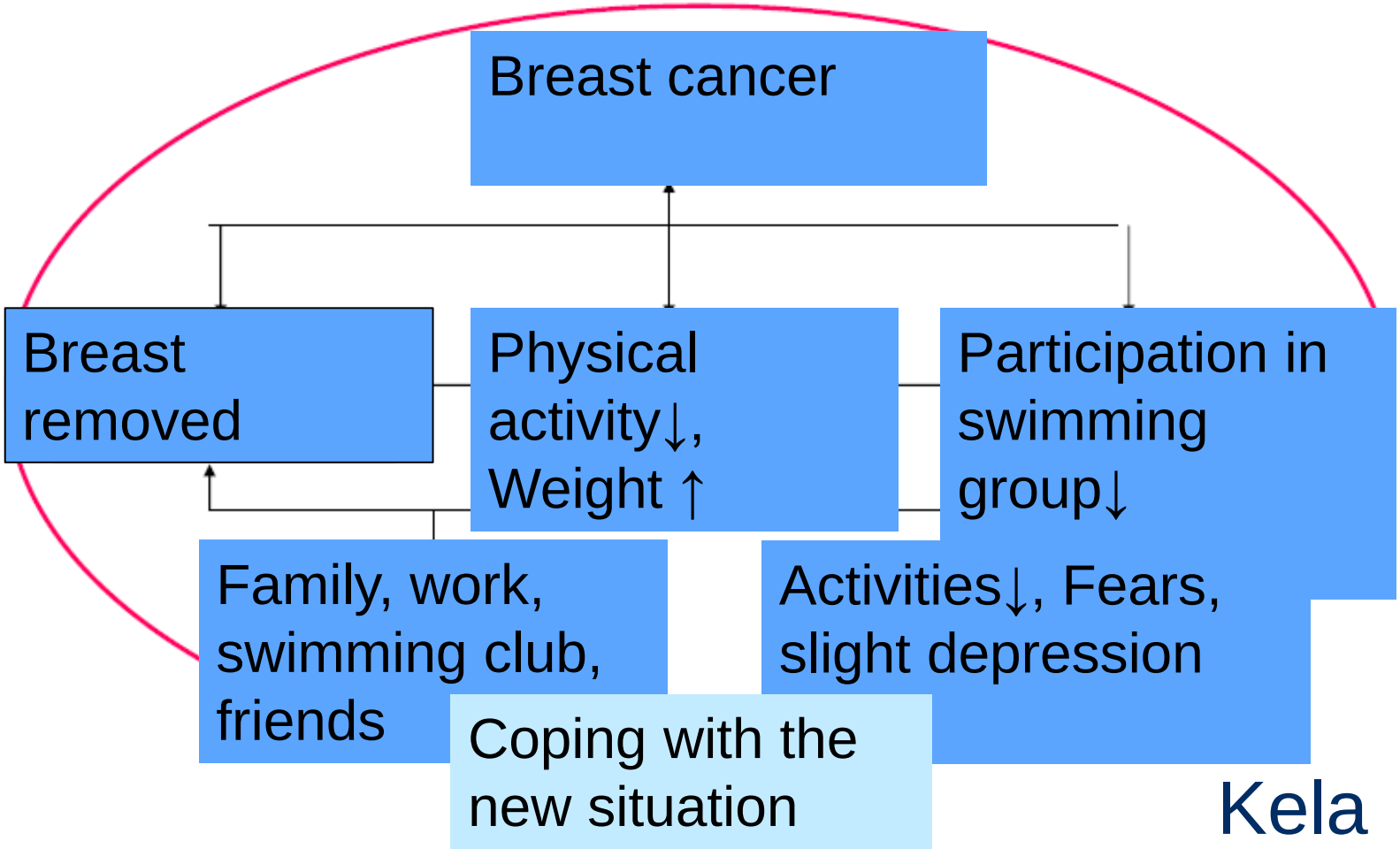
Fear for social encounters

Fear for going to the swimming hall

Kela

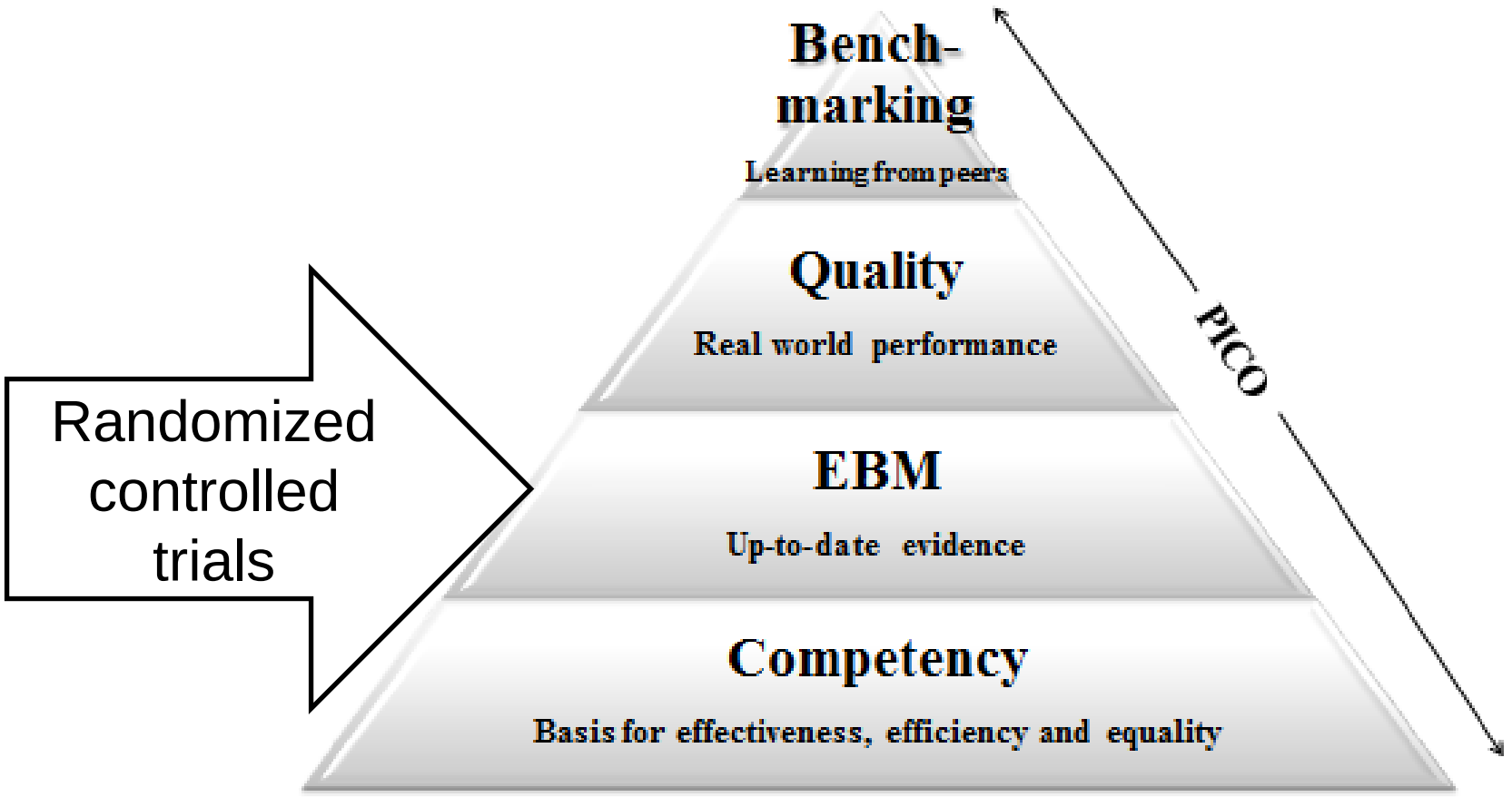
ICF kuntoutuksen viitekehyksenä

International classification of function



Kela

Real-Effectiveness Medicine



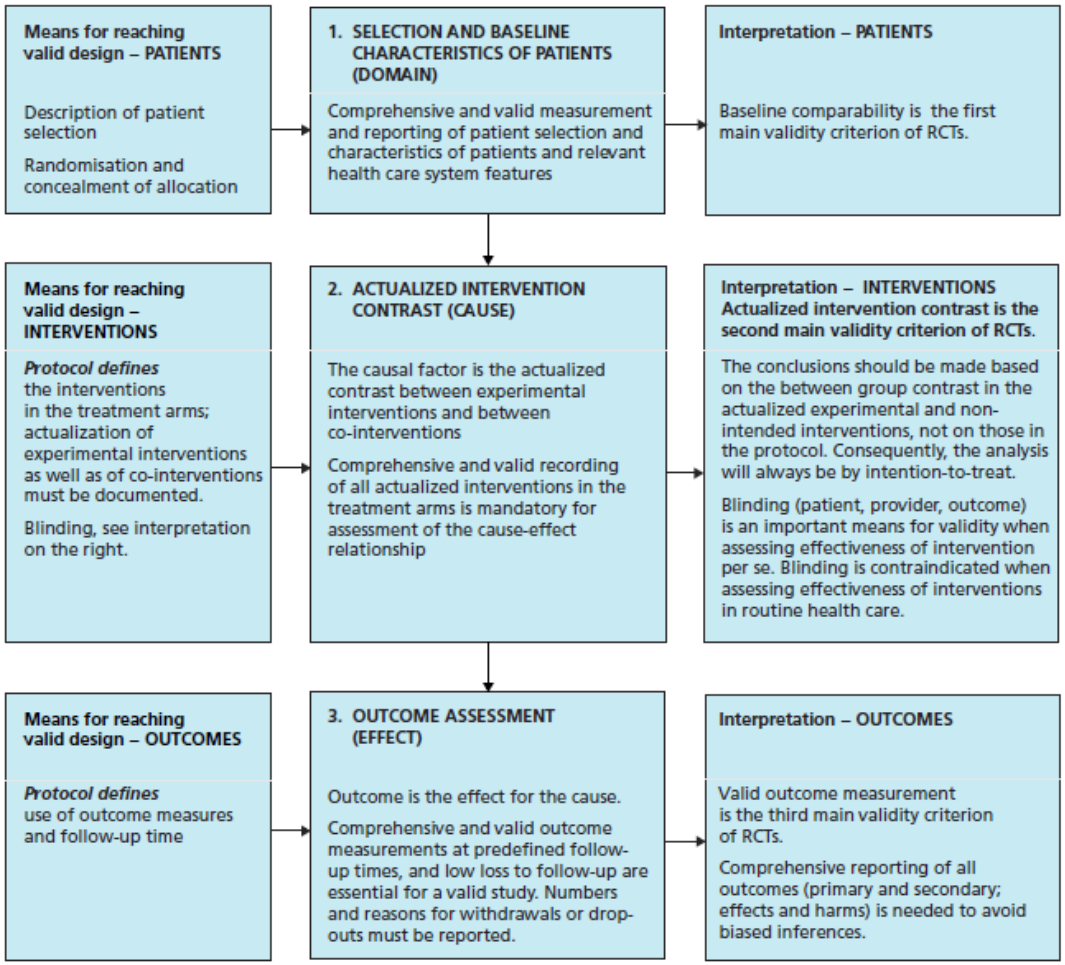
Malmivaara A. Real-Effectiveness Medicine – pursuing the best effectiveness in the ordinary care of patients. Annals of Medicine 2013;45:103-106.

REM – Evidence (level 2)

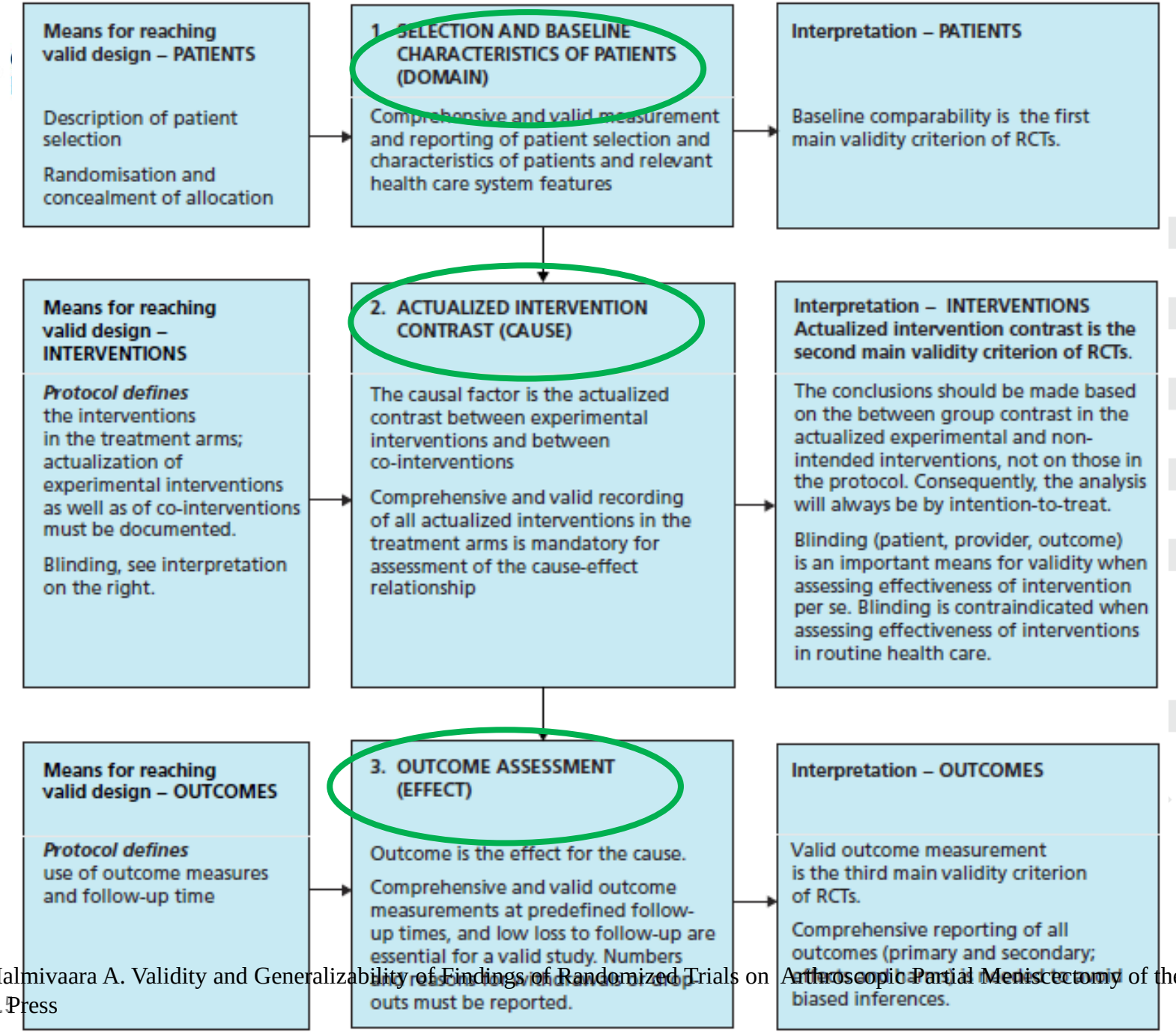
The second level of REM consists of the utilization of up-to-date of high quality scientific evidence, particularly from RCTs and systematic reviews, health technology assessment (HTA) reports, and clinical guidelines.

Also other scientific and patient-based information (e.g. on diagnostic tests and patients' values and preferences) according to the EBM (Evidence Based Medicine) framework should be used

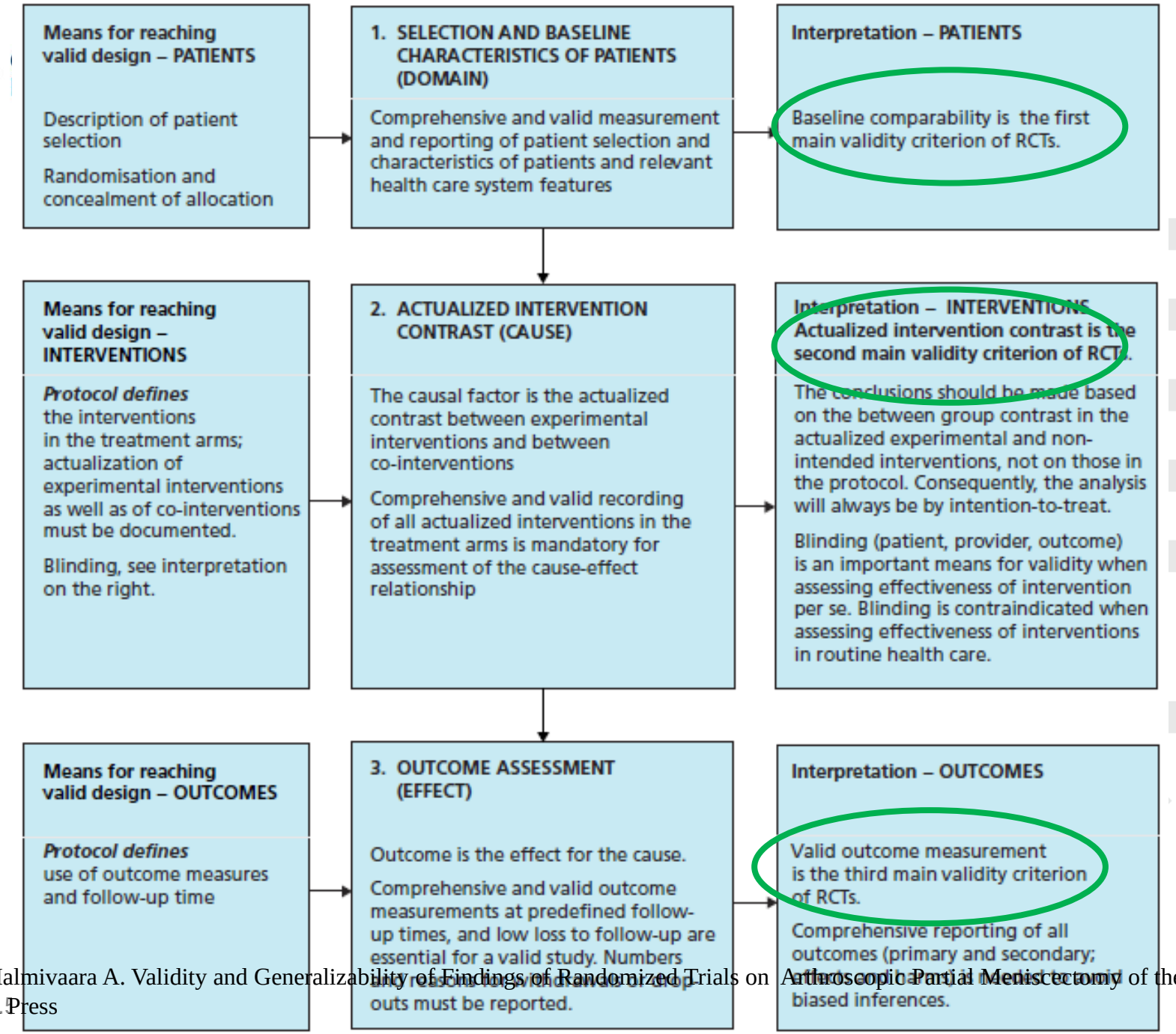
Domain, cause and effect in RCTs



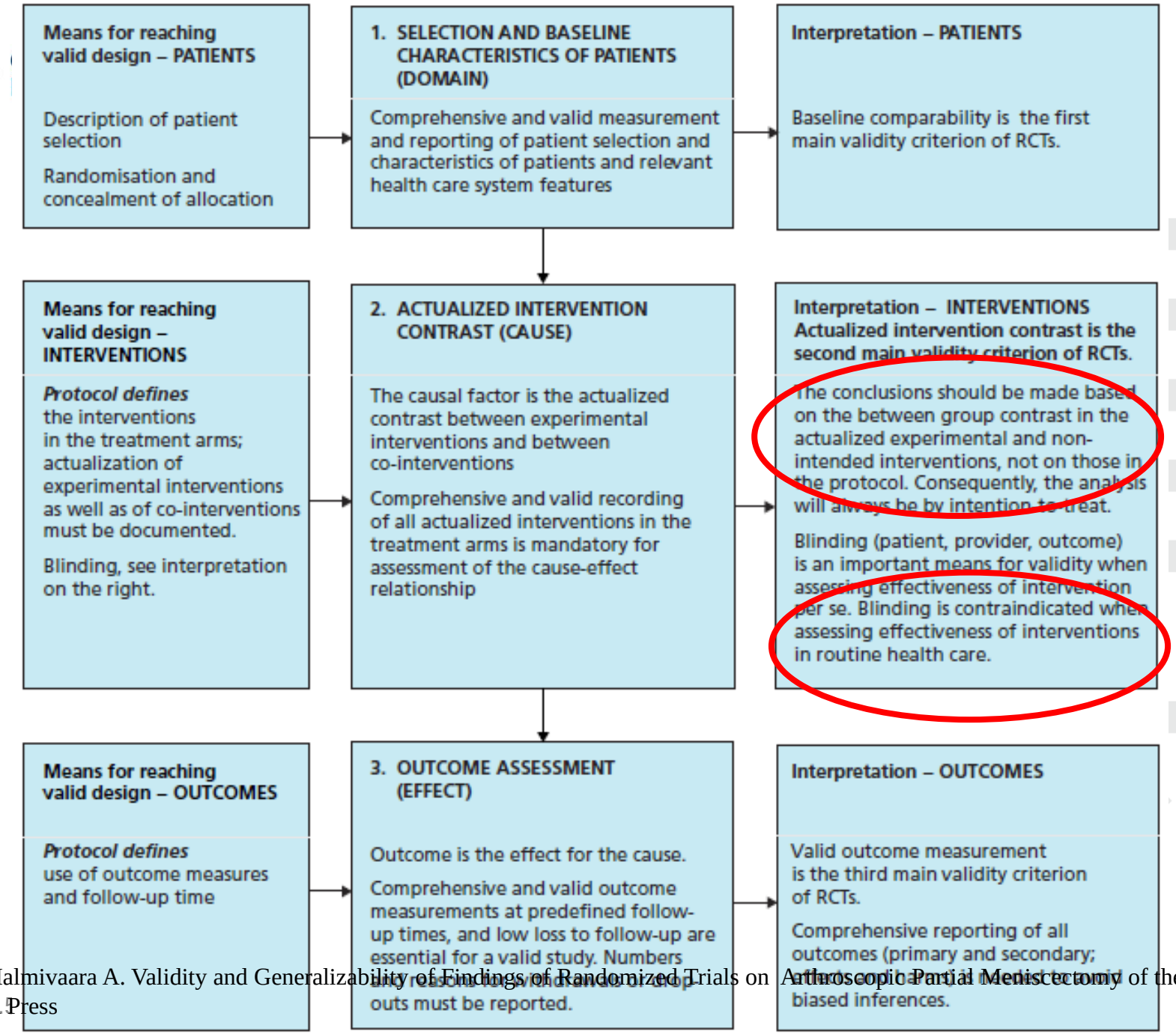
Malmivaara A. Validity and Generalizability of Findings of Randomized Trials on Arthroscopic Partial Meniscectomy of the Knee. In Press



Malmivaara A. Validity and Generalizability of Findings of Randomized Trials on Arthroscopic Partial Meniscectomy of the Knee. In Press



Malmivaara A. Validity and Generalizability of Findings of Randomized Trials on Arthroscopic Partial Meniscectomy of the Knee. In Press



Malmivaara A. Validity and Generalizability of Findings of Randomized Trials on Arthroscopic Partial Meniscectomy of the Knee. In Press

Randomized trials – Biological or real world effectiveness?

1. Intervention effect per se (biological) – blinded design

- Assesses merely biological effect; is abstract effectiveness, not realizing in ordinary care

-Number-needed-to treat – figures are not valid for real world effectiveness

2. Intervention effect in ordinary care – non blinded design

-Assesses besided biological effectiveness, also the placebo effect and effects of information and guidance, and those of support and empowerment

Malmivaara A. Validity and Generalizability of Findings of Randomized Trials on Arthroscopic Partial Meniscectomy of the Knee. In Press

Randomized trials – Biological or real world cost-effectiveness?

1. Blinded design – abstract knowledge

- Assesses mere biological intervention effectiveness and related use of health care services and respective costs

- Does not reflect real world cost-effectiveness, although used for this purpose (e.g. £ per HRQoL in UK)

2. Open, non-blinded design – real world knowledge

- Assesses biological intervention effectiveness + that related to placebo effect and use of health care services and costs

- However, cost-effectiveness varies according to staff competence, productivity and characteristics of health care system

Malmivaara A. Validity and Generalizability of Findings of Randomized Trials on Arthroscopic Partial Meniscectomy of the Knee. In Press

Malmivaara A. Quality of Reporting of Randomized Controlled Trials in the Leading Medical Journals (Manuscript)

Systematic review of reporting on internal and external validity of RCTs published between 1.1.2017 - 30.9.2017 in NEJM, JAMA, Lancet and BMJ

161 RCTs (N on rehabilitation):

- BMJ 4 (0)
- JAMA 50 (2)
- Lancet 71 (1)
- NEJM 36 (0)

→ 3/161 = 1,9 % on rehabilitation

Cochrane Rehabilitation

NATIONAL INSTITUTE FOR HEALTH AND WELFARE FINLAND

DUODECIM CURRENT CARE GUIDELINES

Intensive speech and language therapy in patients with chronic aphasia after stroke: a randomised, open-label, blinded-endpoint, controlled trial in a health-care setting

Caterina Breitenstein, Tanja Grewe, Agnes Flöel, Wolfram Ziegler, Luise Springer, Peter Martus, Walter Huber, Klaus Willmes, E Bernd Ringelstein, Karl Georg Haeusler, Stefanie Abel, Ralf Glindemann, Frank Domahs, Frank Regenbrecht, Klaus-Jürgen Schlenck, Marion Thomas, Hellmuth Obrig, Ernst de Langen, Roman Rocker, Franziska Wigbers, Christina Rühmkorf, Indra Hempen, Jonathan List, Annette Baumgaertner, for the FCET 2EC study group†*

Lancet 2017; 389: 1528–38
Published Online
February 27, 2017
http://dx.doi.org/10.1016/S0140-6736(17)30067-3

Summary

Background Treatment guidelines for aphasia recommend intensive speech and language therapy for chronic (≥6 months) aphasia after stroke, but large-scale, class 1 randomised controlled trials on treatment effectiveness are scarce. We aimed to examine whether 3 weeks of intensive speech and language therapy under routine clinical conditions improved verbal communication in daily-life situations in people with chronic aphasia after stroke.

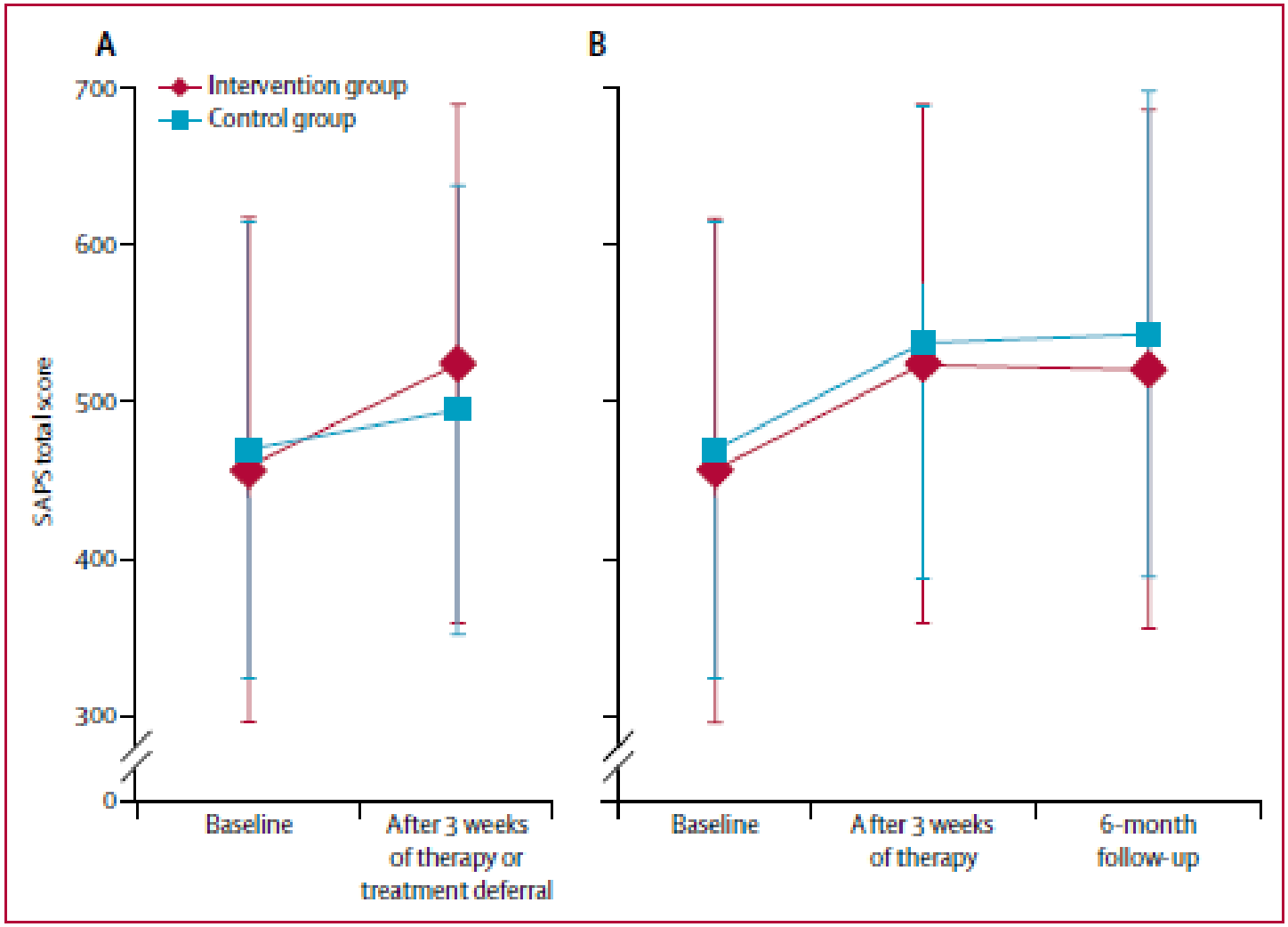


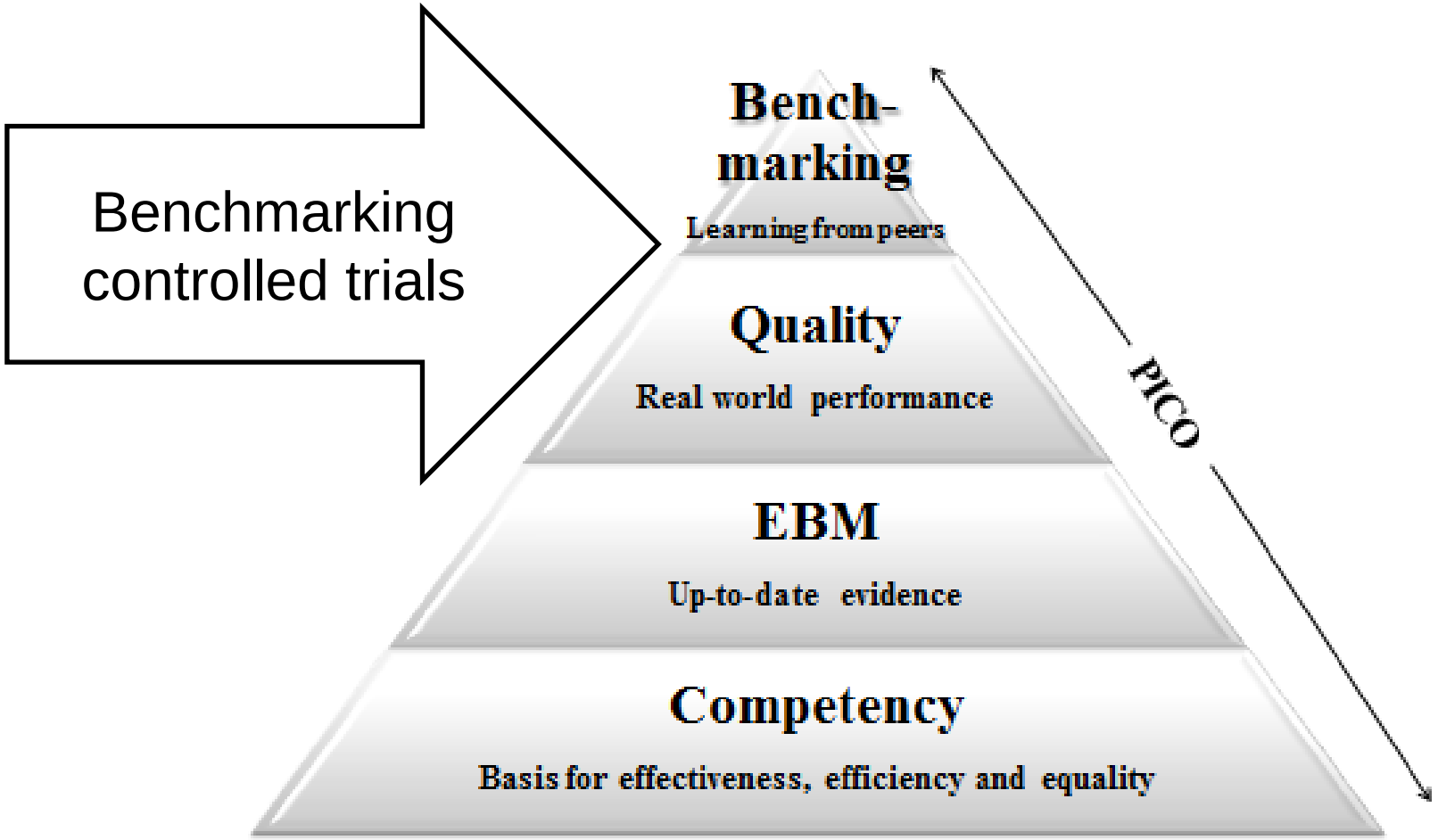
Figure 4: SAPS total score

(A) Mean score for the linguistic measure (SAPS total score) from baseline to after 3 weeks of intensive speech and language therapy in the intervention group and from baseline to after 3 weeks of treatment deferral in the control group. (B) Mean SAPS total score from baseline to after 3 weeks of treatment and 6 months after end of treatment in both the intervention and control groups. Minimum SAPS total score is 0 points, maximum is 900 points. Error bars represent SD. SAPS=Sprachsystematisches Aphasiescreening (language-systematic aphasia screening).

Conclusions

Interpretation 3 weeks of intensive speech and language therapy significantly enhanced verbal communication in people aged 70 years or younger with chronic aphasia after stroke, providing an effective evidence-based treatment approach in this population. Future studies should examine the minimum treatment intensity required for meaningful treatment effects, and determine whether treatment effects cumulate over repeated intervention periods.

Real-Effectiveness Medicine



ORIGINAL ARTICLE

Benchmarking Controlled Trial—a novel concept covering all observational effectiveness studies

Antti Malmivaara

Centre for Health and Social Economics, National Institute for Health and Welfare, Helsinki, Finland

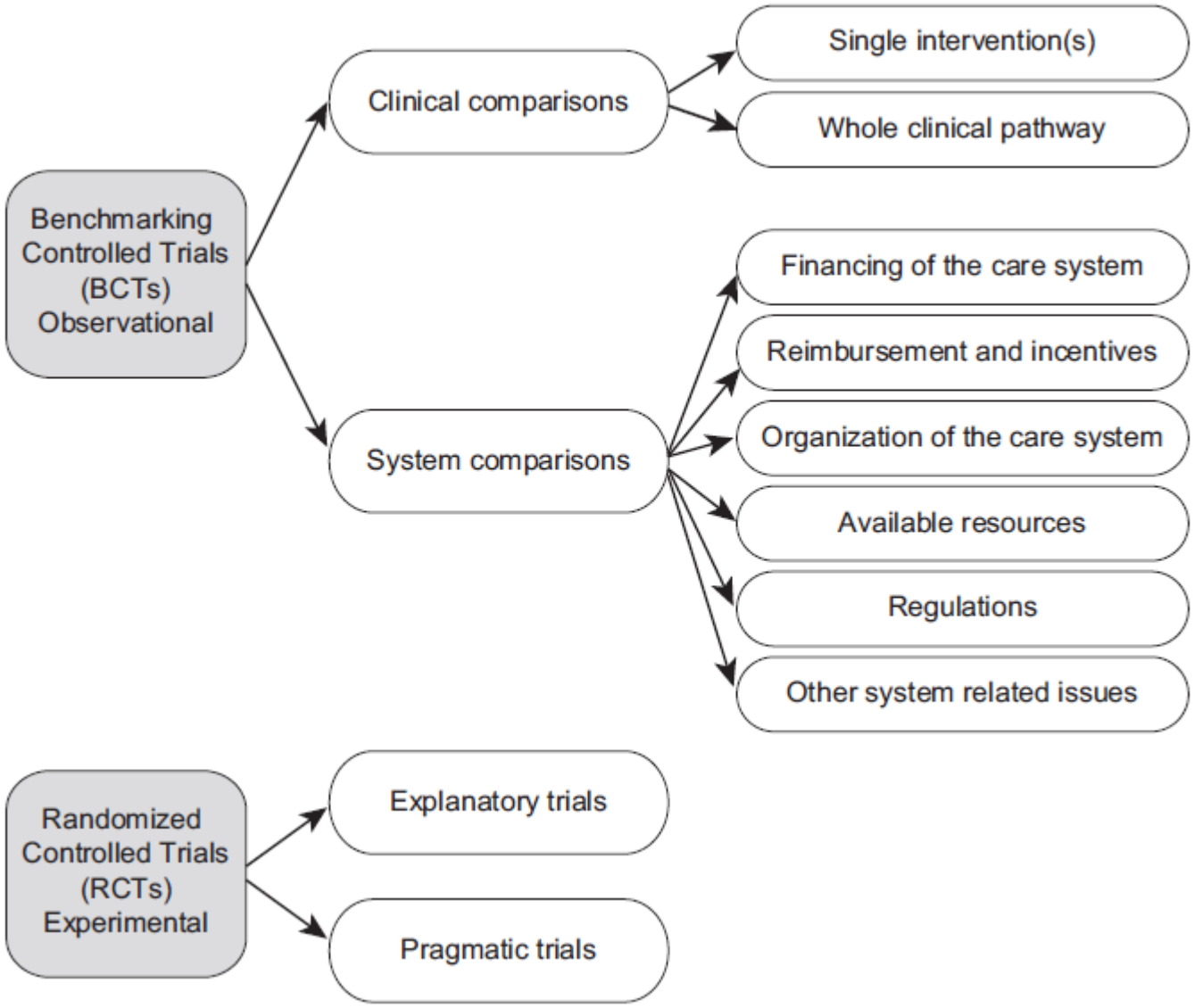
The Benchmarking Controlled Trial (BCT) is a novel concept which covers all observational studies aiming to assess effectiveness. BCTs provide evidence of the comparative effectiveness between health service providers, and of effectiveness due to particular features of the health and social care systems. BCTs complement randomized controlled trials (RCTs) as the sources of evidence on effectiveness. This paper presents a definition of the BCT; compares the position of BCTs in assessing effectiveness with that of RCTs; presents a checklist for assessing methodological validity of a BCT; and pilot-tests the checklist with BCTs published recently in the leading medical journals.

Key words: benchmarking controlled trial, cost-effectiveness, effectiveness, inequality, real-effectiveness medicine

Key messages

- The Benchmarking Controlled Trial (BCT) is a novel concept which covers all observational studies aiming to assess effectiveness.
- BCTs assess difference in effectiveness between single or a set of intervention(s), between clinical pathways, or between interventions targeting health care system factors with an aim to increase effectiveness.
- Published BCTs have currently several methodological limitations, some of which could be avoided, and others should be acknowledged.
- BCTs support both clinical and policy decisions, and should be given a high priority in research and in improvement activities.

Malmivaara A. Benchmarking Controlled Trial – a novel concept covering all observational effectiveness studies.. Annals of Medicine 2015;47:332-40.



Malmivaara A. Benchmarking Controlled Trial – a novel concept covering all observational effectiveness studies. Annals of Medicine 2015;47:332-40.

ORIGINAL ARTICLE

OPEN ACCESS

Clinical Impact Research – how to choose experimental or observational intervention study?

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ABSTRACT

Background: Interventions directed to individuals by health and social care systems should increase health and welfare of patients and customers.

Aims: This paper aims to present and define a new concept Clinical Impact Research (CIR) and suggest which study design, either randomized controlled trial (RCT) (experimental) or benchmarking controlled trial (BCT) (observational) is recommendable and to consider the feasibility, validity, and generalizability issues in CIR.

Methods: The new concept is based on a narrative review of the literature and on author's idea that in intervention studies, there is a need to cover comprehensively all the main impact categories and their respective outcomes. The considerations on how to choose the most appropriate study design (RCT or BCT) were based on previous methodological studies on RCTs and BCTs and on author's previous work on the concepts benchmarking controlled trial and system impact research (SIR).

Results: The CIR covers all studies aiming to assess the impact for health and welfare of any health (and integrated social) care or public health intervention directed to an individual. The impact categories are accessibility, quality, equality, effectiveness, safety, and efficiency. Impact is the main concept, and within each impact category, both generic- and context-specific outcome measures are needed. CIR uses RCTs and BCTs.

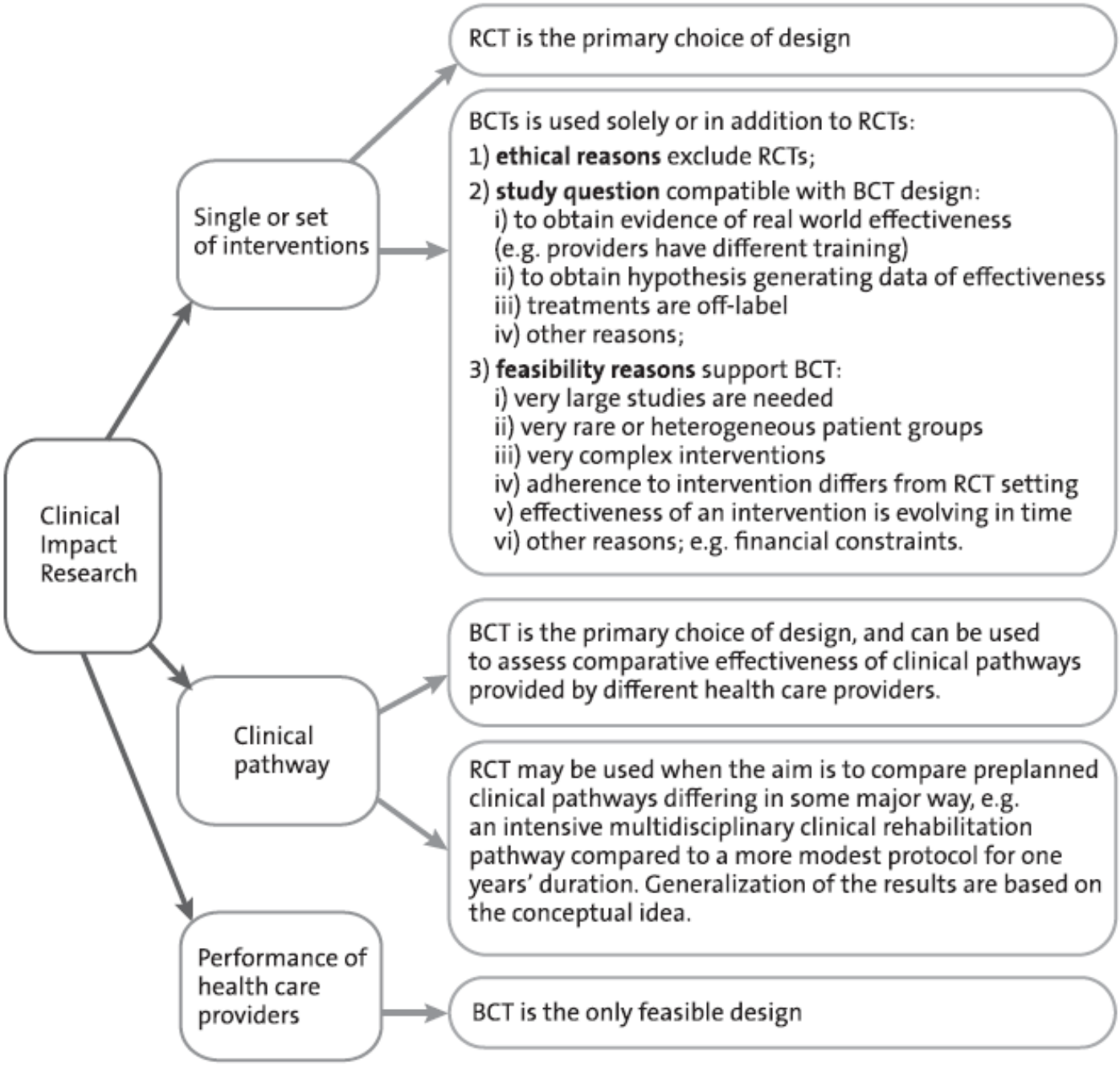
Conclusions: CIR should be given a high priority in medical, health care, and health economic research. Clinicians and leaders at all levels of health care can exploit the evidence from CIR.

ARTICLE HISTORY

Received 17 March 2016
Revised 27 April 2016
Accepted 2 May 2016

KEYWORDS

Accessibility; benchmarking controlled trial; clinical impact research; effectiveness; efficiency; equality; health care; quality; randomized controlled trial; safety


Clinical Impact Research
Single or set of interventions
RCT is the primary choice of design
BCTs is used solely or in addition to RCTs:
1) ethical reasons exclude RCTs;
2) study question compatible with BCT design:
i) to obtain evidence of real world effectiveness (e.g. providers have different training)
ii) to obtain hypothesis generating data of effectiveness
iii) treatments are off-label
iv) other reasons;
3) feasibility reasons support BCT:
i) very large studies are needed
ii) very rare or heterogeneous patient groups
iii) very complex interventions
iv) adherence to intervention differs from RCT setting
v) effectiveness of an intervention is evolving in time
vi) other reasons; e.g. financial constraints.
Clinical pathway
BCT is the primary choice of design, and can be used to assess comparative effectiveness of clinical pathways provided by different health care providers.
RCT may be used when the aim is to compare preplanned clinical pathways differing in some major way, e.g. an intensive multidisciplinary clinical rehabilitation pathway compared to a more modest protocol for one years' duration. Generalization of the results are based on the conceptual idea.
Performance of health care providers
BCT is the only feasible design

ANNALS OF MEDICINE, 2016
http://dx.doi.org/10.1080/07853890.2016.1186830

Taylor & Francis
Taylor & Francis Group

ORIGINAL ARTICLE

Assessing validity of observational intervention studies – the Benchmarking Controlled Trials

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ABSTRACT

Background: Benchmarking Controlled Trial (BCT) is a concept which covers all observational studies aiming to assess impact of interventions or health care system features to patients and populations.

Aims: To create and pilot test a checklist for appraising methodological validity of a BCT.

Methods: The checklist was created by extracting the most essential elements from the comprehensive set of criteria in the previous paper on BCTs. Also checklists and scientific papers on observational studies and respective systematic reviews were utilized. Ten BCTs published in the Lancet and in the New England Journal of Medicine were used to assess feasibility of the created checklist.

Results: The appraised studies seem to have several methodological limitations, some of which could be avoided in planning, conducting and reporting phases of the studies.

Conclusions: The checklist can be used for planning, conducting, reporting, reviewing, and critical reading of observational intervention studies. However, the piloted checklist should be validated in further studies.

ARTICLE HISTORY
Received 29 March 2016
Accepted 2 May 2016
Published online 30 May 2016

KEYWORDS
Checklist; validity; benchmarking controlled trial; effectiveness; cost-effectiveness; inequality; real-effectiveness medicine

Table 1. Criteria for the judgment of acceptable validity (scored 'Yes'*) for the sources of risk of bias in Benchmarking Controlle Trials (3).

1	Statistical power calculated. Score Yes, if description of power calculations and rationale on how the study size was arrived at; post-analysis power calculation is also accepted.
2	Selection of patients described. Score Yes, if clear description of patients' clinical path before eligible for the study; or if the patient population was comprehensive of the catchment area.
3	Valid and sufficient documentation of baseline characteristics *in both index and control populations.** Score Yes, if demographic and socio-economic factors, clinically important data relevant to the particular disorder/disease (e.g. severity), general health/risk status, comorbid conditions, behavioural and environmental factors when relevant, were sufficiently documented. (N. what constitutes 'sufficient' should be appraised in relation to the study context: whether or not the risk of bias is increased).
4	Baseline comparability acceptable.* Score Yes, if groups are sufficiently similar at baseline regarding demographic and socio-economic factors, duration and severity of the main indication, co-morbid conditions, and value of main outcome measure(s). (N.B. what constitutes 'sufficient' should be appraised in relation to the study context: whether or not the risk of bias is increased). If baseline documentation is insufficient, score 'Unclear'.
5	Valid and sufficient documentation of degree of adherence to the main intervention(s), and of other processes *in both index and control po ulations.* * Score Yes, if relevant factors for each particular study question are sufficiently reported, like intensity, duration, number and frequency health services; and if there were no confounding interventions or they were similar between the index and control groups. (N.B. what constitutes 'sufficient' should be appraised in relation to the study context: whether or not the risk of bias is increased).
6	Valid and sufficient documentation of outcomes *in both index and control populations*, including identical timing of outcome assessment.[a] Score Yes, if validity of the outcomes has been documented for both index and control populations, and the follow-up time points are similar; when relevant: if outcomes are assessed also among disadvantaged patients. (N.B. what constitutes 'sufficient' should be apprais in relation to the study context: whether or not the risk of bias is increased).
7	Drop-out rate acceptable. The number of included participants who did not complete the observation period or were not included in the analysis must be described and reasons given. Score Yes, if the percentage of withdrawals and drop-outs does not exceed 10% and does not lead to sub stantial bias. (N.B. the percentage is arbitrary, not supported by literature, and should be appraised in relation to the study context).
8	System related features sufficiently documented *in both the index and control health care providers.* Score Yes, if relevant system related factors are sufficiently documented and adjusted for in the statistical analyses: financing of the car system, organization of the care system, available resources, reimbursement and incentives, regulations. If system related features are n relevant in the study context: score 'Yes' (N.B. what constitutes 'sufficient' should be appraised in relation to the study context: whether or not the risk of bias is increased).
9	Staff competence, use of up-to-date evidence, quality and benchmarking activities sufficiently documented *in both the index and control health care providers*. Score Yes, if differences in staff competence, use of up-to-date evidence, quality and benchmarking activities Real Effectiveness Medicin framework (2) are sufficiently documented between the index and control groups. If these items are not relevant: score 'Yes' (N.B. what constitutes 'sufficient' should be appraised in relation to the study context: whether or not the risk of bias is increased).
10	Statistical analyses appropriate. Score Yes, if all appropriate statistical methods have been used to increase the validity of the comparisons (e.g. instrumental variables (when feasible), propensity score matching, baseline-adjustment between observed groups, use of multilevel modelling or survival modelling).

European Journal of Neurology 2014 doi:10.1111/ene.12560

Comparing ischaemic stroke in six European countries. The EuroHOPE register study

A. Malmivaara[a], A. Meretoja[b,c], M. Peltola[a], D. Numerato[d], R. Heijink[e], P. Engelfriet[e], S. H. Wild[f], É. Belicza[g], D. Bereczki[g], E. Medin[h], F. Goude[h], G. Boncoraglio[i], T. Tatlisumak[b], T. Seppälä[a] and U. Häkkinen[a]

[a]*Centre for Health and Social Economics, National Institute for Health and Welfare, Helsinki;* [b]*Department of Neurology, Helsinki University Central Hospital, Helsinki, Finland;* [c]*Departments of Medicine and the Florey, University of Melbourne, Parkville, Vic., Australia;* [d]*Centre for Research on Health and Social Care Management, Bocconi University, Milan, Italy;* [e]*National Institute for Public Health and the Environment, Bilthoven, The Netherlands;* [f]*Centre for Population Health Sciences, University of Edinburgh, Edinburgh, Scotland;* [g]*Semmelweis University, Budapest, Hungary;* [h]*Department of Learning, Informatics, Management and Ethics, Karolinska Institutet, Stockholm, Sweden; and* [i]*Department of Neurology, Fondazione IRCCS Istituto Neurologico Carlo Besta, Milan, Italy*

Keywords:
benchmarking, case fatality, Europe, hospitalization, international differences, ischaemic stroke, mortality, quality, register

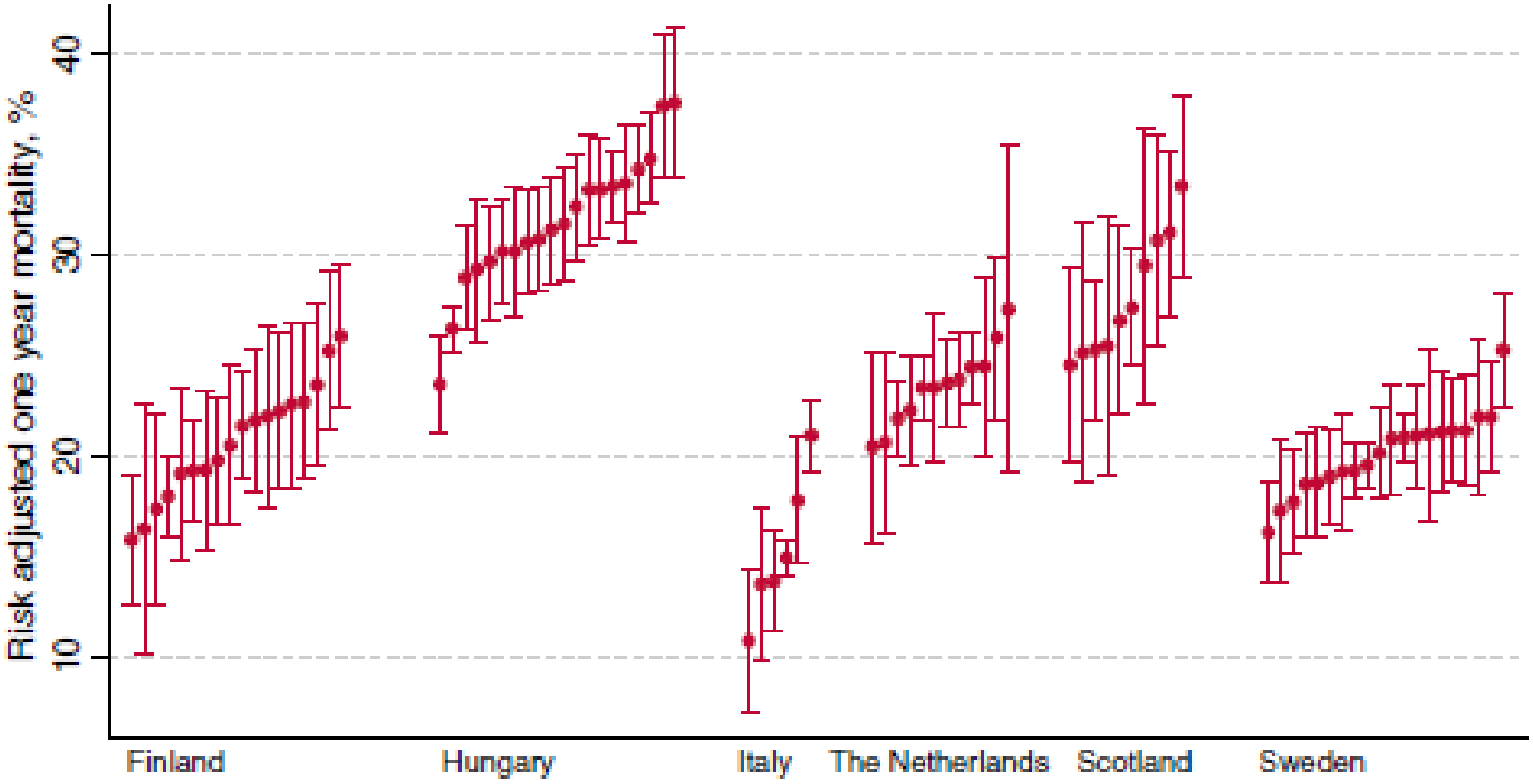
Received 27 February 2014
Accepted 25 July 2014

Background and purpose: The incidence of hospitalizations, treatment and case fatality of ischaemic stroke were assessed utilizing a comprehensive multinational database to attempt to compare the healthcare systems in six European countries, aiming also to identify the limitations and make suggestions for future improvements in the between-country comparisons.

Methods: National registers of hospital discharges for ischaemic stroke identified by International Classification of Diseases codes 433–434 (ICD-9) and code I63 (ICD-10), medication purchases and mortality were linked at the patient level in each of the participating countries and regions: Finland, Hungary, Italy, the Netherlands, Scotland and Sweden. Patients with an index admission in 2007 were followed for 1 year.

Results: In all, 64 170 patients with a disease code for ischaemic stroke were identi-

EuroHOPE-project. One year mortality for ischaemic stroke in six countries.



Malmivaara A, Meretoja A, Peltola et al. Comparing ischaemic stroke in six European countries. The EuroHOPE register study. Eur J Neurol, 2015;22:221–418

ORIGINAL ARTICLE

OPEN ACCESS

System impact research – increasing public health and health care system performance

Antti Malmivaara

Centre for Health and Social Economics, National Institute for Health and Welfare, Helsinki, Finland

ABSTRACT

Background Interventions directed to system features of public health and health care should increase health and welfare of patients and population.

Aims To build a new framework for studies aiming to assess the impact of public health or health care system, and to consider the role of Randomized Controlled Trials (RCTs) and of Benchmarking Controlled Trials (BCTs).

Methods The new concept is partly based on the authorã s previous paper on the Benchmarking Controlled Trial. The validity and generalizability considerations were based on previous methodological studies on RCTs and BCTs.

Results The new concept System Impact Research (SIR) covers all the studies which aim to assess the impact of the public health system or of the health care system on patients or on population. There are two kinds of studies in System Impact Research: Benchmarking Controlled Trials (observational) and Randomized Controlled Trials (experimental). The term impact covers in particular accessibility, quality, effectiveness, safety, efficiency, and equality.

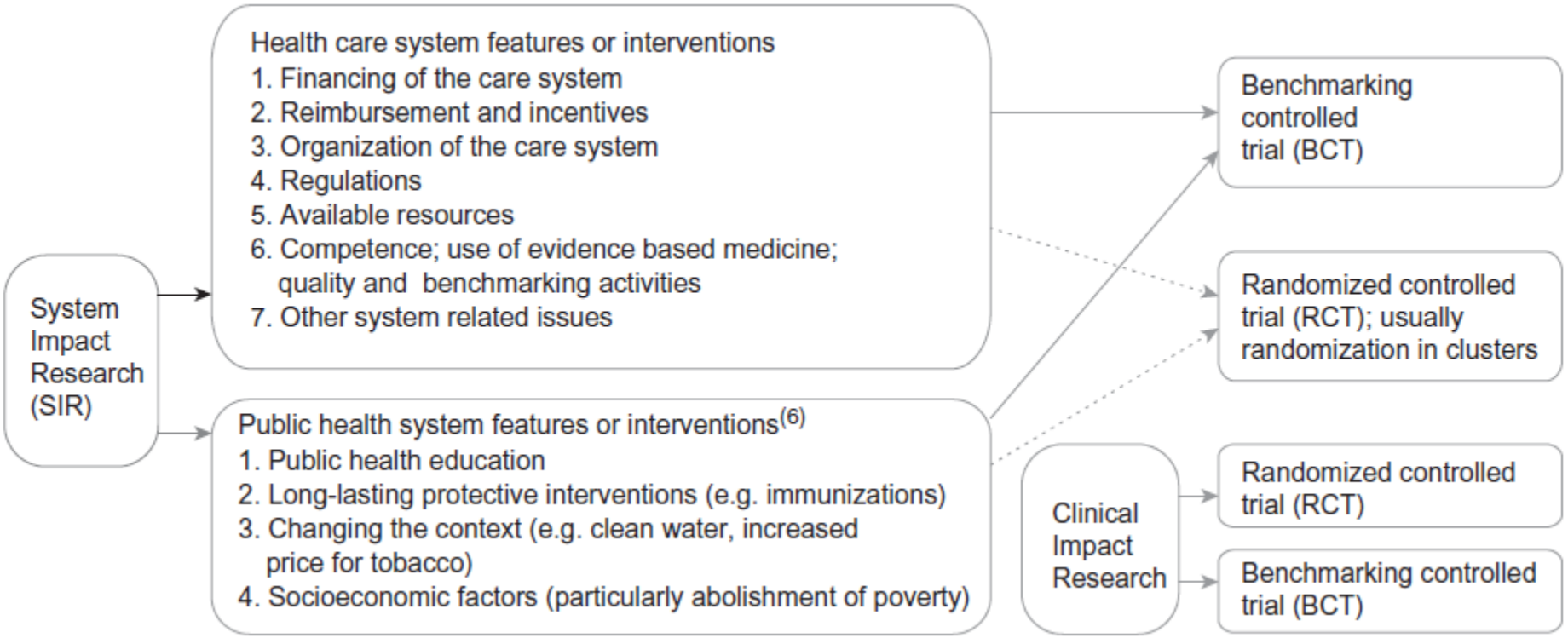
Conclusions System Impact Research – creating the scientific basis for policy decision making - should be given a high priority in medical, public health and health economic research, and should also be used for improving performance. Leaders at all levels of health and social care can use the evidence from System Impact Research for the benefit of patients and population.

ARTICLE HISTORY

Received 28 October 2015
Revised 14 January 2016
Accepted 13 February 2016

KEYWORDS

Health care; public health; health economics; system impact research; randomized controlled trial; benchmarking controlled trial; effectiveness; safety; efficiency; equality

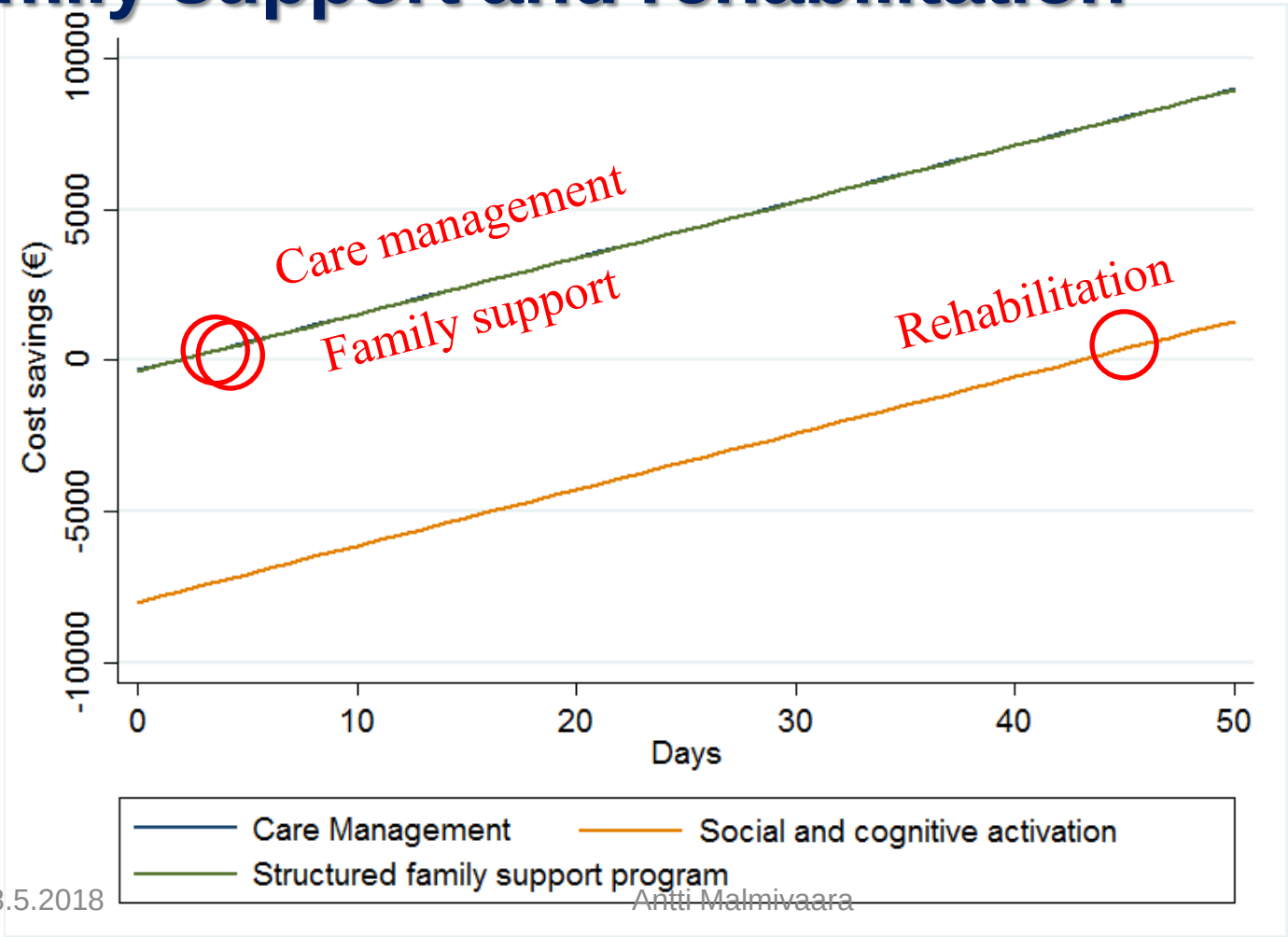


Malmivaara A. System Impact Research – increasing public health and health care system performance. Annals of Medicine 2016;March 15:1-5

Potential cost savings of selected non-pharmacological treatment strategies for Alzheimer's disease in Finland - a cost-neutrality model (Manuscript)

Ari Rosenvall, Lauri Sääksvuori, Harriet Finne-Soveri, Ismo Linnosmaa, Antti Malmivaara

Cost savings due to care management, family support and rehabilitation



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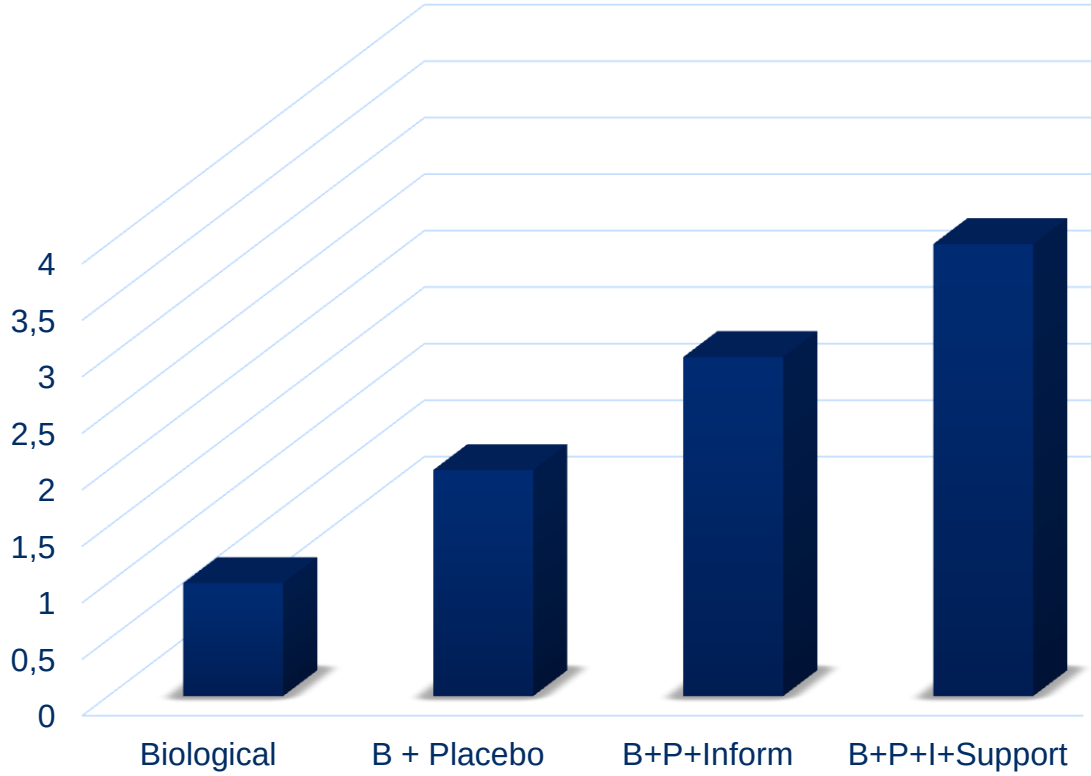
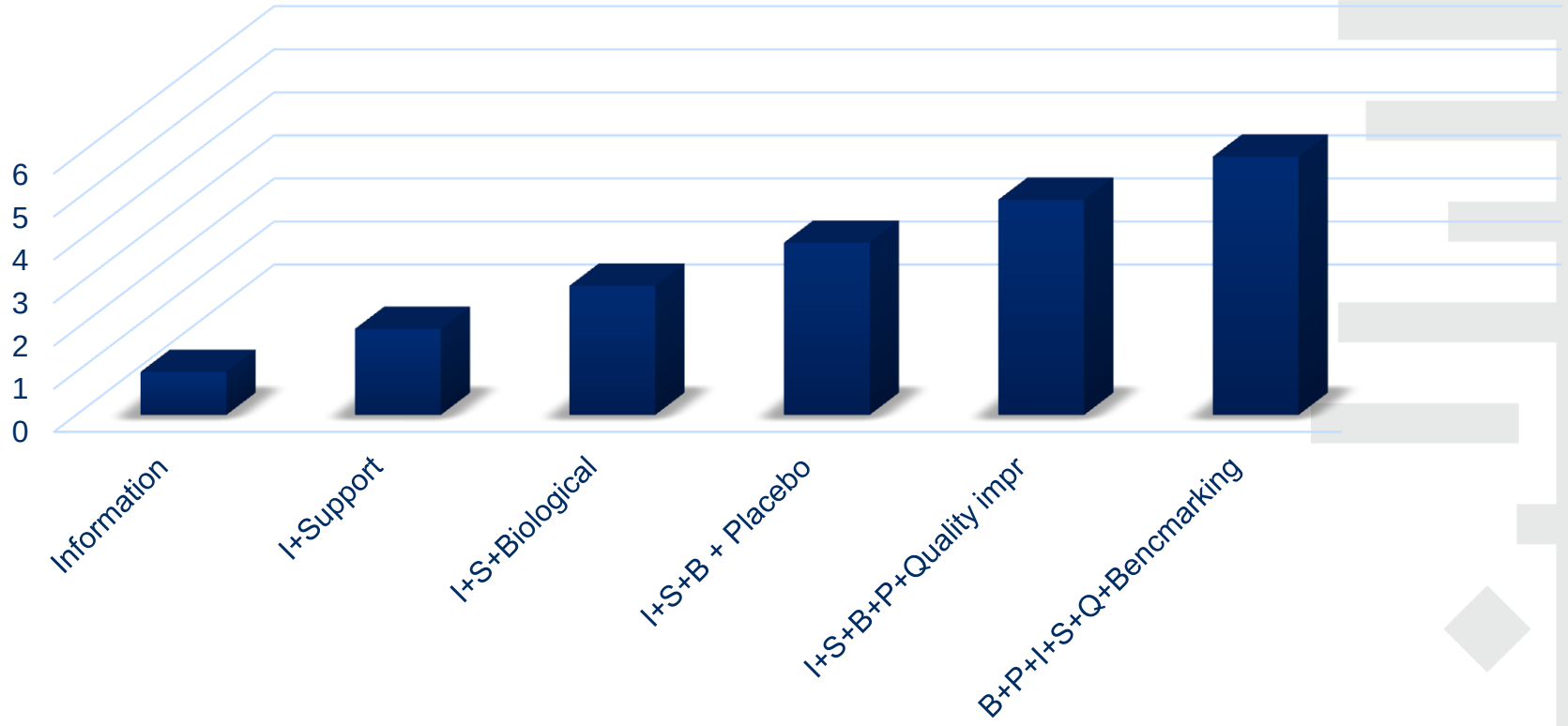
Conclusions

Cumulative effectiveness in rehabilitation, methodological view



Malmivaara A. Validity and Generalizability of Findings of Randomized Trials on Arthroscopic Partial Meniscectomy of the Knee. In Press

Cumulative effectiveness in rehabilitation, clinical practice view

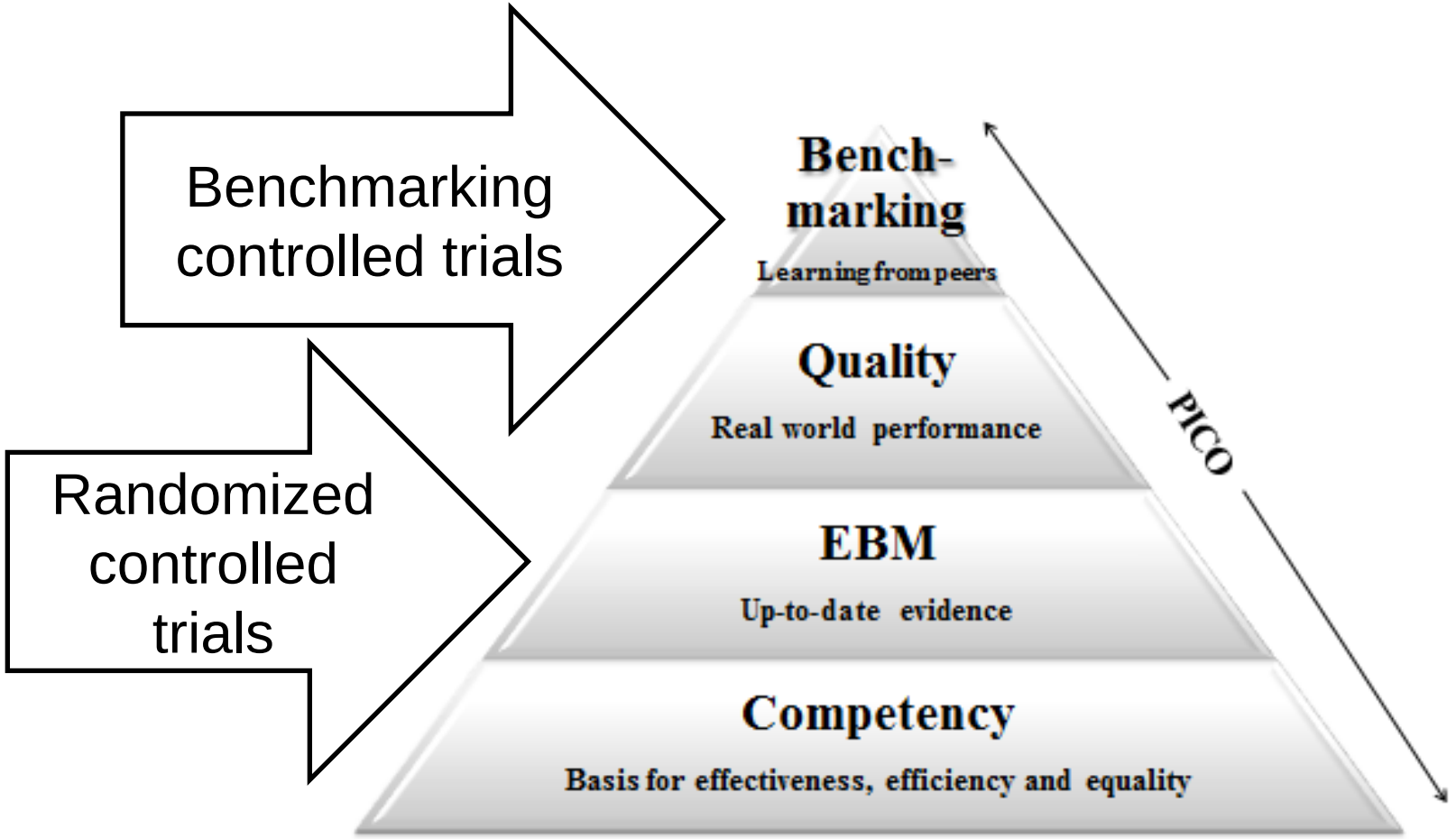


Malmivaara A. Validity and Generalizability of Findings of Randomized Trials on Arthroscopic Partial Meniscectomy of the Knee. In Press

The six stages in pursuing scientific evidence of effectiveness in rehabilitation

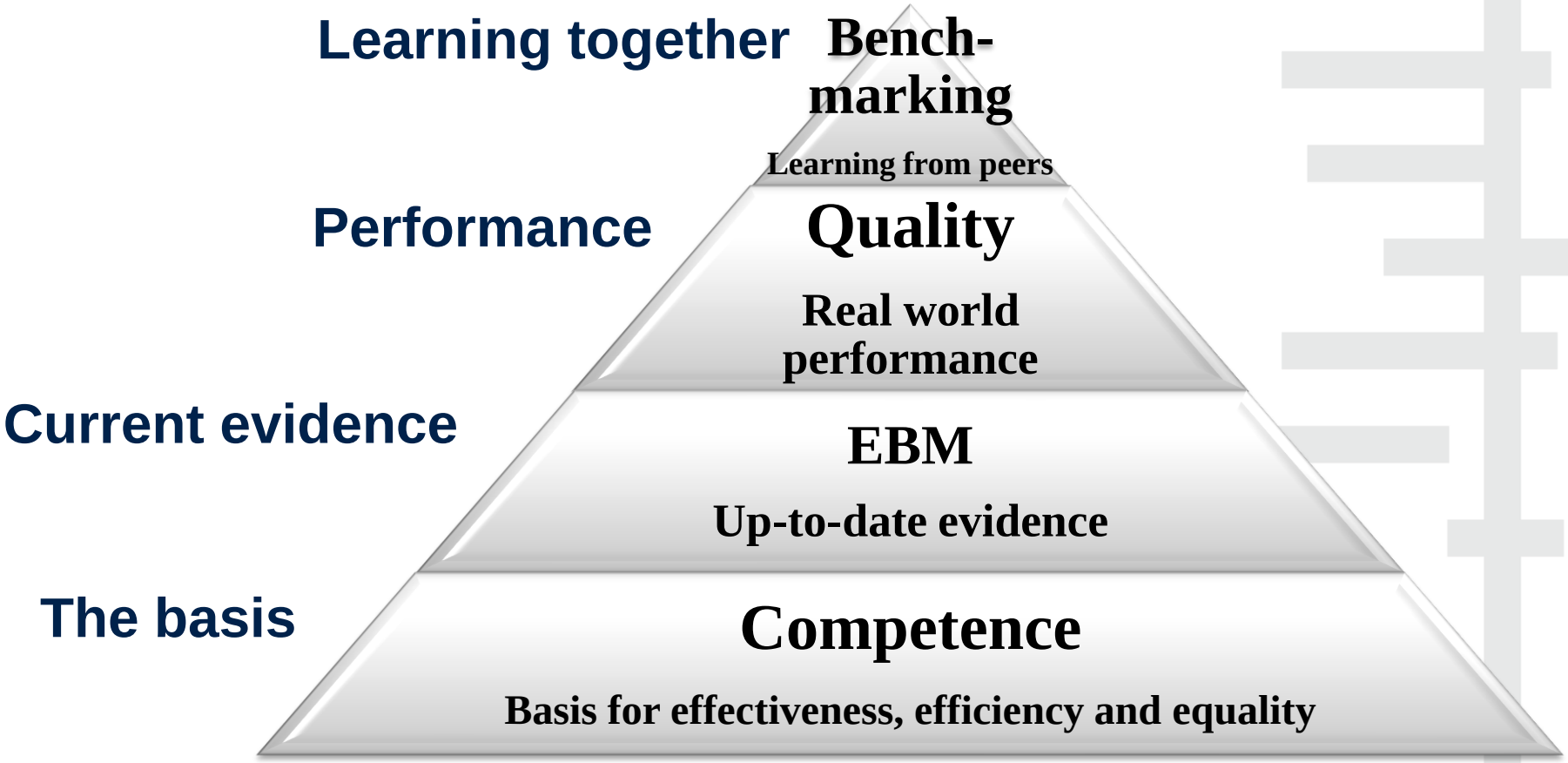
1. Decide upon the most relevant study question(s)
2. Decide whether RCT or BCT is the study design of choice
3. Ensure good description of patient selection, patient characteristics, adherence to interventions and use of valid outcomes to be able to draw conclusions of generalizability of findings
4. Ensure best design in terms of internal validity
5. Ensure good conduct of the protocol
6. Report according to recommendations

Real-Effectiveness Medicine



Malmivaara A. Real-Effectiveness Medicine – pursuing the best effectiveness in the ordinary care of patients. Annals of Medicine 2013;45:103-106.

Strategy for rehabilitation



Malmivaara A. Real-Effectiveness Medicine – pursuing the best effectiveness in the ordinary care of patients. Annals of Medicine 2013;45:103-106.

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Thank you!