



NATIONAL INSTITUTE FOR HEALTH AND WELFARE

# The human risks of bias in medical and rehabilitation practice and research

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# 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

European Academy of Rehabilitation Medicine, Chair of the Foresight Committee

Cochrane Back and Neck Review Group, Editorial Board

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



# Introduction

- The human mind is liable to make biased interpretations.
- Whether and in what degree the human risk of bias poses a threat to good medical practice and to valid scientific work depends on what one considers the aim of health care. The premise of this paper is, that the aim of health care is to provide accessible, high quality, fair, effective, safe and efficient health services to the patients and the populations.

Tversky A, Kahneman D. Judgment under Uncertainty: Heuristics and Biases. *Science* 1974;185:1124-31

Kahneman D, Tversky A. On the reality of cognitive illusions. *Psychol Rev* 1996;103:582,91

MacCoun R, Perlmutter S. Blind analysis: Hide results to seek the truth. *Nature* 2015;526:187-9

Let's think about cognitive bias. *Nature* 2015;526:163

Malmivaara A. System impact research - increasing public health and health care system performance. *Ann Med* 2016:1-5



# Aims

1. To define the term human risk of bias.
2. To identify and define the categories of potential human risks of biases in medical and rehabilitation practice and research.
3. To gather the available evidence of effects of these human risks of biases.



# Methods

The human risk of bias (HRoB) was defined by the author as human factors (extrinsic to the empirical methods and data), which create bias in obtaining or interpreting clinical evidence, or in medical research.

List of conceivable categories of human risk of bias was produced by the author based on the available medical scientific literature and on common sense. Altogether eight categories were recognized: *identity, integrity, independence, intelligence, ideology, interest, incentive, and inequality.*

The definitions of the eight categories were taken from the Oxford Dictionary of English (second edition, 2003).



# Methods (2)

- A narrative literature review was undertaken using the following key words: risk of bias, validity, systematic review, identity, integrity, independence, intelligence, ideology, interest, conflict of interest, incentive, inequality.
- PubMed and Web of Science databases were sought to find the relevant articles. The articles that were considered most relevant for answering the study questions were included and considered in the paper.



# Results - definitions and available evidence



# Integrity

- *The quality of being honest and having strong moral principles.*
- There is evidence that positive results and statistically significant outcomes are more likely to be published. In addition, publications have often been found to be inconsistent with their protocols.
- There is also evidence of the use of ghost authors.

Chan AW, Hrobjartsson A, Haahr MT, et al. Empirical evidence for selective reporting of outcomes in randomized trials: comparison of protocols to published articles. *JAMA* 2004;291:2457-65 doi:10.1001/jama.291.20.2457 [doi].

Flanagin A, Carey LA, Fontanarosa PB, et al. Prevalence of articles with honorary authors and ghost authors in peer-reviewed medical journals. *JAMA* 1998;280:222-4



# Interest

- *The advantage or benefit of a person or group.*
- Financial conflict of interests are associated with favourable interpretations of effectiveness of interventions. The scope and impact of financial conflicts of interest in biomedical research is substantial.
- The non-financial conflict of interests have been studied less, but there is evidence that these also favour the intervention under study.

Bekelman JE, Li Y, Gross CP. Scope and impact of financial conflicts of interest in biomedical research: a systematic review. *JAMA* 2003;289:454-65

11 Lieb K, Osten-Sacken J, Stoffers-Winterling J, et al. Conflicts of interest and spin in reviews of psychological therapies: a systematic review. *BMJ Open* 2016;6:e010606,2015-010606



# Inequity

- *Lack of fairness or justice.*
- RCTs often exclude disadvantaged patient groups. Only 1% of a random sample of systematic Cochrane reviews assessed effectiveness across socioeconomic factors. Clinical guidelines utterly rarely consider the disadvantaged patient groups.
- There is evidence that disadvantaged people have on average poorer access to services, and they get less often treatments shown effective in RCTs.

Welch V, Brand K, Kristjansson E, et al. Systematic reviews need to consider applicability to disadvantaged populations: inter-rater agreement for a health equity plausibility algorithm. *BMC Med Res Methodol* 2012;12:187,2288-12-187

Berkowitz SA, Aragon K, Hines J, et al. Do Clinical Standards for Diabetes Care Address Excess Risk for Hypoglycemia in Vulnerable Patients? A Systematic Review. *Health Serv Res* 2013



# Identity, intelligence, ideology, independence and incentive: definitions

- *Identity: the characteristics determining who or what a person is.*
- *Intelligence: the ability to acquire and apply knowledge and skills.*
- *Ideology: the set of beliefs characteristic of a social group or individual.*
- *Independence: the fact or state of being independent. Independent: free from outside control; not subject to another's authority.*
- *Incentive: a thing that motivates or encourages someone to do something.*



# Identity, intelligence, independence, ideology and incentive: the evidence

- No studies were found that explicitly and primarily focused on the association between identity, intelligence, independence, ideology or incentive of an individual or group, and biased interpretations in medical research or clinical practice.
- Considering intelligence, there is evidence that better competence of health care staff is associated with better outcomes. However, competence in medical research or clinical practice is dependent also on other characteristics than mere intelligence.

Birkmeyer JD, Finks JF, O'Reilly A, et al. Surgical skill and complication rates after bariatric surgery. *N Engl J Med* 2013;369:1434-42



# Discussion – the biases

- Interests (material or immaterial) are an impediment to objectivity in medical practice and research. A conflict of interest is a situation in which individual's or group's motivation may be corrupted because of other interests than that of the explicitly stated goal of action.
- Incentive is related to the concept of interest, but is usually time and context dependent and can be used as a specific motivator for better performance.
- Inequity means that some population groups are neglected in original research, systematic reviews and clinical guidelines; and that the accessibility of services of uniform quality according to need is not similar in different population groups.



# Discussion – the biases

- Identity of a person or group of persons (e.g. that related to a medical specialty) was considered a fundamental feature of a human being with a powerful effect on behavior.
- Integrity is a prerequisite for valid results and honest interpretations.
- Independence from outside influence is important as a prerequisite for maintaining integrity.
- Intelligence is mandatory for understanding of the scientific method and for valid inferences on evidence.
- A balanced ideology on what is important and what should be pursued is important for low risk of bias in medical practice and research.



# Discussion – the biases

- The eight categories of human risks of bias overlap with each other. For example a prestigious scientist may as a reviewer reject a paper compromising his own theory. In this case the biased interpretation of the paper may primarily be related to the immaterial interests of the scientist, but also reasons related to identity, integrity and ideology of the scientist may be involved.
- Assessment of whether human risk of bias is present should be related to a particular study or decision question. Overall judgement of individuals' or groups' HRoB may lead to untoward effects, even to ad hominem argumentation. A fundamental problem lies in the difficulty of appraising the presence and magnitude of human risk of bias, as these cannot be judged from the published paper. Scientifically valid tools for this purpose should be developed.

Ioannidis JP. Why most published research findings are false. PLoS Med 2005;2:e124

Rosenbaum L. Understanding bias--the case for careful study. N Engl J Med 2015;372:1959-63



# Discussion – medical research

- The conceptual and empirical findings of this paper refer both to biomedical and rehabilitation field
- The research on HRoB has focused mainly on the financial conflict of interests and on integrity of people in the scientific field.
- Inequity has not been studied as a question of risk of bias, but as a problem itself, although the evidence indicates that inequity causes biases in medical practice and research.
- There seems to be lack of studies assessing the impact of other categories of human risks of bias for medical practice or research.



# Discussion - medical practice

- Individuals' or a group's high degree of intelligence, integrity and independence obviously promote the aims of the health care.
- Strong identity, e.g. of being a surgeon, may promote good medical practice, but may also do the contrary e.g. if the possibilities of own specialty are overvalued.
- Incentives may be a way to motivate towards better performance, if the reason for the reward is based on valid data and the behavioral change will be favorable. However, incentives may have adverse effects, e.g. cause unanticipated neglect of other important actions.
- The ideology of an individual or group, may advance good medical practice, particularly if it focuses on a mission to care for people. However, an ideology that puts more emphasis on other goals than benefiting the patients, may conflict with the aims of health care.
- Inequity is harmful for the aim to pursue better health care, and is a source of HRoB.

Sihvonen R, Paavola M, Malmivaara A, et al. Arthroscopic partial meniscectomy versus sham surgery for a degenerative meniscal tear. *N Engl J Med* 2013;369:2515-24

Chassin MR, Loeb JM, Schmaltz SP, et al. Accountability Measures - Using Measurement to Promote Quality Improvement. *N Engl J Med* 2010;363:683-8

Malmivaara A. On decreasing inequality in health care in a cost-effective way. *BMC Health Serv Res* 2014;14:79,6963-14-79



# Discussion - limitations

- Recognition of six of the eight categories of the human risk of bias were based on common sense, while only two (integrity and interest) were found in the medical literature. In previous literature inequity has been dealt with as an issue itself, but not explicitly as producing biased interpretations.
- Due to the study question of the present paper, no searches on other disciplines than medicine were made.
- The review of literature was narrative. Unlike in a systematic review, the literature search was not comprehensive, and the validity of the studies was not assessed. Furthermore, the field of this review is so wide that the author had to choose those papers which he considered best for answering the study questions. Also, some important studies may have been missed.
- The conclusions are dependent of the stated aims of the health care.



# Conclusions

- The evidence shows that conflict of interest, deficient integrity and inequity are important factors causing human risk of bias in medical research.
- Other potential human risks of biases have been studied very little or not at all. There are very few studies on how the human risk of bias affects clinical practice.



# Conclusions

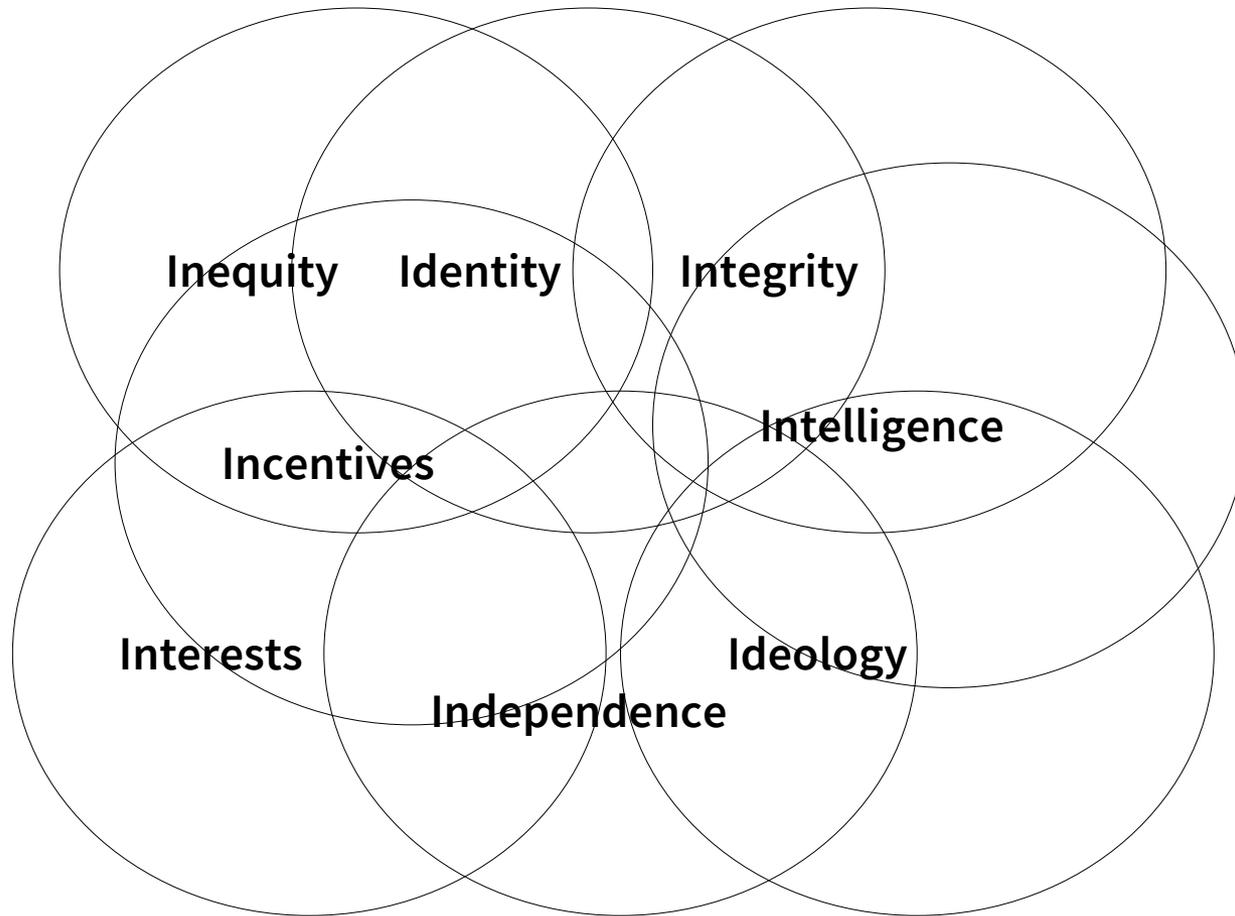
- Three steps are suggested for research and action on reducing human risk of bias.
- The first step in aiming for less bias in clinical practice and research is to acknowledge human beings' strong liability to biased thinking, and multifaceted nature of HRoB.
- The second step is to use the best verified existing means to reduce the human risk of bias.
- The third step is to invest in research, particularly on identifying and reducing human risk of bias in medical practice and research.
- These actions may be as important as actions aiming to increase the validity of the scientific method.

Malmivaara A. The human risks of bias in medical and rehabilitation research and practice: the 8 I's.  
Eur J Phys Rehabil Med. 2019 Apr 15.

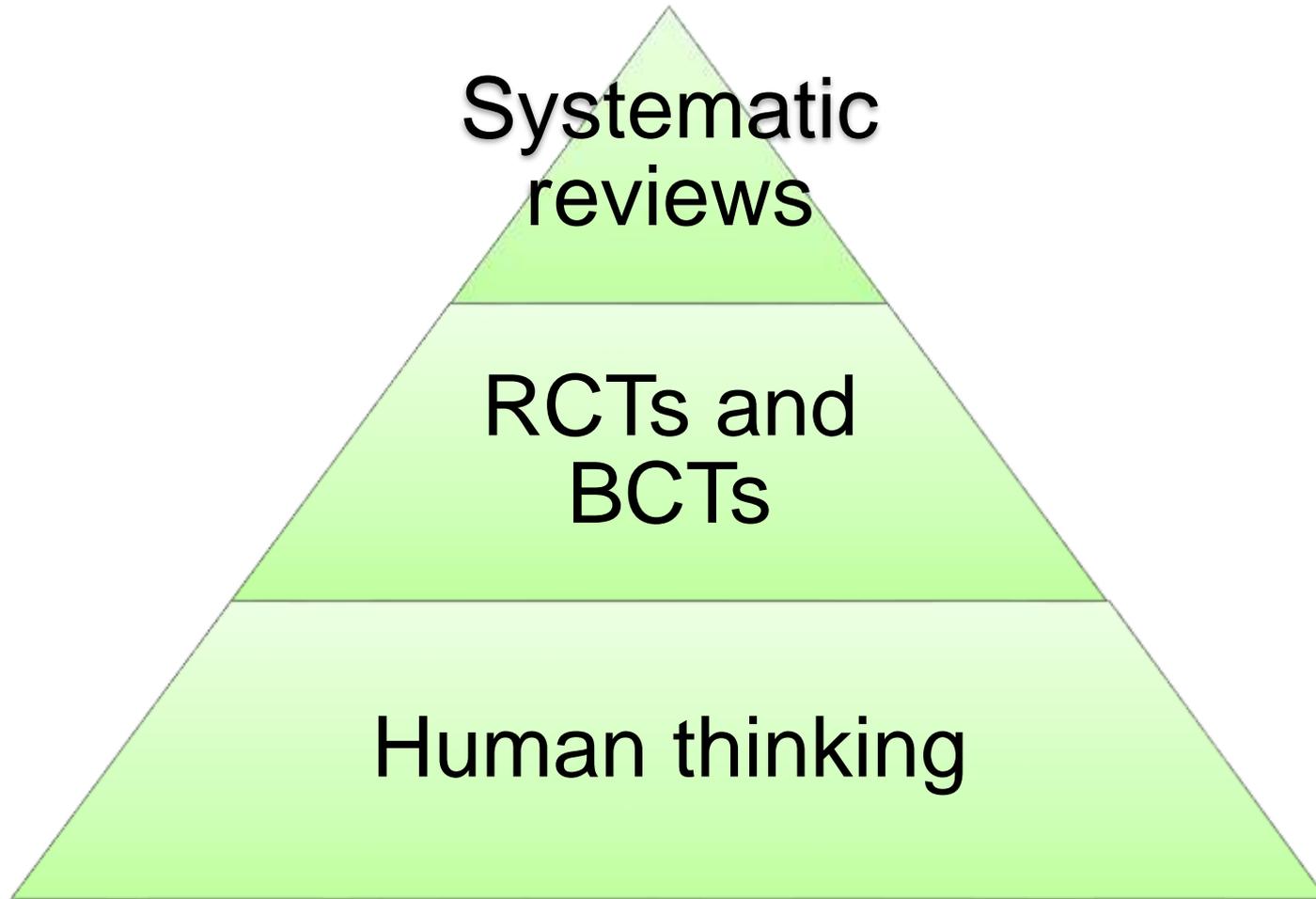
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# Human risk of bias: the eight I's



# Levels of risk of bias in effectiveness research





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**Thank you!**