

# Medical scientists and philosophers worldwide appeal to EBM to expand the notion of ‘evidence’

The rapid dominance of evidence based medicine has sparked a philosophical debate concerning the concept of evidence. We urge that evidence based medicine, if it is to be practised in accordance with its own mandate, should also acknowledge the importance of understanding causal mechanisms.[1–7] The undersigned include 42 clinicians and philosophers from interdisciplinary research networks working specifically on questions related to causation in medicine worldwide.

Our research has developed out of a conviction that philosophical analysis ought to have a direct impact on the practice of medicine. In particular, if we are to understand what is meant by ‘evidence’, what is the ‘best available evidence’, and how to apply it in the context of medicine, we need to tackle the problem of causation head on.[1,8–12] In practice, this means understanding the context in which evidence is obtained, as well as how the evidence might be interpreted and applied when making practical clinical decisions.[7,13] It also means being explicit about what kind of causal knowledge can be gained through various research methods. The possibility that mechanistic and other types of evidence can be used to add value or initiate a causal claim, should not be ignored.[3–7,14–15] This appeal for a broader approach to evidence is also important to patients, who need clear information on the benefits and harms of medicines.[16]

We have arrived at several overlapping conclusions with implications for policy and practice in research and clinical care, which we summarize briefly:

1. ‘Evidence’ is typically evidence of causation. Common terms used in EBM, such as ‘intervention’, ‘outcome’, or ‘increased risk’ are relevant to evidence-based decision-making only insofar as they point to causal matters: causal interventions and their effects. Although there is growing reluctance to make causal claims in areas of uncertainty, the correct response to such uncertainty is not to avoid talking about causation, but instead to improve our methods of understanding it.
2. Establishing causation often requires the use of multiple methods, since no single method will be universally applicable or perfect for this purpose. This means that statistical approaches, in particular RCTs and systematic reviews, cannot uncover all causally relevant information, contrary to their widespread assumed status as the universal gold standards of EBM.
3. An understanding of causal mechanisms can help to determine *whether* an intervention works (i.e. its efficacy shown in experiment or effectiveness in clinical practice). In addition, we should strive to understand *how* an intervention works (i.e. its mechanism) and how it can be made to work (i.e. the conditions under which it works best). Understanding mechanisms is essential for both of these. For instance, a medical intervention that works experimentally might not do so when combined with a negatively interacting substance.

4. Although animal experiments can shed light on causal mechanisms, other types of evidence can add to our understanding. This is because causal mechanisms are complex, involving multiple causal interactions of various factors. These factors play roles in the effectiveness of the treatment and in interactions between the treatment and the individual patient.
5. Given the multiplicity of methods (cf 2) and a wide interpretation of what counts as a mechanism (cf 3 and 4), causation should be understood in non-reductionist terms. That is, the scope of relevant causal interactions extends beyond the molecular, pharmacological, and physiological levels of interaction. Any thorough causal account should also include higher-level factors, such as the behaviour of tissues, whole organs, and individuals, including psychological and social factors.
6. 'Causal evidence' should be extended to include different types of evidence, including case studies and case reports, which can in some cases provide valuable information for understanding causation and causal mechanisms. This is particularly important when dealing with rare disorders, marginal groups, or outliers.
7. Patient narratives and phenomenological approaches are useful tools for looking beyond evidence such as symptoms and outcomes, and to elucidate the core causes or sources for chronic and unexplained conditions.
8. Causation has a non-negligible temporal aspect. Whether of long or short duration, a causal interaction cannot be fully understood from a 'snapshot', but requires both backward-looking perspectives (towards the origin) and forward-looking perspectives (towards the outcome).

These conclusions provide a philosophical framework for taking causation seriously in evidence-based approaches to medicine. They also suggest how improvements can be made in the methodological basis of medical science and in the application of research results in clinical practice.

Signed by:

Rani Lill Anjum, PI of CauseHealth, NMBU Centre for Applied Philosophy of Science, Norwegian University of Life Sciences, Aas, Norway

Jeffrey K Aronson, Centre for Evidence Based Medicine, Nuffield Department of Primary Care Health Sciences, University of Oxford, Oxford, UK

Stefano Bonzio, PhilPharm, Department of Biomedical Sciences and Public Health, Marche Polytechnic University, Ancona, Italy

Alexander Broadbent, Department of Philosophy, University of Johannesburg, Johannesburg, South Africa

Brian Broom, CauseHealth, Auckland DHB Clinical Immunology and Allergy, Auckland City Hospital and Dept of Psychotherapy, AUT University, Auckland, New Zealand

Nancy Cartwright, Department of Philosophy, University of Durham, Durham, UK and Department of Philosophy, University of California, San Diego (UCSD), USA

Pasqualina Castaldo, PhilPharm, Department of Biomedical Sciences and Public Health, Marche Polytechnic University, Ancona, Italy

Benjamin Chin-Yee, Toronto Philosophy of Medicine and Healthcare Network and Department of Medicine, University of Toronto, Toronto, Canada

Brendan Clarke, EBM+, UCL Department of Science and Technology Studies, University College London, London, UK

Samantha Copeland, CauseHealth, NMBU Centre for Applied Philosophy of Science, Norwegian University of Life Sciences, Aas, Norway

Vincenzo Crupi, Center for Logic, Language, and Cognition, Department of Philosophy and Educational Sciences, University of Turin, Turin, Italy

Francesco De Pretis, PhilPharm, Department of Biomedical Sciences and Public Health, Marche Polytechnic University, Ancona, Italy

Ralph Edwards, CauseHealth, Uppsala Monitoring Centre, Uppsala, Sweden

Karin Mohn Engebretsen, CauseHealth, Institute of Health and Society, University of Oslo, Oslo, Norway

Emanuele Frontoni, Department of Biomedical Sciences and Public Health, Marche Polytechnic University, Ancona, Italy

Jonathan Fuller, Toronto Philosophy of Medicine and Healthcare Network and Institute for the History and Philosophy of Science and Technology (IHPST), University of Toronto, Toronto, Canada

Linn O. Getz, CauseHealth, Department of Public Health and Nursing, Norwegian University of Science and Technology, Trondheim, Norway

Donald Gillies, EBM+, UCL Department of Science and Technology Studies, University College London, London, UK

Trish Greenhalgh, Nuffield Department of Primary Care Health Sciences, University of Oxford, Oxford, UK

Kai Brynjar Hagen, CauseHealth, Regional Centre for Morbid Obesity, Nordland Hospital, Bodo, Norway

Phyllis Illari, EBM+, UCL Department of Science and Technology Studies, University College London, London, UK

Michael P Kelly, EBM+, Department of Public Health and Primary Care, Institute of Public Health, University of Cambridge, Cambridge, UK

Roger Kerry, CauseHealth, Division of Physiotherapy & Rehabilitation Sciences Faculty of Medicine & Health Sciences at the University of Nottingham, Nottingham, UK

Anna Luise Kirkengen, CauseHealth, Department of Public Health and Nursing, Norwegian University of Science and Technology, Trondheim, and Department of Community Medicine, UiT, Tromsø, Norway

Jürgen Landes, PhilPharm, Munich Center for Mathematical Philosophy, Ludwig-Maximilians University, München, Germany

Marie Lindquist, Uppsala Monitoring Centre, Uppsala, Sweden

Matthew Low, CauseHealth, Musculoskeletal Therapy Services, The Royal Bournemouth and Christchurch NHS Trust, Bournemouth, UK

Stephen Mumford, CauseHealth, Department of Philosophy, University of Durham, Durham, UK

Charles Norell, EBM+, Cancer Research UK, London, UK

Barbara Osimani, PI of PhilPharm, Department of Biomedical Sciences and Public Health, Marche Polytechnic University, Ancona, Italy

Elena Rocca, CauseHealth, NMBU Centre for Applied Philosophy of Science, Norwegian University of Life Sciences, Aas, Norway

Federica Russo EBM+, Department of Philosophy, University of Amsterdam, Amsterdam, Netherlands

Armando Sacco, PhilPharm, Department of Biomedical Sciences and Public Health, Marche Polytechnic University, Ancona, Italy

Beth Shaw, EBM+, Centre for Evidence-Based Policy, Oregon Health & Science University, Portland, USA

Jan Sprenger, Center for Logic, Language, and Cognition, Department of Philosophy and Educational Sciences, University of Turin, Turin, Italy

Jacob Stegenga, Department of History and Philosophy of Science, University of Cambridge, Cambridge, UK

Jan Vandenbroucke, EBM+, Leiden University Medical Center, Leiden, the Netherlands

Christian Wallmann, EBM+, Department of Philosophy & Centre for Reasoning, University of Kent, Canterbury, UK

Sietse Wieringa, CauseHealth, Centre for Evidence Based Medicine, University of Oxford, Oxford, UK

Michael Wilde, EBM+, Department of Philosophy & Centre for Reasoning, University of Kent, Canterbury, UK

Jon Williamson, PI of EBM+, Department of Philosophy & Centre for Reasoning, University of Kent, Canterbury, UK

Vegard Bruun Bratholm Wyller, Department of Paediatrics and Adolescent Health, Akershus University Hospital and Institute of Clinical Medicine, University of Oslo, Oslo, Norway

CauseHealth - Causation, Complexity and Evidence in Health Sciences

EBM+ - Evaluating Evidence in Medicine

PhilPharm - Philosophy of Pharmacology: Safety, Statistical standards and Evidence Amalgamation

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