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Treating real people: science and humanity

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## Treating real people: science and humanity

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## Philosophy Thematic Edition 2018: Editorial Introduction

Title: Treating real people: science and humanity

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## Abstract:

Something important is happening in applied, interdisciplinary research, particularly in the field of applied health research. The vast array of papers in this edition are evidence of a broad change in thinking across an impressive range of practice and academic areas. The problems of complexity, the rise of chronic conditions, overdiagnosis, co- and multi-morbidity are serious and challenging, but we are rising to that challenge. Key conceptions regarding science, evidence, disease, clinical judgement, health and social care, are being revised and their relationships reconsidered: boundaries are indeed being redrawn; reasoning is being made 'fit for practice'. Ideas like 'person-centred care' are no longer phrases with potential to be helpful in some yet-to-be-clarified way: theorists and practitioners are working in collaboration to give them substantive import and application.

### The story so far

The editorial to the previous philosophy thematic edition of this journal[1] noted the extraordinary change that has taken place in discussions of reasoning, evidence and clinical decision-making in the context of what one important paper characterised as “the great rationality debate”. [2] Once, attempts to discuss underlying questions that frame the debate about health research and practice – questions about the nature of scientific method, the importance of social context to our understanding of knowledge both in research and in clinical practice, the role of value judgement in clinical reasoning – were dismissed as “unhelpful”, “impractical” and even “anti-scientific”. [1] More recently, however, a broad range of commentators (including colleagues who could in no way be plausibly characterised as either oblivious to the practicalities of research and practice or indeed “anti-scientific”) have recognised the urgent need to address these questions, if we are to develop responses to the real problems that now confront us, such that health science and practice can truly “move forward”. [1] Debates about the relationship between science, society and value are not “irrelevant” to science, but rather they are essential in defining, establishing and defending its relevance to humanity, in an age when science and reasoning are increasingly under attack. [3,4]

Treating real people, in all their diversity and complexity, requires being prepared to re-examine fundamental assumptions about scientific method, evidence as understood in the on-going dialogue about evidence-based medicine (EBM) and evidence as needed in the clinic. Conceptual dichotomies (such as the strict divide between evidence and value) that may once have played an important role in intellectual progress may, at this point, be holding us back in our efforts to deal with contemporary problems [1,5] – a situation that invites us to review the relationship “between science as a human activity and distinctive way of understanding the world, and other human activities, capacities, and dispositions”, including emotional reactions, ethical attitudes, and social commitments. [1]

We concluded that:

“All of this suggests that, in the debate about clinical practice, we are going to have to be more explicit and rigorous in future in developing and defending our views about what is valuable in human life. This is not an alternative to the continued development of empirical research, but a precondition of its adequate interpretation and application in real world contexts.” [1]

Reassured by the high quality of the contributions to the edition, and the willingness on the part of authors to examine critically their own assumptions and to challenge established preconceptions, we confidently predicted that the ‘great rationality debate’ would indeed move forward, “in the sense of developing ideas and arguments to enable the cultivation of good judgement in clinical practice.”

We are delighted to report that, in the year following these comments, we have received a vast amount of correspondence and submissions from some of the most insightful and influential commentators in health research and practice, taking this “great debate” forward in just the way we had hoped. This thematic edition of the *Journal of Evaluation in Clinical Practice* (the largest single edition of the JECPC in its 24 year history) includes over fifty papers, reviews and reports of conferences [6-57] that reflect the attention being given across the board – by practitioners, guidelines

developers, systematic reviewers and philosophers – to the relationship between evidence, science, context, bias, truth, value and methodology, with the quintessentially pragmatic goal to develop accounts of these concepts to assist decision-making in practice. It includes specific sections consisting of papers delivered to major conferences on diagnostic categories (focussing on both their limitations[27-34] and their over-use[19-26]), clinical guidelines[35-41] and mechanisms in medicine.[42-44] Contributors discuss the latest developments in evidence-based healthcare, person-centred care and the relationship between health and social care. The edition also includes a section consisting of expert commentaries on the Grading of Recommendations, Assessment, Development and Evaluation (GRADE) framework.[45-53] These contributions include proposals to develop GRADE, to provide a “sorely needed missing link” between Clinical Practice Guidelines and patient outcomes, thus “connecting decision science to clinical care”.[51] critical discussion of these proposals [52,53] and work identifying ways to avoid the “pitfalls” of GRADE while drawing on its strengths.[45] The edition concludes with reviews of recently published texts addressing pressing conceptual and practical problems for medical science and health practice,[54-56] followed by a paper in the Debates section, responding directly to a paper in the previous thematic edition.[57]

#### Science, context and value: Expanding conceptions, rethinking categories

The edition opens with a discussion of the relationship between truth and bias in Evidence-based Healthcare(EBHC). While the concept of truth has been extensively debated within philosophy, Sietse Wieringa and colleagues argue persuasively that its operation in EBHC remains “hidden and almost undisputed through the linked concept of bias”.[6] They provide a helpful summary of different theories of truth and its relationship to knowledge, facts, interests and social reality, using a case study to illustrate the problems in applying dominant approaches to truth and bias in EBHC to the single case scenario. Citing approvingly authors such as Nussbaum,[58] they argue that facts are “invariably value-laden” and that EBHC needs to develop a more nuanced view of the relationship between truth and bias, if it is to prevent unwarranted relativism in an era of “alternative facts, factoids and post truths”.

The need for clinical education and broader professional debate to focus more specifically on issues of value, is strongly supported by the empirical work and analysis of Christopher Mayes and colleagues.[7] Investigating the views of Australian medical students on the influence of commercial interests on medical practice, researchers found that students typically “uncritically appealed to science in the abstract as a management solution for conflicts of interest”. Further, the specific conception of science espoused by students corresponds to a framework identified in philosophical literature as “scientism”.[5] The authors argue that a “scientific style of reasoning is reinforced through medical curricula” that “marginalise” the study of ethics. They conclude that students need to be made aware “of the epistemological assumptions that underpin science, medicine and EBM in order to address the ethical challenges associated with commercialised healthcare”.

Continuing the theme of science, evidence and bias, Scott Eustace argues that new technologies, while frequently improving the reliability, efficiency and availability of medical research, can also introduce profound new sources of bias that current EBM frameworks do not accommodate.[8] Using numerous examples to show how technology “informs the extent to which we value different sources of evidence”,

Eustace proposes augmenting EBM models in response to the changing nature of evidence.

Andrew Jones and Daniel Steel suggest that debate on the use of evidence hierarchies pays insufficient attention to how clinicians evaluate medical evidence and make decisions in real world contexts.[9] Exploring how different contexts influence the value of using evidence evaluation techniques (EETs), the authors sanction applying simple EETs to the "best" available evidence when clinicians must promptly manage uncertainty over how to manage an individual patient. In contrast, thorough assessments and integration of multiple types of evidence are needed for the extended, collaborative development of practice guidelines. Even in the latter context however, evaluating all available evidence may not be feasible or productive.

In an important paper that resonates with the conclusions of both Wieringa et al[6] and Mayes et al,[7] Bjorn Hofmann and colleagues discuss the relationship between fact and value in health technology assessment (HTA).[10] Explaining the crucial role that philosophy (in particular ethics) plays in addressing the relationship between facts and values in HTA, they defend an Aristotelian "middle way" between the traditional positivist account of "evaluating facts" and the social-constructivist account of "facting values," which they label "factuation". Like Wieringa et al, they stress the importance of being clear on this relationship and its implications for valid inference in an era of "fake facts" and "truth production." [10]

Patrick Daly presents a model of clinical reasoning integrating diagnosis, prognosis, and therapeutic decision-making, focussing on the operations of knowing and doing performed by persons engaged in the direct care of patients.[11] Daly's concern is to provide "a methodical way to study questions regarding the operations of clinical reasoning as well as what constitutes significant clinical data, clinical expertise, and virtuous healthcare practice". The paper provides appealing discussions of intuition and case-based reasoning. Like Hofmann et al[10], Daly makes use of Aristotelian insights regarding reasoning and knowledge to develop his own account of evidence and value in the treatment of individual patients.

The relationship between fact, value and diagnosis has for many years been a major preoccupation of discussions of psychiatry, with many authors assuming (in line with the "scientific" preconceptions identified by Mayes et al[7]) that only value-neutral diagnostic criteria are compatible with psychiatry's status as a legitimate scientific discipline.[59,60] In his detailed analysis of this debate to date, Diogo Telles-Corriea makes the interesting point that only the employment of value-laden (harm) criteria keeps psychiatry in line with broader medical practices.[12]

The criterion of harm, as employed in general medical diagnosis, is also a key preoccupation of the first of two single-authored papers by Bjorn Hofmann,[13,14] both of which draw on ideas about facts and values informing his co-authored paper.[10] Addressing a problem that becomes the key focus of the next section of this edition, that of overdiagnosis, Hofmann argues that contemporary scientific tests give "great opportunities for earlier and more precise diagnostics" but they can also "expand disease, produce patients, and cause unnecessary harm", increasing costs and leading to overtreatment. Hofmann warns that, unless we correct the errors that lead us to "decouple diagnostics from harm", scientific medicine risks becoming "like the ancient tragic hero Oedipus, succumbing because of his very best abilities in the search for knowledge".[13] In the paper that follows, Hofmann begins to develop a person-centred and value-laden solution to this major problem, addressing

the serious difficulties associated with counter-factual reasoning by “getting personal” on overdiagnosis. Hofmann explains that this involves “directing the attention of overdiagnosis estimates towards what matters in medicine: the experience of individual persons.”[14] This approach “challenges traditional epistemic hierarchies in Evidence Based Medicine”, focusing debates in future on the development of person-centred approaches and shared decision-making.

A similarly person-centred approach to the problems of evaluation in wound care is developed in admirable detail by Fania Pagnamenta and Monique Lhussier.[15] The authors note that “developing a body of evidence for dressing selection is fraught with methodological challenges,” arguing that the traditional dominance of a conception of “value-free” science in EBM discourse has seriously compounded these problems. They propose a solution based on the work of pragmatist philosopher John Dewey, using his framework of 'experimentalism' to outline a series of practical methods for incorporating patient stories and values, as well as staff perspectives and expertise, into the decision-making process.

Their paper is followed by two articles focussing on the relationship between health and social factors. Stefania Cobbinah and Janice Lewis discuss the demonstrable and yet, they argue, under-researched relationship between racism, in both institutional and cultural forms, and public health.[16] They note that engagement with the overtly political and evaluative issues of collective well-being, civil rights and addressing educational injustice is a pre-requisite for a meaningful commitment to improving public health, illustrating their argument with reference to the achievements of, and problems for, attempts to address racialised health inequalities. Ramesh Prasad discusses attempts to explain the sex disparity in living kidney donation, with females being “consistently overrepresented among living donors”.[17] To understand this, Prasad calls for multi-disciplinary collaboration among medical, feminist, and public health scholars in kidney donor research, with the goal of improving both short- and long-term living kidney donor outcomes.

The section ends with a paper exploring the philosophical foundations of the developing movement for person-centred medicine(PCM). Thomas Fröhlich discusses the use of the terms “centre” and “inside” in general discourse, in philosophy and in relation to the idea of “person-centredness”, proposing a “conceptual framework corresponding to PCM”.[18] He attempts to apply a “polycentric grid approach” to replace what he identifies as the rival Cartesian, orthogonal grid, discussing the implications of the approach for attempts contained in recent UK guidelines to “tailor healthcare services for each patient”.

### Too much medicine

This section presents papers from a conference held at Oxford University in April 2017. Its theme was overdiagnosis in the broadest sense, including not only the problems Hofmann identified with novel tests[13], but also the unnecessary pathologizing of a wide range of social and behavioural problems and traits. In their engaging conference report, the organisers, Jeremy Howick and Susanne Uusitalo, characterise the problem of “Too much medicine” as “disease mongering, whereby diseases are arguably invented, or at least the thresholds for what counts as a disease, are lowered”.[19] As their report makes clear, a key goal of the conference was to facilitate dialogue and collaboration between philosophers and medical researchers to address this problem, persuading medical scientists to engage with

philosophical methods of analysis, and philosophers to “get their hands dirty with data”.

Jonathan Livingstone-Banks explains nosology as “the science of defining and classifying diseases”, and meta-nosology as “the study of how we do this”.[20] His paper illustrates the need for everyone involved in diagnosis to think about the philosophical assumptions that frame the diagnostic process, including pragmatic issues regarding why we gather certain problems together under particular headings and the assumptions we make about the reality of disease: “any definitive schema for disease must be sufficiently backed by an underlying theory of medical ontology”.

Wendy Rogers and Mary Walker propose a solution to the problem of overdiagnosis by developing an account of a *précising* definition of disease.[21] Challenging the notion that disease is a concept whose vagueness may contribute to overdiagnosis, the authors stipulate what constitutes disease in the context of combating overdiagnosis (diseaseODx). They suggest that a condition is a diseaseODx if and only if it is characterized by dysfunction that carries a significant risk of causing severe harm. After defining the concepts of dysfunction, risk and harm, the authors test their definition in practice and show how currently over-diagnosed clinical conditions, such as well-differentiated micro-papillary thyroid cancer, are not diseases in the absence of revised diagnostic criteria.

A different solution is proposed in the paper by Huw Llewelyn, which raises concerns about “the scope and conventions” of EBM.[22] Llewelyn outlines a number of ways in which this scope could be widened to combat the problem of “too much medicine”. They include broadening the range of evidence to be considered and methodological proposals for “balancing the probabilities of beneficial outcomes against the probabilities of harmful outcomes and other costs”.

Taking up Livingstone-Banks' challenge to engage in meta-nosology, Benjamin Smart and colleagues illustrate the problems in this area with reference to the classification of “Chronic Kidney Disease”(CKD).[23] They point out that this phrase functions as an “umbrella term” covering an unduly wide range of kidney health states. Drawing on analyses of disease in philosophy literature, and arguments about the well-being of patients, they argue that “the most prevalent stages of CKD are not, in fact, diseases”. They note that an attentive study of the philosophy of medicine on the part of medical policy-makers would lead to a change in practice, to the benefit of patients.

Examining factors affecting avoidable hospitalisation for nursing home residents, Petra Mäkelä notes that professionals must “navigate a grey area in clinical decision making about whether to send a resident to hospital for medical treatment, in which they balance perceived risks and wellbeing with moral and ethical tensions”.[24] A greater understanding is needed of the factors affecting avoidable transfers to a hospital environment for elderly patients, as such transfers can be associated with increased morbidity, mortality and a reduced quality of life. Using Judith Butler's work on performativity, Mäkelä considers ways to respond to the “medicalisation of frailty” and to develop a more person-centred approach to practice in this area.

With their focus on person-centred approaches, both Mäkelä's paper and the contribution that follows it, by Saloni de Souza,[25] very much resonate with the contributions to the following section of the edition, on 'Rethinking Disease'. While (on some definitions, at least) it is tautological that illness is bad for us, de Souza



notes that, in the context of the lives of specific persons, conditions typically classed as illnesses may indeed be preferable to health. Failure to recognise this on the part of clinicians can lead to over-treatment. In urging practitioners to look at the whole context of a patient's life, including "values, circumstances, identity, goals and projects", de Souza advocates an approach in line with advocates of person-centred care in previous editions of this journal. Her proposals for adapting the consultation model put us in mind of the work of Yelovich on treating the clinical encounter as a "meeting of experts", [61] and as noted they are taken up in some depth in the contributions to this edition on 'Rethinking Disease'.

The final paper in this section provides a very powerful illustration of the immense practical significance of the philosophical questions raised by numerous authors in this issue of the journal, regarding objectivity, truth, interests and value (epistemic and ethical). Lynette Reid shows that our assumptions about objectivity as an "epistemic ideal", and associated ontological assumptions about the nature of disease, can lead to dangerously oversimplified conclusions about medical imaging. [26] She illustrates this point with reference to breast cancer screening and thyroid cancer diagnosis, showing how the assumption (to many of us, a "natural" one) that improvements in the technical quality of imaging will lead to greater accuracy, reliability and precision, is simplistic and fails to take into account that these "dimensions of objectivity" may be in tension with each other in practice. She concludes with an allusion to Wittgenstein, to the effect that sometimes "an indistinct picture" can be "exactly what we need".

### Rethinking disease

Looking not from the perspective of research, medical education, or the politics of clinical professions, but from that of treatment and persons in treatment, why are diagnostic categories limited, what are their limits, and what steps can be taken to overcome them and improve practice and care? The first 5 contributions under this heading deal with this major concern and offer various answers. The occasion for most papers included here was the conference "Rethinking Disease: New Theoretical Foundations for Clinical Treatment", organized in November 2017 at the University of Bucharest by Alexandra Pârvan and Jennifer Radden. Addressing also medicine taken broadly, the event was centred on proposing new ways to construe psychiatric categories that would better serve both patient and clinician needs for good practice, drawing on knowledge from a broad range of areas, including the sociology of psychiatry, medical anthropology, phenomenology, metaphysics, and art.

This section raises issues such as: the ontology of disease/disorder – discrete biological entities vs. dimensional network entities, or meta-biological, non-fixed, person-dependent states; [27,30] the interplay of history of medicine, history of psychiatry, and cultural history in making up the identity of mental disorder [27,30,31]; fictitious clinical categories, futile diagnoses, the utility of diagnostic categories [27,28]; popular culture stereotypes of certain mental disorders and the role these [31,31] as well as communal attitudes play in the life of the mentally ill [33,34]; stigma [31,32,34]; capability focused vs. deficit centred care [27,32,33]; the possibility of living well within illness [27,33,34].

Alexandra Pârvan [27] develops a case against treatment dominantly based on diagnostic categories in somatic or psychiatric settings. The case is supported with arguments from metaphysics, qualitative healthcare studies, cultural history, and

history of psychiatry. The alternative, person-centred model of care proposed uses resources and frameworks of analysis typical to metaphysics and art, that can be imported in clinical settings without requiring expertise in metaphysics or art from the practising clinician. The concept of the "mind electric" is introduced as the psychiatric counterpart of the "body electric", which she developed in previous work published in this journal.[62] Both denote a patient's personal state of health within illness, which is independent of clinical categories and biochemical, physical data, and both ground her demonstration that health is for each person something irregular, specific to that person, which cannot be produced with the instruments of science alone – something like Van Gogh's purple cornfield.[27] Hence the restated, leitmotif claim in Pârvan's work that *metaphysical* care[63] is a requirement of good practice. Her distinctive version of person-centred care is developed in opposition to what she regards as the standardized, "black-box" treatments aimed at addressing disease categories instead of treating persons and seeking to generate personal states of health in them. The pivotal point in the case against these "black-box" treatments rests in an empirical, case-based, multi-layered demonstration that the full identity of disease is only given in its relation with the person and never by diagnosis alone.

Heinz Katschnig[28] offers a clinician's viewpoint of how Pârvan's critique of the use of diagnostic categories in clinical practice might have limited application and require future nuancing regarding the specific contexts of care in order to "win over clinicians". He endorses Pârvan's "electric" concept, which affirms health as a personal reality, independent of physical evidence, and the need for non-standardized treatments that results from this. Katschnig, however, sees a split between medical school training, medical research, and payment systems, all of which heavily rely on clinical categories and scientific medicine, and the actual clinical practice, where diagnostic categories are not as dominant as Pârvan avers. The "electric" proposal, he suggests, should take into consideration the fact that medical practice often involves fuzzy, or multi-morbidity, or primary care situations where the doctor is little able to use guideline or standardized treatment, as well as clear-cut situations, such as infectious diseases, radiology or surgery cases where treatment ruled by diagnosis is perhaps desirable. In addition, Katschnig argues that psychiatric care is fundamentally different from somatic care, such that a critique of one-size-fits-all treatments can barely apply to it, and, again, is valid only with respect to biological psychiatry done mostly in academia. In contrast, the requirements inherent to the working contexts of practising psychiatrists preclude them from offering treatment guided by diagnoses. As further proof of that, the utility of diagnostic categories, challenged by Pârvan when taken in absolute, has also been recently questioned by the World Psychiatric Association.

George Graham's commentary[29] on Pârvan takes on board her point about treatment based on diagnostic categories not being able to provide best care. He calls it the "Particularist Thesis", and discusses its worth and its links with fundamental issues in mental healthcare. Under the same diagnosis one could find no common causal pathway in two persons, such that their conditions can be considered and need to be treated as different. Pârvan argues against an approach of disease-in-a-person as a purely negative entity and, along this line, Graham speaks of the epistemic quality that an illness can have for the person suffering it. Pârvan stresses that a view of disease as "all bad" ignores the normal processes involved in it, and patients' experience of chronic diseases as their personal normality. Pressing on a similar point, Graham assumes the position he calls "Purpose Driven Continuum Theory", holding that the line between mental health and

illness can be drawn for the same case in various places, depending on the clinician's specialization, or the various purposes and contexts of the clinical encounter. Like Pârvan, Graham is against rigid work with discrete diagnostic categories or, as he puts it, forcing the mind "into unnatural divisions and joints". Also with Pârvan, Graham maintains that such a position does not deny shareable features of a disorder, but claims that the patient cannot be addressed as the host of a disorder full stop: it is always only *someone's* disorder that requires treatment.

Arguing against descriptions of psychiatric disorders as categorical, discrete entities, Jennifer Radden[30] suggests as possible source for the manifold current flaws of the DSM and ICD disease classification systems, the bacterial model of disease launched in the 19th century, of which she discusses "syphilis" as a typical case. A more fitting, not strictly biological model of mental disorder had already been provided in the early modern conception of "melancholy", especially as portrayed by Robert Burton. His analysis of this disorder has much in common with the current "network model" approach to classifying and understanding mental illness, which conflicts with the DSM position with respect to the latter's categorical nosology and causal presuppositions. Thus, the psychiatric disorder is not seen as a natural kind, with stable biological attributes common to all cases. Instead, it is seen as a loosely bounded dimensional entity that presents like a network of relatively stable sets of traits and epistemically relevant diverse symptoms, in multi-directional interactions and feed-back loops between mind-body-world. Mental disorder cannot be attributed to a single cause and cannot be addressed with "magic bullet" drug-treatments, as is typical in biologically-based models of disease; remedial responses to it need to be accommodated to the multiple, causally interconnected specific networks that build its diagnostic identity.

Heinz Katschnig's diachronic analysis of the diagnostic identity of schizophrenia[31] shows it as a hybrid, artificial, scientifically ungrounded, made-up entity. It was composed throughout a historical process of picking up bits and pieces from three major descriptions of schizophrenia and mixing them up into a diagnostic category that significantly conflicts with all three original descriptions taken separately. Importantly, the resulting category retains from all three accounts exactly those elements most able to generate stigma and harm the patients: that schizophrenia is a chronic brain disease, incurable and degenerative; that, given its name, it entails incoherent, disintegrated, erratic behaviour and affect, which encouraged the "split personality" image in popular culture; and that is defined by hallucinations and delusions, which, again, for the general public are notorious manifestations of "craziness". The search for something easy to identify, assess, define, classify and ameliorate with drugs led to the "invention" of a scientifically non-legitimate, not valid clinical category. This disease entity serves not the patients but the pretence of scientificity associated with the DSM discrete disease entities approach, the pharmaceuticals industry which is able to produce drugs that address particular symptoms (e.g. hallucinations and delusions), and the politics of the profession, which identifies itself as a branch of biological medicine.

Katschnig's historical investigation shows the diagnostic category of schizophrenia to be an invention of psychiatrists, which fuelled an ungrounded, stigmatizing public image of the affected persons as dangerous, unpredictable, and "crazy" because of their hallucinations, delusions, or split personality. In the same vein, Ion Copoeru[32] shows that clinical and public views of addiction also go hand in hand, are not sufficiently grounded, generate stigma, and are not helpful to persons

needing treatment. Both Katschnig and Copoeru press the point that these patients self-stigmatize and avoid seeking treatment on account of the negative moral load assigned to these diseases in popular culture. In this context, Copoeru speaks of categorization as a form of violence, and looks into phenomenological resources for alternative ways to portray addiction. He gives an account of addiction based on capabilities, instead of deficit, highlighting the point also raised in Pârvan's paper that proper ways to care for persons cannot be based on deficit, or clinical categories that by force emphasize defect and dysfunction. Misperceived as weak-willed and less of a human, the addict can be seen as assuming, in fact, a practical power in addiction, a habitual form of doing things that affirms him as a subject that does not lack control and fights annihilation. Looking from the perspective of the addict's lived body, non-pathologizable experience of temporality and embodied relation with the world and others, an account of addiction can be given that does not do violence to the persons included in this category. Furthermore, that account would be based on their lived experiences rather than moral judgements, and focused on their capacities and their inclusion in the community of fellow humans.

The last two papers in this section are also concerned with this communal inclusion and the healing potential it possesses, as well as the capacities of people challenged by mental illness to live a good life. Diana Heney[33] submits that, either as a clinician or a member of the community, one could usefully adopt the revised, non-perfectionist version of Aristotelian constitutivism that she advances, which claims that the imperfect rationality of the mentally disordered does not preclude their possibility to flourish as human beings. Using George Graham's account of mental disorder[64], she argues that "truncated rationality" keeps open for these people the possibility to live "a life high in well-being", all the while admitting with Aristotle that rationality is the constitutive norm of human nature, and required, though not in perfect degree, for human flourishing. To learn more about how reason can be redeemable, how we can build ideals of rationality and recovery and how, as members of the community, we can practice a caring constitutivism toward the disordered, we can turn to patient narratives.

This step is taken by Şerife Tekin and Simon Outram[34] in their analysis of patient memoirs. Like Heney, they are interested in recovery and the role of community; like Copoeru, they look at patient experiences and discuss the unsettled relation between stigma and the categorization of mental illness as a biochemical entity. Tekin and Outram use patient narratives to identify types of resources for coping and recovery in disorders such as depression, bipolarity, ADHD and schizophrenia, and then explore these findings against the backdrop of a model of care employed in developing countries to address schizophrenic persons. Three common components stand out: community inclusion and performance of social role or job; regular, healing group activities; attitudes toward mental illness in family and community. The authors conclude, along the line of a patient statement, that finding "the life that's right for you" is more important than recovery. In light of Heney's and Pârvan's arguments, one could say that achieving that life is, in fact, a form of personal recovery. Living a good life with illness, even if it is not a life good for everyone, is one's personal and continuous manner to recover or flourish (Heney), or find "the electric", the way to be well in illness and live a full, personally-constructed, unique human life (Pârvan), which is, as all these papers and patient reports agree, a challenge for everyone.

### The Guidelines Challenge

This section follows from a conference held by the CauseHealth philosophy project, which aims to elucidate the ways that theories of causation influence the practice and policy of healthcare today. The Guidelines Challenge conference took on the specific issue of the increasing dependence upon guidelines in healthcare, as they shape the standards of practice and are used to create policy, a direct result of the continuing dominance of the EBM paradigm. Throughout the papers in this section, written by invited keynotes and CauseHealth collaborators who spoke at the conference, the importance of relating the underlying theory—philosophy—to the actual practical and political outcomes of healthcare guidelines is a common theme.

The first two papers make the shape and aims of the conference itself clear. The conference report[35] was written by core CauseHealth project members, Rani Lill Anjum, Samantha Copeland, Roger Kerry and Elena Rocca. The report not only summarizes the key points of each talk and the themes into which the talks were grouped, but also draws out and reflects upon the main messages conveyed by the speakers and the discussion that occurred during the conference. Participants were from many of the realms of healthcare: practitioners of diverse fields and representing diverse patient populations, academics both in favour and critical of EBM approaches, and representing a diversity of disciplines within the clinical sciences, social sciences, biological sciences, and humanities. The key messages were several, but a particular emphasis was placed on questions about how we can and ought to make conclusions about causal relationships—a basic component of any guideline meant to give good advice about what is best to do—given the evidence we have. Critiques of over-reliance on randomized controlled trials were balanced with critical assessments of how to assess, integrate and access evidence that is both nuanced and context- as well as patient-dependent.

The second paper, by Rani Lill Anjum, introduces the conference with a review of the challenges identified by the project core team to frame the discussion.[36] Anjum provides a summary and reflection upon the interaction between philosophy, practice and policy that the conference sought to bring to the fore and work within in respect to guidelines. Anjum also describes the CauseHealth objectives and how the project's grounding philosophy has been refined through years of collaboration and discussion. In particular, she develops the impact of taking a dispositional approach to causation on how we might view the challenges that guidelines present to practice and policy, and on the solutions we might propose. A dispositional approach to causality emphasises features such as "causal complexity, context sensitivity, individual variation, causal interference, causal singularism, and individual propensities." It thus stands in opposition to positivist norms, such as those emphasised in most EBM approaches, which give priority to data over theory, to quantitative over qualitative methods, to statistical tools over clinical judgement, and to the frequency of outcomes in populations over individual and context-dependent propensities. Anjum further draws out the impact of dispositionalism on the norms we ought to have for science in general.

Trish Greenhalgh provides the perspective of a practitioner and academic working to change evidence based approaches to medicine, so that they better represent the complexity and context-dependency of the clinical encounter with individual patients.[37] To do this, she draws from her own experience as a patient, in a narrative that reflects on both clinician and patient perspectives of the same experience, telling a story shaped by the use and misuse of healthcare guidelines. This paper emphasises the importance of looking for the truth beyond the obvious. For instance, Greenhalgh highlights how she was grouped primarily according to her

age at the time of a serious fall from her bicycle, putting her into the category of patients who had fallen whilst over a certain age, and for this reason her treatment wrongly followed that guideline instead of the more appropriate guideline for falls taken by athletes who suffered a head injury. As she points out, this is one way that standardizing patients—or moving from the general to the particular—tends to go wrong in contemporary practice guided by EBM and healthcare guidelines. As in other work, here Greenhalgh seeks to push EBM to take up the methods and needs of practising clinicians, who ought to be encouraged to “practice case-based moral reasoning”—a key component of clinical judgement—as much or more than the kind of rationality (based on classification and rule-following) that tends to be over-valued by EBM approaches.

In her discussion of “What evidence should guidelines take note of?”[38] the philosopher of science, Nancy Cartwright, provides a theoretical assessment of the rationality we need in order to best practice what Greenhalgh would call “real EBM”. [65] She specifically takes up the question raised by CauseHealth, “How do we incorporate more types of causally relevant information in guidelines?” Rather than provide a single method for incorporating more types of such evidence, she first provides a philosophical argument in support of the need to do so, and then reviews some alternatives and, so far, neglected methods that would be useful to that end. Cartwright focuses on demonstrating that randomized controlled trials (RCTs) “do not tell us much”—rather, they give us ideal information, on populations that are not the same as the one to which an individual patient is likely to belong. Some of the alternative methods for determining relevant causal relationships she then provides are “clinchers”—they give the means for deductively assessing causality—and some are “vouchers”—giving us good reasons to draw a conclusion even if we cannot be absolutely certain that the effect will follow. In either case, they are more useful for guidelines developers and users than RCTs.

Anna Luise Kirkengen draws on her experience as a general practitioner to highlight the importance of getting to know individual patients over time to understanding how to categorize the illnesses of those patients.[39] Specifically, Kirkengen emphasises the impact of multimorbidity on the practitioner’s ability to apply guidelines, insofar as those guidelines tend to reflect an assumption grounding EBM approaches, that illness categories can be delineated even when they are simultaneously experienced by an individual patient. In contrast to this, the narratives provided in this paper show that different causes interact within an individual to produce a medical condition that can only be understood—and thus can only be effectively treated—by seeing the patient as a whole, and never by attempting to break that whole up into fragments of independent diseases and disorders.

Along the same lines, Karin Mohn Engebretsen shares the understanding she has gained through her phenomenological study of people suffering from burn out.[40] Like multimorbidity, medically unexplained syndromes such as burn out tend to fall outside of the lines drawn by guidelines, which rely on a close relationship between diagnosis and intervention. During the interviews from which statements about the experience of burn out are drawn within this paper, Engebretsen found that the pressure upon practitioners to diagnose and treat their patients often led to the misuse of guidelines. For instance, the tendency to take one of the symptoms of burn out, depression, as determining the appropriate guideline to follow and thereby the nature of the intervention, through anti-depressant medication, tended to worsen rather than improve the condition and thereby the life of the patient. Engebretsen

describes her own phenomenological approach to burn out to highlight the harm that can be caused when we fail to see “both mechanisms and the whole person...within his or her environment as individual, relational, and contextual.”

In the final paper of this section, Mike Kelly draws on his first-hand experience as a guidelines developer to discuss the intellectual history of EBM, and its impact on the development of institutions (such as the Cochrane collaboration and NICE) that now determine the policy and practice of medicine in the UK and elsewhere.[41] The dominance of the RCT in EBM owes much to its empiricist intellectual heritage, in particular the work of the philosopher David Hume. Hume's analysis of causal explanation focussed on “association” rather than a rational explanation of underlying mechanisms, and this influence led to a focus on statistical reasoning and general patterns – generating great progress but leading inevitably to questions about how to apply the evidence from RCTs to patients who are “heterogeneous” biologically, psychologically and socially.

To respond to these questions, Kelly proposes a “rationalist turn” in EBM. He contends that rationalism, understood as the principle that theoretical understanding grounds our interpretations of empirical, or observational, evidence, has always played a role in EBM. By recognising this explicitly, EBM can shed the constraints of its own “empiricist orthodoxy.” Consequently, the challenges being presented to EBM by contemporary theorists, practitioners and guidelines developers, such as the “knotty problem of judgement”, are more easily resolved. As Kelly points out in his conclusion, what is needed is for as much effort to be expended by the proponents of EBM on these complex problems with rationalist roots as has been expended on refining empirical methods such as the clinical trial. These points, regarding rationalism, judgement and mechanism in EBM, are taken up by contributors to the next section of this edition.

### Mechanisms in Medicine

While EBM has focused much attention on population-level research for the advancement and practice of medicine, the role of mechanistic understanding and reasoning has lately garnered some attention. Russo and Williamson have argued that both mechanistic understanding and statistical, difference-making evidence are normally required to determine causality in medicine.[66] Beyond causality, philosophers and clinicians are exploring ways mechanistic reasoning may inform other aspects of medical practice, including drug discovery and regulation as well as clinical decision making. In July of 2017, scholars interested in employing evidence of mechanism in medicine met at a conference in Canterbury, UK. Participants from that conference have contributed three pieces to this issue.

Jeffrey Aronson and colleagues argue that, despite a dependence upon RCTs, mechanistic evidence rightly enters into every step of the drug development and approval process.[42] While currently mechanism may implicitly or surreptitiously enter into deliberations that claim to be focused on empirical clinical research alone, the authors convincingly advocate for a more systematic and explicit incorporation of mechanistic evidence.

Using apoptosis, the process of programmed cell death, as an example, Stavros Ioannidis and Stathis Psillos attempt to redefine mechanism in biomedical science.[43] These authors reject the common ontological view, one that sees mechanisms as entities themselves, arguing instead that a theoretically described

causal pathway is sufficient to describe a biomedical mechanism. Such a methodological definition of mechanism would allow for early incorporation of mechanism into medical reasoning, though does not address what evidentiary value a purely or mostly theoretical mechanism might have for scientific inference or clinical decision making.

Elena Rocca considers the kind of evidence that best supports decision-making in clinical practice.[44] This author notes that proponents of EBM rely on evidence of associations from population studies alone. This reliance is born of scepticism of the epistemic value of the evidence for mechanisms of causal relationships. Scepticism arises because evidence of mechanisms reflects judgements that depend on incomplete background knowledge external to the research evidence being evaluated. To answer this scepticism Rocca discusses the example of the effect of oestrogen replacement therapy on coronary heart disease. She indicates how evaluations based on even the best study designs necessarily imply making such judgements, which are fallible and should therefore always be kept under scrutiny.

### GRADE

The issues covered in the important conferences discussed above are given a specific, applied focus in the following section. How to translate research findings to clinical practice so that patients may benefit from that knowledge has long been a challenge to health care providers. Evidence based clinical practice guidelines have become a common tool by which to translate research to practice. The Grading of Recommendations, Assessment, Development and Evaluation (GRADE) framework has been widely adopted as the preferred method for developing guidelines. However, the GRADE framework has thus far received little in the way of philosophical scrutiny.

In the first article of this section, Peter Wyer examines the strengths and weaknesses of the GRADE framework, as well as the critiques of GRADE presented in this section of the Journal, in a historical context.[45] Wyer notes that GRADE was in many ways (and perhaps ironically) a response to an emphasis by guideline panels on study design, with little attention to the quality or reliability of the research, and a failure of those panels to distinguish between the rating of the research evidence and the strength of the recommendation. Despite advances in guideline development made by GRADE, the framework has raised new problems and challenges. Wyer offers suggestions that may advance the GRADE framework further. Perhaps most important, he raises the notion that it may be time that structured processes for guideline development elevate social processes for decision making above research evidence.

Next, Mathew Mercuri and Amiram Gafni present a three article series examining the evolution of the GRADE framework.[46-48] The authors note that GRADE has undergone several modifications since it was first presented in 2004. This series highlights three important issues with the GRADE framework. First, absent in GRADE is theoretical and/or empirical justification for why the presented criteria for determining the quality of evidence and the components for determining the strength of a recommendation were included in the framework, and others excluded. Second, many of the criteria/components are not clearly defined, nor is it clear how to operationalize them. Finally, it is not clear how one integrates the criteria/components when using the framework. Mercuri and Gafni advise that until such



time that these issues are resolved, enthusiasm for the GRADE framework should be tempered.

In the next article, Mercuri and colleagues challenge the logic of the GRADE framework and its conceptualization as a method for assessing evidence.[49] Here, the authors critically examine the basic structure of the framework. They claim that application of GRADE is reliant on the judgement of the user. The authors note some implications such judgement has on both GRADE's structure and status as the best available method for determining the quality of evidence and strength of a recommendation. First, if one has the necessary knowledge to exercise good judgement about the quality of evidence, then the need for criteria proposed by GRADE might seem redundant. Second, if judgement is required of the user, then it is not clear how GRADE is better than other systems that also rely on judgement.

Returning to the issue of how one judges the quality of evidence, Mercuri and Baigrie examine the GRADE notion of confidence in the estimate of effect of a therapy through a Bayesian lens.[50] Their analysis shines light on the rigidity of the criteria for determining the quality of evidence, which the authors believe is out of step with our intuitions about evidence. Their conclusion is that more should be done in the GRADE framework to ensure that assessments of confidence in the effect estimate are based on the whole body of evidence, and that such confidence is proportional to the evidence.

The examination of GRADE rounds out with a debate on incorporating fast-and-frugal decision trees (FFT) into the process of guideline development to improve clinical care. Ben Djulbegovic and colleagues argue that the usefulness of guidelines, and our ability to assess them in practice, are limited by their lack of theoretical structure.[51] The authors argue that FFT may provide the needed structure. Djulbegovic et al. believe that the benefit of guidelines for clinical practice may be realized by converting guidelines and clinical pathways into FFTs. Mercuri[52] agrees that the proposal by Djulbegovic et al. may do much to improve our ability to assess the appropriate use of guidelines in practice, but believes it falls short in providing guideline panels with a theoretical basis to justify what is considered and how when developing a guideline (an issue raised in the three article series by Mercuri and Gafni[46-48], described above). Upshur[53] questions whether the binary logic of FFTs is appropriate for clinical decision making. Furthermore, Upshur raises the crucial issue of whether guidelines are indeed the answer to clinical problems or if care is just about decision making. Indeed, the usefulness of FFTs (and for that matter addressing the concerns with GRADE raised by Wyer, and Mercuri and colleagues) is predicated on where one stands on the questions raised by Upshur.

### Book reviews

As noted in the previous JECPP philosophy thematic edition,[1] the growing literature on medical philosophy is extremely diverse and arguably establishes the area as a field of inquiry distinct from its origins in medical ethics and bioethics – a point confirmed by Mark Tonelli in the first book review in this edition.[54] Tonelli reviews *The Bloomsbury Companion to Contemporary Philosophy of Medicine*, edited by James Marcum. This important collection gathers together over a dozen original papers by a group of both established and emerging philosophers of medicine. Sandwiched between an introductory chapter that offers an outstanding survey of the most salient philosophical issues facing medicine, and a concluding chapter that attempts to predict new directions for the field, are stand-alone papers on specific

areas of ongoing debate. Tonelli notes that overall, the work can be seen as not only a convincing assertion of the relevance of philosophy to modern medicine, but as a call to action for philosophers to engage with biomedical scientists and clinicians.

Cosima Locher and colleagues[55] review Robin Nunn's *After placebo: In Medical Research and Clinical Practice*. Nunn argues that the time has come to abandon the placebo construct altogether, to build a "post-placebo paradigm," in which the concept of placebo will be as unrecognisable as "the structures of ancient medicine" are today. Locher et al review Nunn's comprehensive empirical and theoretical arguments for this radical conclusion, finding his contribution to the somewhat protracted debate about terminology in placebo studies to be "refreshingly original". Whether or not we support his position (and the reviewers are by no means certain that it is really necessary to eradicate the language of placebo as Nunn proposes) this is an intellectually significant contribution. They note that its clear, engaging and evocative style make it an accessible read for an interdisciplinary healthcare audience.

James Tabery's book *Beyond Versus: The Struggle to Understand the Interaction of Nature and Nurture* deals with the long discussed relation between genes and environment, which he considers causative of human behaviour and disease, as well as with the corresponding need to design interventions that take into account this relation, rather than considering genes only. Şerife Tekin's review [56] takes Tabery's findings further, as she develops her own concept of "genenthusiasm", defined as the propensity to grant causative power (exclusively) to genes, and ignore or neglect the gene-environment interaction as a relevant causal power. As Tabery's position is examined, the impact of genenthusiasm on education, parenting, stigma, bioethics, and even distribution of research funding is explored. Thus, the review gives readers an account of both Tabery's views and Tekin's own ideas for new research that can further develop this line of inquiry.

### Debates

Lex Rutten's paper on "flawed statistics" [57] responds to Lytsy's paper on "statistical evidence of the untrue" in the previous thematic edition of this journal.[67] Lytsy argued that testing impossible hypotheses is detrimental to science, regarding homeopathy as one such impossible hypothesis. Drawing analogies with initial responses to Copernican cosmology, Rutten maintains that Lytsy "confuses paradigm with truth", ignoring signs that "his paradigm is incomplete". He accuses critics of homeopathy of inconsistency in their use of scientific method and RCTs, noting that homeopathy is "an interesting case for evaluating the scientific method". It is interesting to consider this exchange in the context of the papers on mechanisms and Kelly's paper on EBM and rationalism[41] in this edition.

### Future instalments?

Something important is happening in applied, interdisciplinary research, particularly in the field of applied health research. The vast array of papers in this edition are evidence of a broad change in thinking across an impressive range of practice and academic areas. The problems of complexity, the rise of chronic conditions, over-diagnosis, co- and multi-morbidity are serious and challenging, but we are rising to that challenge. Key conceptions regarding science, evidence, disease, clinical judgement, health and social care, are being revised and their relationships

reconsidered: boundaries are indeed being redrawn;[68] reasoning is being made 'fit for practice'[69]. Ideas like 'person-centred care' are no longer phrases with potential to be helpful in some yet-to-be-clarified way[70]: theorists and practitioners are working in collaboration to give them substantive import and application.

The next instalment is of course not yet written. That is the work of our excellent readers and contributors, and we look forward to it.

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