What is the Guidelines Challenge? The CauseHealth Perspective

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Abstract

This paper is an introduction to the conference, The Guidelines Challenge, held in Oxford in October 2017. My aim is to explain our motivation for organising this conference, as part of the research project Causation, Complexity and Evidence in Health Sciences. Depending on the professional starting point, the guidelines challenge can be interpreted in a number of ways. Our idea with this conference was to discuss guidelines from three overarching perspectives: practice, policy and philosophy. In particular, we wanted to discuss some of the challenges that face anyone developing and implementing clinical guidelines in the evidence based era of medicine. This introduction gives a brief overview of what CauseHealth sees as the guidelines challenge from these perspectives. More attention is given to the philosophical issues with which the CauseHealth project is particularly concerned, although a proper treatment or discussion of these issues naturally falls outside the scope of this introduction.

Introduction

Depending on the professional starting point, the guidelines challenge can be interpreted in a number of ways. When the interdisciplinary research project *Causation, Complexity and Evidence in Health Sciences* (CauseHealth) organised the Guidelines Challenge conference in Oxford in October 2017, the idea was to discuss guidelines from three overarching perspectives: practice, policy and philosophy. In particular, we wanted to discuss some of the challenges that face anyone developing and implementing clinical guidelines in the evidence based era of medicine.

I will here give a brief overview of what CauseHealth sees as the guidelines challenge from these perspectives. The purpose of this conference was to enable explicit and detailed discussion of the ideas presented here and their relationship to practice, so my aim now is mainly to provide some background and motivation for organising a conference on the challenges of guidelines. As part of this I will focus on the philosophical issues with which the CauseHealth project is particularly concerned, although a proper treatment or discussion of these issues naturally falls outside the scope of this introduction.

Challenges for clinical practice and for policy

Starting from the perspective of practice, the guidelines challenge points to a tension between the clinical context, dealing with unique patients, and the general purpose and constraints of guidelines. We thus see a need for addressing some issues concerning how guidelines can be used and produced in a way that works best for the patients.

- How to square the needs of the clinic with the public health purpose of guidelines to offer general recommendations?
- How to provide the best care for individual patients based largely on statistical evidence from other patients?
- How to use guidelines for single illnesses for patients with multiple health issues?
- How to help patients with chronic illness when one lacks a medical explanation of it, or even a diagnosis?

For the purpose of policy, the guidelines challenge points to wider structural, methodological and political constraints and motivations for producing guidelines. Rather than being produced in a vacuum, guidelines are supposed to serve a number of interests, some of which are economical and administrative. From this perspective, the challenges relate to the societal dimension of developing and implementing guidelines as part of a national health system.

- How to develop clinical guidelines in a society where co- and multi-morbidity is the norm rather than the exception?
- How to write guidelines that still allow for clinical judgement if one aim of the evidence based framework was to minimise expert bias?
- How to avoid that guidelines are misused as a New Public Management tool, promoting standardised treatment and cost efficiency of care?
- How can health policies move away from the positivist and reductionist assumptions incorporated in the current medical paradigm?

Although these issues are all practically oriented, they do have some clear links to more fundamental matters, of philosophy. I will now go on to present and briefly explain why the philosophical dimension should not be ignored when discussing the guidelines challenge.

Philosophical challenges for guidelines

As emphasised in the CauseHealth project, there is a close relationship between science and philosophy, especially concerning the choice of methods for establishing causation [1-3]. Any scientific method by which medical evidence is generated will necessarily come with a number of philosophical assumptions concerning, among others, the nature of causation. What causation is remains a philosophical discussion about ontology, but medical researchers and practitioners should nevertheless find it useful to know about and even engage with these issues. The following challenges are philosophical in nature, yet practical in their methodological constraints.

- How to study and understand causal complexity if causes must be established one by one, or in isolation?
- How to understand illness as belonging to the whole person if this whole is studied through fragmentation; part-by-part?
- How to deal with large individual variations if the same cause is supposed to give the same effect, under some normal or ideal conditions?
- How to make causal decisions about an individual case if the causal evidence is largely statistical?

Allowing a philosophical perspective would bring in a new dimension to the debate on guidelines, especially if we thereby acknowledge that there is no clear-cut distinction between philosophy and medicine.

Since these philosophical guidelines challenges might be the least familiar ones in the context of clinical practice, they might require some extra comments.

Philosophically, complexity is sometimes contrasted with composition. Composition means that the whole is the sum of its parts, which in medicine would suggest that the machine metaphor of the human body is more or less accurate. Complexity in the stronger, ontological sense, however, typically emphasises features such as nonlinear interaction and processes, emergent properties and holism [4-7]. Complexity in this stronger sense cannot be treated simply as composed of multiple factors that do not interact or affect each other. If we take complexity to be something more than the multifactorial composition of parts, then understanding the way in which the different parts interact will be crucial. One question, then, is how we can study and accommodate causal complexity in medicine without, for instance, treating each factor in separation from its interactions with the context: the aching back, the fatigue, the irritable bowel, the high blood pressure [8]. This is related to a discussion of the relationship between parts and wholes. Philosophical holism would deny any form of dualism or other division of the whole into its parts. Analytic approaches in philosophy, however, have a long tradition of analysing complex problems into their smaller, manageable parts. Once each part is sorted out, they can be put back together, as suggested by René Descartes' analytic-synthetic method [9]. A question is whether a person can be approached in this way, as a mechanical object or a philosophical problem.

While we know that all patients are different, scientific methodology typically works by checking whether the same cause produces the same effect, at least under some normal or ideal conditions. That causation works like this, was first stated by David Hume [10] (I, iii, 15) and has since become part of the folk notion of causation [11, 12]. To establish causation, one then needs to see if the purported cause and effect regularly follow each other under sufficiently similar conditions. In the lab settings, this can be done by creating genetically identical models, in a context with minimal interfering factors. Once we move to the clinical level, however, no conditions are exactly identical. Still, we expect that the same type of intervention, if it is causally effective, should bring about the same type of effect under similar conditions. What counts as sufficiently or relevantly similar conditions, however, can only mean exactly this: that the same effect follows the same cause. If the effect differs in two similar cases, we must infer that there was some causally relevant difference between them, so they weren't similar enough. From this philosophical perspective, individual variation becomes a problem for establishing causation, unless one can classify the various effects into other sub-groups that are sufficiently and relevantly similar to this particular patient.

This shows a practical tension between making clinical decisions for individual patients and the statistical evidence on which these decisions should be based. Philosophically, this suggests a tension between different theories of probability. There is a philosophical theory of probability, that individual propensity cannot be given by statistical frequencies [13, 14]. In contrast to this, a frequentist theory will calculate probabilities in the individual case based on a sequence of occurrences over a series of trials. This means that if we want to know the probability of an intervention to have its targeted effect, this can be generated statistically. An effect in 6 out of 10 cases would give a 60 percent probability, for instance. On a propensity account, one would expect that each individual, even in a similar sub-group, would have different properties and dispositions to respond to a treatment, and that this would give them different propensities. To make predictions or decisions about individual treatment based on statistical averages would then be a mistake. Instead one ought to gain more knowledge about the individual patient and which causally relevant factor might affect the interaction with the treatment. For instance, if someone lacks a protein with which a drug interacts, then the chance of the drug being effective for them is zero, even if most people have that protein and could get an effect.

These are only some of the philosophical debates that we should engage in when discussing the guidelines challenge. By doing this, we might find that certain norms and practices need to be discussed as well.

Challenging positivist norms and practices via ontology

Complex challenges like the ones presented here cannot be dealt with by individual people or single disciplines. Instead, they require collaboration; a joint effort across disciplines. This is why we invited philosophers, medical researchers, clinicians, guidelines network representatives, public health experts and social scientists to come together at this event and discuss what positive changes they would like to see in medicine. What would the best possible medical system and practice look like? Many of the invited speakers are already practicing their ideals in their daily work, but there are still some systemic limitations in place.

The motivation behind the CauseHealth project and its collaborative network is that we want to see a paradigm change in medicine [15, 16]. Not primarily a scientific paradigm change, of medical theory, but an ontological revolution. Ontology is about the most fundamental assumptions we have, about how the world is. For instance, we might think that people cannot be treated as divided into minds and bodies, but as wholes. That suggests an ontological intuition of holism with respect to persons rather than dualism. Another ontological assumption is reductionism, the idea that any higher-level phenomena are identical to, caused by, or in principle could be explained in terms of, lower-level phenomena. Reductionism is one of most discussed issues in related to the biomedical model, since one here typically looks for physiological explanations and causes. In the everyday work of medicine, however, such ontological assumptions are usually implicit. By making them explicit, it is possible to critically discuss them, and see whether we like how they influence scientific theory and practice.

The CauseHealth project is a contribution to an ontological paradigm change in medicine, away from positivism and toward dispositionalism [15]. Positivism is in this discussion seen as closely linked to Humean ontology, or 'Humeanism' [17, 18], emphasising evidence that is empirically observable and measurable, free from metaphysical and theoretical speculation. This positivist or Humean ideal can be detected in standard scientific approaches, where priority is given to

- data over theory
- quantitative methods and large data sets over qualitative approaches
- statistical tools for prediction over clinical judgement
- frequency of outcomes in populations over individual propensities.

These are only some of the positivist aspects detected in science. Many think of positivism as an outdated programme in philosophy, but its influence on scientific methodology continues, almost unnoticed. Today, positivism is perhaps most dominant in evidence based approaches, in medicine and social science, with their statistical methods and large data sets. Within evidence based medicine, correlation data, and comparisons of these, supposedly provide all the causal knowledge we need for (i) choosing an intervention, (ii) making a prediction or (iii) deciding a new policy.

In contrast with this positivist approach, causal dispositionalism, as developed by Anjum and Mumford [19], is the ontological foundation of CauseHealth. Causal dispositionalism emphasises features such as

- causal complexity
- context-sensitivity
- individual variation
- causal interference
- causal singularism
- individual propensities.

A shift from a Humean ontology to a dispositionalist one would also involve a shift in default expectations concerning methodology. Figure 1 illustrates how our preferred scientific approach could be motivated by implicit ontological assumptions (for a detailed discussion, refer to [15]).

HUMEAN ONTOLOGY	POSTIVIST METHODOLOGY	DISPOSITIONALIST METHODOLOGY	DISPOSITIONALIST ONTOLOGY
Empiricism	Data	Theory of mechanism	Metaphysics
Universal law	Standardised treatment	Adapted treatment	Tendencies
Frequencies	Statistical tools	Individual dispositions	Propensities
Regularity	Homogeneity	Variation	Context-sensitivity
Reductionism, dualism	Biomedical approach	Person-centered approach	Holism, emergence
Composition	Single disease guidelines	Co- and multi-morbidity	Complexity
Isolated units	Idealised	Situational	Interaction
Same cause, same effect	Repeatability	Medical uniqueness	Causal singularism

DIRECTION OF POSITIVIST DEFAULT EXPECTATION   DIRECTION OF DISPOSITIONALIST DEFAULT EXPECTATION

Figure 1: Different ontologies motivate different scientific approaches. (To be read vertically for position, horizontally for comparison.)

New norms of science

If we want to make substantial or systematic changes in a discipline, therefore, we cannot ignore the influence of ontological assumptions on scientific norms and methodologies. In *Causation in Science. On the Methods of Scientific Discovery* [20], nine dispositionalist norms are proposed to replace the positivist norms of science:

The metaphysics norm. Science cannot be free from metaphysics, or ontology. Instead, ontological commitments should be acknowledged and critically examined. Especially those related to scientific methodology, such as causation, probability and complexity.

The causal norm. Causal talk cannot be avoided or replaced in science. Instead, to uncover causes and use them should be considered one of the central aims of science.

The norm of involvement. Scientists should not be disengaged or neutral. Rather, we must accept that we are causally involved with the world, and that this is a precondition for the possibility of knowledge.

The tendency norm. We should not focus our causal knowledge on observing whether the same type of cause gives the same type of effect, under some same or similar conditions. Instead we should think of causes as tendencies, and expect different effects also for slightly different contexts.

The norm of deep understanding. Causal science should be about understanding causation and not just discovering it. We should aim for rich theories that tell us not only what causes what and how often, but also in explaining how and why.

The norm of negative results. Our causal theories should be developed in line with negative and unexpected results rather than focusing primarily on repeated corroborations of the theory. Discrepancies present a major opportunity for new knowledge.

The symptoms norm. Success under a method should be treated as symptomatic of causation, not definitive of it. One needs to adopt methods that best reflect the plural symptoms of causation.

The fallible norm. No absolute scientific certainty should be expected: it is neither required nor possible for rational belief in a causal theory. All causal predictions are fallible.

The contextual norm. Causation rarely if ever happens under ideal, normal or identical conditions. Instead, scientists ought to embrace the messiness, the complexity, and the real rather than the ideal.

The way forward

In CauseHealth, and in the Guidelines Challenge conference, the aim has been to contribute to a change in medicine that is not restricted to the way in which it should be practiced. To motivate such changes, we also need to consider critically the ontological foundations for the norms and methodologies on which this practice is based. This requires a joint effort across disciplines, which is what this conference was meant to initiate.

We saw that the guidelines challenges range from practice and policy to philosophy. In particular, the challenges point to the tension between the general statistical approach, suited for standardised treatments of single conditions of some average or normal patient, and the clinical needs of the single, unique patient. Dispositionalism starts from the perspective of causal singularism, context-sensitivity and complex interaction of causes. By challenging and replacing some ingrained, positivist norms of science with dispositionalist ones, new methodologies and practices can follow [21-26]. In medicine, this should mean a change of focus, to where the default expectation in guidelines is a need for accommodating individual variations, complex illness and co-morbidity, individually adapted care, contextual considerations, theories of causal mechanisms and trust in clinical judgement.

Acknowledgement

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