Prof. em. Dr. phil. habil. Johann Behrens

The EbM+Theory approach

An appraisal of its 6 assumptions and its risks and side effects

The health services research community endeavours to provide evidence in order to reduce the uncertainty of our everyday decisions in economics, politics, treatment of illness and health-promoting care (Soziale Welt Behrens 2015). Holger Pfaff and Jochen Schmitt presented an 'EbM+Theory Approach' in 2023 and 2021. As their diagram (2023, p.3, Figure 1) shows, they assume that there are two separable quality hierarchies of scientific studies: one for 'theory-based knowledge' and one for 'evidence-based knowledge'. 'Scientific knowledge' is the result of the combination of both independent knowledge hierarchies.

Summary

In their 'EbM+Theory Approach' (2021 and 2023), Holger Pfaff and Jochen Schmitt address questions of evidence-based decision-making that evidence-based healthcare research dealt with 30 years ago. Their EBM+Theory Approach is based on at least six assumptions, the practical-empirical tenability of which is examined. A conclusion addresses the risks and side effects of the EBM+Theory approach and predicts that this approach will survive forever because it is based on eminence.

Key words

Philosophy of science, anthropologically modest epistemology, evidence-based health services research, EbM+Theory Approach, systems theory

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>> The contributions by Pfaff and Schmitt* have the merit of adopting excerpts of achievements that the self-reflection of evidence-based nursing, evidence-based medicine and other movements of practitioners achieved a quarter of a century ago, i.e. at the end of the last millennium, and published, for example, as 'Methods and Ethics of Nursing Practice and Health Services Research' (summarised in Behrens & Langer 2004 and 2022, Behrens 2019), and discussing them for health services research. They address a few of the numerous knowledge problems of evidence-based** action that had to be overcome theoretically at the end of the last millennium. At least programmatically, they are turning away from a mechanistic approach to action and intervention research and turning to a systems theory approach that no longer analyses the world according to the model of a clock whose gears are completely open to the watchmaker - like the omniscient 'watchmaker' God in Leibniz and Bourdieu (Behrens & Zimmermann 2017). This is undoubtedly a great achievement.

The proposed 'EbM+Theory Approach' is based on far-reaching assumptions, including the assumption that there can be any 'evidence-based knowledge' that is not 'theory-based'. However, the proposal to supplement empirical evidence** with theoretical evidence and further with 'experience and context-based knowledge', as held by eminent experts, to form an EBM+theory approach is based on six assumptions that may unfortunately not be realisable for humans and are therefore not consistent with an anthropologically justifiable, i.e. modest, epistemology. This is to be examined in this essay. (The hope for eminences that are not bound to anthropological limits of cognition will, of course, never die out. The hope is too beautiful). The assumptions that Pfaff and Schmitt need for their proposal of an EbM+Theory approach are: 1) There would be a huge area in health care and health promotion in which one could directly derive (action) decisions in a generalising way from (RCT) studies - and therefore may quietly ignore all the criticism that the EbP movement has been working on since the previous millennium about this far too naive assumption about RCTs. With this first assumption, they miss the most common standard situation of evidence-based professional action. With the second assumption, the authors attempt to save the thesis of the spread of 'non-complex' interventions - whereby they claim Luhmann as a witness: There would be an organic, a psychological and a social system, into each of which the 'healthcare' system could intervene separately, as can be seen, for example, in the effects of 'drugs' and 'surgical interventions'. Irrespective of whether Luhmann's systems theory includes this assumption, it deserves to be discussed because it is widespread and has far-reaching consequences.

The third assumption seems to be that with collectives the generalisation problem is small and that no additional internal evidence of the individual natural or legal person needs to be built up. The fourth assumption is that RCTs overcome all major biases of external evidence. The fifth assumption is that there can be a theory-free empirical study. The sixth assumption is that there are eminent theory experts who can supplement the mere empirical evidence - ideally based on a 'generally accepted theory'. All six of these assumptions deserve careful discussion - not only out of gratitude to Pfaff and Schmitt, but also because of their widespread use and their high-risk consequences. A conclusion addresses the risks and side effects of the EbM+Theory approach and makes a prognosis for the eternal survival of this approach.

1. there is a widespread area of stable 'non-complex' interventions in which the correct action can be generalised directly from RCTs.

There is indeed an area of nursing, medical and therapeutic action for which the 'traditional form of standardised, burocratic knowledge production, review, and transfer (knowledge processing) is suitable for stable environments, but not for unstable environments' (Pfaff & Schmitt 2021, p. 2). Such a 'stable environment' can be imagined. In reality, it exists at most exceptionally.

The claim that the correct nursing, medical and therapeutic action in individual cases can be derived from studies, even RCTs, would come as a great surprise to all those actually practising

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* For Holger Pfaff on 14 March 2025 with gratitude

** The author always uses the term evidence in the English spelling, because evidence in English means circumstantial proof. Since the Romantic period, 'Evidenz' in German has meant an evidential experience: a revelation that falls like scales from your eyes and requires no empirical proof. In other words, the opposite of evidence.

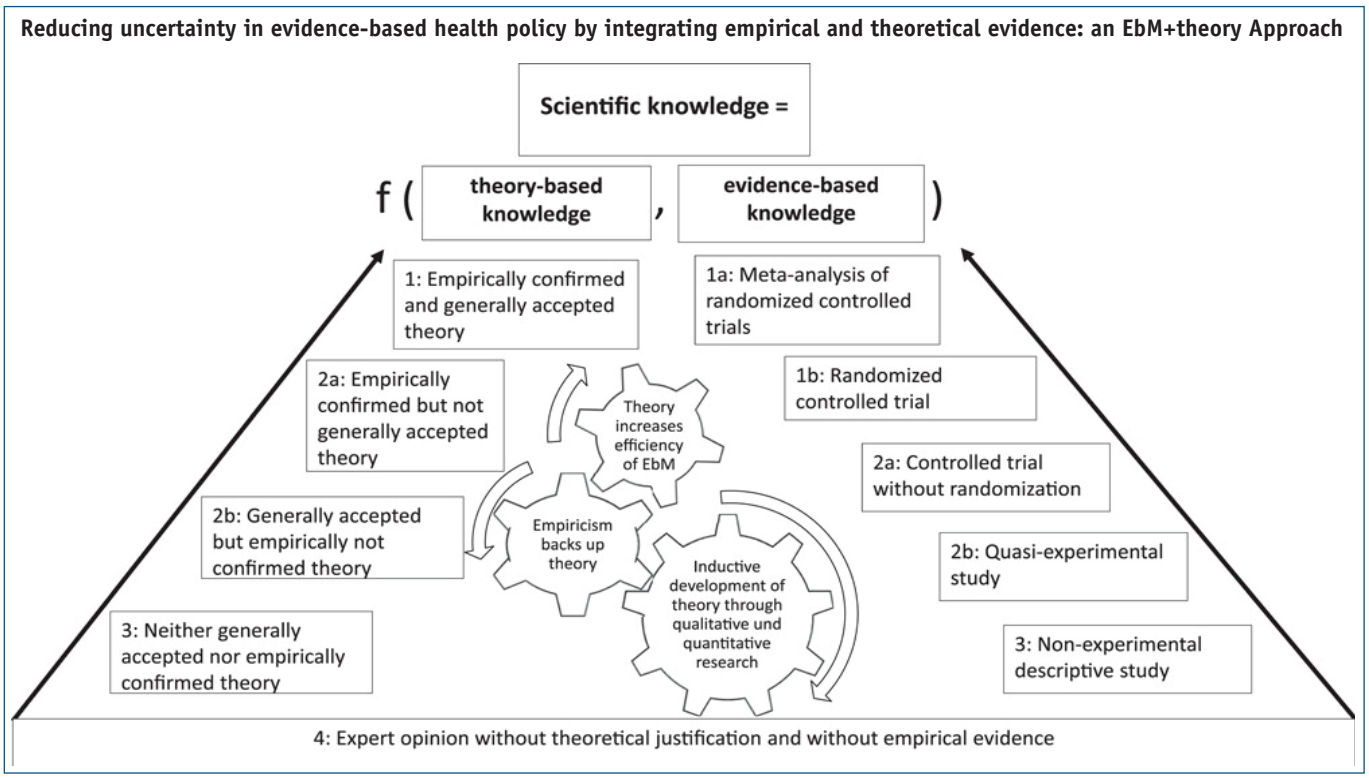


Abb. 1: Pyramide des wissenschaftlichen Wissens: Wissenschaftliches Wissen als Ergebnis der Kombination von evidencebasiertem und theoriebasiertem Wissen. Quelle: Pfaff H, Schmitt J, Reducing uncertainty in evidence-based health policy by integrating empirical and theoretical evidence: an EBM+Theory approach. J Eval Clin Pract 2023;1-15, hier: S. 3, Figure 1.

these treatments worldwide. There is a systematic reason for the falsification of this first assumption. Anyone who studied statistics at school as a youngster knows the systematic reason: our knowledge from studies is largely available in the form of frequency statements. Out of 100 people who use a certain treatment, this treatment almost never helps all of them, but usually only some of them, e.g. 76 out of 100. This frequency statement is often summarised in the construct of an 'average man'. However, it is never possible to draw sufficiently reliable conclusions about the individual case from a frequency statement. You can never be sure in advance whether a person is one of the 76 people who will benefit greatly from the treatment or one of the 24 for whom the adverse effects will significantly limit the benefit.

For a herdsman-king, this frequency number may seem sufficient to treat his herd (but see assumption 3 below). In public health, medicine, care and therapy, however, we treat the individual case of a natural or legal person (e.g. municipality or country), not the constructed average case. This dilemma is also not solved by randomisation in access to the intervention or control group. This is because this randomisation may overcome the selection bias and thus compensate for the unobserved heterogeneity of all the factors (contexts, resources, dispositions, modes of action) which, together with our intervention, influence the outcome of the action. But randomisation only compensates for these different factors for the group as a whole, not for an individual natural or legal person. This simple fact alone refutes the idea that the result of frequency distributions - i.e. in the best case, well-documented external evidence from studies - alone can be sufficient for a decision to act. The internal evidence of the natural or legal person must always be established. For this reason alone, the 'stable environment' that Pfaff and Schmitt presuppose for large areas of healthcare hardly exists.

In the individual case of a natural or legal person, almost every action is complex and in an 'unstable environment'. As we will show, this also applies to interventions with pharmaceuticals. Continuous development of internal evidence is essential.

Almost every treatment decision - whether self-treatment or treatment of others - is a decision under uncertainty in an 'unstable environment' caused by this uncertainty. Even the largest and best-documented studies do not eliminate this uncertainty in individual cases. There is always an existential decision to be made under uncertainty. (Only in the case of an unforeseeable number needed to treat = 1, when all those treated benefit equally from a treatment, would a decision be superfluous). At the end of the last millennium, the standard situation of evidence-based professional-behaviour was therefore defined as follows: Medicine, the therapeutic sciences and nursing science are all - like the counselling political, economic and social sciences (Behrens and Langer 2004 and 2022, Soziale Welt 2015) - action sciences with a specific object that can be separated from the contemplative sciences of biology and sociology, among others:

Their object is the future-uncertain but reasonable innovative crisis decision in each unique case - under pressure to act and justify together with the respective unique clients.

Calling them 'arts' instead of action sciences, as Gross and Löffler (1997, p. 8) do, makes their practice as 'reasonable' undiscuss-

able, uncriticisable, unresearchable.

This decision should by no means be made by tossing a coin, but should be reasonably justifiable, especially when reflecting on all uncertainty. This is why, at the end of the last millennium, we rejected the division in the 'theory of medicine' that research is science and practice is more art (Gross and Löffler 1997, p.8). Because then a treatment decision could no longer be reasonably criticised and justified. It would become arbitrary. 'Ut aliquid fiat' - i.e. an arbitrary action to do anything - has rightly been frowned upon in the health sciences for thousands of years.

Who needs to put themselves in a position to make this existential decision that cannot be derived from studies?

Obviously those who bear the consequences of this decision. Only in cases of gross negligence or wilful intent are the nursing, medical or therapeutic practitioners alone. As a rule, it is the 'treated' or 'counselled'. They must therefore be able to build up 'internal evidence'. Internal evidence includes everything that can only be known by the person being treated. They choose the outcomes of treatment that are relevant to them, i.e. the participation in life that they want to achieve in a self-determined manner under restrictions (see the UN CRPD, in Germany Section 1 of the German Social Code IX). Only this natural or legal person perceives the discomfort and pain, but also the relief. Only this person can recognise individual resources and contexts. All these highly personal characteristics and information cannot be deduced from any study - not even, see below, if you know the 'diagnosis'. These highly personal characteristics, the 'internal evidence', can only be learnt from the person themselves. Typically, a natural or legal person does not know their internal evidence before they become ill, in need of counselling or in need of care. It is therefore not possible to query it in the same way as 'preferences' in economic consumption theory. After all, people have 'preferences' for or against poppy seed buns or cream cake. But very rarely, before they become ill, in need of counselling or care, for or against amputations or side-effect-rich interventions.

People in crisis must first develop the internal evidence for this - some people appreciate it when a professional sits down with them to build up their internal evidence, with whom they can openly discuss all options and their needs and build up their internal evidence (Behrens & Langer 2004, 2022, Behrens 2019). Once they have built up their internal evidence, it is reasonable for them to make an existential decision. Building internal evidence is therefore something quite different from obtaining consent (a signature) for a decision that nursing, medical or therapeutic practitioners - in a caring, patronising manner - consider to be right for this person.

In reality, the development of internal evidence for a decision cannot be developed just once, e.g. at the beginning of treatment. As the situation, i.e. the decision-relevant 'environment', changes during the recovery process or crisis - sometimes on a daily basis - a one-off decision is not enough. Decisions have to be made again and again. Internal evidence must be built up again and again as a basis for decision-making. There is almost never much time for this.

Therefore, the 'environment' of almost every treatment or consultation is doubly 'unstable'. On the one hand, the available external evidence changes. On the other hand, the situation in which decisions have to be made changes, and therefore the internal evidence that needs to be built up. The internal evidence regularly gives rise to new questions for the available external evidence. However, the external evidence is almost never completely sufficient for the systematic statistical reasons mentioned above. A decision must always be made under uncertainty. There can be no question of a 'stable environment'. One can of course imagine the utopia of a 'stable environment'. But it is not yet a reality.

2. Assumption that it is possible to intervene separately in the organism and the psyche

With a second, possibly utopian assumption, the authors try to save their thesis of the spread of non-complex interventions. They write that there are

'interventions in healthcare, if noncomplex, often intervene in one of these subsystems of the healthcare system, for example, the organism (e.g., drugs and surgical intervention). In contrast, complex interventions occur in more then one subsystem, for example, in organisms and psychic systems '

(Pfaff and Schmitt 2023, p. 8).

Complex interventions are therefore defined by the fact that they intervene in the organism and psyche at the same time. Are there any interventions that do not do this? The idea of separate intervention in the organism and psyche has been widespread since 'psychologists' used the body-soul theme of theology and philosophy to create an independent field of work alongside medicine. As a result, souls without bodies and bodies without souls seemed to be treatable. This construction deserves clarification. In fact, it would be a dream not only of many practitioners, but also of their patients, to be able to treat organs independently of people, e.g. through medication or surgery. As with modern cars, parts could be removed from people and organs and tissue could be repaired in peace and then reused or replaced with newly manufactured ones. Unfortunately (?) this is largely a utopia. Organs are attached to the person and cannot be successfully separated from them in the long term. A person's organic, psychological and social systems cannot be treated separately in the long term. Intervening in an organism without a psyche is as utopian as intervening in a psyche without a body. You can operate and inject drugs under general anaesthesia, but the general anaesthesia can never last long enough for recovery to be complete. Only acting persons can fully recover. Every drug also has a psychological effect, and every psychotherapy triggers organic reactions.

Seven effective factors of a medication prescription:

Pharmacy has long since had to say goodbye to the utopia that organisms can be treated without the psyche. Since then, the effect of almost every drug has been measured in comparison with a placebo. In other words, it is compared with the effect of the psychosocial relationship without the substance under investigation. The psychosocial relationship is undoubtedly one of the main effects of medical treatment, if not its greatest effect. A substance has to have a very strong effect to surpass the placebo effect.

For every prescribed or recommended tablet, at least 7 factors are at work: 1. a beautiful doctor or pharmaceutical-technical assistant 2. in a white coat 3. looks you firmly in the eye 4. and speaks in a friendly voice 5. 'Take this morning, noon and night' 6. 'and you will soon feel better' 7. the substance works.

The effect of factors 1 - 6 can be so strong that the 7th factor, the substance of the medication, can itself be ineffective or even harmful: The effect of the 7th factor can be surpassed by the 6 other factors. The 5th factor is particularly interesting: chronobiologically, it may be nonsense to take the same dose in the morning, at noon and in the evening, because the substances have different effects depending on the time of day. But the 'morning, noon and evening' calls for times of (table) prayer or at least times of increased self-care during breaks for eating and drinking. This is why Factor 6 is a great ritual prophecy.

The previous president of the IQWiG, which is responsible for the approval of drugs by the Federal Joint Committee (G-BA), Windeler, once asked the author at a congress what he would do if a grumpy doctor looked him in the eye instead of a beautiful PTA or doctor (Factor 1). 'Shit happens. That's life' was the answer, at his age you are used to grief. The systematically correct answer is, of course, that the beauty of the PTA or doctor is only one of 7 effective factors, the lack of which must and sometimes even can be compensated for by the other 6 effective factors.

As far as the apparently only organic surgical interventions cited by Pfaff and Schmitt are concerned, the following applies to them: there is probably almost no more psychologically impressive treatment than going under the knife. The thesis that surgical operations only intervene in the organism, but not in the psyche, would have to be substantiated more precisely than the authors do.

Now one could counter: aren't all these accompanying factors of a tablet prescription, this entire unobserved heterogeneity of diverse contributing factors, statistically balanced out by randomisation, so that only the effect of the tablet substance remains purely as a result? Yes, perhaps in the frequency distribution of a large study that forms the external evidence. But of course not for the individual case. Because, as explained above, you cannot draw conclusions from a frequency distribution to the individual case. And: In everyday practice or counselling, an entire study population is never treated as a whole, but always one specific natural or legal person after another. We come to the apparent exception of the cattle-breeding kings, who are only interested in the herd, not the individual, under the third assumption.

Does Luhmann guarantee separate intervenability in the organic, psychological and social systems?

Pfaff and Schmitt refer to Luhmann for their separation of the organic, psychological, social and machine 'healthcare subsystems' (Pfaff & Schmitt 2023, p. 7). From the fact that there are psychological or medical practitioners (interaction), psychological or medical practices and clinics (organisation) and professional codes (society), they seem to conclude that the human being is actually divided into organs and psyche that can be treated separately. I think this is a biologisation of communication systems that goes too far. I wouldn't go that far, nor would the nursing profession, and Luhmann certainly wouldn't go that far. Luhmann (Luhmann 1975, 1981, 1993, Behrens 2019) examines the differentiation of communication systems. Communication systems can be roughly visualised as responsibilities for questions. Individuals (people) do not merge into these systems of responsibility as persons, but rather form their 'unmarked space', of which no more is known and no more needs to be known than that it does not belong to the communication system. Thus, in modern societies, science is responsible for the distinction between true and not true, even if scientists as persons may be interested in quite different distinctions. The (capitalist) economic system is focussed on the distinction between money/more money, even if managers and employees as individuals may have completely different interests than just 'more money'.

Judges and lawyers, who are responsible for distinguishing between right and wrong, can deeply regret the consequences of their judgements in their free time, but as judges and lawyers they must abide by them. A judge who sits on the bench in pursuit of a personal interest in more money is corrupt and no longer acts within the legal communication system. Similarly, scientists who place their personal interest in more money or the justification of the law above the distinction between true/not true are no longer part of the communication system of science, even if they still receive a salary from a research institution and do not transfer the salary back. Psychologists are communicatively responsible for the mental system in the sense that they treat souls without bodies. Social workers and sociologists are communicatively responsible for the social system, even if it is difficult to distinguish between these systems. And doctors, are they responsible for the organic system? For Luhmann, they are responsible for 'illness' in distinction to the unmarked space 'without findings'. For Luhmann's physicians, there are thousands of diseases, but only one health, about which nothing more can be said medically than that there are (as yet) no findings to diagnose. For the communication system of patient treatment, healthy people are not (yet) diagnosed as ill (Luhmann 1975, 1981, 1993). Therefore, for Luhmann there is actually no health system, but only a system of treating illnesses. A communication system that is geared towards health and beauty and in which people invest a great deal of effort on a daily basis is the care system - not investigated by Luhmann - with the code 'health-promoting care/uncare' (see Behrens 2009 and 2019).

The problem with the communication system of treating the sick is obviously that it is so difficult to separate illnesses from sick people. This is quite different in other communication systems. A court judgement can be legally right or wrong, regardless of who is judging and, above all, who is being judged. A capital investment can recognisably have brought in more money or lost money without having to know the persons to whom the capital belongs or who were employed to increase the capital. But in the system of treating illnesses, as we know, people are treated, not illnesses. A disease cannot be cured or even overcome without the decisive involvement of the person. 'Operation successful, patient dead' is not a sufficient indicator of the success of medical treatment. 'Fiat justitia et pereat mundus', on the other hand, proves success in the legal system. Justice can be validly pronounced without the defendant and plaintiff surviving. But illnesses cannot be treated without the people who fall ill.

In Luhmann's huge oeuvre, there are only three short writings on the system of treating the sick, although the public's interest in this topic - measured by citations of the three short essays - was enormous and Luhmann himself returned to the system of treating the sick several times in around 90 notes (the co-editor of Luhmann's now five volumes of 'Schriften zur Organisation', Ernst Lukas, has identified all of these 90 notes and footnotes, see Luhmann 2019-2022). However, in contrast to all other communication systems in society, Luhmann never systematically presented the system of treating the sick in a book. The book 'The Treatment of the Sick in Society' does not exist, although more people were waiting for it than for the book 'The Art of Society'. Perhaps it was too implausible to locate the person in the 'unmarked space' of the communication system in the system of treating the sick. This is why Luhmann never systematically returned to the topic despite the great interest of the audience. At least that is our assumption.

Pfaff and Schmitt cannot refer to Luhmann for their far-reaching assertion that separate interventions in 'organic, psychological and social healthcare subsystems' (Pfaff & Schmitt 2023, p. 7) are indeed possible, that much is certain.

3. The apparent uncertainty reduction of the herder kings: the generalisation problem

But doesn't the external evidence from frequency distributions at least allow us to draw conclusions about the correct treatment of collectives, even if it is not possible to draw conclusions about individuals? Is it possible to dispense with the development of internal evidence when treating collectives? In fact, owners of large herds can hardly claim to have to do justice to the individual. The fact that they cannot draw statistical conclusions about the individual from a frequency distribution need not be extremely worrying for owners of large herds. On the contrary, an epidemiological frequency distribution seems to correspond precisely to their interest in the herd as a whole and not, as is the case with nursing, medical or therapeutic practitioners, in the individuals. Frequency distributions therefore reduce uncertainty among livestock breeders much more than among carers, doctors or therapists. At the latest with the absolutism of the 'cattle-breeding kings' of England and France, the king's view of the people - advised by the physician Quesnay - was that of a cattle-breeder who is concerned about the health of his herd, the people, in order to get the most out of them. The good shepherd feeds his sheep and, when the time comes, leads them to the slaughter (bank). Knowledge of frequency distributions seems to be enough for this. But this is only apparently true. Because a methodological problem remains, even if one is satisfied with frequency distributions: The conclusion from one study result (frequency distribution) to the next situation in which one has to act remains challenging. Generations of sociologists and psychologists have tried to solve this problem.

It is surprising that Pfaff and Schmitt do not mention this problem at all. Yet it is agonising. The great Cronbach (1982) heroically endeavoured to solve it for decades and formulated the conditions under which I draw conclusions from a field study about the situation in which I have to act: According to Cronbach (1982), transferring the result of a field study to a next field is only possible if one has convinced oneself of the existence of four conditions: The units (subjects), treatments (intervening treatments), observing operations (observations, measurements) and the setting (context) must match in both fields (Cronbach 1982, p. 78 ff.).

Cronbach speaks of 'UTOS' after the initial letters of these four necessary matches. If even one of these four matches is not demonstrably fulfilled, Cronbach states that a transfer is not possible. But how can we know whether these four matches are present? Obviously, it is not possible to recognise whether these conditions are met or not without examining the situation for which you want to draw conclusions anew and thoroughly, i.e. without building up the internal evidence of this situation. (Social World 2015, Behrens 2019, p. 99). Consequently, the herdsman-king, who is only interested in the fate of his herd or his people and not in the individual, must also build up internal evidence as soon as he wants to draw conclusions from one day to the next or from one herd to another.

It is possible that Pfaff and Schmitt do not even mention the transfer or generalisation problem in evidence-based research because they know a deus ex machina who solves the generalisation or transfer problem for them: the theory expert (see assumption 6).

4th assumption: RCTs overcome all major biases of external evidence

Pfaff and Schmitt (2021 and 2022) are surprisingly uncritical of randomised controlled trials in their hierarchy of evidence-based knowledge (Pfaff and Schmitt 2023, p. 3 and Figure 1; 2021, p. 8, Figure 2). In their diagram, there is a one-dimensional hierarchy of evidence in which RCTs are at the top. In this, they lag almost 30 years behind the self-reflection of the various networks for evidence-based practice and thus health services research. By the end of the last millennium, word had already got around that randomisation of access to the intervention and control group only overcomes one of the many risks of bias in studies. This one bias is the selection bias. Selection bias means that the composition of the intervention and control groups is not comparable, especially because the heterogeneity of the groups could not be observed beforehand. Randomisation copes with previously unobserved heterogeneity if the group size is large enough. But selection bias is only one of many risks of bias.

All the many other risks of bias cannot be overcome by randomisation alone. As already demonstrated in Chapter 4 of Behrens & Langer 2004 and 2022 (pp. 155-304), there is (unfortunately) no single method that can overcome all the most relevant risks of bias at the same time. Therefore, there can logically be no one-dimensional quality hierarchy of studies, as Pfaff and Schmitt refer to in 2021 and 2023, as each study type only copes with certain risks of bias. A 'meta-analysis of randomised controlled trials', allegedly the highest level of 'evidence-based knowledge' in Pfaff and Schmitt 2021 and 2023, can be completely irrelevant in terms of informative value if the mechanism of action of the intervention is not carried out in a comparable manner, the representativeness of the population is unknown or the outcome is not appropriate, i.e. does not meet the needs for self-determined participation as defined by the UN and Section 1.2.2 of the German Social Code. The outcome was not determined in accordance with the UN and

Section 1 of the German Social Code IX. Many RCTs are completely irrelevant and also not transferable. By the 4th semester at the latest, the members of the networks for evidence-based practice and health services research expected all students of the various health sciences to be able to weigh up the strengths and weaknesses of each study method. Observational studies and representative panel studies have strengths that can never be expected from real-life RCTs, and vice versa. Each type of study copes best with a risk of bias. Whoever undertakes a study must decide which bias he or she fears the most. And those who analyse or evaluate studies for themselves must also be clear about their own priorities when it comes to overcoming the risk of bias. This is explained in detail in Chapter 4 of Behrens and Langer 2004 and 2022. (The validity of all studies is based on hermeneutic-interpretative (vulgo: qualitative) methods.

The expectations of the students of health, nursing and therapy sciences to be able to assign the individual study methods to different risks of bias were never disappointed. In the fourth semester, almost all students were able to competently weigh up the strengths and weaknesses of each method and knew that statistical 'quantitative' studies only make sense on the basis of interpretative-hermeneutic 'qualitative' investigations. .

Strangely, however, Pfaff and Schmitt 2021 and 2023 do not know of any other 'high-quality' studies for generating external evidence, 'evidence-based knowledge', than meta-analyses of randomised controlled trials. Stranger still, they only recognise one main weakness of RCTs: their time requirement. Almost 30 years ago, nobody in the EbM, EbN and EbP networks was this optimistic about RCTs. The time requirement is undoubtedly only one and not the biggest problem.

5. assumption: there is evidence-based knowledge that is not theory-based

Pfaff and Schmitt 2021 and 2023 (Figures 1 and 2 respectively) see the solution as being to place 'evidence-based knowledge' alongside 'theory-based knowledge'. The proposal is based on the surprising assumption that there is any 'evidence-based knowledge' that is not 'theory-based'. Without a theory, anthropologically speaking, a person is incapable of seeing, observing, understanding, explaining or treating anything (Singer 2017, Behrens and Langer 2004 and 2022). Nobody even raises a hand for a planned action without having an (at least implicit) theory of what this action could achieve (Singer 2017, Behrens & Langer 2004, Behrens 2019). The theory in question can and often does turn out to be wrong. People then correct their theoretical expectations and form a new theoretical expectation, which they base their actions on and which may prove to be wrong again. They refine their theories and are disappointed less and less often.

There is only one thing that is not given to people: to allow the objectivity of the world to be inscribed directly in people as if on a blank sheet of paper. This is what Locke (1670) and Hume (1748) had hoped. Most recently, Lenin (in his critique of Mach) and Stalin advocated this idea of objectivity. But the hope for an objectivity of the world that inscribes itself on us like a blank page is in vain. We approach the objectivity of the world, including the starry sky above us, exclusively as subjects who construct subjective-theoretical expectations and form them anew with every disappointment. This is no different in everyday life than in science (Behrens & Langer 2004, 2022, Behrens 2019).

Only subjects form theories and, without subjective theories, they can neither perceive nor act nor use theoretical expectations that turn out to be wrong to construct new theories. Charles S. Peirce (2008) established this almost 200 years ago. Rudolf Carnap (1966) was the last person to attempt inductive theorising at the beginning of the 20th century. When he failed, he shifted to a theory of decision-making under uncertainty and ignorance. It is Peirce, the late Carnap (1966) after the failure of inductivism and the art historian and criminalist Carlo Ginzburg (1983) on whom evidence-based practice - committed to individual natural and legal persons, using 'circumstantial evidence' and building up internal evidence in the encounter - is mostly based.

If it is anthropologically impossible for humans to perceive and act without theoretical expectations, it can be completely ruled out that the complicated actions required to generate evidence-based knowledge can do without theoretical expectations. Theories can be wrong and often are. But theory-free evidence-based knowledge cannot exist anthropologically. Therefore, theory-based knowledge cannot be a supplement to evidence-based knowledge, because a deficient or fruitful theory is already the basis of every study, even if the researchers are unaware of it and therefore do not make it explicit.

The fiction of a theory-free evidence-based knowledge - especially if one has convictions such as the assumptions 1 to 5 described above - leads to the implicit and explicit theories of each study no longer being perceived and critically analysed. This is a major risk and a considerable undesirable effect. The results of evidence-based knowledge appear as 'data and facts' without examining the theoretical expectations with which the 'facts' were made (Latin facere) and each 'datum' was given (Latin dare).

6. experts of a 'generally-accepted theory' versus 'evidence-based knowledge' - 'generally-accepted' eminences, their risks and side effects

If we take a closer look at the two essays by Pfaff and Schmitt, the proposal to supplement 'evidence-based knowledge' with 'theory-based knowledge' is not even intended to prove that theory-free evidence-based knowledge exists. Rather, they are explicitly concerned with positioning and defending 'experts' and their 'generally accepted' statements (expert opinions) against evidence-based knowledge (Pfaff and Schmitt 2021). This becomes systematically clear in their hierarchy of 'theory-based knowledge' cited above. In addition to 'empirically confirmed', 'generally accepted' is an independent characteristic. This means that the consensus and the citation cartels of the ordinaries have their own weight in addition to empirical confirmation. A theory that is empirically confirmed but not generally accepted by the full professors and similar experts must not be regarded as the pinnacle of 'theory-based knowledge'. It only proves to be worthy of this place when it has been 'generally accepted' (Pfaff and Schmidt 2023 and 2021, p. 3.). Once a theory is in this top position, its experts can advise policymakers, who are under time and decision-making pressure, almost immediately, without time-consuming studies of EBM, without time-

consuming development of internal evidence and without further empirical confirmation.

To understand the history of the eminent experts in the evidence-based practice movement, it is worth looking back at the emergence of these Eb movements in anti-authoritarian student movements. At McMaster University in Canada, the students, groaning under the amount of teaching and examination of teaching and examination material, demanded that they only have to learn theories with proven evidence. Professors had too often explained in their lectures that they didn't know the evidence for the theories either. They only knew that they were prescribed in the curriculum and that treatment according to these theories would be remunerated in Canada. The anti-authoritarian students thought that if they no longer had to cram all these theories and only had to learn evidence-based theories, the examination material would be considerably reduced. (As we know today, this was wrong: problem-based learning, which emerged with the demand for evidence-based learning, is much more work than simply writing down in frontal teaching which answer to a multiple-choice exam question has to be ticked (Them et al., 2002). The students' criticism of eminent experts was therefore directed against the inadequate fundamentals they called upon. An expert opinion whose empirical evidence did not substantiate their theory should be the very last thing. The trustworthiness of an eminent expert should no longer be determined by their salary grade (C 4 or W 3) or by their years of service (= experience). It should be determined solely by the intersubjectively verifiable evidence it provides. For Cochrane Reviews, for example, it is completely irrelevant in which pay grade their authors work. According to Habermas, it is the argument that counts - not the person presenting the argument, whether they are a nursing student with a secondary school leaving certificate or a senior doctor. Of course, authors of Cochrane Reviews have 'expertise' - but their personal opinion is largely irrelevant. Unsurprisingly, the EBM movements caused enormous narcissistic offence, as if long-serving chief physicians were no longer particularly trustworthy. A countermovement was and is only too understandable. Today, it is no longer about personal expert status, but solely about the expertise on which this status is verifiably based.

Here, the criterion of a 'generally accepted theory' emphasised by Pfaff and Schmitt 2023, p. 3 is highly problematic.

In their pyramid of theoretical knowledge, the 'generally accepted theory' is the highest level of trustworthiness, just like, strangely enough, the meta-analysis of RCTs in their pyramid of 'evidence-based knowledge'. The danger of the criterion of general acceptance among theory experts has become obvious in many cases. For example, in the treatment of pressure ulcers, from which almost all people who are bedridden will soon suffer - in other words, many millions of people. The 'generally accepted theory' of modern treatment and prevention of pressure ulcers ('decubitus ulcers') by professors and experts was blow-drying and ironing. It corresponded to the physiological theory according to which skin irritation alternating between heat (blow-drying) and cold (iron) led to better blood circulation in the skin. Blow-drying and ironing was an extremely time-consuming and expensive treatment. Nevertheless, it was practised with love and care. It was so much in line with the theory, experience and intuition of all the experts that virtually nobody found it ethically responsible or even necessary to measure the effect of blow-drying and ironing on a control group who were denied this loving and expensive treatment with blow-drying and ironing. Almost nobody attributed the fact that the pressure ulcer often did not regress or even got worse after blow-drying and ironing to blow-drying and ironing. It seemed to lie in the development of this disease. Almost no expert was the least bit surprised by this. It was in line with theory, experience and intuition. With more pressure sores, more blow-drying and ironing seemed necessary rather than less. It was only when, more or less by chance, a comparison was made between two groups of pressure ulcer sufferers with and without blow-drying and ironing - using primitive rather than sophisticated methods - that the realisation gradually spread that blow-drying and ironing, although lovingly administered, was a particularly torturous and damaging treatment for pressure ulcers. Anyone suffering from pressure sores who had been denied treatment with blow-drying and ironing out of economic greed and unkindness had been lucky. Gradually, blow-drying and ironing was labelled as torture with the same theoretical certainty with which this method had previously been declared to be theoretically without alternative. But the term torture is inappropriate. Torture presupposes intent: people are deliberately tortured. In this case, however, guilt does not lie in intent, but in grossly negligent reliance on a 'generally accepted theory' (Behrens and Langer 2004 and 2022, chapters G1 and G2).

When did the separation of theory and empirical evidence originate?

Today we know that there can be no anthropological empirical evidence without theory (Behrens & Langer 2004, 2022, Singer 2017, Behrens 2019). This was completely different for centuries. For there was a distinction between human empirical and divine theoretical knowledge. As we can still read in Kant's very witty essay 'On the Controversy of the Faculties' (Kant 1995, pp. 5-140), the higher faculties were based on the revelations of God or the princes appointed by God, while the lower faculty, the 'philosophical' faculty, was based on human empiricism and reasoning. Privileged access to divine knowledge was provided by theological priestly ordinations; the access to knowledge of priests, and later to a somewhat lesser extent of pastors, was definitely distinct from that of the laity. Privileged access to divinely gifted princely knowledge was provided by princely appointment to the faculty of law or the judgeship. For both faculties, 'you believe what your boss says' (the not-so-free translation of 'cuius regio, eius religio') applied. Kant endeavoured to keep the lower faculty as autonomous as possible from the demands of the higher faculties. Only human reason should apply in the lower philosophical faculty. Academic ordinations should not be priestly ordinations in the lower faculty. 'Therefore the biblical theologian (as belonging to the higher faculty) draws his teachings not from reason, but from the Bible, the teacher of law not from natural law, but from the law of the land, the medical scholar his method of healing going to the public not from the physics of the human body, but from

the medical order. ... Therefore the higher faculties must be most anxious not to intermarry with the lower, but to keep them as far apart as possible, so that the reputation of their statutes may not suffer from the free reasoning of the latter' (Kant 1995, p. 27 f., marginal note 23, bold emphasis added by jb).

In order to preserve this autonomy of the lower philosophical faculty, Kant is prepared to make far-reaching compromises in order to regulate overlaps. One obvious overlap is that the revealed Holy Scriptures and books of law are also texts. And as texts, they are capable of philological, i.e. logical-human interpretation, as practised by the lower faculty. Kant's compromise of demarcation is that pastors and lawyers who use human philology to interpret texts may under no circumstances present their philological interpretations from the pulpit or in the courtroom. From the pulpit and in the courtroom, knowledge should only be proclaimed as divine knowledge or knowledge revealed by God-given authority. This is the only way to prevent the lower faculty from coming into conflict with the higher faculties and provoking an encroachment on their autonomy by the authorities. Kant found this demarcation most difficult in medicine. This is because medicine traditionally belongs to the higher faculties. At the same time, however, its methods are based to a large extent on empirical observation of nature by the lower philosophical faculty and not only on revelation by the authorities. Here Kant seeks a formulaic compromise. He claims that the God-gifted authorities only have an interest in the medical 'Polizey' ('Medicinalordnung'). Details, which the philosophical faculty's observation of nature was concerned with, were supposedly of no concern to the authorities. (Today, the Faculty of Medicine feels comfortable, at least in its place, in its 'mismarriage' with the old, lower, empirically orientated faculty).

The theologian Albertus Magnus, who then had to wait 700 years to be canonised, had already struggled with this division of divine-theoretical and human-empirical knowledge in the 13th century. He sharply criticised the fact that the theoretical revelation of the Holy Scriptures should apply in vegetabilibus (the science of agricultural care, i.e. agricultural plant knowledge) instead of the human empirical evidence of experimentation:

'A principle that is inconsistent with experimental sense perception is in reality not a principle but a fundamental error '

(Magnus, 1981, p. 144).

Even today, there is no better way to justify methods of external evidence.

Today, historical anthropology, which has become modest, sees theory in all empiricism. Theory is no longer divine revelatory knowledge. Theory is human. Academic ordinations are no longer priestly ordinations for them.

7. Conclusion and prognosis

Pfaff's and Schmitt's contributions have the merit of adopting some of the achievements that the self-reflection of evidence-based practitioners achieved and published a quarter of a century ago, at the end of the last millennium. These include the programmatic rejection of a mechanistic approach and the shift towards a system-theoretical approach that no longer analyses the world according to the model of a clock whose gears are completely open to the watchmaker - like an omniscient 'watchmaker' god in Leibniz and Bourdieu. Even a few of the numerous cognitive problems of evidence-based action that had to be solved theoretically at the end of the last millennium are being addressed again. This is undoubtedly a great achievement. However, their proposed solution of supplementing empirical evidence with a theoretical 'justification' by means of a 'generally accepted theory' and further with experience and context-based knowledge to form an EbM+theory approach is based on six assumptions that are unfortunately not realisable for humans and are therefore not compatible with an anthropologically justifiable, i.e. modest, epistemology. As demonstrated by Pfaff and Schmitt, their distinction between 'theory-based knowledge' and 'evidence-based knowledge' (Pfaff and Schmitt 2021, p. 6) or even 'empirical and theoretical evidence' (Pfaff and Schmitt 2023, p. 1) led to the extremely uncritical handing down of a version of 'EBM' that has been outdated for 30 years. Pfaff and Schmitt completely relieve 'EBM' of the 30-year challenge of explicating and analysing the implicit theories of each study and prioritising the risks of bias that usually cannot be overcome by a single method: Pfaff and Schmitt simply place 'theoretical evidence' next to it that is independent of it. The phenomenon is familiar from house building. Instead of repairing and renovating an old house, a new, somewhat shaky extension is simply added. After a while, both the house and the extension collapse. Without a doubt, a study that claims to be able to make theory-free empirical evidence-based contributions and generalise would have nothing to do with evidence-based research. Theory-free perception is not possible for humans - in contrast to the omniscient God - even if quite a few people claim to participate in his omniscience through a personal procura of the omniscient God as God's authorised representative. The movements of evidence-based practice unfolded as theory-orientated attempts to overcome any risks of distorted perceptions and theoretical fallacies.

Forecast on the eternity and risks and side effects of the 'Ebm+Theory Approach '

It is not difficult to make a prognosis: the limits of evidence-based reasoning are such an imposition that people will always place their hopes in theoretical eminences that promise to reduce the limitations of human knowledge by referring to 'theory' - or to parts of the knowledge of the superhumanly omnipotent God that have been exclusively revealed to them. As long as there are human beings, eminences will probably not pass away. Some may retire, others may be expelled, but new eminences will continue to emerge. The limitations of human knowledge are simply too hard to bear. It forces us to make existential decisions in the face of uncertainty, decisions which, despite all the uncertainty, must be justified to our fellow human beings as 'reasonable' and for which we must take responsibility. Being able to hand over this burden to seemingly eminent experts will always remain a highly attractive temptation. What is so bad about this understandable coping strategy? That relying on theory to supplement and relativise evidence hinders the ability of human societies to learn and prolongs human suffering, because their overly naive idea of evidence-based knowledge considers the necessary development of internal evidence to be superfluous and instead surrenders to eminences of 'generally

accepted theory'.

The handling of the Covid-19 pandemic in particular illustrates the difference between external evidence and decision-making, which was often legitimised at press conferences. A scientist usually stood silently next to a responsible, parliamentarily elected minister or head of office, as if external evidence and decision were one and the same. Academies recommended what politicians urgently needed to do. The distinction between (limited) empirical external evidence and decisions to be made in parliament seemed to have been levelled out and the development of internal evidence was no longer necessary. As is well known, the available external evidence was very limited at the beginning of the Covid-19 pandemic. Decisions that would subsequently turn out to be wrong could neither be avoided nor criticised. What was reproachable, because it was easy to avoid, was the failure to conduct methodologically sound studies from the outset not only on the effects but also on the 'risks and side effects' of the decisions, e.g. for those in need of inpatient care and younger students, as well as many other groups. The external and internal evidence could have increased more quickly and thus provided a better basis for decisions. For the next pandemic, which is sure to come, much more external evidence would have been made available. On a positive note, the book 'www.corona-verstehen' by David Klemperer with the collaboration of Joseph Kuhn and Bernt-Peter Robra, which was first updated every 14 days and then every month (now in its 78th version), summarised the latest state of knowledge and should certainly be supplemented.

Over the last 30 years, since the movement of the anti-authoritarian students at McMaster University, it has always been to be expected: the eminences will strike back. They will be welcomed and celebrated with utopian hopes. Thus celebrated, few eminences will return to the - indeed tedious and unglamorous - work of critically analysing the theories and methods in EbP studies of external evidence and being available to individual clients in their construction of internal evidence. <<

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The EbM+Theory Approach – an appreciation of its 6 assumptions and its risks and side effects

In their "EbM+Theory approach" (2021 and 2023), Holger Pfaff and Jochen Schmitt address questions of evidence-based decisions that evidence-based health services research worked on 30 years ago. Their EbM+Theory approach is based on at least six assumptions, the practical-empirical validity of which is examined. A conclusion deals with the risks and side effects of the EbM+Theory approach and predicts eternal survival for this approach, since it supports Eminence.

Keywords

Philosophy of science, anthropologically modest epistemology, evidence-based health services research, EbM+Theory approach, Systems Theory

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Prof. em. Dr. phil. habil. Johann Behrens

war Gründungsdirektor des ersten Instituts für Gesundheits-, Therapie- und Pflegewissenschaften an einer öffentlichen Medizinischen Fakultät in den deutschsprachigen Ländern (D-A-CH), der Universität Halle-Wittenberg. Er war Vorstandsmitglied der auch in der Versorgungsforschung aktiven DFG-Sonderforschungsbereiche 186 (Bremen 1988–2000) und 580 (Halle/Jena 2000–2012) sowie der Dekanekonferenz Pflegewissenschaft. Zudem war er Gründungsmitglied des German Centers for Evidence based Nursing „sapere aude“. Kontakt: Johann.Behrens@medizin.uni-halle.de

