

**Give organisational innovation a chance:
The implementation gap, structural conservatism and the critical influence of evidence-based
medicine purism – toward context-specific evidence levels**

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Conflict of interests

- This presentation is based on a manuscript currently under revision
- Holger Pfaff, no conflict of interest
- Jochen Schmitt, is:
 - Member of the Government Commission for Modern and Needs-Based Hospital Care, Germany
 - Member of the German Advisory Council on Health and Care of the German Ministry of Health

I. The problem: implementation gap

II. Evidence-based Medicine: the transformation

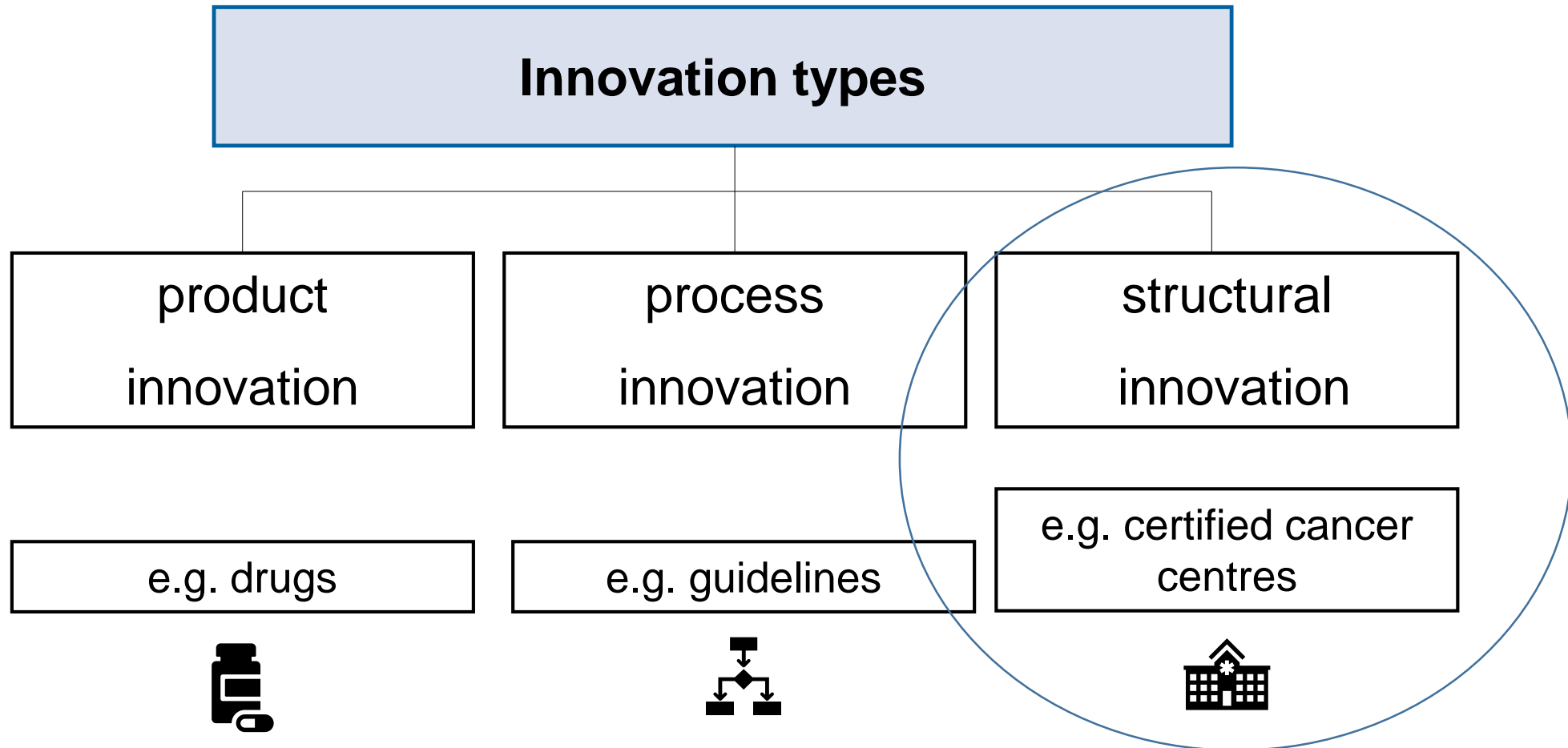
III. Evaluating structural innovations: 7 limits

IV. Structural conservatism

V. Overcoming structural conservatism

VI. Conclusion: Toward context-specific evidence levels

There are different kinds of innovation in healthcare



Implementation gap

- Germany: struggle to implement innovations in care structures and processes
(Schubert et al. 2021; Groene et al. 2017; Schmitt et al. 2023; Heytens et al. 2021).
- Gap in the implementation of healthcare innovations in Germany

Schubert, Ingrid; Stelzer, Dominikus; Siegel, Achim; Köster, Ingrid; Mehl, Claudia; Ihle, Peter et al. (2021): Ten-Year Evaluation of the Population-Based Integrated Health Care System "Gesundes Kinzigtal". In: *Deutsches Ärzteblatt international* 118 (27-28), S. 465–472. DOI: 10.3238/arztebl.m2021.0163.; Groene, Oliver; Pfaff, Holger; Hildebrandt, Helmut (2017): Scaling up a population-based integrated healthcare system: The case of "Healthy Kinzigtal" in Germany. In: Jeffrey Braithwaite, Russell Mannion, Yukihiko Matsuyama, Paul Shekelle, Stuart Whittaker und Samir Al-Adawi (Hg.): *Health Systems Improvement Across the Globe. Success Stories from 60 Countries*. 1st ed. London: CRC Press.; Schmitt, Jochen; Klinkhammer-Schalke, Monika; Bierbaum, Veronika; Gerken, Michael; Bobeth, Christoph; Rössler, Martin et al. (2023): Initial Cancer Treatment in Certified Versus Non-Certified Hospitals—Results of the WiZen Comparative Cohort Study. In: *Deutsches Ärzteblatt international* (Forthcoming), arztebl.m2023.0169. DOI: 10.3238/arztebl.m2023.0169.; Heytens, Heike; Walther, Felix; Kefßler, Laura; Bremer, Daniel; Frenz, Elisa; Härter, Martin et al. (2021): [Characteristics of Innovation Fund-supported Intervention Studies: Review and Document Analysis of Study Protocols, Publications and Final Reports]. In: *Gesundheitswesen* 83 (5), e20-e37. DOI: 10.1055/a-1448-2412.

Explaining the implementation gap: The structural conservatism hypothesis

Implementation gap = f (*inherent structural conservatism of EBM*).

We hypothesise that structural conservatism is due to an

- uncompromising application of the highest EBM criteria to structural innovations in healthcare.

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First-generation EBM advocates: The case of “applied EBM”

The first-generation EBM approach

- "best available evidence" (not the highest evidence)
- **application-oriented**

The founders of EBM were **practitioners**

=> EBM as a **resource** for healthcare professionals

(Sackett et al. 1996; Sackett 1997; Katz 2001; Schünemann und Guyatt 2014).

Sackett, David L.; Rosenberg, William M.; Gray, J. A.; Haynes, R. Brian; Richardson, W. Scott (1996): Evidence based medicine: What it is and what it isn't. In: BMJ 312, S. 71–72.;

Sackett, David L. (1997): Evidence-based medicine. In: Seminars in Perinatology 21 (1), S. 3–5. DOI: 10.1016/S0146-0005(97)80013-4.;

Katz, David L. (2001): Clinical epidemiology and evidence-based medicine. Fundamental principles of clinical reasoning and research. Thousand Oaks: Sage.;

Schünemann, Holger J.; Guyatt, Gordon H. (2014): Clinical Epidemiology and Evidence-Based Health Care. In: Wolfgang Ahrens und Iris Pigeot (Hg.): Handbook of epidemiology. 2.a ed. New York: Springer Science, S. 1813–1873.

Second-generation EBM advocates: The case of “pure EBM”

Second-generation EBM advocates:

- high degree of **professionalism** regarding EBM as a method and science
- **no longer practitioners** themselves
- not **responsible** for decisions based on their rules
- **basic researchers** rather than applied researchers

Hypothesis (sociological viewpoint): EBM has turned into an autopoietic system

The EBM transformation hypothesis:

- *The originally pragmatic and empowering concept of EBM has been transformed into a theoretically pure EBM concept that strives for the theoretical highest scientific standards*
- Important role of institutions in promoting and protecting this transformation (e.g. NICE; IQWiG; Cochrane Network).
- Sociological interpretation: EBM has transformed itself into an **autopoietic system**
Characteristics: Centrifugal decoupling, own rules, independence

Mayntz, Renate (1988): Funktionelle Teilsysteme in der Theorie sozialer Differenzierung. In: Renate Mayntz, Bernd Rosewitz, Uwe Schimank und Rudolf Stichweh (Hg.): Differenzierung und Verselbständigung : zur Entwicklung gesellschaftlicher Teilsysteme. Frankfurt am Main: Campus, S. 12–44. Online verfügbar unter https://pure.mpg.de/rest/items/item_1235956/component/file_2505580/content.

Luhmann, Niklas (2008): The autopoiesis of social systems. In: Journal of sociocybernetics 6 (2), S. 84–95.

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Hypothesis:

Not taking into account the **limits** of the applicability of the highest EBM principles in the area of structural innovations unintentionally promotes structural conservatism

Definition of structural conservatism:

A policy and practice that makes decisions in a way that systematically - intentionally or not - preserves old structures and impedes the development of new ones.

What are the limits?

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Limit 1: Resistance to change

Structural changes through innovations can cause

- individual and social resistance to change,

as structures are particularly linked to interests, routines, resources and power.

=> Intervention into social systems (not into bodies)

Coch, Lester; French, John R. P., Jr. (1948): Overcoming resistance to change. In: *Human Relations* 1 (4), S. 512–532. Online verfügbar unter <http://hum.sagepub.com>.

Carlstrom, Eric; Olsson, Lars-Eric (2014): The association between subcultures and resistance to change - in a Swedish hospital clinic. In: *J Health Organ Manag* 28 (4), S. 458–476.

Limit 2: Time expenditures

Time for

- planning
 - participation of interest groups
 - setting up the technical infrastructure
 - staff training.
 - personnel and organizational development
-
- It takes several years for new structures to be established and to function properly and to evaluate them
 - EBM-time lag

Limit 3: Dismantling costs

In the event of a negative evaluation of a structural innovation:

- 1) Is it possible to dismantle the new buildings, the new facilities and the installed technologies that were part of the negatively evaluated innovation?
- 2) Is it possible to simply rebuild the healthcare structures that were abolished as part of the experiment but proved to be useful in the experiment?

⇒ No simple switch-off and switch-on

⇒ Negative impact on the decision to participate in a structural experiment.

Limit 4: Complexity

- EBM is a suitable method for simple interventions (e.g. medication)
 - but only partly suitable for complex interventions
(e.g. complexity: many causes, actors, system components and feedback loops)
- => RCTs and CRTs only partially capture the causal complexity that is usually inherent in organizational innovations.

Structural innovation = multi-system-interventions

Structural innovation in healthcare
= interventions in ...

technical
systems



body systems



psychological
systems



social
systems



+



-

Applicability of theoretical highest evidence standards

Limit 5: Dynamic context and EBM lag

EBM is suitable in stable environments,

- not necessarily in dynamic environments

(e.g. COVID-19; AI; oncology) (Pfaff & Schmitt 2021)



EBM lag =

- Delay between the emergence of a new condition and the availability of systematic reviews on the effectiveness of an intervention in treating the new condition

(Pfaff & Schmitt 2022)

=> EBM knowledge is quickly outdated in the case of changing conditions.

The Organic Turn: Coping With Pandemic and Non-pandemic Challenges by Integrating Evidence-, Theory-, Experience-, and Context-Based Knowledge in Advising Health Policy

Holger Pfaff^{1*} and Jochen Schmitt²

Pfaff, Holger; Schmitt, Jochen (2021): The organic turn: coping with pandemic and non-pandemic challenges by integrating evidence-, theory-, experience-, and context-based knowledge in advising health policy. In: Frontiers in public health 9, S. 1607. DOI: 10.3389/fpubh.2021.727427.;

Ogburn, William F. (1957): Cultural lag as theory. In: Sociology & Social Research 41, S. 167–174.

Limit 6: Low evaluation culture

- EBM is a robust approach to generating evidence within an evaluation culture
- If the evaluation culture is poor, the willingness to engage in randomized experiments is often low
- Unfavorable evaluation cultures are characterized by historically grown structures
=> little opportunity for randomization and experimental change

Limit 7: Decentralized healthcare systems

- The nature of the healthcare system influences the evaluability of structural innovations
- The Medical Research Council's model for evaluating complex interventions is more feasible in centralized than in decentralized healthcare systems (e.g. UK vs. Germany).

centralized healthcare systems = hierarchy-based

decentralized healthcare systems = network- or market-based

Craig, Peter; Cooper, Cyrus; Gunnell, David; Haw, Sally; Lawson, Kenny; Macintyre, Sally et al. (2012): Developing and evaluating complex interventions: The new Medical Research Council guidance. In: *Int J Nurs Stud* 66 (12), S. 1182–1186. DOI: 10.1136/ijech-2011-200375.

Skivington, Kathryn; Matthews, Lynsay; Simpson, Sharon Anne; Craig, Peter; Baird, Janis; Blazeby, Jane M. et al. (2021): A new framework for developing and evaluating complex interventions: update of Medical Research Council guidance. In: *BMJ (Clinical research ed.)* 374, n2061. DOI: 10.1136/bmj.n2061.

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Hypothesis:

Structural conservatism could be the result of the (unintentional) interplay between “vested interest” and “basic scientists”

Structural conservatism could be the result of an interplay between

(a) "vested interests" and "structural profiteers" and

(b) basic scientists and statisticians

- who strive for freedom from doubt and only give their placet when there is absolute freedom from doubt and
- which provide the structural profiteers with the arguments to hold on to their own structures

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The motto of science-based structural conservatism:

"Preserve the old until the new is proven beyond doubt to be better"

- The scientist's (and practitioner's) fear of the 1st kind of error

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No "equality of arms"

The motto of structural conservatism

only makes sense

if the "old" has also proven its effectiveness before its introduction in one or more similarly rigorous test procedures (e.g. RCT; meta-analyses)

But. In the past, existing care structures were rarely subjected to effectiveness tests

⇒ No "equality of arms" between "new" and "old"

⇒ asymmetric evidence

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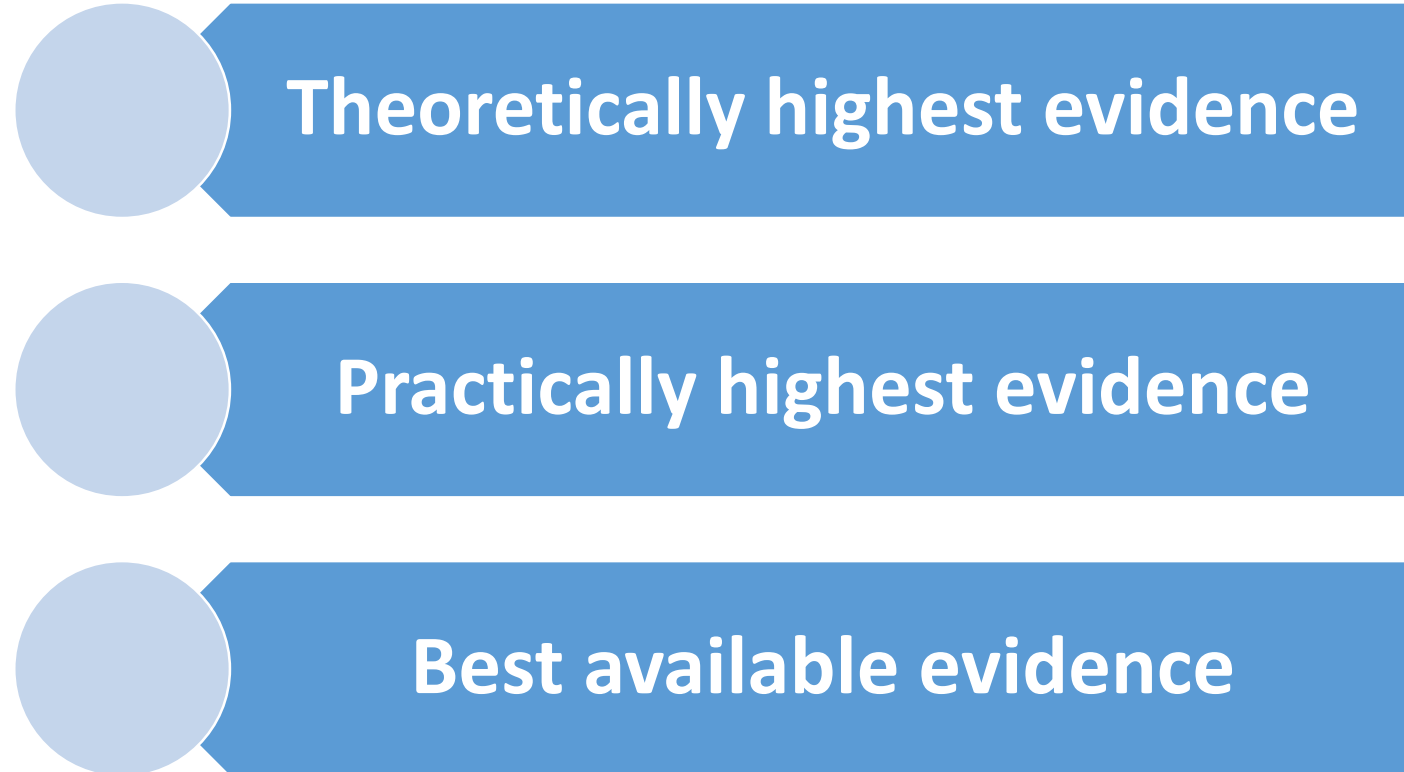
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Proposal 1:

Distinguishing pragmatic evidence levels



Evidence levels

Examples

Theoretically highest evidence

RCT, CRT & meta-analysis
(WiZen study does not meet these
criteria: Stang 2023)

Practically highest evidence

Missing, as new territory

Best available evidence

Decision situation: „hospital reform in
Germany 2024“ (best available
evidence for certified cancer centre:
WiZen study (Schmitt et al. 2023))

Schmitt, Jochen; Klinkhammer-Schalke, Monika; Bierbaum, Veronika; Gerken, Michael; Bobeth, Christoph; Rössler, Martin et al. (2023): Initial Cancer Treatment in Certified Versus Non-Certified Hospitals—Results of the WiZen Comparative Cohort Study. In: Deutsches Arzteblatt international (Forthcoming), arztebl.m2023.0169. DOI: 10.3238/arztebl.m2023.0169.; Stang, Andreas (2023): Evaluability of the effect of oncology center certification. In: Deutsches Arzteblatt international. DOI: 10.3238/arztebl.m2023.0184.

Proposal 2:

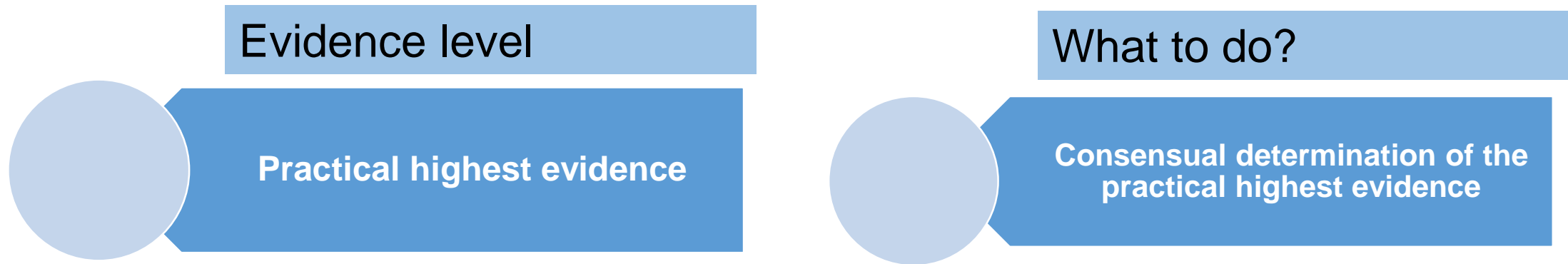
Focusing on the practical highest evidence

Guiding question:

What is the maximum level of evidence that can be obtained in country X under the given

- legal provisions
- reimbursement conditions
- time restrictions
- financial restrictions
- evaluation culture
- health and organizational cultures and
- data protection regulations?

The consensus path



- Step 1: Analyze, define and become aware of the given contextual conditions (context setting)
- Step 2: Define the possibilities and limitations of the applicability of EBM principles under these conditions
- Step 3: Determine the level of highest practical evidence in a nationwide consensus process
- Step 4: Plan and conduct studies that can provide the highest level of practical evidence

Proposal 3: Creating a culture of uncertainty

- Mindset: Decision-making under uncertainty as the "new normal"
- Defining levels of uncertainty in science
- Defining levels of uncertainty in policy and practice
- Communication the two levels of uncertainty in scientific recommendations and practical decisions

Defining degrees of recommendatory and decisional uncertainty: an example

Evidence level	Recommendatory and decisional uncertainty
Theoretical highest evidence	No uncertainty
Practical highest evidence	Practical no uncertainty
Best available evidence	Lowest uncertainty currently available
Below best available evidence	Moderate uncertainty
Expert knowledge	High uncertainty
Gut decisions	Highest uncertainty



Artinger, Florian M.; Gigerenzer, Gerd; Jacobs, Perke (2022): Satisficing: Integrating Two Traditions. In: *Journal of Economic Literature* 60 (2), S. 598–635. DOI: 10.1257/jel.20201396.

Simon, H. A. (1997): *Models of Bounded Rationality: Empirically grounded economic reason*: MIT Press (*Models of Bounded Rationality*). Online verfügbar unter <https://books.google.de/books?id=9CiwU28z6WQC>.

Defining and communicating uncertainty

Theoretically highest evidence

Practically highest evidence

Best available evidence

Determine and communicate the difference between theoretical highest and practical highest evidence

Determine and communicate the difference between practical highest and best available evidence

**Minimize
diff.**

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Proposal 4:

Combining EbM, EbM+ and theory => EbM+theory

Step 1



Step 2



Step 3

Theory:
Identification or creation of useful theories and derivation of possible causal mechanisms

EBM+:
Research and description of causal mechanisms through mechanistic studies

EBM:
Conducting (quasi-)experiments to determine the effectiveness of a treatment



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DOI: 10.1111/jep.13890

ORIGINAL PAPER

Journal of Evaluation in Clinical Practice
WILEY

Reducing uncertainty in evidence-based health policy by integrating empirical and theoretical evidence: An EbM+theory approach

Holger Pfaff Dr. phil^{1,2} | Jochen Schmitt³

Greenhalgh, Trisha; Fisman, David; Cane, Danielle J.; Oliver, Matthew; Macintyre, Chandini Raina (2022): Adapt or die: how the pandemic made the shift from EBM to EBM+ more urgent. In: *BMJ Evidence-Based Medicine* 27 (5), S. 253. DOI: 10.1136/bmjebm-2022-111952.; Pfaff, Holger; Schmitt, Jochen (2023): Reducing uncertainty in evidence-based health policy by integrating empirical and theoretical evidence: An EbM+theory approach. In: *Journal of evaluation in clinical practice* n/a (n/a). DOI: 10.1111/jep.13890.

Proposal 5: System thinking

Step 1: Creating a systemic model of the interactions of the target system

e.g. theory of complex adaptive systems
(Greenhalgh & Papoutsi 2018; Braithwaite et al. 2018)

Step 2: Assess the unintended and intended consequences of structural innovations compared to the “old structure”

Step 3: Communicate the knowledge from steps 1 and 2 to decision-makers and stakeholders (e.g. using "stories")

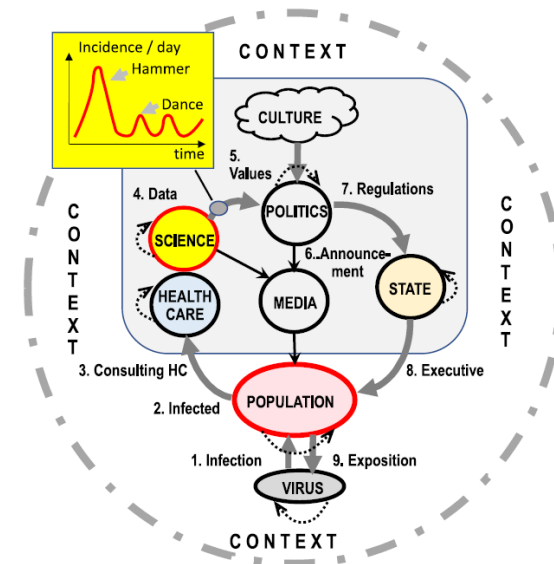


FIGURE 1 The management of the Corona problem from a systemic view of the control loop paradigm of systemic management: From the virus to the virus. Delayed responses and intrinsic dynamics of subsystems and small loops (science-media-population-health care-science) can evoke critical fluctuations of the incidence curve.³

Tretter, Felix; Marcum, James (2022): 'Medical Corona Science': Philosophical and systemic issues: Re-thinking medicine? On the epistemology of Corona medicine. In: Journal of evaluation in clinical practice. DOI: 10.1111/jep.13734.

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Conclusion: Toward context-specific evidence levels

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- 1) To overcome structural conservatism structural innovations should not be evaluated on the basis of the Theoretical Highest Evidence (THE) but on the basis of the Practical Highest Evidence (PHE)
- 2) The practically highest evidence is context-specific and therefore not universal (like the THE)
- 3) For each definable contextual setting, we need a context-specific PHE level that has been established by stakeholder consensus

Thank you very much for your attention!

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