Concepts of Evidence-Based Practice: Analysis of Evidence-Based Practice and Its Debate

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Abstract

Evidence-based practice (EBP) is a model for clinical decision-making, representing an interdisciplinary approach to clinical practice that aims to optimize clinical decision-making by emphasizing the use of evidence from well-designed research. An evidence-based decision is made by the individual clinician on basis of the best evidence available, in accordance with the patient's preferences and circumstances. Since 1992, EBP has been a central concept within a growing range of professional fields of health care. At the same time, EBP has been subject to incessant criticism. EBP proponents have responded to criticism, and their responses have then become the object of further criticism. The basic principles of the EBP-model, along with the claims by proponents and opponents for and against these principles, which compose the EBP debate, are the main subjects of this thesis.

The thesis has four chapters. In Chapter 1, the principles of Clinical epidemiology are presented as the main scientific framework of EBP. It is through this framework that epidemiologic, outcome-based data is considered the most reliable source of evidence for clinical interventions.

In Chapter 2, the constitutive elements of EBP are analyzed, with particular attention to what kind of scientific knowledge (i.e., "research evidence") and non-scientific knowledge and beliefs (i.e., "clinical expertise" and "patient preferences") that are inherent in the concept of EBP. In addition, I differentiate between three theoretical concepts of EBP – "narrow", "moderate", and "maximal" – which differ relative to the degree to which "clinical expertise" and "patient autonomy" are included in the concept or not. I claim that only "moderate" EBP" is representative for an adequate understanding of the EBP model.

Chapter 3 presents an analysis of central claims in the international EBP debate while Chapter 4 attends to central claims in the Norwegian EBP debate. I argue that the most relevant criticism pertains to the confidence in and the application of epidemiologic

evidence-sources. This kind of criticism must be distinguished from the claim that EBP represents a narrow scope of evidence. The latter claim is based on a misunderstanding about what "evidence" entails in EBP literature and is representative to a narrow concept of EBP. Yet another kind of criticism, claiming that the EBP model ignores clinical expertise and patient autonomy, is also based on misunderstandings, largely due to lack of clarity in the EBP literature.

A general conclusion is that the tendency to imply a narrow interpretation of EBP in much of the criticism, as well as the tendency to conceptual unclarities in much EBP literature, contribute to a less constructive debate. The thesis concludes by suggesting recommendations to both proponents and opponents, which can contribute to a more constructive basis for future EBP debates.

Contents

Introduction

Since 1992, evidence-based practice (EBP) has been a central concept within a growing range of professional fields, especially within health care. EBP is a model for clinical decision-making, representing an interdisciplinary approach to clinical practice that aims to optimize clinical decision-making by emphasizing the use of evidence from well-designed research. EBP is used both on the population level (typically labelled 'evidence-based policy') and on the individual level, concerning individual decision-making, conducted by a single clinician in direct patient care, in accordance with the individual preferences of the patient. The following thesis is restricted to individual decision-making.

Initially, EBP was limited to the medical profession, as evidence-based medicine (EBM). As more professions made use of EBP principles, terminological offsprings were formulated, such as evidence-based nursing, evidence-based dentistry, and evidence-based psychotherapy. While EBM is the most common term in the literature, it is, from a professional point of view, only one "evidence-based approach" among others. Thus, any principles inherent in specific evidence-based professions (such as EBM) coincide with and are equally relevant to EBP. This treatise is about evidence-based *practice*, which concerns the principles of evidence-based models in any evidence-based health profession. To maintain terminological rigour and readability throughout the treatise, I have chosen to refer to EBP as the main designator. This also pertains to cases when I am citing or referring to texts that explicitly make use of the term "EBM". The alternative would be to remark on every singular occasion (of which there are many) that the principles I am addressing are equally relevant to EBP[1] – an alternative I find both cumbersome and unnecessary.

[1] The exception to this rule includes cases in which the professional literature in, for example, evidence-based medicine refers specifically to scenarios or a specific scope of evidence-sources that are specific to

The main attraction of EBP is that it enables identification of effective clinical practice in a reliable way, both by promoting the use of research evidence and offering guidance on how to assess such evidence through clear and concise criteria. However, the confidence in and application of EBP principles have also been the object of incessant criticism both from health care professionals and philosophers of science. EBP proponents have responded to criticism, and their responses have then become the object of further criticism. The basic principles of the EBP-model, along with the arguments by proponents and opponents for and against these principles, which compose the EBP debate, are the main subjects of this treatise.

The main controversy in the EBP debate concerns the justification and relevance of three basic principles: (1) Epidemiologic research results are applied as a basis for clinical decision-making; (2) Outcome-based research is considered superior to other kinds of research; (3) Evidence-sources are critically appraised according to epidemiologic criteria of validity, in particular with regard to risk of bias.

In addition, there are several other non-controversial principles, such as (4) In clinical decision-making, research evidence is never sufficient; both personal experiences and the patient's preferences are necessary elements in any clinical decision; and (5) what is considered "best evidence available" is relative to different clinical questions and circumstances. While the controversial principles are methodological, referring to scientific knowledge, the non-controversial principles are pragmatically oriented, based on non-scientific knowledge, and do not differ from non-EBP models of clinical practice. These non-controversial principles are equally essential to the EBP debate, most often referred to in combination with the controversial principles (e.g., that the attention to epidemiologic data minimizes the autonomy of the patient).

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the profession alone. None of the citations or other references made in this dissertation address such specific references.

The degree of adequacy in the EBP debate has fundamentally to do with an understanding of the basic terminology in the EBP literature. The analysis of the EBP debate thus requires two important preliminary steps: Clarification of the scientific background of EBP and of the necessary and sufficient conditions for the EBP model. These clarifications provide the necessary basis for an adequate analysis of the EBP debate.

Specifically, I address the following six questions:

1. What are the main characteristics of clinical epidemiology, considered as the main scientific framework of EBP?
2. What are the core elements of the EBP model, and what kinds of knowledge are necessary and sufficient conditions for a practice to be "evidence-based"?
3. These questions provides the basis for treating questions concerning the EBP debate:
4. What is the central and typical content of EBP criticism?
5. To what extent are the different kinds of criticism relevant?

On basis of answering these questions, the treatise concludes with a discussion of the future possibilities of the EBP debate:

6. Is it possible to identify a better, more constructive basis for the EBP debate?

Previous research on the subject and the original contributions of this treatise

Earlier research on the subject of EBP is restricted primarily to discussing various aspects of "evidence" in EBP, mostly with regard to EBM (e.g. Ashcroft 2004; Cartwright 2007; 2011; La Caze 2008; 2009; and Worrall 2002; 2007; 2010). There are, however, some philosophers who have conducted research on the multiple aspects of the EBP model as

well as of the EBP debate (in particular Howick 2011; Bluhm & Borgerson 2010; and Wieten 2018).

The novel contributions this treatise provides is the in-depth analysis of clinical epidemiology and EBP, as well as of the EBP debate. In particular, the detailed analysis of EBPs scientific background in clinical epidemiology provides a basis for analysing the EBP debate in an extensive manner that has not been conducted earlier. When analysing the content of the EBP model, I provide an epistemological analysis of what characterizes scientific and non-scientific knowledge in EBP. The EBP literature has always acknowledged the occurrence of non-scientific knowledge, but has been subjected to scrutiny only to a lesser extent (in particular by Howick 2011, and Wieten 2018).

With regard to identification of the specific kinds of criticism in the EBP debate, attempts have been made to categorize essential arguments. The most comprehensive categorizations to date are put forward by Cohen et.al. (2004) and Strauss & McAllister (2000). Both of these categorizations are very general, and lack substantial scrutiny. The innovative aspect of my categorization is the in-depth analysis and clarification of the basic terminology that is addressed in the criticism (chapter 1 and 2). In the absence of such a clarification, discussions of whether certain kinds of criticism are justified become superficial. The treatise also provides more nuanced descriptions of the categories of claims and arguments used in the debate (Chapters 3 and 4).

Structure of the treatise

The treatise consists of four main chapters, with several subsections in each, and a conclusion.

- **Chapter 1: Clinical epidemiology as the scientific framework of EBP**

In chapter 1, I will examine clinical epidemiology as the scientific framework of EBP and identify the reasons why epidemiological, outcome-based data are considered the most reliable source of evidence for clinical interventions. I will also investigate the methodological features through which various kinds of evidence are assessed and viewed hierarchically, in accordance with the principles of validity in the field of clinical epidemiology.

I present the core idea of clinical epidemiology thus: To apply epidemiologic research knowledge as a basis for clinical decision-making when recommending clinical interventions to individual patients. Together with the principles for assessing evidence sources, this constitutes the main scientific framework for EBP. I will argue that this framework constitutes the most characteristic and most controversial feature of EBP.

- **Chapter 2: The concept of evidence-based practice**

In Chapter 2, I will analyse the concept of EBP. The main aim is to clarify the necessary and sufficient elements inherent in the concept of EBP. In particular, I will analyse the kinds of scientific and non-scientific knowledge that are considered necessary within the EBP model.

There are numerous definitions of EBP. Common to most of them is the notion that EBP clinical decision-making includes three elements: "evidence", use of "personal experience" or "expertise", and adherence to the principle that clinical decision-making must be in accordance with "patient preferences". The main aim of Chapter 2 is to clarify what the main elements in EBP entail, and to identify the necessary and sufficient conditions when defining EBP.

While 'evidence' to a large extent is related to knowledge generated through clinical epidemiology methods, the model of EBP also includes evidence sources from a broader professional field. In addition, knowledge and beliefs from personal experiences are

typically considered adequate evidence when scientific knowledge is unavailable. Due to its aim of practical decision-making, EBP also implies a non-scientific foundation in terms of the practical application of research evidence. It is through this foundation that EBP also includes incorporation of the clinician's personal experiences and patient's values. I argue that, in contrast to its clinical epidemiological framework, the non-scientific elements in EBP are uncontroversial, and may seem trivial – it is, after all, what any clinical practice entails. However, this is not the least trivial when it comes to understanding the scope and delineation of EBP. Both the scientific and the non-scientific elements are necessary for an adequate understanding of the EBP model. I also stress that the inclusion of non-scientific knowledge in EBP does not make the model any less "evidence-based": the scientific dimension of clinical epidemiology entails a description of the most typical manner in which the EBM clinician retrieves and assesses the evidence for any clinical decision-making.

After presenting four core principles common to various EBP definitions, I address the need for an extensive definition of EBP that includes the necessary elements of EBP, and I propose the following definition: "Evidence-based practice" is to be considered synonymous with (an) "approach to clinical decision-making, in which the clinician recommends clinical interventions to individual patients, based on the best evidence available, assessed according to methodological criteria of evidence quality, where the evidence is integrated into clinical practice by a clinician who, by making use of clinical experience, identifies, assesses and applies the evidence, in accordance with the patient's preferences and circumstances."

While this extensive definition lacks the pragmatic brevity of most other EBP definitions, it includes all the elements necessary for a sufficient evidence-based practice. The elements of this definition are further examined through an epistemological analysis of the kinds of knowledge that are necessary for the model of EBP. In particular, I examine

what kind of knowledge 'evidence', 'expertise' and 'patient's preferences' represent, and I examine how scientific and non-scientific knowledge are structured within the EBP model.

Based on the possible combinations of scientific and non-scientific dimensions of knowledge, it is theoretically possible to differentiate between three theoretical concepts of EBP: "Maximal", "minimal", and "moderate" EBP, which differ relative to the extent to which non-scientific knowledge is taken into consideration. In light of the analyses in chapter 1 and 2, I argue that only a moderate concept of EBP is justifiable.

The analysis in Chapters 1 and 2 will serve as a conceptual background for the examination of the EBP debate.

- **Chapter 3: Analysis of the EBP debate**

Measured in numbers of publications, the EBP debate is vast and encompasses assertions from proponents and opponents from health professions as well as from social and humanistic studies. At the outset, this literature may seem overwhelming in its multiple claims and nuances on the topic. A closer look, however, reveals that many of the critical arguments are rather similar, so that the quantification of arguments does not necessarily represent the same quantity of topics. Thus, the various claims can be categorized into a considerably smaller number.

In Chapter 3, I will demonstrate that the most central arguments in the EBP debate can be categorized into four main topics:

1. the conceptual unclarity of EBP definitions
2. the scope and justification of evidence
3. the role of expertise

4. patient preferences and autonomy

In the analysis of the EBP debate, various kinds of criticism will be ascribed to one of these four main topics. In total, I identify and discuss ten specific kinds of criticism.

I will also discuss whether each kind of criticism is adequate and relevant. A claim is considered adequate to the extent that it reflects a correct interpretation of its subject matter (i.e., EBP principles). Provided it is adequate, the same argument is relevant to the extent that it affects the justification of one or more EBP principles.

I argue that the most relevant kinds of criticism target the most controversial elements of EBP, i.e., its view of evidence, based on clinical epidemiology principles. In particular, this has to do with specific presuppositions concerning the internal and external validity of evidence. On the other hand, criticism of non-scientific knowledge is to a large extent based on misunderstandings of the content of EBP. In particular, several critics seem to ignore the inclusion of non-scientific elements in the EBP definition, thereby aproximating a minimal concept of EBP.

- **Chapter 4: Analysis of the Norwegian EBP debate**

Chapter 4 is considered an extension of the previous chapter, aiming at a more detailed analysis of some of the main kinds of criticism categorized in Chapter 3, by addressing the Norwegian EBP criticism specifically. The Norwegian EBP debate is not categorically different from the international. However, there are fewer debating participants, and certain misinterpretations have developed into commonplace conceptualizations of EBP.

The analysis of the Norwegian critics consists of two parts. Firstly, I address their specific claims and analyze their arguments and theoretical assumptions in support of these claims. This analysis entails a relatively detailed examination of each of the critics' lines of arguments. As part of this analysis, I also identify which of their arguments that are comparable to the main kinds of criticism analysed in Chapter 3. Secondly, I conduct a

cricial analysis of the Norwegian criticism, by discussing the validity and relevance of the specific claims and arguments identified in the first part. This critical analysis includes a discussion of features in the Norwegian criticism that are not comparable to the international criticism, which I find problematic. In particular, I address what I consider a theoretical approach to interpreting EBP, which demonstrates a tendency to view EBP as a minimal concept, which excludes clincial expertise and patient preferences at the outset. I argue that such an argumentation is unnecessarily theory-laden, over-simplified and based on misinterpretations of several elements in the EBP model.

- **Conclusion**

The last part of this thesis consists of a summary of the central findings of the analyses presented in this treatise. Based on these findings, I will conclude by a short discussion of the future possibilities of the EBP debate, by addressing the question about whether it is possible to identify a better, more constructive basis for the EBP debate.

Chapter 1: Clinical epidemiology as the main scientific framework of evidence-based practice

1.0. Introduction

Evidence-based practice (EBP) as a concept and a model for health care decision-making has its origin in clinical epidemiology, developed by David Sackett and his group at the Department of Clinical Epidemiology and Biostatistics at McMaster University in Canada in the 1990s. The clinical epidemiologists considered laboratory-based knowledge about biology insufficient as a basis for clinical decision-making. To reduce uncertainty in these decisions, a new basis was presented. This basis consists primarily in the application and assessment of epidemiologic studies as an efficient resource for clinical practice (cf. Sackett et.al. 1985; cf. Bohlin, I. & Sager, M.: 2011).

In what follows, I will clarify the scientific background of EBP such as it is founded in clinical epidemiology. I will do so by describing the main characteristics of clinical epidemiology. The main attention in this chapter is clarification of the scientific framework of clinical epidemiology, with particular attention to what the concept of clinical epidemiology entails, its methodological framework, and its view on evidence. The chapter is divided into four main parts, with several subsections: Section 1.1. examines basic characteristics of the concept of clinical epidemiology. Section 1.2. undertakes an exposition of the clinical questions and methods of clinical epidemiology. Section 1.3 provides an examination of evidence in clinical epidemiology. In section 1.4., I will examine the basis on which evidence is assessed in clinical epidemiology, including the criteria of evidence quality, of Critical appraisal, and hierarchies of evidence. In the last subsection of 1.4., I present concluding remarks on clinical epidemiology's view relating to evidence (1.4.4.). Finally, in section 1.5., I will explicate the concept of clinical epidemiology in relation to evidence-based practice, as the final evolution of clinical epidemiology.

My discussion in this chapter will provide the necessary background for my examination of the concept of EBP (Chapter 2) and for the analysis and discussion of central features in the criticism of EBP.

1.1. The concept of clinical epidemiology

In this section, I intend to clarify the concept of clinical epidemiology. I will do so in four steps; firstly, by way of a short exposition of its conceptual and historical background, with particular attention to what the reorientation from epidemiology to clinical epidemiology entails (1.1.1.). Secondly, by a conceptual clarification of its constitutive terms, "clinical" and "epidemiology" (1.1.2.). Thirdly, through an exposition of basic characteristics of clinical epidemiology (1.1.3.). Fourthly, in light of the previous steps, I will provide a definition of the term (1.1.4), to be used as a reference for the main features of clinical epidemiology in the following analysis and discussions of the thesis.

1.1.1. The reorientation from epidemiology to clinical epidemiology

Broadly described, clinical epidemiology is the application of epidemiologic knowledge[2] in clinical practice. The core idea is that the clinician in her clinical practice should consider facts derived from population-based (i.e., epidemiologic) research as a basis for determining whether clinical interventions are effective or not. Thus, clinical epidemiology is *clinical* in that it aims to answer clinical questions and provide guidance for decision-

[2] The phrase "epidemiologic knowledge" means "knowledge derived from epidemiologic studies". "Epidemiology" is typically defined as a "[b]ranch of medical science that deals with the incidence, distribution, and control of disease in a population" (merriam-webster.com), oriented towards "[t]he variation in disease occurrence and reasons for this variation" (Sørensen 2009: 17). In the following use of the term epidemiology, the orientation toward populations, in contrast to individual patients, is the main focus. Its attention to "incidence, distribution, and control of disease in populations", will be generically abbreviated as "attention to disease in populations".

making in clinical practice. On the other hand, clinical epidemiology is *epidemiologic* in that clinical considerations regarding the individual patient are based on population-based methods and research results. In essence, this is also what constitutes the controversial character of clinical epidemiology: the use of evidence from population research applied in a clinical setting regarding the patient. As such, the controversial character of clinical epidemiology is inherent in its title.

Two essential characteristics of clinical epidemiology can be demonstrated by comparing it to the discipline of Epidemiology. The first characteristic concerns its subject matter: Epidemiology is mainly oriented toward disease (and other health states) in *populations* and public health (cf. Broadbent 2011: 215), primarily through preventive measures (cf. Cates: 1982). Clinical epidemiology, on the other hand, concerns interventions with *individual patients,* through interventional processes. The second characteristic concerns its main aim: Epidemiology aims at describing and improving population health, while clinical epidemiology aims at improving clinical decision-making with regard to individual patients.[3]

Clinical epidemiology is a fairly new innovation, dating from 1938, when the term was introduced by John Paul, initially as a new basic science for preventive medicine (cf. Paul 1938: 539). According to Sackett, one of the founders of both current clinical epidemiology and EBP, clinical epidemiology in its original form aimed at population orientation rather than at individual patient orientation, where the education of the student should "[s]tart […] at the bedside and lead him gradually *away* from it" (Sackett 2002: 1161).

Whereas the field of "classical" clinical epidemiology is "the clinicostatistical study of diseased populations" (Feinstein 1968; quoted in Sackett 2002: 1162), the emphasis in

[3] A more precise, although more technical description may be suggested by comparing the object study object of epidemiology as the "distributions and determinants of disease" to the object of study in clinical epidemiology as the "determinants and effects of clinical decisions" (cf. Spitzer 1986; see also 1.1.2 below).

Sackett's reorientation of clinical epidemiology[4] is directed towards application of classical epidemiology and biostatistics to individual patients. In this way, the main focus shifts from the study of diseased populations as such, to evaluating clinical interventions, such as therapy, applied to individual patients, toward efficacious health care practice (cf. Sackett 2002: 1162).

During the 1960s, Sackett presented a reorientation of clinical epidemiology, shifting attention from the object of populations – that is, epidemiology – to individual patients and defined the term thus:

> [t]he application, by a physician who provides direct patient care, of epidemiologic and biostatistical methods to the study of diagnostic and therapeutic processes in order to effect an improvement in health. (Sackett and Winkelstein 1967; quoted in Sackett 2002: 1162)

The attention to "direct patient care" is a key element, referring to the clinical encounter between the clinician and the individual patient. Application of epidemiologic principles to patient-populations – even research on a small number of cases, such as in case-control studies – subsumes it under the heading of epidemiology alone (cf. Last 1988: 161).[5]

Sackett's definition from 1967 is still valid, except for two elements: Firstly, application of epidemiologic and biostatistical methods is not restricted to physicians exclusively but

[4] Note that this difference between "original" and "new" clinical epidemiology is explained through Sackett's narrative. It may be debatable whether the case is so clean-cut. Paul defined "clinical epidemiology" as "[a] marriage between quantitative concepts used by epidemiologists to study disease in populations and decision-making in the individual case which is the daily fare of clinical medicine". (Paul, J. R. I938; quoted in: Last 1988). On the other hand, *Yale school of Epidemiology and Public Health* [online] claims that Paul's "clinical epidemiology concerns "[t]he study of diseases in small communities". Thus, it is some ambiguity in Paul's term of clinical epidemiology, and in the question of the difference between Paul's and Sackett's use of the term. In this treatise, I will not investigate this further, other than underlining that the current presentation of clinical epidemiology is based on Sacket's narrative.

[5] Last considers this fact as an example of the oxymoronic character of the term "clinical epidemiology" and criticize clinical epidemiologists in general and Sackett in particular when stating that the term "clinical epidemiology", when applied to defined populations is inappropriate when applied to single patients (Last 1988: 160).

extends to any health care professional. It is also debatable whether clinical epidemiology can only be used by professionals in direct health care (cf. Spitzer 1986: 413). Secondly, the definition omits prognostic processes. In current clinical epidemiology, the scientific basis for determining prognosis is integral to its methodological literature (c.f., Haynes, R., et al. 2006).

In the same vein as in the quote above, Sackett (1989b) explains the relation between (classical) epidemiology and clinical epidemiology:

> If I was correct that rational clinical practice requires the projection of diagnostic findings, prognoses, and therapeutic responses from groups of patients to the individual patient, it therefore followed that the strategies and tactics used to study groups of patients (housed in the discipline of epidemiology and the science of statistics) ought to be useful to me as an individual clinician dealing with my individual patient. Moreover, it should be possible for me to take a set of epidemiologic and biostatistical strategies developed to study the "distribution and determinants of disease" in groups and populations, recast them in a clinical perspective, and use them to improve my clinical performance. I therefore set about trying to do so. (Sackett 1989b: 309)

In other words, the reorientation from classical epidemiology consists in the translation of epidemiological population data to a clinical perspective towards an improved basis for clinical decision-making regarding individual patient interventions.

Its main idea is to adapt and expand scientific knowledge methods to health care practice, to improve clinical performance by providing a basis for clinical health care decision-making in patient care. Formally, thus, the term "clinical epidemiology" is derived from a combination of scientific evidence, primarily from epidemiology, and clinical health-care decision-making. In essence, this is also what constitutes the controversial character of clinical epidemiology: the use of evidence from population research applied in a clinical setting regarding the patient.

1.1.2. "Clinical practice" and "clinical research"

Another way of describing clinical epidemiology is that it aims at the application of clinical research, primarily from epidemiologic studies, in clinical practice. The terms "clinical research" and "clinical practice", and "epidemiology" are central in the following, and should be adequately explained.

- **"Clinical practice"**

"Clinical practice" has to do with the interaction between patients and health care providers. Due to its interference with a patient's care, it is interventional, involving any clinical intervention in individual patients, including counselling, treatment, and testing. In most medical and philosophical literature on the subject, it is common to speak of treatment, and not intervention. However, treatment refers most often to therapeutic interventions exclusively, which implies a narrower scope than what the present description of clinical epidemiology aims at. In all further uses of the term "intervention", I use it generically, while "treatment" refers only to "therapeutic procedures".

To avoid conceptual unclarity, I will suggest the following definition of "clinical practice":

"any health care-related intervention, including prognostic, diagnostic, and therapeutic procedures, provided by a clinician in patient care".

- **"Clinical research"**

The term "clinical" in clinical epidemiology also concerns "clinical research". This kind of research involves the generation and assessment of scientific investigations within health care, in order to determine the safety, efficacy, and effectiveness of health care interventions. The main concern of clinical research is to translate basic research (or

"bench science", conducted in labs) into information and interventions that benefit patients. In general, the span of clinical research is wide and includes research in epidemiology, physiology and pathophysiology, health services, education, outcomes and mental health as well as clinical trials (cf. research.med.virginia.edu). What counts as clinical research in clinical epidemiology most often refers to a narrower scope of clinical research, based on population data (that is, epidemiology), with particular emphasis on outcomes, or effects, of interventions in clinical trials. The main aim of such studies is to determine whether an intervention is clinically effective or not – e.g., consisting of a randomized controlled trial on the effect of a specific clinical intervention. In turn, the results of these studies are used as clinical evidence in health care decision-making when recommending interventions for individual patients.

- **"Epidemiology" and "clinical epidemiology"**

"*Epidemiology*" is commonly defined as a "[t]he study of the distribution and determinants of health-related states or events (including disease), and the application of this study to the control of diseases and other health problems" (who.int 2019). Clinical epidemiology uses epidemiologic population research as basis for predicting how a clinical intervention is likely to have an effect when recommending a certain intervention to individual patients.

What separates clinical epidemiology from Epidemiology is the focus on application of research data in a clinical setting. Thus, the reorientation from epidemiology to clinical epidemiology can be described in terms of a difference regarding their subject matters: While the subject matter of Epidemiology is the "determinants and distribution of disease", the subject matter for clinical epidemiology can be described as "determinants and effects of clinical decisions" (cf. Spitzer 1986: 411). A "determinant" is a common construct in epidemiology, referring to any factor that may affect the health of individuals

and communities (cf. who.int 2019). Extended to the context of clinical epidemiology, "determinants and effects of clinical decisions" refer to any factor that may affect clinical decision-making, and the subsequent effects of such clinical decisions.

With such a broad object of study, it is also important to note that clinical epidemiology is not exclusively restricted to epidemiology. Instead, clinical epidemiology makes use of a wide scope of scientific knowledge, consisting of multiple scientific disciplines. This is clearly stated in the introduction to the newest edition of *Clinical Epidemiology* (Haynes et al. 2006):

> We are clinical epidemiologists, those odd folks with one foot in clinical care and the other in clinical practice research. As clinical epidemiologists, we apply a wide array of scientific principles, strategies, and tactics to answer questions about health and health care, especially the latter. The principles we use are drawn most often from the discipline of epidemiology—but we purloin research principles from, and collaborate with, colleagues from any methodologically oriented, scientifically based, discipline—statistics, psychology, the social sciences, economics, health policy, health informatics, and beyond. (Haynes et al. 2006: x-xi)

Thus, clinical epidemiology must be considered an interdisciplinary field, with the principles of epidemiology as its centre, aiming at application of research data in order to provide a scientific basis for clinical decision-making in patient-care.

1.1.3. Basic characteristics of clinical epidemiology

Fletcher et al. present a rather thorough description of clinical epidemiology, which also serves to sum up the main points above:

> [t]he science of making predictions about individual patients by counting clinical events in groups of similar patients and using strong methods to ensure that the predictions are accurate. The purpose of clinical epidemiology is to develop and apply methods of clinical observation that will lead to valid conclusions by avoiding being misled by systematic error and the play of chance […]. It is clinical because it seeks to answer clinical questions and to guide clinical decisions making with the best available evidence. It is "epidemiology" because many of the methods used to

> answer questions about how to best care for patients have been developed by epidemiologists and because the care of individual patients is seen in the context of the larger population of which the patient is a member. (Fletcher et al. 2014: 4f)[6]

The first sentence is essential, as it states three important features: (1) The main goal is to make predictions about individual patients, (2) on the basis of "[c]ounting clinical events in groups of similar patients", by (3) "using strong methods to ensure that the predictions are accurate".

(1) is about the very object of clinical epidemiology: to make predictions about individual patients. Based on the above identification of the central attention to clinical interventions (1.1.2), I will suggest an extended description: The object of clinical epidemiology is to make predictions about whether the interventions provided to patients (typically, treatment) are effective. For the health care practitioner, knowledge of whether an intervention is effective or not is essential to enable the practitioner to recommend a specific treatment for the patient.

(2) concerns how this object is enabled. Fletcher et al. describe this rather formally as "counting clinical events". "Clinical event" is a general term, covering a broad range of occurrences, in principle referring to anything that a patient does, and anything that happens to a patient (cf. Hripcsak et al. 1996: 195).[7] In the context of the description given

[6] Following Fletcher et al., EBM (and EBP) may be considered as a sub-category of Clinical epidemiology, as "a modern term for the application of clinical epidemiology to the care of patients" (ibid.). As I will discuss in Chapter 2, such a view represents rather narrow scope on EBM. At the same time, however, Fletcher et al. point to an important difference between clinical epidemiology and EBM: Clinical epidemiology is involved in generation and assessment of epidemiological methods to health care, whereas EBM's main concern is the actual application of research evidence, at the point of clinical patient-care.

[7] WHO defines "clinical events" in line with Hripcsak et al.'s broad conception, but provides increased accuracy by specifying three different elements: "[1] Services provided to patients (history-taking, physical examination, preventive care, tests, procedures, drugs, advice) or [2] information on clinical condition or [3] on patient state used as a patient outcome" WHO Centre for Health Development 2004; numberings

by Fletcher et. al, "clinical event" refers to a more specific event of interest, i.e., the patient state used as a patient outcome (e.g., the occurrence of disease/not disease; pain/not pain; death/not death in the patient). The counting of clinical events, then, can be explained as having to do with quantifying clinical occurrences in patients and in patient's outcome. This quantification is usually done through the use of large population-based data, with a particular interest in the outcomes of these clinical occurrences. These quantifications are then used as basis for providing the predictions in (1).

(3) has to do with the methods used in this quantification, aiming at determining whether interventions are effective. The definition given by Fletcher et al. is rather restrictive in that it only includes "strong"[8] epidemiologic methods, excluding the inter-disciplinary scope of clinical epidemiology (cf. 1.2.). Methods in clinical epidemiology are quantitative and statistical, consisting of population-based studies. The outcomes of interventions are typically observed directly, usually by comparing patient groups who receive treatment with patient groups who do not receive the same treatment.

In sections 1.2., I will examine the methodological features of clinical epidemiology in more detail. Before I turn to this, I will conclude these initial remarks on the concept of clinical epidemiology by providing a definition of the term.

are mine). My interpretation of the specific meaning in Fletcher et al's use of "clinical event" is analogue to the third element in the WHO-definition.

[8] "Strong" methods refer to high standards of internal and external validity, ensuring that methods are conducted in a correct manner, with results that is clearly representative for a designated population. These methodological features will be discussed in section 1.2. and 1.3. below.

1.1.4. A definition of "clinical epidemiology"

On basis of the above remarks, and for the convenience of the following analysis of clinical epidemiology and EBP, I will suggest the following four-partite definition of "clinical epidemiology", of which it is to be considered synonymous with:

- "The study of making predictions about whether interventions provided to patients are effective,
- by producing and/or applying scientific research results and methods, primarily from epidemiology,
- which are assessed for application in clinical health-care decision-making,
- as evidence which justifies recommendations for or against clinical interventions concerning individual patients".

This extended definition is inspired by and comparable to the three definitions mentioned above (in 1.1.1. (by Sackett 1967), 11.2 (by Spitzer 1986), and 1.1.3. (by Fletcher et al. 2014).

The first part of my definition coincides with Fletcher's definition. The two other definitions consider the decision-making in interventional processes to be the main object. The definition provided by Fletcher et al., as well as my own definition, replaces decision-making with a more technical and, in my view, more precise description of the *aim* of the decision-making process – i.e., prediction about the interventions provided to individual patients.

The second part of my definition covers the kind of scientific knowledge upon which predictions are based – attentive to both production and application of research results, as well as to the inter-disciplinary scope of clinical epidemiology. In addition, this part includes both research activity and research application as potential activities for the clinical epidemiologist.

The third part of the definition represents an extension of the other definitions by explicitly including the assessments that are conducted when the quality of the scientific knowledge is considered. These assessments are essential elements in clinical epidemiology, commonly referred to as "Critical appraisal" (see section 1.4 and the subsequent subsections for further descriptions of this).

The fourth and last part of the definition is also an important extension of the other definitions, describing the end objective of clinical epidemiology, i.e., the application of scientific knowledge as a source of evidence to justify recommendations for or against clinical interventions concerning individual patients. These are the justifications that are central to the EBP clinician at the actual point of patient care (cf. Chapter 2).

In the analysis above, I have addressed the first part of the definition. In the following sections, I will provide a more detailed presentation of the subsequent three parts of the definition – as expositions of what is characteristic of clinical epidemiology's research methods (1.2.); its view on evidence in general, evidence-assessment, and evidence hierarchies (1.3); and the relation to EBP (1.4.). Together, this presentation will provide an adequate understanding of clinical epidemiology as the scientific framework for EBP.

1.2. Methods of clinical epidemiology

Clinical epidemiology represents a prioritization of quantitative methods. These methods are used to answer different kinds of clinical questions, in relation to therapy, diagnosis, or prognosis of the patient. *Therapy* concerns questions about treatment; *diagnosis* relates to questions of identification of a disease or disorder; while *prognosis* concerns questions about recovery and of estimating a patient's future course (cf. Guyatt et al. 2015: 22).[9] There are different methods deemed optimal for different questions, each designed to predict as precisely as possible which intervention would be most appropriate to recommend to individual patients.

Clinical research methods can be divided into two main categories, *experimental studies* and *observational studies*. In experimental studies, investigators assign exposures (e.g., a treatment intervention) to participants of a study. In observational studies, investigators observe participants in usual clinical practice (cf. Grimes and Schultz 2002: 58). There are different kinds of studies belonging to both categories.

In *experimental studies*, an exposure is assigned to participants by the investigators of the study, who manipulates the exposure under carefully controlled conditions. The experimental procedure (of either diagnostic, preventive, therapeutic, or palliative kind) is then compared to a control procedure to identify differences in outcomes between the two groups.

[9] Interestingly, when Guyatt et.al 2015, proponents of both clinical epidemiology and EBM, describe the different clinical questions, they focus on the patient: Therapy is explained as "determining the effect of interventions on *patient-important outcomes*" (ibid: 22); diagnosis as "establishing the *power* of a test to differentiate between those with and without a *target condition* or disease" (ibid.); and prognosis as questions about "estimating a patient's future course" (ibid.). Perhaps a more common way of describing the questions are by way of the disease or the intervention. See e.g. Dahlgren's clinical quick reference [online]: *Therapy:* Questions of treatment in order to achieve some outcome. […]. *Diagnosis:* Questions of identification of a disorder in a patient presenting with specific symptoms. *Prognosis:* Questions of progression of a disease or likelihood of a disease occurring".

There are two kinds of experimental studies, randomized and non-randomized trials, distinguished by whether the allocation of participants to exposures is assigned by a random technique or not. If the participants are randomly allocated to different treatment groups, it is a randomized controlled trial (RCT). RCT's are considered the most efficient way of minimizing risk of bias in clinical research (see 1.4.1.1. for a presentation of bias in clinical research). Because of this, the RCT is considered the most reliable method of determining the effects of interventions. The RCT is often referred to as the gold standard of clinical research, in particular regarding therapeutic questions.[10]

Observational studies are non-interventional: Instead of researchers interfering with the patient interventions, they observe the patients' outcomes. Observational studies are either analytical or descriptive, depending on whether the study is comparative – that is, has a control group for comparison – or not. Descriptive studies are the only kind of clinical method that is not comparative (cf. Grimes and Schultz 2002: 58). Instead, such studies describe the frequency, natural history, or possible determinants of a condition (cf. ibid.).

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[10] Generally, "gold standard" is refers to a certain method, test, measure, or procedure that is considered the best available (cf. Oleckno 2008: 584), and functions as a criterion by which scientific evidence is evaluated. There are thus different gold standards for different types of evidence, answering different kinds of clinical questions. For instance, in dentistry, the gold standard for diagnosing proximal carious lesions of posterior teeth (i.e. demineralization of the visible part of molars and premolars) has traditionally been regular examination by the dentist. New technology of micro computed tomography provided a more accurate diagnostic procedure, and thus replaced regular examination as the gold standard for diagnosing the lesions (cf. Cardoso et al. 2014).

In analytical observational studies, the investigators observe – rather than conduct an experiment with – a large number of people, usually by comparing (records of) patients who have received an intervention with similar patients who have not received the intervention. Inferences regarding patient exposures or outcomes are then made on the basis of these passive[11] observations (cf. Howick 2011: 40).

Observational research designs are cohort, case control, or cross-sectional studies. These designs differ depending on how the relation between exposure and outcome is examined: In a cohort study, investigators observe two or more populations receiving different treatments, and then compare the outcomes to detect differences in the effects of the treatments. Thus, cohort studies proceed from exposure to outcome, where treatment exposure is identified at the outset. In a case-control study, investigators select two or more patient groups that differ in the outcome of interest and observe whether their outcomes correlate with some exposure. Case-control studies thus start with an outcome, e.g., a disease, and search for exposures that might have caused the disease. Cross-sectional studies examine the occurrence of outcome and exposure at the same time, in which data concerning the whole population of interest is analysed at one point in time.

What both experimental and observational study designs (except for descriptive studies) share in common is that they study the relationships between exposure (e.g. smoking or vaccination) and outcome (e.g. occurrence of lung cancer or of smallpox), on a certain population, with primary attention on identification and quantification of the relationship between intervention and outcome. Such methods may thus be characterized as outcome-based methods, where the outcomes, or effects, of health interventions (most typically of treatments) are observed directly.

[11] The investigators' observations are passive in that they neither allocate the patients nor administer the intervention (cf. Howick 2011: 40).

These research results are then used as a basis for determining whether a particular treatment option is effective – as evidence justifying recommendation of a similar treatment in clinical practice.

1.2.1. Outcome-based methods and the demarcation of clinical epidemiology from traditional medicine

The use of outcome-based data in clinical decision-making entails a radical shift from the traditional attention to pathophysiologic reasoning – that is, mechanical reasoning, concerned with the underlying pathophysiological mechanisms. Pathophysiologic reasoning focuses on "[i]nferences from (supposed) facts about the underlying pathophysiological and physiological mechanisms of health or disease to conclusions that a treatment will or will not have effects" (Howick: 2011: 16). An outcome-based method on the other hand, "[i]nvolves directly observing the putative outcome relative to the putative outcome produced by a control treatment" (Howick 2011: 16).

The main difference between the two approaches is that outcome-based methods provide a direct empirical link from the results of the research to the application in clinical practice, whereas the former, pathophysiologic approach suggests an indirect link between research results and practice. For example, a doctor who recommends a particular drug to a patient suffering from myocardial infarction (heart attack), based on the supposed causal relation between the mechanism that caused the myocardial infarction and the mechanism of the action of the drug, would be practising pathophysiologic reasoning. On the other hand, a doctor who recommends against the same drug, based on clinical research results which demonstrates that there is a negative outcome in clinical trials in groups that have received the drug, would use outcome-based data in her decision-making.

In clinical epidemiology, the use of outcome-based research is considered more efficient than basing clinical practice on pathophysiological research (or personal experience, for that matter) and then to infer that this mechanism is operating in the patient and will have an effect on the actual clinical outcome of an actual patient.

The reorientation of clinical epidemiology toward the use of outcome-focused methods in clinical research and practice, entails a radical shift from the traditional mechanistic view in that attention to outcomes in principle is independent of the underlying pathophysiological mechanisms.[12] This means that one does not need knowledge of the causal mechanism to decide whether an intervention is effective or not (cf. Lie, R. 2011: 160). The main reason for the preference of outcome-based methods, in particular through the use of experimental methods such as RCTs, is that they provide empirical findings with the least amount of worries about non-observable events (e.g. non-observable mechanisms). The implicated detachment from causal explanations on how the outcome is produced implies an extreme version of empiricism (cf. Lie, R. 2011: 160). As will be discussed in Chapter 3 and 4, the principles and application of outcome-based methods are highly controversial matters.

To sum up, the demarcation of clinical epidemiology from traditional medicine is expressed through the use of outcome-based research, primarily concerning clinical studies of the effect of interventions on populations, and on this basis determining whether clinical interventions are effective or not for an individual patient. In clinical epidemiology (and to a very large degree in EBP as well; see Chapter 2), clinical research

[12] A clarification is needed here: Diagnosis has underlying disorders as its object, but what is "underlying" here is quite different from "underlying mechanisms" operating on another level of the underlying sickness or disease. While the pathophysiological understanding is related to a certain mechanistic (e.g. cellular) level, the main diagnostic question in clinical epidemiology is concerned with neither what the disease is, nor what constitutes its symptoms. Instead, the question is how the disease is best diagnosed, which has to do with the outcome of the diagnosis (cf. Guyatt et al., 2015: 26). Furthermore, the object of diagnosis in clinical epidemiology has primarily to do with the quantifiable frequencies of underlying disorders; not of the disorders themselves (cf. ibid., 2015: 22ff).

is considered superior to both clinical experience and to knowledge of biological causes and mechanisms, taught in traditional medical education. (cf. Bohlin, I. &Sager, M., 2011: 39). Thus, the reorientation of clinical epidemiology implies a break with what traditionally has been considered clinically relevant knowledge in patient care.

However, one should be careful in dichotomizing too much here. Of course, clinical epidemiology does not call for discarding the use of pathophysiological mechanistic explanations (in EBP, such explanations are referred to as "background information" (cf. sections 2.1. and 2.4.2. below).[13] In clinical research (e.g. in descriptive studies) and practice (e.g., in a physical examination), such explanations are considered necessary in many cases, but insufficient. In other cases, it is not considered necessary, e.g. in the case of interventions based on several RCTs, demonstrating the same findings, applicable to the patient. Pathophysiological mechanistic explanations are not necessary to justify such interventions. The attention is instead exclusively on what works in terms of the outcome, and not on how the intervention might produce this outcome.

From these descriptions, there are two features in particular that differentiate clinical epidemiology from other health care sciences: Its aim, and the methods to reach this aim. Firstly, clinical epidemiology is characterized using epidemiological data applied to patient health care, providing the clinician the means to recommend and conduct patient care on a scientific basis. Secondly, it is characterized through comparative, outcome-based methods through which the data to be used in clinical practice is generated.

These two features provide a basic understanding of the systematic, methodological framework of clinical epidemiology. Through this framework, scientific evidence is generated, thereby equipping the clinician with sufficient tools for providing patient care, for both choosing intervention strategies and recommending treatment in individual

[13] I discuss "background information" in more detail in Chapter 2, in the sections 2.1. and 2.4.2.

patient health care. In the following section, I will examine the view of evidence in clinical epidemiology, with attention to how evidence is assessed.

1.3. Evidence in clinical epidemiology

In this section, I will examine how evidence is assessed in clinical epidemiology. In section 1.1.4. above, I presented a four-partite definition of clinical epidemiology. Its first part – The use of scientific knowledge, aiming at determining whether clinical interventions are effective or not – has to do with the outcome-based research methods characteristic of clinical epidemiology. As such, this first part is clarified through section 1.2. The second part of the definition – to be assessed and applied in clinical health-care decision-making as evidence which justifies recommendations for or against interventions concerning individual patients – will be clarified in the following sections. Notably, the application of evidence in actual health-care decision-making falls outside the framework of clinical epidemiology. Instead, the assessment of evidence is assessment with respect to its application. The main objective of the present analysis is to examine what characterizes this assessment of evidence. Before I turn to this examination, however, an initial conceptual analysis of "evidence" is necessary.

1.3.1. What is "evidence"? Some philosophical remarks

In broad terms, "evidence" is anything presented as support of something else, usually by means of a propositional claim. To have evidence of something, then, is to have something that constitutes evidence of, or justifies, something else. Thus, evidence may be considered as a relational concept, through which a claim or an observation constitutes evidence in that it is used as support or warrant for another claim or observation. For

example, the claim stating that "a study concludes that classical acupuncture is more effective in pain relief than analgesics" may be used as evidence for the claim that "patients should be recommended acupuncture rather than analgesics in emergency pain management" (cf. Haneesh Murugesan, et al., 2017).

The relational concept of "evidence" is mirrored in the most common philosophical minimal definition of "evidence" – as "that which justifies belief" (cf. Kelly 2016). From this definition, it follows that "evidence" is something you possess that is external to your belief and which justifies that particular belief. The "external" source of evidence (as that which justifies a certain belief) may refer either to a (mental) belief or to (physical) observable data.

Evidence as a relational concept, defined as that which justifies belief, is a general characteristic applied to the following investigations of clinical epidemiology and of EBP.

1.3.2. "Evidence" in clinical epidemiology

When applied to health care practice, a justification referring to mental beliefs is typically denoted as "personal expertise", while a justification referring to observable data typically relates to empirical (scientific) data. In clinical epidemiology (and in EBP) such data will typically refer to data from research literature. Reference to mental beliefs, e.g., the use of personal experience as evidence, on the other hand, is not a typical attribute of clinical epidemiology.[14]

An essential question is what kind of things the evidence refers to in clinical epidemiology. In general, that which justifies belief is derived from clinical research studies, primarily the results of such studies. This is typically referred to as "external evidence" (e.g., Haynes et al. 2006: 162), referring to scientific research results derived from clinical studies.

[14] However, such evidence is often included in EBM literature; cf. Chapter 2 below.

What, then, are research results derived from clinical studies about? As noted above, these are typically epidemiologic studies of the effect of interventions on populations. The main aim of such studies is to determine whether an intervention is clinically effective or not (e.g. based on knowledge provided from the results of an RCT about the average effect of a specific clinical intervention). Thus, evidence, as that which justifies belief, can be explained in clinical epidemiology as scientific, primarily epidemiological, research results of which the aim is to determine whether an intervention is effective or not (cf., the first part of the definition of clinical epidemiology in 1.1.4 above).

However, the mere fact that a piece of evidence (e.g. empirical research) justifies a belief in that a certain intervention is clinically effective is by itself a necessary but not a sufficient condition on its own merit to constitute applicable evidence. In addition, the piece of evidence must be effective in clinical practice, for the actual clinical decision-making (cf., the two latter parts of the definition in 1.1.4). This has to do with what evidence in clinical epidemiology is *for*.

As stated above, clinical epidemiology's main aim is to improve clinical performance. This improvement is provided by basing clinical decision-making on evidence that an intervention is clinically effective. Any evidence in clinical epidemiology is constituted by some data that affects the belief, directly or indirectly, in a hypothesis that a certain intervention is clinically effective. Thus, there is only evidence if it affects clinical decision-making. For example: A systematic review of RCTs concerning the outcome of a certain intervention on a patient-group is only evidence when it is considered as the justificatory basis for an actual clinical decision-making regarding a particular patient.

In sum, "evidence" in clinical epidemiology refers to "scientific, primarily epidemiological research result(-s),[15] aiming at determining whether an intervention is effective or not,

[15] In both clinical epidemiology and EBP literature, it is common to refer to "evidence" as "(scientific) research" in general (e.g., Haynes et al. 2006) and EBP (e.g., Straus et al. 2011), without a clear distinction

which justifies beliefs in hypotheses about clinical effectiveness for clinical decision-making". This is what I deem to be the basic concept of "evidence" in clinical epidemiology.

1.4. Assessment of evidence

The following section is an examination of the framework for assessing methods and evidence in clinical epidemiology (cf. the third part of the definition in 1.1.4.). In clinical epidemiology and EBM-literature, this is commonly referred to as "Critical appraisal", referring to the process of systematically assessing the outcome of scientific research in terms of trustworthiness, value and relevance in a particular context (cf. cebma.org). These formal criteria serve as the basis on which the content of both Critical appraisal and the evidence hierarchies are construed.

The following examination of evidence-assessment in clinical epidemiology is four-fold: Firstly, I will examine the formal criteria of evidence assessment (1.4.1), before I turn to a general description of Critical appraisal (1.4.2.) and to the hierarchies of evidence (1.4.3.). Based on these examinations, I will add some concluding remarks on clinical epidemiology's view pertaining to evidence (1.4.4.).

between the research result and the research study (including its research-methods) generating this result. I consider this unclear distinction in the literature a product of imprecision rather than in conflict with my definition.
I find it uncontroversial to differentiate between "research study" and "evidence" in this way: "Evidence" is the end-result of the research, whereas the "research study" is constitutive for this product. As I will investigate in detail in the following sections, the quality of the evidence is a question of the content and methodological rigor of the research.

1.4.1 Criteria for assessing quality of evidence: internal and external validity

The methodological features constitute essential characteristics necessary for an adequate understanding of clinical epidemiology. The focus of attention, however, is not on the research results themselves, but on the explicit assessment of the quality of the research studies and of the evidence generated from these. "Quality of evidence" is an often-used term both in clinical epidemiology (e.g., Haynes et al. 2006) and EBP (e.g., Straus et al. 2011; Atkins, D. et al. 2004)., and refers to two specific criteria: (1) the degree of confidence that the research data are correct, and (2) the degree of generalizability (often synonymously referred to as applicability, relevance, and usefulness) of the research data to clinical practice. The common terminology for these criteria is "internal validity" and "external validity", respectively.

According to the Cochrane handbook, "validity" generally "[h]as to do with whether the instrument is measuring what it is intended to measure" (Higgins and Green 2011). Internal validity concerns the trustworthiness of the evidence, and external validity refers to its usefulness[16] in clinical practice. The question of the effectiveness of an intervention in clinical practice is ultimately a question of external validity but requires that the evidence exhibits internal validity at the outset. Thus, external validity is only relevant to assess if and only if the study in question is internally valid. Together, internal and external validity constitute the assessment of the quality of the evidence, both in clinical epidemiology and EBP. Evidence is often referred to as exhibiting high or low quality, depending on the degree to which the evidence at hand fulfils the criteria of validity.

[16] In the following I will apply "usefulness" as a generic term, referring to three specific elements: "generalizability", "applicability", and "usability". While "generalizability" and "applicability are inherent properties in the conceptual construct of "external validity", "usability" is external to "validity" and the scientific framework of clinical epidemiology. Instead, "usability", in my usage of the term, refers to assessment of evidence with regard to patient preferences and circumstances at the point of patient care. I will describe "usability" in more detail in section 2.2., as a necessary element to the assessment of evidence in the practice of EBP.

1.4.1.1. Internal validity and bias

Internal validity refers to the degree to which we can be confident that the study is well conducted. In this context, "well conducted" means that the research is done in an orderly fashion, according to methodological criteria, so that the results are trustworthy. It consists in following transparent methodological criteria, primarily based on a scientific framework of epidemiology and statistics and extended to social science research and qualitative research when the clinical question demands it.

The degree of internal validity in research results is often described relative to the degree of risk of bias.[17] For instance, the *Users' Guide* states that "[s]tudies that have higher internal validity have a lower likelihood of bias/systematic error" (Guyatt et al. 2015: 660). Bias refers to systematic errors, or "deviation from the truth" (cf. Sackett 1979), in results or inferences (cf. Higgins and Green 2011).

In principle, internal validity can refer to any factor that may cause misleading study results. Such factors may be random errors, which happen by chance, or systematic errors, tending in a specific direction (cf. Guyatt et al. 2015: 104). While random errors can be minimized by larger sample sizes (cf. ibid.), systematic errors require more nuanced solutions that differ depending on the specific type of error and the methods used (e.g., misleading information due to flawed selection or errors in allocation of patients in a

[17] It is important to note that measurement of the "degree of bias" has to do with "*risk* of bias". As Blunt (2015) notes, "For [internal] validity to be a useful construct, it must be defined instead as *justifiable confidence in* the absence of (serious) bias in study-results. That is, [internal] validity is a measure not of bias but of *risk* of bias" (cf. Blunt 2015: 55). Furthermore, no study is free of bias; measurements of bias in a study are usually approximations. For instance, *The Cochrane Handbook for Systematic Reviews of Interventions* (Higgins and Green 2011: 188) demonstrates this point when stating that "It is usually impossible to know to what extent biases have affected the results of a particular study". Elsewhere in the literature, however, internal validity of a study is often defined as "[t]he extent to which it is free from bias" (e.g., Higgins et al. 2011: 890). Such a description is inaccurate, due to the fact that it is usually impossible to know to what extent the study is "free from bias". A more accurate description would be "the extent to which the study has a reduced risk of bias".

study). It is these systematic errors that are important in the following presentation of "bias" as a challenge to internal validity.

Most literature addressing bias in clinical research focusses on comparative methods that measure associations between two variables – an intervention (or exposure) and an outcome (cf. 1.2. above). A comparative research design entails that a certain population sample (e.g. group of patients) are allocated to two (or more) groups – one "study group" receiving the intervention under investigation, and one "control group" receiving either a placebo or another intervention. The outcomes of both groups are then compared. A prerequisite for mitigating bias in comparative studies is that "participants in both groups […] should be similar in all characteristics except for the intervention being studied" (Attia 2005: 259).

The main appeal of randomized studies in clinical epidemiology is their presumed ability to minimize types of biases and confounding factors. Compared with randomized studies, observational studies are considered more prone to bias and to confounding factors. Potential biases in clinical research are numerous, and a full presentation of these exceeds the scope of the current analysis.[18] For the purpose of the current examination and for the analysis of the EBP debate below (Chapters 3 and 4), allocation bias and confounding factors are most central. In the following, I will provide a short description of allocation bias and confounding factors, before I turn to the reasons for which randomized trials, and RCTs in particular, are considered the best methodological designs for mitigating allocation bias and confounding factors.

[18] For instance, Chavalarias and Ionnades (2009) identify 235 kinds of biases. It is common in much of the literature to divide specific kinds of biases into a few standardized main categories. Chavalarias and Ionnades suggest a tripartite categorization: selection bias, information bias, and confounding (ibid: 1213). I will examine allocation bias (as a variation of the first main category) and confounding factors below.

Allocation bias[19]

Allocation bias involves the systematic difference in how participants are assigned to treatment- and comparison groups in a trial, resulting in unequal distribution of patient- and disease features between groups, and may include any differences between the groups under comparison, other than the treatment itself, that can influence the outcome of the study (cf. Catalogue of bias collaboration 2018; La Caze: 2009: 518). Allocation bias occurs when recruiters selectively enrol patients in the trial based on what the next treatment allocation is likely to be. For example, the recruiter may allocate patients with a better prognosis to one of the groups, thereby skewing the research result. Consequently, the result of the study would be poor, demonstrating a high degree of risk of bias, and thus exhibiting low internal validity.

Confounding factors

In addition, closely related to risk of bias in clinical studies, there are "confounding factors", or "confounders", through which the effects of interventions are 'confounded' by extraneous factors (cf. Herbert et al. 2005: 20). "Extraneous factors" are factors that are unrelated to the experimental intervention, but which may affect the outcome of the study. Examples of common confounding factors are natural recovery (leading to the patient's condition resolving independently of the intervention) and placebo effects (where the ritual of intervention rather than the intervention itself produces effects). Together, all types of bias and confounders entail factors that are unbalanced between the comparison-groups and have an effect on the outcomes measured, producing

[19] In clinical epidemiology and EBP literature, "selection bias" is sometimes used instead of "allocation bias", specifically referring "[t]o selection of patients into treatment arms" (Paludan-Müller et.al. 2016: 2). Within epidemiologic literature, however, "selection bias" refers more broadly to selection of a non-representative population into a study (cf. ibid.).

imbalances in the study and thereby contributing to deviations that may lead to over- or under-estimations of the effects of interventions.

Specifically, a confounder has an impact as a "[d]istortion that modifies an association between an exposure and an outcome because a factor is independently associated with the exposure and the outcome" (Catalogue of bias collaboration 2018). For instance, in a study examining whether coffee drinking (factor A) causes pancreatic cancer (disease B), it could be that smoking (factor X) may be a risk factor for disease B, modifying the outcome, but not accounted for in the study.[20] Thus, smoking – as a confounding factor – would make it appear that there is an association between the exposure and the outcome even when there is no true association between factor A and disease B. In this way, any confounding factor can provide a potential alternative explanation for the result of a clinical problem (cf. Howick 2011: 36) – by modifying the association between the exposure (coffee drinking) and outcome (pancreatic cancer) of that result. To the extent to which these confounding factors occur as systematic errors, they are to be regarded as sources of bias.[21]

1.4.1.1.1. Randomization as the best way to mitigate risk of bias in clinical research

Methodologically, the most significant feature in comparative trials is that of randomization. Whereas observational studies tend to suffer from these kinds of biases, comparative randomized trials are purportedly designed to minimize risk of these kinds of biases. In this sub-section, I will examine the basis for the claim that randomization is the best way to mitigate risk of bias in clinical research.

[20] This example is partly based on a PowerPoint-presentation by Kaur 2014.

[21] Formally, a confounding factor exhibits three necessary properties: (1) The factor potentially affects the outcome; (2) the factor is unequally distributed between experimental and control groups; (3) the factor is unrelated to the experimental intervention (cf. Howick 2011: 35). These properties are present in the above example.

Methods of randomization when allocating participants to groups, i.e. by distributing participants either to a test intervention or a placebo intervention by chance (e.g. by coin-tossing)[22] is said to minimize, or indeed eliminate, the risk of allocation bias and of confounding factors (cf. Howick 2011: 43). The basic idea is that when a random allocation method is used to allocate people to receive either the experimental intervention or the control intervention, neither assessors nor study-participant have any influence over the subject who will receive the experimental intervention. In contrast, non-random methods of group assignment, e.g., when alternating subjects between one group and the other, may cause a breach in the allocation concealment, and thus increase the risk of the same kinds of biases (as well as other kinds, such as performance bias; cf. ibid.).

In principle, however, randomization may be subverted be investigators or participants who may be able to decipher the random allocation sequence, which in turn opens for an increased risk of bias. Another central feature of randomized trials, namely "blinding", prevents this from occurring. Randomized studies can be concealed by either single blinding (in which the participants are not informed of their treatment allocation) or double blinding (in which neither the participants nor the researchers know which participants belong to which groups). Double blinding contributes towards reducing the potential influence from various confounding factors that arise from the knowledge of which participants are receiving the experimental intervention (cf. ibid: 46f). A double-blind RCT is considered the best study design with regard to minimizing the risk of allocation bias and confounders in clinical studies.

While both randomization and blinding are important features, the essential feature of RCT – as its name ostensibly refers to – is its ability to randomize. The method of the RCT

[22] Coin-tossing is a simple and often used example to demonstrate the inclusion of chance in the procedure. In usual practice other procedures are more common, e.g. the use of envelopes containing randomly generated instructions pertaining to assignment of individual patients to specific groups (cf. Howick 2011: 43).

aims to reduce certain sources of bias when testing the effectiveness of an intervention by randomly allocating test subjects to two or more groups, treating the two groups differently, and then comparing them with regard to the effects of the intervention. It is this random allocation that is commonly deemed to be the main advantage of the RCT when compared to other research designs.

As described above, each confounding factor provides a potential alternative explanation for the result of a clinical problem. Through the random allocation of patients to different groups, comparability of the groups is assured, by preventing, or at least mitigating, confounding of the effects of the intervention due to differences between the groups. Thus, randomization is considered the best way to reduce the risk of confounding (cf. Catalogue of bias collaboration 2018).[23]

To describe it more accurately, randomization is said to provide the basis for the equal distribution of potential confounders between the study groups that may affect results in treatment groups and control groups (e.g., Kuntz et al. 2008; Straus et al. 2011). "Equal" in this context means that the potential confounders are evenly distributed among the comparison-groups, so that they are balanced with regard to the comparison to be made. The claim has been stated even more patently, i.e. that randomization controls for confounders, both known and unknown (e.g. ibid; Kuntz et al. 2008: 3), and that randomization "balances the groups for confounders that we haven't identified yet!"

[23] In addition to randomization, there are several other means by which to prevent the risk of confounding, including stratification and statistical adjustments (cf. ibid.). While these additional means are important aspects of clinical epidemiology methodology, they are not as central to the current analysis, nor to the following chapters. I will not examine the additional means to reduce confounders and bias in clinical research.

(Straus et al. 2011: 187). There is no other research design that exhibits this purported ability.[24]

In sum, randomization provides the means to keep study groups as similar as possible at the outset, thus enabling the investigators to isolate and quantify the effect of the interventions they are studying and to control for other factors. The allocation of patients into comparison groups occurs independently of both researcher and patients, thus mitigating several potential biases, such as allocation-bias as well as confounding factors. The internal validity of a study is directly related to these considerations: To the extent a clinical study manages to mitigate the risk of confounding factors and biases, it is considered internally valid. Provided that a study exhibits a sufficient degree of internal validity, the study can then be assessed for external validity.

1.4.1.2. External validity

To exhibit external validity, the results of the study must be generalizable to other settings and patients (cf. Haynes et al. 2006: 8). External validity measures the degree to which the results are representative and applicable to the individual patient in the actual clinical context. The main focus is on the degree to which the study in general, and its patient-important outcomes in particular, are generalizable and applicable to a patient in clinical practice. It is important that the research study is designed and reported in such a way that it allows clinicians to assess the degree to which the results could reasonably be applied to an individual patient (cf. Rothwell 2007: 61f).[25]

[24] The confidence in RCTs in general, and the purported ability of randomization to balance for both known and unknown confounders in particular, is a controversial aspect in clinical epidemiology (and EBP) methodology. I will come back to these matters when analyzing the EBP debate, in 3.2.3 below.

[25] These considerations are often considered in conjunction with the "strength-of-recommendation" of the evidence, which has to do with how strongly the intervention can be recommended to the patient. The strength of recommendation is graded based on (1) previous assessment of evidence quality and (2) the ratio of benefits and harms. Specifically, (2) concerns uncertainty about three factors in particular: the

For instance, if the inclusion criteria (e.g., age or sex) for those people who participated in an RCT (i.e., the study population) are dissimilar to a patient in clinical practice (i.e., the target population), the external validity would be regarded as weak.[26]

Ideally, this evidence consists of a summary of several RCTs, answering a clinical question identical to the relevant clinical practice scenario, in which the target population exhibits identical eligibility criteria (e.g. patient characteristics such as age, gender, and ethnicity; and disease-characteristics such as co-morbidity) compared with as in the study population (e.g., concerning age, gender, ethnicity, etc.). In such a case, the question of external validity is straightforward, and the external validity would be considered strong. To the extent that the clinical question and the study population differ from the target population (e.g., an individual patient in an actual clinical scenario), the external validity of the study is lower.

In the clinical epidemiology and EBP literature, external validity is often equated with terms like applicability, extrapolation, generalizability, relevance, transferability, and usefulness. In comparison to the explicit content of "internal validity", "external validity" is more complex, with several overlapping determinants that are not easy to separate in an adequate manner (cf. Rothwell 2009). When assessing the external validity of a research study, there are several determining factors that may influence the degree of external validity of the study.[27] Four central factors are:

balance between desirable and undesirable effects; uncertainty or variability in values and preferences of the patient; and uncertainty about whether the intervention represents a sound use of external resources (e.g., finances) (cf. Guyatt et al. 2008b: 926).

[26] It should be noted that the discussions of external validity vary considerably in relation to the methods used. In a systematic review of RCTs, of, say, the testing of a drug to a mass population, the problem of external validity is solved statistically, by comparing the test-groups to a total population. By contrast, assessment of the result of a phenomenological case study description of a patient's experience of her own illness, is at best only suggestive as to how similar patients are to be understood.

[27] The following presentation of external validity is based partially on Dekkers et al. 2009 and Murad et al. 2018. However, there are some discrepancies between these sources, making them incompatible in

(1) The extent to which the study population is representative of the target population, in terms of sample selection and sample size of the study population (which should be "sufficiently large", selected randomly when possible) and consist of a heterogeneous population (homogeneity will not suffice for the study to be generalizable to an "average" person).

(2) The extent to which the study population is representative of the target population, in terms of eligibility criteria whereby potential study subjects are included or excluded. For instance, the research study must be assessed as to whether the conclusion in a study can be generalized to a target population that does not meet all the eligibility criteria (cf. Dekkers et al. 2009: 92).

(3) The extent to which the research results can be applied in a different treatment setting (other than in the study). Dekkers et al. refers to this through the question of "[w]hether the research results are valid for patients to whom results are generalizable but who are in a different treatment setting than the original study population" (Dekkers et al. 90). For example, differences in treatment settings (e.g., availability of diagnostic procedures or of technological equipment; or with regard to the difference between routine treatment and study treatment), administrative policies, or availability of health care expertise in different countries or cities may influence treatment results, and contribute to a lower degree of applicability of the research result.

(4) The extent to which the outcomes of the study are considered important to the target population (e.g. the individual patient). Some research studies include "patient-oriented

certain regards. The initial distinction that Dekkers et al. make between "external validity" and applicability" contrasts with that of Murad et al., who distinguish between "generalizability" and "applicability". I apply the distinction of Murad et al. Another incompatibility between the two is that Dekkers et al. distinguish between eligibility criteria and treatment setting (placed in "external validity" and "applicability" respectively). Conversely, Murad et al. subsume both eligibility criteria and treatment setting within "applicability", attributing to "generalizability" a strictly statistical concept based on statistical sample theory. Regarding this distinction, I follow the distinction of Dekkers et al., subsuming eligibility criteria under "generalizability", and treatment setting under "applicability".

evidence", or "patient-important outcomes", which measure outcomes that matter to patients: morbidity, mortality, symptom improvement, and quality of life (cf. Ebell et .al. 2004).[28] Assessment of external validity in this case would consist in examining whether the study results demonstrate improvements that are considered relevant to the specific target population.

Factors (1) and (2) are often referred to as "generalizability" (e.g., Dekkers et al. 2009; Rothwell 2007; 2009). "Generalizability" concerns how confidently we can transfer the results from a study population to the target population. The degree to which we can be confident in a study's generalizability is assessed by examining the representativeness of the study population to the general target population, in terms of sample selection and sample size of the study population (cf. Murad et al. 2018), as well as the eligibility criteria.

Factors (3), and (4) are often referred to as "applicability" (cf. Dekkers et al. 2009), having to do with particularizing or individualizing the research results to the patient (cf. Glasziou et al. 1999: 33). More precisely, the question of applicability has to do with the question of "[w]hether the research results are valid for patients to whom results are generalizable but who are in a different treatment setting than the original study population" (Dekkers et al. 90). It is also a question of whether the patient-important outcomes are relevant to the patient.

Consequently, assessment of external validity can assess a study to be of strong generalizability (e.g. conducted with rigorous sampling from a population with strict and distinct inclusion criteria) but still be considered to have poor applicability (e.g. when the

[28] These considerations are explicitly included in the "strength-of-recommendation" of the evidence, which has to do with how strongly the intervention can be recommended to the patient. The strength of recommendation is graded on basis of (1) previous assessment of evidence quality and (2) the ratio of benefits and harm (including assessment of whether the evidence is patient-oriented) (cf. Guyatt et al. 2008b: 926).

setting is different, or the patient-important outcomes are unclear, which could make it difficult to apply the results in clinical practice).

Epidemiologic research literature varies with regard to the extent to which these factors are included in the research study, and to whether these factors are reported in an adequate manner. To the extent that they are lacking or poorly reported, it is up to the clinician to make judgments concerning the external validity of a particular piece of research evidence.

The question of the external validity of research evidence when assessing it for application to the individual patient in clinical practice is an integral part of evidence-assessment. Considerations of both internal and external validity are to be considered necessary elements of the critical appraisal-scheme.

1.4.2. Critical appraisal

The criteria for assessment of evidence quality also constitutes the core of the *Critical appraisal*-schemes. Critical appraisal is an important feature of clinical epidemiology, both methodologically and historically. Historically, clinical epidemiology was introduced as a new scientific basis for both problem-based education and production of literature (Sackett et al. 1985), focusing on training the student's ability to independently seek and critically appraise the relevant research results to specific clinical problems, regarding diagnosis, prognosis, and therapy.

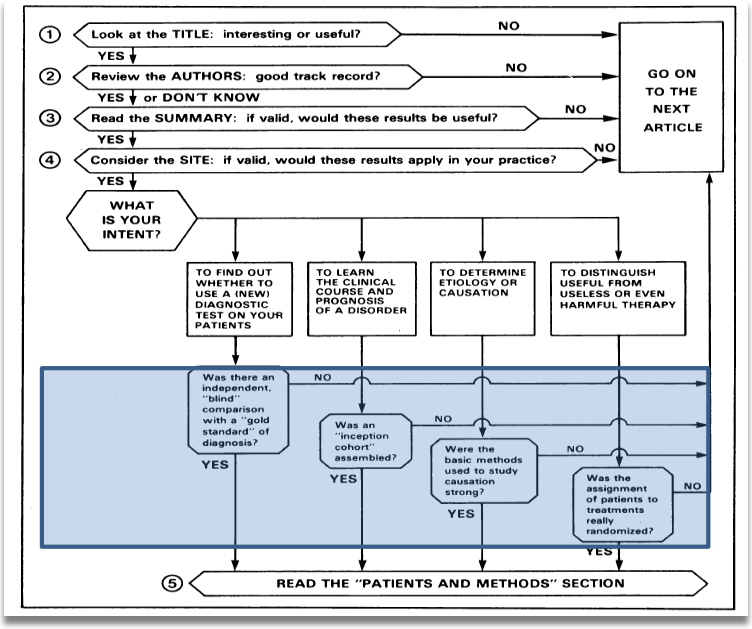
As such, Critical appraisal schemes serve as guides for clinical decision-making, equipping clinicians with tools for independent and efficient assessment of sources of evidence, and then application of the evidence in clinical practice (thus fulfilling the two last parts of the definition of "clinical epidemiology" above).

An important implication of the introduction of critical appraisal schemes, as well as of using the levels of evidence (see the following section below), is that the practice of clinicians who follow them becomes standardized, thereby minimizing the problem of unwanted variation of interventions, and thus reducing ineffective treatment.[29]

Critical appraisal serves as a method by which to assess the evidence in health care practice, by way of explicating certain "inference rules for clinical decision-making" (cf. Sackett 1989b), or later, when presented as an integral part of EBP, as "[t]he application of formal rules of evidence in evaluating the clinical literature" (Guyatt et al., 1992: 2420). The "formal rules" coincide with the criteria for evidence-assessment presented above. In line with the definition of "evidence" (1.3.2.) and the principles of assessment of evidence (1.4.1.), one could redefine Critical appraisal as a kind of formalized way of justifying beliefs with regard to hypotheses about clinical effectiveness for clinical decision-making, by applying principles of evidence assessment developed from clinical epidemiology.

Critical appraisal-schemes forms were developed to guide students and clinicians in appraising evidence in an efficient manner. The illustration below serves as an example of an early model of critical appraisal (Sackett 1981a: 557; blue markings are mine):

[29] As will be discussed in Chapters 3 and 4, this standardization is a central subject in the criticism of EBP.



The questions in the upper half of the form (with exception of the second question)[30] concern questions of usefulness (referring to strength of evidence) on the basis of assessment of validity (referring to the quality of evidence).

The illustration also demonstrates the close relationship between critical appraisal and the view of evidence in clinical epidemiology: The last four questions (marked in blue) concern the kind of research design that has generated the evidence in question. If the evidence generated is not based on the specific research designs of clinical epidemiology, the article is principally discarded. The questions referring to “gold standard”, “strong

[30] The second question differs substantially from the other by being directed towards the authors behind the study, rather than the study itself. The idea seems to be that a good track record implies better quality of the studies produced by the authors. Assessment of authors are removed in later developments of appraisal forms.

causation", and "randomization" have to do with criteria of internal validity of the studies, as necessary conditions for continuing reading the study at all.

The critical appraisal form has been developed into various versions in the EBP literature, but the core components of the assessment, based on the principles of assessment developed in clinical epidemiology, remain unchanged.

1.4.3. Evidence hierarchies

Gordon Guyatt, a prominent figure in both clinical epidemiology and EBP, states that "Not all evidence is equal, and a set of principles can identify more vs less trustworthy evidence" (Guyatt et al. 2015:16). Through these principles, evidence is ranked high or low according to whether they are considered valid. In this section, I will present the hierarchical structure of ranking evidence as a central feature of clinical epidemiology.

A hierarchy of evidence can be defined as "[a] system of classifying and organizing types of evidence" (Guyatt et al. 2015: 658). The classification and organization are conducted according to assessments of the quality and strength of evidence. Typically, evidence is assessed with regard to (1) risk of bias and measurement of outcome, concerning both the accuracy of the measurement and the ability to demonstrate a large effect size (cf. internal validity); and (2) whether the research results are applicable to clinical practice (cf. external validity). As such, hierarchies function as a particular kind of appraisal tool. The main intention is similar to Critical appraisal forms, namely, to guide clinical decision-making. By referring to a hierarchy of evidence, the clinician is able to seek the highest-quality evidence source available to guide her in making clinical decisions.

There are several kinds of hierarchies, for example singular studies (often in combination with systematic reviews of several single studies; e.g. Guyatt and Rennie 2002), aggregated studies (e.g. 6S-system by Haynes et al.: 2001), and methodologies (e.g., Sackett, D.L. 1981b: 986). Common to all of these is the fact that they rank evidence-

sources according to internal validity. Some hierarchies, like GRADE, rank evidence according to external validity as well.[31]

There are also different hierarchies for different clinical questions. For instance, in hierarchies ranking evidence sources for therapeutic questions, the RCT (or summaries of several RCTs) are ranked highest; in hierarchies for prognostic questions, observational studies are typically placed on top (cf. Guyatt et al., 2015: 10).

Initially, the evidence-hierarchies were presented as "levels of evidence". This was originally described in a report by the Canadian Task Force on the Periodic Health Examination in 1979 (Canadian task force 1979). The hierarchy was presented as follows:

Table 1

Canadian Task Force on the Periodic Health Examination's Levels of Evidence*

Level	Type of evidence
I	At least 1 RCT with proper randomization
II.1	Well designed cohort or case-control study
II.2	Time series comparisons or dramatic results from uncontrolled studies
III	Expert opinions

* Adapted from Canadian Task Force on the Periodic Health Examination. The periodic health examination. Can Med Assoc J 1979;121:1193-254

(Source: Burns et al. 2011)

In this hierarchy, evidence sources are ranked with regard to their assumed ability to answer therapeutic questions, i.e., they are rated according to degrees of confidence in the estimates of the effects of health care interventions. RCTs are ranked at the highest level and expert opinions at the lowest level, according to susceptibility of bias. As discussed above, the RCT is typically viewed as the best available evidence because its

[31] According to Blunt (2015), there are no hierarchies that rank evidence explicitly with respect to external validity, only to applicability, which technically refers to evidence strength (of recommendation), and not to evidence quality (of validity) (cf. 1.4.1.2. above). As I stress in 1.4.1.2., the difference between external validity and the strength of recommendation is not always clear-cut in the literature. Blunt seems to agree with this when he states that when the term 'applicability' is used with regard to hierarchies, it "might be used to mean external validity" (Blunt 2015: 56).

design is considered less prone to a risk of systematic errors than other kinds of evidence sources.

Until recently, there were no defined hierarchical structures accounting for evidence in a more nuanced way. From 2008, GRADE (Grading of Recommendations Assessment, Development and Evaluation) has been dealing with this issue. Within GRADE, there is the same tendency to prioritize the method of RCT as in the model above, but in a more complex assessment of ranking evidence relative to a treatment's putative effects, weighing properties of RCTs and Observational studies against each other.

GRADE offers a two-step process to assess the evidence: (1) An initial ranking is ascribed, based on methodology. GRADE only includes RCTs and observational studies and ascribes a "high quality" grade to RCTs and a "low quality" grade to observational studies. (2) Secondary criteria are assessed, which allows the quality of the evidence to be up-graded (e.g., by large and/or consistent effects) or down-graded (e.g., by risk of bias, inconsistency and/or imprecision), and assigned a "high", "moderate", "low", or "very low" rating (cf. Howick 2011: 29f). For instance, an RCT would be down-graded to "very low" if high risk of bias and imprecision occur, and an observational study may be up-graded to "high" if it demonstrates large effects. Based on this ranking system, the clinician is able to decide whether to recommend using the treatment in question, given the balance of effects on the outcomes of interest (cf. Blunt 2015: 47).

Expanding upon La Caze's (2008) concept of "categorical interpretation of hierarchies", I will differentiate between "categorical" and "non-categorical" interpretations of hierarchies. A categorical interpretation of a hierarchy refers to the notion that evidence ranked higher up in the hierarchy always trumps evidence ranked further down the scale. In such interpretations, results from top-ranked evidence sources are always considered superior to the results of evidence sources from further down the hierarchy, relative to methodological considerations exclusively. The Canadian task force hierarchy (see figure

above) is an example of such an interpretation, in which the "type of evidence" is ranked according to methodological considerations, where level-I evidence is categorically superior to level II and III. Conversely, a non-categorical interpretation of a hierarchy refers to the notion that evidence ranked higher up in the hierarchy does not always trump evidence ranked further down. [32] In non-categorical interpretations, there are other conditions in addition to the methodology that are considered when ranking evidence sources. GRADE is an example of a non-categorical interpretation: While the initial ranking is based on methodological criteria alone (corresponding to a categorical interpretation), the secondary up-and-down criteria provide additional conditions to the hierarchical ranking of evidence sources. In the following, I will describe such non-categorical interpretations as "conditional interpretations" of hierarchies.[33]

The developments of hierarchies are more commonly associated with EBP than with clinical epidemiology literature, and the hierarchical view of evidence is indeed a key feature of EBP (cf. 2.2 below). A central point in my thesis is to demonstrate that the principles of evidence assessment upon which the hierarchies are built are based on the specific view of evidence of clinical epidemiology. In the following subsection, I will conclude by summing up clinical epidemiology's view of evidence.

1.4.4. Clinical epidemiology's view on evidence

Clinical epidemiology's stance on evidence may be said to represent a principle of "outcome is everything", thereby separating useful outcome-based research from any other kind of research to be applied in clinical decision-making. Less useful information in

[32] While La Caze describes categorical interpretations in a similar manner as I do above (La Caze 2008: 1), he does not provide a description of non-categorical interpretations. However, he describes the GRADE system as a response to the limited criteria of categorical interpretations (ibid., 18), suggesting characteristics similar to those I attribute to non-categorical and conditional interpretation of hierarchies.
[33] The differentiation between "categorical interpretations" and "conditional interpretations" are inspired by, but not identical to, Blunt's (2015) use of these terms.

this context consists of mechanistic reasoning, the main focus in traditional physiology and pathophysiology.

Research-knowledge is applied in order to determine whether an intervention is effective or not, which in turn justifies beliefs with regard to hypotheses about clinical effectiveness for clinical decision-making. As a prerequisite for this application, evidence sources are assessed according to criteria for evaluating the validity and strength of the evidence. In particular, evidence is assessed in terms of risk of bias and applicability to clinical practice. Evidence hierarchies are used for explicating the evidence assessments through which evidence sources are ranked relative to the degree of confidence they provide in estimating accuracy and/or effects of health care interventions. Through formal rules of evidence appraisal and through the hierarchies, the clinician can seek out the highest quality evidence available to guide their clinical decision (cf. Guyatt et al. 2015: 11).

The criteria by which evidence is assessed hierarchically do not, however, imply that evidence considered to be of less quality (such as mechanistic evidence) is non-valid. The typical clinical epidemiologist's claim would be that mechanistic evidence ranks below outcome research, in particular due to less rigorous and transparent methods (i.e. internal validity) and less attention to relevant outcomes in clinical practice (i.e. external validity). It may still be valid information, but with higher susceptibility of bias.[34]

Within clinical epidemiology, in particular regarding therapy, information provided from mechanistic evidence sources are most often considered less relevant. The primary concern in clinical epidemiology is attention to the outcome of treatments as the basis upon which recommendations of treatment are justified. In cases where information from

[34] Within the literature of EBM, mechanistic, pathophysiological reasoning is often referred to as "background information", concerning necessary but insufficient knowledge the practitioner needs to understand "foreground information", which typically refers to outcome-based research knowledge, directly related to the actual clinical issue. I find it reasonable to assume that this way of thinking is inherent in clinical epidemiology as well.

RCTs are not available, the clinical epidemiologist should provide such research. In the meantime, other available evidential information belonging further down the hierarchy of evidence should be used. Thus, the hierarchy of evidence doesn't exclude research evidence other than RCT's, but the RCT is explicitly set as the standard against which any other information is compared. This is clearly demonstrated in the method of RCT as the gold standard method of answering questions about therapy.

The view on evidence as described above represents clinical epidemiology's core idea of the use of clinical research: The development and use of methods regarding the results (the outcome of interventions) of quantitative studies of populations, to be assessed through explicit evidence criteria. Critical appraisal of evidence is considered a fundamental resource in clinical practice, as justification for clinical effectiveness, concerning decision-making hypotheses about questions as to whether an intervention works. This is the content which constitutes, to use Sackett's words," the revolutionary" impact of clinical epidemiology (cf. Sackett 2002).

1.5. Clinical epidemiology and evidence-based medicine

In 1981, the central teachings of Critical appraisal were published as a seven-part article series entitled “How to read clinical journals” (Sackett 1981a; 1981b). During the following years, Sackett and others published several publications of different aspects of the method of critical appraisals for different study designs. The first publication of EBM (Evidence-Based Medicine Working Group 1992), with its focus on “the application of formal rules of evidence in evaluating the clinical literature” may be read as the final publication of this series (cf. Zimerman 2013).

From these remarks, it is reasonable to claim that EBM, and EBP, grew out of clinical epidemiology in general, and out of critical appraisal in particular (cf. Smith and Rennie: 2014). This does not mean, however, that EBP is reducible to its origins, a conclusion that resonates with Sackett’s own view:

> As more and more clinicians, armed with the strategies and tactics of clinical epidemiology, cared for more and more patients, they began to evolve the final, vital link between evidence and direct patient care. Building on the prior evolutions […], and often incorporating the patient’s own values and expectations […], the *revolution of Evidence-Based Medicine* was introduced by Gordon Guyatt. […] Since its first mention in 1992, its ideas about the use (rather than just critical appraisal) of evidence in patient care and in health professional education have spread worldwide […]. (Sackett 2002: 1164)

There are two important points to be made about this quotation. Firstly, the “final revolution” of EBM is said to provide the link between “evidence and direct patient care”. Clinical epidemiology‘s primary concern is the use of research from epidemiology and biostatistics in a clinical perspective, as a basis for clinical decision-making. This research is to be assessed – through critical appraisal – in the evaluation of direct health care, but the practical dimension of health care as such is placed outside its scope. In the presentation of EBM in the above quote, the principles of clinical epidemiology are

extended to *direct* patient care in medical practice. In the same manner, the evaluation of critical appraisal is turned into application. The last sentence makes this explicit by focusing on "the use (rather than just critical appraisal) of evidence in patient care". A central difference, then, between clinical epidemiology and EBP is that, while the former focuses on generating and assessing scientific knowledge, EBP's main focus is on the practical use of this knowledge, at the actual point of patient care.

The second point to be made regarding the quotation above, is that the "evolution" of EBM and EBP is moving beyond the scope of clinical epidemiology in that it involves "incorporating the patient's own values and expectations". In later definitions of EBM, knowledge concerning the incorporation of the patient's values is considered an equally important aspect as both scientific knowledge and knowledge concerning the practical application of research evidence.

The two points concerning the difference between clinical epidemiology and EBP can be further demonstrated in light of the definition of clinical epidemiology presented in section 1.1.4. above: Whereas clinical epidemiology provides the *assessment* for application of evidence in clinical health-care decision-making (cf. the two last parts of the definition), the EBP clinician is the agent making use of this evidence to justify a recommendation for or against a specific clinical intervention for a particular patient, in accordance with the patient's values and preferences.

When Gordon Guyatt, a student of Sackett, introduces the term EBM,[35] he also includes "judgment" as an additional aspect:

> For the clinician, evidence-based medicine requires skills of literature retrieval, critical appraisal, and information synthesis. It also requires judgment of the

[35] When Guyatt first introduced the idea of practicing evidence-based, he presented it as «scientific medicine». When the faculty of Medicine at McMaster, Canada, reacted to this, arguing that any basic scientists practices scientific medicine, Guyatt's second suggestion was "Evidence based medicine" (cf. Smith and Rennie: 2014).

> applicability of evidence to the patient at hand and systematic approaches to make decisions when direct evidence is not available. (Guyatt: 1991)

The last sentence above is ambiguous in that it is not clear whether the requirement of judgment is present only when "direct evidence" is not available, or if it is a requirement in any application of evidence. To my mind, the most reasonable interpretation is that applicability of evidence necessitates some use of judgment (e.g. as part of the critical appraisal of external validity and applicability), while "systematic approaches to make decisions" (other than critical appraisal-skills) is explicitly stated as a requirement only "when direct evidence is not available".

The sentence clearly represents in EBM a movement beyond the rather strict scientific scope of clinical epidemiology. I will suggest that there are two necessary requirements in the conceptualization of EBP: the *scientific,* clinical epidemiologist foundation with regard to research results considered as evidence; and what I understand as the *non-scientific* foundation, concerning the practical application of research evidence. This latter dimension includes both the incorporation of patient's values, and the use of individual judgment, typically termed "clinical expertise" in the EBP literature.

The non-scientific dimension may seem trivial; it is, after all, what any clinical practice entails. However, it is not the least trivial when it comes to understanding the scope and delineation of EBP. It is important to note, however, that this requirement does not make EBM any less "evidence-based"; the scientific dimension of clinical epidemiology presents the primary scientific basis through which the EBP practitioner retrieves and assesses the evidence for any clinical decision-making.

In the following chapter on the model of EBP, I will examine the two dimensions of EBM in epistemological terms, as scientific knowledge (relating to knowledge of scientific facts),

and non-scientific knowledge, relating both to knowledge of values (regarding the patient) and to practical knowledge (regarding judgment).

Chapter 2: The concept of evidence-based practice

2.0. Introduction

The main aim of this chapter is to provide an adequate understanding of EBP through an epistemological analysis of the kinds of knowledge that constitute EBP. Three essential elements of EBP are identified, with reference to three key terms in the EBP literature that are common in EBP definitions: (1) evidence; (2) clinical expertise; (3) patient preferences and circumstances. In epistemological terms, (1) corresponds to scientific knowledge, whereas (2) and (3) correspond to non-scientific knowledge. This chapter clarifies the content of these three elements. It also discusses the content of the different kinds of knowledge, as well as of how these kinds of knowledge are structured in relation to one other. I will provide a more detailed description of these kinds of knowledge.

To a large extent, scientific knowledge represents the clinical epidemiology framework of EBP and constitutes what is most controversial to EBP. In turn, scientific knowledge is the component that differentiates EBP from non-EBP approaches. Non-scientific knowledge, conversely, characterizes EBPs difference from clinical epidemiology, and at the same time its similarity to non-EBP approaches. As I will demonstrate below, both kinds of knowledge are necessary for an adequate understanding of EBP. One important issue in this chapter is to identify how the various kinds of knowledge inherent in EBP are structured in relation to the concept of EBP as a whole.

To conduct the epistemological analysis of the concept of EBP, a clarification is required of the central concepts and principles in the EBP model. Firstly, I will provide a general overview of how different kinds of knowledge are represented in EBP literature from 1992 to the present day (section 2.1.). Secondly, I will discuss EBP in its extension from clinical epidemiology towards clinical practice. Through this discussion, I will discuss essential features within the concept of EBP and identify the differences between clinical

epidemiology and EBP (section 2.2.). Thirdly, I identify four core principles in EBP, common in standard descriptions throughout the EBP literature (section 2.3.). I conclude section 2.3. by presenting a definition of "evidence-based practice" (section 2.3.5.). This definition will serve as a point of reference with regard to both the subsequent epistemological analysis of the concept pf EBP and for the following chapters on the EBP debate.

Based on these clarifications, I will conduct an epistemological examination of the structuring between scientific and non-scientific knowledge in EBP, with a primary focus on explicating the kinds of knowledge inherent in the concept of EBP (section 2.4.).

The chapter has five main parts: 2.1: A brief history of the representation of scientific and non-scientific knowledge in EBP. 2.2: Evidence-based practice and the extension to practice. 2.3: Core principles in EBP. These three parts provide conceptual background for the subsequent section 2.4: Analysis of scientific and non-scientific knowledge in EBP. This section comprises several subsections in which I will examine different kinds of knowledge separately. Based on the possible combinations of scientific and non-scientific kinds of knowledge, I will then, in section 2.4.4., discuss three concepts, of which "moderate" EBP is by far the most reasonable. Lastly, in section 2.5., I will conclude the analysis by presenting an overview of the most central findings in the previous sections.

2.1. A brief history of the representation of scientific and non-scientific knowledge in EBP

The first official text presenting EBP – as evidence-based medicine – from 1992 describes EBP as a reaction against traditional clinical practice,[36] stressing the need for application of evidence results from outcome-based methods as a basis for clinical decisions. Initially, the aim of EBP was on educating clinicians on assessment and use of published clinical research literature to improve clinical care. As EBP developed, the means to reach the aim of improving clinical care were articulated in greater detail by including processual practice, use of expertise, patient preferences and circumstances as necessary elements.

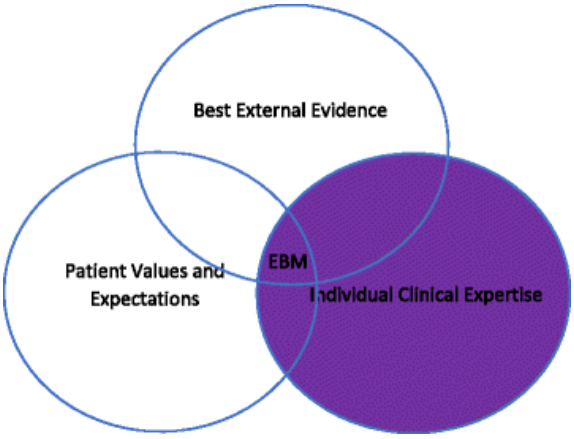
The controversial content in EBP is apparent from the first official text: Traditional health care, with its attention focused on underlying pathophysiologic mechanisms (cf. 1.2.1. above) and use of expertise, was deemed insufficient as a basis for determining whether interventions are effective or not. Instead, research results from epidemiologic, outcome-based methods were to be used as the optimal basis for clinical decisions. In effect, both pathophysiologic mechanisms and expertise were considered inferior evidence sources with regard to measuring the effects of clinical interventions. Instead, such information was considered necessary as "background information" in clinical practice.[37]

Through the use of models of hierarchies of evidence, the EBP literature – as a direct extension of clinical epidemiology literature – was explicit about how the confidence in different evidence sources should be considered, relative to specific criteria of evidence quality (cf. section 1.4.4.ff above). However, the models of EBP did not explicitly address

[36] This is described quite dramatically, and erroneously, as a "paradigmatic shift". In context, the paradigm conception is based on a misinterpretation of Kuhnian philosophy of science, whereby normal sciences, due to accumulation of anomalies, are replaced by a scientific revolution. Instead, "paradigm shift" is used in a broader way to indicate a major change of practice (cf. Blunt 2015: 15). The description of EBP as a "paradigmatic shift" has endured to some extent (e.g. in Bhandari et al. 2004) but is no longer part of the standard descriptions in the EBP literature.

[37] "Background information" is discussed in more detail in 2.4.2. below.

the question of how scientific knowledge was related to other kinds of knowledge. While non-scientific knowledge has always been recognized in the EBP literature, early EBP literature was not clear on how evidence was to be considered in relation to the expertise of the clinician on the one hand, and to the preferences and circumstances of the patient on the other. As a result of increasing attention toward these issues – to a large degree as a response to criticism of that these issues are lacking – EBP authors published new definitions and modifications to earlier EBP descriptions. Particular attention was paid to how EBP was not reducible to scientific knowledge alone, but also included expertise and patient preferences, both equally necessary as evidence. Around 1996, EBP authors introduced models of EBP to illustrate this. [38] The models typically depicted three inter-connected Venn-diagrams, representing (variations of) "evidence", "expertise", and "patient preferences and circumstances" (cf. Wieten 2018), such as in Figure 1 below:



[38] The assertion that the use of EBP models dates from 1996 is an approximation, supported by Wieten (2018).
Initiated in 1991, EBP is a rather new concept, with little research having been done on its historical development. The few articles on the subject (e.g., Bluhm&Borgerson 2010; Raspe 2007; Smith & Rennie 2014; Sur & Dahm 2011) tend to describe the development in EBP as analogous to methodological developments in epidemiology and clinical epidemiology. Wieten (2018), in my view, is an exception, pointing to "[t]hree historical models of expertise integration" (Wieten 2018: 1).

(Wieten 2018: 3)

From 1996 onwards, it became common to include variations of this model in introductions to EBP.[39] In their description of the current model of EBP in 2017, Djulbegovic and Guyatt point to the increasing attention to non-scientific knowledge as one of the most central progressions in EBP:

> EBM progressed to recognise limitations of evidence alone, and has increasingly stressed the need to combine critical appraisal of the evidence with patient's values and preferences through shared decision making. (Djulbegovic & Guyatt 2017: 415)

Thus, the relationship between evidence, expertise, and patient preferences and circumstances has become a highly central topic in the EBP literature. At the same time, in most EBP literature it is not very clear what these elements entail, or how they are interconnected. The main attention in the following is on clarification of this topic, in particular with regard to the different kinds of knowledge in EBP and to how they are structured in relation to each other.

[39] There is much variation in these models, both in shape and in numbers of elements. For instance, Cullum et al. (2008: 12) present a variation containing 5 circles. Four of the circles are partly intersect one another (labelled respectively "clinical state"; "patient preferences and actions"; "research evidence"; and "health care resources"). "Clinical expertise" is placed in the middle, depicted by a dashed line and a square, placed within the frame in which the other four circles intersect. While such an illustration may increase the specificity of the elements, it also contributes to a higher level of complexity that is not often adequately described. To the extent that this complexity is not adequately described, I find it more disturbing than clarifying.

2.2. Evidence-based practice and the extension to practice

As demonstrated in Chapter 1, the scientific background of EBP is terminologically and historically based on clinical epidemiology. Terminologically, central terms and features in EBP literature such as “evidence”, attention to “outcome-based methods”, “critical appraisal” and the “hierarchies of evidence” are developed within clinical epidemiology. Historically, EBP is said to grow out of Critical appraisal, as a tool for assessing research knowledge with respect to application in clinical practice through formal rules of assessment, developed through clinical epidemiology (cf. 1.4. above). As such, EBP is reducible to clinical epidemiology.

The central features that differentiate EBP from other clinical approaches coincide with its clinical epidemiology heritage. In effect, what is controversial in EBP – its emphasis upon evidence from epidemiologic evidence sources and the criteria through which evidence is assessed – also coincides with clinical epidemiology.

However, as stated in 1.5. above, EBP is not reducible to its origins. Instead, EBP extends to direct patient care in clinical practice, in which evidence is to be applied. What does this extension to clinical practice entail? The extension of EBP can be described in two, closely connected, ways: as an extension *from* clinical epidemiology, and *towards* clinical practice.

As described in Chapter 1, the aim of clinical epidemiology is to provide high-quality evidence sources as a basis for clinical decision-making. The methodology of clinical epidemiology provides the means to access and assess evidence sources for application in clinical health-care decision-making. When evidence and the means for evidence assessment are considered necessary conditions for clinical decision-making in EBP, it is to be considered an extension from clinical epidemiology.

While clinical epidemiology represents a scientific structure for providing evidence suitable for justifying recommendations for or against clinical interventions in clinical decision-making, EBP is a model for approaching such clinical decision-making – beginning at the point where the scope of clinical epidemiology ends.

The aim of EBP is to apply the best available evidence in clinical decisions and thereby improve clinical decision-making in individual patient care. The central difference between EBP and clinical epidemiology, then, has to do with the attention to application of the evidence in clinical practice. In the extension towards practice, the evidence must be applied at the point of patient care. At this point, to apply evidence requires knowledge of elements that are external to the clinical epidemiology framework.

As analysed in 1.4.1.2. above, applicability is an attribute of the quality of the evidence in terms of whether the evidence can be used in patient care. From the point of view of clinical epidemiology, this is either exclusively a matter of generalizability from the study group to the patient (or population) at hand, or considered through strength of evidence, in which quantifiable patient-related outcomes are taken into consideration (in addition to generalizability).

At the point of patient care, however, the evidence must be "integrated"[40] (or "translated") into clinical practice by a clinician to ascertain whether the evidence actually corresponds to patient unique preferences and circumstances. In this case, knowledge concerning the clinician's expertise and her ability to integrate, as well as knowledge concerning the patient and the circumstances, are considered necessary conditions in EBP decision-making, in addition to the evidence.

[40] In the EBP literature, "integration" and "translation" of evidence into clinical practice are central terms. These terms serve as metaphors for any activities regarding the application of the evidence at hand. Certainly, this activity is not unique to EBP. Instead, it is a common challenge to all clinical practices, EBP and non-EBP alike.

Thus, the content of the justification for recommending for or against interventions in individual patient care is dependent on the abilities of the clinician, along with knowledge about the clinical setting and the patient's preferences that are provided neither in the research information nor through the framework of clinical epidemiology.

In other words, evidence provided through clinical epidemiology principles does not improve patient-care directly but equips the EBP clinician with information necessary for clinical decision-making. The direct link to clinical practice at the point of patient care is established by the clinician, who makes use of her expertise to apply this evidence in accordance with patient preferences and circumstances.

Thus, it is not enough to be doing research to obtain the best evidence, nor to be able to critically appraise it. The focus of EBP is directed towards the application of this research – EBP is about using, not doing, research.[41] This is the most central demarcation between clinical epidemiology and EBP. Information provided from the research evidence must be assessed for application to the actual clinical situation in clinical practice. In turn, such assessed evidence is used as a tool for the EBP clinician when solving a specific patient-related clinical problem. What is essential to EBP, then, is not only evidence but the practical application of it: For evidence to be applied in direct clinical practice, it must be interpreted by the clinician in her clinical practice, in accordance with the patient's preferences and circumstances.

The critical appraisal forms developed in clinical epidemiology provide the scientific framework for this interpretation: Provided that the evidence exhibits internal validity, the evidence can be assessed for external validity (i.e., generalizability and applicability)[42] in individual patient care. In addition, however, for evidence to be applied in clinical

[41] This is not to say that an EBP clinician cannot conduct research. When conducting research, however, the scientific framework of the research is constituted not by EBP itself, but by principles from clinical epidemiology and other scientific frameworks.

[42] These concepts are analyzed in detail in Section 1.4.1.2. above.

practice at the point of patient care – that is, to be practising evidence-based practice – the input from both the clinician and the patient are necessary requirements. More accurately, any use of evidence in EBP concerns the assessment and application of evidence in a specific clinical setting, conducted by a clinician, in accordance with the patient's preferences.

Clinical epidemiology is involved every step of the way until this application of evidence, but it does not engage in the actual application of the evidence at the point of care, whereby actual clinical decision-making occurs. At this point, the extension to practice takes centre stage, at which point the clinician's encounter with the patient occurs as evidence-based practice.

Notably, assessment of evidence in the extension to practice at the point of patient care, is contingent on information about the specific clinical setting and the patient's preferences that is not provided in the research literature.[43] This kind of assessment comes in addition to, and not integral with, assessment of external validity (which assesses the evidence in terms of the information provided in the research literature). To be able to distinguish conceptually between these two kinds of evidence assessment, I will distinguish between, on the one hand, "generalizability" along with "applicability" of the evidence (belonging to external validity) and, on the other hand, "usability", which refers

[43] This observation is in line with Rothwell (2009), who describes the complexity of "external validity", stating that it "[r]equires clinical rather than statistical expertise and usually depends on a detailed understanding of the particular clinical condition under study and its management in routine clinical practice. External validity is also highly dependent on the particular perspective of the individual making the judgement. For one clinician with a particular patient, a trial result might be almost perfectly applicable, whereas for another clinician and patient the external validity may be extremely low" (Rothwell 2009: 95). In my view, the attention to "[t]he particular perspective of the individual making the judgement" (ibid.) is highly problematical to internalize to a scientific concept of external validity, and I have not seen any systematic attempts to do this. My distinction between "applicability" and "usability" is an alternative way of explaining how the attention to individual perspectives and judgments relates to "external validity", without being integral to this concept.

to the assessment of evidence with regard to patient preferences and circumstances at the point of patient care.[44]

In sum, the features that separate EBP from clinical epidemiology – the need for clinical expertise and attention to patient preferences and circumstances – must be considered as necessary elements. Without this extension, the question of epistemological issues concerning EBP would be answerable by the framework of clinical epidemiology types of knowledge alone. To put evidence into use as a basis for clinical decision-making – that is, to practise EBP health care – the clinician has to consider assessment and application of the evidence with regard to the clinical setting by means of her clinical expertise, in coordination with the patient's preferences. This is what EBP connotes.

In epistemic terms, such an evidence-based practice implies two distinct kinds of knowledge: Scientific knowledge (of evidence) and non-scientific knowledge (of clinical expertise, and of the patient's preferences and preferences). Both kinds are necessary for an adequate understanding of EBP. In section 2.4 and its subsequent subsections, I intend to clarify what the concept of EBP entails, through an epistemological analysis focusing on the kinds of knowledge that are inherent in the concept of EBP. Before I turn to these matters, I will describe the most typical ways the concept is used in the EBP literature.

[44] The main reason for introducing the term "usability" is to explicitly distinguish between evidence assessment based on critical appraisal (i.e. as part of the clinical epidemiology framework) and evidence assessment based on the clinician's expertise. In addition, the term "usability" does not interfere with existing EBP nomenclature, as it is rarely applied in EBP literature.
Importantly, "usability" is not synonymous to "usefulness". As noted in footnote 14 in Chapter 1, "usefulness", in my use of the term, refers generically to "generalizability", "applicability", and "usability". "Usefulness" is an oft-used term in EBP, and rarely defined. In EBP literature, "usefulness" is applied with reference to "applicability", without a clear distinction between application as a technical term (i.e., as part of external validity) and as a generic term referring to "usefulness in practice" in general. For instance, Straus et al. 2011, sometimes equate "validity" with "usefulness" (e.g., at page. 3), while other times distinguish between them (e.g., at page 207).

2.3. Core principles in EBP

For a more thorough presentation of central features of EBP, I will present four core principles that are common to standard EBP definitions and descriptions of EBP.[45] These core principles point to closely connected ways in which EBP is described, as (2.3.1) "five linked ideas"; (2.3.2.) a process; (2.3.3) principles of hierarchy; (2.3.4) a structure for decision making.

2.3.1. EBP as "five linked ideas"

From its beginning, EBP has been explained by means of certain essential principles, or fundamental ideas. In an early article on EBP, Davidoff et al. presented the essential features of EBP as "rooted in five linked ideas":

1) clinical decisions should be based on the best available scientific evidence
2) the clinical problem – rather than habits or protocols – should determine the type of evidence to be sought
3) identifying the best evidence means using epidemiological and biostatistical ways of thinking
4) "conclusions derived from identifying and critically appraising evidence are useful only if put into action in managing patients or making health care decisions
5) performance should be constantly evaluated. (Davidoff et al. (1995: 1085).[46]

Of these five ideas, 2), 4) and 5) are rather uncontroversial and are in line with professional and philosophical ideals of health care. All three ideas concern the application of practice, including the use of non-scientific knowledge with regard to the patient and circumstances. The second idea relates to the actual problem in a practical setting, and to

[45] These principles are usually presented within the evidence-based medicine literature, and I will mainly refer to this literature. The principles are, however, equally essential to EBP.
[46] Sackett & Rosenberg 1995: "The need for evidence-based medicine», pp. 621f, published only months after Davidoff et al., offer a nearly identical description, presented as "principles of EBP".

the importance of clearly formulated clinical questions; the fourth idea refers to the importance of practical implementation, and the fifth refers to evaluation of such implemented practice.

The first and third ideas are primarily issues of scientific knowledge, echoing EBP's clinical epidemiology heritage, and are more controversial.

The first idea states the central idea of both clinical epidemiology and EBP – that any clinical decisions should be based on "best available scientific evidence". The third idea explains what this entails, stating that the identification of such evidence is to be conducted by means of "epidemiological and biostatistical ways of thinking", that is, on the basis of clinical epidemiology principles (as presented in Chapter 1).

Both of these ideas have to do with EBP's controversial view on evidence. Of course, in traditional health care, no one would deny the importance of evidence. However, as presented in Chapter 1, the main attention in traditional health care practices has been on mechanistic evidence sources, whereas proponents of clinical epidemiology argue that comparative, outcome-based methods offer superior support. Moreover, the use of personal expertise and habits has been accepted as evidence to a greater degree than within clinical epidemiology and EBP.

The claim made in the first idea – that clinical decisions should be based on the best available scientific evidence – can be interpreted in two ways, depending on how "best available evidence" is understood.

One version is to interpret "best available" evidence as referring to epidemiologic evidence-sources exclusively. This interpretation is seemingly supported by the third idea concerning "epidemiological and biostatistical ways of thinking".

A second way of interpreting "best available evidence" is to consider it pragmatically, implying that if epidemiologic research is not available (or the clinical problem determines

that other evidence-sources need to be sought; cf. the second idea), clinical decisions should be based on what is the best available non-epidemiologic sources of evidence.

In the analysis of the EBP debate in Chapter 3 and 4 below, the first interpretation is identified as a "categorical interpretation", which derives from misunderstandings of EBPs view on evidence. The second interpretation resonates better with most descriptions of EBP. For instance, the first official EBP text states that EBP "de-emphasizes intuition, unsystematic clinical experience, and pathophysiologic rationale as sufficient grounds for clinical decision-making, and stresses the examination of evidence from clinical research" (cf. Guyatt et al. 1992: 2420). A key element here is that these sources are "de-emphasized", and not omitted as such. In this case, the controversial character is not as apparent as in the first interpretation. However, what is regarded as "best" evidence also implies a hierarchical principle whereby assessment of evidence entails a systematic up- and down-grading of evidence (cf. 1.4.3. above). In addition, the EBP literature varies as to whether non-scientific evidence-sources, such as unsystematic (subjective) experience, are to be regarded as evidence at all (see also 2.4.3. below).

2.3.2. EBP as a process

EBP has been presented as a process since its beginning. For instance, Sackett and Rosenberg describe the practice of EBP as:

> [a] process of life-long, self-directed learning in which caring for our own patients creates the need for clinically-important information about diagnosis, prognosis, therapy, decision analysis […]. (Sackett & Rosenberg 1995: 622).

This way of describing EBP concerns how it is practised, as a process, rather than as a set of ideas, with focus on "doing EBP". Here, EBP is something done, as opposed to something believed (cf. Blunt 2015: 20). Straus et al. (2011) describe the process of EBP in

five distinct steps. These five steps resemble the five "ideas" listed above, but are now to be considered as a description of the complete practice of EBP comprising five steps:[47]

> *Step 1:* converting the need for information (about prevention, diagnosis, prognosis, therapy, causation, etc.) into an answerable question.
> *Step 2:* tracking down the best evidence with which to answer that question.
> *Step 3:* critically appraising that evidence for its validity (closeness to the truth), impact (size of the effect), and applicability (usefulness in our clinical practice).
> *Step 4:* integrating the critical appraisal with our clinical expertise and with our patient's unique biology, values and circumstances.
> *Step 5:* evaluating our effectiveness and efficiency in executing steps 1–4 and seeking ways to improve them both for next time. (cf. Straus et al. 2011: 3)

These steps may be understood as the core elements of EBP. Steps 1, 2, and 3 are recognizable from the clinical epidemiology framework: the clinical questions, attention to evidence sources, and the assessment of these sources. Step 4 is representative of what was described above as the extension to practice, whereby evidence is "translated" for application at the point of patient care. Step 5 is identical to the fifth "idea" above, stressing the importance of continuously improving clinical practice.

The five-step practice of EBP which can be done in three modes, corresponds to three degrees of autonomy of the clinician:

> First, is the "doing" mode, in which at least the first four steps above are completed. Second, is the "using" mode in which searches are restricted to evidence resources that have already undergone critical appraisal by others, such as evidence summaries (thus skipping Step 3). Third, is the "replicating" mode in which the decisions of respected opinion leaders are followed (abandoning at least Steps 2 and 3). All three of these modes involve the integration of evidence (from whatever source) with our patient's unique biology, values and circumstances of Step 4, but they vary in the execution of the other steps (Straus et al. 2011: 3.)

[47] An interesting difference between Straus et al. and Sackett & Rosenberg (1995; just cited above) is that the principles of the latter are understood *within* EBP practice, while Straus et al. seem to understand their steps as *constitutive* for this practice.

The difference between these modes amounts to the different ways of incorporating evidence into practice, relative to the degree to which the clinician is able to perform critical appraisal of the evidence: The clinician can either "do EBP" by appraising the evidence herself, "use EBP" by using pre-appraised evidence conducted by others, or "replicate EBP" by following guidelines developed by other evidence-based clinicians. Notably, every mode presupposes the integration of evidence into practice, whereby the clinician's expertise and knowledge concerning patient preferences and circumstances are considered as necessary elements in the EBP process. As noted in 2.2. above (i.e., through the extension to practice), the integration of these elements is a distinctive feature of EBP, distinguishing the latter from clinical epidemiology.

The autonomy of the EBP clinician when "doing" EBP implies a significant confidence in the use of personal clinical expertise, through which the evidence is assessed for application at the point of patient care. Thus, there is a shift of attention from evidence as such to the clinician's ability to critically appraise this evidence (when "doing" EBP) and to integrate this evidence into clinical practice (in every mode of practising EBP).

Guyatt et al. (2015) presents a similar view of EBP as a process, but with a more moderate, less optimistic view of the autonomous EBP clinician. In this version of the EBP process, the assessments made by the individual clinician are replaced with pre-appraised evidence, thereby making individual clinical expertise – and, hence, non-scientific knowledge – less central. The presentation of EBP as a process by Guyatt et al. as a process demonstrates a more rigorous scientific model, with less room for the individual clinician's independent use of expertise. Notably, in Guyatt et al., the notion of "critical appraisal" – central to the very concept of EBP in Straus et al. – is only found in the preface of the book, with a note that one of the changes from the previous editions of the book will be an

emphasis placed on pre-appraised resources. According to Guyatt et al., this is due to two realizations:

> First, […] that only a few clinicians would become skilled at critically appraising original journal articles and that preappraised evidence would be crucial for evidence-based clinical practice. Second, our knowledge of how best to ensure that clinical decisions were consistent with patient values and preferences was rudimentary […]. (Guyatt et al. 2015: xxiv).

Thus, the clinician's individual expertise concerning "critical appraisal" and "integration" is considered rudimentary by Guyatt et al. In effect, the clinician's independent assessments are to a larger degree made superfluous in Guyatt et al.'s model than in Straus et al.'s. This change reflects a rather pessimistic view of "evidence-doers" as put forward by Straus et al. In Guyatt et al., the EBP clinician is not considered well enough equipped to perform either critical appraisal or integration and should instead base her performance on pre-appraised evidence or guidelines. The critical appraisal, i.e. the activity of assessing evidence, still has a central place in the version of EBP presented by Guyatt et al. (cf. Guyatt et al. 2015: 5). Ideally, however, this appraisal is conducted prior to the individual clinician's use of the evidence, by groups of researchers or practitioners (through consensus based on research data) and produced as pre-appraised evidence and guidelines to be used by individual EBP practitioners. When "critical appraisal" does occur in Guyatt et al., it is labelled "appraisal", directed exclusively at internal validity. Thus, in Guyatt et al., the processual structure of EBP is still a central, albeit more moderate, principle.[48]

[48] In the moderate version of EBP as a process, found in Guyatt et al. (2015), the consequences of the rudimentary knowledge concerning the integration of patient preferences is somewhat unclear. As discussed in Section 2.2., this kind of knowledge has to do with the application of evidence at the point of patient care, which cannot be replaced by critical appraisal-schemes. Guyatt et al. seem to imply that such knowledge nonetheless can be sufficiently supported by pre-appraised evidence. It is highly doubtful that this is the case. Even in a guideline with nearly identical criteria between the scenario suggested and the clinical encounter with the patient, it is the clinician using her expertise that is responsible for applying

2.3.3. EBP as a principle of hierarchy

Yet another typical way of describing EBP is by way of evidence-hierarchies as a fundamental principle. For instance, Guyatt et al. state as a fundamental principle that "EBM posits a hierarchy of evidence to guide clinical decision making" (Guyatt & Rennie 2002: 5).[49]

Hierarchies are central in the EBP discourse, and a controversial topic in much criticism of EBP, which I will address in Section 3.2. below. The underlying idea is expressed by Guyatt et al.: "Not all evidence is equal, and a set of principles can identify more vs less trustworthy evidence" (Guyatt *et al.* 2015:16). As described in Chapter 1 (Section 1.4.3. above), hierarchies rank evidence relative either to its methodological design (e.g., an RCT or an observational study), or to validity criteria (most typically internal validity criteria, such as risk of bias). As such, hierarchies represent the most distinct expression of scientific knowledge in EBP, through which evidence sources are hierarchically structured based on explicit methodological criteria.

There are several different hierarchies occurring in the EBP literature, offering guidance to clinical decision-making in multiple ways. These ways can be demonstrated through the different roles they play in steps 2, 3, and 4 of the EBP process (cf. Blunt 2015, Chapter 1).

knowledge, in accordance with patient preferences and circumstances. Thus, expertise is a necessary element in the application of evidence in clinical practice, regardless of whether knowledge of such application is rudimentary or not.

[49] According to Guyatt & Rennie (2002), there are two fundamental principles of EBP. In addition to the positing of a hierarchy of evidence, there is a principle that "evidence alone is never sufficient to make a clinical decision" (ibid: 5). In the newest edition of the same book (2015) there are three fundamental principles of EBM: "Optimal decision making requires awareness of the best available evidence"; "EBM provides guidance to decide whether evidence is more or less trustworthy"; evidence alone is never sufficient to make a clinical decision" (Guyatt et al.2015: 8). In this version, the principle of hierarchy occurs only indirectly through the second principle. In the 2015-edition, Guyatt et al. also state that "Not all evidence is equal, and a set of principles can identify more vs less trustworthy evidence" (ibid:16). In my view, this is a more precise description of the principle of hierarchies in EBP.

Hierarchies can be used as a tool for step 2 of the EBP process (finding the evidence), serving as a way by which to rank research literature. The idea is that clinicians should prioritize reading reports from highly ranked, often pre-appraised studies, such as the "6S-pyramid" (Straus et al. 2011).[50]

Hierarchies also function as a tool for performing step 3 (appraising the evidence), concerning information about the quality and strength of the evidence, focusing either on the connection between methodology and the evidence generated from this, or between the evidence and the claim of effectiveness of an intervention, such as the Canadian task force hierarchy described above (cf. Section 1.4.3. above). Hierarchies for appraising the evidence, in my view, is the most typical, in both pro- and anti-EBP literature.

Hierarchies also play a role in step 4 (applying the evidence), illustrating connections between the evidence and the recommendations to patients (which in turn is based on the likely effect of treatment on individual patients), such as the GRADE hierarchy (Grading of Recommendations, Assessment, Development and Evaluations).[51] A related use of

[50] The "6S-pyramid" is presented as "[a] 6-level hierarchical structure, with original "studies" at the base, "synopses" of the most clinically relevant studies just above the base, "syntheses" (systematic reviews) of evidence just above, topped by "synopses" of the premier syntheses, then clinical topic "summaries", and, at the pinnacle, the most evolved evidence-based information "systems" that link evidence-based recommendations with individual patients" (Straus et al. 2011: 34).

[51] As described in 1.4.3. above, The GRADE hierarchy is more sophisticated than other hierarchies in that it allows for a more complex assessment of ranking evidence (concerning a treatment's putative effects), weighing properties of RCTs and observational studies against each other. GRADE offers a two-step process to assess the evidence: 1) An initial ranking is ascribed, based on methodology. GRADE only includes RCTs and observational studies and ascribes "high quality" grade to RCTs and "low quality" grade to observational studies. 2) Secondary criteria are assessed, which allow for the quality of the evidence to be up-graded (e.g., by large and/or consistent effects) or down-graded (e.g., by risk of bias, inconsistency and/or imprecision), and assigned "high", "moderate", "low", or "very low" (cf. Howick 2011: 29f). For instance, an RCT would be down-graded to "very low" if high risk of bias and imprecision occur, and an observational study may be up-graded to "high" if it demonstrates large effects. Based on this ranking system, the clinician can decide to recommend or disapprove of the treatment in question, given the balance of effects on the outcomes of interest (cf. Blunt 2015: 47).

hierarchies is to develop guidelines to standardize evidence-assessment (cf. Blunt 2015: 21).

The variation of different kinds of hierarchies makes it impossible to refer to "*the* hierarchy" of EBP. The hierarchical principle however, which refers to the systematic structure of ranking evidence relative to each other according to specific criteria for evidence assessment, is a characteristic feature in EBP, inherited from its clinical epidemiology framework.

2.3.4. EBP as a structure for decision-making

Whereas the three core elements presented above refer to the specific content of EBP on which clinical practice should be based, the core element of decision-making refers to the aim of this practice. Typically, EBP is described as a "[s]tructure for optimal clinical practice" (Guyatt et al. 2015: 17). What distinguishes this practice from a non-EBP practice can be represented based on the EBP process – as a methodological approach to clinical decision-making, presenting steps to access, assess, and apply research results, and thus enabling the clinician to make clinical decisions.

"Evidence" in "evidence-based practice" should thus be considered a means to an end, as an instrument leading towards clinical decision-making. The end has to do with improving clinical decision-making. The means is provided by "good-quality" evidence, including the formal rules of assessment (i.e. critical appraisal; cf. 1.4.2. above) of such evidence.

As noted in 2.2 above however, evidence does not improve patient-care directly. The direct link to clinical practice at the point of patient care is established by the clinician, who uses her expertise to apply the evidence in accordance with patient preferences and circumstances. Thus, the clinician's expertise, the patient preferences and the circumstances are all equally necessary means toward improving clinical decision-making.

The structure of EBP clinical decision-making, then, is constituted by processual steps, in which evidence is accessed, assessed and integrated into clinical practice through the clinician's expertise, in correspondence with the patient's preferences and circumstances.

EBP should therefore not be referred to as a "science", or a "scientific system". I concur with Daly when she states that EBP does not constitute a comprehensive science of clinical care, but instead represents an important initiative in providing scientific evidence for clinical decision-making (cf. Daly 2005: 205).

However, Daly's statement can be interpreted in two different ways, depending on how the decision-making itself is considered relative to the model of EBP. One way of interpreting Daly's claim is to consider decision-making itself as external to the model of EBP. In this interpretation, EBP would be identical to the definition of clinical epidemiology above, whereby evidence is provided for justifying recommendations for or against clinical interventions concerning individual patients. Another, more reasonable way of interpreting Daly's statement, is to expanding the notion of "providing scientific evidence" to include the necessary means for applying evidence in individual patient care, thereby including the clinician's expertise and the patient's preferences and circumstances as necessary elements within the model of EBP (cf. 1.2. above). Such an interpretation takes into account the element of decision-making as an inherent part of EBP and is thus in accordance with the view of that the structure of decision-making is a core element of EBP.

2.3.5. A definition of "evidence-based practice"

Based on the analysis of the extension to practice and of the core principles, I will suggest a definition of EBP. Within the EBP literature, there are numerous definitions of EBP –

most often variations on the same content. One of the most cited definition is from 2011:[52]

> Evidence based medicine requires the integration of the best research evidence with our clinical expertise and our patient's unique values and circumstances. (Straus et al. 2011: 1)

Here, EBM (and EBP) is defined by presenting its constitutive elements: research evidence, clinical expertise, and patient values and circumstances. The "integration" – central to the understanding of EBP as a process (see also 2.2. above) – must be considered a specific ability attributed to the clinical expertise.[53] Most other EBM- and EBP-definitions follow a similar tripartite structure,[54] most often by including "integrating" as well.

One difficulty with this definition is that it does not clarify what constitutes "evidence", what it means to be "evidence-based", and it does not provide any information regarding the difference between EBP and non-EBP models. Another important element that is missing in definition advanced by Straus et al. is explicit attention to clinical decision-making.

A number of critics have attacked this and similar definitions, pointing to their platitudinous character, commenting that health care practice has always been based on

[52] I agree with Blunt (2015: 14) that the most famous definition is formulated by Sackett et al 1996: "Evidence based medicine is the conscientious, explicit, and judicious use of current best evidence in making decisions about the care of individual patients. The practice of evidence-based medicine means integrating individual clinical expertise with the best available external clinical evidence from systematic research". I have chosen to focus on the definition formulated by Straus et al. because of its more rigorous structure.

[53] I will discuss the ability to integrate in more detail in the subsequent sections of 2.4.3. below, as part of the clinician's expertise.

[54] A notable exception is the first official EBM definition (Guyatt et al. 1992): "Evidence-based medicine de-emphasizes intuition, unsystematic clinical experience, and pathophysiologic rationale as sufficient grounds for clinical decision-making, and stresses the examination of evidence from clinical research". In this definition, the attention is given to evidence sources exclusively. However, later in the same text, attention to both expertise patient preferences are described as essential elements.

evidence in some form (e.g., Blunt 2015; Miles 2009a, 2009b; Tonelli 1998; cf. Chapter 3 below). In defence of the definition found in Straus et al., it can be claimed to be more pragmatic than scientific in scope, providing a description of EBP in extension to practice.

Based on the analysis above, a more specific definition can be provided, more in line with the core elements of EBP. I will suggest a five-partite definition of the term "evidence-based practice", of which it is to be considered synonymous with:

- "Approach to clinical decision-making, in which the clinician recommends clinical interventions to individual patients
- based on the best evidence available, assessed according to methodological criteria of evidence quality,
- where the evidence is integrated into clinical practice by a clinician
- who, by making use of clinical experience, identifies, assesses and applies the evidence,
- in accordance with the patient's preferences and circumstances."

The inclusion of five elements provides a comprehensive definition. Compared to the version presented in Straus et al., it lacks the pragmatic aspect but adds a higher degree of specificity to the description of what practice in EBP amounts to.

The first part of this definition concerns the aim of EBP, by including Clinical decision-making as the genus of the definition, encompassing the other elements. The subordinate clause of the sentence demonstrates EBP's connection to clinical epidemiology, referring to the point of which the definition of clinical epidemiology ends (cf. the definition of clinical epidemiology in 1.1.4. above).

The second part includes the element of «best evidence available", making it less restrictive than the focus in Straus et al. on "best *research* evidence" exclusively. However, it is also added to this part that evidence is assessed according to methodological criteria of evidence quality (i.e., through critical appraisal). As discussed in 1.4.1. above, these criteria refer to considerations about internal and external validity of evidence-sources. These criteria are central elements in the EBP literature and constitute the most controversial and distinctive elements in EBP (i.e. its clinical epidemiology heritage; cf. Section 2.2.), thereby explaining the difference between EBP and non-EBP models.

The third part of the definition includes the role of "integration" in clinical practice, which in turn is specified in the two latter parts.

The fourth part includes the use of clinical experience as a necessary element of EBP. I have replaced "expertise" with "experience" as a necessary requirement. In this way, EBP is not restricted to experts alone.[55] This fourth part also presents the objective of clinical experience: identification and assessment of the evidence, as well as the application of the evidence at the point of patient care. This description is a reference to the core element of EBP as a process and thereby incorporates it in the definition. Notably, "assessment of evidence" is included in both the second and fourth part of the definition. In the second part, "assessment of evidence" refers to methodological criteria exclusively (concerning internal and external validity), whereas "assesses the evidence" in this fourth part refers to considerations of whether the evidence is applicable in relation to patient preferences and the actual circumstances (i.e. concerning the usability of the evidence; cf. 2.2. above).

The fifth and last part of the definition includes the patient's preferences and circumstances, further specifying what "integration" (in the third part) entails.

[55] I will examine the difference between «expertise" and "experience" in more detail in 2.4.4.1. below.

In the following section, the content of the EBP definition will be examined through an epistemological analysis of the concept of EBP, with particular attention to what kinds of knowledge 'evidence', 'expertise' and 'patient's preferences and circumstances' represent. I will do so by distinguishing clearly between scientific and non-scientific knowledge in the EBP model, and I will then discuss the specific content pertaining to these main kinds of knowledge.

2.4: Analysis of scientific and non-scientific knowledge in EBP

As discussed in 2.3., when evidence is applied in the extension to practice, clinical decision-making is performed by the individual clinician, using her expertise to integrate evidence into clinical practice in accordance with the patient's needs and preferences. In epistemic terms, both scientific and non-scientific knowledge are implied here, as necessary components of decision-making in EBP. Firstly, the clinical decision is based on scientific knowledge, i.e. research evidence and the criteria for assessment of this evidence. If such evidence is not available, the clinician makes use of non-scientific knowledge.[56] Secondly, the evidence is to be integrated into clinical practice at the point of patient care by the clinician and according to the patient's preferences and circumstances. Thus, the recommendations of interventions at the point of patient care require both scientific knowledge (of evidence and evidence appraisal) and use of additional, non-scientific sources of knowledge, such as the clinicians experience and knowledge of patient preferences and circumstances.

In the following analysis, I will differentiate between and discuss the different kinds of knowledge and beliefs inherent in the concept of EBP. In the previous analysis, I have referred to "scientific" and "non-scientific knowledge", which represent the main distinction I will address. Within this distinction, the three main elements of EBP – evidence, expertise and patient preferences and circumstances – will be analyzed, with regard to what each element entails, and how these elements interrelate.

2.4.1. "Scientific knowledge" and "non-scientific knowledge"

For the benefit of the following analysis, I define "scientific knowledge" in broad terms, as "propositional beliefs, justified through replicable systematic studies and/or by

[56] As I will discuss in 2.3.1. below, EBP models differ regarding inclusion of non-scientific evidence.

methodological principles". "Non-scientific knowledge", conversely, is defined as "belief justified by experience or skill, without any reference to methodology".

In clinical epidemiology and EBP literature, a belief that is deemed to be scientific knowledge may be referred to as "evidence" if that belief is justified through systematic studies which in turn are organized according to methodological principles. A belief that is considered scientific knowledge can also refer to propositions concerning assessments of evidence (e.g. claims concerning the quality of evidence), which are justified through methodological principles (e.g., criteria of internal and external validity).

On the other hand, non-scientific knowledge may refer to either propositional or procedural knowledge (cf. Fantl 2017). Propositional knowledge refers to true or false propositions relating to facts, whereas procedural knowledge refers to knowledge exercised in the performance of some task, manifested in the use of a skill (cf. Stanley & Williamson 2001).[57]

A belief is considered non-scientific propositional knowledge if it is based on experience, without any reference to methodology. For instance, a clinician may make a claim regarding the recommendation of a particular treatment option, based on the clinician's personal experience of the treatment's benefits, irrespective of research literature. When non-scientific knowledge are included in EBP as evidence, it refers to such non-scientific propositional knowledge. For instance, the clinician's personal experience about the treatment's benefits may be used as evidence for recommending that particular treatment.

Non-scientific knowledge may also be manifested through the use of a skill, exercised through practical procedures – as (non-scientific) procedural knowledge, e.g., through a

[57] These categories correspond to what Gilbert Ryle (1949) labels "knowing that" and "knowing-how", respectively.

clinician's know-how concerning how to communicate with the patient in an efficient manner. This clinician's claim of that "I know how to communicate with patients" will be justifiable on the basis of the clinician's ability to communicate with the patient.[58] As I will argue in 2.4.3.2. and its subsequent subsections, several features regarding clinical expertise refer to procedural knowledge.

2.4.2. Scientific knowledge in EBP

What characterizes scientific knowledge in EBP is to a large degree dependent on its clinical epidemiology framework. Thus, scientific knowledge typically, but not exhaustively, refers to three elements: (1) epidemiologic research methods; (2) the results provided from these research methods, typically referred to as "evidence" and (3) the criteria for assessing methods and research results. For instance, a recommendation for a particular intervention to an individual patient is based on scientific knowledge to the extent that the recommendation is justified on basis of some evidence generated from a particular research method (e.g., an RCT). Knowledge of the confidence attributed to that evidence is scientific to the extent that it is based on methodological criteria of validity (e.g. of internal and external validity).

EBP covers a broad field of health-care disciplines, directed at multiple different clinical scenarios. In the same manner as clinical epidemiology, EBP makes use of methods from statistics, psychology, the social sciences, economics, health policy, and so on. Both clinical epidemiology and EBP also includes traditional medical knowledge, such as pathophysiological principles, knowledge about disease and illnesses, etc. – mainly considered "background information". Such information is considered necessary for any clinical practice, e.g. for understanding and justifying physical findings when examining a

[58] In philosophical literature, this way of ascribing knowledge to abilities is labelled "the Ability Account of Knowledge-How" (cf. Fantl 2017), often attributed to Ryle (1949).

patient (see e.g., Guyatt 2015), but is does not support decisions-making directly (cf. Straus et al. 2011: 57). Often, this kind of information is in turn necessary for being able to answer "foreground questions", which refers to specific knowledge relevant to inform clinical decisions (i.e., clinical questions, directed at either therapy, prognosis or diagnosis; cf. 1.2. above).

In addition to the clinical questions of clinical epidemiology, EBP also includes clinical questions relating to "experience and meaning" (e.g. in Straus et al. 2011: 18). This kind of clinical questions refer to scientific knowledge provided from qualitative research. For example, there are instances when clinicians need qualitative research to provide some guidance in deciding whether or not the findings from quantitative studies can be applied to their patients.[59]

Further, every procedural step of EBP (cf. 2.2.2. EBP as a process) is to be considered representative of scientific knowledge in EBP. Even in the hypothetical case that there is no evidence available, a clinical practice is still considered evidence-based to the extent that it is justified by methodological principles. Thus, the very practice of becoming aware of the fact that there is no evidence (by attempting to access evidence according to EBP methodology) would in itself be evidence-based. This demonstrates how the processual steps within EBP constitute a kind of scientific knowledge, regardless of the research evidence – or more accurately, due to methodological knowledge of lack of evidence.

[59] Qualitative research is designed for describing, exploring, and explaining the phenomena being studied (cf. Cullum et al. 2008: 53), answering clinical questions concerning "What is it", "How is it experienced?". For instance, phenomenological studies may provide information about experiences of families towards aggressive behavior by a relative who is affected by dementia (cf. Straus et al. 2011: 110f).

Qualitative methods are additions to the clinical methods in clinical epidemiology (cf. 2.4.2. above). Such methods are mainly oriented towards the process, and not the outcome of clinical interventions (cf. Cullum et al. 2008: ibid.). However, it is important to note that answering such questions is supplemental to application of evidence (see e.g. Straus et al. 2011: 110f), and does not change the primary aim of EBP towards application of outcome-based research.

Conducting the steps of the EBP process is thus representative of scientific knowledge acquisition.[60]

Scientific knowledge in EBP is typically associated with "evidence", i.e. the results of some scientific research, most typically generated from outcome-based research, to be used as a basis for determining whether an intervention is effective or not. However, no EBP model excludes non-epidemiologic evidence sources. As mentioned, EBP covers a broad field of health-care disciplines, directed at multiple different clinical scenarios. These scenarios may create clinical questions of which epidemiologic evidence sources, or any scientific sources, are not always sufficient or available.

Thus, EBP exhibits a broader scope of evidence than in clinical epidemiology. Following Guyatt et al, EBP includes a broad definition of evidence:

> [a]ny empirical observation or report of a symptom or mental state constitutes evidence, whether systematically collected or not. Thus, the unsystematic observations of individual clinicians constitute a source of evidence, a patient's report of feeling tiredness or pain would represent a second feature of evidence, physiologic experiments constitute another source, and clinical trial results constitute a fourth. (Guyatt et al 2015: 16)[61]

As such, evidence refers to any empirical ground for a belief: In this view, even a singular unsystematic observation of a phenomenon would constitute evidential belief. This points

[60] This theoretical argument is inspired by a personal conversation with Per Olav Vandvik, a Norwegian EBP proponent and student of Guyatt. My question concerned whether an EBP practice is considered evidence-based, even in cases where no research evidence is identified. In response, Vandvik claimed that the EBP clinician would have to start by following step 1 and 2 of the EBP process (i.e. formulating answerable questions and search for research-data related to this question). Thus, by following these steps, the very practice of becoming aware that there is no evidence, would itself be based on evidence-based principles.

[61] The definition of evidence put forward by Guyatt et al. may also be paraphrased according to the relational concept of evidence (cf. 1.3.1. above), as "any empirical observation or report of a symptom or mental state constitutes evidence, whether systematically collected or not, to the extent it affects the belief, directly or indirectly, in a hypothesis about that a certain intervention is clinically effective".

to a very broad and pragmatic orientation toward evidence, in principle regardless of whether the evidence is representative of scientific knowledge.

However, not every model of EBP is congruent with this broad conception of evidence. While any EBP model includes non-epidemiologic evidence, there are several models that do not include non-scientific knowledge as evidence. For instance, Herbert et al. state that "In our view, practice can only be evidence-based when it uses high quality evidence clinical research" (Herbert et al. 2005: 2). In effect, such a view on evidence will only accept evidence sources ranked high up in any hierarchy as the best available evidence. A similar view can be found in *evidence-based medicine – how to practice and teach it* (Straus et al. 2011): "Expertise is essential in authoring recommendations for clinical care, but it is not enough to ensure that the recommendations are also "evidence-based"."

At the other extremity, Djulbegovic et al. offer an even broader view on evidence, allowing

> [t]he use of *private evidence* (i.e., a unique patient's experience, pain, etc.) that is not accessible to multiple individuals although it still requires that elicitation of that evidence be reproducible". (Djulbegovic et al. 2009:165)

While it may be controversial to include a patient's experiences as evidence, the requirement of reproducibility suggests that it is viewed – at least potentially – as scientific knowledge.

Regardless of their epistemic origins, all evidence-sources are still assessed, according to clinical epidemiology principles – representative of scientific knowledge. According to the hierarchical ranking of evidence, EBP also exhibits the same preference for outcome-based experimental methods (when available in clinical practice), justified through methodological principles of validity.

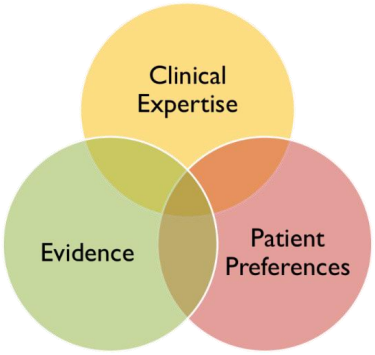
In the following analyses, both of EBP and the EBP debate, "evidence" will be used in the sense of Guyatt's broad definition. The stance on evidence in EBP is thus to be regarded

as the “best available evidence” through a continuum of evidence sources, with systematic reviews of RCTs on the one end of the scale and clinical expertise on the other. While the specific sources of evidence may represent scientific and non-scientific knowledge, the criteria for assessing evidence – i.e. for differentiating between and ranking of different evidence sources with regard to their quality and strength – is based on scientific knowledge.

2.4.3. Non-scientific knowledge in EBP

The term «evidence-based» can be misleading in that it may imply that all clinical practice must be conducted solely on the basis of evidence; that is, exclusively based on scientific knowledge. The usual way of presenting EBP, in accordance with the definition suggested in 2.2.5., is to identify its three necessary components: evidence, clinical experience, and patient preferences and circumstances. All three elements have to be present to validate the applicability of evidence to the patient at hand.

In the EBP literature, variations of these three elements are often depicted in Venn diagrams, illustrating their interdependent relationship, where the practice of EBP occurs at the point where the elements intersect:



(Garcia 2018)

The integration of the three elements should be done in cooperation between the clinician and the patient. The actual clinical decision is thereby made by the clinician, on the basis of evidence, informed by the patient, and finally integrated[62] into clinical practice through the expertise of the clinician. Thus, the point of intersection is enabled by the clinician and her expertise.

Evidence is examined above, as an element of scientific knowledge (cf. section 2.4.2.). Clinical expertise and patient's values and circumstances represent non-scientific elements. I will examine the latter element – patient's values and circumstances – below. In section 2.4.3.2., I will present an analysis of clinical expertise.

2.4.3.1. Patient preferences and circumstances

A typical criticism of EBP is that it minimizes or ignores patient values and preferences (see Chapter 3 for a discussion of this and other kinds of criticism). While it is true that the earliest official EBP definition did not explicitly mention patient preferences (Guyatt et al. 1992), the texts presenting the definition have nonetheless made essential references to the patient. In this text, the underlying main goal of EBP is directly related to the patient: "The proof of the pudding of evidence-based medicine lies in whether patients cared for in this fashion enjoy better health" (ibid., 2424). Later descriptions of EBP express similar

[62] Although "integration" is an often-used term in the EBP literature, there are few clarifying descriptions of it. I concur with Howick (2011) that "integration" in this context is to be understood as a particular kind of "clinical expertise". As a consequence of this, Howick suggests that the definition of EBP offered by Straus et al. (2011) should be changed from "Evidence based medicine requires the integration of the best research evidence with our clinical expertise and our patient's unique values and circumstances" to "EBP requires clinical expertise to integrate the best research evidence with patient values and circumstances" (Howick 2011: 177).

remarks, such as in Straus et al., 2011: 22) stating that patients serve as the starting point for any practice and teaching of EBP.

Patient's preferences and circumstances constitute necessary parts of the decision-making process and concerns, belonging to the non-scientific aspects of EBP decision-making.[63] To maintain systematic adequacy, I will discuss patient preferences and patient circumstances separately.

- **Patient preferences**

In the EBP literature, as well as in the suggested definition of EBP above (cf. section 2.2.5.) knowledge concerning the patient is expressed in relation to the patient's "preferences" and "circumstances". According to Guyatt et al., "patient preferences" refers to

> "The relative value on various health states. Preferences are determined by values, beliefs, and attitudes that patients bring to bear in considering what they will gain – or lose – as a result of a management decision." (Guyatt et al. 2015: 666).

Patient preferences, then, are the sum of the patient's beliefs and attitudes relevant to the clinical encounter with the clinician. The attitudes of the patient involve subjective experiences and value-judgments with regard to what the patient considers desirable or undesirable (cf. Warren et al. 2010). Based on their preferences, patients may override recommendations of clinical interventions. For instance, patients can choose alternative treatments, refuse treatment, and seek second opinions (cf. Cullum et al. 2008: 13).

[63] Of course, the patient can possess justified true beliefs about her condition as well. To the extent that the patient's beliefs are provided by scientific data, these beliefs are justified as scientific knowledge. Cullum et al. note that, due to an increasing degree of access to clinical information, some patients (particularly patients with chronic conditions), often gain more knowledge about their condition than the clinician (cf. Cullum et al. 2008: 13). In the clinical encounter, knowledge possessed by the patient may be expressed, and in any case interpreted by the clinician, with reference to the patient's preferences.

- **“Patient circumstances”**

“Patient circumstances” include two distinct elements: the clinical state of the individual patient, and the clinical setting” (cf. Straus et al. 2011: 1). The patient’s clinical state is the object of which the clinician aims to improve, first by identifying it (through a diagnosis) and then by acting upon it, e.g., by recommending a certain therapeutic course of action, justified by valid evidence considered applicable to both patient preferences and circumstances.

The clinical setting – as the second element of patient circumstances – refers to any external contextual factor, such as limited availability of evidence-sources, medicaments, technology, equipment, or economical limitations. These factors are also included as elements that the clinician has to integrate to consider whether a particular evidence source should be applied in clinical practice.

- **“Knowledge concerning patient preferences and circumstances” in the EBP process**

Together, patient preferences and circumstances pervade every step of the EBP process: The generation of clinical questions (step 1) depends on information interpreted by the clinician concerning the patient’s clinical state and preferences. Identifying the best evidence (step 2) depends on circumstances in the clinical setting – e.g., regarding accessibility of evidence through electronic data-bases. Critical appraisal (step 3) of external validity is dependent on similarities between the test-population and the individual patient (e.g., similarities between inclusion- and exclusion-criteria of the test-subjects in a research study compared with the patient). Integrating the evidence (step 4) entails consideration of whether the recommendation of a particular intervention is preferred by the patient, based on patient preferences, and of whether the surrounding

clinical setting provides the necessary requirements (e.g. with regard to availability of medicaments and equipment). The evaluation of the effectiveness and efficiency in the execution of the previous steps of decision-making (step 5), is directly dependent on whether the clinical decisions conducted through the previous steps led to better outcomes in the clinical care provided for the individual patient.

Epistemologically speaking, knowledge about patient preferences and circumstances concerns how the patient, informed by the EBP clinician, values the content and possible consequences of treatment options. It is thus a necessary part of the decision-making process, belonging to the non-scientific aspects of clinical decision-making.

In the EBP definition suggested in section 2.3.5. above, and in line with most other EBP definitions (e.g., in Straus et al. 2011), patient preferences and circumstances are included as the objects with which every other step of the EBP process must be "in accordance". In this definition, the EBP clinician, by making use of clinical experience, identifies, assesses and applies the evidence – "in accordance with patient preferences and circumstances". What does this entail?

Patient preferences and circumstances are integrated into clinical decision-making by virtue of the clinician's knowledge, based on professional knowledge of the patient's preferences and circumstances. This means that, in order to enable such an integration, the knowledge, beliefs, and attitudes of the patient have to be interpreted by the clinician as explicit preferences regarding the clinical decision (e.g., the patient's preference for one treatment option A over option B).[64]

[64] This is also the case when the patient willfully overrides recommendations of clinical interventions, e.g. by declining treatment. In such cases, the clinician may attempt to convince the patient to decide otherwise – based on an interpretation of the patient's attitudes and claims. If this does not change the patient's decision, the patient is responsible for the decision, in turn interpreted by the clinician and integrated into clinical practice, e.g. by recommending an alternative treatment, or no treatment.

Thus, “patient preferences and circumstances” refers not only to the patient, but also to the EBP clinician’s understanding of and responsibility for the patient‘s knowledge, subjective experiences, and attitudes, as well as of the external circumstances that may affect the clinical decision-making. This has to do with the clinician’s clinical expertise, which I will turn to in the following section.

2.4.3.2. Clinical expertise in EBP

As Howick (2011: 160) notes, “clinical expertise” in EBP is an ambiguous term. In EBP literature, “clinical expertise” is used in several different ways, fulfilling different roles within the practice of clinical decision-making. However, the various roles of expertise are expressed with varying clarity. I will claim that all of these roles must be considered necessary elements of the model.

Clinical expertise refers to non-scientific knowledge. Following the categorization of the two kinds of non-scientific knowledge above (2.4.2.), clinical expertise can be categorized in two main kinds of knowledge, described in 2.3 above: (1) propositional knowledge and (2) procedural knowledge. Examples of expert propositional knowledge are (1) claims about that a therapy is effective for an individual, based on judgments of the clinical situation (cf. Howick 2011: 160); and (2) beliefs about the features that may affect the applicability of research results to an individual patient. Examples of expert procedural knowledge are (3) the ability to elicit patient values and preferences (cf. ibid.), and (4) the ability to perform a surgical operation. In the following subsections, differentiation between propositional and procedural knowledge will demonstrate important nuances when examining “clinical expertise” in the EBP literature.

2.4.3.2.1. "Clinical expertise" in the EBP literature

"Clinical expertise", as defined in standard EBP literature, is typically and implicitly linked with procedural knowledge exclusively. In the EBP literature, "clinical expertise" is typically referred to as the ability to integrate evidence with patient preferences and circumstances, and the abilities necessary to perform specific clinical tasks (e.g. ibid; Straus et al 2011). For instance, Brian Haynes describes "clinical expertise" as:

> [t]he general basic skills of clinical practice as well as the experience of the individual practitioner. Clinical expertise must encompass and balance the patient's clinical state and circumstances, relevant research evidence, and the patient's preferences and actions if a successful and satisfying result is to occur". (Haynes 2002: 37)

In this description, expertise is presented as a "basic skill", referring to what was labelled "procedural knowledge" in section 2.4.1. above. The requirement that expertise has to "encompass" (which refers synonymously to "integrate") the other elements of the EBP definition (evidence, patient preferences, and circumstances) also refers to this kind of procedural knowledge – as something which is exercised rather than claimed.

Straus et al. 2011 defines "Clinical expertise" in a similar way, as an ability:

> By *clinical expertise* we mean the ability to use our clinical skills and past experience to rapidly identify each patient's unique health state and diagnosis, their individual risks and benefits of potential interventions, and their personal values and expectations. (Straus et al. 2011: 1)

Notably, "clinical expertise" is presented here as "an ability to use a skill", making the description of expertise more complex. The differentiation between "ability" and "skill" may serve as a demonstration of the difference between "clinical expertise" and "clinical experience".

"Clinical expertise" is referred to as a certain *ability* to use "clinical skills and past experience", and through this use *identify* relevant health care matters related to the

patient. What are "clinical skills" in this context, and how do they differ from "skills" in general? Straus et al. state that "clinical skills" include "history-taking, and physical examination" (ibid., xv). Skills are also mentioned as relating to "seeking and appraising evidence" (ibid., 7), "asking [research] questions", as well as "listening skills" (ibid., 22), searching skills (ibid., 213), and "discrete "microskills", such as conducting a MEDLINE search or a critical appraisal (ibid., 214). In general, "clinical skills" are related to the skills the EBP clinician is able to perform, on the basis of his or her health care professional education and training.[65]

The focus, however, is not on the use of "clinical skills" or "past experience" as such, but on the "ability" to use these skills. The difference between "skill" and "ability" can serve as basis for differentiating between "skills" in general and "expert abilities": The *use* of clinical skills is something any clinician is capable of doing, but what separates the clinical novice from the clinical expert is the *ability* to use these skills in an efficient manner (i.e., "to rapidly identify" relevant health issues pertaining to her patients). The same goes for the ability to make use of "past experience", where the clinician is able to make use of her experience in an efficient manner (whereas the clinical novice is likely to overlook or rely too much on such experience).[66] An example of this can be drawn from the wording of the definition: "to rapidly identify each patient's unique health state and diagnosis" – a phrase that seems to suggest a differentiation between the "clinical expert" and "clinical novice"

[65] In contrast, "skills" in general refer to any skill regardless of its relevance to EBP practice. Based on this basic difference, it seems appropriate to include "specific skills necessary in EBP practice". In recent EBP literature, this is suggested in descriptions of "core competencies in EBP. See also footnote 29.

[66] Straus et al. tend to present "expertise", "skills" and "abilities" in an unnecessarily complicated manner, not always inherently consistent. This is the case when they add "judgment" to the description, complicating matters even further. Judgment is described as an ability "[a]bout evidence itself or about how to integrate evidence with other knowledge, clinical expertise and patient preferences and circumstances" (ibid., 227). Here, judgment is situated external to expertise. The ability to integrate evidence with patient preferences into a clinical practice, then, is not based on the skill of "clinical expertise" itself but on "judgment". Elsewhere, "judgment" means to integrate evidence "*via* the practitioner's experience and expertise" (ibid., 35), contradicting the former description. These terminological nuances are less relevant to the present analysis, and I will not examine them any further.

through the rationale that identification of relevant matters is made more "rapidly", and presumably on a more experienced basis, by the expert than the novice.

The clinical expert's skills and abilities refer exclusively to what I have described as procedural knowledge, meaning knowledge exercised in the performance of some task (cf. 2.4.1.). Conversely, the definition presented by Straus et al. makes no reference to any kind of propositional knowledge of the clinical expert.[67] In principle, this is problematic, in particular with regard to evidence that has to be expressed in some manner. Even when "tacit" or "private" beliefs based on "hunches" is included as evidence (e.g. by Greenhalgh 1999), it has to be articulated and is thereby propositional knowledge. In defence of Straus et al., the lack of reference to propositional knowledge in the definition is in line with their exclusion of non-scientific evidence sources (cf. 2.4.2. above). However, as I will discuss below, there are several other instances when practicing EBP that require the use of propositional knowledge.

2.4.3.2.2. Five kinds of expertise in EBP

Expertise in EBP can be subdivided into five distinct roles (cf. Howick 2011: 160).

(1) General clinical expertise: personal judgments pertaining to the putative average effects of a therapy.

(2) Individual clinical expertise: personal judgment about the effectiveness of a therapy for an individual.

[67] Recently, Straus and others (Albarqouni et al. 2018) have presented a significantly broader description of skills and beliefs – described as "core competencies" – in EBP. "Competencies" are defined as "a combination of attributes, such as applied knowledge, skills and attitudes, that enable an individual to perform a set of tasks to an appropriate standard efficiently and effectively" (ibid, 2). The paper presents a total of 68 competencies considered necessary for standard clinical practice and sorts these competencies according to the five steps of the EBP process. Most of these competencies implicitly refer to propositional scientific knowledge.

(3) Integrating expertise: knowledge of how the best evidence can be integrated with patient values and circumstances.

(4) Therapeutic expertise: Knowledge of how to amplify the potential therapeutic benefit of an intervention.

(5) Performative clinical expertise: Abilities to solve various tasks involved in the clinical encounter.[68]

The main differences between the five notions of "expertise" are between (1)–(2) and (3)–(5). (1) and (2) are concerned with assessment of the putative effects of some therapy, based on clinical judgment alone (e.g. based on experiences from one's own clinical practice) and can be considered as evidential support for claims about treatment effectiveness (to the extent the particular EBP model includes non-scientific evidence).

Expertise referring to (3) (4) and (5) is not applicable as evidential support and involves tacit knowledge (cf. Howick 160). Instead, these kinds of expertise are to be considered necessary in any practical performance in EBP. "Integrating expertise" refers to the experiences and abilities needed to integrate evidence with patient preferences and circumstances. For instance, a nurse, using her clinical expertise, may override research evidence indicating that a certain intervention is optimal, if, for example, the patient is too frail to undergo the suggested intervention (cf. Cullum et al. 2008: 13).

"Therapeutic expertise" concerns experiences and abilities to improve benefits.[69] Examples of such expertise include procedural knowledge of how to enhance placebo effects (cf. Howick 2011), and of how to communicate empathically with the patient to

[68] This list is a slightly modified model of "[f]ive distinct roles for clinical expertise in EBM", by Howick (2011: 160). Howick refers to the first two kinds as "judgments" (without distinguishing it clearly from "expertise"). What I label "(5) Performative clinical expertise", Howick describes as "clinical expertise», presumably implying that this is what the term typically refers to.

[69] This means benefits other than benefits measured through outcome-based research – the latter refers to claims or empirical observations supported by scientific knowledge.

reduce a patient's anxiety due to uncertainty concerning treatment options (cf. Howick et al., 2018).

"Performative clinical expertise" refers to propositional knowledge that is manifested through the use of particular skills, e.g., the ability to recognize symptoms, elucidate signs, take blood pressure and perform a surgical operation.

None of these five kinds of clinical expertise are controversial. On the contrary, they are universal to any health practice. The most important point in the analysis of different kinds of expertise is that all these are necessary elements in the multiple ways in which EBP practice may be performed.

Further examination of the non-evidential kinds of knowledge would be an interesting topic to explore but falls outside the aim of this PhD dissertation. Instead, I will end this section on non-scientific knowledge with a brief discussion of clinical expertise as evidential knowledge.

2.4.3.2.3. Clinical expertise as evidential knowledge

As discussed in 2.4.2. above, EBP entails a broad definition of evidence, as "any empirical observation about the apparent relation between events constitutes potential evidence". In general, then, evidence refers to any empirically based claim that is able to serve as justification for beliefs in that a particular course of clinical action improves clinical performance. When scientific evidence is not available, most[70] EBP proponents view clinical expertise as an adequate replacement: it would be inefficient in EBP clinical practice to deny the use of clinical expertise in principle whenever other kinds of scientific evidence were lacking. On the other hand, expert knowledge as evidence should never trump any other sources of evidence: In any actual clinical scenario, evidence from

[70] But see 2.4.1. for exceptions to this view.

systematic scientific research (whenever available) is considered superior to the use of expertise as evidential knowledge.

As noted in section 2.4.2, some EBP proponents also allow reference to the patient's unique preferences (e.g. experiences of pain) as evidence. For instance, a patient's complaint of serious chest pain can be applied by the clinician as evidence for recommending an alternative treatment option rather than the intervention that would otherwise be considered the best option. The patient's statement may also be used as evidence that additional information is needed before formulating the clinical question at the beginning of the decision-making process.

2.4.4. Concepts of EBP

Based on the possible combinations of scientific and non-scientific dimensions of knowledge, it is theoretically possible to differentiate between at least three different versions of the concept of EBP. I will conclude this section on the structuring of knowledge in EBP by identifying the three variants in which the EBP model can be interpreted: "Moderate", "maximal", and "minimal" EBP.

Moderate EBP is by far the most reasonable version, in which clinical decision-making is based on scientific research and methods whenever possible, and in which non-scientific knowledge is considered necessary as an additional element when implementing evidence into practice. In the EBP debate, most proponents and opponents of EBP tend to represent this moderate concept of EBP. I will address the moderate concept of EBP in more detail at the conclusion of this section.

At both extremes of the moderate concept of EBP, theoretical EBP concepts can be constructed. At the one extremity, a minimal concept of EBP cab be identified, in which non-scientific knowledge must be considered external to the model, subordinating EBP to

clinical epidemiology. At the other extremity, it is possible to include "maximal EBP", in which clinical expertise is considered superior to scientific knowledge, and thus is able to override evidence at any time during the clinical decision-making process.

I consider the concept of "maximal EBP" as an extremity of no relevance to the actual EBP debate. The minimal concept is also an extremity, and it seems unreasonable to attribute such an interpretation to any author in the EBP debate. However, there are certain descriptions of EBP in parts of the literature that may be said to be tangent to such an interpretation. In most cases, I do not consider it reasonable to equate these interpretations with what the authors actually intend.[71] Instead, my aim is to demonstrate how different descriptions of EBP can be problematic when interpreted in light of the possible combinations of scientific and non-scientific dimensions of knowledge.

A minimal description of EBP is already implied in the discussion of Daly above (2.3.4), with regard to one interpretation of the description of EBP as representing "an important initiative in providing scientific evidence for clinical decision-making" (cf. Daly: 2005: 205). According to this interpretation, EBP is about providing evidence relevant to clinical decision-making but does not include elements from the decision-making process in its concept. Consequently, both clinical expertise and patient preferences are excluded from the concept of EBP.[72]

A typical minimal concept of EBP consists of understanding EBP as synonymous with or subordinate to clinical epidemiology. An example of such a view may be found in Fletcher et al. 2014, who view EBP as a sub-category of clinical epidemiology and describe it as "a modern term for the application of clinical epidemiology to the care of patients" (Fletcher et al., 2014: 4f). A similar view is often presented by critics of EBP; for instance by Miles

[71] However, as I will discuss in Chapter 4, there are certain theoretical conceptions in the Norwegian criticism that seem to imply a minimal concept of EBP.

[72] Notably, this interpretation contrasts with the second interpretation of Daly's description (as presented in section 2.3.4. above), which I find more reasonable.

(2009a), who criticizes EBP's narrow scope by asserting that "EBP remains, simply, the application of epidemiological data to clinical practice, nothing less and certainly nothing more" (Miles 2009a: 928).

One could argue that both Fletcher et al. and Miles open for "moderate EBP" when using the term "application of" clinical epidemiology and epidemiologic data: When epidemiologic evidence is "applied", clinical expertise is implied as a necessary element. But "application" in their descriptions is not specified with regard to whether it is based on clinical epidemiology principles alone, or is understood in accordance with EBPs extension to practice (cf. section 2.2). According to the definition of "clinical epidemiology" in 1.1.4., "application of evidence" refers to evidence assessments exclusively in terms of internal and external validity, regardless of patient preferences and circumstances in the actual decision-making at the point of care. In this case, the external validity would consist in questions about generalizability of the (average) research result to another population and applicability, without any judgments concerning unique patient preferences and circumstances (cf. 2.2. above). In this context, I am interpreting "application" in a very restricted, perhaps unreasonable way, and I do not think that Daly, Fletcher et al. or Miles would agree with me. If asserting agreement, however, they would have to specify how and to what extent "application of evidence" moves beyond the framework of clinical epidemiology.

A third example, in my view, is more reasonable. This interpretation derives from Greenhalgh's description of EBP:

> "Evidence-based medicine is the use of mathematical estimates of the risk of benefit and harm, derived from high-quality research on population samples [that is, epidemiology], to inform clinical decision-making in the diagnosis, investigation or management of individual patients. The defining feature of EBP, then, is the use of figures derived from research on populations to inform decisions about individuals." (Greenhalgh 2010: 1)

Through such a definition, EBP is understood exclusively based on principles of clinical epidemiology, that is, on scientific knowledge. Thus, neither the patient's values nor clinical expertise are included in the concept of EBP. Greenhalgh seems to imply that the practical extension of EBP (which differentiates it from clinical epidemiology in the first place; cf. 2.2.) is not inherent in the concept at all. Instead, non-scientific knowledge is included in what Greenhalgh labels "narrative-based" knowledge:

> […] Dave Sackett emphasized that evidence-based practice was no threat to old-fashioned clinical experience or judgment. The question of *how* clinicians can manage to be both 'evidence-based' (i.e. systematically informing their decisions by research evidence) and narrative-based (i.e. embodying all the richness of their accumulated clinical anecdotes and treating each patient's problem as a unique story rather than a 'case of X') is a difficult one to address philosophically […]. (Greenhalgh 2010: 5f)

In Greenhalgh's terminology, "narrative-based" seems fully comparable to what is described above as the extension to practice, in which the clinician has to make use of clinical expertise to be able to assess and integrate evidence into the clinical situation according to the patient's preferences and circumstances. In effect, Greenhalgh's distinction between "evidence-based" and "narrative-based" implies that any use of non-scientific knowledge is exterior to the concept of EBP. Through such a position, it is difficult to understand how non-scientific knowledge is to be related to scientific knowledge at all, leaving EBP as a scientific rigorous, though practical vague concept. While my interpretations of Daly, Fletcher et al. and Miles are arguably weak, I find it difficult to interpret the quotes from Greenhalgh in any other way.

2.4.4.1. A moderate concept of EBP

In "moderate EBP", clinical decision-making is based on scientific research and methods whenever possible, and where non-scientific knowledge, such as expertise and patient

preferences, are considered necessary elements when applying evidence into clinical practice. In addition, if scientific knowledge is not available, clinical expertise may constitute evidence.

On basis of the previous analysis in this chapter, the moderate concept of EBP is not only most typical, but the only reasonable combination of scientific and non-scientific knowledge. Every EBP model and description I have referred to in this chapter – with the exception of Greenhalgh's version above – is representative of the moderate concept. Davidoff et al.'s (1995) "five linked ideas" (cf. 2.3.1. above) and Straus et al.'s (2011) process of EBP (cf. 2.3.2. above) may serve as typical examples. Guyatt et al.'s (2015) alternative model of the EBP process is also representative of a moderate concept of EBP, albeit to a lesser degree than Davidoff et al. and Straus et al., because the individual clinician's autonomy in performing EBP is limited in favour of following guidelines. Within this moderate concept of EBP, it is also possible to distinguish EBP models that include non-scientific knowledge as evidence (such as Guyatt et al 2015) from EBP models that do not (such as Straus et al. 2011 and Herbert et al. 2005).

The concept of EBP in Miles (2009a) may be interpreted as a moderate concept of EBP if "application of epidemiological data to clinical practice" (implicitly) refers to the non-scientific elements of the clinician's expertise and the patient's preferences. In this case, Miles' description would refer to a moderate concept of EBP, with a restrictive range of epidemiologic evidence sources.

It is reasonable to assume that differences within the moderate concept of EBP are a matter of professional differences: Some health care professions may have good reasons for including or excluding non-scientific knowledge as evidence, and equally good reasons for different degrees of confidence in the individual clinician's clinical expertise. However, these differences are in turn interpreted by EBP opponents, who may understand EBP as a more unified concept. Some opponents may also misinterpret a limited confidence in

individual expertise in favour of following guidelines as a function which in effect excludes clinical expertise completely. In the following analysis of the EBP debate (Chapters 3 and 4), I will demonstrate that such interpretations do occur.

2.5. Conclusion

The main aim of this chapter has been to clarify the concept of EBP, in particular by examining scientific and non-scientific kinds of knowledge. In 2.1., a brief history of the development of EBP demonstrated that an increasing recognition of different knowledge sources is an essential feature of EBP literature. In 2.2., the essential differences between clinical epidemiology and EBP were analysed through a discussion of what the extension to practice entails: At the point of care, the clinician has to integrate evidence into clinical practice according to the patient's preferences. At this point, the clinician is dependent on certain kinds of knowledge that are not provided through the clinical epidemiology framework.

In 2.3., EBP has been described in multiple, contiguous, ways where four core elements have been identified: (1) EBP can be described through certain "linked ideas" pertaining to the basis for clinical decision-making, whereof the attention to clinical (epidemiological) research evidence is the most controversial. (2) EBP can be understood as a process consisting of certain steps the clinician should undertake in order to practice evidence-based practice. The process of EBP is something that is either done, used or replicated, corresponding to the degree of the clinician's autonomy in assessing and using evidence in clinical practice. (3) EBP can be described as a principle of hierarchies, whereby evidence is ranked with regard to various criteria, mirroring the five processual steps of EBM. (4) EBP is also identified as a structure for decision-making, which constitutes the main aim of EBP.

In clinical decision-making, the use of evidence in EBP is not only a question of scientific knowledge but relates to non-scientific knowledge as well – in particular referring to knowledge concerning clinical expertise and patient preferences and circumstances. On the basis of these core elements, a five-partite definition of EBP was presented. Through

its extensive range, the definition identifies demarcating features with regard to its main aim of clinical decision-making, its controversial character and its dependence on both scientific and non-scientific knowledge.

In 2.4., the concept of EBP has been examined in more detail through the structuring between scientific and non-scientific knowledge in EBP. This examination demonstrates what kinds of knowledge are inherent in the concept of EBP. In particular, I have differentiated between scientific knowledge (research evidence) and non-scientific knowledge (clinical expertise and patient preferences). Based on the analysis of scientific knowledge, I suggested an interpretation of evidence in EBP as a continuum between "best available evidence" – typically consisting of RCTs – on the one extremity, and clinical expertise on the other. Non-scientific knowledge was further defined as either propositional or procedural knowledge. Both kinds of knowledge are necessary for EBP. Analyses of the EBP literature demonstrated that procedural knowledge is the most common when referring to expertise. However, five different kinds of clinical expertise were identified, with only one specific kind (performative clinical expertise) referring to procedural knowledge exclusively. Furthermore, some of these kinds of expert knowledge can also be applied as evidential knowledge. To the extent that non-scientific knowledge is included in EBP models, it is always ranked at the bottom of evidence hierarchies.

Based on the possible combinations of scientific and non-scientific dimensions of knowledge, I presented three different theoretical concepts of EBP: "Maximal", "minimal", and "moderate" EBP. The concepts differ relative to the extent to which non-scientific knowledge is taken into consideration. In light of the previous analyses, only moderate EBP is justifiable. However, I also discussed instances in the EBP discourse in which some descriptions tended to imply a minimal concept of EBP.

While non-scientific knowledge in general is both important and challenging, it is not unique, neither conceptually nor practically, to EBP. In any health care (and presumably

in any practical profession in general) where scientific knowledge is somehow involved, there will necessarily be a structural relation to non-scientific knowledge. In my view, the reason that this relation seems to occur more often in the EBP literature than in non-EBP literature, is that the discourse on evidence and the affinity to scientific vocabulary makes it more palpable, and not more controversial or problematic than in non-EBP practice.

Based on these considerations, I will conclude the examination of EBP by highlighting its epistemic structure. In general, this structure of EBP is rather simple: EBP consists of three main elements – evidence, clinical experience, and patient's preferences. The first element represents scientific knowledge and the two latter represent non-scientific knowledge. Evidence refers most typically to scientific knowledge. In cases where such evidence is lacking, clinical experience is often allowed as non-scientific knowledge. There are several other important features in this tripartite structure, as discussed in the chapters above. The most important feature with regard to the following chapters, 3 and 4, on the EBP debate, is that both kinds of knowledge are equally necessary to the concept of EBP. In the following chapter, I will turn to an analysis of the EBP debate.

Chapter 3: Analysis of the EBP debate

3.1. Introduction

Since its inception in 1992, EBP has become highly influential in modern health care, with considerable impact in health care practice, education and policy-making. Proponents have disseminated literature on EBP through a vast number of textbooks, journals and websites. Although definitions and descriptions vary among different authors and across various professions, the core content of EBP is the same: to provide an adequate and efficient basis for clinical decision-making with regard to treatment options in individual health care by basing clinical decision-making on the best available evidence, assessed and applied by the clinician, in consultation with the patient (cf., section 2.2. above). The novel idea of this model is that the basis for decision-making is based on scientific evidence, provided through the scientific framework of clinical epidemiology (cf., Chapter 1).

The main attraction of the concept of EBP is that it enables identification of an effective treatment in a reliable way by using clear and concise criteria. However, the confidence in and the use of EBP are highly controversial matters. EBP has been the target of incessant criticism attacking various aspects of the EBP model. EBM proponents in turn have responded to some of the criticism, and these responses have then become subject to further criticism. The arguments by proponents and opponents for and against EBP comprise the EBP debate, which is the subject in this chapter.

While parts of the EBM debate provide nuanced and important points, other parts tend to be less sensitive, creating an over-simplified and superficial image of EBP, leading to neither a constructive debate nor a better understanding of the subject. Notably, these characteristics are commonly shared by proponents as well as opponents. Regarding the

opponents, the criticism has tended to be too narrow and one-tracked. In addition, many of the critical arguments are similar to one other, so that the quantity of contentions does not necessarily represent differentiated objections. In terms of the proponents, criticism is seldom met with adequate responses. When responses are given, the criticisms being refuted are typically labelled misconceptions, which in turn leads the EBM opponents to accuse proponents of arrogance and lack of critical rigour in the EBP debate. The main aim of Chapter 3 is to identify the main arguments against EBP and to discuss whether the arguments and claims raised are valid and relevant.

In the following analysis of the EBP debate, I will demonstrate that most criticisms can be categorized broadly within four main issues. I will also demonstrate that parts of the criticism present nuanced and important points, while other parts tend to be less sensitive to the EBP model. Such images of EBP are often over-simplified and superficial, creating straw-man fallacies about EBP, leading to neither a constructive debate nor a better understanding of the subject.

3.1.1. What is controversial in EBP?

In general, the EBP debate concerns a controversy about whether or not the EBP model provides an adequate basis for clinical decision-making. The essential controversial point here is the use of evidence from epidemiologic research in a clinical setting. In Chapter 1, I presented the reasons why epidemiologic, outcome-based data is considered the most reliable source of evidence for clinical interventions and listed the methodological features through which various kinds of evidence are assessed and viewed hierarchically in accordance with clinical epidemiology principles. In particular, randomized comparative studies are considered the best kinds of evidence available due to their ability to reduce the risk of bias, and thereby ensure high internal validity. Such studies aim at determining the effectiveness of clinical interventions in general, measured by the average effect of

interventions in groups of patients. To implement such results in the form of evidence to justify recommendations for or against clinical interventions in direct patient care, criteria of external validity are applied so as to assess the degree to which the evidence is to be considered useful in clinical practice. Both the view of outcome-based data as the most reliable evidence source and the degree to which such evidence is useful in clinical practice are controversial.

In Chapter 2, I demonstrated how EBP's extension to practice entails an expansion from the clinical epidemiology framework. This expansion consists in a broadening of the definition of evidence and includes two additional elements pertaining to non-scientific knowledge: the use of expertise and the attention to patient preferences and circumstances. Neither expertise nor patient preferences and circumstances are controversial by themselves. Rather, these elements become controversial when discussing the extent to which the use of expertise and patient preferences and circumstances are compatible with the methodological features of clinical epidemiology.

What is beyond controversy is the principle that health care practice should be based on some form of evidence. As John Worrall, a prominent critic of aspects concerning RCT's in EBP, states: "It is surely obvious that medicine, like any other rational activity, must be based on evidence. The interest is in the details" (2007: 1). The following examination of the critical arguments against EBM will proceed with the same motive – to look at the details in the criticism. I will identify the specific aspects of the EBP model that are addressed and will discuss the extent to which the specific kinds of criticism offer valid and relevant arguments with regard to deficiencies in the EBP model. I will also comment on cases where EBM proponents have responded to the criticism and examine whether these responses are adequate.

3.1.2. Four main kinds of criticism of EBP

A general observation concerning the EBP debate is that every kind of criticism raises claims that basic principles and concepts within the EBP model are too narrow or too unclear to provide an adequate basis for clinical decision-making. In my view, there are four main topics of criticism against EBP: the conceptual unclarity of EBP definitions (3.2); the scope and justification of evidence (3.3); the role of expertise (3.4); patient preferences and autonomy (3.5). In the following analysis of the EBP debate, various types of criticisms will be ordered under one of these four main topics.

The three latter topics of criticism are tightly interconnected, corresponding to the tripartite model of EBP, and sometimes conflated (cf. 3.3.2 below). Criticism concerning expertise and patient autonomy is seldom discussed without a particular view of EBP's view of evidence. Criticism regarding evidence is the most common kind, and this will be the subject of the most comprehensive analysis, comprising several subsections.

3.2. Criticism concerning conceptual unclarity of EBP definitions

Several critics point out that the EBP and EBM literature and definitions in general tend to be too general and uninformative (e.g., Blunt 2015; Ekeland 2009; Ekeli 2002; Martinsen 2009; Miles 2009a). A typical version of this kind of criticism is that the general definitions veil the essential content of EBP (e.g., Ekeli 2002; Martinsen 2009).[73] Some critics make this observation more aggressively than others. For instance, Miles (2009a) describes it as EBP's "enormously vague character", whereas Tonelli (2007) points to variations in different definitions and asserts that the "Humpty Dumpty character of EBM" entails that

[73] Ekeland 2009, Ekeli 2002, and Martinsen 2009 will be discussed in detail in Chapter 4, including examination of their criticism of the vague concept of EBP.

the term of EBM (and EBP) "[m]eans just what the speaker chooses it to mean, neither more nor less" (Tonelli 2007: 504).

In particular, critics stress the uninformative character of descriptions concerning clinical expertise. For instance, several critics (e.g., Blunt 2015: 15; Charlton and Miles (1998); Goldenberg 2006; Loughlin (2006); Miles (2009a; 2009b); Tonelli 2006; Zarkovich and Upshur 2002) have claimed that the phrase "[c]onscientious, explicit, and judicious use of current best evidence" found in the 1996 definition of EBM (Sackett et al. 1996: 71) is nothing more than a platitude.

I consider criticism regarding conceptual unclarity of EBP definitions as relevant. Ideally, there should be consensus on a singular standard definition of EBP, exhibiting necessary and sufficient requirements for a clinical practice to be evidence-based. The lack of such an operational definition makes the EBP debate unnecessarily imprecise at the outset.

However, criticism concerning this issue is seldom worked out in further detail, nor argued for. Instead, it may be read as an attitude towards conceptual clarification of what EBP really amounts to. Through this attitude, the critics identify and argue against what they consider to be untenable assumptions regarding the basis for clinical practice, in principle regardless of the definitions they make use of. It is the identification and contested content of these assumptions, along with the arguments made against them that constitute the essence of their criticism regarding evidence, expertise and patient preferences and circumstances in EBP – the content of which I will present in the remaining analysis of the criticism of EBP.

3.3. Criticism concerning evidence

Criticism regarding evidence in EBP primarily targets EBP's clinical epidemiology framework, i.e. the attention to and confidence in epidemiologic outcome-based methods and data. There are four aspects of this framework that critics address in particular. Firstly, they claim that the epidemiologic methods exclude other sources of evidence, so that what counts as evidence in EBP becomes too narrow in scope. Secondly, they criticize the justification of alleged superiority of RCTs – that is, the claim in EBP literature that data generated from RCTs is the most reliable (i.e. internally valid) source of evidence. Thirdly, they contend that the usefulness of epidemiologic evidence sources in clinical practice (i.e. concerning external validity) is limited. Fourthly, they claim that there is a lack of empirical evidence showing that epidemiologic methods produce better outcomes than other methods.

Criticisms of the second and third aspects are more nuanced and technical than the others. It should also be noted that criticism with regard to external and internal validity does not argue against the model of EBM as such. Rather, the main target in the criticism concerning external and external validity refers strictly speaking to the clinical epidemiology framework, and hence to the methodological presuppositions of EBP.

Across these four aspects, the EBP debate is characterized by a huge amount of attention to evidence hierarchies. Arguments, pro and con, concerning justification of evidence hierarchies address the issues of how and on what basis hierarchical ranking of evidence can or cannot be justified. Such arguments concern both the scope of hierarchies and the criteria for evidence quality in terms of external and internal validity, where critics attack the ranking of epidemiologic evidence – and of RCTs in particular – above other kinds of evidence. In the following discussion on criticism regarding evidence, arguments

concerning evidence hierarchies will be considered through the four main aspects of criticism.

Furthermore, there is a tendency in most criticism primarily to discuss evidence in EBP in relation to therapeutic questions. While therapeutic questions are important and likely represent the most typical topic in the EBP literature as well, these may lead to an unnecessarily narrow content and scope in the debate over EBP.

The following discussion of criticism regarding evidence in EBP encompasses four main claims: The scope of what counts as evidence is deemed to be too narrow (3.2.1.); the alleged superiority of RCTs (3.2.2); the usefulness of applying results from randomized comparative evidence sources in clinical practice is limited; (3.2.3); there is lack of empirical evidence that EBP methods produce better outcomes than non-EBP methods (3.2.4). These four claims are connected, but contain distinct features, with different lines of arguments. I will examine each of these issues in the following sections.

3.3.1. The scope of what counts as evidence is deemed to be too narrow

This kind of criticism is set forth in two variations: either by a categorical claim that the content of what counts as evidence is narrow, or by a conditional claim that, even though several kinds of evidence are potentially included in EBP, the criteria for assessing the quality of evidence are too reductive and restrictive, systematically favouring epidemiologic kinds of evidence over other kinds of evidence.

The categorical version is essentially a claim that only epidemiologic evidence sources constitute evidence in EBP (e.g. Miles 2009a). Sometimes the claim is expressed even more narrowly with the assertion that only randomized trials or systematic reviews constitute the evidence in EBP (e.g., Hampton 1997 and Swales 1999; cf. Straus &

McAlister 2000). As Strauss and McAlister (2000) point out, such criticism is based on a misperception of EBM/EBP.

While the more general categorical claim is theoretically justifiable in terms of a narrow concept of EBP (cf. 2.4.4.), it does not reflect the moderate concept of EBP, which is by far the most reasonable version (ibid.). Through a moderate concept of EBP, such a claim is swiftly dismissed by reference to the definition of "evidence" as "any empirical observation or report of a symptom or mental state constitutes evidence, whether systematically collected or not" (Guyatt et al: 2015: 16; see also 2.4.2. above), or by reference to most existing hierarchies, which include non-randomized evidence sources, such as case studies. Such interpretations also serve as a straw-man fallacy to further debates.[74] While such categorical claims are easily dismissed, the conditional claim is more sensitive to nuances in the model of EBP.

The conditional claim holds that evidence in EBP has a narrow scope in that it systematically favours epidemiologic kinds of evidence above other kinds of evidence sources. This is a more relevant kind of criticism in that it targets the essential controversial matters of EBP – the use of epidemiological evidence from clinical research.[75]

For instance, Miles (2009a) and Tonelli & Callahan (2001), and Tonelli (2007) claim that evidence in EBP (primarily in the context of EBM) is too narrowly defined through its clinical epidemiology framework, which in turn implies a limited methodology, systematically favouring epidemiologic evidence above other evidence sources (Bluhm

[74] An entertaining example of such a straw-man claim is that of Miles et al: "The EBM protagonists are dazzled scientists who set out to dazzle, rejoicing like aerobatic children vaulting through the statistical stratosphere, casting down meta-analyses and systematic reviews to clinicians below» (Miles et al.: 1997: 84). It should be unnecessary to point out that such descriptions of EBP proponents and methodological considerations are inaccurate, creating over-simplified depictions which are easy for other critics to refute.
[75] Critics presenting variations of this conditional claim most often express an awareness of the tripartite model of EBP and criticize the other elements of the model as well (cf. sections 3.3. and 3.4.).

2005, Blunt 2015, and La Caze 2008; 2009 have also contributed with highly relevant arguments to this kind of criticism). In the same vein, Upshur et al. (2001) and others also criticize EBP proponents for demonstrating an inappropriate reliance on epidemiology,[76] through EBPs assessment of any kind of evidence based on epidemiologic interpretation properties (i.e., internal and external validity). This is a relevant kind of criticism to which EBP proponents seldom respond.

Other critics, like Sturmberg (2009), goes further, arguing that the narrow methodology allows only for a few clinical problems to be solved. Such criticism seems to interpret evidence in EBP as able to address therapeutic questions only. As described in Chapter 1, epidemiologic methods are designed to answer clinical questions concerning diagnosis and prognosis, as well as therapy.

While both categorical and conditional claims about the narrow scope of evidence in EBP may be dismissed by referring to the aforementioned broad definition of "evidence", critics may respond that the matter is less clear-cut across the EBP literature, where descriptions of evidence are frequently narrower in scope.

In particular, many critics refer to a particular sentence from the textbook *Evidence-Based Medicine – how to practice and teach it*:

> If the study wasn't randomized, we'd suggest that you stop reading it and go on to the next article in your search. *(Note: We can begin to rapidly critically appraise article literature by scanning the abstract to determine if the study is randomized, if it isn't we can bin it*.). (Straus et al. 2011: 70 [italics in original])

[76] By "inappropriate reliance on epidemiology", some critics also refer to the exaggerated confidence in epidemiologic evidence, claiming that the alleged superiority of epidemiologic evidence is unwarranted. This kind of criticism addresses methodological problems regarding internal and external validity; these will be discussed in the following sections 3.3.2. and 3.3.3. below.

Such statements, critics claim, demonstrate the narrow scope of evidence provided through the EBP model (e.g., Borgerson 2009). However, most critics fail to notice that the quoted section does not account for evidence assessment in general but is restricted to assessment of therapy only. The book also accounts for assessment of diagnosis, prognosis, and aetiology as well, without an equally strong recommendation of randomized research.

Critics may still argue, of course, that the recommendation of randomized evidence pertaining to therapy is too narrow. There are, however, few critics who make such a claim. Tonelli takes a different route, arguing that "[i]t is time to remove evidence, both term and notion, from clinical decision making, for it no longer serves any useful purpose, if it ever did" (Tonelli 2009a: 320). Although EBP proponents consider non-evidential beliefs to be useful and indeed necessary to clinical decision-making (cf. Chapter 2.4.3), such a stance is explicitly in opposition to EBP's stance on evidence and serves more as a radical alternative to EBP than an argument against it.

Perhaps the most usual line of criticism claiming that the scope of evidence in EBP is narrow are the arguments targeting evidence hierarchies. Indeed, most critics of EBM seem to characterize EBM's scope of evidence by describing one or more hierarchies, and thereby discuss the scope of evidence in EBP according to how it is demonstrated through evidence hierarchies. The Grade Hierarchy – such as it is described in Chapter 1 above – is one of the hierarchies that is typically addressed.[77]

When examining criticism of hierarchies, it is important to recall what the main function of hierarchies in EBP is and is not. As stated in chapter 1.4.3., hierarchies are systems that classify and organize types of evidence sources according to criteria for assessing the

[77] Other hierarchies often referred to in the EBM debate are the levels of evidence (Canadian task force 1979) and the 6S-pyramid (Straus et al. 2011). See sections 1.4.3. and 2.3.3. respectively for descriptions of these.

quality of evidence (cf. Djulbegovic & Guyatt 2017). Hierarchies are thus tools for assessing the quality of certain kinds of evidence, relative to each other. Hierarchies are not intended to replace the other components of the EBP model, but rather to complement the EBP clinician's assessment of evidence. Following this, when discussing the usefulness of hierarchies, it must be said that hierarchies provide only initial information, in terms of internal and external validity, while the complete assessment of usefulness of the evidence requires the clinician to consider the clinical context and the patient's preferences (cf. 2.2). For instance, if the study to be used exhibits poor quality according to a down-grading in GRADE relative to internal or external validity, it will necessarily have poor usefulness in the actual clinical decision-making. If the study exhibits sufficient quality, the clinician will then consider its usefulness in line with the individual patient's preferences. This demonstrates that assessments of evidence in clinical practice cannot be discussed based on hierarchical principles alone, contrary to the approach that critics often take.

When discussing hierarchies, critics also tend to speak of "*the* hierarchy", when they are actually referring to different hierarchies, differing in various ways (e.g., Sackett's "levels of evidence", and Guyatt et al.'s GRADE hierarchy; cf., section 1.4.3. above). In addition to there being different hierarchies for different clinical questions, there are also different interpretative assumptions in different hierarchies, in particular concerning the difference between categorical and conditional hierarchies (cf. ibid.). However, the main principle of hierarchies remains the same and is the main concern for the analysis below: evidence from certain kinds of research is ranked higher than other kinds. In GRADE hierarchies, this ranking is based on two interpretation properties of the evidence – its internal and external validity. In hierarchies concerning therapeutic questions, which is the topic for most of the debate, epidemiologic research is ranked higher than other kinds of data, with randomized research data on top.

The claim that evidence hierarchies represent a too narrow scope of evidence imply the following interpretation: EBP hierarchies only allow certain kinds of evidence, i.e. epidemiologic data, to count in clinical decision-making. The justification of such claims depends on which particular hierarchy critics are referring to.[78]

This claim is not justified if one refers to hierarchies in general, which mirror the broad definition of "evidence" in EBP and which in principle include any empirical and systematic observation (cf. Guyatt et al. 2015: 11; see also section 2.4.2 above). The "hierarchy of evidence" in the *User's Guides* (2015: 11), demonstrates this, with a depiction of N'of-1 clinical trial on top, followed by RCTs, observational-studies, basic research, and clinical experience ranked at bottom. On the other hand, the criticism is justifiable when referring to the GRADE hierarchy in the same *User's Guides*, which represents "[a] more sophisticated framework" (ibid.) than the hierarchy of evidence just mentioned.

Both versions are presented by Djulbegovic & Guyatt 2017, where GRADE (on the right side of the figure) is depicted as including randomized and observational studies exclusively, in stark contrast to the far more inclusive "traditional" hierarchy (placed on left side of the figure):

[78] An interesting variation of the criticism concerning the narrow scope of evidence in hierarchies is that the principles of evidence hierarchies do not acknowledge the intimate relationships between different kinds of research. For instance, Bluhm argues that this intimate relation is ignored when bench research (e.g., physiological studies) is placed near the bottom and clinical research is placed at the top of most hierarchies (Bluhm 2005: 537f). I consider this argument very interesting in that it identifies an aspect that is under-communicated in most EBP literature. However, EBP proponents could respond by claiming that bench research is included as a necessary element of EBP practice (i.e., as background knowledge"), but refers to a kind of evidence source that is inherently sub-optimal with regard to both risk of bias, and to the specific knowledge relevant to inform clinical decisions (i.e., foreground knowledge), and is thus placed hierarchically lower than other kinds of evidence sources. ("Background" and "foreground" knowledge is discussed briefly in 2.4.2. above.)

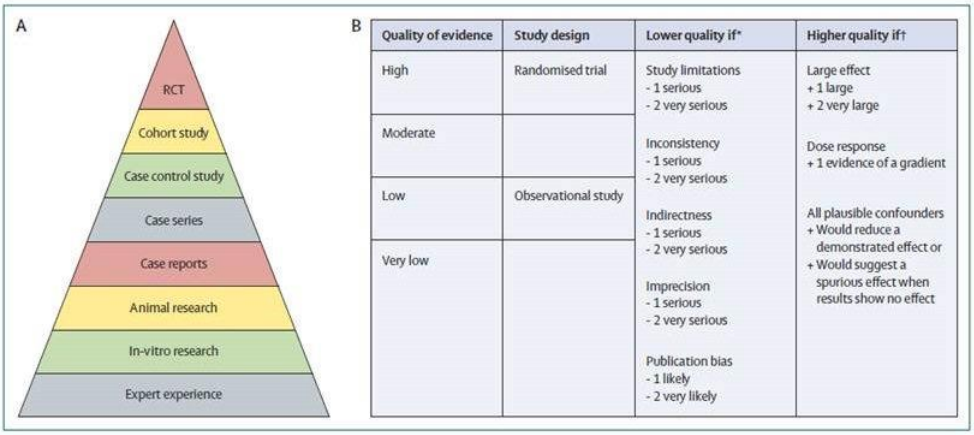


Figure 1: **Hierarchy of evidence: traditional EBM versus GRADE**
Comparison of traditional EBM hierarchy of evidence (1991–2004)[26] with GRADE classification of the quality of evidence (confidence, certainty; 2004 to present).[27] (A) Traditional EBM hierarchy of evidence. (B) GRADE classification of the quality of evidence. EBM=evidence-based medicine. GRADE=Grading of Recommendations Assessment, Development, and Evaluation. RCT=randomised controlled trial. *Quality of study moves down one or two grades. †Quality of study moves up one or two grades.

At the right-hand side of the figure, the GRADE hierarchy is presented with two study designs, randomized trials and observational studies. One could easily argue that such a depiction of GRADE represents a narrow view of evidence in hierarchies and resonates with criticism claiming that EBP is a movement characterized by a preference for prioritizing epidemiological evidence. Such a hierarchy may correctly be criticized for excluding numerous sources of research information (e.g., Rosner 2012).

On the other hand, it would be wrong to claim that GRADE hierarchies in general exhibit too narrow scopes of evidence. GRADE, in the same manner as the concepts of EBP and EBM themselves, have evolved. Initially, GRADE focussed on studies rating effectiveness, but has later moved on to consider methods for grading diagnostic and prognosis studies, and to include both qualitative and quantitative studies. For instance, within the GRADE model, a system has been developed for ranking qualitative research quality (CER-

QUAL).[79] When Guyatt et al. (2008) state that there is "*[a]n emerging consensus on grading recommendations*", and the World Health Organization (WHO) describes GRADE as "internationally agreed standards for making transparent recommendations" (cf. Blunt 2015: 104), the most reasonable interpretation in my view is to consider the statements in light of the expanded version of GRADE. Critics may further reply that GRADE is not the consensus tool it has been portrayed as being, and users of GRADE do not always use it consistently (cf. ibid.).

Some critics, in part based on the observations described just above, claim that the principles and content of evidence hierarchies within EBP literature lack unity and clarity (e.g., Blunt 2015; La Caze 2008). This claim is both valid and relevant: There are several different hierarchies in EBP, and their specific criteria for assessing evidence quality are not always adequately explained.

In my view, the criticism that evidence hierarchies are narrow is of less relevance, because EBP proponents commonly make use of evidence hierarchies representing a scope of evidence proper to their professional fields. The argument that the principles and content of evidence hierarchies within EBP literature lack unity and clarity (e.g., Bluhm 2005; Blunt 2015; La Caze 2008) – mirroring the criticism of unclarity of EBP definitions – is a more relevant criticism.

In sum, there are three particular kinds of criticisms targeting the narrow scope of evidence sources in EBP: a categorical claim that only epidemiologic data count as evidence and a conditional claim that evidence in EBP systematically favours epidemiologic evidence sources over non-epidemiologic evidence sources. The categorical version is based on a misunderstanding of what evidence amounts to in EBP, whereas the conditional version is more sensitive to the EBP literature and presents a

[79] See: https://www.cerqual.org/publications/

more relevant kind of criticism. Both the categorical and conditional version can in principle be dismissed with a reference to the broad definition of "evidence" in EBP. However, critics are correct in stating that the scope of evidence is not clear-cut across the EBP literature, as descriptions of "evidence" often vary.

The third main kind of criticism concerning the narrow scope of evidence in EBP addresses the scope of evidence in hierarchies, and the conditions by which evidence sources are hierarchically ranked. Critics may be correct when criticizing a narrow scope of evidence sources, depending on which hierarchy they are referring to. However, the fact that several critics tend to ignore that hierarchies include a broader scope of evidence sources and that there are different hierarchies for different types of clinical questions, makes parts of this criticism less relevant

3.3.1.1. The narrow scope of what counts as evidence demonstrates a positivistic tendency

The most extreme version of criticism concerning the narrow scope of evidence in EBP is that because EBP promotes only epidemiologic research, it limits the scope of what is relevant health care knowledge in a positivistic manner (Anjum 2016; Miles 2009b; Silva and Vyer 2009; Tonelli 2009b; Walsh & Gillett 2011). This line of argument characterizes positivism, quite crudely, as an epistemological approach that bases scientific knowledge on quantifiable (logical and mathematical) principles, in addition to what can be verified empirically. It recognizes only scientifically verifiable propositions as meaningful (cf., Goldenberg 2005).[80] One central tenet in the positivist theory is that "positive" knowledge is exclusively derived from sensory experience, interpreted through logical inferences.

[80] None of the references to Goldenberg is meant to suggest that she is representative of this kind of criticism. Rather, Goldenberg discusses positivistic claims in the EBP debate in a manner similar to my approach.

Thus, positivism holds that it is possible to justify only those knowledge claims that are reducible to either logic or sensory perceptions. In such an epistemology, claims based on non-sensory beliefs (e.g., theological and ethical) are deemed unverifiable and, hence, nonsensical.

Broadly described in this way, one might argue that there are some similarities between positivism and EBP. Grimen (2009) points to several similarities: Both movements share the same considerations about which methods provide the most reliable and useful knowledge; both movements are attentive to how scientific knowledge can improve practice, they share the same positive attitude to studies that provide generalizable knowledge; and there is a belief in a simple translation from scientific knowledge to practice. At the same time, Grimen points out, there are explicit discrepancies as well: EBP does not entail a vision of a fundamental, unified science, nor is the hierarchical structuring of knowledge reducible to such a unified view; EBP provides no philosophy of language; and EBM is open to qualitative studies (cf. Grimen 2009: 195f).

The equation between positivism and EBP is typically suggested by pointing out that EBM has a similar concept of evidence by which scientific beliefs are constituted by scientific "hard" evidence alone (cf., Goldenberg 2005). Thus, critics claim, EBP only endorses evidence derived from systematic and methodologically rigorous clinical research, whereby intuition, unsystematic clinical experience, patient preferences, and pathophysiologic rationale, are considered irrelevant.

In such a line of argument, a rather simple straw man is made of EBM, which then is criticized. For instance, some critics present "post-positivist" claims stating that EBP ignores subjective interpretations as necessary requirements for scientific practice (cf. Goldenberg 2005). Such a view of EBP are based on misreading of the EBM and EBP literature. For instance, the first official EBM text published, states that

> Evidence-based medicine *de-emphasizes intuition*, unsystematic clinical experience, and pathophysiologic rationale *as sufficient grounds* for clinical decision making and stresses the examination of evidence from clinical research. (Guyatt et al. 1992: 2420 [emphasis mine])

One could argue that this statement endorses evidence derived from systematic and methodologically rigorous clinical research and presents a model for clinical practice wherein scientific knowledge is the primary authority. But this authority is not thereby equated to positivistic tenets.

A more nuanced criticism, such as is found in Goldenberg 2005, is that the authority of scientific knowledge and methods may be out of step with current post-positivistic thinking. Goldenberg then points out that many of the arguments for this claim are similar to arguments used in philosophical criticism of positivism. Such a criticism seems more relevant to a debate, partly due to the fact that it does not equate EBP with positivism at the outset.

However, the equation between EBP and positivism is fuelled by Djulbegovic, Guyatt & Ashcroft, who state that:

> The concept that reliable empirical observation (i.e., fundamental units of evidential significance), together with rules of evidence that separate "truth" from "falsehood" (in clinical research), is reminiscent of logical-positivism — a movement that dominated the philosophy of science about 80 to 90 years ago. Like logical-positivism in the early 20th century, EBM today has re-exposed a central tension in epistemology regarding the relationship between observed reality and unobservable reality (2009: 161),

and

> Like positivism, EBM suggests we should restrict ourselves to the observed reality, and when we go beyond our observations, the focus is on extending our inferences about the unobserved world. Reality, however, remains ultimately unknowable. This positivist approach has some affinities with EBM, which for instance tends to

> privilege knowledge about what can be shown to work over deeper questions about why it does so. (ibid.)

On the other hand, Djulbegovic, Guyatt & Ashcroft also stress that the logical-positivist stance is too restrictive, and that EBP proponents "[a]re not committed to positivist theses about meaning and truth in science and medicine or about the kind of facts that can be known or not known" (ibid: 162). These qualifications should be unnecessary to provide. A positivist stance is too restrictive for any science. No scientist nor philosopher will defend the essential tenets of positivism. Djulbegovic, Guyatt & Ashcroft's statements are unnecessarily linked with a term with negative connotations and will only serve as inspiration for other straw-man depiction of EBP. A more adequate description would involve a reference to the empiricist nature of epidemiologic evidence (cf. section 1.2.1. above). Thus, the central focus should be on "empiricism", not "positivism". Thereby, the presentation of a philosophical basis for EBP could potentially provide the basis for a constructive debate as well.

3.3.2. The alleged superiority of RCTs is unjustified

EBP proponents consider epidemiologic evidence, and in particular RCTs, superior to other kinds of evidence sources. This is demonstrated in hierarchies concerning evidence for therapeutic interventions, where epidemiologic data is consistently ranked higher than non-epidemiologic evidence sources, with randomized studies on top. When non-epidemiologic evidence sources are considered, they often serve as supplementary evidence, insufficient in themselves. Indeed, the view of non-epidemiologic evidence as "insufficient" and primarily useful as "background knowledge" (cf. 2.4.2), is in line with the novelty of EBP leading to a characteristic confidence in epidemiologic data.

In particular, as described in the subsections of 1.4., randomized comparative research designs, and in particular the RCT, are considered superior to other kinds of evidence sources, primarily due to their ability to reduce risk of bias – such as allocation bias and other confounding factors.[81]

This view of comparative randomized research designs as superior to other evidence sources, is a central feature of EBP: Within the EBP literature, such designs are considered the best available with regard to justifying claims about therapeutic effectiveness of health care interventions. This is also explicit in most evidence hierarchies, where such evidence sources are ranked higher than others. The justification for this, according to clinical epidemiology and EBP proponents is their presumed ability to mitigate risk of bias and to balance confounding factors (cf. section 1.4.1. above). This justification is also used as a basis for inclusion criteria for systematic reviews of therapeutic interventions (cf. Howick et al. 2015). As noted above (1.2ff), this is the main basis for the view of RCTs as the gold standard of clinical (therapeutic) research.

Critics disagree with these considerations and argue that the alleged superiority of randomized research designs, and of RCTs in particular, is unjustified. The most cited criticism on this issue is that of Worrall (2002, 2007, 2010).[82] Worrall's main concern is about the confidence in RCTs and the claim of that EBP's stance on ranking randomized studies above observational studies is unjustified.

Worrall considers potential benefits of randomization, and concludes that the only actual benefit of randomization is that it is able to rule out allocation bias – which Worrall describes as "[d]ifferences between the two groups resulting from the selections made by the researchers involved concerning which patients are assigned to which groups" (2007:

[81] See Section 1.4.1.1. above for a description of these terms.
[82] There are many prominent critics addressing the same issue. Often, many of their arguments refer to Worrall's' account (e.g. Borgerson 2005; Grossman and Mackenzie, 2005).

1008).[83] This benefit, however, is not a feature exclusive to the method of randomization at all:

> [r]andomization as a way of controlling for selection [i.e. allocation] bias is very much a means to an end, rather than an end in itself. What does the methodological work here is really the blinding—randomization is simply one method of achieving this. (Worrall 2002: 14).

The important methodological point here, Worrall states, is that the controlled distribution of trial participants to different groups is taken away from the experimenters. Blinding, as along with other well-conducted observational methods can see to allocation of participants with equally strong rigour. In turn, well-conducted observational methods can provide equally strong evidence in this regard (cf. Worrall 2002; Borgerson 2009: 225).[84] Therefore, randomized studies are not superior in minimizing the risk of allocation bias.

Worrall also attacks another central claim in favour of the superiority of RCTs, namely, that randomization controls for confounding factors. As described in section 1.4.1.1.1. above, there are several EBP proponents who claim that randomization in an RCT controls for confounders, both known and unknown (e.g. Straus et al. 2011: 70, 187; Kuntz et al.

[83] Worrall refers to this kind of bias as "selection bias". As noted in footnote 20 (in Section 1.4.1.1.), "selection bias" and "allocation bias" is sometimes conflated, as in Worrall's case. "Selection bias" usually refers to a skewed selection of trial population, with non-representative attributes to the population at large (cf. ibid.).

[84] For instance, there is also a method of "minimization", through which an algorithm allocates each patient to the group, thereby minimizing imbalances in confounders between the groups (cf. Blunt 2015: 129). EBP-related literature, such as the Cochrane Collaboration, considers such minimization to be equally able to exclude selection bias as randomization can (Higgins & Green 2011; cf. Blunt 2015: 129). The superiority of randomized studies is thus not necessarily a categorical view shared by all EBP proponents. On the other hand, such a modified view is not explicit in most EBP literature.

2008: 3), so that they are evenly balanced with regard to the comparison groups.[85] Worrall (2002), on the other hand, demonstrates that this claim is false.

Firstly, Worrall deems the claim that randomization controls for confounding factors as "trivially unsustainable" (Worrall 2002: 10), and continues:

> It is perfectly possible that a properly applied random process might "by chance", "unluckily" produce a division between control and experimental groups that is significantly skewed with respect to some prognostic factor which in fact plays a role in therapeutic outcome but which was not initially controlled for. (ibid.)[86]

The main point, as trivial as it is valid, is that it is impossible to *control* for factors that are not controlled for initially. Thus, randomization cannot guarantee that unknown confounding factors are controlled for.

Secondly, Worrall targets the claim that randomization controls for known confounders so that they are evenly balanced with regard to the comparison groups. In principle, if there are many confounding factors in the allocated group, the chance that all confounding factors are evenly distributed in a given random allocation is low. Thus, randomization cannot guarantee that all factors that may have an effect on the trial outcome are balanced.

[85] According to Cartwright, another prominent critic, the "canonical answer" for "what's so good about RCTs?" is that "RCTs control for unknown confounders" (cf. Cartwright 2011).

[86] Worrall goes further, stating that statisticians know this to be a fact: "Giere, and above all Fisher, of course knew this and so presumably what they meant, despite what they say, is something weaker—only that the randomization controls for all factors, known or unknown, "in some probabilistic sense"."(ibid.). Worrall does not explain what he means by "some probabilistic sense". La Caze provides the following explanation, referring to a statistical, more formal concept of "bias" than is used in EBP literature (as well as by Worrall): "'[b]ias is used in statistics in a number of more formal ways. In parametric statistics, statistical bias refers to the expectation of an estimator of a parameter. An estimator is unbiased if its expectation is equal to the true value of the parameter. This is often informally referred to as an estimator's long run average. It is *only* in the statistical sense that randomisation eliminates bias due to confounding factors, known and unknown. This is because statistical bias entails consideration of the entire sample space." (La Caze 2009: 13).

The reason for this is quite simply that a random allocation does not by necessity balance all confounding factors (patient-features and disease-features) evenly between groups. On the contrary, a random allocation may distribute in any possible way, evenly as well as unevenly. For instance, there is no guarantee that a random allocation will distribute factors such as age or sex evenly into different groups. As Blunt notes, "[i]t is possible (if unlikely) for a random allocation to distribute all 50 men to one group and all 50 women to another. Less extreme but still important imbalances are not so improbable". (Blunt 2015: 127).[87]

In principle, the chance that all confounding factors are evenly distributed in a given random allocation is low. Thus, randomization cannot guarantee that all factors that may have effect on the trial outcome are balanced.

Moreover, Worrall suggests that even EBP proponents are aware of this when they recommend checking allocation for baseline imbalances in potential confounding factors. If identified, investigators will then re-randomize where baseline imbalances are found, until a suitably balanced allocation is conducted (cf. Blunt 2005: 128). In these cases, Worrall notes, it is not randomization itself, but the check for baseline imbalances and the following re-randomizing that allow one to control for known allocation confounders.[88] While EBP literature recommends checking for baseline imbalances (cf. Worrall 2007), attention to the importance of re-randomization is less central.

[87] According to Worral, when EBP proponents claim that RCTs control for confounding factors, they commit what he calls a "quantificational fallacy" (Worrall 2002: 12): "Even if there is only a small probability that an individual factor is unbalanced, given that there are indefinitely many possible confounding factors, then it would seem to follow that the probability that there is some factor on which the two groups are unbalanced (when remember randomly constructed) might for all we know be high. Prima facie those frequentist statisticians who argue that randomization "tends" to balance the groups in all factors commit a simple quantificational fallacy." (bid.)

[88] Worrall also points out that checking for baseline imbalances can identify only known confounders, not unknown confounders, despite the claims of several prominent EBM proponents.

While re-randomization may mitigate risk of allocation bias to a larger degree, randomization will still provide no *guarantee* for the equal distribution of confounders. From this perspective, the claim that randomization controls for confounding factors is weakened.

Thus, Worrall directs criticism at the alleged superiority of RCTs above other evidence sources: RCTs are not able to rule out allocation bias in any better way than other methods, and the process of randomization provides no guarantee of control for known confounding factors. Worrall thus provides highly relevant criticism to the alleged superiority of RCTs over other evidence sources.[89]

Blunt sums up Worral's argument about challenges in controlling for allocation bias in a clarifying manner: "To justify ranking RCT evidence above non-randomized study evidence on the basis of allocation biases, an argument that non-randomized studies cannot or do not exclude imbalances in known confounders would be needed" (Blunt 2015: 128). This challenge has not been explicitly responded to by EBP proponents.

As a response to Worrall's criticism, EBP proponents have argued that even if other methods exclude such imbalances, RCTs have the potential for ruling out more kinds of biases[90] and confounding factors than observational studies have (Howick 2011: 51: Howick & Mebius 2015: 1; La Caze et al. 2011). Howick maintains his defence of the RCT's superiority to other kinds of evidence sources, concluding that: "[a]ll other things being equal […] randomized trials provide superior evidence to non-randomized trials" (ibid.).

[89] Other critics, to a large extent based on Worrall's arguments, extend their criticism to the principles of the ranking-system in EBP hierarchies, claiming that the ranking of randomized evidence sources above other evidence sources is unjustified (e.g., Bluhm 2005, Blunt 2015, and La Caze 2008; 2009). In principle, it is the same kind of criticism, addressing the same methodological problems within the hierarchical system. I consider this criticism just as relevant as Worrall's.

[90] Specifically, proponents point to "confounding by indication", or "choice of treatment bias", as potentially being eliminated through a well-conducted RCT, while the same bias is difficult to rule out in observational studies (ibid; Howick 2011).

“All things being equal”, in this context, entails that, if randomized and non-randomized trials were compared, and provided the studies under comparison are conducted correctly, with a fully comparable research population, directed at an identical clinical question, the randomized trials would have higher internal validity than the non-randomized trials (cf. La Caze 2009). It is not clear whether Worrall would agree or disagree on such a claim.

Yet, Worrall’s main point about the differences between randomized and non-randomized studies being considerably less distinct than EBP proponents tend to claim remains a highly relevant criticism. While randomization has some benefits, such as preventing some types of allocation bias, which Worrall and other critics do not argue against, RCTs certainly do not ensure infallibility. Randomization does not, for instance, ensure that experimental groups are equally balanced for all confounding factors. In sum, criticism addressing the justification of the alleged superiority of RCT limits at least challenges the justification of RCTs as hierarchically superior to other evidence sources.

In sum, Worrall and others criticize the alleged superiority of randomized trials, and in particular the RCT. According to critics, the advantages of such methods are exaggerated and are deemed to be considerably more fallible than how the same methods are depicted in the EBP literature. The claim that RCTs control for unknown confounders is refuted.

EBP proponents respond to the criticism by stating that Worrall and others ignore that there are several kinds of biases in observational studies, for which an RCT is unable to account to a large extent. Another response is to claim that when all other things, except method, are equal, randomized trials will prove superior to non-randomized trials. Notably, this response does not explicitly refute Worrall’s criticism, but instead emphasizes issues that Worrall and other critics do not explicitly address. It is uncertain whether Worrall would disagree with this.

3.3.3. The usefulness of applying results from randomized comparative evidence-sources in clinical practice is limited

In the same manner as in the previous kind of criticism, this kind of criticism also primarily targets comparative randomized research data, and in particular RCTs. The concern that randomized data have limited usefulness in clinical practice represents a common criticism concerning evidence in EBP. The usefulness of evidence has to do with external validity, which refers to the generalization[91] of the research results with regard to the effect found in a trial population setting to other populations in other settings (cf. Section 1.4.ff.). There are several challenges to this generalization. Perhaps the greatest challenge is the application of population-based research-findings to an individual patient. Several related challenges are linked with the methodological conditions used to enhance internal validity of a clinical trial, e.g. a narrowly specified trial population, stringent inclusion criteria that may exclude patients in another setting (excluding older patients, and patients with co-morbidities), and the removal of conditions other than the treatment condition in the test that may affect treatment or disease progression.[92] In these cases, the enhancements of internal validity would also enhance the risk of decreasing the external validity of the evidence.

These challenges are discussed by critics, who claim that because individual circumstances and values may vary, and because there are so many uncommon diseases, epidemiologic data pertaining to average effects are often insufficient in real-world circumstances. In turn, this claim serves as a basis for the criticism that the EBP model represents an exaggerated and unjustified confidence in randomized comparative evidence sources.

[91] "Generalization" in this context is used generically, including assessment of both the generalizability and the applicability of the evidence (cf. 1.4.1.2. above).

[92] In addition, clinicians may administer interventions differently than the expert clinicians who performed the trial, which further exacerbates the problems of application into clinical practice. This problem, however, does not relate directly to external validity, but to the usability of the evidence, which is based on the clinician's expertise, when the evidence is to be applied in clinical practice at the point of patient care, according to patient preferences and circumstances (cf. section 2.2. above).

Several critics claim that the randomized trials, and RCTs in particular, despite their (presumed) ability to enhance internal validity, have several methodological weaknesses regarding external validity. They argue that evidence from randomized research rarely has sufficiently high external validity in a target population (e.g., Bluhm & Borgerson 2010; Cartwright 2007, Lexchin 2003, Rawlins 2008; Pocock 2000, Tonelli 1998).

Such arguments have been proposed since the inception of EBM and EBP. Feinstein (1994) and Feinstein and Horwitz (1997) present some of the earliest criticism concerning this issue, while later criticism to a large extent represents variations on the same theme. An overall concern in their criticism is that evidence based on epidemiologic data alone leads to limited knowledge and is therefore not always useful in clinical practice.

Feinstein & Horwitz identify several problems with EBP's attention to epidemiologic data, and with RCTs in particular. The four most important arguments are:

1) Epidemiologic data exclude pathophysiologic principles, ''soft data'' distinctive to individual patients and therapeutic expertise, such as "[d]ecisions to start or stop remedial therapy with oxygen, mechanical ventilation, blood transfusion, or for patients with electrolyte alterations will almost always depend on individual pathophysiologic status, not on published evidence." Feinstein & Horwitz 1997).

2) There are practical limitations to RCTs, due to ethical consideration (e.g., in investigating the effects of smoking, or by testing an intervention that is manageable by simpler interventions; cf. Feinstein & Horwitz 1997: 533), or to other contextual considerations, such as economy or time.

3) Many RCTs have restricted eligibility criteria, enrolling a restricted population exclusively comprising patients expected to be highly responsive to treatment.

4) The results of randomized studies show comparative efficacy of treatment for an ‘‘average’’ randomized patient and ignore clinical features such as severity of symptoms, illness and comorbidity. [93]

While all of these points are important and valid, it is not granted that they are devastating to the model of EBP.[94]

Argument 1 is true – per definition: As described in section 1.2.1., the main demarcation between epidemiologic data and pathophysiologic data is that epidemiologic data are the result of outcome-focused methods, which entails a shift from the traditional focus on the underlying pathophysiological mechanisms. Hence, to the extent clinical problems have to do with pathophysiological mechanisms, as in the examples provided in the argument above, population research data will be of minimal relevance.

However, the claim that “[e]pidemiologic data exclude pathophysiologic principles and therapeutic reasoning” could be interpreted to mean that the application of epidemiologic data in EBP clinical practice would exclude pathophysiologic principles.[95] Such an interpretation would approximate a straw man fallacy: No model of EBP (or EBM, for that matter) entails such a view. As described in Chapter 2, EBP’s stance on pathophysiology is that it is insufficient as a basis for clinical decision-making, but not considered as unnecessary. Even EBM proponents when stating “if the study isn’t randomized, bin it” do

[93] Feinstein & Horwitz also emphasize that epidemiologic randomized data lead to major disadvantages in EBM textbooks, including that such literature offers no instruction for the pathophysiologic and other judgmental reasoning used in clinical decisions (cf., Feinstein & Horwitz 1997: 533). In turn, this makes it challenging to individualize treatment in accordance with the patient’s personal preferences. I will discuss this point in more detail in Section 3.5.2. below, in conjunction with criticism concerning patient preferences in EBP.

[94] Notably, Feinstein & Horwitz do not propose this criticism as an anti-EBP argument. On the contrary, they state that they have “[f]riendly admiration for proponents of EBM, but worry about its current methods” (1997: 529). Later critics who cite Feinstein & Horwitz (e.g. Bluhm & Borgerson 2010; Upshur 2006) or present similar arguments are not as friendly.

[95] I do not mean to imply that Feinstein & Horwitz 1997 suggest such an interpretation. Their focus regarding claim (1) is on the formal limitations that arise when the result of an RCT is the sole element of clinical decision-making.

explicitly refer to the need for non-epidemiologic data as supplemental knowledge (e.g. Straus et al. 2011). Thus, in actual clinical practice, the EBP clinician, based on clinical experience and professional expertise, would make use of pathophysiologic "background knowledge" (cf. section 2.4.2. above) when applying epidemiologic data in clinical practice.

Arguments 2-4 are valid and demonstrate some of the shortcomings in data generated from RCTs, especially concerning small trials in which correspondence between trial groups and target groups may be considered low, most often due to too stringent exclusion criteria for test participants. Furthermore, there are clinical questions that are answerable only by using non-epidemiologic data, hence demonstrating that epidemiologic data are not always useful.

However, it is not necessarily the case that non-RCT evidence always has higher external validity. Considerations of confidence in the result of any kind of study is to a large degree dependent on the generalizability of that result. Often, the challenges of external validity increase with the decrease in size and increase in eligibility criteria of the test-population, but this need not necessarily be the case. Some EBP proponents claim that the assumption about the inherent weak external validity of RCTs is taken for granted by critics like Worrall, Cartwright and others, without citing any evidence to support this (e.g., Howick & Mebius 2015; Solomon 2011).

If EBP proponents ignored the problems of external validity, they could indeed be criticized for exaggerating the usefulness of epidemiologic data. This is not the case, however, in most EBP literature. Indeed, much of the EBP literature on epidemiologic research is attentive to problems of external validity, and there are at least three aspects in the EBP literature that explicitly relate to these problems.

Firstly, criteria for high-quality evidence include assessments of generalizability and applicability with regard to the target population (i.e. concerns relating to external validity; cf. section 1.4.1.2. above). If, for instance, an RCT does not meet these criteria, the evidence will not be assessed as high quality.[96] This is a matter that many critics seem to ignore.

Secondly, there are pragmatic trials, including RCTs, that prioritize external validity. Pragmatic trials aim to replicate real-world conditions, by using real-world clinicians (and not professional investigators) in actual clinical settings (e.g., in hospitals), on broad study populations, where the participants are more representative due to less strict eligibility criteria. (cf. Blunt 2015: 150).

Thirdly, EBP promotes the use of n-of-1 trials, in which a single patient constitutes the entre trial population. In n-of-1 RCTs, the clinician tests which treatment is the best option by testing different treatments on a single patient, using random allocation to determine the order of an experimental and a control intervention. Guyatt et al.'s (2015) "hierarchy of strength of evidence for prevention and treatment decisions" ranks N-of-1 RCTs at top level, above standard RCTs, which indicates a high degree of attention to external validity. On the other hand, critics could respond that few other hierarchies demonstrate the same attention to external validity, and there are no explicit criteria for differentiating between explanatory and pragmatic trials in evidence hierarchies (cf. Blunt 2015: 151). Other than Blunt's recommendations to expand GRADE's up- and down-grading criteria to take these factors into account (cf. ibid.), I have not observed any criticism regarding this.

Fourthly, the EBP literature also takes into account the abilities of the clinician when integrating evidence in accordance with patient preferences and circumstances – referring to what I have labelled assessment of the usability of the evidence (cf. section 2.2. above).

[96] Within the GRADE hierarchy, such an RCT would be explicitly assessed inferior to a high-quality observational study.

As discussed in Chapter 2, the extension to practice necessitates the clinician's expertise and ability to integrate, as well as personal knowledge concerning the patient and the circumstances. Integration and knowledge concerning the patient and the circumstances are considered necessary conditions in EBP decision-making, in addition to the formal assessment of the external validity of the evidence (cf. ibid.).

Critics may respond to this argument by stating that the EBP literature is less developed regarding the content and explicit implementation of these abilities. A general counter-response from EBP proponents to any criticism concerning the extrapolation of evidence to individual patients is that problems of extrapolation from any kind of research knowledge is problematic in application of any kind of evidence, whether from basic or applied research. Thus, this is not a problem unique to EBP, but occurs universally in any health care framework (cf. Straus and McAllister 2000: 838).

To sum up, critics claim that evidence generated from randomized comparative evidence sources have limited usefulness in clinical practice. This has specifically to do with challenges of external validity. There are four arguments in particular for this claim: (1) randomized research knowledge excludes pathophysiologic principles, ''soft data'' distinctive to individual patients, and therapeutic reasoning; (2) there are practical limitations to RCTs; (3) restrictive eligibility criteria, and (4) comparative efficacy of treatment only demonstrate effects for an ''average'' randomized patient, and not of the individual patient in direct health care practice. All of these arguments are valid and relevant.

However, there is disagreement between opponents and proponents with regard to the extent of these problems. Two general responses from EBP proponents are that the problem of external validity is not a problem unique to EBP but occurs universally in any health care; and that it is not necessarily the case that non-RCT evidence always has higher external validity. There are also responses specifically addressing arguments (1), (2), (3),

and (4). Concerning argument (1), critics tend to ignore that the EBP literature also takes into account the abilities of the clinician who integrates evidence in accordance with patient preferences and circumstances. In this way, the challenges regarding external validity of the evidence are accounted for in any application of randomized data into clinical practice. Concerning arguments (2), (3) and (4), there are methodological tools specially designed to mitigate the challenges of external validity: there are pragmatic trials and n-of-1 trials, both of which are equipped to mitigate risk of external validity, and thus reduce the severity of these problems.

3.3.4. Lack of empirical evidence that epidemiologic methods produce better outcomes than non-epidemiologic methods

Critics claim that EBP is not 'evidence-based' because it does not meet its own empirical requirements for efficacy (e.g., Buetow et al. 2006; Dobbie et al. 2000; Miles 2009a; Tanenbaum 2009; Tobin 2008). For instance, Buetow et al. (2006) states that, "There is still a lack of empirical evidence that, by its own rules, EBM produces better health outcomes than conventional medicine […]".[97]

In Buetow et al.'s claim, the phrase "by its own rules" refers to the application of best available high-quality evidence, generated from epidemiologic randomized comparative, outcome-based methods. EBP proponents have also taken note of this, stating that even though the core of EBP is the proposition that patient care can be improved by basing clinical decision-making on information from statistically valid clinical trials, there is no evidence from the same evidence sources that this is actually the case (cf. Haynes 2004;

[97] In this quotation, I have omitted the last clause of Buetow et al.'s sentence: "[a]nd can be effectively transferred into clinical practice". By "transferred into clinical practice", Buetow et al. address the problem of external validity. Thus, it seems that Buetow et.al. in this last section imply that there is lack of empirical evidence of the external validity of outcome-based evidence as well. This is a somewhat odd claim; it is easy to point to empirical evidence showing that evidence from outcome-based research has in fact been implemented into practice.

Jenicek 2006; Reilley 2004; Straus & McAllister 2000). Such evidence is impossible to provide as well. As Haynes states:

> No one has done a randomized trial of EBM with patient outcomes as the measure of success. Such a trial, would be impossible to conduct, given that the control group could not be effectively isolated from the research that EBM is attempting to transfer, and it would be regarded unethical to do so. (Haynes 2004: 237)

Thus, the belief in that epidemiologic methods produce better outcomes than non-epidemiologic methods is without scientific support from clinical trials (based on epidemiologic methods).

However, the core belief within EBP that outcome-based studies provide the best available basis for recommending interventions to patients can in principle be documented by other kinds of outcome-based research. Straus and McAllister refer to such documentation when stating that "[o]utcomes researchers consistently document that patients who receive proven efficacious therapies have better outcomes than those who do not" (Straus and McAllister 2000: 839). Critics could respond negatively to this documentation, as Straus and McAllister provide only three studies as examples of this, and as Blunt (2015: 239) remarks, it is unclear whether these studies would be ranked as high-quality evidence.

Another line of argumentation responding to this criticism, is to demonstrate the historical impact of epidemiologic methods. Djulbegovic and Guyatt do this, referring to the impact of well-known randomized trials, pre-dating EBP:

> [A] criticism of EBM is that there is no high-quality evidence that its application has improved patient care. We would rebut by noting the history of a decade-or more delays in implementing interventions, such as thrombolytic therapy for myocardial infarction, and […] routinely administered useless and harmful interventions, such as lidocaine to patients after myocardial infarction, placing infants on their stomachs to sleep, or hormone replacement therapy for postmenopausal women, that preceded the widespread implementation of EBM. (Djulbegovic and Guyatt 2017: 420)

The central claim here is that randomized trials have demonstrated that several common clinical interventions, based on non- epidemiologic methods (e.g. based on pathophysiologic principles), in fact exhibit useless or harmful effects. The attention to the delays in implementing interventions preceding EBP is also important to the argument. The implementation of interventions based on the results from epidemiologic methods coincides with the initiation of EBP. It is due to clinical practice of EBP, precisely through the implementation of research findings derived from epidemiologic methods, that clinical practice was improved. Thus, the reference to these randomized trials serves as empirical evidence that epidemiologic methods (RCTs) produce better outcomes than non-epidemiologic methods (out of which the useless or harmful interventions were implemented in the first place).

Opponents could respond by pointing to the examples that Djulbegovic and Guyatt refer to, by maintaining that they are few in number and thus insufficient for a claim that epidemiologic methods in general produce better outcomes than non- epidemiologic methods.

In my view, the very basis for the debate concerning lack of empirical evidence for EBP methods is problematic precisely because of the facts addressed by Haynes (2004) above. Any evidence supporting the claim that epidemiologic methods produce better outcomes than do non-epidemiologic methods will by necessity be partial, and this partiality would then become subject to further criticism.

3.3.5. An overview of the criticism concerning evidence

I will end this section on criticism concerning evidence by presenting some concluding remarks.

Criticism concerning evidence in EBP is addressed with variations of four claims in particular: (1) the scope of what counts as evidence is too narrow; (2) the alleged superiority of RCTs is unjustified; (3) the usefulness of applying randomized comparative data as evidence in clinical practice is limited; and (4) there is a lack of evidence that epidemiologic methods produce better outcomes than non-epidemiologic methods.

In 3.1.1., I claimed that what is controversial in EBP is the application of epidemiologic methods and research results in clinical practice based on methodological principles from clinical epidemiology. This is demonstrated in all four kinds of criticisms: They all primarily concern methodological principles from clinical epidemiology, and in particular with the ranking of randomized trial evidence above other evidence sources.

To the extent that critics target the methodological principles from clinical epidemiology in an adequate manner – that is, by clearly separating these methodological issues from the more expansive EBP model – their criticism addresses issues that constitute methodological presuppositions in the EBP model. Such criticism is demonstrated above, through Worrall's criticism of the alleged superiority of RCTs, as well as through Feinstein & Horwitz' criticism of the limited usefulness of applying results from RCTs as evidence. Both of these kinds of criticisms identify basic methodological limitations with regard to the RCT, and contribute, in my view, to the most relevant kind of criticism concerning evidence. The fourth main kind of criticism – addressing the lack of evidence showing that epidemiologic methods produce better outcomes than non-epidemiologic methods – is also valid in that it also addresses methodological concerns. The relevance and impact of this claim, however, is weakened due to that it cannot be completely responded to, neither by proponents nor critics.

On the other hand, there are critics who target the methodological principles from clinical epidemiology in an inadequate manner, by conflating clinical epidemiology principles and the more expansive elements in the EBP model. This is the case in much of the criticism regarding the narrow scope of evidence in EBP. In this criticism, the range of evidence sources in EBP is erroneously criticized on basis of clinical epidemiology's view of evidence. The flaw in such an argument is that the broader conception of evidence and evidence sources in EBP is ignored. This is the case in what I have described as categorical claim about that the content of what counts as evidence is too narrow. By contrast, conditional claims about the reductive and restrictive criteria for assessing the quality of evidence, systematically favouring epidemiologic kinds of evidence to other kinds of evidence, is more relevant, due to its distinctive perspective on methodology rather than on the actual content of evidence sources.

The conflation between clinical epidemiology principles and the more expansive elements in the EBP model are also apparent in the criticism regarding the limited usefulness of epidemiologic evidence. Feinstein & Horwitz' criticism is both valid and relevant to the extent that they take into account methodological considerations of clinical epidemiology. When the same criticism targets evidence assessment concerning the application of evidence within the EBP-model, there are several mitigating factors that impact the criticism – not least the assessment of the usability of the evidence, in which the patient preferences and circumstances are accounted for. In sum, the validity and relevance of the criticism are related to whether the critics address methodological and controversial presuppositions concerning evidence in EBP, as rooted in its clinical epidemiology framework.

As noted above, the other elements of the EBP model – expertise and patient preferences and circumstances – are not controversial in and of themselves. Rather, these elements become controversial when discussing the extent to which the use of expertise and

patient preferences and circumstances are compatible with the methodological features of clinical epidemiology. This is the subject matter of the following analysis.

3.4. Criticism concerning clinical expertise

Criticisms of clinical expertise and patient preferences are often intertwined. Before I address the two topics individually, I will comment generally about both.

Broadly speaking, criticisms concerning clinical expertise and patient preferences in EBP concern the degree to which these elements are included in the EBP model. There are critics who claim categorically that clinical expertise and patient preferences are rejected altogether (e.g., Charlton 1997). Such categorical claims can be easily dismissed with reference to any definition of EBP. As demonstrated in Chapter 2, both clinical expertise and patient preferences must be considered necessary requirements in the concept of EBP. Most often,[98] however, there is a more nuanced claim that the inclusion of clinical expertise and patient preferences is too limited, and that the relationship between these two kinds of non-evidential aspects on the one hand and evidential knowledge on the other is problematic.

In the following discussion of the criticism, I will address criticism concerning clinical expertise below as well as in the main section 3.5 concerning patient preferences. Criticism concerning clinical expertise can be categorized under two main sections: 3.4.1: EBP minimizes the role of clinical expertise and 3.4.2: the autonomy of the clinical expert is reduced.

3.4.1. EBP minimizes the role of clinical expertise

Examples of this kind of criticism are that the EBP model leaves little or no room for clinical expertise, and that the EBP model ignores the fact that clinical research can never replace

[98] Sometimes, critics present unqualified, categorical claims that EBP rejects personal experience and patient preferences, but make a more nuanced, more careful statement later in the same texts, where focus is on the downgrading of these aspects and a privileging of scientific knowledge (e.g. Loughlin 2008).

clinical expertise (e.g., Braude 2009; Charlton 1997; Charlton and Miles 1998; Horwitz 1996; Maynard 1997; Martinsen 2009; Miles et al. 1998; Naylor 1995; Tanenbaum 1993; 1995; 2009; Tonelli 1998; 1999). For instance, Tanenbaum (1995) claims that "Evidence-based medicine argues for the fundamental separability of expertise from expert and of knowledge from knower" (quoted from Greenhalgh 1999). The critics' contention that the EBP model categorically lacks clinical expertise (i.e., is omitted entirely, as in the case of Tanenbaum's claim) can be dismissed as erroneous based on EBP definitions.

Less categorical arguments point out the tendency to downplay the challenges to clinical expertise in complex clinical interactions with the patient (e.g. Naylor 1995), in line with the general criticism presented above. To a large extent, this kind of criticism is correct. EBP textbooks and research tend to devote most attention to methodological concerns about how evidence is provided, while discussions of clinical expertise are few and brief, typically delimited to non-complex scenarios.

There are also cases where critics seem to conflate clinical expertise as evidential and non-evidential. For example, Charlton and Miles (1998) and Tonelli (1999; 2006) take the fact that clinical expertise is ranked low in evidence hierarchies as an argument in support of the claim that clinical expertise is minimized. Such a claim is perhaps valid when applied to the evidence hierarchy, where clinical expertise is considered as a particular kind of non-scientific evidence and, due to a larger risk of bias than other evidence sources, is placed at bottom of the hierarchy. However, when applied to clinical expertise as non-evidentiary knowledge, beliefs, skills, and abilities of the clinician, which are considered necessary for extending evidence into practice, the claim is less straightforward. A possible relevant line of argumentation would be to point to cases in which clinical expertise is present in the non-EBP clinician's practice but somehow disabled in EBP practice. Otherwise, the claim seems to ignore the other elements of the EBP model, as

well as the "second principle of EBP" – that evidence alone is never sufficient (cf. Guyatt et al. 2008a; 2015),[99] referring to clinical decision-making as constituted by three equally necessary elements – evidence, patient preferences and circumstances, and clinical expertise (cf. Chapter 2).

3.4.2. The autonomy of the clinical expert is reduced

Criticism about the autonomy of the clinical expert in EBP is often connected with standardization and the so-called "cookbook medicine" argument, i.e. that EBP promotes a "cookbook approach" to clinical health care (cf. Feinstein & Horwitz 1997; Straus and McAllister 2000). This argument refers to the supposition that EBP clinical practice is controlled by formal rules of conduct, such as guidelines and pre-appraised evidence, which in turn presumably minimizes the use of clinical reasoning and leads to automatic decision-making.

Many critics make use of variations of this argument, e.g., that the evidence hierarchy standardizes views on evidence (e.g. Blunt 2015) and that guidelines standardize clinical practice, leading to "a massive standardization movement" (Timmermans and Epstein 2010: 80; cf. Knaapen 2014), thereby reducing the autonomy of the clinical expert (e.g., Timmermans and Berg 2003). Another variation is that the model of EBP as a whole is a substitute for clinical judgment (e.g. Cohn 1996: 161). A more refined variation of this claim is presented by Tonelli, in which the patient, due to the lack of attention to non-evidential aspects of clinical practice, "[c]annot help but practice "cookbook" medicine, for they will have been provided none of the insight or skills that would enable them to successfully deviate from the "recipe"." (Tonelli 1988: 1239).

[99] The "second principle" is discussed briefly in Chapter 2, footnote 49.

Most EBP proponents will agree with the claim that EBP presents a model of standardized care. Indeed, standardization of clinical practice is often considered one of the strengths of EBP, since development and application of guidelines represents a reaction against unwanted variation of medical care (cf. Djulbegovic and Guyatt 2016: 4). The main disagreement is whether such standardization leads to reduced autonomy or not. This will be discussed in the following.

Several critics point out that EBM's use of research evidence, systematic reviews, and checklists make the individual clinician dependent on the manufacturers of such evidence and reviews (e.g., Charlton and Miles 1998; Greenhalgh et al. 2014; Horwitz 1996). Charlton and Miles (1998) present their case quite aggressively:

> But EBM regards clinical expertise as mainly a matter of collecting, analyzing and summarizing research done by other people. Hence the final arbiters of EBM practice are 'systematic reviewers' drawn from biostatistics, epidemiology, health economics and other 'Infostat' disciplines […]. Clinical advice has been neatly bypassed and subjected to external performance criteria. […] Suffice it to say that there is not a shred of evidence to suggest that an understanding of medical research and its interpretation for practice can be reduced to the routine application of checklists and formulae. […] In a nutshell, EBM involves a takeover of the clinical consultation by an alliance of managers and their statistical technocrats who are empowered to define 'best practice'. The upshot is that the EBM apparatchiks acquire substantive influence over millions of clinical consultations, but without any responsibility for the clinical consequences. (Charlton and Miles 1998; 372)

The main concern here is that the authority of the clinical expert is replaced by either epidemiologists ("statistical technocrats") or managers, who do not partake in the clinical encounter. In principle, this is a legitimate concern. EBP proponents may legitimately respond that clinical expertise is not reducible to merely "collecting, analyzing and summarizing research done by other people". As described in Chapter 1, the critical appraisal conducted by the clinician is also about assessing the evidence in terms of external validity, including the question of applicability to the individual patient, in which

the clinical setting and patient-important outcomes are considered (cf. Chapter 1.4.1.2.). The responsibility for the clinical consequences in using evidence is thus ultimately in the hands of the clinical expert.

However, this response presupposes that the individual clinician conducts the critical appraisal. A more nuanced line of criticism from Bluhm and Borgerson (2010) point out that the extensive use of guidelines and pre-appraised evidence represents a new form of authority, thereby reducing the autonomy of the clinical expert:

> This approach to EBM is efficient, but in cutting out the critical evaluation physicians once again put themselves in a position of subservience to authority. In this case it is the authority of those who produce systematic reviews and guidelines, but given that there will always be social and political pressures on those producing the reviews and guidelines, this seems to be a risky endeavor. […] In establishing predigested reviews and guidelines as the new authority, EBM users once again drift away from the demands of critical thinking. Whenever this occurs, there is reason for concern.[…] [a]s EBM becomes the new authority in medicine, it no longer fulfills its own claims to anti-authoritarianism. (Bluhm and Borgerson 2010: 216).

In other words, following the three-mode typology for EBP practice found in Strauss et al. (cf. Chapter 2.3.2.), when the EBP clinician is no longer "doing", but only "uses" or "replicates" EBP, clinical expertise is reduced.

In my view, this is a highly relevant criticism that is not easily countered in current EBP literature. Proponents may respond by pointing out that even though critical appraisal is removed, the act of integrating evidence into practice and putting it to use according to the patient's preferences and circumstances is still the most crucial step in evidence-based practice and can only be done by the individual clinician. (cf. Chapter 2; see section 2.2. in particular). While such a response may be legitimate, the current EBP model is not clear as to what kind of expertise is needed and how it is to be applied.

Moreover, as discussed in 2.2., and demonstrated in the definition of EBP in section 2.3.5 above, assessment of the evidence in accordance with the patient's preferences and circumstances can formally be considered external to the critical appraisal. Thus, the lack of response from EBP proponents is not necessarily because there is no room for this kind of clinical expertise, but because this kind of expertise is not adequately accounted for, neither in the EBP literature in general, nor in official definitions in particular.

I will suggest a theoretical defence, by referring to the concept of "usability", which entails assessment of evidence when applied at the point of care, in accordance with patient preferences and circumstances (cf. section 2.2. above). Such a defence mitigates any criticism relating to pre-appraised evidence, because the clinician's expertise is still considered a necessary element when integrating any kind of evidence, including pre-appraised information, into clinical practice.

3.4.3. An overview of the criticism concerning clinical expertise

There are two main claims concerning criticism of clinical expertise in EBP – that EBP minimizes the role of clinical expertise, and that the autonomy of the clinical expert is reduced. The first claim is often presented categorically and maintains that EBP relies on the fundamental separability of evidence and expertise. In parts of this criticism, there is also a tendency to conflate clinical expertise as evidential and non-evidential knowledge, and to ignore that the component of expertise that is non-evidential is considered a necessary element, in line with, and not subordinated to, evidence. Such a claim is erroneous with regard to EBP definitions.

Conversely, conditional claims point out the tendency to downplay the challenges to clinical expertise in complex clinical interactions with the patient. This is a more relevant kind of criticism: Discussions of clinical expertise are few, and often limited to non-complex scenarios.

The second main claim addresses the autonomy of the clinical expertise and that this autonomy is reduced in the EBP model. This kind of criticism is directed at the standardization of clinical practice. Such standardization does not need to imply that the autonomy of the clinician is reduced: standardized practice in EBP still includes the external validity of standardized evidence and guidelines. Other critics address the application of pre-appraised evidence in EBP, which, according to critics, reduces and makes redundant the autonomy of the clinician. The impact of such a criticism can be mitigated by referring to the act of integrating evidence into practice, whereby patient preferences and circumstances are included; this is still the most crucial step in evidence-based practice. The strength of this response is weakened by the fact that current EBP literature does not explain expertise and the act of integration in a sufficiently adequate manner.

3.5. Criticism concerning patient preferences

As demonstrated in chapter 2, the patient's individual preferences are considered necessary elements of the EBP model. Patient preferences refer to the sum of the patient's beliefs, attitudes, subjective experiences, and value judgments relevant to the clinical encounter. The debate concerning patient preferences is focused on the extent to which these preferences are accounted for in evidence-based clinical practice,[100] and on whether the autonomy of the individual patient in EBP clinical decision-making thereby is maintained.[101]

Critics point out that discussions of the role of patient values are lacking in the EBP literature (e.g., Henry et al. 2007; Miles 2009a) and that the individual and complex nature of the patient-clinician relation is downplayed (e.g., Bluhm and Borgerson 2011; Greenhalgh et al. 2014; Rogers 2002; Schattner & Fletcher 2003; Tonelli 1995). To a large extent, this kind of criticism is correct. In comparison to literature on methodological issues on evidence, there is considerably less attention paid to investigating methods by which to elicit patient preferences and values, and how to integrate these into clinical decisions.[102] However, there has been a growing attention to these issues in the EBP

[100] In the debate, there is no specific attention to patient circumstances, and I will not address this in the following analysis.

[101] The analysis will be restricted to whether patient preferences are accounted for through the *model* of EBP. In addition, there is the question of how the EBP clinician actually conducts the patient-oriented practice. For instance, the clinician may implement evidence in clinical practice based on poor evidence assessment or by ignoring patient preferences. Such examples of evidence-based mal-practice are less relevant to the following analysis, as such malpractice is due to the clinician, and does not refer to inherent deficiencies in the EBP model.

[102] Interestingly, there are debates within the EBP literature as well: While Greenhalgh et al. 2014 maintains that patient values are highly problematic to integrate in the model of EBP, Djulbegovic and Guyatt explicitly disagree, responding that EBP has always promoted the importance of clinical judgment in critical appraisal and decision-making, as well as the need to consider the patient's values and preferences (Djulbegovic and Guyatt 2017). In my view, Greenhalgh's considerations are a direct effect of her exclusion of patient's values and clinical expertise regarding the concept of EBP (see 2.4.5. for a short discussion on Greenhalgh's description of what amounts to a minimal concept of EBP. The aim of the

literature, where several EBP proponents discuss the role of the patient-clinician relationship, values in clinical decision-making, and patient autonomy (e.g., Djulbegovic & Guyatt 2017; Greenhalgh et al. 2014; 2016; Guyatt et al. 2015; Haynes 2002; Haynes et al. 2002; Kelly et al. 2015; Mebius et al. 2016).[103]

The main subject matter in the debate concerns the relation between epidemiologic evidence and patient preferences. More accurately, critics question the extent to which patient preferences can be accounted for when applying epidemiologic evidence sources into clinical practice at the point of patient care.

This subject matter is addressed in various ways and can be organized as criticism addressing three claims: A categorical claim that the element of patient preferences is lacking, contrary to what the definitions of EBP may state. I will analyse this kind of criticism in 3.5.1. below. A second claim addresses specific concerns that epidemiologic evidence sources are sub-optimal with regard to the individual preferences of the patient. According to critics, the problem is that epidemiologic evidence is difficult to "individualize" according to patient preferences, due to the fact that outcome-based data from population-research limits attention to patient individuality and autonomy. There are two specific variations of this kind of claim, and I will examine them in 3.5.1. and 3.5.2. respectively. A third claim is that patient autonomy is reduced, because it is not the patient, but the clinician who integrates patient preferences and circumstances. I will examine this claim in 3.5.3.

current analysis is to examine the main kinds of criticism concerning patient preferences in EBP, and I will not examine this internal debate in any detail in the following.

[103] In particular, there has been increased attention to shared-decision-making, referring to models for informed patient choice, in which the patient is presented with the evidence and with the advantages and disadvantages of alternative intervention options, enabling the patient to make informed decisions (e.g. Guyatt et al. 2015). There are several challenges to shared decision-making, and a full account of these exceeds the scope of the treatise. In my analysis, I will limit the analysis to the subject of the extent to which the EBP model is able to account for patient preferences in general.

3.5.1. Attention to patient preferences in EBP is lacking

Similar to some cases of criticism concerning evidence and expertise, there are categorical interpretations with regard to patient values and autonomy as well, claiming that patient values are lacking in EBP models. At the outset, such interpretations may be dismissed as erroneous according to EBP definitions. However, critics claim that the inclusion of patient values is nothing but "lip-service" (cf. Miles 2009a) or "empty rhetorical gestures" (cf. Devisch & Murray 2009). Henry et al. claim that any kind of non-scientific evidence is excluded in EBP:

> Despite […] attempts to develop more nuanced definitions, in everyday speech evidence-based medicine connotes adherence to the hierarchy of evidence and is considered separate from or even antithetical to reliance on clinical expertise or patient values. (Henry et al. 2007: 293)

Notably, EBP proponents have also suggested the same criticism, specifically addressing the "[l]ip service to shared decision-making" (Greenhalgh et al. 2014: 5). Greenhalgh et al. direct this criticism toward what they understand as poorly conducted evidence-based practice (sometimes described as "rubbish EBM"; Greenhalgh 2015) as opposed to "real "EBM", based on the "founding principles" of EBP[104] (Greenhalgh et al. 2014: ibid.). The criticism advanced by Greenhalgh et al. is thus not intended as a general criticism of the "real" principles of EBP. Nevertheless, their criticism provides support for similar, but less restrictive, criticism.

In general, the criticism that patient preferences in EBP are lacking is more assertive than argumentative. Without argumentative support, any criticism of this issue is, in my view, erroneous, either because such criticism ignores EBP definitions, or because it is an

[104] These founding principles refer to the rather broad ideals "[t]o individualise evidence and share decisions through meaningful conversations in the context of a humanistic and professional clinician-patient relationship" (ibid., 4). Such broadly described ideals refer to any clinical practice. The important point is the question of how the model of EBP is able to ensure such ideals. In my view, Greenhalgh et al. make suggestions that are too general and too tentative to provide adequate answers to this question.

argumentum ad hominem, attacking the motives of EBP authors (or, in the case of Greenhalgh, of the clinician's ability) rather than the content of their descriptions and arguments.

3.5.2. Outcome-based data from population-research limits attention to patient preferences

Critics claim that the application of epidemiologic evidence sources, with its attention to knowledge about the average outcomes of interventions on populations, is sub-optimal with regard to individual patient care. Most of the criticism concerning the extent to which patient preferences are accounted for can be categorized as variations of this claim. The basic assumption in this kind of criticism is that the limited usefulness of applying epidemiologic evidence in general (including the criticism supporting these limitations; cf. Section 3.3.3. above) extends to patient care. On the basis of this assumption, critics claim that it is highly problematic to account for the individual preferences of the patient.

This kind of criticism, with its affinity to criticism of external validity, has been proposed since the initiation of EBP. For instance, Feinstein 1994 claims, correctly, that results from RCTs aim to demonstrate average efficacy rather than an "[o]ptimum management for individual patients" (Feinstein 1994: 801). Feinstein also states that decision-analysis aimed at mitigating the challenges of external validity "[c]annot accurately portray the true "values" for individual persons" (ibid., 803). In essence, this is the core content of criticism that outcome-based data from population-research limit attention to patient preferences. In the following, I will identify four typical variations of this kind of criticism.

Variations of Feinstein's criticism concerning the limits of the usefulness of evidence, extended to the limits of patient care suggest that the challenges to external validity and the principles through which external validity is accounted for (i.e., Critical appraisal) lead to a situation where it is problematic to take into account attention to patient individuality

and autonomy (e.g., Cohn 1996; Devisch & Murray 2009; Naylor 1995; Tonelli 1998; Upshur 2006). Another example is Bluhm and Borgerson's criticism aimed at "[t]he specific rules [i.e., of critical appraisal] tying medical practice to medical research in EBM, which fail to capture important distinct elements of medical practice" (Bluhm and Borgerson 2010: 219).[105]

One of the more comprehensive versions of Feinstein's criticism is proposed by EBP proponents. Greenhalgh et al. 2015 identify six difficulties regarding the incorporation of patient values in evidence-based practice: (1) published research have minimal input; (2) population-based research devalues attention to patients and carers; (3) EBP conflates patient care with decision-making tools; (4) there are power imbalances between the clinician and the patient; (5) EBP over-emphasizes the clinical consultation; (6) EBP is primarily concerned with people who seek care and ignores sub-populations with a great need for care (cf., Greenhalgh et al. 2015: 8).

While the categorical quality of their arguments may be contested, the issues Greenhalgh et al. identify are all important contributions to the ongoing debate on patient values in EBP. It will exceed the scope of this treatise to examine each of these six issues. The debate concerning these issues is primarily occurring within the EBP community and is of less relevance to the general analysis of common arguments in the EBP debate. More relevant for the present analysis is the claim that follows from these six specific issues. These issues, Greenhalgh et al. claim: "[c]an all be traced back to the assumptions and preferred focus

[105] The description that "practice is tied to research" is a critical remark in itself, suggesting that the practice of EBP is restricted and constrained by being forced to follow research rules and research evidence. This remark is based on a misinterpretation: In clinical epidemiology and EBP literature, it is common to describe the rules of assessment in the opposite direction, i.e., that the research rules and research evidence, through assessment of external validity, is tied to clinical practice (and not the other way around, which is the case in Bluhm & Borgerson's description). This direction from research knowledge towards clinical practice is highly relevant, as it describes the very purpose of conducting critical assessment of external validity in the first place.

of the discipline of epidemiology: the science of experimental and observational studies of diseases in populations" (Greenhalgh et al. 2015: 8).

Following this claim, the challenge to include patient preferences in EBP patient care derives from the application of epidemiologic evidence sources. At the outset, this a fair point: Epidemiologic evidence results provide information about the average effects of clinical interventions, conducted upon a specified trial population, not directly applicable to individual patients. As such, this is a problem of external validity, extended to individual patient care. Thus, the outcome-based data from population-studies limit attention to patient preferences, including the patients' individuality and autonomy.

Likewise, when arguing that outcome-based data from population-studies limit attention to patient preferences, critics claim that the over-representation of epidemiologic evidence leads to under-representation of other kinds of knowledge. For instance, Rogers claims that the attention to epidemiological evidence "[l]eads to under-representation of relevant data (especially qualitative evidence)", which in turn limits patient choice (Rogers 2002: 101). Feinstein & Horwitz emphasize that the over-attention to epidemiologic data leads to lack of attention to "[p]athophysiologic and other judgmental reasoning used in clinical decisions" (Feinstein & Horwitz 1997: 533). In turn, this makes it challenging to individualize treatment in accordance with the patient's personal preferences.

One last variant of the claim that outcome-based data from population-research limit attention to patient preferences is broader in scope and considers attention to epidemiologic evidence sources more or less irreconcilable with patient preferences. For instance, Tonelli states that:

> An intrinsic gap exists between clinical research and clinical practice. Failure to recognize and account for this gap may lead to unintended and untoward consequences. Under the current understanding of EBM, the individuality of patients tends to be devalued, the focus of clinical practice is subtly shifted away

> from the care of individuals toward the care of populations […]. (Tonelli 1988: 1234)[106]

Thus, according to Tonelli, there is a shift of attention away from individual patient care to "the care of populations", fulfilling goals of public health but not of individual patient care (cf. ibid., 1236). In effect, attention to patient preferences is minimized. Similar lines of argumentation have been presented by Upshur, who states that care and decision-making are two distinct issues, of which EBP with its "[e]mpiricist mode of conceptualizing medicine" (Upshur 2006: 286) only accommodates decision-making, at the expense of care (cf. Upshur 2006: 285f).

In essence, this broad kind of criticism implies an inherent dichotomy in EBP distinguishing, on the one hand, attention to epidemiologic research, and on the other, the preferences of the individual patient. This dichotomy leads to a situation where attention to patient preferences is "relegated to inferior status" (cf. Charlton & Miles 1998: 327).

In my view, the broad descriptions of the dichotomy or "gap" between epidemiologic research data and clinical care, lack consideration of the role of evidence, the clinician and the patient in the EBP model. Instead, such a broad description approximates a minimal conception of EBP, in which non-scientific knowledge is excluded from the model (cf. section 2.4.4.).[107] Conversely, as demonstrated in Chapter 2, the common (i.e. moderate)

[106] The last sentence continues: "[…] and the complex nature of sound clinical judgement is not fully appreciated". This last point is formally an argument concerning restrictions made to the clinician's autonomy (as discussed in section 3.4. above). As such, "the gap" Tonelli is referring to is equally relevant to the clinical as to the patient.

[107] I must note that I find the tendency to dichotomize and distinguish between epidemiologic evidence and individual patient care rather extreme. In my view, this is a result of an unnecessary exaggeration of the difficulties in applying epidemiologic evidence to an individual patient. Despite the arguments presented above, I consider it highly doubtful that any of the critics would deny the applicability of epidemiological evidence in clinical patient care on such a general basis. For instance, when Guyatt confronts Tonelli with this question, Tonelli responds by stating that: "I never said that the results of clinical

concept of EBP includes non-scientific knowledge as a necessary element. In this model, patient preferences carry greater weight than the professional opinions of physicians, to the point where the patient's preferences may override the best research evidence available (cf. section 2.4.3.1. above).[108]

It is true that there are challenges when applying epidemiologic evidence in individual patient care – in particular due to the problems relating to external validity; cf. section 3.2.2. above. These challenges, however, are to a certain extent accounted for and mitigated through the clinician's assessment of external validity of such evidence. In addition, the evidence is assessed in accordance with the patient's individual preferences through the following integration of evidence into clinical practice at the point of patient care, according to patient preferences and circumstances (cf. section 2.2. above). In addition, EBP literature recommends using qualitative data as an additional guide to inform decision-making otherwise based on epidemiologic data. As stated in section 2.4.2., there are instances where the clinician needs qualitative research that attempts to provide some guidance in deciding whether or not the findings from quantitative studies can be applied to his or her patients. These examples demonstrate that a categorical claim

trials are never applicable or are never informative. That would be an indefensible position. What I said is that clinical research can never be directly or deductively applied to individual patients. That this has to be an active process that incorporates other forms of medical knowledge" (Guyatt & Tonelli 2012: 79). Compared to the previous quote from Tonelli above, this latter claim is considerably more qualified, and enables an alternative account of the disagreement between opponents and proponents regarding the inclusion of patient preferences in patient care. In this alternative account, there is minor disagreement: The main critical point in the latter citation is that "clinical research can never be directly or deductively applied to individual patients". This is an observation EBP proponents would wholly agree to. Indeed, the purpose of the critical appraisal scheme and the concept of integrating evidence into clinical practice is to provide a basis for the application of evidence at the point of patient care (cf. Section 2.2. above). The only disagreement would be on what kinds of "other forms of medical knowledge" should be included.

[108] Bluhm and Borgerson argue that it may be tempting for clinicians to strongly guide patients to the correct evidence (Bluhm and Borgerson 2010: 220), or toward the clinician's personal convictions about the best course of action, and thus override the values of the patient. This observation is correct and refers to a practical challenge in clinical practice. However, this is a problem of clinical practice in general, not a problem inherent in the EBP model.

implying a binary interpretation of epidemiologic evidence sources and individual patient care are problematic.

Responses to the criticism that outcome-based data from population-research limit attention to patient preferences can be organized under three categories:

(1) Responses referring to technical tools aiming at mitigating the tension between epidemiologic evidence results and the individual patient. EBP proponents respond to this kind of criticism by describing the extent to which the applicability of epidemiologic evidence is improved by models of shared decision-making (e.g. Guyatt et al. 2015; Djulbegovic and Guyatt 2017; Straus et al. 2011) and the inclusion of patient-relevant outcomes in clinical research (e.g., ibid.).

(2) Responses referring to definitions of EBP (e.g. Straus and McAlister 2000). By referring to definitions, claims that EBP ignores patients' values and preferences are deemed misperceptions (ibid., 838). A related response is to distinguish between challenges unique to EBP versus challenges universally applicable to any health care. Difficulties in applying evidence to the care of individual patients are considered a universal challenge to any health care, thereby mitigating several general variations of criticism on this issue.

Another related response might be to distinguish clearly between the clinical epidemiology scientific framework of EBP and the application of evidence in evidence-based practice. As stated in section 2.2. above, evidence provided through clinical epidemiology principles does not improve patient-care directly but equips the EBP clinician with information necessary for clinical decision-making. The direct link to clinical practice at the point of patient care is established by the clinician, who makes use of professional expertise to apply this evidence in accordance with patient preferences and circumstances. At this point of patient care, the evidence has to be integrated into clinical practice, by a clinician, to ascertain that the evidence actually corresponds to patient-

unique preferences and circumstances. In this case, knowledge concerning the clinician's expertise and ability to integrate, as well as knowledge concerning the patient and the circumstances, are considered necessary conditions in EBP decision-making, in addition to the scientific knowledge provided through the clinical epidemiology framework.

Much of the criticism can be mitigated and/or labelled as the product of misunderstanding, by stressing that the application of evidence presupposes the application of evidence at the point of patient care and is not limited to clinical epidemiology principles. As some of the critics correctly point out, there are several challenges to individual patient care when applying epidemiologic evidence sources, but none of these challenges has to do with the fact that the preferences of the individual patient are excluded. Rather, considerations of assessment and application of evidence in EBP at the point of patient care must, by the very definition of EBP, include patient preferences.

(3) Responses referring to the benefits of outcome-based research with regard to the individuality of the patient. For instance, Brody et al. respond to criticism that outcome-based data from population-studies limit attention to patient individuality, by claiming that, rather than limiting attention to the patient, the application of population-based studies does in fact *promote* the individual:

> Instead of being treated as a bundle of tissues that demonstrate certain biochemical responses, the patient is now a member of a population that demonstrates more or fewer major complications of diabetes, such as premature death, blindness, and loss of limbs. Offered a choice of which "impersonal" way they would prefer to be viewed, most patients would probably opt for the latter, where the outcomes of research appear to have real, personal meaning. (Brody et al. 2005: 575)

This is a point that the previous criticism ignores. The advantage of outcome-based research is that information about the direct effects of clinical interventions is more

distinct, both for the clinician and for the patient. In future debate, both views should be addressed in a coherent way.

3.5.3. It is not the patient, but the clinician who integrates patient preferences and circumstances

Critics have also claimed that EBP is more focused on the clinician's decisions than on helping patients to become more involved in making decisions for the themselves, thereby decreasing the autonomy of the patient (cf. Brody 2005: 574. E.g., Brase 2005; Bluhm & Borgerson 2010, Charles 2010; Charlton & Miles 1998; Upshur 2006).[109]

Bluhm and Borgerson make their claim in close connection with the EBP model (as presented in Chapter 2 above):

> [a]ccording to EBM, it is still up to the *physician* to "integrate" patients' values and preferences with the evidence obtained from clinical trials and thus to determine the best treatment, suggesting that EBM's contribution to *patient* autonomy is minimal. (Bluhm and Borgerson 2019: 220) [110]

While the description of the physician's (or, more generally, the clinician's) role in the EBP process is accurate, the inference of minimal patient autonomy is not necessarily true. As described in 2.4.3. and in the subsequent subsections above, the integration should be done in collaboration between the clinician and the patient. In addition, patient preferences are the central factor in every step of the EBP process (cf. 2.2; 2.4.3.ff).

[109] A variation of this kind of criticism is that the main attention is to following directions from guidelines more than facilitating the patient's choice (e.g., Rogers 2002).

[110] A similar version is presented by Upshur: "[t]he patient is seen as a vehicle or object from which to extract information. The clinician searches databanks for methodologically sound studies, critically appraises them and then brings them back for the application to the patient and evaluates the outcome. Patients are almost complete bystanders to the process of EBM as originally described." (Upshur 2006: 284)

As described in 2.4.3.1.1., the expression "patient preferences and circumstances" in EBP refers not only to the patient, but also to the EBP clinician's understanding of and responsibility for the patient's knowledge, subjective experiences, and attitudes, as well as for the external circumstances that may affect the clinical decision-making. The attention to "understanding of and responsibility to the patient's knowledge, subjective experiences, and attitudes" supports Bluhm & Borgerson's argument that "it is still up to the physician to "integrate" patients' values and preferences",[111] but this does not entail reduced patient autonomy. Rather, I consider the physician's role as a presupposition for ensuring patient autonomy at the outset, whereby the patient's values, beliefs and attitudes toward one or more possible courses of clinical actions are assured to be considered by the clinician.

3.5.4. An overview of the criticism concerning patient preferences

Criticism concerning patient preferences in EBP is more complex than the previous main kinds of criticism. Most arguments concern how patient preferences are related to and limited by EBPs stance on evidence and clinical expertise. Most of the criticism addresses the extent to which patient preferences are compatible with the attention to epidemiologic evidence sources. Some critics claim that patient preferences are in fact not included at all, as they are subjugated to epidemiologic evidence. I consider such a claim erroneous, contributing only to a straw-man argument, where the model of EBP is ignored.

[111] Personally, I find this argument a bit odd: Bluhm & Borgerson seem to imply that it should be up to the individual patient to integrate her own values and preferences with the evidence, into clinical practice. In my view, this amounts to an irresponsible model for clinical decision-making. It should be the *clinician* who has responsibility for the *clinical* decisions to be made. For instance, the clinician could present two different therapeutic strategies for the patient, and carefully explain the advantages and disadvantages of each. When the patient finally decides to pursue a particular strategy, this is not a part of the integration of the evidence into practice, but is instead based on this integration.

The most common criticism concerns the extent to which outcome-based data from population-research limit attention to patient preferences. There are several variations of this claim, some of which imply a dichotomous relation between epidemiologic evidence sources and attention to patient preferences. This implication is invalid and leads to an over-simplified understanding of how evidence is assessed and applied in evidence-based health care. Other variations of this criticism point to challenges with regard to both external validity extended to the point of patient care, and to the potential under-representation of relevant data and use of expertise. These criticisms identify challenges which are both valid and relevant concerns with regard to the inclusion of patient preferences in EBP. However, these challenges are well known to EBP proponents, and there are tools for mitigating them. Moreover, many of these problems are not unique to EBP, but extend to any health care practice.

A third argument concerning patient preferences addresses the role and autonomy of the patient in EBP practice, claiming that it is not the patient, but the clinician who integrates patient preferences and circumstances. While it is true that the integrative process is the responsibility of the clinician, the critical claim ignores the central role of the patient as the main subject in every step of the EBP process, including that of integration.

A general observation of the criticism is that there is a tendency to ignore the extent of non-scientific knowledge in EBP. In particular, the role of expertise is both necessary and important to ensure that patient preferences are included in clinical decision-making at the point of individual patient care.

3.6. Conclusion

In this chapter I have identified the main arguments against EBP and discussed whether the arguments and claims provided are valid and relevant. I have demonstrated that most of the criticism can be categorized under four main topics: (1) criticism of the conceptual unclarity in the concept of EBP; (2) criticism of the scope and application of evidence, as well as lack of evidence that EBP interventions provide better outcomes than non-EBP interventions; (3) criticism of clinical expertise; and (4) criticism of the extent to which patient preferences, including the patient's values and autonomy, are accounted for in evidence-based practice. In the discussions above, I have also demonstrated that parts of the criticism present nuanced and important points, while other parts tend to be less sensitive to the EBP model, sometimes creating over-simplified straw-man fallacies about EBP.

As stated in the introduction to this chapter, the essential controversial point in the EBP debate is the use of evidence from epidemiologic research in a clinical setting. In particular, the confidence in and the application of epidemiologic evidence sources constitute the core controversial elements. These elements have to do with the methodological presuppositions of EBP such as they are developed through clinical epidemiology. All four of the main topics of criticism are related to these presuppositions: The unclarity of the concept of EBP is primarily a problem of clarifying how epidemiologic and non-epidemiologic elements are combined; the scope of evidence has to do with the extent to which non-epidemiologic evidence sources are subordinated to epidemiologic evidence sources; while the topics of expertise and patient preferences have to do with whether and to what extent they are compatible with the epidemiologic principles of EBP.

In my view, the most relevant criticism is presented by critics who are able to distinguish clearly between the methodological presuppositions from the model of EBP in general.

Conversely, critics who are unable to distinguish clearly between the methodological presuppositions from the model of EBP in general, generate irrelevant criticism.

An example of relevant criticism is Worrall's attack on the methodological presuppositions for the justification of ranking randomized evidence sources above non-randomized evidence sources. In my view, criticism concerning the justification of randomized evidence sources as superior to other evidence sources is the kind of criticism where EBP opponents and proponents seem to disagree the most.

Another example of relevant criticism is Feinstein & Horwitz' arguments about the limited usefulness of applying results from randomized comparative evidence sources in clinical practice. While the arguments in Feinstein & Horwitz' criticism have been reflected in EBP literature and are in part mitigated (e.g., by the inclusion of pragmatic trials), this kind of criticism, similar to Worrall's, addresses the methodological presuppositions of EBP.

Examples of irrelevant criticism include categorical claims that EBP in general only includes epidemiologic evidence sources and that the EBP model excludes clinical expertise and patient preferences. These are examples of misinterpretations of what EBP is, often due to erroneous inferences from the model of clinical epidemiology (regarding clinical epidemiology principles) to the model and practice of EBP (regarding the actual application of evidence at the point of patient care.)

In between these extremes, there is criticism that addresses different elements of EBP, with regard to whether they are accounted for in an adequate manner (such as whether the terms of "evidence and "expertise" are adequate) and the extent to which these elements are compatible with each other (such as the extent to which the view of evidence in EBP is compatible with clinical expertise and patient preferences). With the exception of categorical claims, all these criticisms are relevant.

These kinds of criticisms are relevant in that they identify challenges to clinical practice. The controversy in these criticisms, however, is minimal because they are recognized by EBP proponents and are problems that demonstrate the need for increased conceptual attention and clarity more than issues of methodological deficiencies.

Disagreements between EBP proponents and opponents with regard to whether the elements of the EBP model are accounted for in an adequate manner have primarily to do with criticism of vagueness and impreciseness in key EBP terminology, such as “evidence”, “expertise” and “integration”. Most of these disagreements can be avoided by more accurate and unified terminology in EBP literature, and by more careful readings by critics.

Criticism addressing the extent to which certain elements are compatible with each other can be understood as disagreements about the extent to which elements of the tripartite definition of EBP are combinable. Compared to criticism concerning evidence, criticism concerning both clinical expertise and patient preferences is less technical and more complex. It is less technical because the scientific terminology is less technical, and more complex because it problematizes the relationship between scientific knowledge on the one hand, and non-scientific knowledge concerning expertise and patient preferences on the other. Criticism concerning the autonomy of the clinical expert targets the relation between evidence and the role of clinical expertise. Most of this kind of criticism is mitigated considerably by stressing the necessary interdependent relation between them: In order for research data to be applied as evidence in clinical practice, to recommend interventions for individual patients, the research data have to be assessed in terms of both internal and external validity and in accordance with the patient’s preferences and circumstances. It is important, however, to stress that mitigation does not mean that the problems critics raise are less important or that the problems addressed are unnecessary to improve.

Based on the criticisms above, at least two improvements can be suggested: Firstly, that the hierarchical ranking of evidence sources should be based on and be more sensitive to an expanded set of criteria, e.g., by distinguishing between pragmatic and non-pragmatic trials. Secondly, more attention should be paid to the challenges of external validity, including clarifications of "generalizability" and "applicability" and of the extent to which assessment of evidence in general is dependent on non-scientific, contextual and personal knowledge, at the point of patient care.

With regard to the EBP model as a whole, my analysis of the EBP debate demonstrates in particular two important features: firstly, that the confidence in and justification of randomized trials above other evidence sources is problematic and in need of adjustment. In particular, with regard to the hierarchical ranking of evidence sources, attention to constructive criticism should be based on and be more sensitive to an expanded set of criteria, e.g., by distinguishing between pragmatic and non-pragmatic trials. Secondly, it should be acknowledged that many controversies in the debate could be mitigated or eliminated by a more rigorous and unified terminology, whereby misinterpretations and lesser disagreements can be avoided.

Chapter 4. Analysis of the Norwegian EBP debate

4.0. Introduction

The main claims set forth by Norwegian opponents are similar to the main kinds of criticism discussed above. In my view, the Norwegian EBP criticism does not exhibit more misunderstandings, simplifications, or straw man fallacies than in the international debate. However, since the number of participants in the EBP debate in Norway is considerable smaller than in other countries, skewed understandings of EBP are somewhat more noticeable, and therefore tend to be a more common part of the EBP debate as well. The following analysis may also serve as a demonstration of features in EBP criticism in general as well.

In the Norwegian EBP debate, several people have participated, some more prominent than others. In particular, there are three critics who have been essential to the debate, creating a typical standard for a critical conception of EBP, often cited by others: Ekeli (2002), Ekeland (2009), and Martinsen (2009). In the following, I will attend to their criticism in chronological order, aiming for an overview of the central arguments in their criticism. When citing the Norwegian authors, I have translated the text into English. All translations are mine. In section 4.5, the analysis of the Norwegian critics will serve as basis for a critical analysis of the central features of this criticism.

4.1. Criticism addressing the conceptual unclarity of EBP definitions

A common feature in all three critics is their claim that the definitions of EBP are too general, vague, and uninformative, covering up the essential content. As such, their criticism resembles the international criticism of the same topic (see section 3.2.) to a large extent.

Of the Norwegian critics, Ekeland provides the most detailed criticism of conceptual unclarity. As part of his criticism, Ekeland addresses the uncontroversial character of EBP definitions, with regard to the relation between theory and practice:

> In the definition, little is said about what the clinician does when these conditions do not coincide, or about who determines the weighting and interpretation of the different dimensions. If the reality was as the definition suggests, and that these are assessments made autonomously by the individual practitioner set above the individual case, there is not very much new to discuss. (Ekeland: 2009: 151)

Of course, what is implicated here, is that EBP definitions do in fact not suggest the realities of EBP. Central claims expressed by all three critics are that EBP evidence-sources are narrowly defined and exhibit limitations in clinical practice, and that the individual EBP practitioner does not possess any significant autonomy. In particular, Ekeland addresses "evidence" in EBP definitions, in which the "extremely specific rules" (ibid.,153) pertaining to evidence remain unclarified.

All the Norwegian critics tend to specify the content which EBP definitions are covering up. They present variations of the following claim: Definitions of EBP cover up the fact that its basis lies within evidence-based medicine and its epidemiologic heritage (e.g., Ekeli 2009: 145-152, Ekeli 2002: 8; Martinsen 2009: 88f). Such a specific criticism contributes to a characteristic difference from the international criticism of the same topic.

The Norwegian criticism also differs from the international criticism in that the Norwegian critics also comment on the Norwegian translation of EBP to "Kunnskapsbasert praksis" (literally: "Knowledge-based practice"). They consider this translation problematic, in that "kunnskap" ("knowledge") is too inclusive and covers up that EBP is directed at scientific evidence specifically, and not "knowledge" in general (in particular, see Ekeli 2002: 55).

Ekeland also states that the problem with the translation from "evidence" to "knowledge" is its implication of that that there is no alternative, that is, a practice that is not based on knowledge. (cf. Ekeland 2009: 154).

As stated in 3.1., criticism of this kind is seldom the core subject of the critics' argumentation. This is also the case with the Norwegian variation on this theme. Instead, main attention is on what EBP really amounts to – which is indicated but not argued for in their criticism of EBP definitions. All three critics identify and argue against what they consider untenable assumptions regarding the basis for clinical practice. It is the identification and alleged content of these assumptions, and the arguments provided against them, that constitute what I considers their essential criticism, which I will attend to in the following analysis.

4.2. Ekeli's criticism of EBP

Ekeli's analysis is comprehensive, ambitious, and rather original, covering a broad range of topics. Ekeli's professional background is physiotherapy, and the main object of criticism is evidence-based physiotherapy. Indeed, the main motivation of Ekeli's text is the initiation of evidence-based physiotherapy in Norway. In Ekeli's own words, her book presents a study of the ideal of knowledge [kunnskapsidealet] that constitutes the basis for EBP (cf. Ekeli 2002: 5). Her main aim is to conduct a critical review of the understanding of knowledge in EBP (ibid), in particular in relation to "the insights and competence necessary to solve real-life health care issues" (ibid.). Ekeli's conclusion is that EBP provides insufficient basis for individual patient care in clinical practice, and in particular with regard to complex health issues (cf. ibid, 62).

The attention to real-life health care issues in clinical practice is formally similar to criticism targeting the scope and usefulness of research evidence. However, instead of discussing the extent to which epidemiologic evidence-sources (or in Ekeli's own words: "medical research"),[112] are sufficient as evidence in clinical practice in terms of scope and validity (as is the case in the international criticism; cf. sections 3.3.–3.3.5 above), Ekeli's discussion takes place within a more comprehensive and theoretical framework, addressing what she considers implicit theoretical premises for the EBP system (cf. ibid., 5). In broad terms, Ekeli's general view of EBP is that it exhibits a one-dimensional and

[112] In Ekeli's text there are very few references to epidemiology (and only one to clinical epidemiology), and discussions about "methods" and "evidence" in EBP are made with reference to "medical" or "scientific" research" in general. "Medical research" refers to objective criteria and data (cf. ibid, 19) and attention to "[s]imilarity, generalizability, and precise definitions" (ibid, 67). These latter characteristics make is reasonable to infer that "epidemiologic evidence" is implied. Although her main criticism of evidence in EBP addresses population-based (i.e., epidemiologic) research, it is not clear whether Ekeli means to, or are fully aware of, the differences between non-epidemiologic and epidemiologic evidence-sources. This will also be discussed in my critical analysis of the Norwegian criticism. In the analysis of Ekeli's criticism, I will refer to epidemiologic evidence only in the cases where Ekeli explicitly makes such references. In other cases I will refer to "biomedical research, which also includes epidemiologic research.

instrumental understanding of knowledge, insufficient to justify physiotherapy decision-making in clinical practice (cf. ibid., 55).

Ekeli is primarily concerned with evidence-based physiotherapy, and many of her own examples are from the field of physiotherapy. On the other hand, when she argues that EBP exhibits a one-dimensional and instrumental understanding of knowledge, insufficient to justify physiotherapy decision-making in clinical practice, she does so by presenting more general claims, addressing EBP in general. In the following analysis of her main claims, I will primarily attend to these general claims and arguments.

Ekeli's main criticism contains four main claims. The first claim is that there is lack of evidence for assertion that the EBP model provides the best available health care. Her second claim concerns the narrow scope of evidence in EBP. A third claim attends to the limited usefulness of biomedical (including epidemiological) evidence sources in general, and a fourth claim is aimed at practical implications of the use of evidence, which may lead to marginalization and instrumentalization of clinical expertise. I will conclude my analysis of Ekeli by providing a brief overview of the main elements of the criticism.

In the following analysis of Ekeli's criticism, I will thus attend to the following main sections:

4.2.1. There is lack of evidence for that the effectiveness of EBP practice.

4.2.2. EBP represents a narrow scope of evidence.

4.2.3. The usefulness of applying biomedical evidence to individual patients is limited

4.2.4. Evidence-based practice minimizes the use of clinical expertise and the autonomy of the patient.

4.2.5. An overview of Ekeli's criticism.

4.2.1. There is lack of evidence for the effectiveness of EBP practice

In her initial discussion of the basis for EBP, Ekeli asks: "Where is the evidence for that […] knowledge [in EBP] makes us better physiotherapists or physicians?" (cf. ibid., 12).[113] According to Ekeli, the documentation for EBPs quality-improving effects is solely based on "belief, authority and strong opinions" – that is, attributes to what the EBP literature allegedly constitutes a reaction to (cf. section 2.1 above). On this basis, Ekeli claims that EBP proponents have provided neither scientific evidence, nor believable argumentation for their claim (cf. ibid., 16). In short: "[t]here is no documentation that EBP provides quality-improving effects" (ibid.). I consider this to be her main claim regarding lack of evidence for the effectiveness of EBP practice.[114] As I will discuss in section 4.4.2. below, I consider this argument a variant of the international criticism I have analyzed in 3.3.4. above.

4.2.2. EBP represents a narrow scope of evidence

Ekeli provides two different lines of arguments to support this claim. The first is theoretical, based on an interpretation of EBPs biomedical ideal. The second is empirical, addressing the content of hierarchies in EBP literature.

[113] It is interesting to note that whereas most critics in the international debate address the issue of lack of evidence about whether EBP provides the best available health care for *patients*, Ekeli addresses the question with attention to the EBP *clinicians.*

[114] Ekeli is not very precise at this point. The complete context from which I quote consists of a rather complex structure. After examining how three EBP authors present themselves by using anecdotes from previous experiences, Ekeli claims that these authors only refer to "confessions" (ibid., 15). On this background, she infers that: "Therefore, *we stand before the paradox of a system that aims at communicating the pinnacle of medical research, conducted according to the strictest criteria, which is based on a basis of beliefs and experiences*. […]. Thus, if it is not considered necessary to document the quality-improving effects of EBP; will this mean that one ascribes a priori status to that knowledge which is communicated through the system?" (ibid.,16) [italics mine]. There are a number of potential claims at this point. In my view, the most relevant implied claim here is expressed in the middle question (highlighted by italics).

Firstly, Ekeli presents a theoretical line of arguments, addressing what she considers to be the one-dimensional scope of EBPs view of evidence. According to Ekeli, EBP includes only "biomedical" (including epidemiologic) evidence-sources. Supported in part by readings of Foucault (cf. ibid., 17), biomedical research is characterized by its adherence to empiricism (cf. ibid., 59) and a strict attention to objective criteria and data (cf. ibid., 19), demanding objective signs of sickness (cf. ibid., 26; 66) and attention to "[s]imilarity, generalizability, and precise definitions" (67), while excluding any other forms of data.

The main problem of such a view on evidence, Ekeli claims, is that it is characterized by an exclusive attention to objective criteria (cf. ibid., 19). These criteria are too narrow to include non-objective symptoms, such as "subjective symptoms", "invisible pains" and "subjective pain".[115] Within EBP, such non-objective characteristics, Ekeli infers, would be considered as interfering with the methods and measurements, and would therefore implicitly be defined as irrelevant. Thereby, "[m]uch of what makes us humans – which is part of our intersubjectivity reality – falls outside the scope of science" (ibid., 22f), and hence, outside the scope of evidence in EBP.[116]

In this line of criticism, Ekeli addresses what biomedical (including epidemiologic) methods can and cannot include. Although she does not explicitly refer to qualitative methods in

[115] Ekeli stress that such qualitative criteria are common within the field of physiotherapy.

[116] Ekeli also discusses the narrow scope of EBP through Kuhn's concept of "paradigm" and "normal science". Ekeli describes EBP as representative of the biomedical paradigm. As a "normal science" within this paradigm, the main function of EBP is not to bring forth new theories, but to clarify what is already within the paradigmatic framework, i.e., "[t]o bring forth results which strengthen the paradigm's position" (cf. ibid., 42). On this basis, EBP is described as a "[p]aradigmatic project, oriented towards keeping practitioners within the biomedical way of thinking" (ibid., 63). According to Ekeli, a scientific revolution is a necessary requirement for the development of new "medical theory" that is able to explain complex issues, such as fibromyalgia (cf. ibid., 45). I consider this line of argument to be a variant of addressing the narrow scope of evidence in EBP. This variant is not further developed in any detail, and I will not examine it further.

her criticism, it seems reasonable to interpret Ekeli as claiming that EBP excludes qualitative methods.

Another theoretical approach in Ekeli's criticism of the narrow scope of evidence in EBP is her claim that the EBP model represents only one of several kinds of propositional knowledge. Conversely, clinical practice must include knowledge of both the user's experiences and of the communication which occurs between user and physiotherapist (cf. ibid., 66f). In such a practice, both propositional and non-propositional knowledge[117] are necessary. Ekeli stresses that the idea of an evidence-based physiotherapy will "[n]ever approximate the ability to fulfill the need for [both propositional and non-propositional] knowledge […] in physiotherapy. It can only represent one among many kinds of propositional knowledge" (cf. ibid., 67). In this way, evidence in EBP exhibits a one-dimensional and narrow understanding of knowledge cf. ibid., 55.

To sum up the theoretical argument Ekeli presents, EBP is described as being representative of a biomedical research ideal, with exclusive attention to objective, propositional knowledge. In effect, EBP exhibits a one-dimensional and narrow scope of evidence. The narrow scope of evidence is also demonstrated through Ekeli's claim about that the EBP model represents only one of several kinds of propositional knowledge and ignores non-propositional knowledge. Compared to the international criticism, Ekeli's theoretical line of arguments represents variants of what has been described above as a categorical claim that only epidemiologic evidence-sources constitute evidence in EBP (cf. section 3.3.1. above) – with the notable difference that evidence-sources are extended to biomedical evidence.

[117] Ekeli refers specifically to two non-propositional kinds of knowledge: knowledge of acquaintance and skills [fortrolighets- og ferdighetskunnskap] (ibid.). The distinction between propositional and non-propositional knowledge corresponds broadly to the distinction I made in 2.4.1. above, between "propositional knowledge" and "procedural knowledge".

Secondly, Ekeli provides an empirical line of argument, where she addresses EBP's scope of evidence by discussing the hierarchical ranking in two different EBP texts.[118] In the first EBP text (Bjørndal, Flottorp, Klovning (2000), Ekeli recognizes that the evidence hierarchy contains eight levels, with systematic reviews of randomized studies on top and expertise and consensus statements at bottom. In a second EBP source, Ekeli describes a hierarchy on the evaluation of research in physical rehabilitation (Helewa, Walker 2000). In this latter hierarchy, there are five levels, with 'Large randomized trials with low false-positive and low false-negative errors' ranked on top and 'Case series without controls' at bottom. She notes that this latter source ascribes 100% trustworthiness (i.e. internal validity) to evidence-sources at the upper level, and 0% at bottom level (Ekeli 2002: 59). From these two sources, Ekeli infers that when non-epidemiologic evidence-sources (including non-scientific knowledge) are, at best, included in the EBP evidence-hierarchy at all, such sources have a trustworthiness that equals zero (cf. ibid., 67).

What is inferred here is highly central to Ekeli's argument: Because non-epidemiologic evidence-sources exhibit a trustworthiness that equals zero, Ekeli can claim without contradicting her former two arguments about the one-dimensional scope of epidemiologic evidence in EBP, that non-epidemiologic evidence is deemed irrelevant in an EBP perspective (cf. ibid., 22). On the same basis, she also claims that "When champions of EBP demand documentation, it is typically only results of RCTs or cohort-studies presented in the form of charts or curves that have assertive power" (cf. ibid, 66). In this way, Ekeli describes the scope of evidence in EBP by referring to the basis of medical research and epidemiologic evidence-sources exclusively. On the basis of Ekeli's assumption that non-epidemiologic evidence-sources exhibit trustworthiness that equals zero, these sources can be considered irrelevant to the scope of evidence in EBP.

[118] Ekeli also refers to an article introducing the concept of "Knowledge-based physiotherapy" (Jamtvedt, Hilde, Risberg 2000), which does not present a hierarchy but, according to Ekeli, in which experience is "zeroed out" as a valid basis for clinical decision-making (Ekeli 2002: 58f).

In sum, Ekeli provides two lines of arguments in her criticism of the narrow scope of evidence in EBP, one theoretical and one empirical. The theoretical arguments are representative of a version of a categorical claim – only biomedical (including epidemiologic) evidence-sources are included in EBP. The empirical claim addresses the hierarchical ranking in the EBP literature, in which the criteria for assessing the quality of evidence are too reductive and restrictive, systematically favoring epidemiologic kinds of evidence to other kinds of evidence, to the point of irrelevance of non-epidemiologic sources.

4.2.3. The usefulness of applying EBP evidence in complex clinical practice is limited

Initially, Ekeli admits that the search for "proofs" of disease processes and treatment effects have achieved great success in medical science, by providing research results with minimum interference from random errors and from the subjectivity of the researcher (cf. ibid., 29). She also states that "[c]learly, it is useful to know about research and new knowledge within the field which one works. It is not a view of EBM as one evidence-source among others that I argue against" (cf. ibid., 60).[119] Instead, Ekeli addresses the one-dimensional attention to research-based knowledge and claims that this kind of knowledge is not representative for the knowledge necessary nor useful to understand a fibromyalgia patient and their complex, often comorbid, disorders (cf. ibid., 62). In her view, the one-dimensional understanding of evidence in EBP is insufficient to justify physiotherapy decision-making in clinical practice (55).

As such, the target of Ekeli's criticism is rather narrow, addressing the usefulness of epidemiologic evidence in a highly specified patient group. However, many of her arguments entail a considerable broader scope, arguing for the "[l]ack of correspondence

[119] This statement is Ekeli's reply to a question raised by two Norwegian EBP proponents, addressing whether Ekeli means that the results from research (their example is epidemiological research on Sudden infant death syndrome) should have relevance for clinical practice at all (cf. ibid.).

between the knowledge- and research-ideal which in EBP […] and the kind of knowledge necessary to understand humans with sufferings, which is not graspable by the biomedical paradigm" (ibid., 63). "Lack of correspondence" in this context resembles the problem of generalizability discussed above, as an attribute of external validity (section 1.4.1.2. above). Due to this lack of correspondence, Ekeli considers the (allegedly) narrow scope of evidence-sources in EBP to be of minimal usefulness in clinical practice.[120]

Early in her text, Ekeli asks the following questions concerning the usefulness of EBP evidence:

> [The EBP system] presents "quality assured", "valid", and "useful" knowledge through systematic reviews, based upon the "newest and best" research. However – what is meant by scientific quality in this context? Is it given that knowledge which fulfills the scientific criteria of quality is in accordance with that [knowledge] which is relevant, useful, and valid with regard to clinical practice? (ibid., 12)

Her first question about "quality" is answered by the biomedical ideal of science: Strict attention to objective signs, similarity, generalizability, and precise definitions (in line with her argument of the narrow scope of EBP). Her second question addresses issues of external validity. In the international criticism, this is typically discussed with regard to the extent to which it is possible to generalize from epidemiologic research-results about the average effects of interventions in a specific population and setting, generalized to individual patients in another clinical setting.[121] In comparison to this, Ekeli's criticism takes a more categorical form, claiming that there is no basis for such a generalization:

> [I] have yet to identify believable explanations regarding how results from statistical investigations on large populations can provide "more certain" [sikrere]

[120] As such, her criticism is a variant of the international criticism that addresses the limited usefulness of epidemiologic research, with specific regard to comorbidity (cf. section 3.3.3. above).

[121] This is discussed in section 3.2.3. above.

> basis for clinical expertise[122] with regard to individual patients in life-situations, which lack any similarity to controlled standard conditions. (ibid., 60)

In this way, Ekeli claims that scientific, population-based knowledge entails a severe limitation of the usefulness of applying biomedical (including epidemiologic) evidence in clinical practice. [123]

Ekeli also states that knowledge in EBP, with its basis in the biomedical ideal, is only valid within the realm of "the reality of medical science" (ibid., 21ff). Indeed, any fact generated through biomedical research is only valid within this realm (cf. ibid., 25). Research-results from the biomedical methods in EBP are "[s]haped by the scientific process, i.e. that the knowledge is created in the image of science, of the logic of the scientific reality, and not of that rationality which characterizes the field of practice" (ibid., 36).[124]

Conversely, Ekeli describes a non-EBP physiotherapy as being in line with non-biomedical knowledge. When developing professional theoretical perspectives within (non EBP)

[122] Notably, Ekeli does not refer to application of population-based research in relation to clinical practice, but to population-based knowledge in relation to expert knowledge. This is an important difference concerning the distinction she is addressing. This fully in line with her own ambition, described just above the citation above: "My claim is epistemological […]. It is not a description of practice" (ibid.).

[123] Notably, the last part of the latter sentence – "with regard to individual patients in life-situations, which lack any similarity to controlled standard conditions" – may be interpreted in two different ways: One interpretation would refer to patients with severe forms of co-morbidity, who *de facto* lack *any* similarity to the test conditions of a trial. In this case, the claim is a priori true, and redundant. Another interpretation refers to the fact that individual patients in *general* lack any similarity to controlled standard conditions. The first interpretation is highly specific and the second is highly general. I find the second interpretation most reasonable. However, as I will discuss in 4.4.4.2. below, there is a discrepancy in Ekeli's arguments with regard to the specificity and generality of different claims and arguments in Ekeli's criticism.
I consider this quotation to be highly central in Ekeli's text, addressing both the usefulness of EBP methods as well as what she considers to be the "basis for clinical expertise". In the current analysis, I will only address the first claim. The latter point is related to her criticism of expertise in EBP, which I will attend to in the following section 4.2.4.

[124] At this point, Ekeli alludes to philosophical theories she presents in the opening of her text: Shutz' "multiple realities" (cf. ibid., 21f) and Bourdieu's distinction between common and scientific reasoning as different "universes of meaning" (cf. ibid.,). On basis of these theories, Ekeli claims that knowledge produced by EBP methods is considered fundamentally different to daily-life knowledge

physiotherapy, Ekeli continues, non-propositional knowledge, addressing the subjective and intersubjective character of the clinical encounter, is to be considered equally essential as scientific propositional knowledge (cf. ibid., 50f). Without such knowledge, Ekeli claims that EBP evidence is not adapted to the practice field it attempts orienting itself towards (cf. ibid., 41). This is also presented as a stronger claim: "To understand phenomena, especially sick people, or how treatment has effect on them, lies far beyond EBPs field of interest and capacity" (ibid.,58). Indeed, the main reason for which "[s]everal decades of biomedical research has contributed so little to increase understanding of [fibromyalgia] issues" is because "these health issues fit poorly within the biomedical formula for knowledge and knowledge-searching" (ibid.,61).

Ekeli also provides an empirical support for her claims, by referring to a personal conducted case-study where physicians are interviewed about their clinical interactions with fibromyalgia patients (ibid., 26-36). In her descriptions of these interviews, Ekeli points to the fact that research to a large extent is lacking, and that most of current research has been focused on finding biological changes defined as causes, which constitute basis for treatment (ibid., 32). The key point of these interviews, Ekeli claims, is that physicians rather than making use of such research findings, base their patient-interaction on personal experience. In Ekeli's own words, the physician is left with "[t]he intersubjective reality of daily life", in which non-scientific propositional and non-propositional knowledge are being used (cf. ibid., 32). As such, these interviews also serve as empirical examples of her theoretical claim above, concerning EBP's sole attention to scientific knowledge as being less useful. In Ekeli's view, the interviews also demonstrate that the EBP ideal of standardization and objectivity does not cohere with the reality of clinical practice (ibid., 28), and that EBP evidence is not fit to handle the kinds of clinical problems the physicians encounter (ibid., 63).

4.2.3.1. The limited usefulness and the instrumentalist mistake of clinical questions in EBP

In extension of this criticism, Ekeli also addresses the limited usefulness of the clinical questions in EBP. In Ekeli's view, all the clinical questions[125] in EBP are understood in strict correspondence to EBPs scientific reductionist character[126] (cf. ibid. 61). In Ekeli's interpretation of the clinical questions in EBP, all the different questions are answerable by the same reductionist standard, focused on "biology and double blinding" (cf. ibid., 64). "However," Ekeli continues, "the conscious human will never become "pure biology" (ibid.). According to Ekeli, questions concerning humans and things belongs to different categories, which are conflated through the reductionistic character of the clinical questions in EBP. This conflation, Ekeli claims, is tantamount to an "instrumentalist mistake". Such an instrumentalist mistake is said to occur when human beings are reduced to "[a] thing in technical actions", i.e., objectified through quantitative research (cf. ibid., 65).[127] Through this mistake, EBP proponents allegedly ignore that humans and objects belongs to different categories, answerable through different kinds of knowledge (cf. ibid.).

The problem of the clinical questions of EBP, then, is that they all imply such an "instrumentalist character", which reduces any clinical question to biology and double blinding methodology. In other words: All clinical questions are limited to biomedical (including epidemiologic) methods. In effect, this is not only problematic due to the

[125] Ekeli refers to an expanded list of clinical questions with five specific types, including "experience and meaning". This list resembles the kind of clinical questions I have discussed in sections 1.2 and 2.4.2. above.
[126] "Reductionist character" is described as "[t]hat the phenomena which are studied, are subdivided and reduced to something less than they are" (cf. ibid., 44). While Ekeli considers such a reductionist method to be useful to solve medical problems, she claims that the same methods exhibit minimal usefulness for non-medical problems (cf. ibid. 44; 61).

[127] Ekeli also makes use of the instrumentalist mistake in her criticism of clinical expertise and patient preferences in EBP. I will examine this criticism in section 4.2.4 below.

limited usefulness of biomedical evidence, but also due to that other kinds of potentially more useful knowledge thereby are omitted.[128]

In this way, neither the knowledge provided through EBPs narrow scope of evidence, nor its clinical questions, are representative for the knowledge necessary to understand fibromyalgia patient and their complex disorders (cf. ibid., 62). Hence, neither the clinical questions nor the evidence used to answer them are representative of what Ekeli considers to be useful knowledge in clinical practice. Due to this, Ekeli claims that there is a lack of correspondence between knowledge provided by EBP research standards and the knowledge necessary to understand complex health issues.

On the basis of these arguments, Ekeli argues that the usefulness of applying biomedical evidence in clinical practice is severely limited, in particular in relation to complex clinical interventions, such as with fibromyalgia patients.

4.2.4. Evidence-based practice exhibits minimal room for clinical expertise and patient autonomy

According to Ekeli, the EBP model's one-dimensional attention to scientific objective knowledge also leads to deterioration of the practitioner's expertise and of the patient's autonomy (cf. ibid., 45f). I consider this to be her main claim with regard to the roles of the clinical experts and patients in EBP. Ekeli provides one empirical and two theoretical arguments for this claim.

[128] Ekeli provides several examples of questions which is not represented within EBP, and which she considers to be of far more importance than the clinical questions of EBP (cf. ibid., 62). For instance, Ekeli presents the following three questions as examples: (1) "Which effect does the physiotherapist's understanding of the bodies have, with regard to facilitation of preventive interventions and treatments?" (2) "What is good physiotherapy?" (3) "How is the relation between bodily afflictions and lived lives?" (cf. ibid.).

The empirical argument addresses the elements of 'clinical expertise' and 'patient preferences' in the tripartite model of EBP literature (similar to the figure I present in 2.1. above). She quotes from a Norwegian book on Knowledge-based practice (i.e., the Norwegian translation of EBP), which states that:

> The [EBP] figure illustrates that knowledge-based practice is more than just research-based practice. The main message is nevertheless that one should use research as a knowledge-source to a greater extent within professional practice". (Jamtvedt, Hilde, Risberg 2000: 24; in Ekeli, cf. ibid., 60)

Ekeli interprets the last statement in this quote as implicating the one-dimensional priority to research-based knowledge she argues for: "This [last statement] is indeed the main purpose of the EBP system altogether". (ibid., 60). In this way, Ekeli interprets "one should use research knowledge as a knowledge-source to a greater extent" in EBP literature as the main purpose of EBP, through which research-knowledge is said to provide "more certain" basis for clinical expertise. According to Ekeli, this demonstrates that the EBP model implies a distinct priority to research-based knowledge (ibid., 58f), through which research evidence is made the main priority, at the expense of the relational aspects of clinical practice. Thereby, attention to the practitioner's expertise is deteriorated.

In a second line of arguments, in direct extension from the first, Ekeli claims that the priority of research evidence at the expense of the relational aspects of clinical practice represents a shift of attention away from the relational dimensions in practice (cf. ibid., 60). According to Ekeli, this shift of attention must be considered as an instrumentalist mistake, through which the "[i]nstrumentalist rationality becomes directional for human communication and social interaction" (ibid., 68). According to Ekeli, the instrumental rationality in EBP entails that objective knowledge will deteriorate attention to and confidence in clinical expertise. In Ekeli's own words: "With the final victory of objective knowledge, experience-based knowledge and clinical expertise will be "expired". Then, the physician will be reduced to a technician. Professional assessments […] will be

safeguarded by electronics" (cf. ibid., 46). Thus, according to Ekeli, the clinical expertise is replaced by scientific knowledge.

A third argument addresses the implications of the instrumentalist mistake with regard to the individual patient. Ekeli claims that the individual patient must be understood as autonomous individuals and in the context of their daily life. Because of EBP's scientifically one-dimensional way of thinking, such an understanding of the patient is minimal: Within the statistical research studies provided from EBP, "[t]he "human factor" is reduced to the minimal" (38). In such research studies, patients are only present as test-groups and clinicians only as interpreters of the results. According to Ekeli, this demonstrates that de-contextualization and fragmentation are preconditions for clinical practice in the EBP system (39), delimiting attention to both clinical expertise and patient autonomy. Indeed, through the "instrumental system" of EBP, the patient will be reduced to an object and treated only within a technical (evidence-based) practice (cf. ibid., 65). On this basis, Ekeli concludes that, "To understand the patient's symptoms in a contextual way is uninteresting or irrelevant in an EBP perspective" (ibid., 46). In this line of argument, then, the ideal of objective knowledge in EBP makes personal and contextual relations incompatible with the EBP model,[129] thus minimizing the roles of the patient.

[129] Ekeli expresses this even stronger in the form of a (rhetorical) question: "How can research whose ideal is to reduce the "human factor", in any component, to the minimal, provide a valid basis for understanding human suffering?" (cf. ibid., 47)

4.2.5. An overview of Ekeli's criticism

In sum, Ekeli provides a theoretical analysis of what she considers implicit assumptions inherent in the EBP "system of knowledge". Partly based on these considerations, Ekeli puts forth four claims against EBP. These four claims address (1) the lack of evidence for the effectiveness of EBP practice; (2) narrow scope of evidence; (3) limited usefulness of EBP evidence; and (4) minimal room for clinical expertise and patient autonomy. The arguments provided in support of these claims are to a large extent based on the theoretical constructs about EBPs "system of knowledge", while other arguments are based on empirical findings, with reference to EBP literature.

4.3. Analysis of Ekeland's criticism

Ekeland has criticized EBM and EBP in several publications, primarily in relation to psychiatry and social work (e.g., Ekeland, Bergem & Myklebust2018; Ekeland 2015; Ekeland, Stefansen & Steinstø 2011; Ekeland 2013; 2009; 1999). Of these publications, Ekeland 2009: "What is the evidence for evidence-based practice?" [Hva er evidensen for evidensbasert praksis?"] is the most comprehensive attack on EBP. In the following analysis of Ekeland's main critical points, I will take this text as my point of departure.

Ekeland's main issue is the complex relation between research and practice, which in his view is deeply problematic with regard to the model of EBP (cf. Ekeland 2009: 149). His main arguments for this are: (1) EBP exhibits a narrow scope of evidence; (2) In EBP, the RCT is over-estimated as useful evidence in clinical practice; and (3), contextual complexity in EBP clinical practice is under-estimated.[130] Whereas (2) primarily addresses the question of usefulness of the RCT in clinical practice, (3) addresses what he considers to be limited attention to the clinician and to the patient in EBP. As such, Ekeland's criticism resembles three of the main kinds of criticism discussed in Chapter 3 above, concerning the limited scope of evidence-sources in EBP, the limited usefulness of applying evidence to individual patients, and the limited autonomy of the clinical expert. I will conclude my analysis of Ekeland's criticism by providing a brief overview of his main claims.

Before I turn to these topics, I will examine Ekeland's criticism of two additional topics: That the confidence in RCTs in EBP is unjustified, and that there is of lack of evidence for the effectiveness of EBP practice. Ekeland discusses these issues only briefly, and I do not

[130] Ekeland also addresses ethical and political-ideological issues, warning about that standardization (both of evidence and of clinical expertise) may lead to a New Liberalism and New Public Management "control regimen" [styringslogikk] which in turn may reduce clinical practice to production, and evidence-based knowledge to commercial interests. These issues are addressed on the basis of his main claim regarding limitations of evidence in EBP and is not developed in any noticeable detail (but see: Ekeland 2014: 217). In the (2009) text, statements concerning these topics are few and scattered. I will not examine these issues in any further detail.

consider them as part of his main criticism. I will present a brief analysis of Ekeland's treatment of these additional claims just below, in sections 4.3.1, and 4.3.2., before I turn to what I consider to be his main claims in the subsequent sections 4.3.3., 4.3.4., and 4.3.5.

4.3.1. The confidence of RCTs in EBP is unjustified

Regarding the justification of the superiority of RCTs, Ekeland discusses risk of bias with regard to randomization in RTCs. This is done briefly, by stating that RCTs may contain methodological errors and that meta-analyses aggregating the findings of several RCTs, are ill-suited to identify these errors in RCTs (Ekeland 2009: 156). In addition, he refers to La Caze (2008), who has confirmed challenges to randomization in RCTs (ibid., cf. 155).[131] On the basis of these two arguments, Ekeland claims that the confidence of RCTs in EBP is unjustified. These two arguments are fully comparable to the international debate which addresses the justification of the superiority of RCTs (cf. section 3.3.2.).

4.3.2. There is lack of evidence for that EBP practice is effective

Ekeland also targets the lack of evidence for that EBP practice is effective. According to Ekeland, the one-sided attention to outcome-based methods – to what "what works" – makes the EBP practitioner ignorant in relation to "in relation to what?" (Ekeland 2009: 149). This is, Ekeland claims, tantamount to "[a] critical breach in the logic of evidence" in EBP: "One takes for granted that if research evidence is implemented, one will, *ipso facto* [i.e., by that very fact] create better practice" (ibid.). On this basis, Ekeland states that the

[131] La Caze is a central figure in the EBP criticism. In the sections 3.3.1. and 3.3.2. above, several central claims criticizing the scope of epidemiologic evidence-sources and the internal validity of RCTs is made by La Caze. It should be noted, however, that La Caze is considerably less negative towards the justification of RCTs than other critics, such as Worrall (cf. section 3.3.2. above). Indeed, together with Djulbegovic and Senn, La Caze argue against some of Worrall's critical arguments (cf. La Caze et al. 2012; see also section 3.3.2. above).

question of whether an "implemented EBP really works" is an empirical question which is not often examined, just taken for granted at the outset. As such, Ekeland concludes, the "evidence-movement" is without any evidence-basis (ibid.). This kind of criticism is a variant of the international criticism of the same topic (as analyzed in section 3.3.4 above).

4.3.3. EBP exhibits a narrow scope of evidence

Regarding the scope of evidence, Ekeland states that evidence is highly specified in EBP, restricted to specific research designs and statistical methods (cf. ibid., 151). Moreover, these designs and methods exhibit a one-sided attention to "what works" (cf. ibid., 147) – i.e., only to research results from epidemiologic, outcome-based, research.

In Ekeland's view, the most essential attribute in EBP consists of a "gold standard", which refers to "[a] hierarchy of methodical standards and designs that research must fulfill in order to declare the intervention or treatment as evidence-based" (cf. ibid., 154f).[132] Ekeland's main problem with this hierarchical structure is that randomized trials are considered better and more valid than other kinds of knowledge (i.e., with regard to internal validity).

According to Ekeland, the hierarchical structure of evidence in EBP entails a one-sided attention to epidemiologic research, which will lead to an eradication of alternative methods, thorough which potentially important insights are disregarded due to strict criteria of validity, such as risk of bias (cf. ibid., 148). Because of this, Ekeli argues, EBP conflicts with the broad accept of "methodical pluralism" in modern science (cf. ibid.

[132] Ekeli presents a similar description of the "gold standard", as the standard for all development of knowledge within medicine.

157f).[133] EBPs narrow view on evidence is thus contra-productive to the inclusion of other methods in clinical practice.

Ekeland claims, similar to Ekeli, that the view on evidence in EBP is based on the biomedical ideal of context-free science (cf. ibid., 165). By "context-free" here is meant "control for all or most variables in a study", such as risk of bias in RCTs. This context-free ideal is demonstrated by the RCT, as a "[r]esearch design […] suitable to test drugs is exalted as the best approach, regardless of the complexity and character of the intervention" (ibid., 147). Ekeland claims that in effect of EBPs narrow view of evidence, with its context-free ideals, EBP is comparable to traditional positivism, in which research methods are the only decisive element (cf. ibid., 153).

Ekeland's attention to the RCT as "best evidence" and the conflict with "methodical pluralism" resembles the categorical claim in the international criticism (discussed above, in section 3.3.1). Ekeland's comparison between EBP and positivism is similar to the criticism discussed in section 3.3.1.1 above.

4.3.4. In EBP, epidemiologic evidence-sources over-estimated as useful evidence in clinical practice

Ekeland claims that the evidence-sources in EBP have limited usefulness in clinical practice. He argues for this in two ways. Firstly, he addresses the problem of usefulness by attending to what he views as the "context-free ideal" of scientific knowledge in EBP. Secondly, he addresses specific challenges of external validity with regard to application of RCTs.

[133] It is not further specified what other kinds of evidence that are included. In light of Ekeland's attention to "context-free methods", it seems reasonable to interpret Ekeland's view as implying that methods in EBP consist of biomedical (including epidemiologic) methods only, and excludes, at the very least, qualitative methods.

- **Context-free research knowledge has limited usefulness in clinical practice**

As a consequence of EBPs narrow scope of evidence, with its biomedical research ideal of context-free research-evidence, Ekeland maintains that there is minimal attention to contextual understanding in EBP. He demonstrates this by addressing the lack of attention to external validity in the hierarchical ranking of evidence in EBP, which in Ekeland's view is representative of the ideal of context-free evidence-sources, such as the RCT). Thus, the evidence hierarchy of EBP ignores the fact that every research method exhibits unique strengths and weaknesses regarding research questions and different contexts (cf. ibid., 157f).

Without attention to context, biomedical research evidence is considered problematical with regard to its usefulness in individual clinical practice. He admits that the scientific ideal of a universal or context-free medicine has provided great progress within biomedical *research*, through which drugs can be tested without regard for the complexity and character of clinical interventions. The problem, however, Ekeland states, is that there is no context-free treatment in clinical practice (ibid., 164f).

In particular, Ekeland states that the RCT is not suited for psychotherapy, because the RCT-design will "[s]uppress essential elements in psychotherapy as a phenomenon, such as the idea that the individual variation is categorized as systematic errors [feilvarians]" (cf. ibid., 160). Rather than basing psychotherapy on epidemiologic evidence, psychotherapy must be understood as a "contextual medicine". 'Contextual science' refers to any practice in which the methodological and technical aspects of an intervention cannot be separated from its relational aspects e.g., conversations with the patient (cf. ibid.). Ekeland stresses that such contextual knowledge should be considered equally important evidence as scientific knowledge. In EBP, however, Ekeland claims, there is strikingly little interest in such knowledge (cf. ibid., 165). In this way, the context-free ideals of EBP is highly problematical with regard to application of research in contextual clinical practice.

- **In EBP, the RCT is over-estimated as useful evidence in clinical practice**

Ekeland also provides more specific arguments against the usefulness of RCTs, from a methodological perspective, attending to inherent limitations regarding external validity and usefulness due to their design. In particular, Ekeli identifies three problems with regard to external validity:

Firstly, internal validity does not imply external validity nor clinical usefulness (cf. ibid., 155f). According to Ekeland, many proponents seem to misunderstand this issue, and interpret internally valid RCT-results as being externally valid and useful in each individual case (cf. ibid., 156ff).

Secondly, the statistical documentation provided by RCTs is often incorrectly interpreted as prediction of that the effect of the intervention under testing will be reproduced in the future. Ekeland states that the statistical models used in RCTs do not account for such conclusions (156), and that such predictions can only be interpreted in light of theories about the (pathophysiologic) mechanisms (i.e., its causal inference) that generate the effect of the outcome in the first place.

In contrast, knowledge provided from RCTs supports knowledge of the association between intervention and outcome. On basis of such knowledge, statistical (probabilistic) predictions are made with regard to how a clinical intervention is likely to have effect when recommending a certain intervention to individual or groups of patients, regardless of knowledge of the causal mechanism.[134] The core of Ekeli's claim here is that EBP clinician conflate these two different kinds of predictions.[135]

[134] This is discussed in the sections 1.2.1. above.

[135] The description of predictions based on RTCs (which in turn is based on outcome-based research) is my explanation of Ekeland's line of argument. In Ekeli's text there are no reference to predictions based on RCTs.

Thirdly, RCTs provides knowledge of the average effect of an intervention in one test-population, compared to the average effect of an alternative intervention (or placebo treatment) in another test-population. Such knowledge, Ekeland claims, is characterized by a one-sided attention to outcome-based methods, or to "what works" – at the expense of understanding "in relation to what" (cf. ibid., 149). Ekeland considers this one-sided attention to "what works" to be less problematical in medicament treatment[136] but is highly problematic in other fields of health care, such as social services and psychiatry (cf. ibid., 147ff). In non-medical fields, Ekeland continues, such objective, context-free knowledge is less central, and questions of effect and outcome will not necessarily be as useful in clinical practices.

According to Ekeland, the central point is that there is different ways in which knowledge is used. "For example", Ekeland claims, "there is an essential difference between recommendations on population-level and clinical practice" (cf. ibid., 158). In other words, outcome-based methods (and RCTs in particular) are only considered useful to the "average patient" on population-level, not on the level of the individual.

What does this more specifically entail? On the one hand, Ekeland addresses "drug-treatment" and then contrasts between "population-level" and "clinical practice" on the other. It seems that what Ekeland has in mind when referring to "drug treatment", is recommendations for public health interventions (e.g., vaccination programs), where the intervention is provided to a group as a whole (cf. Frohlich 2014). Thus, Ekeland seems to imply that epidemiologic research knowledge is useful *only* within clinical practices that

[136] It is not entirely clear what Ekeland means by "less problematical in drug treatment" [medikamentell behandling] (ibid., 158). He states that "[i]t may be *seemingly* unproblematic to define baseline or criteria for "positive effect" in medical treatment […]" (cf. ibid., 147; italics mine), which seems like a heavily qualified claim concerning whether or not attention to "what works" is considered useful. Presumably, Ekeland implies that it seems unproblematic only at the outset. As I will discuss immediately in the following, Ekeland argues that the relevance of knowledge about "what works" (i.e., on basis of population-based data on average effect of clinical interventions) is limited to population-level exclusively.

have to do with drugs. In any other clinical practice, the generalizations from RCT-findings to the individual patient are a complicated matter and associated with very high risk[137] – and can only be accounted for by the clinical expert – which according to Ekeland has been discredited in EBP (cf. ibid., 158). Without the flexibility and individualization of the clinical expert, the problem of external validity when applying population-based research on the level of the individual patient cannot be mitigated (ibid.).

These three arguments addressing problems with regard to the RCT-design support Ekeland's main claim that the RCT is over-estimated as useful evidence in clinical practice. Ekeland's arguments are variations of the argument that the usefulness of applying results from randomized comparative evidence-sources in clinical practice is limited (as analyzed in section 3.3.3. above).

Noticeably, the latter argument also includes criticism concerning the lack of autonomy of the EBP clinician. This topic is further developed in Ekeland's criticism concerning the under-estimation of contextual complexity in clinical practice.

4.3.5. Contextual complexity in clinical practice is under-estimated in EBP, leading to limited attention to clinician and patient.

Ekeland claims that contextual complexity in clinical practice is under-estimated in EBP, which in turn leads to a limited attention to clinical expertise and patients. One of the main problems with the use of epidemiologic evidence in general, is what Ekeland labels EBP's "empirical pragmatist character"; that is, the attention to documenting what works, rather than an attention to why (ibid.,149). The one-sided attention to "what works" makes the EBP practitioner ignorant in relation to "in relation to what?" (ibid.). According

[137] Ekeland does not explain what he means by "high risk" (cf. ibid., 158), but it seems reasonable that he implicitly refers to risk of misinterpretations when the research information is to be applied at the point of individual patient care.

to Ekeland, this is in essence the problem of practice in biomedicine, extended directly to EBP: “One is good at treating diseases but bad at treating sick people. A stronger turn to evidence may enhance this problem” (ibid., 150).

As a consequence of the lack of considerations concerning how something works, Ekeland claims, clinicians may become alienated from what they do, and from why they do it (cf. ibid., 156). According to Ekeland, this lack of attention concerning how something works also entails an objectification of patients. In Ekeland’s view, this objectification is directly related to the attention to outcome-based research. While the researcher (producing “context-free medicine”) may view the patient abstractly as an object, the clinician in in her clinical practice must view the patient as a living subject (cf. ibid., 150).

According to Ekeland, the relation between research and practice in EBP entails a symbiotic relationship, in which clinical practice is instructed from research (cf. ibid.). In this way, Ekeland claims, the relation between clinician and patient becomes a “technical-instrumental matter of affairs” (ibid., 147), in which clinical practice becomes standardized on basis of research evidence.

These arguments are similar to what was above described as the so-called “cookbook approach”-argument, in which the practice of the EBP clinician becomes controlled by formal rules of conduct (cf. 3.4.2.) and that the use of epidemiologic evidence limits attention to patient preferences (cf. 3.5.2.). However, instead of referring to guidelines as the main source of formalization of clinical practice, Ekeland claims that the “technical-instrumental matter of affairs” coincides with Skjervheim’s “instrumentalist mistake” (cf. ibid.,147f),[138] through which individualization of both clinician and patient is ignored.

In particular, due to the minimal interest in EBP literature to include “non-instrumental methods” (such as use of context as a health-resource in clinical practice; cf. ibid.,165),

[138] This reference is similar to Ekeli’s use of the same term; cf. section 4.2.3.1. above.

the practice of EBP will “eliminate the autonomy of which is a prerequisite for [both] communicative practice and for realizing important aspects in medicine, such as empathy, ethics, and care” (165).

On basis of these arguments, Ekeland’s criticism of the limited attention to the clinician and the patient must be considered quite fundamental, leaving the EBP model as a strictly scientific approach to clinical practice, with close to no room for neither clinical expertise nor attention to the individual patient.

4.3.6. An overview of Ekeland’s criticism

In sum, Ekeland’s criticism consists of three main claims: the criteria for assessing evidence are too restrictive, the confidence in RCT is over-estimated, and contextual complexity is under-estimated. The over-estimation of the RCT has primarily to do with problems of external validity and usefulness in clinical practice. The under-estimation of contextual complexity has to do with how the evidence in EBP is ignorant of contextual issues, thereby demonstrating minimal attention to usefulness of evidence in clinical practice.

The narrow, context-free and limited usefulness of EBP evidence also have implications the role of the clinician and the patient in an EBP clinical practice. Within EBP, clinical practice is in danger of being subdued to scientific research in that practice in EBP is instructed, and not only informed, from this scientific basis (cf. ibid., 148). In turn, this entails an objectification of patients, and a reduction of flexibility and individualization, which in turn potentially leads to increased potential for clinical malpractice. Indeed, according to Ekeland, if EBPs scientific ambitions are implemented, the result could be devastating for both research and practice (cf. ibid., 149).

4.4. Analysis of Martinsen's criticism

Martinsen has criticized EBP in several publications, addressing the field of nursing in particular (e.g., Martinsen 2005; 2006; 2009). Her essay "Evidence – delimiting or enlightening?" ("Evidens – begrensende eller opplysende?")[139] is one of her most comprehensive works on this issue. The main aim of Martinsen's criticism is "to explore and to challenge the evidence-basis of EBP" (cf. Martinsen 2009: 81f), in light of what she labels "evidentialism" (I will clarify this term below, in section 4.4.1.).[140]

The essay is divided in three parts. The first part investigates the concept of evidence in EBP, where Martinsen's main claim is that EBP's view of evidence has turned into what is labelled "evidentialism". The second part is presented as a historical contextualization of EBP (cf. ibid., 100), whereby Martinsen discusses how the rise of modern clinical medicine has changed and narrowed down what is considered relevant clinical knowledge, through which controlled experiments and statistics are considered in terms of usefulness and profitability, at the expense of personal and bodily experience (cf. ibid., 113f).[141] In

[139] This essay is published as a second half of the book *To see and to realize – On different forms of evidence* (*Å se og å innse – Om ulike former for evidens*); Martinsen & Erikson: 2009.

[140] The criticism presented by Martinsen differs from the former critics by having a more philosophical scope, exploring the basis of EBP through a more abstract terminology. In the same vein as Ekeli, Martinsen makes extensive use of several theoretical thinkers: Foucault, Løgstrup, Ricoeur, Skjervheim, and Weber. With these thinkers, Martinsen explores the philosophical implications of the biomedical basis of EBP's view on evidence, as well as alternative ways of "working with evidence" on the other. With exception of Skjervheim's "instrumental mistake", the other thinkers are used as contextual back-drops when building up to her own argumentation. In the following presentation of Martinsen's criticism, I will not attend to her use of these thinkers.

[141] Readers of Martinsen may argue that I am simplifying Martinsen's essayistic and philosophical explorations. Martinsen conducts the historical contextualization by way of a "criticism of modernity" (ibid., 82), to a large degree on basis of readings of Weber, Foucault and Løgstrup. Also, Martinsen's style tends to be richly theory-laden with concepts uncommon in most EBP criticism. In particular, Martinsen propose a reading of modern western medical history as a "dechantment of knowledge" (ibid.,113), and in particular, "[d]echantment of the perception, intangibility, and enigmatic character of the body" ["[a]vfortylling av kroppens sanselighet, uhåndgripelighet og gåtefullhet"]; ibid.,99). Her claim here, however, can be condensed to that knowledge in the medical profession has been reduced (or in Martinsen's word: "disenchanted") to statistical and quantifiable connections (cf. 156) – which contains

essence, this main topic in the contextualization resembles claims of limited usefulness and the narrow scope of evidence in EBP.[142] In the third part, Martinsen discusses ways of working with evidence in another fashion than "evidentialism".

As an alternative and reaction to "evidentialism", Martinsen also brings forth an alternative concept of evidence, based on humanistic and philosophical traditions (cf. ibid., 10). I will attend to Martinsen's alternative view on evidence as part of her criticism of the narrow scope of evidence-sources in EBP.

Martinsen identifies in particular three limitations with regard to this kind of knowledge, all of which mirrors the main kinds of topics from the other Norwegian critics: a narrow scope of evidence-sources; limited usefulness of research evidence in clinical practice, and limited room for clinical expertise.[143]

On this basis, the following analysis of Martinsen's criticism is divided into three main sections: (4.4.1.) EBP exhibits a narrow scope of evidence-sources; (4.4.2.); application of research evidence has limited usefulness in clinical practice; and (4.4.3.) EBP represents an instrumentalization of clinical practice with limited room for clinical expertise. These three claims are comparable to the typical kinds of claims in the international criticism analyzed above, in sections 3.3.1, 3.3.3., and 3.4.2., respectively).

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the same content as I address in the subsequent sections below. In the following analysis of Martinsen's criticism, one of the underlying aims is to clarify such condensed argumentative structures, and make them fit for comparison to similar kinds of criticisms.

[142] Through this contextualization, an ideological criticism is also suggested, in which political and economic interests are embedded in EBP (e.g., ibid.,156) – in the same manner as in Ekeland (see footnote 31). These suggestions, however, constitute no clear criticism by themselves, other than indicating a variation of criticism of EBPs stance on evidence in general, i.e., with regard to potential weaknesses in the production and application of evidence. These indications are made apparent by other arguments as well, more directly related to the topics of which I will attend to in the following analysis. On this basis, I do not consider it necessary to attend to Martinsen's ideological criticism.

[143] Martinsen's claims are often interwoven in such a way that several characteristics of EBP are criticized at once. The separation of Martinsen's claims into three main topics are based on my interpretations of the text, motivated by the attempt to analyze her criticism in a manner that comparable to other critics in the EBP debate.

4.4.1. EBP exhibits a narrow scope of evidence-sources

The main concern in Martinsen's criticism has to do with the claim that EBP equals the content of EBM, but is applied outside the field of medicine. The problem, Martinsen claims, is that "The concept of […] EBP conceals that the standard for evidence is located in the evidence-based medicine" (cf. ibid., 89). Thus, when Martinsen claims that EBP entails a narrow view of evidence, it is because "evidence" only refers to "medical research-based knowledge" (cf. ibid., 95). Such evidence is described as being based upon statistical methods and randomized trials (cf. ibid., 86), which presumably refers to epidemiological evidence-sources exclusively.[144]

When epidemiologic EBP extends to non-medical health care professions, its narrow view of (medical, epidemiologic) evidence becomes "directional and decisive" (cf. ibid., 83) for clinical practice. That evidence becomes "directional and decisive" entails that it excludes other kinds of evidence-sources.[145] When this occurs, Martinsen states, "evidence" becomes "evidentialism" (ibid.). According to Martinsen, evidentialism represents a certain attitude towards "only one way of working with the problem of evidence [that] becomes standardizing and universal […] which over-simplifies and covers up what should be considered diverse and complex" (cf. Martinsen 2009: 26). Consequentially, such an attitude entails a narrow scope of what should be considered evidence-sources in clinical practice. In particular, non-scientific beliefs based on perception [sansning] and experience is under-played as evidence-sources (cf. ibid., 82).

[144] It must be noted that Martinsen does not refer explicitly to "epidemiology" or "epidemiologic evidence" at all. In her essay, Martinsen primarily refers to evidence in EBP as "medical research" and "research knowledge". However, she describes "research knowledge" and "medical knowledge" as being based on "statistical methods and randomized trials" (cf. 86). I consider it reasonable to interpret these characterizations as referring to epidemiologic evidence-sources (see also section 4.3.1. below). On this basis, and for maintaining terminological coherency to the treatise at large, as well as for comparability to other critics, I will refer to epidemiologic evidence in cases where Martinsen refers to "research knowledge" and "medical knowledge".

[145] As I will discuss in the following section 4.4.2., being "directional and decisive" also has to do with the application evidence, and its (allegedly) limited usefulness.

With its narrow view of evidence-sources, several phenomena fall outside EBPs scope: patient groups with complex or vague conditions, as well as "unlimited and intangible" phenomena such as suffering, sorrow, shame, longing, and hope (cf. ibid., 114f). Also, "the residential and local, bodily and experience-based knowledge is not evident for the medical gaze" (ibid.,114), and is placed outside the scope of EBP.

Slightly paraphrased, Martinsen's claim can be expressed as: EBP has a narrow scope of evidence, in which only epidemiologic evidence-sources are considered adequate as evidence to be applied in clinical practice. As such, Martinsen's claim is a variation to the categorical claim concerning the narrow scope of evidence in EBP (cf. section 3.3.1. above). According to Martinsen, the central problem of the narrow scope of evidence in EBP, is that it – in its evidentialism – ignores several phenomena in its belief that everything can be evident in the same way (cf. ibid., 89).

4.4.1.1. Martinsen's alternative view of evidence

Martinsen also discusses alternative kinds of «working with evidence» (cf. ibid., 82), through which she addresses what kind of evidence she considers to be useful in clinical practice. For the purpose of analyzing Martinsen's view of evidence in EBP, her exploration of alternative evidence provides relevant information about what Martinsen consider to be lacking in the evidence-basis of EBP.[146]

[146] Martinsen's exploration of this problematic is comprehensive, covering almost half of her essay. Her exploration relies heavily on interpretations of Løgstrup's philosophy or perception, demonstrates a kind of phenomenological analysis of perception of daily-life and art, without explicit relation to her view on EBP. Indeed, Martinsen's main aim in large parts of her essay (in particular pp. 127-155) is to discuss various aspects of Løgstrup's philosophy. These discussions are not explicitly related to her criticism of EBP. Rather, these discussions serve as a thematic and conceptual framework for her alternative view of evidence. In the presentation, I limit my analysis to the elements of Martinsen's analysis which explicitly relates to EBP.

According to Martinsen, the challenge is to provide other forms of evidence, which does not reduce individual perception to a question of controlled observations (cf. ibid., 137). Through a phenomenological perspective, Martinsen explores an alternative concept of evidence, in which perception is explored in a more proper way than within EBP (cf. ibid., 126). One main problem in EBP, Martinsen claims, is that perceptions, through EBPs tendency towards instrumentalization, are "[r]educed to technique and controlled knowledge" (ibid., 137). In this way, EBP clinicians are able to articulate findings from research-data, but unable to apply expertise [skjønn] and to be open towards other kinds of knowledge (cf. ibid., 148). As an example of perceptions alternative to the narrow concept of evidence in EBP, Martinsen suggests "evidence by experience" (erfaringsevidens"), which are based on impressions:

> [Evidence] has among other things to do with the power of impression [inntrykkets kraft], with vulnerability, sorrow, shame, joy […], but in different ways. This is evidence by experience based on impressions. It is a [kind of] evidence which continually is created with innovative words, that others can receive, resonate to, reshape, and pass on, anew, in other combinations of words. (ibid.,161)

The main point here is that instead of using scientific, instrumentalist reason, the practitioner has to think and resonate for herself, in a way that opens up for alternative perceptions. "Practice", Martinsen explains, "[m]ust be continually invented; the practitioner has other ways to solve the situation than the researcher […]" (ibid., 97). Such practices, based on evidence by experiences, Martinsen maintains, are not based on scientific rules, only contextual information (cf. ibid., 98). Following Martinsen's train of thought: To the extent EBP does not include such alternative evidence, its narrow scope of evidence is thereby demonstrated.

Martinsen's conception of a non-EBP practice are further explored through the autonomous practice of the clinician, labeled as "freedom practice". According to

Martinsen, freedom practice is about resistance to the current evidence-base epistemic hegemony of knowledge; a practice of resistance, of obstinacy, of self-formation and new ways of expressing oneself (cf. ibid., 123ff), which aims at other ways of encountering the problem of evidence (158). Somewhat more concretely, freedom-practice consists of resistance to the constrictions of the rigorous model of EBP, in which clinical practice is reduced to following procedures and applying scientific research knowledge (cf. ibid., 157).

The concept of freedom-practice is further described as a philosophical-phenomenological way of working with words, to gain closer access to impressions that surround the clinician (ibid.,159). Freedom-practice, Martinsen describes, "[s]hows itself when the nurse dears to encounter the patient's vulnerability, affectedness, and shame" (ibid.,125). A somewhat more concrete example is provided in the context of nursing:

> The nurse listens to find the tunes of the patient, not primarily to "confess" to the physician, but to come into tune [komme i samklang] with the patient. In this encounter, the nurse disciplines herself, in that she shapes and leads her body for the sake of the other, and for […] finding the rhythm together. Thereby, the patient is also able to find his shape, in such a way that he does not become shameless, that he does not become shapeless. (ibid.,124f)

In this example, the "freedom-practicing" nurse observes the individual person, and does not reduce him to an object of scientific knowledge. Such an example demonstrates an important point to Martinsen's criticism: Instead of an evidence-based encounter, in which both the patient and clinician become "intrumentalized" and objectified, the clinical practice in Martinsen's example aims at demonstrating an encounter in which both the clinician and the patient maintain their individuality. Her examples also demonstrate an

approach to the "unlimited and intangible" phenomena such as suffering, sorrow, shame, longing, and hope, which she claims are placed outside the scope of EBP (cf. 4.4.1.).[147]

4.4.2. Application of research evidence has limited usefulness in clinical practice

Similar to Ekeli and Ekeland, Martinsen addresses the challenges of generalizing research results from population-based studies to the individual. She notes that epidemiologic research provides knowledge about the average patient, not of the individuality of and difference between the individual (cf. ibid., 26). She also states that "[t]he individual human being is something more than only a statistical average human", and that it is deeply problematic to recommend such research knowledge in individual clinical practice (cf. ibid., 85).

Also similar to the two other Norwegian critics, Martinsen is not opposed to the idea that evidence in evidence-based practice is useful within the medical field, i.e., when delimited to evidence-based medicine [EBM]. On the contrary, Martinsen notes that "[e]vidence-based medicine, of course, demonstrates evident insights within its area of validity [gyldighetsområde]"[148] (cf. 99). In this particular context, to exhibit "evident insights within its area of validity" has to do with being applicable or useful in clinical practice.

Within evidence-based medicine, then, applications of epidemiologic evidence-sources are considered useful (or, in Martinsen's terminology, "evident"). Conversely, the same evidence-sources are not considered useful in other health care professions (cf. ibid.,99).

[147] Also, the highly metaphorical language in Martinsen's examples seems to cohere with the main aim of her examination, which is to explore alternative ways of working with the problematic of evidence. Presumably, the metaphorical examples are meant to demonstrate stark contrast to the scientific terminology of EBP, and thus demonstrate alternative ways of understanding evidence.

[148] Martinsen (ibid., 96) refers to "validity" but not to "internal" or "external" validity. Instead, "validity" is used generically, relating to the validity of both research knowledge (i.e., internal validity) and clinical knowledge (i.e., external validity). When Martinsen discusses validity in relation to application of research knowledge, I consider this to be a question of external validity.

According to Martinsen, the attention to epidemiologic knowledge-sources becomes "evidentialism" when evidence-sources (the "evident insights") are applied in a broader field of healthcare, through which the area of validity is transgressed. Following Martinsen's line of thought, this would imply that if epidemiologic evidence-sources are applied within, say, nursing, this application is considered representative of evidentialism.

In general, Martinsen is highly skeptical of any application of epidemiologic research evidence into non-medical clinical practice. Similar to Ekeli above (section 4.2.1.), she claims that research knowledge and practical knowledge are of fundamentally different kinds, based on different logic (cf. ibid., 96). According to Martinsen, "research practice", with its attention to methodological rules and conduct, is governed by instrumental practice, while "clinical practice" is governed by practical reason, and which cannot be reduced to neither research knowledge nor applied research (cf. ibid., 96). In effect, generalization – and thereby the usability – of any scientific knowledge, including epidemiologic evidence, into non-medical clinical practice is deemed extremely problematic.

Notably, Martinsen does not only address epidemiologic evidence (which in her case refers to medical research only), but to research knowledge in general. Martinsen claims, that "[o]ften, application of scientific results is neither possible nor desirable" (ibid.,96). In line with her concept of "freedom practice" (discussed in the previous section), the nurse must invent her own practice, and be able to think for herself (cf. ibid., 97). Indeed, Martinsen's negative attitude towards the application of research evidence corresponds to a positive attitude towards the autonomy of the clinician:

> In the clinical practice, one may refer to research […] but not bring practical solutions from research. Because clinical practice is not applied research. […] Research is not irrelevant to clinical practice. But through her critical way of asking, it is the clinical practitioner's personal thinking and judgment which decide how one should relate to research. (ibid.)

Thus, Martinsen insists that the decision of whether research-knowledge is relevant for application is entirely up to the individual clinician. Martinsen does not address the question of whether or how the practitioner should assess research. Her main point here is that it is up to the practitioner whether she should relate to research at all. Thus, the question of valid knowledge within clinical practice is only answerable by the individual clinician, based on her practical reasoning. In effect, the assessments of the usefulness of research-based knowledge (generated through research practice) are also up to the individual clinician alone.

In sum, and in more common terminology, what is at stake in Martinsen's criticism is the justification of the application of scientific evidence into clinical practice. While epidemiologic evidence may be useful the medical field (i.e. as evidence-based medicine), it is considered problematic with regard to any other health care profession. In Martinsen's view of a sound clinical practice, what is considered useful evidence should be fully up to the individual clinician, on the basis of her practical reasoning alone.

4.4.3. EBP represents an instrumentalization of clinical practice that entails limited room for clinical expertise and patient individuality

Martinsen claims that application of epidemiologic evidence entails an instrumentalization of clinical practice, which in turn entails a minimizing of the role of the EBP clinician and of the patient. Allegedly, this occurs when clinical practice is subjugated to a *scientific* clinical practice (cf. ibid., 94). Such a scientific clinical practice refers to an idea of clinical practice that is fully reducible to scientific knowledge, which "[c]onstructs and absolutizes which [clinical] practice that should prevail" (ibid.). This idea, Martinsen continues, is tantamount to Skjervheim's "instrumentalist mistake", in which pragmatic,

instrumental, reasoning (as opposed to practical reasoning) is considered superior and directional to any clinical practices and relations (ibid.).

Through this instrumentalist mistake, a technification and control of clinical practice occurs, in which clinical practice is "manualized", i.e., reduced to scientific standards and rules (cf. ibid., 95). Thereby, the subjectivity and clinical expertise of the clinician is marginalized, and the patient is "instrumentalized" through statistical research, "[r]educed to an average human being" (ibid.).

In addition, the (alleged) scientific clinical practice of EBP also lacks attention to contextual knowledge with respect to the social field in which the method is to be applied (cf. ibid., 94). In effect, attention to "understanding, interpreting and applying, all at once" (ibid.) is excluded for the EBP clinician. In these ways, Martinsen concludes, methods are used without any reflection, without regard to professional expertise nor situational analysis (cf. ibid., 94).[149]

In the same vein of criticism, Martinsen warns: "To directly recommend technologies or procedures for an actual practice on basis of research results leads to impelled instrumentalization" (ibid.,96). Martinsen does not provide clarification to what "direct" recommendation of procedures amounts to, but it seems that Martinsen views the EBP application of research evidence as a recommendation without *any* sort of autonomous reflection from the clinician who make use of such evidence. My interpretation of Martinsen at this point seems rather extreme but is supported by other claims: The strain toward instrumentalization approximates "practice according to rules and standards, and

[149] This kind of criticism is similar to Ekeli's and Ekeland's claims about that contextual knowledge in EBP is lacking.

to ignore anything else" (98). Another passage states that EBP clinicians "[d]o not think. To think is think beyond the outcome measurement […]" (ibid.,148).[150]

In line with her own alternative view on evidence (see section 4.4.1.1.), Martinsen contrasts expertise in EBP and non-EBP practice: Instead of the non-reflective EBP clinician, Martinsen states that the (non EBP-) clinician "[m]ust be able to act reflectively [ettertenksomt] (as opposed to only act "knowingly"), in concrete situations which demand commitment" (cf. ibid.,157f). To support her claim, Martinsen also refers to research by Glasdam, who demonstrates how physicians apply personal expertise in their clinical practice, and that use of such expertise provides a basis for recommending a specific treatment, different to what kind of treatment that research may predict. In Martinsen's view, such a demonstration of a clinician's autonomy is beyond the scope of EBP (cf. ibid.).

4.3.5. An overview of Martinsen's criticism

In Martinsen's criticism of EBP, she addresses three topics: The narrow scope of evidence, limitations of the usefulness of epidemiologic evidence-sources in clinical practice, and the limited room for expertise and patient autonomy. According to Martinsen, EBP only applies epidemiologic evidence-sources, which becomes directional and decisive for clinical practice, which in turn excludes other evidence-sources and minimizes the roles of both clinician and patient.

[150] As such, this kind of criticism is an extreme version of what has been discussed in the international criticism as arguments against the standardization of clinical practice in EBP (cf. section 3.4.2. above).

4.5. Critical analysis of the Norwegian criticism

Through the analysis of the three Norwegian critics, variations of all the four main topics of EBP criticism discussed in Chapter 3 have been demonstrated: Criticism addressing (1) unclarity of EBP definitions, and limitations to (2) evidence, (3) expertise, and (4) patient autonomy. When reading these critics, a number of characteristic features appear, which I will attend to in the following. Most of these features are comparable to the international criticism, but often presented in variations that differ with respect to the broadness and the precision of their claims and arguments.

There is one line of argumentation that I consider both unproblematic and valid: Ekeland's argument addressing the justification of RCTs. He presents two arguments in support of his claim: that RCTs may contain methodological errors and, by reference to La Caze (2008), that there are challenges to randomization in RCTs (cf. 4.3. above). Both of these claims are valid and relevant. These two claims are similar to claims in the international debate, addressing the justification of the superiority of RCTs (cf. section 3.3.2.), and therefore equally relevant as well.

As I will demonstrate in the following critical analysis of their arguments, all other claims presented by the three critics include elements that I find problematic, either due to too broad descriptions for an adequate discussion of specific challenges to EBP, or due to misunderstandings of what the model of EBP entails.

4.5.1. Critical analysis of the claim that the concept of EBP is uninformative

Common to all three critics is the claim that the concept of EBP, through its various definitions, is too broad and uninformative (cf. 4.1). This claim is similar to the international debate, discussed in 3.1. above.

On the same basis as with the international criticism of the same topic, discussed in in 3.1., this is a relevant kind of criticism: The lack of consensus on a singular standard definition of EBP, exhibiting necessary and sufficient requirements for a clinical practice to be evidence-based, makes an adequate understanding of EBP difficult, and the EBP debate unnecessarily imprecise at the outset.

The Norwegian critics also provide an additional claim, not usually addressed in the international debate: Definitions of EBP cover up the fact that its basis lies within evidence-based medicine and its epidemiologic heritage (cf. 4.1.). This additional claim is not as straightforward as the first claim. Notably, the additional claim is not a claim about that definitions of EBP are uninformative, but about that they are disinformative. The Norwegian critics seem to imply that, instead of including general characteristics, EBP definitions should address more specific criteria, explicitly exhibiting epidemiologic elements.

My response to this kind of criticism is twofold. Firstly, I do not agree that the broad EBP-definitions are disinformative. Rather, the problem with broadness of these broad definitions is that they do not make the demarcation between EBP and non-EBP models sufficiently clear.

Secondly, I am disagreeing with that EBP definitions should be changed to EBM. Their claim at this point are based on an understanding EBP principles as identical to EBM, clinical epidemiology, and even to biomedicine in general. On the other hand, I am sympathetic to the idea that an EBP definition may demonstrate more distinct criteria –

such as my definition suggests in Chapter 2.[151] By including specific criteria, clarifications about specific differences between EBP and non-EBP models would clearer, and members of the EBP debate would have the opportunity to base their disagreements on a more clarified common ground. However, this argument presupposes that proponents and opponents do read definitions as well as accept the content of them. As the following analysis of the Norwegian EBP debate will demonstrate, these presuppositions are not always fulfilled.

Another interesting feature in their criticism of EBP definitions is that they also address the Norwegian translation from EBP to "Knowledge based practice" (KBP). More specifically, their claim here is that the translation from "evidence" to "knowledge" is problematic in that "knowledge" ("kunnskap") is too inclusive and covers up that EBP is directed at scientific evidence specifically and not "knowledge" in general (cf. 4.1.).

I agree with that the translation may be considered problematic: There are at least two important nuances between "evidence" and "knowledge" that is under-communicated in the translation:

In ordinary language, "knowledge" refers to a larger class of potential objects than "evidence" (both in English and in Norwegian). For instance, knowledge in ordinary language usually refers very broadly to something one knows or is able to do (cf. Ichikawa, Jenkins & Steup 2018) whereas evidence refers more specifically to certain discourses, such as within scientific research and law.[152] Another important difference is that whereas

[151] In section 2.3.5. above, EBP is defined as an "Approach to clinical decision-making, in which the clinician recommends clinical interventions to individual patients, based on the best evidence available, *assessed according to methodological criteria of evidence quality*, where the evidence is integrated into clinical practice by a clinician, who, by making use of clinical experience, identifies, assesses and applies the evidence, in accordance with the patient's preferences and circumstances." The clause marked in italics is not explicitly referring to Clinical epidemiology, but nonetheless makes the methodological elements of EBP more apparent.

[152] However, from a commonplace philosophical point of view, the opposite is the case: "Evidence" is more inclusive than "knowledge". "Knowledge refers to "justified, true belief" whereas "evidence refers to "that

"knowledge" refers to "objects one can think about", evidence refers to its justificatory function of being evidence for something else (cf. 2.4.3.).

I consider both of these issues to be implied when Ekeland states that the problem with the translation from "evidence" to "knowledge" is its implication that that there is no alternative, i.e., that there is no practice that is not based on knowledge (cf. Ekeland 2009: 154). While one could separate clearly between an *evidence*-based practice and any clinical practices based on (some non-evidential kind of) knowledge, this is not possible with regard to *Knowledge*-based practice. It is "[a]s if not all professional practice has been and is knowledge based" (Martinsen 2009: 88). The problem, then, has to do with the wide scope of "knowledge", which is broader than "evidence"

While I agree to such a criticism with regard to the term "knowledge" in isolation (cf. "knowledge" in ordinary language, just above), I disagree with that the *definition* of KBP exhibit the same problem. In the Norwegian translation of the three elements in the EBP model, "evidence" are translated to "forskningskunnskap" (literally: "research knowledge"), "expertise" to "erfaringsbasert kunnskap" (literally: experience-based knowledge), and patient preferences to "brukerkunnskap" (literally: user-knowledge). There are two points to be made with regard to these Norwegian terms:

which justifies belief". An "evidence-based practice", then, includes any beliefs that may function as evidential support for another claim (cf. section 1.3.), in principle regardless of the inherent justification of the particular piece of evidence. On the other hand, a "Knowledge-based practice" would only include beliefs that are justified (by other beliefs). From this point of view, "knowledge" is actually less inclusive than "evidence". In the same line of argument, "knowledge" in "Knowledge based practice" would not coincide with Guyatt et al.'s (2015) wide definition of "evidence" (see section 2.4.2.), due to that "justification" is not a necessary attribute to evidence-sources in this definition. For instance, Guyatt et al.'s definition of "evidence" includes "empirical observations", regardless of whether these observations are justified or not. This philosophical point of view, however, is not what critics nor KBP proponents have in mind when addressing the difference between "EBP" and "KBP", and I will not pursue this point any further.

Firstly, “Research knowledge” is significantly more precise and less extensive than “knowledge” in general. The novel idea of KBP – analogous to EBP – is to base clinical decisions on research knowledge (when available), and not knowledge in general.

Secondly, in the same manner as with the international definitions, the main purpose of the definition is to consider the three elements in relation to each other (cf. Chapter 2). Thus, another novel idea of KBP –also analogous to EBP – is that a clinical practice should be based on a combination of these kinds of knowledge.

Both of these points address features of which is easily distinguishable from other kinds of (non EBP/KBP) clinical practices. On this background, then, Martinsen’s complaint about that “all professional practice has been and is knowledge based” (Martinsen 2009: 88) is incorrect.

As stated above, I consider the criticism concerning EBP and KBP definitions more as expressions of the critics’ initial attitude towards EBP, than a main argument on its own. The content of this implication has to do with their main criticism against EBP. As mentioned in 3.1. (regarding the international criticism) and 4.0. (regarding the Norwegian criticism), the core arguments critics present are oriented toward specific elements of evidence, clinical expertise and patient autonomy rather than on concrete arguments about the concept of EBP or of Knowledge-based practice. The structure of argumentation of all of the three Norwegian critics is mainly about identifying and arguing against what they consider untenable assumptions regarding the basis for clinical practice. It is the identification and alleged content of these assumptions, and the arguments provided against them, that constitute what I considers their essential criticism, of which I will attend to in the following sections in this chapter.

4.5.2. Critical analysis of the claim that there is lack of evidence for the effectiveness of EBP

Ekeli addresses the question of whether knowledge in EBP "[m]akes us better physiotherapists or physicians". Ekeli argues that EBP is based solely on "belief, authority and strong opinions", and concludes that there is no documentation that EBP provides quality-improving effects (cf. 4.2.2. above). While Ekeli's argument in some ways resembles the international criticism, there is an important difference: The central critical claim in the international criticism is *comparative*, addressing whether epidemiologic methods produce *better* outcomes than non-epidemiologic methods. Ekeli's claim on the other hand attends to whether EBP provides documentation for its quality-improving effects at all, that is, in a non-comparative manner. Presumably, Ekeli means that non-EBP methods provides better documentation, but this is not part of her argument.

As noted in 3.3.4., there is in fact documentation for that epidemiologic evidence does improve clinical care.[153] In turn, the documentation of the effect of EBP health care contradicts Ekeli's argument that EBP is solely based on "belief, authority and strong opinions". Of course, Ekeli may reply by stating that this evidence is not sufficient, but that is not relevant to her claim as it currently stands.

Ekeland claims that the question of whether an "implemented EBP really works" is an empirical question not often examined, just taken for granted at the outset. Thus, according to Ekeland, EBP is without any evidence-basis (ibid.). Ekeland also addresses the question in a non-comparative manner (see section 4.3. above) and is thus open to the same criticism as of Ekeli's claim above: Ekeland is incorrect with regard to the claim that this question is taken for granted: There is in fact research on the subject. As discussed in section 3.3.4. above, this belief cannot itself be documented by clinical trials (based on

[153] For instance, EBP proponents refer to historical documentation of the impact of epidemiologic studies, and to studies that document that patients who receive proven efficacious therapies have better outcomes than those who do not (section 3.3.4).

epidemiologic methods), but is documented through other kinds of research. Thus, Ekeland's claim is incorrect (or imprecise), missing the central point of the international criticism about whether epidemiologic methods produce *better* outcomes than non-epidemiologic methods.

On this basis, I consider both Ekeli's and Ekeland's claim to be of low relevance to the EBP debate.

4.5.3. Critical analysis of criticism regarding the narrow scope of evidence in EBP

When addressing the scope of evidence in EBP, all three critics present categorical claims about evidence in EBP: In her theoretical lines of argument, Ekeli states that EBP only addresses biomedical evidence-sources. Ekeland claims that evidence is restricted to specific outcome-based research designs and statistical methods, and Martinsen presents a variant in which only quantitative medical research is included.

All three critics seem to share the assumption that there is only one evidence-hierarchy in EBP, and that evidence-sources within this hierarchy are synonymous with evidence-sources in EBM. Both assumptions are incorrect. Firstly, evidence-sources may vary between evidence-based medicine and other evidence-based models. Secondly, even within EBM it is common to include non-epidemiologic evidence-sources.[154]

In the same manner, all three critics tend to ignore the broader definition of "evidence" in EBP (see section 2.4.2.). In addition, both Ekeli and Ekeland seem to misunderstand what "gold standard" is when they describe it as a standard for all kinds of evidence-sources.[155] As discussed in 1.2., the gold standard refers to a certain method, test,

[154] I have discussed this topic above, in section 3.3.1. above.

[155] Ekeli's description of the "gold standard" is not a central development in any of her main arguments. I have made a brief notice of Ekeli's description of "gold standard" in a footnote in section 4.4.3, when commenting on Ekeland's use of the same term.

measure, or procedure that is considered the best available, by which scientific evidence is evaluated with regard to different clinical questions. For instance, the RCT is typically referred to as the gold standard with regard to therapeutic questions, but not with regard to qualitative questions.

On this basis, their criticism of the narrow scope of evidence in EBP is based on misperceptions of central elements in the EBP literature.

A common feature in all of the Norwegian critics, is that they address the lack of attention to evidence-sources necessary to encounter complex health care issues. The critics differ slightly in what they specifically address as lacking: Ekeli addresses the lack of attention to "non-objective criteria", Ekeland claims that "context-sensitive evidence" is lacking, and Martinsen provides a number of examples of non-scientific beliefs based on perception, which allegedly is "underplayed" (to the point of omission) in EBP (cf. section 4.4.1.).

It is not clarified what kind of evidence "non-objective", "context-sensitive" and "perception-based" evidence entail. Presumably, the critics intend to refer to qualitative methods and non-scientific knowledge as evidence, and then claim that such kinds of evidence-sources are excluded in EBP. This latter claim is incorrect: As discussed in Chapter 1 and 2, most EBP hierarchies include several non-epidemiologic evidence-sources, such as qualitative methods and clinical expertise (ranked lower than epidemiologic evidence due to higher risk of bias). Their arguments also ignore that different questions are answered by different kinds of evidence (see sections 1.2. and 2.4.2. above). Moreover, a large part of the context-sensitive and non-scientific knowledge and beliefs that are used in a clinical practice, is provided by the clinician and the patient, in addition to the evidence, as non-evidential knowledge and beliefs (cf. section 2.4.). Indeed, the Norwegian critics seem to conflate the differences between evidential and non-evidential knowledge altogether, by attending only to evidential knowledge. This demonstrates not only ignorance with regard to the tripartite model of

EBP, but to a lack of basic understanding of the different kinds of knowledge within clinical practice in general.

In essence, all the claims provided from the Norwegian critics regarding the narrow scope of evidence in EBP are variants of what have been described in chapter 3 above as categorical claims. In 3.1.1., I described the categorical claim as stating that only epidemiologic evidence-sources constitute evidence in EBP. As discussed in that section, such categorical claims are only justifiable with regard to the minimal concept of EBP. Conversely, such claims do not reflect the moderate concept of EBP, which is by far the most reasonable version.[156] As such, their criticism of evidence in EBP can be dismissed due to an incorrect understanding of what evidence in EBP amounts to.

There are, however, certain distinguishing features to all three critics, which deserve more detailed attention. In my view, these features exhibit interpretations of EBP that are typical to the Norwegian debate. In the following, I will address five such features, and provide corrections to claims that are based on incorrect or imprecise understanding of what evidence in EBP is and is not.

- **Correction to the use of a "biomedical research ideal"**

A challenge when analyzing the three Norwegian critics has been to identify what kind of evidence-sources they address, and to what extent they actually disagree with the usefulness of epidemiologic evidence. When they are not specifically addressing challenges in RCTs, they tend to discuss "evidence" in terms of "biomedical" or "medical" research. Conversely, there are very few references to "epidemiologic research".

[156] The narrow and moderate concept of EBP is discussed in section 2.4.4, above.

References to “biomedicine” and “medical research” are sub-optimal when discussing evidence-sources in EBP. “Biomedicine” is a broad term, sometimes referring to “mainstream medicine”, “western medicine” in general, or to “clinical medicine based on the principles of the natural sciences, such as biology and biochemistry” (“biomedicine” in *medical-dictionary* 2019). While “biomedicine” may refer to epidemiologic evidence-sources, “biomedicine” is neither sufficiently broad to include all potential evidence-sources in EBP, nor specific enough to the specific epidemiologic evidence-sources that are characteristic of EBP.

In particular, references to “biomedicine” are insensitive to the distinction between epidemiologic and pathophysiological research. A central feature in clinical epidemiology and EBP literature is that pathophysiological reasoning is considered less trustworthy than epidemiologic evidence.

When Ekeli states that “knowledge” in EBP refers to the “biomedical research ideal” and its strict attention to objective criteria and data (see section 4.2.1.), this is, at best, imprecise. “Biomedical research”, for instance, outcome-based reasoning of clinical epidemiology and the mechanistic reasoning of pathophysiology, differs substantially (cf. section 1.4.1. above). Thus, when Ekeli points out that the tendency in “medical research” is exclusively to attend to “objective criteria”, it is unclear whether such criteria are typically included in outcome-based methods or not. In other places, Ekeli explicitly refers to pathophysiologic principles, for instance when stating that “effective treatment of disease” pertains to “finding the causes for the disorder” (Ekeli 2002: 30). As stated in 1.2.1., attention to causes is a typical feature within pathophysiologic reasoning, not outcome-based research.

Similarly, when Ekeland describes EBPs attention to context-free treatment within clinical practice, and claims that this is in essence the problem of practice in biomedicine, in which “one is good at treating diseases but bad at treating sick people (cf. 4.3.2.), it is equally

imprecise with regard to the EBP debate. In clinical epidemiology and EBP, pathophysiological reasoning is considered less trustworthy than epidemiologic evidence.[157] Related to the same issue, Martinsen sometimes conflates biology and epidemiology. For instance, she states that the relation between research and research-application "[b]ecomes deductions from biological theories, that is, technique" (Martinsen 2009: 85). This conflation is enabled precisely because of an imprecise distinction between biology and epidemiology, and a correspondingly vague understanding of what outcome-based research is and is not. In turn, it also makes her concept of "technique" inadequate with regard to clinical epidemiology and EBP.

My point here is not that their references to "biomedicine" are incorrect, but that the use of "biomedicine" in their criticism is too broad for an adequate discussion of specific challenges to EBP.

- **Correction of Ekeli's assumption about non-propositional knowledge in EBP**

Ekeli provides the most original and least precise criticism of evidence in EBP, stating that the EBP model represents only one of several kinds of propositional knowledge, and excludes any other kinds of propositional knowledge as well as non-propositional knowledge. Presumably, Ekeli means that the "one kind of propositional knowledge" in EBP refers to outcome-based epidemiologic evidence-sources. This is not only grammatically wrong, but ignores the obvious fact that different epidemiologic methods make use of different kinds of propositional knowledge, in particular concerning methodical terminology.[158] I find it difficult to interpret what is included and excluded in

[157] Such impreciseness is also occurring within EBP literature. Ekeli provides several citations from EBP proponents who makes use of "biomedical research" in the same imprecise manner (e.g., Ekeli 2002: 12; 54). I must stress that reference to biomedicine is not incorrect, just imprecise.

[158] For instance, non-interventional observational studies include quite different propositions than, say, analytical observational studies, such as an RCT.

EBP with regard to Ekeli's "propositional knowledge", as anything else than quantitative and qualitative methods. As such, her criticism is identical to Ekeland and Martinsen, opening up to the same response as I presented in the section just above.

With regard to "non-propositional knowledge", Ekeli is correct that such knowledge is not included as evidence in EBP hierarchies.[159] Ekeli provides no examples of what she means by "non-propositional knowledge". Presumably, such knowledge refers to non-scientific knowledge that is considered necessary to clinical practice. As I have discussed in my analysis of expertise in EBP, such knowledge is commonly included in descriptions of clinical expertise in EBP literature, as necessary non-evidential elements, in addition to evidential knowledge.[160] To the extent Ekeli would disagree to this, she would have to argue for how tacit knowledge would constitute evidential knowledge. In her text, Ekeli does not provide any clarifications on this matter. On this basis, Ekeli's criticism of that EBP exhibits a narrow scope of evidence because it excludes non-propositional knowledge, is of minor relevance.

- **Correction to Ekeli's view on evidence hierarchies in EBP**

Ekeli is correct that there are some evidence-hierarchies that are more restrictive than others, and do not include, for instance, expertise. However, Ekeli also explicitly identifies hierarchies that include non-epidemiologic evidence-sources.

In Ekeli's empirical line of argument, she discusses how two different EBP sources rank evidence-sources hierarchically. Firstly, she identifies two different hierarchies, one containing non-epidemiologic evidence-sources (including expertise), and another that

[159] As discussed in 2.4.2. above, there are some EBP authors who include "tacit" or "private" beliefs based on "hunches" as evidence (e.g. Greenhalgh 1999; Djulbegovic et al. 2009). To be considered evidence, however, these beliefs have to be articulated.
[160] This is discussed in detail in section 2.4.3., and in the following subsections.

only includes epidemiologic evidence-sources.[161] In the second EBP-source that Ekeli cites, trustworthiness (i.e., internal validity) is ascribed as 100% to evidence-sources at the upper level, and 0% at bottom level. Secondly, Ekeli infers the general claim that when non-epidemiologic research and non-scientific knowledge-sources in general are, at best, included in the "EBP system" at all, such sources have a trustworthiness that equals zero (cf. ibid., 67). As discussed in 4.2.2., this is an important inference in Ekeli's criticism, on the basis of which she claims that non-epidemiologic evidence is deemed irrelevant, and that only epidemiologic evidence exhibits assertive power in an EBP perspective.

The problem, however, is that the inference is invalid: The inference from one source, which ascribes 0% trustworthiness to the bottom level of the hierarchy (including only epidemiologic evidence-sources) to another hierarchy (including both epidemiologic and non-epidemiologic evidence-sources) is erroneous. In fact, it seems that Ekeli conflates the two different EBP sources she is citing: The two hierarchies are highly different, and there is no reason to assume that what is ranked at the lower levels in the first hierarchy is ascribed as identical to the second hierarchy. On the contrary, the inclusion of any source in a hierarchy usually implies that different evidence-sources at lower levels in a hierarchy exhibit relative lower degrees of trustworthiness, compared to higher levels. As discussed in chapter 2.4., this is a question of what is considered best available, and when evidence-sources ranked at the upper levels are not available, lower ranked evidence-sources are considered adequate.[162]

[161] As noted in a previous footnote, Ekeli also refers to an article introducing the concept of "Knowledge-based physiotherapy" (Jamtvedt, Hilde, Risberg 2000), which does not present a hierarchy but, according to Ekeli, in which experience is "zeroed out" as valid basis for clinical decision-making (Ekeli 2002: 58f). This is an erroneous reading of the text. The text explicitly states that research-based knowledge is not sufficient for clinical decision-making, and that without clinical expertise, there is a danger of that the "[p]ractice-field becomes tyrannized by research" (Jamtvedt, Hilde, Risberg 2000). In addition, the authors stress the importance of qualitative evidence-sources as well.

[162] I consider Ekeli's example of the hierarchy that ascribes "0 % trustworthiness" to be an exception to the rule. I have not read the source Ekeli is citing (Helewa, Walker 2000). If it is correct that the EBP authors

Thus, the basis of Ekeli's empirical lines of argument is erroneous due to an invalid inference. Her claims that non-epidemiologic evidence-sources exhibit trustworthiness that equals zero, and that these sources therefore can be considered irrelevant to the scope of evidence in EBP, are not representative of common EBP literature.

- **Correction to Ekeland's assumption of that EBP is comparable to traditional positivism**

In extension of the misperceived view of the scope of evidence in EBP, Ekeland also claims that EBP is comparable to traditional positivism, in which quantitative research methods are the only decisive element (cf. 4.3.3.). Such a claim is synonymous with what was discussed with regard to the international criticism, in section 3.3.1.1 above. In that section, I dismissed such an argument because it is based on a misunderstanding of what EBP amounts to, both with regard to its evidence-scope and to the tripartite EBP-model. Such a claim entails an over-simplified straw man of EBP, contributing to an unnecessary polarization in the EBP debate.[163]

state that the lowest level exhibits *no* degree of trustworthiness, I find it strange it is included as an evidence-source at all.

[163] The latter point is somewhat ironic in that Ekeland in his text states that the EBP debate is too complex for polarization (Ekeland 2009: 162).

- **Correction to Martinsen's alternative view on evidence**

As analyzed in section 4.4.1.1., Martinsen's alternative evidence consists in "evidence by experience", which is based on sense impressions and contextual information, not scientific knowledge or rules. As a part of her criticism of EBP, references to such evidence-sources are irrelevant. In fact, "evidence by experience" seems identical to what I have described above as non-scientific knowledge in EBP (section 2.4.3 above).

Martinsen also describes the application of evidence as a "freedom practice", which entails that the clinician "[d]ears to encounter the patient's vulnerability, affectedness, and shame" (Martinsen 2009: 125). Here, Martinsen addresses the clinician's responsibility to understand and respond to the patient's emotions. I do not agree that such a responsibility is unique to Martinsen's "freedom practice". On the contrary, the content of "freedom practice" seems synonymous with what any experienced clinician is able to do when in her clinical encounter with the patient. In EBP terminology, this is included in the integration of evidence in accordance with patient preferences and circumstances, which is considered a necessary element in the EBP process (cf. Chapter 2 above). Specifically, the "freedom practice" of the clinician resembles what I have labelled individual clinical expertise, i.e., the use of personal judgment about that a therapy is effective for an individual (see section 2.4.3.2.2.). In any EBP encounter, in which evidence is integrated at the point of patient care, the knowledge, beliefs, and attitudes of the patient have to be interpreted by the clinician as explicit preferences regarding the clinical decision. On this basis, I see no essential differences concerning the content of "freedom practice" and the integrative practice of the EBP clinician.

However, I disagree that this refers to evidence. Interpretation of the patient's preferences and circumstances refers to an ability, not a piece of external evidence. All of Martinsen's examples (e.g., to resonate to the patient's subjective experiences, and to "come in tune" with the patient; cf. section 4.4.1.1.) refer to skills and abilities of the

clinician, and not to evidence. Thus, it seems that Martinsen conflate evidence as a basis for a clinical practice and the abilities necessary for such a practice.[164] On this basis, I consider Martinsen's alternative view on evidence to be of minimal relevance to the EBP debate.

4.5.4. Critical analysis of criticism about that usefulness of evidence in EBP is considered minimal

Criticism concerning the usefulness of evidence seems to be the main attention of all three critics. In essence, the Norwegian criticism states that application of biomedical (including epidemiologic) evidence-sources does not provide a useful basis for clinical practice at the point of patient care. As stated above (section 4.2.) Ekeli's main aim is to critically review knowledge in EBP, in particular in relation to solving real-life health care issues (Ekeli 2002: 5). She concludes that epidemiologic evidence-sources are poorly equipped for providing a basis for actual clinical decision-making, in particular with regard to complex health issues, such as fibromyalgia. Ekeland sees the main problem as the relation between research and practice, of which EBP, through its biomedical "context-free ideal", underestimates the complexities of clinical practice (cf. 4.3.). According to Martinsen, the scientific scope of EBP is tantamount to an idea of a *scientific* clinical practice, i.e., a belief that practice is fully reducible to scientific knowledge. Such a belief is then described as

[164] Not least, in a footnote in my interpretation of Martinsen's alternative evidence above (section 4.4.1.1.), I suggested that the highly metaphorical language in Martinsen's examples seems to cohere with the main aim of her examination, which is to explore alternative ways of working with the problematic of evidence, demonstrating a stark contrast to the scientific terminology of EBP. In this, Martinsen succeeds quite well. At the same time, however, the metaphorical character of her descriptions makes them limited in terms of usability. While I am sympathetic to her phenomenological style of thinking, I do not consider such a phenomenological approach to be optimal in clinical practice at the point of patient care. On the contrary, the more rigorous five-step process suggested in EBP literature is easier to follow, and includes all the content of Martinsen's (not so) alternative view on evidence.

an instrumentalist mistake and a feature of "evidentialism", through which EBP proponents are not aware of the limitations of this kind of research knowledge (cf. 4.4.).

Notably, most of their arguments tend to be very broad, addressing the usefulness of scientific knowledge in general. In the following subsections, I will discuss the relevance of the Norwegian criticism in four steps. Firstly, (in 4.4.4.1.) I will comment on the extent to which this criticism is comparable to the international criticism on the same topic (as discussed in 3.3.3. above). To this extent, the Norwegian claims are subject to the same criticism as well. Secondly, I will discuss three specific features in their criticism, which differ from the international criticism. These features will be presented as corrections to (4.4.4.2.) the discrepancy between the specificity of certain claims and the broad character of the arguments supporting these claims; (4.4.4.3.) the claim that "RCT is only about the average patient, not the individual patient"; (4.4.4.4.) Ekeland's criticism of the limited usefulness of RCTs.

4.5.4.1. Comparison of the Norwegian criticism and the international criticism on the limited usefulness of evidence in EBP

As discussed in sections 1.4.1.2. and 3.3.3. above, the question of the usefulness of epidemiologic evidence has to do with external validity, which refers to the generalization of the research results about the effect found in a trial population setting to other populations in other settings. All the Norwegian critics' claims concerning the limited usefulness of epidemiologic evidence-sources are variations of claims that such sources involve severe challenges to this generalizability when the evidence is applied in individual clinical practice. Formally, this is a valid kind of criticism, highly relevant in that it targets the main controversial feature in EBP: the application of evidence from clinical research in a clinical setting, in which epidemiological, outcome-based data are considered the

most reliable source of evidence for clinical interventions.[165] In essence, their claims are variations of the international criticism of that application of evidence based on epidemiologic data alone leads to limited knowledge, and is therefore not always useful in clinical practice (cf. 3.3.3. above).

The Norwegian criticism touches upon variations of the four central arguments in the international debate (cf. section 3.3.3. above):

(1) That epidemiologic data exclude pathophysiologic principles, such as ‘‘soft data’’ distinctive to individual patients.

(2) That RCTs have practical limitations, such as the dependency on additional pathophysiologic data).

(3) That RCTs exhibit restrictive eligibility criteria; enrolling restricted populations.

(4) That the results of randomized studies show comparative efficacy of treatment for an ‘‘average’’ randomized patient, and ignores clinical features such as severity of symptoms, illness, and comorbidity.

While argument (4) is easily recognizable in all the Norwegian criticism, the arguments (1)-(3) are presented in broader terms than in the international criticism. In the Norwegian criticism, “soft data”, “additional data”, and attention to “eligibility criteria” are discussed more broadly and less precise, as “contextual knowledge”. Such knowledge is then discussed with regard to alleged methodological inabilities to relate to the complexities in clinical contexts, and to a corresponding lack of attention by EBP clinicians to the importance of contextual knowledge in clinical practice.

[165] This is discussed in detail in Chapter 1. It is also a common kind of criticism in the international debate. See section 3.3.3. above for an analysis of this debate.

As discussed in section 3.3.3. above, the challenges to external validity in arguments (1)-(4) are important and valid, but they are to a considerable extent mitigatable, e.g., by assessments of generalizability and applicability with regard to the target population. The Norwegian critics do not express awareness to any of these mitigating circumstances. Not least, the Norwegian critics seem unaware that that it is not necessarily the case that non-RCT evidence always has higher external validity. Likewise, none of the Norwegian critics problematizes the fact that the problem of external validity is not unique to evidence in EBP but occurs universally to any evidence-source within any health care.

4.5.4.2. Correction to the specificity of central claims in Ekeli and Ekeland

At core, the Norwegian criticism about the limited usefulness of evidence in EBP is that it does not correspond to the necessary contextual knowledge in specific professional fields. In Martinsen's case, the specific professional field she is addressing (nursing) is only apparent in her descriptions of her "alternative evidence" (see 4.4.1.1.) and does not affect her claims and arguments. This is not necessarily a weakness of her criticism, only a characterization of that her criticism exhibits a broad scope, with relevance across different fields within health care.

The contextual knowledge in Ekeli's and Ekeland's criticism is more specific. In Ekeli's case, her main attention is on the limited usefulness of epidemiologic knowledge with regard to understanding fibromyalgia patients and their complex and co-morbid disorders (Ekeli 2002: 62).[166] In Ekeland's case, he specifies that the RCT has limited usefulness with regard to psychotherapy, considers as a "contextual science" (Ekeland 2009: 160). These are highly specified subject matters. Conversely, however, most of the arguments presented in support for the claims are very general, relevant to far broader claims about the limited

[166] As remarked in a footnote in 4.2.3. above, the specific and general character of different claims can be difficult to separate clearly when reading Ekeli's text, and may be interpreted in different ways.

usefulness of epidemiologic evidence in general. Thus, in Ekeli's and Ekeland's criticism, there is a certain discrepancy between the specificity of their main claims and the generality in the arguments supporting these claims. As such, both of their criticisms demonstrate a tendency to use disproportionate generality of argumentative support to address a highly specified problem.[167]

When considered in isolation, regardless of their argumentative support, the claims are of minor relevance to the issue of usefulness of epidemiologic evidence-sources. In Ekeli's claim, what is at stake is the *understanding* of fibromyalgia patients' subjective experiences. As Ekeli correctly observes, this is a matter of understanding the phenomena of fibromyalgia. A flaw in her criticism, however, is that she interprets the clinical questions of EBP as being answerable by the same "reductionist standard" of epidemiologic evidence-sources exclusively. This is a fundamental misunderstanding of the content and application of questions in EBP. Through this misunderstanding, Ekeli ignores the fact that a question concerning understanding in EBP literature would be considered answerable through qualitative research methods (cf. 2.4.2. above).

When Ekeli later claims that "To understand phenomena, especially sick people, or how treatment has effect on them, lies far beyond EBPs field of interest and capacity" (Ekeli 2002: 58), this is based on a misinterpretation of what clinical questions in EBP amount to. In particular, Ekeli ignores the diversity of such questions, and that different questions are answered by different methods. With regard to Ekeli's own example about understanding fibromyalgia patients, the EBP clinician would, in line with EBP literature (e.g., Straus et al. 2011), not consider this a question of outcome/effect, nor of therapy at all. When searching for research knowledge about understanding fibromyalgia patients,

[167] As noted above, despite these initial specific claims, their main arguments are, similar to Martinsen's, characterized by a considerably broader scope, addressing the generalization of "scientific knowledge" in general into "clinical practice". Most of their arguments refer to both "scientific knowledge" and "clinical practice" in a generic way, with a content that is considerably broader and less specified compared to their initial contextual specifications of their initial claims.

epidemiologic evidence would therefore be deemed irrelevant for answering the clinical question. Instead, understanding patients pertains to questions that are typically considered best answered through qualitative methods.[168] Consequentially, her line of argument concerning the limited usefulness of the clinical questions in EBP is based on a misperception of EBP literature.

In effect, this also entails that her entire line of argument for that clinical questions in EBP demonstrates an "instrumentalist mistake" is erroneous as well. When Ekeli claims that, the conflation of "things" (outcome) and individual subjects is a categorical mistake, this mistake does not reflect what the clinical questions in particular, or EBP practice in general amount to. Rather, the mistake occurs inherent in her own line of argument, based on a misunderstanding of EBP and the scope of its different clinical questions. In effect, Ekeli's argument is of no relevance to the EBP debate.

Ekeland's claim exhibits a similar irrelevance to the topic of usefulness of epidemiologic evidence-sources: To the extent to which psychotherapy is inseparable from its relational and dialogic aspects, the RCT would be considered of little use. This is completely valid and uncontroversial claim. To the extent that there is no external evidence of the effect of such interventions, Ekeland's claim is of low relevance when debating the usefulness of RCT evidence.[169]

[168] As discussed in section 2.4.2. above, this is described in common EBP literature as "background information".

[169] It should be noted that there are RCTs providing information about the effects of psychotherapy interventions/treatments (e.g., Mahbobeh, Shala, & Shahnaz 2015). As analyzed in 4.3.4, Ekeland's point is that much of the clinical psychotherapy practice is done in intimate dialogue with the patient, and that this dialogical character and the specific characteristics of each individual patient cannot be separated from the intervention. Because of this, information about the effects of such interventions are of little use. Such a claim may be debatable, but this exceeds the scope of my current analysis. Instead, I base my analysis on the assumption that Ekeli is correct in this case.

Of course, both Ekeli's and Ekeland's claims can be considered arguments in support of the claim that epidemiologic evidence, and RCTs in particular, is not always available, but such a claim would be even less controversial, and hence not relevant to the EBP debate.

4.5.4.3. Correction to "RCT is only about the average patient, not the individual patient"

All three critics claim that the transition from a population level to the individual level is extremely problematic. In Ekeli and Martinsen's case, they seem to dismiss any justification of this transition from statistical research on a population to individuals. Both critics demonstrate rather extreme attitudes on this matter.

Ekeli claims that there are no credible explanations for how statistical population research is able to constitute a basis for individual clinical care at all, and that RCTs fail to include the rationality of the practice field. Martinsen's claim is essentially similar, stating that the estimates of average treatment effects do not apply to individuals, or that it is at least extremely problematic to do so. Ekeland presents a less extreme attitude, limiting his view of the translation from epidemiologic research results to individual care as a complicated matter (cf. Ekeland's third argument against the usefulness of RCTs; see 4.3.4.).

In essence, what these attitudes seem to amount to, is that epidemiologic data on average effects exhibit severely limited usefulness when applied to real-world circumstances, because average effects do not apply to individuals. As discussed in 3.3.3. above, there are indeed challenges to applying epidemiologic research results to individual patients, and the extent to which these challenges are mitigatable is the central relevant topic in the EBP debate. However, there is a tendency in the Norwegian criticism to interpret this categorically (i.e. without conditions), and in dichotomic terms, where knowledge of average effects on an "average patient" is considered in binary opposition to the "individuality" and "subjectivity" of the individual patient.

In Ekeli's and Martinsen's criticism, the dichotomies they describe are purely theoretical, based on binarities between propositional and non-propositional knowledge and of the "different logics" of scientific and practical realities (Ekeli 2002: 36) and between research knowledge and practical knowledge (Martinsen 2009: 96). In this way, instead of discussing the extent to which epidemiologic evidence-sources are useful in clinical practice in terms of generalizability and applicability,[170] they tend to interpret the problems in a more theoretical way, by establishing a dichotomy between EBP and non-EBP knowledge and practice. In the same manner as in the international criticism, I find the tendency to dichotomize between epidemiologic evidence and individual patient care rather extreme, because of an unnecessary exaggeration of the difficulties in applying epidemiologic evidence to an individual patient. As I note in 3.5.2. above, such dichotomic descriptions entail an approximation to a minimal conception of EBP, in which non-scientific knowledge in EBP practice is excluded from the model. As such, the dichotomies do not reflect the moderate concept of EBP, common in most EBP literature. In effect, criticism that is based upon such dichotomies is not particularly relevant to the EBP debate.

At the outset, Ekeli seems to have a stronger argument than Martinsen, in that Ekeli also provides empirical support for her claims, referring to her own case study, in which physicians are interviewed with regard to their clinical interactions with fibromyalgia patients (as analyzed in the latter part of section 4.2.4. above). The core message in this example is that physicians, rather than making use of scientific research findings, base their patient-interaction on personal experience. The reasons, however, for that the physicians make use of personal experience, is not a demonstration of limited usefulness of epidemiologic evidence. On the contrary, Ekeli explicitly states that such evidence is lacking. The kind of evidence that Ekeli and her interviewed physicians are in opposition

[170] This is the main topics in the international criticism of the same topic; cf. sections 3.3.–3.3.5 above, and also in Ekeland's criticism above.

to, is pathophysiologic evidence about biological mechanisms, which EBP proponents also would be careful to use as basis for recommendations.[171]

Compared to Ekeli's and Martinsen's lines of arguments, Ekeland represents an alternative approach, referring to what he views as an essential difference between recommendations on population-level and individual clinical practice.[172] This line of argument also implies a dichotomic relation between recommendations at population-level and at the level of the individual, in clinical practice. Based on this dichotomic difference, Ekeland claims that outcome-based methods (and RCTS in particular) are useful only when pertaining to the "average patient" on population-level, not on the level of the individual, and only useful in "drug treatment" (i.e., recommending drugs to patients).[173]

I find Ekeland's approach more informative than the approaches of Ekeli and Martinsen. Through Ekeland's approach, it is clear what he means for epidemiologic evidence to be useful within medical practice, and not within other professional clinical practices. Ekeli and Martinsen also state that they are not opposed to the idea that epidemiologic evidence is useful within medicine, but in their lines of arguments, this seems to contradict their general claim that epidemiologic evidence is dichotomously different from the "logic" of clinical practice. Perhaps, they imply the same difference between recommendations on population-level and clinical practice as in Ekeland's view.

[171] Another issue is the very format of her example: The case study she refers to is based on unstructured "depth interviews" with 15 female fibromyalgia patients and 7 randomly selected physicians (cf. Ekeli 2002: 26). As such, neither the internal nor the external validity of her research can be considered particularly high. When Ekeli makes the conclusion that the interviews also demonstrate that the EBP ideal of standardization and objectivity does not cohere with the reality of clinical practice (ibid., 28), the generality of her conclusion does not at all cohere with the external validity of her own research results.

[172] At this point, my discussion of Ekeland's approach only attends to his dichotomic structure. I will attend to Ekeland's criticism in more detail in the subsequent section just below.

[173] Notably, Ekeland does not deny that generalizations from RCT-findings to the individual patient are possible, but states that it is a complicated matter and associated with "very high risk", which can only be mitigated by the clinical expert, which according to Ekeland has been discredited in EBP.

To the extent these dichotomic claims are interpreted categorically,[174] they are erroneous. As noted above, there is in fact several ways though which this challenge can be mitigated. Rather than stating the rather obvious observation that application of research results of average effects from research results is problematic, or the more extreme version that such application approximate the impossible, a more nuanced, more common, and more relevant criticism is that epidemiologic data on average effects is often *not sufficient* to generalize into real-world circumstances. In other words, the issue of usefulness is a matter of degrees, not of kind. The Norwegian critics' tendency to dichotomize makes their criticism invalid.

4.5.4.4. Corrections to Ekeland's criticism of the limited usefulness of RCTs

As described in 4.3., Ekeland's main issue is the complex relations between research and practice, which in his view is deeply problematic with regard to the model of EBP. When arguing for this, Ekeland claims that the RCT is over-estimated as useful evidence in clinical practice. In particular, he presents three arguments for his claim (these are described in more detail in section 4.3.2.).

His first argument is that internal validity does not imply external validity nor clinical usefulness. As discusses in chapter 3., this is not necessarily true. Here, Ekeland's criticism is similar to the international criticism, in its tendency to assume that the RCT exhibits inherent weak external validity, without citing any evidence to support (see 3.3.3.). Due to this lack of empirical support to this assumption, I consider the argument to be rather weak.

[174] Ekeland's statement mentioned in the previous footnote may indicate a conditional statement, albeit very weak, due to the fact that clinical expertise is considered discredited. If Ekeland in his criticism discussed the extent to which the expert can or cannot mitigate the challenges pertaining to the application and generalizability of epidemiologic evidence, his criticism would be considerably more relevant.

Ekeland's second argument is that EBP proponents often conflate what the RCT may or may not predict: While an RCT enables predictions with regard to how a clinical intervention is likely to have effect in a patient, the RCT does not enable prediction about that the effect of the intervention under testing will be reproduced in the future. His main point here is that prediction of the latter kind can only be interpreted in light of theories about the (pathophysiologic) mechanisms. While his main point may be true, his claim that EBP proponents often conflate these two kinds of predictions remains unsupported. I have not identified such a conflation in the EBP literature. Moreover, it is far from clear whether causal predictions would be more useful in practice. At this point, EBP proponents may reply by stating that predictions based on outcome-based research data of how a clinical intervention is likely to have effect in a patient, is of direct use in patent case,[175] while the causal predictions of an assumed underlying pathophysiological mechanism does only provide indirect knowledge of its putative effect.

His third argument claims that treatment recommendations are often only relevant to the average patient on population level, not on the level of the individual (cf. ibid., 158). Strictly speaking, such a claim is tantamount to claiming that RCTs primarily are relevant within epidemiology (relating to populations only), not clinical epidemiology (relating to individuals, in direct patient care; cf. section 1.1.1 above).[176] His argument in support of this claim is that the problem of generalization is a complicated matter, which can only be accounted for by the clinical expert – which according to Ekeland has been discredited in EBP. The assumption that the clinical expert (and, hence, clinical expertise) has been discredited, is erroneous.

[175] Provided, of course, that the prediction is based on trustworthy data.

[176] This kind of argumentation is comparable to Tonelli in the international criticism, who claims that there is a shift of attention away from individual patient care to "the care of populations", fulfilling goals of public health but not of individual patient care (this is discussed in section 3.5.2. above). In my analysis of Tonelli's criticism, I claimed that it erroneously implies an inherent dichotomy in EBP. The same criticism can be addresses to Ekeland's argument.

At this point, Ekeland demonstrates a tendency to ignore the central role of clinical expertise in the EBP model. An implication of ignoring this is minimal attention to how and the extent to which the clinician may assess such evidence. Ekeland is correct that generalization of epidemiologic evidence to the individual patient is a complicated matter. As I have described in 1.2. and 3.3.3., any generalization (or in broader terms, any extension to practice) necessitates the clinician's expertise and her ability to integrate the epidemiologic research knowledge into clinical practice. Thus, if Ekeland was correct that the clinical expert is discredited in EBP, he would be correct in claiming that these "complicated matters" would be difficult, if not impossible, to solve. Such an argument, however, approximates a minimal concept of EBP, in which clinical expertise is excluded from the EBP-model. This exclusion approximates a straw man fallacy: Ekeland addresses a simplified (and incorrect) image of EBP as including 'evidence' only (while excluding the clinical expert) – and then claims that the complicated matters of generalizing evidence into clinical practice depends on the clinical expert.

In my view, all the arguments above demonstrate Ekeland's ability to address relevant *topics*: The claims address issues which are controversial about the use of epidemiologic evidence-sources in EBP. As I have commented here, however the *content* in the arguments, though relevant, lacks empirical support. The third argument also presupposes approximation to a minimal concept of EBP, which makes the argument easily dismissible as a misinterpretation and a potential straw man fallacy.

4.4.5. Critical analysis of the criticism that the roles of clinical expertise and patient autonomy in EBP are minimized

In the Norwegian criticism, the arguments are closely connected to their view of the one-dimensional scientific framework of EBP, which is said to minimize attention to expertise and patient preferences. At the outset, this is comparable to the international criticism. In

the international criticism, the ways in which expertise and patient preferences are minimized, are typically addressed by discussing the extent to which the values for individual patients are portrayed sufficiently and accurately (e.g. by Feinstein 1994), or by discussing whether epidemiologic evidence leads to under-representation of other kinds of knowledge (e.g. by Rogers 2002).[177] The Norwegian criticism is tangent to such topics, but is also characterized by a broader scope, with a tendency to categorical claims addressing how application of epidemiologic research leads to minimization, or even elimination, of the roles of expertise and patients in EBP. Here, "minimization" must be understood in a superlative sense, i.e., as reduced to an absolute minimum, and not in a comparative sense, which would entail the extent to which attention to expertise and patients is reduced.[178] The superlative sense of minimization can be exemplified in each of the three critics:

In Ekeli's view, the ideal of objective knowledge makes personal and contextual relations incompatible with the EBP model, and will lead to deterioration of the practitioner's expertise and of the patient's autonomy (cf. Ekeli 2002: 45f). Moreover, in the statistical research studies applied within EBP, "[t]he "human factor" is reduced to the minimal" (ibid., 38). In such research studies, patients are only present as test-groups and clinicians only as interpreters of the results. According to Ekeli, this demonstrates that de-contextualization and fragmentation are preconditions for clinical practice in the EBP system. Ekeland claims that the narrow and non-contextual, "instrumental" methods of EBP will eliminate the autonomy of personal communicative practice, through which the individualization of both clinician and patient is ignored (cf. Ekeland 2009: 165). In

[177] These examples are discussed in section 3.5.2. above.

[178] Comparative claims are typical in conditional claims in the international criticism. For example, the claim that application of pre-appraised evidence and guidelines can be problematic, and claims addressing the extent to which such use could minimize use of clinical reasoning and lead to automatic decision-making, are both implying a comparison to other kinds of reasoning, or a matter of degree to which clinical reasoning is minimized. These examples are discussed in section 4.4.3. above, but without attention to the distinction between comparative and superlative kinds.

Martinsen's criticism, the autonomy of the clinician is replaced with scientific standards (Martinsen 2009: 94), and the patient is "instrumentalized" through statistical research, thereby omitting patient individuality (cf. ibid., 85). In all of these claims, there are no conditions with respect to the extent to which these challenges are problematic. On the contrary, the critics suggest that these challenges are fundamental, entailing that attention to clinical expertise and patient preferences is excluded altogether.

Formally, the content of their criticism is comparable to the international criticism addressing the "standardization" of and the "cookbook approach" to clinical practice (as discussed in section 3.4.2. above). Notably, however, rather than discussing the extent to which attention to the clinician's autonomy and patient preferences is lacking when following guidelines, the Norwegian critics replace attention to guidelines with their own concept of the "instrumentalist mistake": That the roles of clinical expertise and patient autonomy in EBP are minimized (in the superlative sense) by being reduced to, or replaced by (i.e., mistakenly considered on the basis of) scientific research knowledge exclusively. In effect, attention to the clinician and the patient is minimized: Clinical expertise is replaced by scientific knowledge, and the patient is "objectified" through statistical research results.

All three critics make use of "the instrumentalist mistake" in a similar manner: Ekeli states that the relational dimensions in practice is replaced by research evidence, at the expense of the relational aspects of clinical practice (Ekeli 2002: 60), whereas Ekeland claims that the mistake entails that individualization of both clinician and patient is ignored (Ekeland 147f). Martinsen describes similar content, as that clinical practice through the instrumentalist mistake is "[r]educed to technique and controlled knowledge" (Martinsen 2009: 137).

In this criticism, it seems that their view of the one-dimensional scope of EBP evidence (which I argue is incorrect; cf. section 4.4.3. above) is extended to the application of

scientific knowledge in clinical practice, through which evidence is applied directly, with little to no attention to or input from the clinician or from the patient. The use of the "instrumentalist mistake" in the criticism of the limited attention to expertise and patient preferences in EBP is based upon an interpretation of clinical decision-making in EBP as excluding expert and patient knowledge, in which such knowledge is replaced with scientific knowledge exclusively. This implies a specific misunderstanding of what clinical decision-making in EBP entails.

To commit an "instrumentalist mistake" includes reducing the patient to "objective", scientific, knowledge. To provide an example of such a "mistake": When a clinician bases her recommendation on findings from an RCT, the individual patient is reduced to the statistical knowledge of the average effect of an intervention, tested on a certain test-population, selected through specific eligibility criteria (typically referred to as "the average person" by the Norwegian critics). In this case, the application of the RCT is conducted without any interference from the clinician nor the patient. The "instrumentalist mistake" of this application, then, is to apply epidemiologic evidence about the "average person" *directly* (i.e., without any input from the clinician nor the patient) when recommending a clinical intervention to an individual patient. The central core of the "instrumentalist mistake" is thus its implied criticism of the direct application of evidence at the point of patient care.

In the remaining part of my analysis of their criticism, I will attend to how this view of "direct application" is problematic in all three of the Norwegian critics, in various ways. I will argue that their arguments not only approximate but indeed demonstrate minimal concepts of EBP.

- **"Direct application" in Ekeli's criticism**

Central to Ekeli's empirical argument above (section 4.2.4.), is her interpretation of Norwegian EBP literature. After describing the tripartite model of EBP, the EBP authors state, "The main message is nevertheless that one should use research as a knowledge-source to a greater extent within professional practice" (Jamtvedt, Hilde, Risberg 2000: 24).[179] Ekeli interprets this statement in the following way:

> This [last statement] is indeed the main purpose of the EBP system altogether. But I have yet to identify believable explanations regarding how results from statistical investigations on large populations can provide "more certain" basis for clinical expertise with regard to individual patients in life-situations, which lack any similarity to controlled standard conditions (ibid., 60).

According to Ekeli, this demonstrates the distinct priority of research-based knowledge in EBP, which minimizes (in the superlative sense) attention to expertise and patient preferences. When considered at face value, Ekeli's "basis for expertise" implies that expertise is replaced by scientific knowledge – which is indeed what she also argues for (cf. section 4.2.5.). Consequentially, in such a practice, the only basis left would be scientific knowledge, on which recommendations of interventions in clinical practice would be based, exclusively. It is in this way that Ekeli's conception of application of scientific knowledge in clinical practice understood, through which evidence is applied directly, i.e. on basis of scientific knowledge alone, without any interference from clinician nor patient.

However, Ekeli's interpretation of the EBP quotation, and thereby her basis for criticism is based on two misunderstandings: The first concerns the main purpose of EBP. The main purpose of EBP is not to use scientific research. By itself, evidence is a means to an end. Rather, as discussed in Chapter 2, the main purpose of EBP is to provide a model for clinical

[179] Both the quotation and Ekeli's interpretation is analyzed in more detail in 4.2.5. above.

decision-making, in which the clinician recommends clinical interventions to individual patients.[180] The second misunderstanding is perhaps more technical, but of relevance to what "direct" application of evidence refers to in Ekeli's criticism: She states that epidemiologic evidence "can provide "more certain" basis *for* clinical expertise". This is incorrect:[181] The goal of EBP is to provide an improved basis for clinical decision-making, not for expertise.

- **"Direct application" in Ekeland's criticism**

In Ekeland's criticism, a similar understanding of "direct" application of evidence is demonstrated, through his dichotomization between attention to epidemiologic, outcome-based knowledge and non-epidemiologic knowledge. According to Ekeland, the one-sided attention on "what works" (i.e., outcome-based knowledge) makes the EBP practitioner ignorant in relation to "in relation to what?" (i.e., non-epidemiologic knowledge) (cf. Ekeland 2009: 149). Thus, in Ekeland's view attention to "what works" exclusively refers to epidemiologic knowledge, at the expense of any other kinds of knowledge, including both methodological and contextual knowledge.

Taken at face value, the position Ekeland argues for is rather extreme: When epidemiologic evidence is to be applied as basis for clinical practice, then, the only information this basis provides is restricted to the average effects of outcomes in

[180] See section 2.3.5. in particular. For instance, Guyatt et al. describes the main purpose explicitly in relation to the patient: "The proof of the pudding of evidence-based medicine lies in whether patients cared for in this fashion enjoy better health" (Guyatt et al. 1992: 2424; see also 2.4.3.1, where this is discussed).

[181] Strictly speaking, it is also nonsensical. In EBP, expertise is considered non-scientific knowledge, based on personal experience (cf. 2.4.3.). From an epistemological point of view (which Ekeli claims to take; cf. 4.1. above), it does not make sense to say "my expertise about X is based on scientific knowledge" – if this was the case, expertise would not be based on experience. One could say, of course, that "My knowledge about X is based on scientific knowledge", but in this case, knowledge would not refer to expertise.

epidemiologic trials. This is what "directly applied" means in Ekeland's criticism. Through such a direct application of evidence into clinical practice, any other kinds of knowledge, e.g., pertaining the circumstances of the specific clinical scenario, including knowledge of the individual patient and her preferences, are deemed as something that the EBP clinician is ignorant of.

This claim presupposes a dichotomization between "what works" and "in relation to what", similar to the dichotomization discussed in section 3.5.2. above,[182] implying a dichotomy or "gap" between epidemiologic research data and clinical care. Through such a dichotomization, attention to epidemiologic evidence (i.e., what works) correlates to a lack of attention to the role the clinician and the patient (i.e., in relation to what) in the EBP model. Such a description of EBP does not only approximates, but is tantamount to a minimal conception of EBP, in which non-scientific knowledge is excluded from the model (cf. section 2.4.4). In contrast, the moderate concept of EBP, representative of the EBP model in standard EBP literature, includes non-scientific knowledge as a necessary element. In this model, evidence is something that must be integrated by the clinician, according to patient preferences. Further, patient's preferences carry greater weight than those of clinicians, to the point where the patient's preferences may override the clinician's recommendations of clinical intervention (cf. section 2.4.3.1. above). Ekeland's criticism is thus, at best, relevant only to the minimal concept of EBP.

Another problem with Ekeland's dichotomization between "what works" and "in relation to what" is that it conflates research knowledge with the application of such research. Ekeland is correct in that outcome-based methods are non-contextual, in the sense that

[182] In section 3.5.2., I described how several critics in the international criticism argue, often implicitly, for an inherent dichotomy in EBP due to, on the one hand, its attention to epidemiologic research, and at the other hand, the preferences of the individual patient. A notable difference in Ekeland's version is that he also includes the clinical expert, who becomes alienated from what they do and from why they do it (cf. Ekeland 2009: 156; see also 4.3.5. above).

their primary attention is to the outcomes of an intervention.[183] However, when such evidence is applied at the point of individual patient care, attention to the clinical context in general and the patient preferences in particular is considered necessary elements in an EBP practice (cf. Chapter 2). Ekeland's criticism, primarily due to his view of "direct application "of epidemiologic evidence, ignores this essential difference between research knowledge and the knowledge necessary to apply it. By ignoring this, his criticism lacks relevance to the moderate concept of EBP, common in most EBP literature.

- **"Direct application" in Martinsen's criticism**

In Martinsen's criticism, she refers to "direct application" explicitly: "To directly recommend technologies or procedures for an actual practice on basis of research results leads to impelled instrumentalization" (Martinsen 2009: 96). This entails that EBP practice allegedly is based on scientific, non-contextual knowledge alone. As described as part of my analysis of Martinsen's criticism (in section 4.4.3), she does not offer clarification of what she means by directly recommend technologies or procedures. However, from her arguments, it is clear that she views "direct application" of evidence as clinical recommendations without *any* sort of autonomous reflection from the clinician who makes use of such evidence (cf. 4.4.3).

In essence, this is similar to Ekeland's argument, exhibiting the same ignorance of the distinction between research knowledge and the application of such evidence when recommending interventions in clinical practice at the point of patient care.[184] By ignoring

[183] As discussed in the previous section, there are, however, a number of mitigating elements to outcome-based research. Regarding the patient, one central mitigating element is the inclusion of patient-important outcomes, which measures outcomes that typically matter to patients: morbidity, mortality, symptom improvement, and quality of life (cf. section 1.4.1.2. above).

[184] A notable difference to Ekeland's argument is that Martinsen attends to lack of attention to the autonomy of the clinician while Ekeland focusses on the autonomy of the patient. While this is an important nuance to their line of arguments, it is not a relevant distinction to the current analysis.

what EBP practice amounts to, Martinsen is also guilty of a straw man fallacy when stating that the non EBP- clinician "[m]ust be able to act reflectively [ettertenksomt] (as opposed to only act "knowingly"), in concrete situations which demand commitment" (cf. ibid., 157f). To imply that the EBP clinician (and, indeed, any clinician at the point of patient care) does not act reflectively, is to depict what EBP practice amounts to, in a crude, over-simplified and incorrect way.

In a similar way, Martinsen's reference to Glasdam's research also demonstrates ignorance of what application of evidence in clinical practice amounts to. According to Martinsen, Glasdam claims that physicians apply personal expertise in their clinical practice, and that use of such expertise provides a basis for recommending a specific treatment, different from what kind of treatment that research may predict. In Martinsen's view, this demonstrates an application that is beyond the scope of EBP (cf. ibid.). In EBP literature, however, such an aspect of evidence-application – in which evidence or guidelines are deemed insufficient or unwanted (e.g., by the patient's preferences) is considered an essential element of patient care.[185] There is nothing wrong with Glasdam's research on expertise and evidence-application (except, perhaps, that the results Martinsen refers to are rather obvious and non-controversial), but it is erroneous to infer that such evidence-application is beyond the scope of EBP.

All three of the Norwegian critics could argue that use of pre-appraised evidence and guidelines can be problematic, and discuss the extent to which such use could minimize use of clinical reasoning and lead to automatic decision-making – such as it is typically done in the international criticism – as discussed in section 4.4.3. above. In the same section, I described the main disagreement between proponents and opponents as being about whether such standardization leads to reduced autonomy or not. Such a discussion is an example of a constructive EBP debate. In contrast, the one-sided attention to "direct

[185] This is discussed in a number of passages throughout chapter 2. See 2.4.3.1. in particular.

application", the conflation between research evidence and application of such research, and the categorical statements about that expertise and patient preferences are excluded at the outset, are neither correct not constructive.

In conclusion, the Norwegian criticism of the limited roles of clinical expertise and patients in EBP is closely connected their view of the one-dimensionality of evidence-sources in EBP: Their (mostly incorrect) view of evidence in EBP is directly extended to their understanding of what application of evidence in EBP amounts to. The main flaw in the Norwegian criticism of the minimal attention to clinical expertise and patient preferences in EBP, is the tendency to make categorical claims about that expertise and preferences is lacking. Thereby, the central claims and arguments in their criticism approximate a minimal conception of EBP, in which non-scientific knowledge is excluded from the model. Such an understanding of EBP does not reflect the moderate concept of EBP, which is the standard concept in EBP literature. Consequentially, their criticism of the roles of clinical expertise and patient autonomy in EBP is of minimal relevance to the EBP debate.

4.6. Conclusionary remarks on the analysis of the Norwegian EBP debate

In the analysis above, I have demonstrated that most of the Norwegian criticism tend to be insensitive to the necessary elements of the EBP model. In effect, many of their main arguments creates over-simplifications, leading to straw-man fallacies about EBP.

In my view, the most problematic feature common to all three critics is their minimal attention to the tripartite model of EBP. Indeed, Ekeli is the only one of the critics who explicitly addresses the model at all. As noted in the analysis of Ekeli above (in section 4.2.5.), she admits that attentions to 'clinical expertise' and 'patient preferences' are "important nuances", but stresses that research-based knowledge is the main source, and indeed the main purpose of the "EBP system". Ekeland rarely speaks of "expertise" in EBP at all. When he does, "expertise" is described as an element belonging at the bottom of a description of a hierarchical system of how EBP is organized (Ekeland 2009: 152f).[186] Regarding Martinsen's criticism, the EBP model is not subject to her criticism. Rather, clinical expertise and patient autonomy are only discussed as elements which are ignored in EBPs "evidentialist" practice.

Instead, the Norwegian critics focus their criticism exclusively on epidemiologic evidence, and on the challenges to the application of such evidence. Noticeably, all the challenges that are addressed have exclusively to do with challenges pertaining to the scope and generalization of population-based research, with no attention to how and the extent to which the clinician may assess and make use of such evidence in accordance with patient preferences and circumstances. The same tendency occurs in criticism concerning the roles of the clinician and of the patient, which is addressed, either by extending the

[186] Notably, this description is not comparable to descriptions of evidence-hierarchies in EBP literature. Ekeland describes the "hierarchical logic of action [handlingslogikk] in EBP (cf. ibid., 153). In this hierarchy, "research literature" is ranked on top, with a "control-level" below, and the clinician at bottom level. This description is not part of his main claims.

criticism of the limited usefulness of the evidence or by the procedures following the application of scientific evidence.

By ignoring two of the three necessary elements in the EBP-model, the Norwegian critics not only approximate but indeed demonstrate the minimal concept of EBP. In section 2.4.4. above, the minimal concept of EBP is characterized by that non-scientific knowledge is external to the model, and thus subjugating EBP to clinical epidemiology. Indeed, this seems to be the standard interpretation of the concept of EBP in the Norwegian criticism. This interpretation has serious implications for their criticism of the usefulness of evidence and of the role of clinical expertise and patient autonomy in EBP. Consequently, a large part of the Norwegian criticism becomes less relevant to the EBP debate.

Above all, the lack of attention to the tripartite EBP model, and the consequent tendency to reduce EBP to clinical epidemiology, leads to a simplified understanding of what EBP amounts to. When reading Ekeli, Ekeland, and Martinsen, one is presented with the description that EBP is "the direct application of research evidence in clinical practice".

As discussed in detail in Chapter 2, EBP is essentially an approach to clinical decision-making, in which the clinician recommends clinical interventions to individual patients. As part of this decision-making, evidence sources are identified and assessed according to clinical epidemiology principles. An equally essential part is that this evidence then is integrated into clinical practice by a clinician, who, by making use of clinical experience, identifies, assesses and applies the evidence, in accordance with the patient's preferences and circumstances (cf. 2.3.5. above). The Norwegian critics address the first part but not the second. Their depiction of EBP involves a simplified version of EBP including only the first part, onto which most of their arguments address the lack of the second part. As such, their arguments tend to constitute straw-man fallacies more than relevant arguments.

Not least, their categorical claims and arguments are seldom nuanced, and do not contribute to the EBP debate by addressing the extent to which patient preferences are accounted for in EBP, nor to which extent the autonomy of the individual patient in EBP decision-making is maintained.

Compared to the international criticism the central claims presented by the Norwegian critics resemble the categorical versions, essentially claiming that clinical expertise and patient preferences are rejected or minimized to the point of total omission. As discussed in 3.4., such claims can be easily dismissed by reference to any EBP definition. Through their categorical arguments, the Norwegian critics seem to ignore the two additional elements of the EBP model. Connected to this, they also ignore the "second principle of EBP" – "evidence alone is never sufficient to make a clinical decision",[187] which refers to that clinical decision-making in EBP is constituted by three equally necessary elements – evidence, patient preferences and circumstances, and clinical expertise.

In sum, central parts of the Norwegian EBP debate are based on misunderstandings, thereby providing minimal relevance to the EBP debate.

[187] Cf. Guyatt et al., 2008; 2015. This principle is discussed briefly in a footnote 49 in Chapter 2, section 2.3.3.

5. Conclusion

This treatise has presented analyses of the concept of EBP and of the EBP debate, the former analysis being a prerequisite for the latter. As stated in the introduction, the degree of adequacy in the EBP debate has fundamentally to do with understanding of the basic terminology in the EBP literature. The analysis of the concept of EBP has been conducted by clarifying the central scientific background of EBP and of the necessary and sufficient conditions for the EBP model, regarding both scientific and non-scientific knowledge, both equally necessary to the concept of EBP. On this basis, the epistemic structure of EBP was highlighted, through which EBP consists of three main elements – evidence, clinical experience, and patient's preferences and circumstances. Further, based on the possible combinations of scientific and non-scientific dimensions of knowledge, it is theoretically possible to differentiate between three theoretical concepts of EBP: "Maximal", "minimal", and "moderate" EBP, which differ relative to the extent to which non-scientific knowledge is taken into consideration. In light of the analyses in chapter 1 and 2, only moderate EBP is justifiable.

In turn, these clarifications provided the necessary basis for an adequate analysis of the EBP debate. In Chapter 3 and 4, the main arguments against EBP was identified, and discussed with respect to their validity and relevance. The analysis demonstrated how the criticism can be categorized into four main topics, addressing: (1) the conceptual unclarity in the concept of EBP; (2) the scope and application of evidence; and the extent to which (3) clinical expertise; and (4) patient preferences are adequately accounted for in evidence-based practice. Through the analysis of the EBP debate, it was demonstrated that the essential controversial point in the EBP debate has to do with the use of evidence from epidemiologic research in a clinical setting. In particular, the confidence in and the application of epidemiologic evidence-sources constitute the core controversial elements.

These elements have to do with the methodological presuppositions of EBP such as they are developed through clinical epidemiology.

The analysis showed that the validity and relevance of the criticism are related to whether the critics address methodological and controversial presuppositions concerning evidence in EBP, as rooted in its clinical epidemiology framework. The non-scientific elements of the EBP model – expertise, and patient preferences and circumstances – are not controversial in and of themselves, but rather become controversial when discussing the extent to which the use of expertise and patient preferences and circumstances are compatible with the methodological features of clinical epidemiology. Conversely, criticism that does not separate clearly between the methodological presuppositions from the model of EBP in general, generate irrelevant criticism. Examples of irrelevant criticism include categorical claims that EBP in general only includes epidemiologic evidence sources and that the EBP model excludes clinical expertise and patient preferences. These are examples of misinterpretations of what EBP is, due to erroneous inferences from the model of clinical epidemiology to the model and practice of EBP. Such categorical claims approximate a minimal concept of EBP, and are thus dismissible as erroneous. In Chapter 4, the critical analysis of the Norwegian criticism showed that most of the critical claims are comparable to the international debate. However, several of the central arguments imply a tendency to theoretical approaches when interpreting EBP, which in turn demonstrate a tendency to view EBP as a minimal concept, which excludes clinical expertise and patient preferences at the outset. Such an argumentation is unnecessarily theory-laden, over-simplified and based on misinterpretations of several elements in the EBP model.

These findings are what I consider to be most important in the analyses presented in this treatise. Based on these findings, I will conclude by discussing the future possibilities of

the EBP debate, by addressing the question about whether it is possible to identify a better, more constructive basis for the EBP debate.

What kind of recommendations, then, based on the above analysis of the EBP debate, may be suggested to EBP opponents, so that the debate would be more constructive? Conversely, what recommendations can be given to EBP proponents, so that their descriptions of EBP as well as their response to criticism would be consider constructive?

A first recommendation is to avoid categorical interpretations of the concept of EBP. What is perhaps the most apparent and least constructive issue throughout the above analysis of the EBP debate, is the occurrence of categorical claims, based on erroneous interpretations of the EBP model, which exclude expertise and patient preferences and circumstances at the outset. Such erroneous interpretations are demonstrations of what has been labelled a minimal concept of EBP. As stressed on several occasions throughout the analysis of the EBP debate, such interpretations are both unnecessary and unfortunate in the EBP debate, as they contribute only to over-simplifications and straw man fallacies, and thus do not contribute to a constructive debate.

As discussed in Chapter 3 and 4, categorical claims also occur with respect to evidence, where erroneous interpretations include that the scope of evidence in EBP relates to epidemiologic evidence exclusively and that evidence and evidence-hierarchies only address therapeutic questions. In the same vein, categorical claims stating that EBP only include epidemiologic evidence, or in the even more extreme version, stating that EBP is restricted to RCT exclusively, based on erroneous interpretations of what evidence in EBP refers to, should also be avoided. A considerable part of EBP criticism would be considerably less extensive, and less aggressive, if categorical claims were omitted.

A second recommendation is to distinctively separate between what is and is not controversial in EBP. As discussed in Chapter 3, the inclusion of expertise and patient

preferences and circumstances are not controversial in and of themselves. Rather, these elements become controversial when discussing the extent to which the use of expertise and patient preferences and circumstances are compatible with the methodological features of clinical epidemiology. Likewise, the central tenet of EBP that clinical practice should be evidence-based, i.e., based on best available evidence in support of a clinical decision, is not controversial by itself. Rather, the subject of controversy relates to what particular kinds of evidence that are considered as best.

In general, the EBP debate should be concerned about whether or not the EBP model provides an adequate basis for clinical decision-making. The essential controversial points in this regard are the use of and confidence in evidence from epidemiologic research in a clinical setting, including how evidence is ranked hierarchically relative to each other. These issues have to do with principles based on clinical epidemiology. In addition, there are non-controversial principles addressing challenges to how expertise and patient preferences are to be included in EBP clinical practice. These latter principles are common to any model for clinical decisions, EBP and non-EBP alike. The former set of principles has to do with clinical epidemiology methodology principles, and the latter has to do with taking the EBP model seriously. An adequate understanding of the difference between these sets of these principles should be considered a minimum requirement for partaking in the EBP debate.

A third recommendation relates to terminological and argumentative accuracy. A more constructive basis for the EBP debate has to do with increased conceptual precision of claimsand arguments. In the EBP debate, the subject matter primarily concerns specific evidence-sources, typically the RCT. When addressing alleged shortcomings pertaining to specific evidence-sources, critics should also identify what kind of evidence that exhibit attributes with less shortcomings. At the very least, critics should express awareness of that evidence-sources promoted by EBP proponents are not considered optimal in

principle, a priori superior in any clinical situation. Rather, 'best evidence' in EBP translates to 'the best available source of information, with the least degree of deficiency, compared to other available sources'. Following this, critics should not only address the shortcomings of a particular evidence-source, but also present what kind of evidence, in their opinion, that would be considered a better alternative. For instance, criticism about limitations of an RCT in relation to a specific clinical situation is not sufficient for claiming that the use of RCTs should be avoided. In addition, an alternative source of evidence should be suggested, that is arguably less limited in the clinical situation in the same clinical situation. Without this addition, the criticism is of less relevance. Conversely, by presenting an alternative source of evidence, allegedly better for a specific clinical situation, the debate between opponents and proponents would be constructive and important.

The controversial features of EBP can and should be discussed in terms of internal and external validity. With regard to internal validity, critics should present their criticism on basis of the more or less established current disagreement, related to the criticism from Worrall and others, addressing the central claims in favour of the superiority of epidemiologic evidence-sources, such as the benefits of randomization. Worrall presented his highly relevant criticism in early 2000. There have been some relevant response to this criticism, mostly by philosophers of science (e.g., from Howick), but EBP literature should reflect this kind of criticism to a larger degree. For instance, claims about that randomization in an RCT controls for confounders, both known and unknown, should be presented with considerable more reservations than what is often the case in current EBP literature.

With regard to external validity and the issue of the usefulness of applying population-based research as evidence in individual clinical practice, there is a tendency that critical arguments lack precision. Firstly, as discussed in Chapter 3, there are a number of

methodological tools designed to mitigate the challenges of external validity, e.g., pragmatic and n-of-1 trials, as well as the development of the GRADE system, which are equipped to mitigate risk of external validity, and thus reduce the severity of these problems. In the criticism, there is a tendency to ignore such mitigating features, and to address the issue of external validity in a simplified manner. Secondly, there is a tendency to ignore the fact usefulness also has very much to do with the role of expertise and patient preferences, i.e., the clinician's assessments of the clinical situation and the patient's preferences at the point of patient care. An increased precision with regard to such mitigating factors would serve as basis for a more constructive debate between opponents and proponents.

Regarding proponents of EBP, suggestions for providing a better, more constructive basis for the EBP debate, also have to do with conceptual clarification.

Firstly, as I have suggested above, in the analysis of the criticism concerning conceptual unclarity of EBP definitions, there should be consensus on a singular standard definition of EBP, exhibiting the necessary and sufficient requirements for a clinical practice to be evidence-based. As discussed in chapter 3 and 4, the lack of such an operational definition makes the EBP debate unnecessarily imprecise at the outset.

Most definitions of EBP include the three main elements – evidence, expertise, and patient preferences and circumstances – but provide little to no information with regard to how these elements are to be combined. In many definitions, the term "integration" is meant to remedy this, by connoting to the dynamic character of how the elements are to be combined. This is not, however, sufficient to clarify the significance of each element. The definition suggested in section 2.3.5. above, demonstrates a way to clarify the specificity of the elements and their relations in a more thorough way, through which both the methodological criteria (implicating its clinical epidemiology framework) and the practical criteria at the point of patient care (implicating the specific roles of the clinician

and the patient) are included. This suggested definition of EBP may serve as an example of a definition that highlights the specific elements and their relations in a more clarifying manner. In effect, critics responding to the definition would have to target their criticism in a more specified manner, potentially leading to a more constructive basis for the EBP debate.

Secondly, the methodological terminology should be presented in a more clarified manner. In particular, EBP literature should increase attention to clarifying the concept of validity, with regard to what "internal" and "external" validity connotes to, with respect to how they are fundamental to evidence assessment (typically through the Critical appraisal schemes) and, by extension, to the evidence hierarchies. A large part of the debate concerning EBP hierarchies would be avoided if descriptions of each hierarchy included accurate information about whether and how the ranking of evidence-sources was based solely on internal validity or in combination with external validity.

In turn, this would provide a better basis for debating the benefits and impediments of particular evidence-sources (most typically, of the RCT). For instance, it would enable the EBP proponents to nuance between critics addressing the methodological principles of evidence-sources (e.g., such as it is presented in Worrall's criticism) and the practical advantages and disadvantages in clinical practice (e.g., such that it is presented in most of Tonelli's criticism).

Thirdly, EBP literature should increase attention to explain and differentiate between its scientific framework and its pragmatic orientation toward the patient at the point of individual patient care (similar to the distinction between scientific and non-scientific knowledge in EBP, which has been discussed in Chapter 2). More concretely, this is related, on the one hand, to what can be conducted on basis of the methodological terminology, and, on the other hand, what must be assessed by the individual clinician in addition to information about the validity of a particular piece of evidence.

This latter point has to do with what has been discussed in Chapter 2 as assessment of the "usability" of evidence at the point of patient care. Explicit differentiation between the methodological concept of external validity and the context- and patient-sensitive assessment of the usability of the evidence would make claims about that EBP ignores expertise and patient preferences less common. If such claims were to occur, EBP proponents could reply more accurately with regard to the specifics of the erroneous character of the claim. In turn, such a reply would be preferable to the less constructive counter-claim that the critic has misinterpreted what EBP amounts to.

Towards a more a more constructive basis for the EBP debate

The above list is far from complete, and only tentative in nature. Nonetheless, the suggested recommendations demonstrate some the possibilities that can contribute to a more constructive basis for the EBP debate. At the very least, if the content of the above recommendations would be realized to a greater extent than is currently the case, the tendency to approximate minimal concepts of EBP would be minimized. This, in turn, would provide a far more constructive basis for future EBP debates.

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