No evidence without context

About the illusion of evidence-based practice in healthcare

raad voor Volksgezondheid en Samenleving

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“Learn the rules like a pro, so you can break them like an artist” – Pablo Picasso

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Foreword

‘Evidence-based’: the magic formula that has penetrated every last nook and cranny of the practice, policy and financing of care. First produce the evidence and then start on the applications, payments or purchases. Guidelines, protocols, supervisory frameworks, quality indicators and care contracts all bear witness to this. The underlying assumption is that proven care will always be good care. These recommendations take a critical look at this assumption: what evidence is there in fact, how did it arise and is it tenable in various situations?

The evidence-based approach has already been a subject of discussion for quite some time and numerous steps have been taken over the years to refine and differentiate the research methods and to add nuances to the evidence presented. The Council wants to go a step further with these recommendations, tackling the misconceptions and shortcomings in a more fundamental sense. When the day-to-day reality of care and welfare has so many different facets, the search for unambiguous evidence is an illusion and an unjustified simplification of what good care means. That is not to say that the quest for evidence should fall by the wayside. On the contrary, what we need is a plethora of evidentiary studies that can only be obtained if scientists and care professionals join forces. This means that professionals will have to embrace the uncertainty in the argumentation and put the focus on the context of their patients. For the scientists, it means acknowledging that scientific evidence is never complete and must always be subject to new insights and experiences. For health insurers, authorities and supervisory bodies, it means that the frameworks they define must give scope for an experimental approach to care practice and that they must prioritise the capacity of care professionals and care organisations to learn from this and to improve.

These recommendations sketch out a different perspective, one that takes the context as the baseline and rejects the idea that evidence can be made absolute. The Council hopes for a fruitful discussion about the power of various genres of good care and the necessity of linking that with a variety of types of knowledge sources.

Pauline Meurs

Chair RVS

The Council for Public Health and Society
(Raad voor Volksgezondheid en Samenleving, RVS)
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The task of the RVS is to advise the government and
both houses of the Dutch parliament (the States General)
about the broad lines of both policy areas.

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Summary

Evidence-based practice (EBP) emphasises the scientific underpinnings of professional actions. It has provided the impulse for the development of professional guidelines, quality indicators and volume norms. EBP engendered a revolution because any professional is able to claim authority after a critical assessment of the scientific literature. As a result, the reliance on a consensus within a specialist discipline has had to make way for reliance on statistics and numbers. This development began in the 1980s in the professional domain of medical care. In the meantime, other disciplines both within and beyond the healthcare sector, governmental authorities, supervisory bodies and health insurers have embraced the principles and tools of evidence-based practice. Under the influence of EBP, external responsibility, transparency, standardisation and checking have become the predominant control and management principles within the healthcare sector.

EBP has substantially improved the quality and safety of care.
Uncertainty and evidence play an express role in practice, which has greatly improved systemic reflection on the consequences of medical actions. Tools have also been developed for converting scientific research into recommendations for practice. There is however a flip side as well. This boils down essentially to the fact that the knowledge that EBP is based on is a simplification of reality.

Firstly, care is given in a context in which the question of the nature of good care plays a role. An inherent risk of EBP is that it will reduce good, patient-oriented care to what has been proven. The right thing to do can vary with the patient and the situation. Moreover, opinions of what constitutes good care are subject to change.

Secondly, the knowledge that EBP relies upon is based on standardised situations and on what is quantifiable, preferably in randomised experiments. Such knowledge does not take sufficient account of the differences between patients and their personal values, the variation in implementation in practice, or the dynamic setting in which care is given. There are also forms of care that cannot be investigated using the EBP methodology. To put it another way, the knowledge that EBP is based on claims to be universally applicable, and that knowledge is impersonal: it has no relationship with the professional or the patient as people. This is ignoring the multifaceted nature of real situations and the fact that knowledge is always personal. Although EBP is formally the result of integrating external knowledge, clinical expertise and patient preferences, the EBP movement has not paid sufficient attention to how this must be done.

Thirdly, EBP and professional guidelines (plus the quality indicators based on them) have become an authority in their own right. If guidelines and quality indicators are not applied critically, this plays into the hands of undesirable standardisation in the care sector. In particular, the environment within which care professionals operate exacerbates this: high pressure of work, care that is organised separately for each discipline, and the use of evidence-based principles by governmental bodies, health insurers and disciplinary colleges. Care professionals spend more time providing quality information for external accountability than they gain by learning from it. Scientific research needs attention as well. Unintentionally, a research system has arisen that can encourage irrelevant and unreliable research, while many elements of customary care have been investigated insufficiently. Taken as a whole, this is pushing care practice in the direction of whatever can be investigated and substantiated using the EBP methodology. This is at the expense of care elements for which this is difficult or impossible, and of care that is commercially not interesting.

Evidence as the basis of good care is therefore an illusion. In addition to external knowledge, good and patient-oriented care requires other sources of knowledge that EBP underutilises: clinical expertise, local knowledge, knowledge from the patients themselves, knowledge of the context – the living conditions and preferences of patients and the setting within which care is given – and of the values that are involved. Because any decision involves a specific request for assistance that is given in a specific context, decision-making in the care sector can be seen as an experiment in linking together the various sources of knowledge. The uncertainty that is inherent in this must not be denied it should indeed be embraced. Every decision can be and should be a learning moment.

Because of the lack of clarity in the content and the shortcomings of EBP, the Council for Public Health and Society is pleading the case for context-based practice rather than evidence-based practice. This is because of the importance of the specific context, the patient and the setting where the various sources of knowledge are used as the basis for the decisions that are taken. This goes beyond a mere local implementation of external knowledge. It means a continuous process of learning and improving together. It also signifies a different approach to education, research and supervisory practices.

For the individual patients' care, this means that care professionals must adjust the practice of shared decision-making to fit the context of the patient, and pay more attention to listening than to the dissemination of information. This practice can be assisted by selection tools to help discover what patients find important. Patients' organisations need to take the initiative for developing the selection tools, together with care providers and other parties involved. An essential skill for care professionals is that they must be capable of understanding the value of various sources of knowledge and integrating them into practice, with an eye for the context and the considerations involved. Developing this competence is something they ought to be doing together with all relevant parties involved, including colleagues from other disciplines and the patients. This capacity goes hand in hand with embracing the uncertainty about the nature of good care. There is already a great deal of attention paid to such skills in the training of care professionals. However, there needs to be more space here for social and mental sciences, for interdisciplinary education and active input from the patients.

The capacity of care professionals and care organisations to learn is enhanced when attention is paid to the working environment. In the early stages of care processes, particularly during the diagnosis and decision-making phases, care organisations should put more time aside for learning. This investment will pay itself back because the effort spent in diagnosis and treatment will be reduced.

In the current care system, quality monitoring is outsourced to third parties and has become divorced from the care professionals themselves. The emphasis has shifted to external accountability, standardisation and checks. The Council believes it is important to shift this practice towards a situation in which care organisations and care professionals decide for themselves what constitutes good care and arrange their organisations and working methods to suit.

To this end, care professionals should start up a dialogue about good care within their own care organisations, not only amongst themselves but also with their managers and with the patients. Care organisations should take the initiative to enter this dialogue with other interested parties: other care providers in the region, health insurers, patients' organisations and municipalities. Tools for this could for instance include quality figures and other local data, the system of patient tracers, annual reports and patients' stories. Because of the principles involved, this dialogue has to take place in an open “moral forum”. This moral forum or “agora” can be seen as the vehicle for legitimising decision-making in the care sector about what goals are being aimed for and using what resources. The importance of that legitimisation means that the dialogue is not optional: it becomes obligatory. This is how the parties involved fulfil the public tasks that they have been assigned, and how they can be held accountable for the results achieved. In order to ensure the development and the quality of this moral agora, it is important that it becomes part of the governance of care institutions. This shift has consequences for the system of scientific research. Utilising external evidence in the local situation is more than merely a question of implementation. It must be part of a learning process in which the effect of contextual factors on the care outcome is made explicit. Researchers and those financing healthcare research must therefore pay more attention to the effect of the context of the practice within which care is provided. This can be done for example by making use of local data from practice, and by combining quantitative and qualitative methods in the same studies.

When making recommendations about how packages should be managed, the National Health Care Institute should take account of the context within which care is provided and of other sources of knowledge than scientific evidence. This can be encouraged by involving professionals, patients and the general public.

Finally, the focus for quality supervision and care contracting needs to shift from uniform quantitative outcomes of care towards learning and improving on the part of care professionals and care organisations.

1 Background

Evidence-based medicine
It seems obvious nowadays that care professionals will rely on scientific evidence. The evidence is, after all, an essential component of the legitimisation and standardisation of professional treatment. Its roots go back to the 1980s. A movement arose in healthcare that is now known as evidence-based medicine (EBM), “the conscientious, explicit, and judicious use of current best evidence in making decisions about the care of individual patients.” (Sackett et al., 1996). EBM has provided an impulse for innovation of medical education and research and for the development of professional guidelines or standards to help care professionals when taking decisions in the care of individual patients.

From evidence-based medicine to evidence-based practice
Evidence-based working is now no longer restricted to the medical domain; it has extended to other disciplines and domains both within the healthcare sector and elsewhere, such as care provided by medically associated professions, youth care, the public healthcare system, long-term care, social work and education. Evidence-based principles have also made inroads in policy and monitoring. To help develop this broader development, we will use the term *evidence-based practice* (EBP) here. The term ‘EBM’ will however be used on occasion when referring to specific historical developments.

Personalisation of care delivery
We are now decades further. There have been a variety of changes in the care sector that are important for the role that evidence plays within it. Firstly, the substantive content of care has changed a great deal. There has been an increasing emphasis on the personalisation of care (i.e. patient-focused care): care that it is tailored to suit the individual need for aid, the characteristics and preferences of the patient, and their personal context. The type of evidence that is typical for EBP (derived from research among selected populations and in strictly controlled circumstances) is not always sufficient for this. This needs to be translated to individual people and their situations. Solutions that are effective in one situation will not necessarily be applicable to other situations.

Changing environment
Secondly, not only the content but also the environment of care practice has changed significantly (Noordegraaf et al., 2016). Professional activities are increasingly becoming a question of teamwork. Several disciplines are often involved with any given patient or client, each bringing in their specific expertise.

In addition, confidence in professional expertise has become less self-evident. Professionals are increasingly being expected to provide accountability to third parties. External supervisory bodies such as the Healthcare Inspectorate use evidence-based tools such as professional guidelines and quality indicators based on them to monitor that accountability. The same applies to package management by the National Health Care Institute and the way that health insurers contract care. These developments mean that scientific evidence is becoming more and more institutionalised and subject to vested interests. This creates tensions. Attention is also required for the relationship between professional practice, scientific research and policy practice that are based upon scientific evidence.

Care that has been proved to work is not necessarily good care
Medical activities and 'using the best evidence' always has a moral context in which the question of the nature of good care plays a role. Moreover, opinions of what constitutes good care are subject to change. An understanding of values is therefore required for setting treatment goals and for weighing things up. The entire process of providing evidence is in fact driven by values: the programming and implementation of research, the selection of measures of outcome and measurement methods, the translation of research results into guidelines, manuals and protocols, and the use of that knowledge within individual patients' care. Ethical considerations of what good care involves therefore also demand attention in the way scientific evidence is used. Good care is therefore more than merely that which has been proved to work.

Purpose of the recommendation
The personalisation of care, the changing environment and the morally charged context of care all add to the tensions that exist between the ideal of EBP (proven care is the same thing as good care) and its use in practice. The proponents of EBP are themselves well aware of these tensions and are working on improvements. Actual practice reveals further important bottlenecks, however. At the same time, the tensions between the ideal of EBP and its practice raise the question of how much that difference is a consequence of its fundamental principles.

Question
The recommendation is based on the following question:

If good care is more than merely that which has been proved to work, how can scientific evidence be used in providing good care and giving it legitimacy?

Scope of the recommendation
The Council is aiming to play a part through these recommendations in the analysis of the tensions between the ideal of EBP and its practice, and wants to suggest avenues for possible solutions for the appropriate use of scientific evidence in care practice and care policy. The underpinnings and the examples in these recommendations have largely been drawn from medical care practice, because evidence-based working has made the most inroads there and because it is the area where there is the most experience. The bottlenecks and areas of tension that are associated with evidence-based working are however present in other domains as well, both within the healthcare sector and elsewhere, in practical work and in policy. These recommendations are therefore relevant to a number of domains.

Reading guide
The tensions between the ideal of EBP and its practice are examined from the perspective of professional conduct and possible avenues for solutions are given. In order to do justice to the developments within EBP, the structure below has been adopted. An outline description is first given of the development of EBP (Chapter 2) and the added value that it has provided for the care sector (Chapter 3). This is followed by the criticisms of EBP (Chapter 4) and the responses to them by the proponents of the EBP movement (Chapter 5). The recommendations then give an analysis of the current areas of tension within EBP that are related to the fundamental principles of EBP and the use that care professionals and institutional parties make of it (Chapter 6). The recommendations end with a number of directions in which solutions can be sought and recommendations for the bottlenecks (Chapter 7).

2 The rise of EBP

Background
The reason why EBM was developed lies in the fact that the effectiveness and safety of a great deal of medical care practice were unknown or at least dubious. That could be seen from the considerable variations in practice. Reducing that variation in practice and cutting down on ineffective or even harmful care, plus the associated waste of resources, was the key objective of EBM (Berwick, 2016; Timmermans, 2010; Wennberg, 1984). This means that EBM is in line with one of the key Hippocratic principles of medicine, namely not to cause harm.

It started with medical education
The EBM movement was aiming for radical renewal of medical actions, from within. Related ideas and initiatives arose at a variety of places during the same period. Key pioneers were the British epidemiologist Archie Cochrane (Cochrane, 1972), David Sackett from McMaster University (Hamilton, Canada), Feinstein in the USA, and the Danish gastroenterologist Henrik Wulff. EBM began life as a new educational model that was developed at McMaster University. Up–and-coming care professionals were trained to develop a critical (and self-critical) mentality and to justify their own activities through a critical assessment of the scientific literature. EBM is now part of the core of the medical curriculum. EBM was however destined to become much more than the renewal of medical education, providing inter alia the impulse for systematic assessment of literature and the development of professional guidelines for practice.

From authority to evidence
Before the introduction of EBM, medical actions were based on intuition, the physicians own clinical experience and the basic medical knowledge that allowed doctors to reason things out of in terms of pathophysiology or mechanics (Bolt, 2015). This meant that the foundations of their activities were primarily the consensus within their own specialist discipline and the people who were deemed to be an authority within the discipline. Because of growing awareness for the uncertainty, subjectivity and bias in medical knowledge, this went hand-in-hand with falling confidence in professional expertise and authority. EBM engendered a revolution because it rendered junior doctors capable of challenging such authority by calling upon the scientific literature. EBM can therefore also be seen as a democratisation of knowledge.

Through systematic use of scientific evidence, EBM aimed to eliminate the uncertainty, subjectivity and bias in medical knowledge.

The best evidence
A central element in the EBM approach is that it makes distinctions in the levels of proof when assessing scientific information. At the top of the evidentiary hierarchy is the randomised controlled trial or RCT, in which a treatment is compared against an alternative and in which the patients are randomly assigned to one of two groups. This is followed by follow-up studies, case-control studies, case reports and case series respectively as lower evidentiary levels, with the opinions of experts right at the bottom. The best evidence that EBM uses, the RCT, can therefore be seen as group-level evidence: hypotheses are examined using statistical methods based on observations of groups.

EBM therefore signified a shift from relying upon consensus within a specialist discipline (‘disciplinary objectivity’) to relying upon statistics and figures (‘mechanical objectivity’) as a common basis for medical actions (Porter, 1995). This shift in what objectivity involves means that the touchstone of medical actions now involves figures and measurable outcomes from which the personal element has been eliminated. This increasing reliance upon the figures – which has incidentally occurred in multiple domains – moved the care sector into an era in which external accountability, transparency, standardisation and monitoring have become the dominant principles for control and assessment (Porter, 1995).

Development of guidelines
As well as renewing medical education, EBP has provided an impulse to the development of professional guidelines or standards. Key reasons for this development are that the assessment of research results requires specific expertise that care professionals do not always have, and that it is all but impossible for any individual healthcare professional to keep up to date on the scientific literature. In the Netherlands, the CBO (Dutch Institute for Healthcare Improvement) and the NHG (Dutch College of General Practitioners) have taken the lead in developing guidelines, which were initially above all based on consensus. The scientific associations of the professional groups are currently responsible for this, with support provided by the Knowledge Institute of the Federation of Medical Specialists and the National Health Care Institute.The implementation is dealt with by committees with clinical and methodological expertise.

These committees assess the scientific literature about the diagnosis and treatment of a specific condition, weigh up the evidentiary strength and base their recommendations for practice upon it.

Institutional and social context
The development of EBP did not and does not stand alone; it is instead within a changing institutional and social context. The prestige and authority of professionals and of science itself are no longer so obvious. Stricter accountability requirements are being imposed on these parties in order to maintain authority and trust. This public pressure has a variety of causes, inter alia the stronger position of patients, the pressure to use public resources efficiently, the role of the media who denounce abuses in care and legal procedures against healthcare professionals. Several of these developments have been translated into legislation in which evidence-based professional standards have a place, such as the Medical Treatment Contracts Act (Wgbo) and the Healthcare Quality, Complaints and Disputes Act (Wkkgz). Scientific evidence has therefore become part of external control and supervision. This will be dealt with in following paragraphs.

A stronger position for patients
The responsibilities of care providers and those who receive care are legally laid down in the Wgbo and are derived from the applicable professional standards (Art. 7:453 of the Dutch Civil Code). Strengthening of the legal status of patients was part of the background to the Wgbo. Care providers have a duty to provide care in the way a good caregiver should, i.e. in accordance with the applicable professional standards. These are not legally binding standards. Care providers are allowed to deviate from the applicable guideline provided there is justification for doing so. They may even have to deviate from it if required for quality reasons. On the other hand, care providers who observe the guideline are not exonerated from liability for any harmful consequences of their actions (Supreme Court, 1 April 2005, Dutch Jurisprudence (NJ) 2006, 377).

Patients in turn have the option of deviating from a care provider's advice by exercising their right to refuse an examination or treatment. They are not entitled to examinations or treatments that conflict with professional standards (RVZ, 2013).

Supervision of quality and safety
Quality supervision also uses evidence-based instruments such as professional standards and volume standards.

The implementation of the Care Institutions (Quality) Act in 1996 gave the government more responsibility for the quality and safety of care, as well as the legal authority to ensure it. The Care Institutions (Quality) Act has now been replaced by the Wkkgz, which obliges institutions to comply with certain quality requirements that reasonably guarantee the provision of good care, i.e. safe, efficient, effective and client-oriented care. Like the Wgbo, the norm in the Wkkgz has been based on professional standards.

The consequence of these quality requirements is that care providers must measure and record the quality of care systematically. To that end, the National Health Care Institute developed an assessment framework that quality standards (including guidelines) and quality measurement instruments (quality indicators and client questionnaires) must comply with before they are included in the Quality Register (National Health Care Institute, 2014a). One of the requirements is that a quality standard or measuring instrument must have been jointly recommended by healthcare providers, healthcare insurers and patients. The aim is to provide clarity about what these healthcare parties consider to be good care and to ensure that the recommended measuring instruments can be used for quality improvement, supervision, choice information by clients, and for purchasing care.

The National Health Care Institute also has the legal power to develop quality standards. If parties fail to deliver quality standards, the Quality Council of the National Health Care Institute must write the standards, after which the National Health Care Institute includes them in the Quality Register. This may help move discussions forward that were not making any progress in terms of content.

Package management
The National Health Care Institute has adopted the principles of the EBP for package management in the context of the Healthcare Insurance Act and the Long-Term Care Act. Various steps have been taken in the working method to ensure that the context is considered in the package recommendations. These always refer to an intervention in the context of a specific indication. Checks are made at the start to see what healthcare providers and patients consider to be good care. After that, a check is made to determine what evidence should be present (given the nature of the intervention and the indication), what evidence is available, and what the causes of any discrepancies are. The available evidence is then assessed against the legal criterion of the ‘current state of knowledge and practice’ (Health Insurance Decree and Long-Term Care Decree).

This criterion is formally used as an integrated standard, in which insights from scientific research, expertise and experience of healthcare providers and care recipients are ‘combined and incorporated’ (National Health Care Institute, 2015). This integral assessment means that the quality of the available evidence is weighed up; the evidentiary hierarchy mentioned earlier is key. The solidity of the scientific evidence then determines what the insights and experiences gained in practice actually signify. Higher or much lower quality of the scientific evidence is in principle the deciding factor when the decision on reimbursement is taken. Insights and experiences gained in practice can be important if the quality of the scientific evidence is mediocre or low. The term ‘practice’ is taken here to mean treatments that are normative for the professional group as a whole or that are seen as ‘good’ treatment, i.e. not the individual experiences of healthcare providers and care recipients.

Where possible, the assessment of care as part of the insured package is aligned with the recommendations in professional guidelines. However, the dichotomous nature of the package assessment – in which the care for a specific indication type is assessed – differs from the more nuanced approach of recommendations in professional guidelines for the care of individual patients.

Evidence-based purchasing of care
The quality standards (including professional guidelines) and quality measurement instruments of the National Health Care Institute are also the basis on which health insurers contract care.

Evidence-based medicine (EBM) has led to a radical shift in medical care from reliance upon the authority of the physician to scientific evidence and measurable quality. Although EBM was initially ‘owned’ by the medical profession, policy makers, supervisors, health insurers and patients have also adopted EBM’s principles and the associated tools in order to control professional actions.

3 The added value of EBP

The evidence-based approach has made important contributions to the quality of medical care.

Evidence is more explicit
Firstly, scientific evidence is playing a more explicit role in medical care, which reduces uncertainty, subjectivity and bias. A great deal of ineffective or harmful care has been identified and then eliminated. Furthermore, EBP helps curb the introduction of new technology that is insufficiently proven and helps identify domains where insufficient research has been carried out.

Systematic reflection
Secondly, EBP can be considered to be a systematic form of reflexivity. Reflection on the consequences of medical actions takes place jointly and in a more systematic and organised way, compared to 'authority-based' medicine. Under the influence of EBP, an international knowledge platform has developed where clinical experiences are bundled, tested and distributed.

The answer to the knowledge explosion
Thirdly, the emergence of EBP was accompanied by developments that have made it increasingly easy to generate and distribute knowledge. The development of guidelines is therefore also an answer to this explosion of knowledge. The methodology that is applied for assessing and weighing up measurement results has become ever more refined, so that translation into recommendations takes greater account of the degree of certainty or uncertainty.

Development of statistical methods
Fourthly, an important spin-off of EBP is the development of statistical methods for identifying and quantifying the consequences of medical actions.

EBP has made a significant contribution to the quality of medical care because the supporting evidence now plays a more explicit role and because it has encouraged systematic reflection upon the consequences of medical actions. Tools have also been developed for translating scientific research into recommendations for practice.

4 Criticism of EBP

The ambition of the EBP movement was gradually moderated somewhat and the criticism grew. This also came from the evidence-based movement itself, fitting the attitude advocated by EBP. Some have even raised the question of whether EBP was in a crisis (Greenhalgh et al., 2014).

4.1 Evidentiary hierarchy open to discussion

This criticism targets the evidentiary hierarchy and the position of the RCT first of all. Leaders of the EBP movement have also expressed their doubts and proposed alternatives (Howick et al., 2008). The claim of proponents is that only RCTs provide pure evidence about the effects of diagnosis and treatment.

Two scientific paths: evaluate and explain
The first counterargument here is that science is more than *evaluating*. For *explaining* diseases and the efficacy of interventions, and therefore for finding new causes of disorders and new targets for treatment, observational research is more appropriate and more efficient than RCTs. The evidentiary hierarchy for this explanatory research is in fact the reverse of that for evaluation research (Vandenbroucke, 2008). This path of scientific research is erratic and non-linear. Systematic analysis of laboratory experiments, case descriptions and analysis of medical datasets allow existing hypotheses to be made and tested and new hypotheses to be formulated. The spectrum of possible explanations or causes is in principle broad, and the chance of finding something during any given analysis is small. Coincidental findings can mean a new breakthrough, but recognising such coincidences requires a lot of knowledge and experience.

RCTs, on the other hand, focus on the effect of a single intervention, making them ideally suited for evaluating diagnostics and treatment. Due to the high costs and relatively long lead times, these only take place if the chance of showing an effect is estimated to be high, based on all the prior research. How high these ‘prior odds’ should be is in principle the result of ethical and financial considerations (‘do the risks outweigh the potential benefits for patients’, or ‘is the research worth the investment’).

Observational research and randomised studies are thus different but complementary approaches to scientific research. Neither can exist without the other. In principle, the nature of the research question determines the research setup. Every setup has its strengths and weaknesses, and the internal validity has to be weighed against the generalisability of the results (Ottes, 2016).

Limits of RCTs for evaluation studies

In addition to criticism of the evidentiary hierarchy as such, the claim that RCTs provide the most convincing evidence for the effectiveness of care is only partly justified. Without knowledge of the mechanisms that can explain a proven difference, doubts will remain about a causal relationship. In addition, various forms of medical care have never been studied in an RCT but are nevertheless part of regular care. This applies for example to penicillin and to organised screening for cervical cancer (Peto et al., 2004). The results of observational research can be so convincing that it becomes unethical or inefficient to use an RCT to evaluate care that is already customary.

RCTs are not always possible either. This may be due to legal or ethical objections, such as research among the legally incapacitated, children or terminal patients. There can also be methodological reasons for this, such as is the case in research among elderly people with multiple morbidity or research of rare diseases. Blinding is sometimes impossible, distorting the results e.g. in research into the quality of the therapeutic relationship in the treatment of mental disorders (see the boxed text on “Psychotherapy”).

Psychotherapy: the role of non-specific factors and context

The success of the approach adopted can sometimes only be attributed to a limited extent to the method that was followed. People with mental problems who get help usually get a form of psychotherapy to regulate their emotions, behaviour, thinking patterns or personal characteristics. There are many different forms of psychotherapy, all with their own starting points or approaches. Cognitive behavioural therapy, psychodynamic therapy and solution-oriented therapy are some of the most well-known.
However, a great deal is still unknown about why psychotherapy works and about the contribution made by the specific methodology.

There is discussion about the exact extent, but the specific methodology seems to be of only limited importance. This is also called the “dodo bird verdict”, inspired by the quote from the book Alice in Wonderland: “Everyone has won so all shall have prizes”. An explanation for this is that all methodologies share generalised, effective, non-specific factors and placebo effects that partially determine the effect of therapy. An example of an important generalised effective factor is the quality of the relationship between the client and the care provider. Factors from outside the therapy, such as events in their private lives or finding work, also have an influence on the treatment effect.
These observations have far-reaching consequences. They determine whether it is sensible to invest in the development of specific care methods. For care providers, the question is whether it is sensible to look for specific interventions that could be helpful, or whether they are better off investing in training skills that help create good relationships with clients.

And finally, despite strict methodical requirements, many RCTs are not free from systematic distortion of the results (Ottes, 2016). The mere fact that a patient knows they are participating in a study leads to distortions. That this is not a matter of doom and gloom has been shown in a recent overview study of research in various fields. This concludes that, on the whole, the extent of distortion in research results is small (Fanelli et al., 2017).

The context matters
Ultimately, the strength of this flagship of the EBP movement is also its weakness. RCTs follow a strict protocol to prevent influences on the results from factors other than the intervention. Participants, outcome measures and interventions are standardised. Because of this standardisation, less attention is paid to the variation that exists between patients, the desired outcomes and performance practices of interventions, and the dynamics of the setting in which the care is given.

In reality, the results on an individual level within the group studied will vary, and these results can differ for people outside the group studied. Some groups that are systematically excluded from RCTs are at an additional disadvantage here: children, women, the elderly and people with a comorbidity or multiple morbidity (see the boxed text on “RCTs and drug research”).

A great deal of clinical research is carried out in second-line patient groups and is not necessarily usable in primary care where there is a different mix of patients (Steel et al., 2014). Additionally, the personal situations of patients can affect the treatment outcomes and the meaning attributed to them. This shows, for example, the role that parents and teachers play for children with ADHD (see the boxed text on “ADHD”).

RCTs and drug research

After earlier research phases are completed, the effectiveness and safety of pharmaceuticals are tested in RCTs from which the elderly and patients with comorbidity and concomitant medication are usually excluded. This makes it harder to translate research results into everyday practice. There is also the risk that medicines are not licensed for the patients who need them most. TNF-alpha inhibitors against rheumatism, for example, are mainly studied in patients with a high disease activity. This medication is less effective for patients with lower disease activity. Another example is protease inhibitors against hepatitis C. Patients with cirrhosis of the liver and severe portal hypertension are excluded from the trials. The risk of complications is higher in these patients, which hinders therapy compliance and thus reduces the effectiveness of the treatment (Kievit et al., 2016). Medication for preventing fractures in patients with osteoporosis is only tested on women and not on men.

ADHD: should you ask the children, or the parents and teachers?

After the discovery of an amphetamine derivative called methylphenidate in the 1950s, it became incredibly important for the treatment of ADHD in children and adolescents. The place of the medication differs from one guideline to the next. In the multidisciplinary guideline for ADHD, it is the first choice for the treatment of symptoms, whereas the guideline from the NHG (Dutch College of General Practitioners) recommends it if parent/teacher guidance and any psychotherapy is not helping sufficiently. These differences can be traced back to the meaning given to the roles of parents and teachers. The recommendations are based to a great extent on a major study in the 1990s, known as the MTA study. It compared the value of behavioural therapy against medication, or a combination of the two. It was notable that medication resulted in better reduction of symptoms, while parents and teachers were more satisfied with behavioural therapy.

This was shown in the quality of life and general functioning. Behavioural therapy allowed parents and teachers to deal with the behavioural problems of the children better. The researchers also suggested this as an explanation for the fact that many parents stopped the medication after the end of the study (Boer, 2007).

Interventions are messier in practice than in a standardised experiment. This even applies to relatively simple interventions like medication, where carelessness or taking medication with or without food can influence the result (see the boxed text on “Cancer medication with breakfast”).

Cancer medication with breakfast
Some cancer medications appear to be absorbed by the body better if patients take them with a light breakfast. The dosage can then be lowered and the patient is less affected by side effects such as nausea, and there can be cost savings. The Patient Information Leaflet for these medicines says that they should be taken on an empty stomach to ensure an even concentration throughout the body. This happens when clinical research shows that food influences the absorption in the body. Such research is required by the licensing authorities. In the study on the effectiveness of the medicine, that it should be taken on an empty stomach is now part of the protocol. More research to check the influence of different types of breakfast on each medicine could help achieve more personalised pharmacotherapy. It is important that patients do comply with certain breakfast regulations (Volkskrant, 27 March 2017).

Finally, the research results are not universally applicable because they are partly dependent on the setting in which the care is given. The experiment with free provision of heroin that took place in the 1990s is a good example of this. The circumstances under which it was to be used were substantially different from normal heroin use, and therefore the results could not be considered as representative for a natural situation (see the boxed text on “Free provision of heroin: a created reality”).

Another example of the influence of the treatment context is measuring high blood pressure (see “White coat hypertension”).

Free provision of heroin: a created reality

To back up the policy of the ‘Purple’ (Left Right coalition) cabinet to provide free heroin (“heroin on prescription”) to those heavily addicted, the parliament decided in 1999 to conduct a randomised study. The then Minister Els Borst argued that only an RCT could pass judgement on this politically controversial issue. The study was conducted under the responsibility of the medical/scientific Central Committee on the Treatment of Heroin Addicts (CCBH). For various reasons, it is doubtful whether such a randomised experiment could give the final answer on an issue as complex as heroin addiction (Dehue, 2002). One of the reasons is that the addicts taking part knew that the outcomes were a deciding factor in whether heroin was provided. It was in the interests of those who got heroin to show progress, which was not the case for those in the control group. Another reason is that they had to work with a group of heavily addicted people.

This is problematic, given that it is known that addiction is to a large extent a matter of subculture and social factors. Use is connected to specific circumstances and rituals. In the experiment, heroin was provided in strictly controlled circumstances, namely under supervision and with a strict regime of use. It is therefore unlikely that the participants were representative. Additionally, this research setup reduces heroin addiction to a problem of the individual; social factors that play a role in addiction are ignored. The results are therefore the result of a created reality that is far from the natural situation. This example also shows that an excessively close relationship between science and politics has its downsides because the experiment stifled political discussion of the problem of heroin addiction.

White coat hypertension
Detecting high blood pressure is not as easy as it seems.
It appears that the setting in which the blood pressure measurement takes place can make a difference. Some patients have higher blood pressure if a doctor does the measurement than when they measure at home. This difference is generally attributed to increased stress. This is the case in up to 20% of people. The result is that more patients than necessary use antihypertensive medication.

Absence of proof is no evidence of absence of effect
These nuances in the evidentiary hierarchy and the purity of RCTs, and the role of context, mean that the absence of proof is not necessarily proof that there is no effect. Strict application of EBP can crowd out potentially good but unproven care.

4.2 Evidence-based practitioners en evidence users

A second point of criticism levelled against EBP is that the focus has shifted more to developing systematic overview articles and professional guidelines rather than to developing a critical (or indeed self-critical) attitude among practising doctors. Only a limited few have managed to acquire knowledge of the methods and techniques for critical assessment of the literature. According to the Dutch Federation of Medical Specialists, there are over 500 guidelines for medical specialist care, of which about 100 are renewed or developed further every year; there are about 100 NHG standards for general practitioners. Assessment of literature and the development of guidelines has become its own specialist field, and care professionals are more “evidence users” than “evidence-based practitioners” (Gordon Guyatt, quoted in Daly, 2005). For them, guidelines and guideline developers are a new authority (Greenhalgh, 2014). What started as an anti-authoritarian movement has itself become a new authority.

Standardisation of care
Standardisation of care through the use of guidelines is not necessarily undesirable. When variation in practice is the result of subjectivity, bias and uncertainty, standardisation helps to reduce randomness and differences inaccess to care that cannot be justified. However, guidelines can also play into the hands of undesirable standardisation of healthcare.

This risk increases if guidelines suppress people's own professional expertise and experience, if substantive medical reasons for deviating from the guideline do not get enough attention, if contextual factors are not sufficiently taken into account, if the experiences and preferences of patients are not given sufficient space and if guidelines are applied rigidly for purchasing and supervision. 'Better avoided' lists can add to this, despite the fact that their intention is to reduce ineffective care (see the boxed text on "Better avoided list"). The trick is to not let reduction of undesirable variation come at the expense of desirable variation.

'Better avoided' list
Under the responsibility of the Netherlands Federation of University Medical Centres (NFU), a 'better avoided' list was created based on evidence-based recommendations from existing guidelines. It includes more than 1300 medical actions that, after assessment of the underlying proof, are discouraged or strongly advised not to be applied as a matter of routine. The list aims to reduce unnecessary care that has no added value or can be harmful (Wammes et al., 2016).

4.3 Systemic failures in scientific research

A third point of criticism is that a number of undesirable and interrelated research practices arose that were exacerbated by well-meaning rules and stimuli in the research system (Reijmerink, 2014).
A group of scientists exposed these practices in the journal the Lancet. This includes excessive attention to small differences in randomised studies that are statistically significant, which impacts negatively on the attention paid to what is clinically or socially relevant, research that has been set up poorly, omitting displeasing results in publications, or even not publishing disappointing results at all.
The result is that a lot of clinical research is unreliable, even research that is widely cited (Ioannidis, 2005a; Ioannidis, 2005b). Consequently, there is considerable and potentially avoidable wastage in healthcare research. Forty per cent of pharmaceutical trials do not get published, a large proportion of the research results in psychology are not replicable if the study is repeated, and a critical assessment of the underlying research has raised serious doubts about the benefits of psychopharmaceuticals (see the boxed text on "Serious doubts about the benefits of psychopharmaceuticals).

Serious doubts about the benefits of psychopharmaceuticals
In an extensive study, physician and epidemiologist Peter Gøtzsche criticism include the facts that the proven benefits of these drugs are too small to be significant, harmful side effects such as suicidality are systematically concealed, and problems that occur when discontinuing or reducing medication are ignored (Gøtzsche, 2016). A great deal of knowledge has been accumulated about the complicated interplay of biological and environmental factors in the development of psychological disorders. Gøtzsche's observations mean that the practical benefits of this knowledge are minimal as of yet for the pharmacotherapeutic treatment of patients.

4.4 The "evidence-based" quality mark

A final point of criticism is that "*evidence-based*" has become a quality mark for good, proper care that has benefited the pharmaceutical and medicinal industry (Greenhalgh, 2014). The RCT, the most expensive form of research, has become their instrument for determining the agenda, execution and publication of research. As a result there is a relatively large amount of studies into medication, published results are often disproportionately positive, and pharmacotherapy takes up a key position in guidelines. Areas of research that are not commercially interesting or that are not backed by financially strong parties are at a disadvantage.

The rhetorical power of the term "evidence-based" has also not failed to affect other domains within healthcare and beyond, as well as the management, policy, supervision and contracting of care. Taken as a whole, these developments have resulted in healthcare being directed towards whatever can be investigated and substantiated using the EBP methodology.

In this context it is remarkable that scientific research pays more attention to the effectiveness of treatments than to diagnostics. There are more therapeutic trials than diagnostic ones. This is surprising, given the finding that a lot of unnecessary care and complications in practice are the result of under-diagnosis or over-diagnosis. Knowledge of treatments exists in principle only for the patients on whom they have been studied, and is therefore linked to the disease concept that was adopted, to how it is defined and to how it is diagnosed. Advancing insights into the nature and causes of disorders and diagnostic innovations can in practice lead to a shift in diagnoses. As diagnostic tests become more sensitive, for instance more sophisticated imaging diagnostics, more cases of a disease can be detected; this can however also lead to over-diagnosis and over-treatment (see the boxed text on “Over-diagnosis”).

Over-diagnosis

A prime example of over-diagnosis is care for patients with suspected pulmonary embolisms (blood clots in the pulmonary vessels). The advent of CT angiography (X-ray combined with contrast agent) in the 1990s has greatly changed the care for these patients. Before that time, pulmonary angiography and perfusion scintigraphy (a test using radioactivity) had the key position in the diagnosis.

The Dutch guideline recommends CT angiography if clinical investigations mean there is a strong suspicion of pulmonary embolism. Because CT scans are much more sensitive, the incidence of pulmonary embolism has almost doubled Treatment with anticoagulants is recommended as standard for these patients. It is striking that the overall mortality rate from pulmonary embolisms decreased slightly after the introduction of CT scanning, whereas the number of complications – haemorrhages are a known complication – increased by about half. It can be deduced that over-diagnosis has increased due to CT scanning:
more patients were found with small clots who would never have experienced symptoms or other consequences if left untreated.
There are many other examples of over-diagnosis, such as with organised cancer screening, the preventive consultations in GP practices, the removal of gallstones, and the shifting limits of risk factors in general.

Sources: *Bossuyt, 2011; Wiener et al., 2011; Welch et al., 201*

There is growing criticism of EBP. First of all, the idea of an unambiguous evidentiary hierarchy with randomised controlled trials (RCT) as its flagship has been called into question. The standardisation inherent in RCTs is also the greatest weakness, including underemphasising variation between patients and the context of healthcare. The results of RCTs are consequently not universally applicable. Conversely, this means that care that is not underpinned according to evidence-based principles is not necessarily unproven.

A second point of criticism is that EBP and professional guidelines have become an authority in themselves. Insufficiently critical application can also lead to undesirable standardisation of healthcare.

Thirdly, EBP has unintentionally contributed to a research agenda that is insufficiently controlled by what is clinically or socially relevant. Together with the institutionalisation of evidence-based practice, this reinforces development in which healthcare practice is directed towards whatever can be investigated and substantiated using the EBP methodology.

Finally, a research system has been unintentionally created under the influence of EBP that has embedded stimuli for research that is unreliable and not clinically or socially relevant. As a result, questions are not answered properly and research resources are wasted.

5 Responses to criticism of EBP

The criticisms mentioned above have led to various adjustments that were initiated by the EBP movement itself.

Reflexive research practices
One of the criticisms concerns the standardisation in RCTs. In much experimental research, situations and events that may occur in practice are taken into account. Reflecting on these circumstances leads to adjustments in the research setup. Research practice is thus becoming less formalistic in its methodology, which benefits the links with practice (Bal, 2015). Various types of research have been developed that form an alternative to the conventional RCT (Tavecchio, 2014). These alternatives pay greater attention to whether the intervention and the study population match the practice, to the various perspectives and values of the stakeholders involved, or to the learning process during the experiment.

The development of alternatives is related to the fact that research financiers such as ZonMW (the Netherlands Organisation for Health Research and Development) use “suitable evidence” as a criterion. The basic assumption is that there will be a check of whether the research setup fits the question, which creates scope for alternatives to RCTs. The criticism of RCTs is thus not being resolved by a methodological battle but by an approach with multiple methodologies in which different types of research complement each other.

Nuanced approach to uncertainty in guidelines
Another criticism is that professional guidelines can also play into the hands of undesirable standardisation of healthcare. However, the development of guidelines has changed so that there is a better link between guidelines and practice. Guidelines increasingly make distinctions between subgroups. The GRADE methodology for guideline development that is now the standard makes a strict distinction between weighing up the available evidence and making recommendations for decision making. This helps make the uncertainty more explicitly clear and helps nuance the use of the available evidence when making recommendations. Attention is now also paid more explicitly to the clinical relevance of research results.

Limited number of guidelines per specialism
Thirdly, the huge growth in the number of guidelines can be put into perspective. Although there are more than 500 medical specialist guidelines, the average medical specialist has to deal with about 10-15 of them, of which 2 to 3 are updated annually. General practitioners are expected to know about 100 NHG standards that have been made available in digital form.

Reflexive use of guidelines
Finally, the use of professional guidelines in consulting rooms usually involves reflection too: they are not applied unthinkingly. The existing picture of this has become clouded by the way it is researched. This mainly concerns research that is based on an approach in which national or international guidelines are implemented locally. Compliance then means applying the decision-making rules of the guideline. When a closer look is taken at the practice, it turns out that the recommendations in guidelines are generally considered carefully. Deviations from them are usually for a good reason.

The practice of research, guideline development and the use of guidelines in individual patient care shows that various reflexive mechanisms are incorporated in this that ensure a better link between research and guidelines in practice. It is important to make a distinction in the criticism of EBP between the formalistic version and the way it is developing in practice.

6 Continuing tensions in practice

The developments in the previous chapter do not change the fact that evidence-based practices mean that care professionals are confronted with various areas of tension and bottlenecks that need solutions. The reasons for this can primarily be found at a fundamental level and in the institutional care environments, as well as in the GP's surgery.

6.1 Fundamental tensions in EBP

The following bottlenecks and tensions are present at a fundamental level.

EBP gives a reduced picture of reality
EBP features a scientific approach to reality. Just as in natural sciences, EBP focuses on deriving generally applicable laws from experimental observations (induction). It is about universal, generic knowledge about (in the medical domain) the causes and the course of diseases, the characteristics of diagnostic tests and the effects of treatments.

This type of evidence is attractive because of its claim to universality, but remains a reduced synthesis of reality. It assumes that the reality is a closed whole ("totality"). Moreover, it can only be unlocked through empirical observations (positivism). The underlying assumption is that this form of knowledge can ultimately answer all questions (scientism). We will comment on these elements in order.

To begin with the "ultimate reality" or "reality as a whole" is not an a priori fact, but a product of our own thinking. It exists alongside other products of our thinking, so the reality can logically speaking not be a totality (Gabriel, 2014). On the other hand, there are various possible cognitive and normative perspectives on reality. This pluralism means that there are countless true stories about reality that cannot be derived from any single coherent scientific narrative (Staman et al., 2012).

In the case of a social problem such as obesity, a physician may point to a genetic component, while a sociologist looks for a link to people's education, and an urban planner looks at the design of public spaces. This multifaceted perspective also means that the concepts used in empirical research are not neutral. Scientific research focuses not only on revealing or uncovering a previously stated reality, but also on shaping that reality (see the boxed text on "Science is discovering and shaping reality").

Science is discovering and shaping reality
It is a misunderstanding that science is only about 'discovering' a previously determined reality. Science is also about how it is "shaped" or "designed" (Dehue, 2016). This is the core of the constructivist perspective on science. Diagnoses are an example of this. These are by definition constructs or concepts. Diseases do not exist a priori (Smulders, 2016). The concepts that we use to describe them are only tools for carrying out a focused survey and determining the treatment plan. This means in abstract terms that facts do not exist separately from interpretations and meanings. Nietzsche put this insight concisely: "There are no facts, only interpretations". That insight is hugely important. Diagnoses are not neutral: there are underlying values and opinions that determine our perspective on the facts (Ralston et al., 2015). They are fluid and dynamic and can change under the influence of scientific and cultural developments.
In psychiatry, for example, DSM is a widely used classification of disorders that is modified every few years.

EBP is based on statistical evidence, so only measurable, quantifiable factors count. Disease and care are about existential matters and often impinge upon the essence of life and how we think about it. Not everything has a value that can be measured. This applies e.g. to non-measurable aspects of quality, ethical choices, professional expertise, or the behaviour and emotions of patients.

Finally, due not only to the complexity of the reality but also because financial resources and human subjects are scarce, it is an illusion to think that all disease mechanisms and interventions can someday be researched according to the principles of EBP.

There will always be uncertainty and there will always be patients who do not ‘fit’ the guideline. This applies specifically to the increasing number of patients with comorbidity or multiple morbidity.

Contextual factors matter
Related to the insight that reality is multifaceted in nature is the relevance of context. The scientific evidence that EBP is based on is universal and generic, suggesting that its validity is independent of context. Randomised studies are characterised by standardisation in terms of the actual practice. As indicated in Chapter 4, the context – that of the patient, the practice and the setting in which care is provided – has an influence on the effectiveness of interventions and therefore on the validity of research results. This is even more the case in the social domain than in the medical domain, due to the larger part played by the environment in which social interventions take place.

People are not intrinsically separate from their context: their social networks, their norms and values and their economic and cultural capital also influence their health, what it means to them and the way they deal with it. This context can also determine the treatment plan. The emphasis on scientific, empirical knowledge in medical education conflicts with this insight. It yields a schizophrenic situation: it is a human science that we are approaching without using the humanities.

Additionally, care is always given in a specific context with specific professional capital and resources, and it always has its own history. Innovations or policy that are developed elsewhere cannot just be rolled out, implemented or replicated. The wheel must be partly reinvented by adapting something that was developed and researched elsewhere. It has to be experimented with and people then have to use the results to improve their own practice.

Episteme, techne and phronesis
Given the multifaceted perspectives of reality, it is natural that there are various sources of knowledge. The philosopher Aristotle distinguished between episteme, techne and phronesis. Episteme is the theoretical, universal knowledge that teaches how the world works and is aimed at explaining (“to know”, “know why”).

This knowledge is context-independent and easily transferable. Techne is the technical or instrumental knowledge corresponding to professionalism and a specific skills set ("know how"). This knowledge is aimed at realising a product. The third form of knowledge is phronesis, which concerns practical knowledge and practical ethics. This knowledge is aimed at practical use, is context-dependent and includes the ability to weigh up considerations and reflect critically on the consequences. This knowledge is aimed at *understanding* and it is meaningful. It is not easily transferable and has to be learned in practice.

EBP misaligned with the relationships between parties

The definition of EBM at the beginning of these recommendations goes even further, designating clinical expertise as a source of knowledge in addition to externally obtained scientific evidence: "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." (Sackett et al., 1996). Another definition also mentions the input from patients: "the integration of best research evidence with clinical expertise and patient values" (Sackett et al., 2000). This later definition started in reaction to earlier criticism that EBP overemphasises epidemiological, generic evidence (Bolt et al., 2015). Besides that, this definition assumes a relationship between the parties that does not reflect reality and may never have existed: science provides knowledge, professionals provide expertise, and patients have preferences. However, science is not value-neutral, professionals also have values and interests, and patients bring knowledge accumulated through experience.

Provisional conclusions

Several provisional conclusions can be drawn from the above. The evidence that EBP uses is based on a reduction of reality, ignoring the context in which this knowledge is applied. There is therefore an intrinsic gap between EBP's knowledge and its decision-making rules on one hand and the reality of individual patient care on the other. This gap still remains if these decision-making rules are individualised as much as possible by taking characteristics of the patient into account, for instance in clinical decision making. This calls into question the fact that there can be evidence-*based* actions.

There is at most a fragile basis to which other sources of knowledge should also be added; at the very least, speaking about evidence as the *basis* for professional actions or policy leads to false expectations or suggests a false sense of security.

Secondly, because every decision is ultimately made with regard to a specific help requirement and in a specific context, that decision may not necessarily be derived from knowledge. Every decision and every action that follow can be seen as an experiment in putting together the various sources of knowledge. This also makes each decision in itself a new experience that can be learned from. Putting together various sources of knowledge also yields practical knowledge or practical ethics that can be distinguished from universal knowledge and technical knowledge (see boxed text on “Episteme, techne and phronesis”).

Thirdly there are tensions in the relationship between EBP and learning. Knowledge is the dynamic product of a continuous accumulation of learning experience. On the other hand, results of experimental research and professional guidelines can be seen as a form of solidified knowledge. Guidelines comprise a summary and an assessment of explicit knowledge at a certain moment, translated into practice. Guidelines themselves are not focused on personal learning; they only lead to new knowledge when they are consulted and applied. They are by definition based on knowledge from the past, so they become out of date and have a conservative effect on medical practice. The dominant position of RCTs in these guidelines reinforces this. RCTs take years and the intervention or other aspects of the protocol must not be changed throughout the duration, so as not to influence the results (for example due to new insights); the results are therefore often already outdated by the time they are published.

On the other hand, personal learning experiences do get included in guidelines. Committee members bring along their own experiences, reasons and considerations when translating explicit knowledge into practice. Expert opinions may possibly play a greater role than intended or expected as ‘lower’ forms of evidence.

6.2 The institutional environment

As stated in Chapter 2, EBP has not remained limited to the professional domain but has also been embraced by institutional parties. Supervisors, disciplinary courts, care insurers and policy making bodies use scientific evidence in their work.

These parties derive their authority in part from the same scientific evidence and from professional standards. Tensions may arise when these parties interpret and make practical use of scientific evidence, guidelines and measuring instruments in a different way than healthcare providers and care professionals do.

Package management
In Chapter 2, it was noted in the case of package decisions by the National Healthcare Institute within the context of the Healthcare Insurance Act and Long-Term Care Act that the quality of scientific evidence is in principle the deciding factor when the decision on reimbursement is taken. Although EBP is formally the *integration* of scientific evidence, expertise and experience, the National Healthcare Institute actually uses a hierarchy of sources of knowledge to deal with the inherent tension that can exist between the three. This practice relates to the macro-perspective on decisions about healthcare packages and it has in the meantime also acquired legal force (see boxed text on “Evidentiary hierarchy legally legitimised”).

This has various consequences. First of all, the scope of the insured package does not necessarily have to comply with the recommendations in professional guidelines, even though both are based on the same scientific evidence. A negative reimbursement decision reduces the options available and therefore also the room for considerations in individual patient care. Secondly, due to pressure on public expenditure or changed political views, EBP can be used to ‘clear away’ unwanted practices. Thirdly, this working method is threatening to marginalise care professionals and patients as a source of knowledge (Carel et al., 2014). This may have far-reaching consequences for elements of healthcare where RCTs are difficult or impossible, such as in the case of rare disorders, disorders that can become manifest in very diverse ways, or forms of care that make a blinded study setup impossible.

Evidentiary hierarchy legally legitimised
Using EBP principles for healthcare package management was ratified in a recent court judgement (Moes et al., 2016). The case concerned a lawsuit filed against the National Healthcare Institute because of a negative reimbursement decision regarding bladder fluids in interstitial cystitis, a specific type of bladder inflammation. The effectiveness of this treatment could not be sufficiently demonstrated based on two RCTs and the applicable professional guidelines.

The heterogeneous character of the condition made it particularly difficult to prove this.

The defence argued that this makes experimental research impossible and that witness statements from patients who claim to benefit from the treatment had been given too little weight. Unfortunately, this defence did not offer a remedy. Although the National Healthcare Institute did not deny that individual patients can benefit from bladder fluids, individual experiences are too susceptible to subjectivity and placebo effects to support the statement that this intervention meets the "state of science and practice" reimbursement criterion (Moes et al., 2016). This ruling also added legal weight to the idea that experimental research has added value compared to other sources of knowledge (Moes et al., 2016). As a result of the verdict, the National Healthcare Institute did decide to systematically involve patients' organisations in package decisions.

Healthcare procurement

The contracting of medical curative care by healthcare insurers may include conditions about following professional guidelines. This is then tested using benchmark information, and practices that deviate from a predetermined standard – such as the average of all practices – can be identified. This method turns professional guidelines that are meant to be recommendations into standards that care should meet for all patients with the indication in question. The standard thus adopted may conflict with the way guidelines are interpreted and applied in practice. This can mean not compensating actions that are recommended in guidelines in exceptional cases due to the low quality of underlying evidence. However, the lack of evidence does not mean that something has been proved to be ineffective (see Chapter 4). There may also be a different local patient mix. In that case, the standard that compliance with guidelines is tested against does not reflect the complex assessment process in practice, and it also involves patients who fall outside of the scope of the guideline. The consequence is an undesired uniformity and standardisation of care, with less room to experiment and learn.

Concentration of specialist medical care
In quality supervision and healthcare procurement, the concentration of complex medical care is a key principle for improving quality. This policy is motivated by an assumed relationship between the volume and quality of care and it is implemented based on volume standards. The consequences of this policy can be far-reaching for the institutions concerned and for society at large (Paauw, 2016).

Although the concentration policy is based on alleged evidence it conceals the commercial reasons that parties have for concentrating care. Furthermore, the evidence consists of a statistical relationship between volume and quality, particularly in the case of high-risk surgical procedures (Mesman et al., 2015). It is not clear whether there is a causal relationship, nor is it known what explains this relationship: better compliance with protocols, certain institutional characteristics, the degree of specialisation, or otherwise (Mesman et al., 2015). Other sources of knowledge, such as ethnographic research into the quality of care, could throw light on this. The results of a treatment are also determined by the care after the intervention and outside the hospital. A higher concentration of specialist medical care requires aftercare to have been adequately dimensioned for it.

Quality indicators
Quality indicators are often used in quality supervision and healthcare procurement: quantitative data that gives an indication of the quality and safety of healthcare institutions. The Healthcare Inspectorate, healthcare insurers and patient associations come up with one indicator after another: process indicators that show whether the professional standards and internal agreements are complied with; outcome indicators; institution-wide indicators, and patient experience data (CQ-index, complaints).

Although this is intended to create transparency about quality, in practice this is hardly the case at all. Several years ago, the General Court of Audit concluded that the stability and quality of most indicator sets that measure quality are limited and that barely any indicators have been developed to measure the results of care (General Court of Audit, 2013). The accumulation of indicators and the contradictions that can exist between indicators may cause institutions to lose track of the overall picture. Many indicators are inconsistent with practical experience and as a result employees lose the motivation to work on quality improvement. The result is that the institution is busier collecting quality information while losing sight of the underlying goal of quality improvement and greater learning capacity (Weggelaar et al., 2016).

This illustrates that an absolute ‘mechanical objectivity’ (reliance on numbers) is an inadequate alternative for the ‘disciplinary objectivity’ of medicine that is based on authority, and it is met with resistance from health care providers.

Besides the fact that there is no emphasis on the intended transparency of quality, there are also objections to the content of this approach. A set of quality indicators, no matter how broadly formulated, can be at odds with a multifaceted concept of quality. Quality is not always measurable, and there is a risk that attention will only be paid to aspects that can be measured (“teaching to the test”). These substantive dilemmas and considerations that are associated with healthcare cannot be described in quality indicators, but they can provide useful experience to learn from.

6.3 EBP in the consultation room

In individual patient care, there are the following bottlenecks and areas of tension relating to the application of EBP.

Care that has been proved to work is not necessarily good care
As stated in Chapter 1, individual patient care is provided in a morally charged context in which values and preferences play a role: those of the patient, professional values (professional ethics) and organisation-wide values, as well as public interests. Patients can decide against effective care, or may prefer an option that is less effective but in their eyes offers them a better quality of life. Scarce resources and local circumstances (available clinical experience, availability of specific equipment) can play a part in the choice of what is right or justified. The right thing to do can vary with the patient and the situation (Kremer, et al., 2017). Care that has been proved to work is thus not the same thing as good care.
To provide good care, every situation inevitably requires considerations to bridge the “normative gap” that exists between scientific evidence and practice (Tonelli, 1998).

The preferences of healthcare providers and patients are not necessarily the same, so healthcare providers face the task of separating facts and values when giving choice options. On the one hand, this is to prevent them from imposing their own set of norms and standards, on the other hand because respecting the preferences of patients too much can put pressure on their own judgement.

It's not always clear beforehand what the right thing to do will be. In particular if there are multiple problems, the object or mechanism that you are focusing on – the disease, side effects, lack of control, debts, parenting issues, addiction – is a part of a search process that may involve multiple disciplines. This search process means that goals should be continually adjusted and that the practice is fluid.

Good care: the result is what counts?

As can be seen in the definition mentioned earlier, the intention of EBP is to use the best evidence to make decisions while taking patient preferences into account. EBP emphasizes the outcome of care: clinical results and increasingly relevant outcomes for the patient (patient-reported outcome measures, PROMs). One example of this is the Value-Based Health Care initiative of the International Consortium for Health Outcome Measurement (ICHOM). This initiative is based on systematically measuring outcomes of care that are relevant for patients – including health, safety, quality of life and patient-centred care – and it aims to improve hospital care.

However, for various reasons, this emphasis on outcomes can conflict with offering good healthcare. The first reason is that outcomes are used as a general criterion for every patient and every situation, whereas the right thing to do can vary with the patient and the situation. Secondly, this approach assumes that care is by definition good if the outcomes are good. Other ethical perspectives on care are also possible in addition to this consequentialist approach (see boxed text on "What is good care?"). Thirdly, emphasising one specific, quantifiable outcome of care means that other values that are relevant for patients but that cannot be measured or objectivised come under pressure. The quality of the relationship between healthcare provider and client, plus values such as presence and attention or the possibility of participating in decision-making cannot be expressed in terms of size and number (RVZ, 2007). This can result in forms of care that focus specifically on these values but do not fit the EBP research methodology unintentionally getting less space or a lower status (Delnoij, 2016). In particular, this creates a watershed between medical care and long-term care; Askheim et al., 2017

What is good care?
There are no generally applicable, unambiguous standards for good care. There are various perspectives in ethics on how to decide what good care is (Beauchamp, 1991). *Consequentialist theories* focus on the outcomes of care: care is good if the result is good. In this vision, the care provider as a person does not matter and is purely instrumental. According to *obligation ethics*, good care reflects certain intrinsic principles that people use consciously, such as doing no harm and being respectful. These standards are intrinsic because they automatically follow on from moral laws that are 'ingrained' in healthcare. These can be traced by sensible reasoning. *Virtue ethics* does focus on the healthcare provider as a person and emphasises the importance of developing an appropriate attitude and character. These determine the provider's actions towards patients. In this vision, good healthcare providers are the key to good care.

Uncertainty has the upper hand
It has been noted previously that it is an illusion to say that all medical actions can be investigated scientifically. Incomplete information and uncertainty are inherent to medical actions. Medical actions have only been experimentally researched in a small minority of the patients in which they are used. This epistemic gap between what is known based on scientific research and the requests for assistance by patients frequently leaves care professionals on the horns of a dilemma (see boxed text on 'Case studies'). It is not always evident whether you can or should deviate from the guideline, given the specific characteristics of a patient. There may also be treatment options that have been researched in different patient groups or for which no research has been done at all, although there are reasonable grounds to suspect that it may be effective. Generally the number of treatment options is increasing and so multiple, more or less equal options may exist for a given situation.

EBP puts professional expertise under pressure
In uncertain situations, research, professional guidelines and protocols can offer guidance; they can however also put personal professional expertise under pressure. Uncritical use leads to undesirable standardisation and uniformity of healthcare, and unnecessary diagnostics and treatment. Experience seems to play a major role in this.

The insecurity of inexperienced care professionals makes them more inclined to follow treatment protocols than experienced care professionals, even where a different approach may be justified. In other words experience helps professionals to make use of the space that guidelines give. In addition to experience, contextual factors also play a role. In particular this includes the fear of disciplinary measures and a high workload. The latter also means that there is not enough time to talk with patients and that there are insufficient possibilities for consulting an experienced colleague who then sees the patient themselves.

EBP puts the input from patients under pressure

EBP also puts the input from patients and adjustment of care to their situation under pressure (Greenhalgh et al., 2015). One example of this is, surprisingly, the use of decision aids for medical decision making. In the conversation with the patient, these help give a picture of the benefits and disadvantages of the options that are available. Although the aim is to involve patients more in decision-making, these decision aids depend heavily on scientific research and are therefore mainly framed from a medical perspective (Greenhalgh et al., 2015). Sending information gets given more space than listening to the context.

Although the importance of shared decision-making and an equal role for patients is being acknowledged more and more, the way healthcare providers handle patients who are uncertain is crucial. The way they translate scientific evidence and their own expertise into treatment options can be the opposite of what might have been expected of them (Fried, 2016). Healthcare providers may in particular be intuitively inclined to leave patients to make a decision when the benefits and risks of the options are uncertain and they themselves are ambivalent about it. The reverse is also true: the more certain the expected outcomes of the various options are, the more healthcare providers will be inclined to recommend them.

The information puzzle

Although the EBP movement states that in practice external scientific knowledge must be integrated with clinical expertise and patient preferences, no statement is made about *how* this should be done and what expertise is necessary for this. Healthcare professionals in individual patient care have to deal with diverse types of knowledge: scientific knowledge from external sources, research results, findings from physical examinations, information from the patient themselves, and knowledge about values, preferences and the context.

This knowledge is transferred through various information carriers such as literature, guidelines, images, figures, graphs, stories and emotions. Care providers have the task of using their basic medical knowledge and experience to solve this jigsaw puzzle of information and turn the pieces into a coherent image. This image acts as a tool for formulating and testing hypotheses, and for weighing up the considerations and taking decisions (Van Baalen et al., 2014).

The linear and rational, *rule-based* way of decision-making that typifies EBP falls short when integrating these puzzle pieces: explicit, scientific knowledge is distributed and then translated to the individual patient case using systematic reviews and guidelines. Practice can be very dynamic and creative when it comes to the styles of reasoning that healthcare professionals use for making the links between all the pieces of information and deriving and testing hypotheses. 'Embracing' the uncertainty and integrating different sources of knowledge within the specific context in which care is provided requires a more active role than that of the passive 'evidence user.

Case studies
A few cases are described below to illustrate the dilemmas when using evidence and professional guidelines. We have endeavoured to provide a spread of examples that have no evidence or hard evidence, have one or more options, and the role of the patient and the healthcare professional in the decision-making process.

Case 1: Prostate cancer surgery or radiation – patient preference
Mr Harmsen is told at the age of 59 that he has prostate cancer. His doctor explains the treatment options: surgical removal of the prostate gland or radiation. After prostate gland surgery there is a chance that the patient will be unable to stop the flow of urine or may get erectile dysfunction. On the other hand, radiation leaves a slightly higher chance of the cancer coming back and can be associated with urinary and stool complaints. There is scientific evidence for both options, but there is no "best" treatment.
Mr Harmsen's preference will ultimately be the deciding factor in opting for treatment by radiation.
(multiple options with hard evidence, patient decides)

Case 2: Gall bladder infection – remove or wait?
Mrs Jansen (age 47) arrives at Accident & Emergency with abdominal pain and vomiting. She turns out to have an acute gall bladder infection due to gallstones. In some cases, the gallbladder is removed in its entirety and sometimes it is possible to wait and treat with antibiotics. Removing the gall bladder comes with the risks of surgery, whereas waiting can also cause complications such as the infection returning. Studies have shown that both strategies are comparable in preventing disease and mortality, but that immediate surgery ultimately leads to a shorter duration of the illness. Based on this evidence, it was decided to operate on Mrs Jansen. *(multiple options with hard evidence, clinical expertise decides)*

Case 3: Two blood thinners
Mr Huisman had a cerebral infarction when he was 64. To reduce the risk of a stroke in the future, he takes medicines, including a blood thinner. Despite the medication, he shows symptoms of loss of function again. One option is to take two different blood thinners. This option is not described in the guideline because it increases the risk of large haemorrhages in the long term. The doctor decides to temporarily prescribe two blood thinners because for this patient the risk of a new cerebral infarction is greater in the shorter term than the risk of a haemorrhage. *(little evidence, clinical expertise decides)*

Case 4: Puncturing the eardrum for a middle ear infection Sam, aged 6, has a fever and severe ear pain due to an infection in his middle ear. Despite painkillers, the pain has persisted for three days. The pain is unbearable for Sam and his mother asks if there is something that can be done immediately. An option that works quickly is to puncture the eardrum. Puncturing a bulging eardrum can be beneficial as pain relief in the initial phase. This treatment is not described in the guideline. Studies show that other treatments such as antibiotics work better for children with persistent complaints. In consultation with Sam’s mother, the choice is made to puncture the eardrum to relieve the pain at that moment.
(no evidence, treat anyway)

Case 5: Surgery with stoma for intestinal cancer
Mr de Boer, aged 85, has been diagnosed with rectal cancer. He recently became a widower. The doctor suggests operating on his intestine and fitting a stoma. A stoma is an artificial exit of the intestine via the skin of the abdomen, where the stools are collected in a bag on the stomach. There is evidence for better survival after surgery for intestinal cancer as opposed to waiting. In research, people with a stoma say that they have a poorer general quality of life than people without a stoma. Mr de Boer does not want to undergo major surgery and get a stoma. Despite the evidence for the effectiveness of that treatment he chooses not to have surgery.
(hard evidence, patient prefers quality of life instead of a longer life)

Case 6: Success of rheumatism treatment
Mrs Plaat (42) has rheumatism in her joints. The aim of the treatment is to achieve the lowest possible disease activity score. This score measures inter alia the experience of the patient and the number of swollen or painful joints. It has been proved that intensive measurement of the disease activity, followed by adjustment of medication, has a positive effect on the occurrence of recovery. The treatment seems to work well for Mrs Plaat, because her disease score decreases. She herself does not consider the treatment to be so successful because of the side effects she has experienced. She suffers from nausea, diarrhoea and inflammation in the mucous membrane of her mouth. Together with the doctor, she chooses not to keep going with the treatment until she reaches a lower disease score because the side effects are causing her too much trouble. Instead she starts taking a different rheumatism medication.
(hard evidence, dilemma of continuing treatment versus side effects)

Case 7: A patient with multiple morbidity
A woman aged 79 has osteoporosis, osteoarthritis, diabetes mellitus type II, hypertension and COPD. How should this patient be treated? Based on the guidelines for the various conditions, this patient should be taking a total of 12 different medications at five different times of day (Boyd et al., 2005).

The guidelines are often based on RCTs in which patients with just a single condition such as osteoporosis, diabetes or hypertension have been studied. Additionally, they are often younger patients, sometimes a lot younger. There is also the phenomenon of 'reversed epidemiology', in which the classical relationships between risk factors and results change direction. For example, people over 85 with lower blood pressure and/or low levels of cholesterol in the blood die earlier than elderly people with higher blood pressure and/or higher level of cholesterol. There is also a lack of scientific evidence for combination treatments for multiple morbidity, while the different medications have all sorts of side effects that can amplify or counteract each other. Medication to lower blood pressure can cause dizziness. If a patient with osteoporosis falls, there is a significant risk of a hip fracture which is high-risk at this age.
(lack of hard evidence for combinations of treatments)

The heart of the problem
Based on professional practice, the Council has produced the following summary of bottlenecks of EBP. EBP has the risk that it will reduce good, patient-oriented care to what is evidence-based. Due to its reductionist concept of knowledge and because it ignores the (morally charged) context in which evidence is used, EBP offers a false claim to reality that under-utilises the wealth of knowledge from other sources (clinical expertise, local expertise, knowledge of patients and context). *There* is no evidence as a basis for medical treatment, and uncertainty is inherent in medical actions. Evidence as the dominant foundation of good healthcare is therefore an illusion. In individual patient care, each decision can be seen as an experiment in putting together the various sources of knowledge. This also makes each decision in itself a new experience that can be learned from.

The EBP movement does not pay enough attention to the ways in which care professionals can integrate external sources of knowledge (such as personal expertise, the experiences and preferences of patients and local data). EBP allows the healthcare professional to keep denying the uncertainty that is inherent in patient care.

EBP and the development of professional guidelines and quality indicators have been embraced by health research, policy, supervision and the contracting of care. Taken as a whole, this is directing healthcare towards whatever can be investigated and substantiated using the EBP methodology. This is at the expense of healthcare domains for which this is difficult or impossible, and of healthcare that is not commercially interesting. Unintentionally, a research system has arisen that contains incentives for irrelevant and unreliable research, while many elements of customary care have been investigated insufficiently. The use of professional standards by external parties and high workloads are also leading to uncritical use of guidelines and protocols. As a result there is less of a focus on differences between patients and situations than is desirable. Healthcare professionals spend more time providing accountability information than they gain by learning from it.

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7 Solutions and recommendations

The Council concludes that proper care is more than proven care. Evidence-based practice (EBP) is an illusion. In order to answer the question of how scientific evidence can be used to provide proper care and legitimise it, the tensions within EBP and its shortcomings must be recognised and tackled. In this chapter, the Council presents solutions for this issue and makes recommendations to that end.

We will start with a general, overarching solution and recommendation. After that, we will discuss the effects at various levels: the consulting room, the healthcare organisation and the institutional context. The same distinction as used in the previous chapter has been adopted.

7.1 From evidence-based to context-based practice

Whereas EBP was originally limited to the professional domain in order to support individual patient care, policy bodies, supervisory bodies, care insurers and other parties have also welcomed scientific evidence and professional standards as instruments. Because these parties assign different meanings to ‘evidence’, EBP has become a layered concept, the content of which has also become more and more elusive. The Council intends these recommendations to help determine the position of scientific evidence for providing and legitimising good care. The Council is doing so by stating the results of EBP (Chapter 3) and its shortcomings in providing proper, patient-oriented care (Chapters 4 and 5) and by listing the tensions between the various stakeholders who rely on ‘evidence’ (Chapter 6). Because of the unclear content and the shortcomings of EBP, the Council recommends that the term ‘evidence-based practice’ should no longer be used.

Others, including the precursors of the EBP movement, previously recommended that evidence-*informed* practice should be used, as the concept of ‘evidence-based’ raises false expectations (Glasziou, 2005). However, the Council prefers *context-based practice*. This is how the Council wants to draw attention to the importance of the specific context, of both the patient and the setting in which various knowledge sources are used and decisions are made.

This context is morally charged, multifaceted and dynamic. Decisions do not automatically or deterministically follow from the 'best evidence'. Uncertainty is inherent in healthcare practice. Against this background, it would be better to consider decisions in care as experiments that connect various knowledge sources, explicit and implicit knowledge, and the experiences of care professionals and patients. In addition, every decision inherently consists of weighing up the interests, standards and values of stakeholders: those of the patient, the professional, the organisation and society as a whole.

Recommendation 1: The council recommends that 'context-based practice' be used rather than 'evidence-based practice'. Although evidence plays a role as a source of information, it does so alongside many other sources of information. The specific context determines how these knowledge sources are connected together.

How context-based practice is implemented and what is required for it will be dealt with in the sections below. We will start in the consulting room; after that we will also show what consequences the recommendations at the consulting-room level have for organising care provision and for the institutional context in which care is provided.

7.2 The consulting room

Shared decision-making
Context-based practice requires the participation of patients in the decision-making regarding their care. The aim is to create a partnership between care provider and patient. The importance of this is becoming increasingly widely recognised (RVZ, 2013). It allows patients to communicate their wishes and preferences, permitting insights into their personal context, and make a choice that suits them, together with the care provider.

Digital medical records, patients' versions of guidelines and medical information from the Internet and social media have greatly improved the information position of patients. Despite this, shared decision-making is complex in practice. Because of their lack of knowledge and the uncertainty, stress, anxiety and dependence associated with being ill, active involvement of patients is not necessarily obvious. There are also differences between patients regarding the degree to which they wish to be involved and can be involved. There is nothing wrong with this, provided they were able to make that choice for themselves.

The form that shared decision-making can take may therefore be different for every patient and every situation. It should therefore not become a dogma (Smulders, 2016). If the emphasis is on the question of who takes part in decision-making and to what extent, people may lose sight of the fact that this is ultimately about care that is tailored to the patient's needs and lifestyle (Mol, 2008). A care provider must therefore be able to verify whether the choice being made is one that suits the patient. To that end, listening is more important than dispensing context-independent information. Developing a good client-caregiver relationship is essential for this.

Recommendation 2: Shared decision-making is essential to determine what constitutes good care. Care professionals tailor it to the patient's context, and pay more attention to listening than to dispensing information.

The input of patients can come under pressure if decision-making is dominated by what is considered to be proven care. This may also be the case if, vice versa, care professionals leave the decision up to the patient because they themselves are uncertain about what the best option is in a given situation (Fried, 2016).

Input from patients should be improved by designing decision aids that help to find out what patients think is important, using reasoning that is not based on a medical perspective or on the available care. Patients' organisations must take the lead in this, working together with the professional group and the other parties involved.

Recommendation 3: Patients' organisations should take the initiative to develop decision aids (together with care providers and other parties involved) that are based on what patients feel is important.

Connecting knowledge sources

An essential skill for care professionals is the ability to integrate or link multiple sources of knowledge: external knowledge from manuals, guidelines and scientific literature; experience; information about the patients and their personal situation, values and preferences; information about the local setting, and the options and their limitations. Successive steps are targeted searching for information that is relevant for the decision-making, making connections and testing hypotheses, and then assessing the collected information for the decision-making.

The use of guidelines is part of this process: a rule-based way of reasoning in which observed frequencies in epidemiological research are generalised to individual patients. However, it is not always clear in clinical practice where deviating from a guideline is possible, where other forms of reasoning are required, and where care professionals have to be able to cope with uncertainty and ethical considerations. Care professionals must therefore be able to reason and weigh things up, have an eye for the context, welcome uncertainty, and utilise the scope that is offered by the guidelines in a responsible way.

Recommendation 4: Care professionals should embrace the uncertainty about what constitutes good care. Together with the relevant parties, they must learn to assess and integrate various sources of information.

These recommendations, which are based on context-based practice, are not only significant for the practice in the consulting room but also have consequences for care organisations and the institutional context of care. In the following sections, we will describe a number of solutions and make a number of recommendations.

7.3 Learning care organisations

For context-based practice, care organisations should focus on learning together and improving care: learning to connect various knowledge sources together within the morally changed and multifaceted context of patient care. All relevant parties must be involved in this, which will put the various relevant perspectives in the right places. Learning therefore becomes learning together. A number of years ago, a recommendation from the Health Council of the Netherlands centred on learning professionals and learning care organisations. They are expected to put flesh on the bones of their own learning processes by continuously reflecting upon their own actions, by learning from them, by bidding farewell to old routines and by making room for new ones (Health Council of the Netherlands, 2000). In a learning practice, the result of one process is the input for the next.

Attention to learning during training and in everyday practice
A great deal of attention is paid to learning and developing these skills during training and in the everyday practice of care professionals (see boxed text on “Mind lines: internalising knowledge through collective learning”). Medical education also pays a great deal of attention to clinical reasoning – excluding the improbable, identifying diseases as early as possible and preventing complications and to the use of professional standards.

Furthermore, discussions about patients, multidisciplinary meetings, necrology and discussions about complications are common forms of peer review. Such meetings give care professionals the chance to test the picture that they have constructed of their patients, using all the available information. The criterion is not whether this picture represents 'the truth', but whether it is logically consistent and coherent and whether it is suitable or had been suitable for making considerations and taking decisions (Van Baalen et al., 2016).

Mind lines: internalising knowledge through collective learning
How are knowledge sources linked together in practice? Observations show that care professionals hardly use formal guidelines at all but that they rely on 'mind lines', i.e. internalised guidelines (Gabbay et al., 2004). These 'mind lines' are a mixture of explicit and implicit (see boxed text on "Tacit knowledge"), individual and shared knowledge. Their 'mind lines' serve as a vehicle for handling the many facets of reality and integrating multiple knowledge sources: knowledge originating from their own experiences, guidelines, and knowledge sources that care professionals deem to be reliable. These could be colleagues in their own practice or in the region, opinion leaders, guideline developers, scientists or patients. Care professionals exchange knowledge and validate it in the consulting room, in consultations with colleagues, in meetings and working groups. The internalisation of knowledge therefore takes place collectively and in interaction within the networks of care professionals (Wieringa et al., 2015).

Tacit knowledge
What is the difference between an expert and a layman? Why is it that experienced doctors are able to diagnose better and more quickly? Polanyi has analysed the nature of knowledge thoroughly (Polanyi, 1962). He defined the problem of the 'false ideal' in science that universal, objective knowledge exists independently of people. Knowledge, he argues on the other hand, never exists independently from a person: all knowledge is personal knowledge. A typical feature of this personal knowledge is 'tacit knowing', the implicit or tacit knowledge that is produced and used in practice. Tacit knowledge is not the *opposite* of objective or explicit knowledge – knowledge that exists independently from a specific context – but it is the *flip side* of it (Tsoukas, 2003).

To Polanyi, there is therefore no strict difference between universal, technical and practical knowledge (see the boxed text on “Episteme, techne and phronesis”). The ‘implicit’ element is that the person is not aware of the rules that they are following when applying knowledge. For instance, people usually recognise a face without being able to explain how they do it. In fact, a subconscious perception process takes place rapidly using a number of physical facial characteristics. Similarly, experienced doctors are able to use large amounts of knowledge and information, gained through study and experience, when assessing a patient. They also have less difficulty than inexperienced doctors in targeting their search for information and identifying patterns. Although implicit knowledge remains elusive and unspoken, in essence, its transfer and the associated learning processes usually take place by interaction. Implicit knowledge includes skills that can be identified and reflected upon in order to learn from them. This could for instance be reconstructing a decision later on to see what information had been used, the reasoning and the way that the decision was taken (Van Baalen, 2016).

However, there is greater room for improvement if it is about being able to connect multiple knowledge sources, and the use of evidence in the morally charged context of practice. The Council specifically asks attention to be paid to:

- Training for carrying out qualitative research.
- The interpretation of research results and their meaning for practice.
- The limitations of professional guidelines and the scope provided by guidelines. This requires knowledge about how guidelines are created, the underlying assumptions, the weighting of evidence and the translation into recommendations.
- Making it possible to talk about uncertainty and doubt, including talking with colleagues who are higher in the (informal) hierarchy.
- The personal context of patients.
- Learning together with various parties involved, such as patients, the general public and other care professionals.
- Weighing the considerations up carefully in the decision-making, and identifying ethical issues as well as the medical considerations.

The Council suggests the following solutions for this.

- More room for social science and humanities in medical education, preferably integrated into existing subjects and modules, and linked to practical situations.
- Participation in interdisciplinary education.
- An active role for patients in education, for instance as buddies for students, or by having patients tell about their experiences of their care and treatment as an element of lectures.

Recommendation 5: Residency programme directors should include social science and humanities, interdisciplinary education and active contributions from patients in their curriculums.

Organising learning processes

The learning ability of care professionals and care organisations must be enhanced by paying attention to the working environment. High pressure of work in healthcare and the vertical organisation of medical care into professional groups and disciplines puts pressure on the scope for learning processes. As a result, the possibilities for assessing a patient jointly and testing your own arguments against those of an experienced colleague who has a broad substantive expertise are limited in the event of doubt. Under time pressure, it is more difficult for care professionals to resist their more demanding patients; there is less time for an exchange of knowledge and recording a previous history that takes a broader look. Super-specialists predominantly focus on their own guidelines and do not take sufficient account of the vulnerability and multiple morbidity in their patients. High work pressure and the organisation of care therefore make care professionals rely on guidelines and protocols more easily, and use them to justify diagnostics and therapy even where leaving them out is justified.

Good, patient-oriented care can therefore benefit from a reduction in the pressure of work and a different organisation of medical care, provided this creates more room for learning processes. An example is the availability of experienced care professionals with a broad expertise of what the front line of the care process involves. Additionally, checks should be made to see what the benefits are if the organisation of medical specialist care is shifted from single disciplines to multidisciplinary teams that are tailored to patients' care needs and situations. Reduction of workload pressure and organisational changes do not necessarily result in higher care costs if the expenditure is recouped through fewer diagnoses and treatments.

Recommendation 6: Care organisations should reserve more time at the front line of care processes, in particular during the phase of diagnosis and decision-making.

Moral forum

In the current healthcare system, quality monitoring is outsourced to third parties and has become separated from the healthcare professionals themselves. The emphasis has shifted to external accountability, standardisation and control of care (see also the section below). As part of context-based practice at organisational levels, the Council believes it is important to tilt this practice of external accountability towards situations in which care organisations and care professionals are given more scope to steer behaviour towards good care, and to tailor their organisations and working method to this.

Care professionals must therefore embark upon a dialogue about good care, not only with each other but also with their managers and patients. They must regularly discuss quality ratings and other local data in order to learn from them and improve performance. A system of 'patient tracers' was recommended previously in order to assess whether the organisation is meeting the targets set and the standards for delivering good care (Council for Public Health and Care, 2013). It is an assessment method that looks at the entire care process that a patient has been through. Information about complaints is also a useful source of data that we can learn lessons from that extend beyond people's own departments.

Care professionals and care organisations must also enter into a dialogue about good, patient-oriented care and how to deploy scarce resources to deal with external stakeholders, e.g. other care providers in the region, care insurers, patient organisations and municipalities. This approach fits in with the horizontal nature of the relationships in the healthcare sector and the mutual dependencies between care providers and other stakeholders. This is therefore conditional on the parties involved recognising that there is no single party that dominates and decides.

Because of the principles involved, this dialogue has to take place in an open 'moral forum'. This moral forum is the vehicle for the legitimisation of decision-making in care about what targets have to be aimed for and with what resources. For the decisions to be legitimate, it is not only important how they came about (for instance which knowledge sources were used), it is also about which stakeholders have taken part in the realisation of choices. The importance of that legitimisation means that the dialogue is not optional: it becomes obligatory.

This is how the parties involved fulfil the public tasks that they have been assigned, and how they can be held accountable for the results achieved. In order to ensure the development and the quality of this moral forum, it is important that it becomes part of the governance of healthcare institutions.

To shape this moral forum, care providers must invest in regional consultation structures. The parties involved develop a shared assessment framework that can be used as a moral compass for decision-making.
They develop indicators using everyday practice as the starting point and then focus on quantifying and interpreting it, and on improvements and quality assurance. The principle is that results – effectiveness, safety, patient-orientation – can be used and learned from e.g. to ensure improvement. As a secondary purpose, they can be used for external accountability and choice information. Other sources that can be used in this dialogue are annual reports and analyses of local practice data. Care parties that are part of the network can emulate each other, exchange data, knowledge and learning experiences, and draw conclusions at an umbrella level. This means that the results are indicative for changes in the patients' health, and that it must be possible to create a link to an intervention.

Recommendation 7: Care organisations must take the initiative to invest in a dialogue about good care with interested parties in the region (moral forum). This moral forum is part of the governance of care institutions.

7.4 The institutional environment

Using a context-based approach no longer puts the emphasis on evidence but instead on critical interpretation of evidence jointly with other information sources within the morally charged context in which care takes is given. This requires new activities and competences from care professionals and care organisations. To give them room to realise the aspects mentioned above, the parties in the environment of care professionals and organisations – and in particular parties who depend heavily on evidence-based instruments such as policy bodies, care insurers, supervisory bodies and research organisations – must be encouraged to adopt a different approach.

The Council is giving the initial impetus for this and providing solutions and recommendations relating to research, package management, development of guidelines and quality supervision.

To that end, we are focusing first on the way that various stakeholders in care interpret and use evidence.

A stratified concept of evidence

Because of its emphasis on epidemiological, generic knowledge as the cornerstone of professional actions, EBP suggests that evidence is an unambiguous concept. However, 'evidence' can have multiple meanings and functions, thereby raising different expectations (De Jong, 2016). This layering results in the first instance from the fact that there are multiple sources of knowledge that contain indications about the truth – scientific research, clinical expertise and experience, the experiences and personal situations of patients, and local practice data (to name but a few). Furthermore, there is always someone involved who interprets these knowledge sources and links them together. The way that this is done depends on the context and the values and interests that are at stake. It is important for patients to get access to the care that suits them best, for care professionals it is about being able to provide care in accordance with the standards of their own professional group, for care insurers the interest is efficient care for the people they have insured – i.e. affordable high-quality care – and the interest for quality supervision is that care providers meet the preconditions that reasonably guarantee the quality and safety of care.

Tensions between the parties in care that use scientific evidence as an instrument are connected with the various meanings that they give to 'evidence' (De Jong, 2016). To one party, the evidence is an indication for an objective truth. The parties hope to get closer to this truth by testing hypotheses. This idea of evidence fits in with the perspectives of both scientists and care providers. At the same time, care providers are not ultimately (or not exclusively) aiming to uncover objective truths. Their primary task is finding solutions for and with their patients, weighing things up and making compromises (Van Baalen et al., 2014). To that end they create a picture of the patient using everything they know about the patient, utilising all the explicit and implicit knowledge sources at their disposal, and this picture can be used for clinical reasoning. This design does not have to represent the truth: what is important is that it works in practice (Van Baalen et al., 2014). This is therefore a pragmatic idea of evidence.

Evidence is also everything that convinces. The better a new fact can be framed within existing knowledge, the greater its persuasive strength. This idea of evidence fits in with the perspectives of not only care providers but also patients. It is because they have to be convinced of the assessment of their situation and of the suitability of a prescribed treatment.

Finally, evidence may also function as a neutral referee, for instance between effective and non-effective or harmful care. The use of evidence as a referee in order to make decisions dominates quality supervision, healthcare procurement and package management.

In order to handle the tensions between them, parties in the care sector will have to recognise these different conceptualisations of evidence. How they assess and weigh up evidence – such as the interpretation of certain outcome measures or quality indicators – is intertwined with the interests that these parties represent. Agreement about the interpretation and weighing up of the available evidence must be promoted by making these interests explicit and weighing them jointly in mutual dialogue.

A better research system

As has been explained in previous chapters, EBP contributed unintentionally to creating a research system in which some patient groups, regular care, diagnostics and forms of care that cannot be assessed properly using randomised controlled trials (RCTs) systematically receive less attention. The research system also often contains stimuli and rules that unintentionally allow space for flawed research and selective publication. The Council specifically asks for attention to be paid to the fact that guidelines and research results that are obtained externally cannot be simply implemented in any setting, and to the existing gap with respect to the way that various knowledge sources must be integrated.

There is no ‘magic bullet’ for promoting proper, socially relevant and efficient health research (i.e. based on both the disease burden and the care costs). This requires a joint, multi-faceted approach by research financers, the people who perform scientific research, scientific journals and regulatory bodies. Research financers in particular play a key role. ZonMw (the Netherlands Organisation for Health Research and Development) maintains an active policy for this (Nasser et al., 2017).

To start with, more knowledge is needed about the causes of systemic failure in order to get a picture of new solutions and to improve research practices. The first steps have already been made for this (see the boxed text on “Scrutiny of the research system”).

Research financers may impose requirements on the content in order to steer research agendas towards what is socially needed. An example of this is the financial support from ZonMw for the initiative taken by medical/scientific associations of the professional groups to assess regular care. This may look at healthcare interventions where there is doubt about the effectiveness and safety, or comparative research into various options that are both used in practice. These associations have undertaken to include the results in their guidelines.

However, the bulk of government financing of the research at university medical centres (UMCs) comes from the Ministry of Education, Culture and Science. No requirements are imposed on this in terms of the content. These resources are predominantly spent on research themes that university medical centres score well at in terms of publications (performance financing) and/or themes that are predominantly about healthcare (Health Council of the Netherlands, 2016). UMCs focus predominantly on fundamental and translational research, and on research into medical specialist care. In addition, their patient population is becoming more and more complex, which is caused by the concentration of highly complex medical specialist care. It is therefore desirable that UMCs should start to function as the “motor of research and innovation for care and prevention across the full breadth”, in cooperation with all the providers of care and prevention, knowledge centres, patients and municipalities (Health Council of the Netherlands, 2016). Government, municipalities and healthcare insurers must finance this research jointly and structurally.

In addition to paying attention to the research agenda, the way research is carried out also needs to be examined. Better access for researchers to methodological expertise and better access to research data helps identify the distortion of research results and helps improve the setup of research (Health Council of the Netherlands, 2016). This also promotes reuse of existing research data. The use of checklists by research financers to test the soundness and efficiency of research proposals must be encouraged. When assessing research results, research financers must check if a research design will provide evidence that fits with the local need for knowledge. This leaves more space for forms of research other than the RCT and promotes efficient use of research resources (see boxed text on “Surgical care safety”). Furthermore, in order to avoid distortion, research financers must demand that all research results are published.

Researchers and research financers must also involve other stakeholders – such as patients and user groups – in the programming, setup, assessment and execution of the research. This will enhance the relevance and quality of research.

Recommendation 8: To promote good, socially relevant and efficient health research, financers of health research must impose requirements on the substantive targets, and on publication of research. They must actively involve stakeholders such as user groups and patients in this.

Using external evidence in the local situation is more than a question of implementation: it is part of a learning process. RCTs aim to standardise the care setting, the intervention and the target group. Checking the results in everyday practice requires research that can explicitly show the influence of contextual factors on the results. This could involve a non-standard patient mix, the link between outcome measures and patient preferences, specific expertise and skills of the caregivers, the presence of specific infrastructure or cooperation agreements with other disciplines or chain partners. Having a better picture of the influence of contextual factors lets the parties involved obtain insights into the required preconditions for successful use of interventions. This requires a variety of research forms, both quantitative and qualitative. Important aspects of this are having a picture of the strengths and weaknesses of alternative research methods, and acquiring experience in combining various methods into a single piece of research.

Recommendation 9: Researchers and financers of health research must pay attention to the influence of the context of the practice in which care is provided. This can be done by using local practice data and by combining quantitative and qualitative methods into one and the same form of research.

Imposing more requirements on research also means that more resources have to be reserved for the programming and assessment of research. This could mean that less research funding is spent directly on research. This is not a problem if these additional overheads compare favourably to the more efficient use of research resources.

Scrutiny of the research system

With the BVO research programme (‘Promoting Responsible Research Practices’) ZonMw is improving knowledge about the research system, and the stimuli and rules that determine the quality, integrity, social relevance and efficiency of research. This could involve factors such as the peer review system for scientific articles, publication pressure, data accessibility and remuneration mechanisms. The following studies have recently been awarded grants:

— Researcher allegiance in research on psychosocial interventions: Impact on effects and mechanisms.
— Optimizing the responsible researcher: towards fair and constructive academic advancement.
— Fostering the responsible use of residual biospecimens and data in medical research in the Netherlands.
— The myth of null-hypothesis significance testing in scientific research.
— Fostering responsible conclusions in Health Services Research.
— Follow the Money: Does Competitive Research Funding Contribute to Questionable Research Practices?
— A systematic approach to identify determinants of questionable research practices in clinical trials.
— Improving Peer Review: interventions that work (IMPER).

Safety during surgery
The fact that assessing the suitability of a research design can be effective is illustrated by the introduction of the ‘goal-directed fluid therapy’. This is an anaesthesiological intervention that reduces the risk of complications during surgery. The effectiveness and efficiency had already been shown in foreign research. A request for a Dutch clinical trial was therefore rejected. The development of a business case to transpose foreign results into the Dutch situation was chosen in consultation with the requesting party. This is considerably less expensive than a clinical trial. Because it was also more in line with the questions from hospitals and anaesthetists, it promoted the use of the intervention in operating theatres.

Package management
There are differences between decision-making about reimbursement of care as part of the Healthcare Insurance Act and the Long-Term Care Act (in which the National Healthcare Institute has an advisory task) and the recommendations in professional guidelines and the decision-making in individual patient care. This is partly caused by the different meanings and functions of 'evidence' adopted by the National Healthcare Institute, scientific associations of the professional groups – which are responsible for the development of professional guidelines – and care professionals. It is linked to the various interests that they represent: mutual solidarity in the basic insurance package, and the provision of care to individual patients in accordance with these parties' own professional standards. Because of the hierarchy of knowledge sources used by the parties just listed, this particularly affects care forms and patient groups that are difficult to assess through randomised clinical trials.

As has already been described in Chapter 2, the National Healthcare Institute has already taken a number of steps in order to consider the context in the package recommendations. To bridge the differences between remuneration decisions, guidelines and decision-making in practice, the National Healthcare Institute, professional associations and patients must enter into a dialogue with each other about how they interpret the available evidence, and about the evidence required for the decision about remuneration to be positive. This is because the assessment framework of the National Healthcare Institute leaves room for other research methods than randomised clinical trials.
Professional groups and patient organisations can then check the possibilities for achieving the required burden of proof, for instance through systematic analysis of clinical databases, local practice data and patient experiences. This lets professional groups see whether they can adopt a consensus point of view. An example of this approach is the remuneration of epilepsy dogs (see boxed text on 'Epilepsy dogs').

Recommendation 10: When giving advice about package management, the National Healthcare Institute provides space for the context in which healthcare is delivered, and it also uses other knowledge sources besides scientific evidence. To achieve this, the National Healthcare Institute involves professionals, patients and the general public in its advice.

Epilepsy dogs: from double-blind to appropriate evidence
Epilepsy dogs (dogs that help their owner during and after an epileptic seizure) are not paid for from the basic package.

In 2014, the National Healthcare Institute judged that providing them fails to meet the current state of science and practice (National Healthcare Institute, 2014b). The few existing studies are too small and of low quality. The National Healthcare Institute then determined what minimum burden of proof is required to reach a positive judgment, which included a sufficient number of patients and an appropriate description of the patient's situation before and after the deployment of an epilepsy dog. A randomised trial is therefore not required and there are objections to the approach anyway, as patients may prefer having or not having a dog. Although the assessment framework of the National Healthcare Institute assumes a hierarchy of evidence, this example shows that 'lower' levels of evidence can also be acceptable, however without giving assurances beforehand about the final decision. As a result of the Potters amendment, the Ministry of Health, Welfare and Sport granted a subsidy for the research through ZonMw. A feasibility study was started at the end of 2016 to check if research that meets the requirements imposed is a possibility.

Development of guidelines

To promote patient-oriented professional guidelines, the involvement of patients must be encouraged. Practice tells us that this requires a nuanced approach. It turns out that the adage "the more involvement the better" does not hold water. For patient-oriented guidelines, there seems to be no connection with the degree of patient participation (Van den Bovenkamp et al., 2013). Because of their lack of knowledge, it is difficult to exert influence, whereas their representativeness is bought into doubt if they professionalise by developing such expertise. Additionally, it is difficult to make the input of patients transparent and traceable in guideline committees. Patients should in particular be involved in the development of guidelines at the right moment. There have been good experiences with input from patients in the preparation phase. The scope of a guideline and the choice of outcome measurements are determined in this phase and important moments of choice can be identified, in which the desires and preferences of patients play a role (Den Breejen, 2017).

Recommendation 11: Guideline developers are working on the patient orientation of professional guidelines by involving patients, the general public and other stakeholders systematically in setting up and changing them.

Quality supervision and care contracting

Evidence-based instruments are an important element of quality supervision and healthcare contracting: compliance with professional guidelines, centrally determined quality indicators based on guidelines, and volume standards for specialist medical care. This approach fits in with steering care towards a situation in which external accountability and control are the leading principles. This approach has resulted in a 'quality industry' in which quality has become disconnected from professionalism – it has been outsourced to the quality departments of care institutions and to external supervisory bodies. This way of creating accountability does not fit in sufficiently well with everyday practice, does not result in learning and quality improvement, and reduces the motivation of care professionals to record quality (Weggelaar et al., 2016).

This approach should therefore be replaced by an approach in which quality is appropriated by care professionals and care organisations who make it part of their learning and improvement cycle. External quality supervision and healthcare procurement must focus on this cycle and on verifiable criteria that this learning practice must comply with. Preconditions that reasonably guarantee the medical quality and safety of care and that care providers must meet for their 'licence to operate' are part of these criteria.

Recommendation 12: The focus of quality supervision and care contracting must shift from uniform quantitative results of care to learning and improving care professionals and care organisations.

8 Recommendations

‘‘No evidence without context’ is the title of these recommendations. That is because evidence is always used in a concrete context, and evidence only then acquires its meaning. Context-based practice requires care professionals who listen to their patients, who dare to welcome uncertainty, and who will enter a dialogue about good care. This results in suitable, patient-oriented care in which evidence has a place and is part of the accountability for the care provided. Care professionals cannot do this alone, but have to do it together with patients and other parties involved. This requires a different approach in scientific research, education and supervisory practices.

Care professionals and organisations in domains outside healthcare that EBP has managed to access can learn from these recommendations. The Council calls upon them to follow the recommendations in this advice and to translate them into their own practice.

Context-based practice
The Council recommends that the term ‘context-based practice’ should be used rather than ‘evidence-based practice’. Although evidence plays a role as a source of information, it does so alongside many other sources of information. The specific context determines how these knowledge sources are connected together.

The consulting room: patients and healthcare professionals
Shared decision-making is essential to determine what constitutes good care. Care professionals tailor it to the patient’s context, and pay more attention to listening than to dispensing information.

Patients’ organisations should take the initiative to develop decision aids (together with healthcare providers and other parties involved) that are based on what patients feel is important.

Care professionals should embrace the uncertainty about what constitutes good care. Together with the relevant parties, they must learn to assess and integrate various sources of information.

Learning care organisations
Care organisations should reserve more time at the front line of healthcare processes, in particular during the phase of diagnosis and decision-makin

Care organisations must take the initiative to invest in a dialogue about good care with interested parties in the region (moral forum). This moral forum is part of the governance of care institutions.

Education
Residency programme directors should include social science and humanities, interdisciplinary education and active contributions from patients in the curriculum.

Research
To promote good, socially relevant and efficient health research, financers of health research impose requirements on the substantive targets, and on publication of research. They must actively involve stakeholders such as user groups and patients in this.

Researchers and financers of health research must pay attention to the influence of the context of the practice in which care is provided. This can be done by using local practice data and by combining quantitative and qualitative methods into one and the same form of research.

Package management
When giving advice about package management, the National Healthcare Institute provides space for the context in which healthcare is delivered, and it also uses other knowledge sources besides scientific evidence. To achieve this, the National Healthcare Institute involves professionals, patients and the general public in its advice.

Development of guidelines
Guideline developers are working on the patient orientation of professional guidelines by involving patients, the general public and other stakeholders systematically in setting up and changing them.

Supervision and care contracting
The focus of quality supervision and care contracting must shift from uniform quantitative results of care to learning and improving care professionals and care organisations.

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Preparation of advice

These recommendations have been drawn up by Jan Kremer (Council member with primary responsibility), Liesbeth Eelens-Noordegraaf (Council member), Willem Jan Meerding, Leo Ottes and Martijn Felder (advisers). Gabie de Jong (surgeon, Rijnstate) wrote one of the background studies. Noor Mutsaerts (medicine student, UMC Utrecht) prepared the patient case histories.

The following background studies have been written as preparation: They are available from www.raadrvs.nl. (Only in Dutch)

Martijn Felder, Willem Jan Meerding (2016). *Een toekomst voor evidence-based medicine? [A future for evidence-based medicine?]* The Hague: RVS.

Gabie de Jong, Willem Jan Meerding (2016). *Betekenissen van bewijs [Meanings of evidence].*
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The Council provides advice independently. The discussions during the preparation of the advice were not aimed at acquiring support. The people taking part in the discussions have made no commitment to the recommendations.

Publications

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