



# Who contextualises clinical epidemiological evidence? A political analysis of the problem of evidence-based medicine in the layered Dutch healthcare system



Martijn Felder<sup>a,\*</sup>, Hester van de Bovenkamp<sup>a</sup>, Willem Jan Meerdling<sup>b</sup>,  
Antoinette de Bont<sup>a</sup>

<sup>a</sup> Erasmus School of Health Policy & Management, Erasmus University, Rotterdam, the Netherlands

<sup>b</sup> Meerdling Advies, Gouda, the Netherlands

## ARTICLE INFO

### Article history:

Received 17 April 2020

Received in revised form 1 September 2020

Accepted 20 September 2020

### Keywords:

Evidence-based medicine

Institutional layering

Politics

Healthcare decision-making

Qualitative research

## ABSTRACT

We critically examine the discussion on the role of evidence-based medicine (EBM) in healthcare governance. We take the institutionally layered Dutch healthcare system as our case study. Here, different actors are involved in the regulation, provision and financing of healthcare services. Over the last decades, these actors have related to EBM to inform their actor specific roles. At the same time, EBM has increasingly been problematised. To better understand this problematisation, we organised focus groups and interviews. We noticed that particularly EBM's reductionist epistemology and its uncritical use by 'professional others' are considered problematic. However, our analysis also reveals that something else seems to be at stake. In fact, all the actors involved underwrite EBM's reductionist epistemology and emphasise that evidence should be contextualised. They however do so in different ways and with different contexts in mind. Moreover, the ways in which some actors contextualise evidence has consequences for the ways in which others can do the same. We therefore emphasise that behind EBM's scientific problematisation lurks a political issue. A dispute over *who* should contextualise evidence *how*, in a layered healthcare system with interdependent actors that cater to both individual patients and the public. We urge public administration scholars and policymakers to open-up the political confrontation between healthcare actors and their sometimes irreconcilable, yet evidence-informed perspectives.

© 2020 The Author(s). Published by Elsevier B.V. This is an open access article under the CC BY license (<http://creativecommons.org/licenses/by/4.0/>).

## 1. Introduction

In many countries, 'evidence-based medicine' (EBM) has become an important principle in healthcare governance [1]. It emerged in the field of clinical epidemiology and gained prominence amongst professionals in the 1990's [2]. EBM aimed to reduce unexplained variation in the provision of care. It advocated treatment based on the best epidemiological evidence available [1] and criticised healthcare decision-making based on professional authority. It encouraged more standardised forms of decision-making, based on statistical evidence about the effectiveness of interventions. EBM furthered randomised controlled trials (RCT's) as the gold standard of evidence [3].

The standardising qualities of EBM are increasingly problematised [4]. In the academic literature, EBM is criticised along two

lines of argumentation. Firstly, authors criticise its epistemological reductionist approach and complex methodology; emphasising that EBM draws predominantly on statistical data derived from selective populations, analysed in ways that only methodological experts understand [5]. Secondly, authors criticise its use in – and beyond – the counselling room. Their critique is that professionals, healthcare managers, policymakers, health insurers and regulators base their treatment plans, policies or monitoring instruments on statistical data, without considering the situation of individual patients [4,6].

The questioning of EBM's scientific principles and uncritical use have become laden affairs in hospitals, knowledge centres, insurance companies and government offices. Actors defending evidence-based healthcare decision-making are classified as orthodox positivists ([7] [responses]). Actors questioning the dominant role of statistical evidence in healthcare decision-making are accused of quackery [7]. At conferences, the vices and virtues of EBM are celebrated and disqualified. Presenters are lauded

\* Corresponding author.

E-mail address: [felder@eshpm.eur.nl](mailto:felder@eshpm.eur.nl) (M. Felder).

or hooted (personal observations 2017). The EBM discussion has become a site of pluralism, conflict and strive [8].

We argue that a political analysis of the discussion generates insights that cannot be captured by biomedical or professional approaches. Informed by Mouffe [8] and Bacchi [9], we conceptualise contemporary healthcare systems as highly political. On the one hand, such systems consist of different regulatory frameworks (from professional self-regulation to regulated markets [10,11]). On the other hand, such systems harbour a plurality of actors [12]. These actors can (re)shape and legitimise actors-specific roles and positions by relating to different regulatory frameworks and scientific truth claims at different times and for different reasons [13–15]. Problematising regulatory frameworks and scientific truth claims can therefore go hand in hand with attempts to improve specific roles and positions, possibly at the cost of others [16]. A striking example is the establishment of a division between ‘us’ critical interpreters of evidence versus ‘them’ naïve users of evidence [8] and the question who has more legitimacy to make healthcare decisions [13]. In this light, it is important to look beyond the problem itself and study strategic relations that have gone into a problem’s making [9].

Informed by the above, we examine: a) how EBM informs the identities, roles and positions of different actors in layered healthcare systems; and b) the perceived problems that emerge from such differences when it comes to healthcare decision-making. We do so by answering the following research question:

*How and by whom has the role of EBM in healthcare decision-making been problematised and why is that the case?*

The Netherlands has become an exemplary case to reveal the complex relations in which EBM has become constituted as a problem that needs to be solved. Here, healthcare governance, traditionally controlled by professional authority, has been supplemented with a plethora of market and state-based regulatory arrangements [10]. In doing so, the Dutch case resonates with the healthcare systems in many Western countries [1,17].

Our political analysis reveals that behind the epistemologically and professionally framed discussion unfolds a dispute over who is able – and should be allowed – to interpret and contextualise clinical epidemiological evidence in decision-making that does right to individual patients and upholds the quality, safety and affordability of a collective healthcare system. The future of EBM should therefore not just be an epidemiological or professional project. Instead, we urge policymakers and scholars of public administration to take the EBM discussion seriously and to start focusing on the layered healthcare systems in which evidence-informed decisions are being made.

## 2. EBM in the layered Dutch healthcare system

As in many Western countries, the dominant position of Dutch healthcare professionals has been called into question [18]. EBM played an important role in this process as it scrutinised healthcare decision-making based on professional authority and stimulated decision-making based on the best evidence available [2]. The early advocates of EBM however still intended for evidence-based decision-making to be a professional affair; describing it as a process of critical appraisal [4]. Critical appraisal here referred to the use of: (a) clinical epidemiological evidence, (b) clinical experience and (c) patients’ needs and wishes, during shared decision-making with patients in the counselling room [2].

However, Dutch healthcare governance was changing beyond the confines of professional self-regulation. As new governance principles such as ‘accountability’, ‘efficiency’ and ‘affordability’ became important frames of reference [1], so too were new

regulatory arrangements introduced on top of professional self-regulation. A Dutch example is the introduction of the Health Insurance Act in 2006 [19]. This act aimed to reduce costs and raise the quality of healthcare through the introduction of market mechanisms. It decreed that professionals should start competing on the quality and price of healthcare services. Concurrently, it strengthened the position of health insurers. They should start negotiating with providers about the price, volume and quality of healthcare provided.

Meanwhile, the Dutch healthcare system was not entirely left to the whims of the market. In addition, several semi-governmental organisations were charged with safeguarding access to care and minimum quality [10]. The Dutch Healthcare Institute was, for instance, charged with stimulating and overseeing the development of quality instruments and with advising the Minister of Health on which care should be included in and excluded from the ‘basic healthcare agreement’. This agreement recognises the minimum care to be covered by health insurers; thereby making such care accessible for (obligatory insured) Dutch citizens. Moreover, the Dutch Healthcare Inspectorate continued to inspect on the quality and safety of care provided.

By introducing market mechanisms beside professional self-regulation and state-based regulation, a layered healthcare system emerged [10]. An effect of such layering is that healthcare decision-making has become fragmented [11]. It prompted a proliferation of ‘professional others’ involved in healthcare decision-making [12]. Examples are health insurers, policymakers, knowledge institutes and inspectorates. Each of these actors has adopted EBM in the ways in which they shape their roles and legitimise role-specific decisions [9,13,14]. But, as we will also show in our empirical section, this wide uptake of EBM has not brought coherence in the governance of care (Fig. 1).

## 3. Materials and methods

Our inquiry stems from a discussion in the Netherlands about evidence-based decision-making. In fact, the first and third author participated as researchers in a Dutch advisory board (de Raad voor de Volksgezondheid and Samenleving [RVenS]) that sought to better understand the implications of this discussion for Dutch healthcare governance [20]. Data gathered for the policy advice is reused in this paper. Although the problems presented below reflect the policy advice, we have placed more emphasis on a political analysis of EBM’s problematisation [9].

To gain insight into the Dutch discussion, the RVenS organised two focus groups in November and December 2016. The first included a variety of experts (N = 7); medical sociologists, a medical history scholar and a medical philosopher, studying and publishing on EBM. The second included healthcare practitioners from the field (N = 5); a medical specialist, a general practitioner, a geriatric practitioner, a medical researcher and a junior medical specialist. To gain complementary insight, the RVenS organised interviews in the spring of 2017. Interviewees were a psychiatrist (N = 1); gynaecologists (N = 2); midwife (N = 1); respondents from the Dutch Healthcare Inspectorate (N = 2); a knowledge institute (N = 5); and a healthcare insurer (N = 2).

With our sampling approach, we aimed to gain insight into the different ways in which EBM was problematised and/or defended and why it was problematised or defended as such. Informed by Bacchi [9], we therefore approached respondents that were: a) actively involved in the discussion; and b) represented different kinds of actors in Dutch healthcare governance. Importantly, our aim was not to work towards a representative sample of one of these actor groups specifically (e.g. a specific group of medical specialists), or the Dutch healthcare system as a whole (with all the

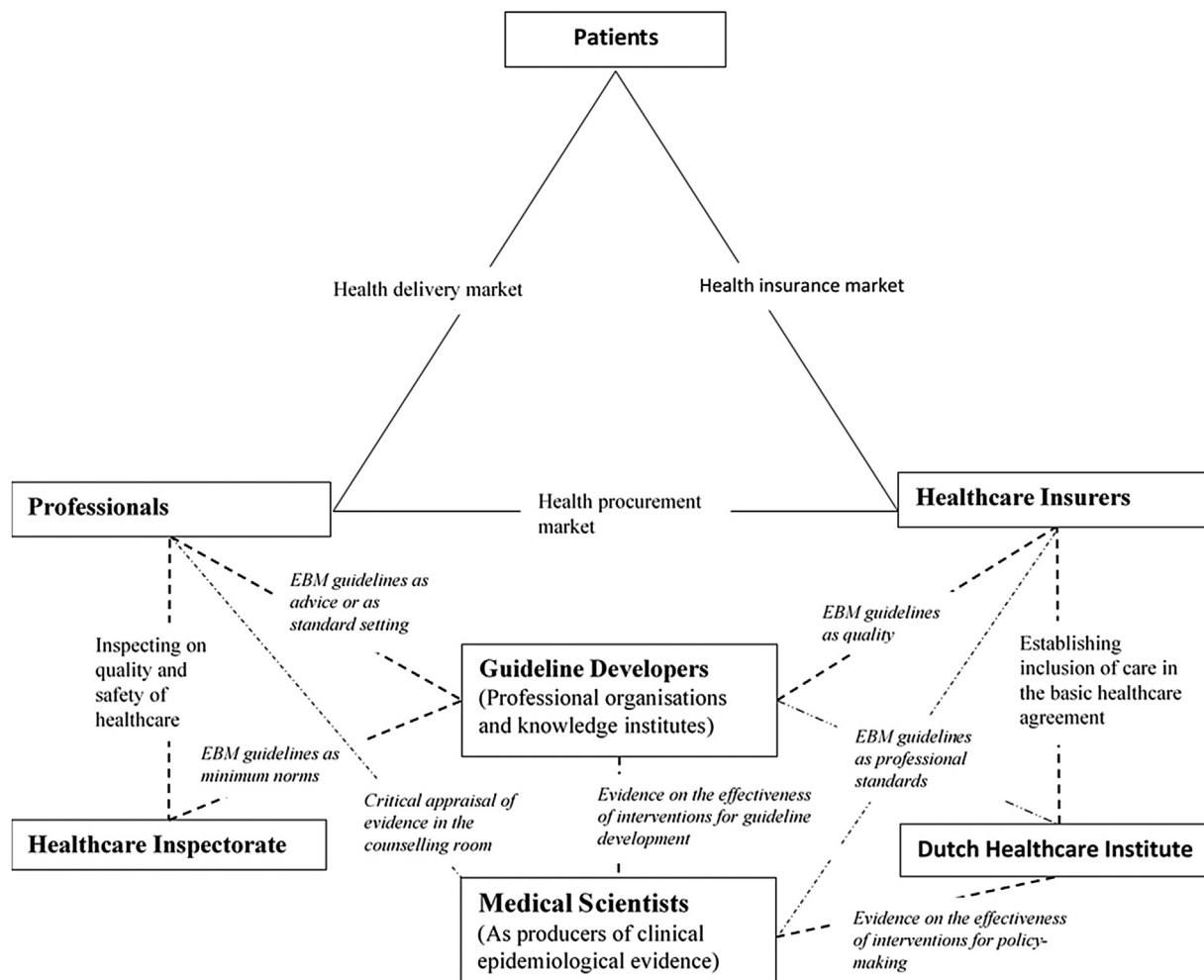


Fig. 1. A representation of the layered Dutch healthcare system and the role of evidence therein.

different actor groups included). Instead, our aim was to identify those actors – and their interrelations – through which EBM had become constituted as a problem that needed to be solved. We reflect on the limitations of this approach at the end of our discussion.

Focus groups and interviews were semi-structured around two questions: I) how does EBM contribute to healthcare provision? and II) which problems or challenges do respondents encounter? Focus groups and all but one of the interviews were audiotaped and transcribed verbatim. Where audiotaping was not possible, fieldnotes were made and further elaborated afterwards. Individual contributions were anonymised.

For this paper, we revisited the transcripts. We coded passages of what EBM is (and what not), what its problems are (and what not) and how it should be used by who (and who not). We member-checked our analysis on two separate occasions in the spring of 2017. We presented our preliminary interpretation on a conference on evidence-based guideline development and during the public release of the policy advice [20]. Comments were used to fine-tune our analysis.

#### 4. Results: the problems of EBM in the Dutch governance of care

This empirical section is divided into three parts. First, we present how EBM informs the actions of actors in Dutch healthcare governance. Thereafter, we present how and by whom EBM

has become problematised. Lastly, we consider how these problematisations mirror decision-making dynamics between actors in the layered Dutch healthcare system.

##### Part 1: the use of EBM by different actors

Each of the actors introduced in Fig. 1 uses EBM in and on their own terms. In the coming four subsections, we describe how.

##### 4.1. Evidence in the counselling room

The professionals we interviewed described themselves as interpreters who make context dependent decisions about individual treatment plans. Such treatment plans are informed by clinical epidemiological evidence, but they cannot be reduced to such evidence. In fact, the interviewed professionals stressed that they should be able to translate evidence to the health problem of individual patients.

*‘The whole idea is that you explore the problem of the patient in the context of the patient, then look into what the [evidence-informed] guidelines say about what we do – on average – with such a problem and after that make a decision together with the patient.’* (Geriatric practitioner, focus group, 2016)

We observed that the way professionals describe their own practice strongly resembles Greenhalgh et al. [4] celebration of an original form of EBM [2]. One thing is different though. There where Sackett et al. [2] emphasised the critical appraisal of the best evidence available, interviewed professionals mostly referred to

evidence-informed professional guidelines. In the next paragraph, we explain why this is an important difference.

#### 4.2. Evidence in guideline development

Although professionals frequently refer to professional guidelines when talking about evidence, such guidelines are more than a representation of clinical epidemiological evidence. In fact, not only in the counselling room, but also in the development of guidelines, such evidence is weighted next to clinical experience and patients' needs and wishes.

*'Guidelines are supported by evidence, but they also include a translation of the international evidence to the Dutch context, the extent of the problem here, its specific organisation of care, the patient perspective. Only after that do we present considerations and recommendations.'* (Gynaecologist, interview, 2017)

Although the relative weight of the patient perspective remains an important point for discussion [21], the abovementioned quote illustrates how professional guidelines claim to be more than a sum of the epidemiological evidence on a topic. In fact, what emerges is a situation in which evidence is contextualised on two levels within a professional context: in the development of guidelines and in the counselling room.

#### 4.3. Evidence in regulating quality and safety

Next to professionals, other actors use professional guidelines to inform their actions. For instance, the Dutch Healthcare Inspectorate uses the developed guidelines to: (a) prospectively influence healthcare processes; and (b) retrospectively assess the safety and quality of care provided (Inspector, interview, 2017).

According to the Inspectorate, the content of care is still in the hands of professional organisations through their key role in guideline development. The Inspectorate, in turn, supervises whether professionals live up to the standards that professionals set for themselves in these guidelines. In the words of an inspector (interview, 2017):

*'There is no evidence that driving on the right side is safer than driving on the left side. Nevertheless, there is enough evidence that supports the idea that a decision needs to be made to either drive on the left or on the right side of the road.'*

The Inspectorate acknowledges the weighing of evidence on the level of guideline development. At the same time and in contrast to the first subsection, the Inspectorate's approach compromises the critical appraisal of such guidelines in the counselling room. To be specific here, the Inspectorate supports the professional's claim that clinical epidemiological evidence needs to be contextualised. The Inspectorate however also emphasises that such contextualisation should be done uniformly and on an aggregate level; that of the professional organisation.

#### 4.4. Evidence in policymaking

Also the Dutch Healthcare Institute uses clinical epidemiological evidence and professional guidelines. They do so to provide policy advice to the Ministry of Health about which treatments should be (preliminary) included in the 'basic healthcare agreement'. This agreement dictates which care is to be considered standard insured care and needs to be covered by health insurers. The Institute's objective is to include care that is proven effective and affordable in order to protect a healthcare system that is collectively financed [22].

The Institute developed a systematic assessment framework to support them in their task [22]. Relative effectiveness is the key

principle in this framework. This means a treatment needs to be an improvement, this improvement needs to be significant, and it should exert itself in professional practice [22]. It is here that professional and patient perspectives are considered, specifically there were evidence is inconsistent or where there is broad consensus about value of treatment [22].

In following these steps, the Dutch Healthcare Institute explicitly relates their actions to the principles of EBM.

*'We use the principles of EBM in our assessment. Although it was developed to aid professionals to make clinical decisions for individual patients, its principles have found a much broader application. It is also used in the development of professional guidelines and policies regarding public health. In these cases, it is no longer about decision-making in relation to individual patients, but rather about advice and decisions on the level of the population.'* ([22]: 6)

The Institute uses EBM's methodological design on how to gather and grade evidence [3], but explicitly departs from [2] emphasis on weighing such evidence in the context of individual patients. Instead, they weigh such evidence in the context of the Dutch population. Although professional insights and the patient perspective are considered, the Institute makes evidence-based assessments independent from the professional organisations.

#### 4.5. Concluding remarks for part 1

All actors presented above legitimise their roles and decisions by relating to clinical epidemiological evidence. Each of them furthermore stresses the importance of contextualising evidence. They do so on different levels and in line with their perceived roles. Individual professionals contextualise evidence in the counselling room in relation to individual patients; professional organisations (and the Dutch Healthcare Inspectorate) do so on the level of guidelines development in relation to patient groups; and the Dutch Healthcare Institute does so in policymaking in relation to the Dutch population.

##### **Part 2: EBM's problematisation**

In this subsection, we present the main problems identified in the Dutch EBM discussion. We emphasise at the onset that it is mainly professionals who voice problems. Below, we discuss these in turn.

#### 4.6. The biddable use of guidelines

A problem frequently voiced by professionals is about other professionals. It addresses the way in which evidence-informed guidelines are used in the counselling room:

*'Guidelines should provide support in the counselling room, but often they are used as key stones. You receive a patient with hypertension and check the guideline for treatment. A second question could then be "who is actually sitting in front of me?" But often, doctors don't do that.'* (Internist, interview, 2016)

These professionals stress the importance of weighing clinical epidemiological evidence next to clinical experience and patients' needs and wishes, but conclude that there is a lack of it in the counselling room. This is a longstanding problematisation of EBM, frequently addressed in the literature as well [23].

Importantly, those that address this problem relate such uncritical use of guidelines to forces external to individual professionals and their actions in the counselling room. A junior medical specialist tries to describe the cause of this problem:

*'It is a kind of defensive medicine; because others can hardly question your actions when you followed the guidelines.'* (focus group, 2016)



This professional articulates uncertainty amongst professionals. A form of uncertainty that constrains them to critically interpret – and where necessary divert from – guidelines in decision-making with and for individual patients.

#### 4.7. Weighing evidence on the right level

We previously observed that professional organisations considered their guidelines as uniform agreements amongst professionals about how to treat patients. Guidelines are therefore informed by clinical epidemiological evidence, clinical experience and the patient perspective. Guidelines are thus much more than representations of clinical epidemiological evidence alone. Yet it is exactly this weighing of evidence on the level of guideline development that is problematised by professionals we interviewed.

*‘When something is proven effective, then there is no problem in presenting that in guidelines [and considering that a uniform agreement]. The problem however is that many things in guidelines are based on consensus or authority. In those cases, I feel it is harder to divert from the guideline.’* (Gynaecologist, interview, 2016)

There where the guideline is based on consensus – or a weighted interpretation of evidence – professional organisations have already included the patient perspective and clinical experience on an aggregate level. In the counselling room, professionals subsequently feel that they are expected to follow the weighted advice. Diverting from the guidelines then no longer means diverting from the clinical epidemiological evidence. Instead, it means diverting from the agreements that professional organisations, in collaboration with other actors, have made as a professional collective for individual professionals.

The professionals we interviewed thus feel that weighing and contextualising is important, but problematise the level on which that is done. These professionals criticise the emergent trend in which professional organisations translate evidence, clinical experience and the patient perspective into general agreements presented in guidelines (previous subsection). These professionals argue that guidelines can never capture the complexity of treating individual patients. They produce a false sense of collective professional control over healthcare decision-making and impede the role of individual professionals; which is to weigh evidence, next to clinical experience and patients’ needs and wishes, with patients and in the counselling room.

#### 4.8. The professional other

The fact that ‘professional others’ use professional guidelines to inform their actor-specific actions further complicates the situation. Such use is problematised by both professionals and representatives of professional organisations that engage in guideline development.

*‘What I find problematic is that many healthcare actors see guidelines as “this is the way things need to be done and when you don’t do it like that it is wrong”. The Inspectorate for instance talks about norms. In that phrasing already lies a very different meaning attached to guidelines.’* (Representative of a knowledge institute, interview, 2016)

*‘The problem is that insurers use insights derived from averages of populations to measure the quality of care delivered to individual patients.’* (Internist, focus group, 2016)

In abovementioned quotes, a precarious tension is articulated between: (a) the way in which professionals translate professional guidelines to the context of individual patients; and (b) the way in which insurers and inspectorates use such guidelines to determine

whether the care that has been provided to individual patients is in line with the uniform agreements made. For most interviewed professionals, it is here that professional guidelines, useful for tinkering in the treatment for and with individual patients, consolidate into rigid norms.

#### 4.9. Concluding remarks part 2

In the discussion on EBM, a distinction is drawn between the (ideal typical) patient-centred individual professional and the (problem typical) standardisation-centred professional other. Whether this professional other is a health insurer, health inspectorate, or professional organisation does not really matter. What matters to those that problematise EBM is that clinical epidemiological evidence is reductionist and needs to be contextualised. At the same time, the counselling room is furthered as the site where such contextualisation should take place. In the next section, we discuss why this line of reasoning needs scrutiny.

##### **Part 3: who decides based on what?**

It is important to underline that other actors involved in the governance of care do not disagree with healthcare professionals that clinical epidemiological evidence needs to be interpreted and contextualised. In fact, most actors involved seem to interpret and contextualise such evidence themselves, albeit in and on their own terms (first empirical subsection). The issues raised above therefore do not seem to be about whether clinical epidemiological evidence should be interpreted and contextualised, but rather about *who* should interpret and contextualise such evidence and *how*.

For most professionals that engage in the EBM discussion, the question who should interpret clinical epidemiological evidence is easily answered:

*‘Health insurers should not be able to say: “there is no evidence for this so we do not pay”. We sit in the counselling room not them. . . Insurers should not determine, only pay.’* (Gynecologist, interview, 2017)

In the Netherlands, after the introduction of the Health Insurance Act in 2006, health insurers are formally given the role to represent their insured (patients) in negotiations with professionals about the price and quality of care. However, neither professionals nor insurers act as independent negotiators. Professionals are deemed by inspectorates to live-up to the uniform agreements presented in guidelines developed by professional organisations. Insurers are obliged to insure care included in the ‘basic healthcare agreement’. In this context, evidence-informed healthcare decisions are no longer under control of either professionals, insurers, patients or the state. Instead healthcare decision-making has become fragmented and dynamic, influencing – and being influenced by – actors in different spheres [10].

This creates direct tensions between actors involved about how to interpret and contextualise clinical epidemiological evidence and about the consequences of such interpretations.

*‘We just had a discussion with the Dutch Healthcare Institute about fertility preservation. . . There is this professional guideline that says it is considered good care when you discuss this and that with patients and when you decide to freeze an ovary. Putting it back, however, is considered another treatment. A process for later. So far, 70 children have been born by a replaced ovary. We thus see that it is possible. But the Dutch Healthcare Institute still considers it experimental [in other words, the clinical epidemiological evidence for this treatment is not yet conclusive]. Hence, it is not considered insured care. It feels so wrong that the professional guideline considers it good care, but the Dutch Healthcare Institute does not recognise it as such. It makes me mad and I think it is terrible.’* (Gynaecologist, interview, 2016)

In abovementioned example, the Dutch Healthcare Institute relates to EBM's evidence hierarchy in order to make a binary decision that counts for all Dutch citizens; the exclusion of a treatment from the basic healthcare agreement due to limited and low graded evidence [24]. Of key concern is that this interpretation of evidence by the Institute differs from – yet does have consequences for – the evidence-informed actions of professionals in the counselling room. These professionals want to interpret the evidence that does exist in the context of an individual patient. However, this becomes impossible because the basic healthcare agreement prescribes what insurers should consider insured care. Professionals, in turn, can hardly recommend treatments that are not covered by health insurers. In the Dutch governance of care, the evidence-informed decisions of some actors can thus exclude the evidence-informed actions of other actors.

It is in response to the above that many professionals problematise EBM's reductionist epistemology and stress the importance of contextualising clinical epidemiological evidence. However, we would like to point out that the problem with EBM in abovementioned example is not necessarily a lack of contextualisation. Rather, the problem is that interdependent actors interpret and contextualise clinical epidemiological evidence in very different ways. Professionals interpret such evidence in the context of the situation of an individual patient; the Dutch Healthcare Institute interprets such evidence in the context of policymaking on the level of the Dutch population. Importantly, when clinical epidemiological evidence is contextualised on the level of the Dutch population, such contextualisation is not necessarily a remedy to EBM's reductionism. After all, in the latter case, reductions are placed in the context of other reductions (e.g. 'general consensus' or 'the patient perspective'). As we pointed out previously, this not only happens on the level of policymaking, but also in guideline development and in negotiations between health insurers and healthcare providers.

## 5. Discussion

In this paper, we formulated the following research question: *How and by whom has the role of EBM in healthcare decision-making been problematised and why is that the case?* We took the Netherlands as our case study. We observed that EBM informs the practices of a variety of actors, operating on different levels (Fig. 1). We furthermore observed that each of these actors underlines the importance of contextualising clinical epidemiological evidence. They contextualise such evidence within their own organisations (from the counselling room to policy offices), according to specific methodologies (from critical appraisal to systematic assessments) and in relation to actor specific objectives and responsibilities (from crafting individual treatment plans to proposing national policies). We however also observed that in a layered healthcare system, the contextualisation of evidence by one actor can limit the ways in which other actors are able to contextualise such evidence. We argue this is an important reason why EBM has been problematised in Dutch healthcare governance and why a division emerged between an 'us professionals and critical interpreters of evidence' versus 'them professional others and naïve users of evidence' [8]. In this light, the Dutch EBM discussion not only concerns the value of clinical epidemiological evidence, but also concerns who should be considered a legitimate actor to make evidence-informed healthcare decisions [13].

Based on the abovementioned observations, we challenge some dominant claims made in the Dutch EBM discussion, as well as in the international medical literature. Emphasis is often placed on the facts that: a) clinical epidemiological evidence is reductionist [25];

b) that such evidence should therefore always be contextualised [6]; and c) that this no longer happens because professional others have adopted EBM uncritically and place constraints on individual professionals to contextualise such evidence in the counselling room [4]. The main issue we want to address in this line of reasoning has to do with step c. As we revealed, clinical epidemiological evidence is interpreted and contextualised on different levels, by different actors and in the context of a great many things; ranging from patients' individual needs and wishes, to quality and safety, healthcare expenditures and the protection of a collectively financed healthcare system. Classifying EBM as a reductionist approach might thus be epistemologically sound and calling for contextualisation might be a logical response. However, such calls for contextualising are not enough to resolve the current tensions that have emerged around evidence-informed decision-making. In fact, most actors agree that EBM is a reductionist approach and that clinical epidemiological evidence needs to be contextualised; but they all do so in and on their own terms. The contextualisation of EBM is therefore not absent. Rather, it is all over the place.

Our inquiry into EBM's problematisation has three important limitations. Firstly, by focussing on the use of clinical epidemiological evidence in healthcare decision-making, we ignore the process in which such evidence is produced. Different scholars have however critically discussed how a plethora of actors participate in and influence this process (e.g. pharmacists and professional experts [26,27]). The clinical epidemiological evidence used in healthcare decision-making should therefore not be considered absolute, objective or neutral (before the politics of contextualising [28]). Secondly, the actors that feature in this paper do not represent homogenous groups. Amongst healthcare professionals – and within the healthcare organisations discussed – deliberations exist about the ways in which evidence should be interpreted [29]. In the EBM discussion, however, such nuances are often backgrounded whilst more clear-cut divisions between 'us' critical interpreters versus 'them' naïve users are foregrounded (see also part two of our results section). Thirdly, we base our analysis on respondents that actively engaged in the EBM discussion. Therefore, not all actors that use EBM in healthcare decision-making are included. Examples missing are the Dutch Ministry of Health and individual patients. We chose to focus on those that engaged in the discussion because it allowed us to identify the strategic relations part and parcel of EBM's problematisation [9]. Nevertheless, we recognise that not participating in the discussion could also be a strategic choice. For instance, following the principles of market regulation and recognising the complexity of the problem, the Ministry could have avoided getting involved, leaving the discussion up to those that engage with one another on this regulated healthcare market. Important examples are professionals, health insurers and those semi-governmental organisations overseeing their conduct (Fig. 1). It is interesting to consider such strategies of non-engagement in future studies into the politics behind EBM's problematisation.

Comparative analyses are another interesting direction to further explore EBM's problematisation and a politics of contextualising clinical epidemiological evidence. Many Western healthcare systems consist of layered regulatory frameworks [10] and a plethora of interdependent actors that relate to such frameworks as well as EBM [12]. In most of these systems, EBM has been problematised [1,4,17]. In this light, it is important to assess whether and how a politics of contextualising exists in these systems and the consequences this has for actor-relations and evidence-informed decision-making. Such insights are important, we argue, because they will deepen our understanding of system specific relations that have fuelled a rather system non-specific (read international) EBM discussion.

## 6. Conclusions

EBM is particularly problematised in a medical and scientific register. However, we argue that the discussion is actually fuelled by: I) tensions between individual and public needs; II) the layering of institutional arrangements that have been introduced to deal with such tensions; and III) the differences between actors and their idiosyncratic roles and positions presumed and legitimised by such layered arrangements as well as clinical epidemiological evidence [10,11]. This makes the EBM discussion not just a professional affair, but rather a question of governance. We therefore urge policymakers and public administration scholars to take the EBM discussion seriously and to start scrutinising the layering of healthcare systems and the ways in which such layers shape evidence-informed healthcare decision-making. We furthermore urge healthcare professionals to take the EBM discussion beyond their counselling rooms and open-up to a broader discussion about the role of clinical epidemiological evidence in layered healthcare systems [1,17].

## Declaration of Competing Interest

This work was financially supported by the 'Vereniging van Artsen Automobilisten' (VvAA), a member organisation and insurer for healthcare professionals in the Netherlands. The data used in this paper has been gathered during the development of a policy advice by the 'Raad voor de Volksgezondheid en Samenleving (RVenS). See further, materials and methods section.

## Acknowledgements

We thank our colleagues that attended the ESHPM Health Care Governance meeting (29 January 2018) for their constructive feedback. Special thanks go to Robert Borst, who was willing to act as a discussant.

## References

- Berwick DM. Era 3 for medicine and healthcare. *JAMA* 2016;315:1329–30, <http://dx.doi.org/10.1001/jama.2016.1509>.
- Sackett DL, Rosenberg WM, Gray JM, Haynes RB, Richardson WS. Evidence based medicine: what it is and what it isn't. *BMJ* 1996;312:71–2, <http://dx.doi.org/10.1136/bmj.312.7023.71>.
- Timmermans S, Berg M. *The gold standard. The challenge of evidence*. Philadelphia: Temple University Press; 2003.
- Greenhalgh T, Howick J, Maskrey N. Evidence based medicine: a movement in crisis? *BMJ* 2014;348:1–7, <http://dx.doi.org/10.1136/bmj.g3725>.
- Berlin JA, Golub RM. Meta-analysis as evidence: building a better pyramid. *JAMA* 2014;312:603–5, <http://dx.doi.org/10.1001/jama.2014.8167>.
- Hargraves I, Kunneman M, Brito JP, Montori VM. Caring with evidence based medicine. *BMJ* 2016;353:1–2, <http://dx.doi.org/10.1136/bmj.i3530>.
- Mol BW, Evers H, Medisch Contact 06-07-2017 Er is maar een werkelijkheid: RVenS-rapport tornt aan het gelijk van evidence based medicine; 2017.
- Mouffe C. *On the political*. London: Routledge; 2005.
- Bacchi C. Why study problematizations? Making politics visible. *Open Journal of Political Science* 2012;2:1–8, <http://dx.doi.org/10.4236/ojps.2012.21001>.
- van de Bovenkamp HM, De Mul M, Quartz JG, Weggelaar-Jansen JWM, Marie A, Bal R. Institutional layering in governing healthcare quality. *Public Administration* 2014;92:208–23, <http://dx.doi.org/10.1111/padm.12052>.
- Felder M, van de Bovenkamp HM, Maaijen MM, de Bont AA. Together alone: organizing integrated, patient-centered primary care in the layered institutional context of Dutch healthcare governance. *Journal of Professions and Organization* 2018;5(2):88–105, <http://dx.doi.org/10.1093/jpo/joy006>.
- Lascombes P, Le Galès P. Introduction: understanding public policy through its instruments - from the nature of instruments to the sociology of public policy instrumentation. *Governance* 2007;20(1):1–21, <http://dx.doi.org/10.1111/j.1468-0491.2007.00342.x>.
- Deacon R. *Theory as practice: Foucault's concept of problematization*. *Telos* 2000;2000:127–42.
- Flynn TR. *Sartre, Foucault, and historical reason, volume two: a poststructuralist mapping of history*. Chicago: University of Chicago Press; 2005.
- Halfman W. *Boundaries of regulatory science*. Amsterdam: Universiteit van Amsterdam; 2003.
- Voß JP, Freeman R, editors. *Knowing governance: the epistemic construction of political order*. Basingstoke: Palgrave Macmillan; 2016.
- Tovey D, Churchill R, Bero L. Evidence based medicine: looking forward and building on what we have learnt. *BMJ* 2014;349:1, <http://dx.doi.org/10.1136/bmj.g4508>.
- Freidson E. *The professions and their prospects*. Thousand Oaks: Sage; 1973.
- Helderma JK, Schut FT, van der Grinten TE, van de Ven WP. Market-oriented health care reforms and policy learning in the Netherlands. *Journal of Health Politics, Policy and Law* 2005;30:189–210, <http://dx.doi.org/10.1215/03616878-30-1-2-189>.
- RVenS, RVenS The Hague No evidence without context: about the illusion of evidence-based practice in healthcare; 2017. Retrieved from: <https://www.raadrsv.nl/documenten/publicaties/2017/06/19/zonder-context-geen-bewijs>.
- van de Bovenkamp HM, Zuiderent-Jerak T. An empirical study of patient participation in guideline development: exploring the potential for articulating patient knowledge in evidence-based epistemic settings. *Health Expectations* 2015;18:942–55, <http://dx.doi.org/10.1111/hex.12067>.
- The Dutch Healthcare Institute. *Beoordeling stand van de wetenschap en praktijk: definitieve actuele versie 2015*. Diemen: Zorginstituut Nederland; 2015. Retrieved from: <https://www.zorginstituutnederland.nl/publicaties/rapport/2015/01/15/beoordeling-stand-van-de-wetenschap-en-praktijk>.
- McCartney M, Treadwell J, Maskrey N, Lehman R. Making evidence based medicine work for individual patients. *BMJ* 2016;353:1–6, <http://dx.doi.org/10.1136/bmj.i2452>.
- Guyatt G, Oxman AD, Akl EA, Kunz R, Vist G, Brozek J, et al. GRADE guidelines: 1. Introduction - GRADE evidence profiles and summary of findings tables. *Journal of Clinical Epidemiology* 2011;64:383–94, <http://dx.doi.org/10.1016/j.jclinepi.2010.04.026>.
- Bolt T, Huisman F. Evidence-based medicine in crisis? Een historisch commentaar op een actueel debat. *Tijdschrift voor Gezondheidszorg en Ethiek* 2015;25:102–7.
- Keating P, Cambrosio A. Who's minding the data? Data monitoring committees in clinical cancer trials. *Sociology of Health & Illness* 2009;31(3):325–42, <http://dx.doi.org/10.1111/j.1467-9566.2008.01136.x>.
- Bothwell LE, Greene JA, Podolsky SH, Jones DS. Assessing the gold standard - lessons from the history of RCTs. *New England Journal of Medicine* 2016;374(22):2175–81.
- Bal R. Evidence-based policy als reflexieve praktijk. Wat kunnen we leren van evidence-based medicine? *Tijdschrift voor Gezondheidszorg en Ethiek* 2015;25(4):108–13.
- Kleinhou-Vliek T, de Bont A, Boer B. The bare necessities? A realist review of necessity argumentations used in health care coverage decisions. *Health Policy* 2017;121(7):731–44, <http://dx.doi.org/10.1016/j.healthpol.2017.04.011>.

**Martijn Felder** is Assistant Professor; he focuses on changing roles of professionals and patients in the context of institutional change.

**Hester van de Bovenkamp** is Associate Professor; she focuses on patient and citizen participation and representation in healthcare decision-making.

**Willem Jan Meerding** is Senior Advisor; he focuses on policymaking in the fields of healthcare and social work.

**Antoinette de Bont** is Professor in Sociology of Innovation in Healthcare; she focuses on the interdependencies between people and technologies in the context of healthcare innovation.