

# Importing Notions in Health Law: *Science and Proven Experience*

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## Abstract

In Swedish law, the notion of 'science and proven experience' (in Swedish, *vetenskap och beprövad erfarenhet*) defines the gold standard for public decision-making and practice, especially in medicine. The notion is notoriously vague but nevertheless plays an important role in the distribution of rights and duties of patients and health-care workers. For example, failure to provide care in accordance with this standard can lead to penal responsibility. The notion also helps to define Swedish patients' right to reimbursement for cross-border healthcare. From a legal point of view, the notion is especially intriguing because it appears to import medical standards into the legal conceptual apparatus. The purpose of this article is to explore the mechanisms of this and kindred 'importing notions' by investigating the role that the notion of science and proven experience plays in Swedish law and in the transfer of information between the legal and medical fields.

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## Keywords

cross-border healthcare – evidence – law and medicine – professional standards – science and proven experience – scientific expertise

### 1 Introduction: Importing Notions

In Swedish law, the notion of ‘science and proven experience’ (in Swedish, *vetenskap och beprövad erfarenhet*) defines the gold standard for public decision-making and practice, especially in healthcare.<sup>1</sup> Healthcare workers who do not provide care in accordance with scientific evidence and proven experience can be criticised by the Health and Social Care Inspectorate,<sup>2</sup> and even be held responsible in penal law.<sup>3</sup> The notion also serves an important role in defining the patient’s freedom of choice of treatments in Sweden,<sup>4</sup> and her right to reimbursement for expenses associated with treatments in other European countries.<sup>5</sup>

From a legal point of view, the medico-legal notion of science and proven experience is intriguing because it refers to scientific/medical practices in defining thresholds for legally acceptable measures in healthcare. Now, it is not unusual for legal notions to refer to something external to the law — in fact, most legal notions (such as ‘property’ and ‘damage’) do this. Nor is it unusual for legal notions to set standards of acceptable behaviour — some of the law’s most fundamental notions (such as ‘negligence’ and ‘intent’) do this. What is so puzzling about the notion of science and proven experience (and kindred notions such as ‘professional standards’, ‘proper medical treatment’, ‘medical necessity’ ‘normal in the professional circles concerned’ and ‘scientific evidence’) is rather that it builds a bridge between law and medicine through which medical *standards* appear to be imported into the legal conceptual apparatus. This means that medical standards and customs provide the legal notion with

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1 Official documents commonly translate this distinctly Swedish notion as ‘science and proven experience’.

2 Patient Safety Act (2010:659), chapter 8.

3 Penal Code (1962:700).

4 Patient Act (2014: 821), chapter 7, section 1; Health and Medical Services Act (1982:763) sections 3a and 18a.

5 Act on reimbursement for expenses associated with cross-border healthcare (2013:513), section 5; Govt. Bill 2012/13:150, p. 51.

meaning and turn into law. In this article we refer to legal notions that have this function as *importing notions*.

It is to be expected that importing notions will give rise to complicated dynamics, and potentially to normative conflicts between the importing and the imported system(s). Whereas the meanings of most legal notions (such as 'property', 'damage', 'negligence' and 'intent') are shaped by legal norms, the meaning of an importing notion like that of science and proven experience is by definition shaped by the norms of the imported system(s), or so it seems. Despite the practical and theoretical problems that notions of this kind give rise to, the mechanisms at work in importing notions have attracted surprisingly little attention. The Swedish notion of science and proven experience appears to be particularly well suited to provide a case study of importing notions and the dynamics they give rise to: First, it operates at the interface of law and medicine, and this interface is notorious for giving rise to epistemic and normative clashes. Second, it occurs in several legal rules of different kinds. And third, the notion combines two domains (*science* and *proven experience*), which appear to be largely independent, and it therefore refers to two potentially competing standards. Moreover, although both standards appear to lack an established meaning in the medical field, the notion of science and proven experience (*vetenskap och beprövad erfarenhet*) is used not only by lawyers but also by medical professionals.

The purpose of this article is to explore the mechanisms of importing notions by investigating the role that the notion of science and proven experience plays in Swedish law and in the transfer of information between the legal and medical fields. Drawing on insights from philosophy of science we will analyse examples from case law and discussions in legal and medical doctrine. We will argue that legal notions like that of science and proven experience are importing in a weak sense only. Like other legal notions, importing notions are there to serve legal purposes. Hence the meaning of these notions is necessarily relative to legal purpose. This means the difficult task of clarifying the legal meaning of these notions cannot be avoided on the basis that other disciplines define their content.

The way medical law conceives of importing legal notions has bearing on most, if not all, questions about the legal acceptability of medical measures. This is so irrespective of whether the question is concerned with the legal space for new medical treatments,<sup>6</sup> relates to the potential negligence of a

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6 L. Wahlberg and N.-E. Sahlin, 'Om icke vedertagna behandlingsmetoder och kravet på vetenskap och beprövad erfarenhet', *Förvaltningsrättslig tidskrift* 2017, forthcoming.

particular physician's actions,<sup>7</sup> or asks whether a treatment would have been part of a Member State's benefit basket, had the treatment been provided in that State.<sup>8</sup> Moreover, the mechanisms of value- and context-relativity that underlie importing legal notions have bearing on an even wider range of issues, including the legitimacy of patient empowerment initiatives which, like the European Patient Academy,<sup>9</sup> aim to increase patient involvement in Health Technology Assessments.<sup>10</sup>

In the final part of the paper, we will use examples from Swedish case law on the right to compensation for cross-border healthcare to show that failure to address the proper function of importing legal notions can hamper the effectiveness of the legal instruments in which these notions occur. This example strengthens our conclusion that as long as the legal meanings of importing legal notions like 'science and proven experience' remain unclear there is a significant risk that these notions cannot be put to meaningful use.

## 2 'Science and Proven Experience' as a Medico-legal Vehicle of Communication

The medical experts who are called upon to help the courts to assess whether a certain treatment is supported by science and proven experience often make explicit use of the notion to communicate their opinions. Here are two typical examples:<sup>11</sup>

The investigation in Germany is complicated and risky, and is not consonant with science and proven experience.<sup>12</sup>

Available medical scientific data and the proven experience of numerous IVF-clinics do not support the claim that her age by itself has significantly decreased her chances of successful treatment.<sup>13</sup>

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7 See section 7 *infra*.

8 Article 13, Directive 2011/24/EU of the European Parliament and of the Council of 9 March 2011 on the application of patients' rights in cross-border healthcare. See sections 7 and 9 *infra*.

9 See online at <https://www.eupati.eu>, visited 16 December 2016.

10 See Section 7 *infra*.

11 All translations from Swedish to English are our own.

12 Neurosurgeon heard by Gothenburg Administrative Court of Appeal, case no 2817-07.

13 Obstetrician heard by the Court of Appeal in Sundsvall, case no 1207-08.

The notion of science and proven experience is also deployed in investigations that were initiated and carried out independently of the cases in which they have come to serve as evidence. Here is one example, in which the Swedish National Board of Health and Welfare is making a recommendation about the appropriate scientific evidence for certain surgical interventions — a recommendation which several legal decisions later quoted:

The National Board of Health and Welfare and the Swedish Council on Health Technology Assessment come to the conclusion that the scientific documentation needs to be improved to allow assessment of whether the treatments are consonant with science and proven experience.<sup>14</sup>

Likewise, lawyers make use of the notion when they ask medical experts to state their opinions. This is illustrated by our next example, in which the prosecutor asks the expert — who has already assessed a treatment using other terms — to state additionally whether the treatment is in keeping with science and proven experience:

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Prosecutor:       And how did it accord, then, with science and proven experience to do this?

Medical expert:   You . . . that's what you mentioned.

Prosecutor:       Umm . . . Umm, but what is your conclusion?

Medical expert:   I think that it was not in accordance with science and proven experience.

Prosecutor:       No . . . And was it a minor or a major deviation?

Medical expert:   I have difficulties estimating that, I must admit.<sup>a</sup>

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a Examination of expert witness in case B 417-12, Eksjö District Court. The dialogue is available online at <http://sverigesradio.se/sida/artikel.aspx?programid=91&artikel=5800801>, accessed 8 July 2016.

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14 Socialstyrelsen, *Förutsättningar för en svensk utvärdering av kirurgisk behandling vid långvariga besvär efter whiplashvåld* (Stockholm, Socialstyrelsen, 2007) p. 6, quoted by e.g. Göteborg Administrative Court of Appeal, *supra* note 7; and Jönköping Administrative Court of Appeal, case no 3501-08.

In these and similar cases the notion of science and proven experience is used as a vehicle of communication between the courts and medical experts. It is important to see that a medical expert's opinion on whether a treatment accords or fails to accord with science and proven experience is a function not only of her assessment of the treatment's evidential support, *but also* of her understanding of the phrase 'science and proven experience'.

### 3 The Indeterminate Legal Notion

We have seen that the notion of science and proven experience appears in various rules in Swedish law and is employed in court by both jurists and medical experts. The frequent use of the notion in Swedish law is also illustrated by the fact that the term (*vetenskap och beprövad erfarenhet*) generates more than 4000 hits in the case law Infotorg database. This can be compared with the less than 1400 hits generated by the well-known legal term 'adequate causation' (*adekvat kausalitet*). Yet, as we shall see in this section, surprisingly little has been said about the legal meaning of 'science and proven experience'.

The notion was, as far as we know, first put to legal use in a Royal Decree governing the work of medical doctors in the 1890s.

Each physician, whether he be an employee at an institution or an independent practitioner of the medical profession, is obliged, as his chief duty, to deliver such counsel, and, as far as circumstances permit, to extend such therapeutic endeavours, to every patient under his care as are necessitated by the patient's condition and as are consonant with science and proven experience.<sup>15</sup>

Since 1994,<sup>16</sup> not only doctors but all health and medical care personnel have been under an obligation to conduct their work in accordance with this standard. Today, the Patient Act states that "The patient shall be delivered competent and careful health and medical care, which is of good quality and

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15 D. M. Pontin, *Författningar m.m. angående medicinalväsendet i Sverige, omfattande år 1890* (Stockholm: P.A. Norstedt & Söner, 1891) § 59. 'Hvarje läkare, antingen han er i tjenst anställd eller enskildt meddelar läkarevård, åligger: 1:o att åt sjuk, som af honom vårdas, meddela de råd och, så vidt möjligt är, egna den behandling, som den sjukets tillstånd fordrar och som med vetenskap och beprövad erfarenhet öfverensstämmer'.

16 Act (1994:953) on the obligations of healthcare workers (annulled and today replaced by the Patient Safety Act, *supra* note 2).

consonant with science and proven experience”,<sup>17</sup> and the Patient Safety Act prescribes that “Health care and medical personnel shall conduct their work in a way that is consonant with science and proven experience”,<sup>18</sup>

The acts that use the notion are identical in respect of how they define ‘science and proven experience’. That is: **Not at all**. Nor are the few attempts at clarification made in preparatory works of much guidance: The government bill preceding the 1994 act states that the standard implies that healthcare workers must ensure that they are *up to date* in their fields and follow guidelines from the National Board on Health and Welfare.<sup>19</sup> The bill also refers to a letter from the National Board on Health and Welfare to a Swedish physician in 1976. In the letter, the Board declared that *both science and* proven experience must be taken into account, but it also stated that one of the two could be sufficient when the other is lacking:

The requirement consists in the demand that the medical doctor, in the exercise of his or her profession, is bound to take account of both science and proven experience. The legal text thus implies an ‘and’ — not an ‘either . . . or’. At the time, for example, at which a new method is introduced, proven experience of it is trivially lacking, and the scientific evidence has to suffice for the decision to accept the method. . . . At other times, long clinical experience might be the dominant evidence in favour of accepting the medical treatment, whereas theoretical and/or experimental evidence for its effectiveness might be lacking.<sup>20</sup>

The government bill preceding the recent act on rights to reimbursement for costs associated with treatments in other European countries states that to determine whether a treatment accords with science and proven experience it is not sufficient to consider the treatment as such; the treatment must also be deemed relevant in the particular case.<sup>21</sup> (It is possible, but not certain, that this statement is meant to imply that the treatment as such must be in accordance with science, and that the relevance in each case must be determined with reference to proven experience.) Science, the bill continues, is typically conceived of as knowledge that has been systematically and methodologically

17 Patient Act, *supra* note 4, chapter 1, section 7.

18 Patient Safety Act, *supra* note 2, chapter 6, section 1.

19 Govt. Bill 1993/94:149 p. 65.

20 *Ibid.*

21 Govt. Bill 2012/13:150 p. 52.

obtained in a particular field. What proven experience is, however, the bill does not say.

The fact that the notion is also used outside the health law context makes its meaning even more difficult to pinpoint. Today, the notion of science and proven experience appears in various regulations on education, social work, veterinary care, and so on. Moreover, it has become part of the everyday vocabulary of medical practitioners, where it tends to lead a life of its own. Hence, 'science and proven experience' is not only an importing notion, which appears to import non-legal standards and turns them into law; it is also what Brooks et al. call a 'migrating concept'.<sup>22</sup>

Characteristically, migrating concepts acquire different meanings in the various fields in which they occur. For example, in the regulations applying to the Swedish educational system both 'science' and 'proven experience' are interpreted in a manner that cannot — obviously, at least — be taken for granted in other legal contexts such as healthcare and medicine. In fact, guidance from the authorities on how the notion is to be understood at a conceptual level is much more common in the educational context than it is in the medical context.

In the context of schools and higher education the relevant authorities interpret 'science' in terms of 'critically evaluate, test, and put individual facts into context', whereas 'proven experience' is partly made precise in terms of 'documented, shared, and evaluated in a collegial context'.<sup>23</sup>

It is not evident that the notion is (or should be) interpreted in a similar way in healthcare regulation, since its meaning would appear to depend on the history and nature of the professions themselves.

The notion also has several distinct functions *within* the legal regulation of healthcare. As we have seen, it not only defines the responsibilities of healthcare workers in both criminal and administrative law, but also serves to demarcate patients' freedom to choose treatment in Sweden and rights to reimbursement for expenses associated with cross-border healthcare. It cannot be assumed in advance that the meaning of the notion remains the same in each of these healthcare contexts. However, despite this, legal practitioners

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22 R. O. Brooks, R. Jones and R. A. Virginia, *Law and Ecology: The Rise of the Ecosystem Regime* (Aldershot: Ashgate, 2002).

23 Högskoleverket, *Uppföljande utvärdering av lärarytbildningen. Högskoleverkets rapportserie* (Stockholm: Högskoleverket, 2008), Skolverket, *Forskning för klassrummet: Vetenskaplig grund och beprövad erfarenhet i praktiken* (Stockholm: Skolverket, 2013).



and academics appear to be very reluctant to define ‘science and proven experience’. The contrast between the very limited legal discussion of the meaning of this notion and the significant efforts that have been made to clarify other important legal notions such as ‘adequate causation’ is striking. It has been said that the legal notion of science and proven experience has a dynamic character, that the legal notion must not be given a meaning that fails to correspond to its medical/odontological meaning, and added that it is fruitless to define the legal notion further.<sup>24</sup>

#### 4 Are Importing Notions Devoid of Legal Content?

What has now been said could be taken to mean that the legal notion of science and proven experience is devoid of legal content and entirely determined by medical standards. If this is the case, the notion is importing in a very strong sense: Its meaning is entirely determined by a non-legal field and immune from legal considerations. Indeed, this was explicitly assumed in a recent official report by the Swedish government. The report (SOU 2014:91 p.196) stated: ‘Medical science decides what is consonant with science and proven experience. The notion does not have any specific legal content; its meaning is known only by representatives of the medical disciplines’.

The Swedish report is by no means unique. In legal texts there are many examples of statements that assume a similarly strong importing function of kindred legal notions. For example, in the well-known English case *Bolam v. Friern Hospital Management Committee* [1957] 1 *W.L.R.* 582, McNair J, in instructing the jury, famously defined ‘professional standards’ in terms of ‘a practice accepted as proper by a responsible body of medical men skilled in that particular art’. This instruction is generally interpreted as saying that the meaning of the legal standard of care in medical malpractice cases is set by medical doctors, not the courts.<sup>25</sup> In other contexts, but in a similar vein, it has been contended that courts must respect scientific standards when assessing scientific evidence.

24 L. Westerhäll, *Den svenska socialrätten* (Stockholm: Norstedt, 1990). See also E. Rynning, *Samtycke till medicinsk vård och behandling. En rättsvetenskaplig studie* (Uppsala: Iustus Förlag, 1994) and E. Axelsson, *Patientsäkerhet och kvalitetssäkring i svensk hälso- och sjukvård. En medicinrättslig studie* (Uppsala: Iustus Förlag, 2011). Cf. J. Garland, *On Science, Law and Medicine: The Case of Gender-“Normalizing” Interventions on Children Who Are Diagnosed as Different in Sex Development* (Uppsala: Uppsala universitet, 2016).

25 E. Jackson, *Medical Law: Text, Cases and Materials* (Oxford: Oxford University Press, 2016) p. 132.

For example, it has been argued that ‘the law should seek verdicts consistent with scientific reality [...] and it can achieve this goal only by requiring scientific evidence to conform to the standards and criteria to which scientists themselves adhere.’<sup>26</sup>

Plausibly, it is a consequence of the assumption that importing legal notions such as ‘science and proven experience’ are devoid of legal content and have meanings entirely determined by professionals in the disciplinary fields to which they refer, that it would be misguided to question or modify the relevant professionals’ interpretations of these notions from a legal point of view. Later in this article, however, we will argue that the view that importing notions are devoid of legal content, and importing in a strong sense, is mistaken.

## 5 Bilateral Problem-Feeding

As we continue our analysis of the importing function of the legal notion of science and proven experience we shall make use of a model of transfer between disciplinary fields that is sometimes applied in philosophy of science and science studies. Interdisciplinary problem solving, it is often claimed, requires those who undertake it to bridge the disciplinary differences between the standards used when selecting relevant problems and the standards used to evaluate potential solutions to relevant problems.<sup>27</sup> The notion of bilateral problem-feeding<sup>28</sup> is designed to account for situations where a problem is formulated in one field (where it cannot be solved) and exported to another field (where it can be solved), with the solution being transferred eventually back to the original field. This is essentially what takes place when a court asks a medical expert to assist in determining whether a measure accorded with science and proven experience. A great deal can happen during this process.

26 B. Black, ‘Evolving Legal Standards for the Admissibility of Scientific Evidence’, *Science*, 239 (1988) 1508-1512, DOI: 10.1126/science.3281252.

27 M. Goddixsen and H. Andersen, ‘Expertise in Interdisciplinary Science and Education’, *PhilSci Archive* 2014; G. Öberg, ‘Facilitating Interdisciplinary Work: Using Quality Assessment to Create Common Ground’, *Higher Education* 57(4) (2009) 405-415, DOI:10.1007/s10734-008-9147-z; M. Borrego and L.K. Newswander, ‘Definitions of Interdisciplinary Research: Toward Graduate-Level Interdisciplinary Learning Outcomes’, *The Review of Higher Education* 34(1) (2010) 61-84, DOI: 10.1353/rhe.2010.0006.

28 H. Thorén and J. Persson, ‘The Philosophy of Interdisciplinarity: Sustainability Science and Problem-Feeding’, *Journal for General Philosophy of Science* 44(2) (2013) 337-355, DOI: 10.1007/s10838-013-9233-5.

Successful bilateral problem-feeding requires problem stability, but solution stability is also important for the success of the process.

Strongly importing notions, it seems to us, presuppose the idea of bilateral problem-feeding. In fact, they seem to establish the link through which bilateral problem-feeding is supposed to occur. The simplest form in which such a process would take place, we would argue, would be the following:

Problem(law): Is  $X$  in accordance with  $Y$  (i.e. science and proven experience)?

Problem(medicine): Is  $X^*$  in accordance with  $Y^*$ ?

Solution(medicine): Yes,  $X^*$  is in accordance with  $Y^*$

Solution(law): Yes,  $X$  is in accordance with  $Y$

In the ideal case: 1)  $X$  is the same as  $X^*$ , and is accepted as such in the four steps above; 2)  $Y$  is the same as  $Y^*$ , and is accepted as such in the four steps above; 3) medicine reliably produces the answer; and 4) the law accepts the answer. 1)-4) are prerequisites of bilateral problem-feeding.

Bilateral problem-feeding, we think, provides a useful model which enables us to understand importing notions. In saying this we do not claim, however, that importing notions have to work through processes of bilateral problem-feeding. Nor, of course, do we claim that the existence of what appears to be an importing notion in one field guarantees that bilateral problem-feeding is in fact possible between this field and the intended problem-solving field.

Expressions such as ‘science and proven experience’ which appear to have an importing function might give rise to problems and conflicts within and between the fields which the notion aims to connect. In the potentially ideal case we sketched above, problems might occur in each of steps 1)-4). In 1) the issues that might arise have to do with whether that which is subject to law is understood in the same way in the problem-solving field. In 2) the law and medicine might interpret ‘science and proven experience’ differently — when it comes either to the expression’s meaning or its extension. In 3) a problem similar to that in 2) arises. In 4) there is a risk that the law will disregard relevant medical information. Granted that medical science reliably produces an answer to the question whether or not something accords with medical science, there remains a question about whether that science can, equally reliably, adjudicate on accordance with proven experience.

In the discussion that follows we will focus on problems raised by the second step of bilateral problem-feeding. If we accept that notions like that of science and proven experience are importing in a strong sense, then step 2 in the scheme above appears unproblematic. For if medical standards determine

the legal meaning of 'science and proven experience', Y will equate with Y\* by definition. If, on the other hand, the legal notion of science and proven experience is not importing in a strong sense, and if, therefore, legal considerations might have a bearing on the meaning that the notion possesses in law, there is an obvious risk that Y (the legal notion) will not equate with Y\* (the medical notion). Whether notions like 'science and proven experience' indeed are importing in a strong sense is therefore a question of critical importance.

In the following sections, we will present two arguments which challenge the assumption that the notion of science and proven experience is importing in a strong sense. The first of these arguments is that there is no univocal meaning of 'science and proven experience' in the medical domain. Hence, there is no obvious candidate for Y\* for the legal notion to import. The second argument is that, even if there were such univocity, the legal meaning of the notion could not — and should not — be reduced to its medical meaning. If we are right about this, and if the legal notion of science and proven experience is *not* importing in a strong sense, there is an urgent need to recognize and address the problems that might arise in the second step of bi-lateral problem feeding when the notion of science and proven experience is put to use in medico-legal communications. Finally, we will give some current examples from case law which, in our view, provide convincing evidence that there is a real need for further discussion of the legal meaning of the notion.

## 6 'Science and Proven Experience' in the Medical Domain

The notion of science and proven experience is not only used by medical experts when they testify in court, but has become part of the everyday vocabulary of medical professionals. However, there is no univocal meaning of this notion in the medical domain. Attempts to establish its meaning raise familiar questions about the essence of scientific evidence and the relevance of clinical practice and encounter difficulties similar to those inherent in the debate over the meaning of 'evidence-based medicine' (EBM). Moreover, both components — and proven experience in particular — are problematic because interpretations not only of their precise content but also of their conceptual dimensions are likely to be both vague and context-dependent.

'Evidence-based' is often introduced as the opposite of 'opinion-based'. Harden et al. for instance, first state that 'the choice may be presented as opinion-based or evidence-based teaching.' Later on they modify this picture somewhat: 'Best evidence medical education can be represented as a continuum

between 100% opinion-based and 100% evidence-based education.’ The nature of the best evidence available varies with context. However, in all cases discussed by Harden et al. there is a stark contrast between what is evidence-based and what is opinion-based.<sup>29</sup>

It is also clear that EBM often focuses heavily on the necessity of making more and better use of *research findings* in clinical decision making. Thus, according to Rosenberg and Donald:

Evidence based medicine is the process of systematically finding, appraising, and using contemporaneous research findings as the basis for clinical decisions. For decades people have been aware of the gaps between research evidence and clinical practice, and the consequences in terms of expensive, ineffective, or even harmful decision making. Inexpensive electronic databases and widespread computer literacy now give doctors access to enormous amounts of data. Evidence based medicine is about asking questions, finding and appraising the relevant data, and harnessing that information for everyday clinical practice.<sup>30</sup>

However, in an influential statement of EBM by Sackett et al. it is clear from the very subtitle of the paper that *clinical expertise* is important, too: “Evidence based medicine: what it is and what it isn’t: *It’s about integrating individual clinical expertise and the best external evidence*”.<sup>31</sup> In other words, EBM highlights the need to *integrate* research findings with individual clinical expertise.

The Swedish notion of science and proven experience clearly resonates with these three characteristics of EBM. It focuses on evidence (rather than opinion), science, and the need for integration. However, it also clearly differs from the notion of evidence-based medicine in that it treats two sources of evidence as special: Science *and* proven experience. The phrase “proven experience” (*beprövad erfarenhet*) appears particularly ambiguous and can be (and has been) understood in importantly different ways. In a previous study, we distinguished six conceptual dimensions of proven experience. We observed

29 R. M. Harden et al., ‘BEME Guide No. 1: Best Evidence Medical Education’, *Medical Teacher* 21(6) (1999) 553-562, DOI: 10.1080/01421599978960.

30 W. Rosenberg and A. Donald, ‘Evidence Based Medicine: An Approach to Clinical Problem-Solving’, *BMJ* 310 (1995) 1122-1126, DOI: 10.1136/bmj.310.6987.1122.

31 D. L. Sackett, W. Rosenberg, J. A. Muir Gray, R. B. Haynes and W. S. Richardson, ‘Evidence Based Medicine: What It Is and What It Isn’t’, *BMJ* 312 (1996) 71-72, DOI: 10.1136/bmj.312.7023.71.

that these have been combined in various ways by medical and healthcare practitioners.<sup>32</sup> The dimensions concern:

- (1) The seriousness of the test (i.e. the evaluation of the experience/practice)
- (2) The practice as origin of the experience
- (3) The practice as a mechanism for testing the experience
- (4) The practice as evidence
- (5) The amount/extent of an individual's experience
- (6) The amount/extent of experience within a defined group

Here, we wish to highlight three of these six dimensions, namely (1), (5) and (6).

### 6.1 *The Seriousness of the Test (1)*

Sometimes the expression 'proven experience' is used to indicate that the experience or practice has been tested, or evaluated, in a *serious* or *scrupulous* manner. According to this dimension, which seems to be the original one, the care with which we have evaluated whether, for instance, a new routine is an improvement is essential to the question whether that routine should be counted as being in agreement with proven experience:

Patients should be able to trust that they are going to be diagnosed and treated in accordance with established methods which are solidly grounded. They have the right to expect their treatments to be in concert with science and proven experience. The concept can here be understood as a stamp of quality.<sup>33</sup>

It should be noted that this conceptual dimension echoes the way we often conceive of science, and therefore it is no surprise that those who highlight it downplay the differences between proven experience and scientific validity:

Proven experience should also be reviewed by peers using criteria that are relevant to the experience's content. Such a review comes close to the

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32 J. Persson and L. Wahlberg, 'Vår erfarenhet av beprövad erfarenhet: några begreppsproffler och ett verktyg för precisering', *Läkartidningen* 112(49) (2015) 2230-2232.

33 T. Flodin, 'Tro och/eller vetande?', *Läkartidningen* 108(49) (2011) 2547.

scientific way of working, but the content of proven experience obtained in that way can still differ from that which science generates.<sup>34</sup>

Sometimes the compound expression ‘scientifically proven experience’ is used.<sup>35</sup> The most straightforward illustration of what it takes for something (let us refer to it as x) to be part of scientifically proven experience, we think, would be for x to have originated in practice and have been tested in a scientific study. This is fully compatible with proven experience being understood in accordance with the present conceptual dimension. Quality improvement registries, such as Riks-HIA/Swedeheart, provide good examples of the way in which proven experience in this sense can emerge.

### 6.2 *The Amount/Extent of an Individual's Experience (5)*

‘Proven experience’ is also used to pick out a *property of someone* (as in ‘he is a man of proven experience’). This sense concerns the individual’s problem-solving abilities and relevant experiences. It comes close, we believe, to what is sometimes referred to as ‘individual clinical expertise’ in the evidence-based discourse.

The many doctors, primarily at big hospitals, acquire scientific knowledge, but do they get enough proven experience? Do they find the time for regular patient care and follow-up, or are the patients too quickly referred back to primary care?<sup>36</sup>

### 6.3 *The Amount/Extent of Experience within a Defined Group (6)*

Sometimes proven experience is less about the internal process leading to knowledge or about the personal experience of individuals than it is about whether something is regarded, accepted, or acted on, as knowledge in the relevant community or sector. This dimension of proven experience resembles the importing function that the compound notion of science and proven experience has been assumed to have in a legal setting. As an example of this collective interpretation, consider the following statement by Maria Jacobsson of The National Board of Health and Welfare (*Socialstyrelsen*): “Proven experience

34 This quote is from a report in the educational context of a committee appointed by the Swedish government (SOU 2008:109, *En hållbar lärarutbildning*).

35 E.g. see S. Gunnarsdotter, ‘Försäkringskassan vill avskeda Elinder’, *Läkartidningen* 50(102) (2005) 3862.

36 G. Lindé, ‘Har vi läkarbrist?’, *Läkartidningen* 107(12) (2010) 850.

consists in methods that are relied on in healthcare and are regarded as efficient. That which the community of physicians deems an established practice can be included here".<sup>37</sup>

#### 6.4 *The Lack of an Unambiguous Standard*

Our point is not that the six dimensions we have identified describe necessary conditions of proven experience, but that it is important to keep these dimensions separate. This is not to deny that the types of *phenomena* involved often, and perhaps typically, overlap. Thus a treatment which has been carefully evaluated in practice (1) would normally be regarded as effective in the relevant community (6). However, while it can easily be imagined that the methods Jacobsson talks of in the passage above were seriously tested in accordance with the first sense of 'proven experience', nothing of the sort is entailed. It may be that the methods are used and are regarded as effective for other reasons entirely.

A document on the Swedish Council on Health Technology Assessment's (SBU) website contains the following short remark on the notion of proven experience:

Perhaps it is still the case that everything good health care requires and that cannot be accounted for by 'science' is made part of the meaning of 'proven experience' — everything from consensus, tradition, professional judgment, common sense, clinical intuition and perception, to individual values.<sup>38</sup>

These observations demonstrate, we hope, how important it is to distinguish the basic dimensions. 'Proven experience' is sometimes used in a way that concerns only one or two of the six dimensions. In these contexts, the user may be relying implicitly on the other dimensions as well, but this is often either unclear or untrue. What is clear is that the dimensions are not invoked in isolation very frequently. Those who emphasise the seriousness-of-the-test dimension typically combine that emphasis with more or less obvious reliance on proven experience in some other dimension, such as originating in the practice.

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37 Quoted in A. Borgström, 'Svårt att definiera beprövad erfarenhet', *Läkartidningen* 104 (2007) 198-199.

38 R. Levi, 'Vad menas med beprövad erfarenhet', 1997, online at <http://www.sbu.se/sv/publikationer/vetenskap--praxis/vetenskap-och-praxis/vad-menas-med-beprovad-erfarenhet/>, accessed 8 July 2016.



Our point is that the conceptual profiles in play differ from one user to another. And certain dimensions and combinations of dimensions imply interesting consequences for the notion of proven experience. Therefore, it makes good sense not to assume that there is only one meaning of the phrase 'proven experience'. There is at least the potential for considerable variation in the meaning different users implicitly or explicitly rely on. Our hypothesis would be that a comparison between different users' concept profiles would show substantial variation in how proven experience is understood.

Based on what has now been said, it appears very optimistic to assume that there is any such thing as *the* medical standard which could be relied upon to determine the meaning of legal expressions such as 'science and proven experience'. To begin with, there is certainly no unambiguous definition of 'science', or 'scientific evidence'. Moreover, the conceptual profiles of 'proven experience' differ among users. Clearly, 'medicine' needs to be spelled out in a more precise way if we want to find a definite field from which to import a relevant answer. But the question of what field, more precisely, we are interested in is not trivial. Is it medical science itself? Or the field in which we know most about proven experience? Or some professional organisation, or authority, which professionally integrates knowledge from the two fields? Similarly, is it medical science itself, i.e. the content of scientific publications, that should be examined, or would an expert or official settle the matter? Since it is not obvious that there is *one* source — one  $Y^*$  — for answering questions of the type 'Is  $X^*$  in accordance with  $Y^*$ ?' it seems to follow that we should be prepared for differences in meaning and disagreements when it comes to decisions about what  $Y^*$  means. Now, if the legal meaning is devoid of legal content, there is no legal argument for choosing among these different views. However, if we recognise the importance of legal considerations, it is reasonable to allow the considerations that made  $Y$  (the legal notion) legally relevant in the first place guide our search for relevant candidates for  $Y^*$  (the medical standard).

## 7 The Legal Dimension of Importing Notions

The discussion in the previous section suggests that within medicine the expression 'science and proven experience' lacks a clear, univocal interpretation. Plainly, this creates a problem for anyone who supposes that the meaning of the legal notion of science and proven experience is set entirely by non-legal considerations and is immune from legal challenge. In this section we will present a second argument against the claim that legal notions like 'science and proven experience' have an importing function in this strong sense and are

devoid of legal content. The thrust of this argument is that the notion serves purposes in law quite unlike those it serves in medicine, and that these purposes shape — and should be allowed to shape — the notion's meaning in the legal context. This argument strengthens the case we are making, since it goes through (if it does) whether or not the notion has univocal meaning in the medical domain.

To begin with, it would probably be agreed that there are situations in which a legal decision maker is entitled to question an expert's opinion. This, for example, would be the case in a situation where the expert's trustworthiness can be called in question. Hence, if there are indications that the medical expert is lying, or that other professionals would not share her view, few of us would be happy to accept her opinion without asking further questions.<sup>39</sup> This observation may be trivial. It nevertheless tells us something important about importing notions, namely that a judgment from another discipline is accepted only if it meets certain requirements. Whatever these requirements more precisely imply (e.g. 'acceptance by a responsible body of medical men' or something similar), their very existence shows that even a strong interpretation of the importing function comes with *legal qualifications*. These qualifications reflect the legal considerations that make an importing notion like that of science and proven experience relevant in law in the first place, and they provide the importing notion with at least *some* legal content.

A more important question is perhaps whether a legal decision maker could be entitled to question an opinion shared by the vast majority of medical professionals. Some have answered this question in the affirmative: Thus in the American case *The T.J. Hooper*, 60 F.2d 737 (2d Cir. 1932), the legendary judge, Learned Hand, stated: 'Courts must in the end say what is required; there are precautions so imperative that even their universal disregard will not excuse their omission'. And in *Bolitho v. City & Hackney Health Authority* [1998], 3 W.L.R. 1151 (which was heard after the *Bolam* case) one of the Law Lords stated that it is the court — and not the physicians — which ultimately decides what the legally relevant standard of care amounts to. One way to explain these views would be to say (with the aid of 'Hume's guillotine' principle that normative 'ought'-judgements cannot be inferred from factual 'is'-judgements) that

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39 D. Walton, *Appeal to Expert Opinion: Arguments from Authority* (University Park: Pennsylvania State University Press, 1997); C. Dahlman and L. Wahlberg, 'Appeal to Expert Opinion: a Bayesian Approach', in T. Bustamante and C. Dahlman (eds.), *Argument Types and Fallacies in Legal Argumentation* (Cham: Springer, 2015), pp. 3-18; C. Dahlman, L. Wahlberg and F. Sarwar, 'Robust Trust in Expert Testimony', *Humana Mente Journal of Philosophy*, 28 (2015) 17-37.

a legal standard of care, being a normative matter, cannot be deduced from actual medical practice. From a normative legal point of view, it does not seem right to give the medical professionals a mandate to define what they are allowed to do by law.<sup>40</sup>

On closer inspection the mechanisms at work here seem to be generally applicable, and relate back to what was said earlier about the (necessarily) legal content of legal notions: Legal notions — including importing legal notions — are there to serve legal purposes. Hence the meaning of these notions is relative to legal purpose. If there is legitimate purpose — from a legal point of view — in modifying, or departing from, the medical meaning of notions like ‘science and proven experience’, then there is no compelling reason not to do so. In medicine, the meaning of this notion is relative to the goals of medical science and practice; in a legal context it is relative also to the goals of law. Thus it has been pointed out that not only standards of care, but also standards of proof, are relative to what is at stake in a particular situation.<sup>41</sup> From this it has been inferred that scientific standards need to be reinterpreted when they are transferred to a legal context,<sup>42</sup> and more generally it has been argued that notions deployed in legal contexts are always — and should be allowed to be — shaped by legally relevant considerations.<sup>43</sup>

The decision by the European Court of Justice (ECJ) in C-157/99 on the interpretation of notions like ‘science and proven experience’ in a cross-border context clearly illustrates the fact that the meaning of legal importing notions is relative to legal purpose. In European Law, patients are entitled to reimbursement for expenses associated with cross-border healthcare in other Member States if the healthcare in question is among the benefits to which the patient is entitled in the Member State of affiliation. It is up to each Member State to define the basket of healthcare to which patients in that state are entitled. Thus Swedish patients are entitled to reimbursement only for cross-border healthcare that meets the Swedish requirement that healthcare is consonant with

40 M. Brazier and S. Fovargue, ‘Transforming wrong into right: What is ‘proper medical treatment’?’, in S. Fovargue and A. Mullock (eds.), *The Legitimacy of Medical Treatment: What Role for the Medical Exception?* (Abington: Routledge, 2016) pp. 12–31, p. 29.

41 See e.g. R.C. Jeffrey, ‘Valuation and Acceptance of Scientific Hypotheses’, *Philosophy of Science* 23(3) (1956) 237–246.

42 C.F. Cranor, *Regulating Toxic Substances: A Philosophy of Science and the Law* (New York: Oxford University Press, 1993).

43 L. Wahlberg, *Legal Questions and Scientific Answers: Ontological Differences and Epistemic Gaps in the Assessment of Causal Relations* (Lund: Media-tryck, 2010); L. Wahlberg, ‘Legal Ontology, Scientific Expertise and the Factual World’, *Journal of Social Ontology*, forthcoming, DOI 10.1515/jso-2015-0022.

science and proven experience. In its decision, however, the ECJ made it clear that when national criteria are used to decide a patient's right to reimbursement for cross-border healthcare, such criteria must be interpreted 'on the basis of what is sufficiently tried and tested by international medical science' (at 94). The court went on to explain that the criteria applied 'must be objective and independent where the providers of treatment are established' (95). This appears to be a clear example of legal considerations (in this case considerations of EU law, relating to the needs of a well-functioning internal market) shaping the meaning of importing legal notions. It is particularly interesting to see that the court's decision says something about what kind of testing is required. When combined with the Swedish notion of proven experience, this ECJ decision points in the direction of the first dimension, identified above in Section 6.1, i.e. the seriousness of the test. Moreover, it seems to set up requirements that such tests must meet: The treatment must be *sufficiently* tried and tested by *international* medical science. Hence the decision illustrates that legal considerations can frame the legal interpretation of importing notions, and that these notions are not devoid of legal content. Furthermore, as the discussion in the previous section indicates, and as other before us have already pointed out,<sup>44</sup> the ECJ too appears to adopt an over-simple understanding of medical science and practice.

Given these considerations, we conclude that the legal notion of science and proven experience is importing in a weak sense only. This means that it should be recognized that the content of the notion is relative to legal purpose, and that it has legal content. This does not exclude the possibility that legal purposes sometimes are best served by leaving the non-legal meaning of an importing notion intact. However, we must recognise that the question of what interpretation is best served by legal purposes is a legal question which requires legally relevant considerations to be balanced. Legally relevant considerations can pertain to predictability, the limits of legal accountability, equity, efficiency, transparency, free movement on the internal market, and so on. To say right away that a notion is devoid of legal meaning, and that its meaning can be determined only by professionals in the field to which the notion refers, is to conceal the need for this important discussion.

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44 M. Frischhut and N. Fahy, 'Patient Mobility in Times of Austerity: A Legal and Policy Analysis of the *Petru* Case', *European Journal of Health Law* 23(1) (2016) 36-60, DOI: 10.1163/15718093-12341378; M. Sheppard, 'Treatments of Low-priority and the Patient Mobility Directive 2011, an End to Legal Uncertainty for the English NHS?', *European Journal of Health Law* 20(3) (2011) 295-314, DOI: 10.1163/15718093-12341281.

Certainly, the observation that standards of proof and other notions are relative to the values and purposes at stake in a particular context has bearing on a wide range of issues. For example, the mechanisms of value- and context-relativity are known to complicate the distinction often made between risk assessment and risk management. According to this distinction, risk assessment is often conceived of as ‘scientific’ and ‘fact-based’, in contrast to the ‘political’ and ‘value-based’ risk management process.<sup>45</sup> As many have pointed out, however, values play important roles in risk assessments too.<sup>46</sup> The distinction between risk assessment and risk management tends to obscure the impact that these values have, thereby making impossible an open discussion on the role that they in fact play in societal decision-making. The mechanisms of value- and context-relativity are also highly relevant to patient empowerment initiatives like the European Patients’ Academy (EUPATI).<sup>47</sup> For example, when discussing patient involvement in Health Technology Assessment (HTA) decision-making processes, EUPATI rightly stresses that values play important roles in these processes, and that there is a consequent need for more transparency.<sup>48</sup> To accept the view that the meaning of value-laden standards like ‘consonant with science and proven experience’ is known only by the representatives of the medical disciplines has the potential to effectively block patients from having a say on these important matters.

## 8 Type III-Errors and the Current Use of ‘Science and Proven Experience’

We have concluded that the meanings of importing notions like ‘science and proven experience’ are relative to legal purpose and can therefore depart from the meaning that these notions have in other disciplines. If the legal meaning of ‘science and proven experience’ differs from its meaning in a medical context, i.e. if  $Y$  does not equal  $Y^*$ , as discussed in section 5 above, then the

45 N. Vareman and J. Persson, ‘Why separate risk assessors and risk managers? Further external values affecting the risk assessor qua risk assessor’, *Journal of Risk Research* 13(5) (2010) 687-700, DOI: 10.1080/13669871003660759.

46 P. Slovic, ‘Trust, emotion, sex, politics, and science: surveying the risk-assessment battlefield’, *Risk Analysis* 19(4) (1999 Aug) 689-701.

47 See <https://www.eupati.eu>, visited 16 December 2016.

48 EUPATI, ‘Patient involvement in the HTA decision-making process’, 2016-06-14, online at <https://www.eupati.eu/health-technology-assessment/patient-involvement-in-the-hta-decision-making-process/>, visited 16 December 2016.

medical answer ‘Yes X\* accords with Y\*’ does not answer the *legal* question ‘Does X accord with Y?’. We should therefore be careful not to confuse Y\* with Y.

Automatic acceptance of the medical answer to a legal question creates a risk of a so-called ‘Type III-error’: *The error of accepting (or giving) the right answer to the wrong question*.<sup>49</sup> From a legal perspective, the risk of Type III-errors is easiest to spot when the expert explains what she means by the terms that she uses. Consider, as an example, the following quotation, which reveals something about the way in which a medical expert appointed by the court interpreted the notion of science and proven experience: “[The surgeon’s] conclusions of the preoperative investigation [...] are not based on science but possibly — in part — on proven experience. These conclusions can hence not justify the comprehensive surgery performed”.<sup>50</sup>

As the remarks indicate, the expert holds that a treatment cannot be justified by proven experience alone. We know that the precise meaning of the requirement that healthcare is consonant with science and proven experience is far from clear. However, we have seen that the Swedish National Board on Health and Welfare has considered the relation between the two components of scientific evidence and proven experience and found that, on occasion, proven experience ‘might be the dominant evidence in favour of accepting the medical treatment, whereas theoretical and/or experimental evidence for its effectiveness might be lacking’ (our translation). The Board’s statement is frequently quoted in legal doctrine and preparatory works. By indicating that proven experience sometimes suffices for acceptance of a medical treatment, the Board’s statement suggests that the expert’s interpretation of the notion, in the passage above, may be too strict. Hence, there is a risk of a Type III-error. It should be noted that this risk would have been invisible had not both the expert and the law (by referring to the Board’s statement) said something about how they conceived of the relation between scientific evidence and proven experience. We know, however, that such explanations are rare, and that the medical meaning of ‘science and proven experience’ is far from clear.

49 I. J. Mitroff and T. R. Featheringham, ‘On Systemic Problem Solving and the Error of the Third Kind’, *Behavioral Science* 19 (1974) 383–393, DOI: 10.1002/bs.3830190605; D. Kriebel, J. Tickner, P. Epstein, J. Lemons, R. Levins, E. L. Loechler, M. Quinn, R. Rudel, T. Schettler, and M. Stoto, ‘The Precautionary Principle in Environmental Science’, *Environmental Health Perspectives* 109 (2001) 871–876; Wahlberg, *Legal Questions and Scientific Answers*, *supra* note 44, L. Wahlberg, ‘Rätt svar på fel fråga: Typ III-fel vid användningen av expertkunskap’, *Juridisk Tidskrift* 4 (2010) 889–900.

50 Expert appointed by Östergötland Administrative Court in case 3690-07 (published in KJO 3989-08, p. 4).

## 9 Lessons from Cross-border Healthcare

We have seen that ‘science and proven experience’ is a very vague legal notion, and that this may hamper effective application of the rules in which it occurs. In this section, we will look at some concrete problems that the indeterminacy associated with the notion created in a recent series of cases on patients’ rights to compensation for cross-border healthcare.

In 2004 the Swedish Administrative Supreme Court was asked to decide whether a patient was entitled to reimbursement from the Swedish state for expenses associated with treatment of an inflammatory disease at a university medical centre in Germany. The treatment given was not provided at hospitals in Sweden. The court observed that it is decisive for the right to reimbursement that the treatment is among the benefits to which the patient is entitled in the Swedish health system. The court went on to note that, at the time in question, the treatment had not gained general acceptance in the international medical community. However, the court also noted that the German medical clinic had provided the same treatment to several patients suffering from similar symptoms. Moreover, the treatment had been mentioned in scientific publications. On this basis, the court found that the treatment would have been among the benefits included in the Swedish health system had it been available in Sweden. Although the court did not explicitly use the term ‘vetenskap och beprövad erfarenhet’ (‘science and proven experience’) it implicitly interpreted the standard set by the notion of science and proven experience and said that this standard was met by evidence and experience of the kinds mentioned. This suggests a conceptual profile of proven experience centring on the fifth dimension, i.e. the amount/extent of experience among the individuals working at the particular German clinic.

The Supreme Court’s interpretation of ‘science and proven experience’ has impacted on decisions in the lower courts. For example, in a series of recent decisions, the administrative court in Stockholm has referred to the Supreme Court’s decision in granting rights to reimbursement for the costs of hyperthermia therapy for cancer in German clinics. In its decisions the administrative court first noted that hyperthermia treatment for certain forms of cancer had not gained general acceptance within international medical science, but that the treatment was given in many countries, including several university medical centres in Germany. The court also noted that the treatment had been discussed in scientific publications.<sup>51</sup> According to the administrative court,

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51 See e.g. Stockholm administrative court’s decisions 18885-12, 20057-12, 19509-12, 25183-12, 26868-12, 20005- 20008-12 and 20012-12.

the evidential and experiential basis for this treatment was therefore analogous to that in the Supreme Administrative Court's decision of 2004.

Not surprisingly, the Swedish Social Insurance Agency were alarmed by this development. In 2013 the Agency contacted the Swedish Council on Health Technology Assessment and asked:

- 1) Can hyperthermia therapy be an effective treatment for cancer if not combined with antineoplastic agents or radiation treatment?
- 2) What systematic literature reviews are available on the effects of hyperthermia therapy for specific forms of cancer?<sup>52</sup>

The Council's reference service, answering the Agency's questions, explained that it confined its search to randomised control trials (RCTs). This meant that the Council's reference service considered scientific evidence only in a very narrow sense and did not consider proven experience at all. The reference service then reported that it had identified no RCTs relating to the first question. Six systematic reviews relating to the second question were identified but most of the studies were small and the results were less than decisive.<sup>53</sup>

Following the Council's replies, the Social Insurance Agency appealed the Administrative Court's decisions to the Administrative Court of Appeal in Stockholm. In its judgments, the Court of Appeal cited the Council's reply, along with other expert opinions pointing in the same direction, and concluded that the treatments given were not consonant with science and proven experience. Consequently, the Court of Appeal overruled the lower court's decision, and found that the patients were not entitled to reimbursement for the expenses associated with the treatments.<sup>54</sup>

These decisions by the Administrative Court of Appeal are a clear example of the way in which medical experts' conception of evidence can determine what meaning the notion of science and proven experience acquires in the application of legal rules. The example is interesting because it clearly shows how the experts' conception of evidence renders the Supreme Court's previous definition of the notion ineffective *despite* the fact that the Council's reference service does not even pretend to apply the legal notion of science and proven experience. One lesson to draw from this is that recourse to expert opinion

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52 Effekt av hypertermibehandling (värmebehandling) vid cancer, available at <http://www.sbu.se/hypertermi> accessed 8 July 2016).

53 *Ibid.*

54 See e.g. Stockholm Administrative Court's decisions 2418-13, 2419-13, 2420-13, 3609-13, 3615-13, 3610-3613-13 and 3642-13.



tends to give the expert the privilege of framing the problem. This implies that the expert's subsequent opinion can be a result of choices and values which are legally irrelevant, but which nonetheless have a significant impact on the court's decision.

The response of the Council's reference service is problematic not only because it seems to rely on a much narrower concept of evidence than that underlying the legal notion of science and proven experience, but also because it appears to disregard the Council's own standards. It is true that RCTs are often regarded as the gold standard in EBM, but very few would claim that these are the only studies with evidential value. On the contrary, the Council on Health and Technology Assessment, in its companion to evaluations of healthcare methods, while stating that RCTs *prima facie* have a higher evidentiary strength than other studies, also makes it clear that this grading can change radically when factors relating to the particular studies (precision, effect size, etc.) are taken into account.<sup>55</sup> When all such factors have been considered, not only RCTs, but also, for example, observational studies, can attain the highest grading — and far from all of the RCTs can be guaranteed to retain their original high grading. In this light, the reference service's decision to narrow its search to RCTs appears to be unjustifiable from the Council's own point of view.

The decisions of the Administrative Court of Appeal to refuse to grant reimbursement were a tragedy for the patients involved in these cases. In a wider perspective, the legal uncertainty introduced by the imprecision of the expression 'science and proven experience' may mean that EU regulation of cross border healthcare is less effective, and the uncertainty can even be said to pose a threat to the rule of law in all legal domains (including criminal law) that make use of the notion. However, the lesson to be learned from examples like this is *not* that a court's (not even the Supreme Court's) interpretation of 'science and proven experience' is by definition preferable to the interpretation of a medical expert. (After all, the Supreme Court did not provide any justification for its liberal interpretation, and the fact that the Court of Appeal in subsequent decisions ignored it<sup>56</sup> can be taken to suggest that it did not approve of the Supreme Court's interpretation). What we should conclude, instead, is

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55 SBU, *Utvärdering av metoder i hälso-och sjukvården: en handbok* (Stockholm; Statens beredning för medicinsk och social utvärdering (SBU), 2014) pp. 143 ff.

56 The Court of Appeal refers only to the Supreme Court's statement that it is decisive for the right to reimbursement that the treatment is among the benefits to which the patient is entitled according to the Swedish health system — not to its subsequent elaboration on relevant kinds of evidence.

that there is an urgent need to discuss and make explicit what ‘science and proven experience’ means *in law*. This is necessary if we want to guarantee effective communication between lawyers and medical experts and wish to achieve a predictable and well-balanced application of rules that make use of the notion.

## 10 Conclusions

The interpretation of importing legal notions plays a vital part in our understanding of the law and in the law’s application, but there is an obvious risk that the meaning of notions, like that of science and proven experience, which operate at the interface of the law and other fields, will escape the legal attention and definitions afforded to hard-core legal notions such as ‘adequate causation’. It is certainly tempting to think that the legal meaning of importing notions must accord with the notion’s medical meaning, or that the notions cannot be further elaborated. However, as we have seen, the problem with these assumptions is not only that there appears to be no such thing as *the* medical meaning of the notion that can be applied in the absence of legal clarification. It is also that if we view matters in this way we may fail to see that significant legal and medical questions (about the value of evidence, appropriate standards of proof, values, prioritizations and so on) are concealed behind medico-legal pseudo-agreement about the meaning of a notion which is in fact so opaque that its applicability may come to be determined almost entirely by the particular interpreter’s discretion. A fundamental question is what, more precisely, the notion of science and proven experience imports from the medical domain and into the law. The points we have now set out have hardened our belief that this is a question of exceptional importance. However, the discussion has also shown that this question is unlikely to be answered until it is specified what, more precisely, the expression ‘science and proven experience’ actually means — and could be taken to mean — in different legal contexts. As long as these and other questions relating to the meaning of the notion remain unsettled, it is hard to see how the notion can be used in meaningful inter-field communication.