European Integration Studies, Volume 21, Number 1 special edition (2025), pp. 155-190. https://doi.org/10.46941/2025.se1.8

#### MONIKA BOBBERT\*

## **Health Care Ethics Committees (HECs) – a useful instrument for legal compliance?**\*\*

ABSTRACT: Until now, health care respective hospital ethics committees (HECs) have hardly been considered as an instrument of compliance. This article presents an initial review of this established structure from the point of view of legal compliance. To this end, the emergence, dissemination, and functioning of HECs in the USA and Germany are presented and questions of quality are addressed. The extent to which the structure of ethics committees in health care facilities can be viewed and utilized as a compliance tool is examined in relation to compliance as a means of ensuring legal conformity, preventing legal violations, and as a compliance culture. It is shown that HECs are suitable as a compliance tool if they function well, but that some improvements are still needed, especially with regard to the ethical and legal expertise of the counselors and the financial resources of the structure.

**KEYWORDS:** Health care ethics committee, ethics consultation, hospitals, legal compliance, patient rights, patient's well-being, legal conformity, prevention.

#### 1 Introduction

Until now, health care respective hospital ethics committees (HECs) - a widespread form of ethical counselling in hospitals and other health care facilities - have hardly been considered as a tool of compliance. This article presents an initial review of this - in industrialized countries - established structure from the point of view of legal compliance.

<sup>\*</sup> Prof. Dr. theol. Monika Bobbert, Dipl.-Psych, Director of the Seminar of Moral Theology, Faculty of Catholic Theology, University of Muenster, Germany. https://orcid.org/0009-0003-3378-127X, m.bobbert@uni-muenster.de.

<sup>\*\*</sup> This study was prepared as part of the linkage project of the Humboldt Research Group "On the systematisation of criminal responsibility of and in enterprises" led by the University of Heidelberg and the University of Miskolc (2020-2025).

To this end, the emergence and dissemination of HECs in the USA and Germany is first described.<sup>1</sup> As HECs have been established in Germany along the lines of HECs in the USA, the structures, tasks and objectives of HECs are then presented, followed by an outline of the possible outcomes and finally questions of quality.

The extent to which the structure of ethics committees in hospitals can be considered and utilized as a compliance tool is examined in relation to compliance as a means of ensuring legal conformity, as a means of preventing legal violations, and as a compliance culture. In conclusion, it becomes clear that HECs are suitable as a compliance instrument if they function well, but that some improvements are still needed – for the sake of the tasks and objectives of HECs – and possibly also because it would make sense to equip ethics committees well and then also use them as a compliance instrument.

In view of the author's research focus on medical and nursing ethics and applied ethics, this article concentrates on the characterization of HECs with a view to the issue of legal compliance. Possible functions and connection points are identified which are of interest for legal compliance and which could perhaps be utilized more intensively in the future. However, a legally orientated specification of HECs in terms of compliance must be delegated to legal science.

### 2 Ethics Committees in Hospitals

### 2.1 Emergence and Dissemination of Ethics Committees

HECs were established in hospitals in the USA from the 1970s onwards to discuss ethical questions that arose during the treatment of patients.<sup>2</sup> This form of ethical consultation, which was outsourced from medical judgement, was partly motivated by doctors seeking guidance in the face of increasingly mechanized medicine that could keep people alive for a long time and partly by patients and relatives who, in the spirit of a citizens' movement, criticized the power of doctors to make decisions and demanded more transparency and participation.<sup>3</sup> In addition, a reference to ethical

<sup>&</sup>lt;sup>1</sup> In Germany an HEC is called "klinisches Ethikkomitee" – different from "Ethikkommission" appraising human experimentation. For the distinction see also 2.2.

<sup>&</sup>lt;sup>2</sup> Alexander, 1962; President's Commission Report, 1983; Annas and Grodin, 2016; Aulisio, 2016; Post, 2021, esp. pp. 257–270.

<sup>&</sup>lt;sup>3</sup> Post, 2021, p. 257.

norms seemed sensible in view of the emerging pluralism of values. Inspired by developments in the USA, ethics committees were formed in hospitals in Germany and numerous other industrialized countries from the 1990s onwards.<sup>4</sup>

Other forms of ethics counselling have also come up, such as individual counselling by an ethics specialist or case and ward discussions with integrated ethical reflection.<sup>5</sup> Nevertheless, the HEC, sometimes combined with the option of forming a subgroup for ad hoc counselling (also known as an "ethics consilium"), remains the structural standard in many countries today.<sup>6</sup>

The following focuses on the main institutional type of a HEC with the possibility of forming an ad hoc subgroup, as it has become established in Germany in line with the USA. This is because a comparative overview of structures across many nations would not only go beyond the scope of this article but also be at the cost of answering the question of legal compliance, which is dependent on a sufficiently clear outline of what clinical ethics consultation in the form of an ethics committee involves.

#### 2.2 Institutional Review Boards: A Distinction

HECs, which advise on the treatment of patients, are to be distinguished from research ethics committees (IRBs), which review medical studies involving research on humans: As medical research is done to gain generalizable knowledge to benefit medical knowledge and treatment there are risks for significant harm to the patient respective research subject. Since 1964, the World Medical Association's Helsinki Declaration has laid down professional ethical standards for research involving human subjects. Today, in the United States of America and the nations of the European Union, among others, IRBs are required by law and bound by a set of regulations that determine the scope of its authority (limited to human subjects research) and set criteria for its deliberations and decisions.

<sup>6</sup> Among others Hajibabaee et al., 2016; Schochow et al. 2019, p. 986; 989: For Germany an empirical overview from 2014 reports that mainly large and middle-sized hospitals had HECs.

<sup>&</sup>lt;sup>4</sup> Deutscher Evangelischer Krankenhausverband e.V. et al., 1997; Neitzke et al., 2010; ten Have and do Ceo Patrao Neves, 2021; Hajibabaee et al., 2016; cf. contributions on the development process in individual European countries and the USA Wasson and Kuczewski, 2022.

<sup>&</sup>lt;sup>5</sup> Among others May, 2010.

<sup>&</sup>lt;sup>7</sup> World Medical Association,1964 respective 2024.

### 3 Ethics Committees in Germany Modelled on the USA

Nowadays, almost all acute care hospitals and sometimes also long-term care facilities, hospices, psychiatric institutions, facilities for the developmentally disabled, and other care-providing centers have HECs that meet on a regular or ad hoc basis.<sup>8</sup>

Between 2000 and 2015 – the main phase in the establishment of HECs – a lively debate developed about different forms of clinical ethics counselling and the associated experiences. This is reflected in numerous publications in English- and German-speaking countries. Following this phase, in which ethics committees were formed in the way described and recommended by the German Medical Association (BÄK) in 2006<sup>9</sup>, additional non-clinical ethics committees were formed in Germany in isolated cases, leading the German Medical Association to adopt a recommendation on this in 2019<sup>10</sup>. In the USA, non-clinical ethics committees have already been widespread in nursing homes and other healthcare institutions for several decades. In the following, however, the focus is on ethics counselling in hospitals as the starting point for institutionally visible ethics counselling. In addition, for the sake of the research question, the similarities will be emphasized; the differences between the USA or the Anglo-Saxon world and Germany or the Germanspeaking world can only be addressed to a limited extent.

#### 3.1. Usual Structures

HECs provide advice at the request of doctors, nurses and, less frequently, patients or their relatives. An HEC, i.e. an interdisciplinary or multiprofessional group of hospital staff, meets to discuss ethical issues relating to the treatment and care of patients. Either a case is discussed retrospectively in order to analyze a difficult constellation and possibly learn from it for the future, or it is an acute case in which decisions are still pending. As the HEC usually only meets at longer intervals and cannot be convened quickly, a subgroup of the committee is usually convened promptly to discuss an acute case on an ad hoc basis.

<sup>&</sup>lt;sup>8</sup> Cf. current overviews Post, 2021; Wasson and Kuczewski, 2022; Fox, 2022.

<sup>&</sup>lt;sup>9</sup> BÄK, 2006.

<sup>&</sup>lt;sup>10</sup> BÄK, 2019.

The result of the consultation does not limit the responsibility and decision-making authority of the attending physicians and other professional groups but serves to support the decision-making of those legally responsible. The HEC deals with ethical issues in everyday clinical practice and thus distinguishes itself from bodies such as an employee representation, complaints management or professional supervision. 11

A HEC consists of around 7 to 20 members from the fields of medicine, nursing, pastoral care, social work and psychology. <sup>12</sup> Employees from the fields of law or administration are less frequently represented. In the USA – unlike in Germany – a patient representative is usually also a member. Some larger hospitals have employed an ethics consultant specifically for the purpose of organization, consultation and training. In most cases, however, there is no full-time specialist for ethics. Instead, the HEC elects a member from the field of medicine or nursing as chair or moderator. The chairmanship can be exercised outside of working hours, i.e. as an honorary position, or with a leave of absence from the employer so that this activity can take place during working hours.

While a HEC usually meets every four weeks, some HECs also offer advice on acute cases by forming an ad hoc subgroup of 2 to 5 members, which conducts a case discussion on site or with those involved in the respective ward promptly, i.e. within one to two days. The sub-groups are organized and moderated by the chair of the HEC.

Overall, the structure of the HEC is not legally regulated. Ethics committees in hospitals and nursing homes can be established 'bottom up', i.e. by employees, or 'top down', i.e. initiated by the management of the institution. A HEC either recruits its members informally and has them confirmed by the facility management, or the members are proposed by the facility management and elected or confirmed by the HEC. Ethics committees either draw up their own rules of procedure or statutes and inform the facility management about the committee's work, or the hospital management specifies the structure and rules of procedure.

In some hospitals, employees work on a voluntary basis and are 'tolerated' by the management; in most hospitals, the management also provides resources (time off during working hours, funding for events or a part-time position for the moderation of the HEC).

<sup>&</sup>lt;sup>11</sup> BÄK, 2006, p. A 1704.

<sup>&</sup>lt;sup>12</sup> BÄK, 2006; AMA, 2022; Fox, 2007.

In the US, HECs have been endorsed by prestigious national commissions and medical professional organizations. <sup>13</sup> Today, all major hospitals in the US must demonstrate a structure for handling ethical conflicts in order to be accredited. <sup>14</sup> In the event of a liability lawsuit, the fact that treating physicians consulted an HEC in a controversial case can have an exempting or at least mitigating effect.

In Germany in the 1980s, for example, hospital managements of denominational hospitals took the initiative. They voted for ethics structures, or desired special certifications that made ethics structures necessary.

Ethics committees are the 'classic form' of ethics counselling. <sup>17</sup> In Germany, there are only rarely other forms of medical ethics counselling: ethics working groups, ethics forums and individual counsellors. <sup>18</sup>

#### 3.2 Tasks and Objectives

HECs typically pursue a threefold function: <sup>19</sup> Firstly, they advise on difficult individual cases of patient treatment from an ethical perspective. Secondly, they develop recommendations for dealing with recurring ethical issues. Thirdly, they offer further education and training events for all professional groups in the hospital.

Most frequently, HECs advise on the treatment of patients in individual cases. In these cases, the ethics committee is, according to the statement of the BÄK in Germany, on independent with regard to the facility management, i.e. not bound by instructions. The American Medical Association (AMA) does not specifically mention independence in its guidelines. Instead, it points out: 'Ethics committees that serve faith-based or other mission-driven health care institutions have a dual responsibility to: (g) Uphold the principles to which the institution is committed. (h) Make clear to patients,

<sup>&</sup>lt;sup>13</sup> According to Fox, 2007, p. 13: President's Commission, 1983; American Hospital Association, 1986; AMA, 1985; American Society for Bioethics and Humanities, 1998.

<sup>&</sup>lt;sup>14</sup> BÄK, 2006, p. A 1703.

<sup>&</sup>lt;sup>15</sup> Deutscher Evangelischer Krankenhausverband et al., 1999; Schochow et al., 2019, p. 988

<sup>&</sup>lt;sup>16</sup> May, 2010, pp. 88f; KTQ, 2004; Schochow 2019, p. 988.

<sup>&</sup>lt;sup>17</sup> Schochow et. al. 2019, p. 988.

<sup>&</sup>lt;sup>18</sup> BÄK, 2006, p. A 1703.

<sup>&</sup>lt;sup>19</sup> AMA, 2022, ch. 10.7; Aulisio, 2014; BÄK, 2006, p. A 1704.

<sup>&</sup>lt;sup>20</sup> BÄK, 2006, p. A 1704.

- physicians, and other stakeholders that the institution's defining principles will inform the committee's recommendations.'21
- However, HECs can also draw up ethical guidelines, although this is 2) rarely the case. They cannot fulfil this task independently of the hospital management and the decision-making structures of the institution. Guidelines can be understood as systematically developed decision-making aids on appropriate procedures for specific problems, from which it is also possible to deviate in justified individual cases.<sup>22</sup> A HEC can develop ethics guidelines for recurring problems and propose an implementation process within the framework of the applicable law and on the basis of professional codes of ethics in medicine and nursing – e.g. for dealing with cardiopulmonary resuscitation and living wills, for therapy limitations in the intensive care unit or the use of a percutaneous endoscopic gastrostomy (PEG) tube in very elderly patients. The scope and binding nature of such a guideline must be clarified in accordance with the institutional decision-making structures and legal responsibility.<sup>23</sup> Under certain circumstances, an ethical guideline can be institutionally anchored in a quality assurance system. Transparent development and good communication promote the subsequent acceptance of the guideline.<sup>24</sup>
- 3) In addition to individual case counselling, HECs perform their task of sensitizing and training in-house members of all healthcare professions by offering a voluntary event on medical and nursing ethics once or twice a year. According to the German BÄK in 2006,<sup>25</sup> a good ethics training program makes it clear that ethical problems should not only be delegated to a committee or ethics experts, but that ethical sensitivity, argumentation, and decision-making competence must lie with all employees of the hospital and should be developed further.

According to the German BÄK, a well-functioning ethics committee can make medical decisions more transparent, improve cooperation between professional groups, and promote a culture of error.<sup>26</sup> 'Clinical ethics

<sup>&</sup>lt;sup>21</sup> AMA, 2022, ch. 10.7.

<sup>&</sup>lt;sup>22</sup> Neitzke et al., 2016.

<sup>&</sup>lt;sup>23</sup> BÄK, 2006, p. A 1705.

<sup>&</sup>lt;sup>24</sup> BÄK, 2006, p. A 1705.

<sup>&</sup>lt;sup>25</sup> BÄK, 2006, p. A 1705.

<sup>&</sup>lt;sup>26</sup> BÄK, 2006, p. A 1707.

committees thus make an important contribution to the cultural, personnel, organizational and quality development of their institution.'27

# 3.3 Synopsis of Perspectives, Moral Consensus or Well-Founded Ethical Judgement?

When ethics committees deliberate on difficult individual cases regarding medical treatment and nursing care in hospitals, they can strive for different types of outcomes: for example, to bring together the professional perspectives and interests of those involved in order to obtain a comprehensive picture of the problem situation; or to identify a moral consensus among the members of the committee; or to reach an ethical judgement that justifiably identifies one or more courses of action as good and right.

In its texts, the AMA shows a certain ambivalence between balancing the values, concerns, and interests of all those involved and prioritizing the rights and well-being of the patient. For example, the AMA's Code of Medical Ethics explains in terms of negotiation: 'Ethics committees, or similar institutional mechanisms, offer assistance in addressing ethical issues that arise in patient care and facilitate sound decision making that respect participants' values, concerns, and interests.' This gives the impression that all interests and values of all participants are to be respected equally.

However, in terms of prioritizing a patient's well-being, it is then stated elsewhere: 'The goal of ethics consultation [as individual consultant or through an institutional ethics committee] is to support informed, deliberative decision making on the part of patients, families, physicians, and the health care team. By helping to clarify ethical issues and values, facilitating discussion, and providing expertise and educational resources, ethics consultants promote respect for the values, needs, and interests of all participants, especially when there is disagreement or uncertainty about treatment decisions. Ethics consultants should seek to balance the concerns of all stakeholders, focusing on protecting the patient's needs and values.'<sup>29</sup> However, there is no mention of ethical norms, only of prioritizing the needs of the patient.

<sup>&</sup>lt;sup>27</sup> BÄK, 2006, p. A 1705 (author's translation).

<sup>&</sup>lt;sup>28</sup> AMA, 2022, ch. 10.7.

<sup>&</sup>lt;sup>29</sup> AMA, 2022, ch. 10.7.1.

The BÄK in Germany outlines ethical reflection in an HEC somewhat more clearly in relation to ethical norms by drawing attention to the difference between a moral majority opinion and an ethical reflection: 'Good ethics counselling does not focus on a majority decision in the form of a vote, but rather on improving the recognition and analysis of ethical problems and the ethical decision-making process. Ethics consultants can make an important contribution to this through good moderation, ethical expertise, and an outside perspective.'30 In connection with outpatient ethics committees, the German BÄK points out in its recommendations from 2019 that the so-called Nijmegen method is used in the clinical area,<sup>31</sup> which, based on a current medical analysis of the situation and a multi-perspective reconstruction of the patient's case, examines which available treatment strategies are appropriate in each case in accordance with the four "classic" medical ethical principles of beneficence, non-maleficence, respect for autonomy, and justice. 32 The latter mentioned principles are derived from the American medical ethicists Tom Beauchamp and James Childress.<sup>33</sup> These principles are related to the patient and this at least signals, even if they are prima facie principles, that ethical-normative guidelines are to be respected.

Obviously, the moral and legal rights of patients and their well-being are not naturally at the forefront of every HEC. In this respect, ethics committees should be critically scrutinized with regard to their ethical norms and criteria for consideration.

The philosophical ethicist Mathias Kettner outlines the characteristics of HECs in Germany as follows: They are multidisciplinary ethical advisory bodies that work in a defined institutional context and are intended to fulfil a specific advisory need through their work by specifically reflecting on the morally problematic side of certain problem situations. He critically lists the possible intentions of introducing a HEC: Better (clinical, structural or strategic) decisions, higher patient satisfaction, higher subjective job satisfaction, higher employee identification with the institution, a better operating result.<sup>34</sup>

<sup>&</sup>lt;sup>30</sup> BÄK, 2006, p. A 1706 (author's translation).

<sup>&</sup>lt;sup>31</sup> Steinkamp and Gordijn, 2005.

<sup>&</sup>lt;sup>32</sup> BÄK, 2019, p. A3.

<sup>&</sup>lt;sup>33</sup> Beauchamp and Childress, 2019.

<sup>&</sup>lt;sup>34</sup> Kettner, 2008, p. 16.

Kettner's description of the variety of goals of HECs meets empirical findings from the USA: The respondents in the US survey study by Fox et al. confirmed that the central objectives of clinical ethics counselling are protecting patient rights, resolving real or imagined conflicts, changing patient care that improves quality, increasing patient/family satisfaction, educating staff about ethical issues, preventing ethical problems in future, meeting a perceived need of staff, providing moral support to staff, suspending unwanted or wasteful treatments, and reducing the risk of legal liability.<sup>35</sup>

Even though in the national empirical study by Fox et al. the rights and well-being of patients are listed first, it is apparently accepted or even desired that a HEC also serves other interests.<sup>36</sup> The empirical study does not provide any information on how conflicts of interest between the actors involved are handled. However, the follow-up study by Fox et al. from 2022 shows that a HEC recommended a single best course of action in only 46% of the cases discussed.<sup>37</sup> Overall, however, ethics committees do not recommend a specific action or a range of acceptable courses of action in around 49% of cases, which suggests that in these cases no conclusive ethical-normative argumentation is given, but rather that only a synopsis of several perspectives and interests has been made.

From an ethical point of view, however, this should be followed by a discussion about which interests are justified and must be taken into account, and which should be put aside. Such ethical reflection would then also result in a well-founded recommendation for one or more courses of action. After all, the parties involved may have different needs, interests and moral concepts, but a HEC should make a moral statement in the sense of a distinction between morally wrong and morally right.<sup>38</sup> The decisive factor is whether morality is based on reason. In this case, the ethical criteria for a right or wrong moral judgement cannot be based solely on a religious source such as the Koran or the Bible or on the majority opinion of a peer group or an ethics committee.

Firstly, the approach of an ethics committee can therefore be limited to compiling different perspectives. Secondly, a moral consensus can be found among the members of the committee without the reasons for the

<sup>&</sup>lt;sup>35</sup> Fox, 2007, p. 16.

<sup>&</sup>lt;sup>36</sup> Fox et al., 2007.

<sup>&</sup>lt;sup>37</sup> Fox, 2022, p. 12.

<sup>&</sup>lt;sup>38</sup> Kettner, 2008, p. 20.

consensus being investigated. Thirdly, a committee can – and this is what Kettner demands – give generally understandable moral reasons for a moral judgement that refer to reasonably comprehensible ethical norms. As a basic qualification, members should be willing to engage with the views and technical jargon of the various professional groups, but above all the ability to justify and criticize moral judgements.<sup>39</sup> The author of this article also sees the task of clinical ethics counselling as making moral judgements for which reasonably comprehensible reasons are given.<sup>40</sup> In view of the pluralism of ethical theories, the ethical standards used and their justifications must be disclosed and remain open to criticism.<sup>41</sup>

The sociologist Nassehi explains why ethics must be represented as a scientific discipline which is able to present good reasons form oral judgements: most forms of order and moral concepts in modern societies are different.<sup>42</sup> The pluralism of world views, ways of life and moral intuitions cannot simply remain side by side in conflicts, but requires the differentiation of ethics and morality in the claim: a morality that is empirically valid can only prove itself through empirical implementation. Ethics as a reflection of morality proves itself through its ability to justify its norms and judgements. Ethical reflection is based on the assumption that reasons can be found for maxims for action that can be found in social practice, which may compete but can be distinguished as more or less convincing from an ethical perspective.

If a HEC wishes to provide advice, it should therefore be able to give convincing reasons for its decisions.<sup>43</sup> A group consensus that is not qualified in terms of content cannot make a justified moral claim from an ethical perspective. The philosopher Rosemarie Tong calls for an ethics of persuasion precisely in order to avoid moral pressure on those being advised.

Nevertheless, only those ethical approaches and norms that are compatible with the applicable law will be acceptable in a HEC. This is because conflicting interests are addressed and prioritized differently with a deontological argumentation based on individual moral rights than with a utilitarian or contractual argumentation.

<sup>40</sup> Cf. in more detail Bobbert, 2009.

<sup>&</sup>lt;sup>39</sup> Kettner, 2008, pp. 20–23.

<sup>&</sup>lt;sup>41</sup> Bobbert, 2009, esp. pp. 196–197.

<sup>&</sup>lt;sup>42</sup> Nassehi, 2008, pp. 163–165.

<sup>&</sup>lt;sup>43</sup> Bobbert, 2009; see alsoTong, 1991.

### 3.4 Frequent Topics and Problems

Ethicist Kettner, who has also been involved in ethics committees, outlined a wide range of topics at the beginning of the establishment of HECs in Germany: HECs dealt with morally irritating questions of therapy and diagnostics, patient autonomy, treatment decisions at the end and beginning of life, conflicts in connection with medical confidentiality and the fulfilment of the patient's right to information under adverse circumstances.<sup>44</sup>

George Annas and Michael Grodin, US experts in the field of health law and medical ethics, outlined the range of topics in an interim report in 2016 as follows: 'Conflicts caused by a disagreement between patient or family and the clinical team about demand for treatment judged to be nonbeneficial or even harmful. Mostly it also can be a communication problem compounded by unrealistic expectations on the part of a patient's family. Hospital ethics committees continue to exist and deal mostly with end-of-life conflicts and policies. Nonetheless, the nature, membership, scope, limits of authority, and accountability of institutional ethics committees have still not been well established.'45

Just to give an impression of the kind of cases which are presented in HECs, two examples will roughly be given: Kettner describes an individual case discussion in relation to treatment issues at the end of life.<sup>46</sup>

In an intensive care unit, a patient with end-stage AIDS who has an acute intestinal obstruction and a medically predicted lifespan of approx. 3 days has to decide whether she should still be operated on or whether she should remain sedated. The surgeons who want to operate again accuse the anesthetists of not allowing continued sedation. The anesthetists reproached the surgeons, saying that surgery was pointless and would cause the patient even more pain. There was no living will and the only available relative, whose relationship to the patient is unclear, was against the operation.

The author of this article can report a HEC's case relating to patient autonomy and the decision-making capacity required for this:

A 64-year-old patient who has had Hodgkin's disease for 11 years and has already survived many crises of illness comes to the emergency department with severe shortness of breath. Due to severe bilateral

<sup>&</sup>lt;sup>44</sup> Kettner, 2008, p. 17.

<sup>&</sup>lt;sup>45</sup> Annas and Grodin, 2016, p. 55.

<sup>&</sup>lt;sup>46</sup> Kettner, 2008, p.19f.

pneumonia, the patient is advised to undergo immediate artificial respiration (intubation). The patient refuses with the words: 'I don't want to be artificially ventilated!' However, the patient allows bronchoscopy ventilated and subsequently mask (CPAP) ventilation<sup>47</sup> and thus survives the night to some extent. The next morning, the patient still requires intubation – as mask ventilation is no longer sufficient. After lengthy discussions with the patient and his wife, the doctor manages to get the patient to agree to intubation for a limited period of three days. But after three days, his condition has barely improved. The wife demands that the artificial respiration be terminated in accordance with the agreement. With a heavy heart, the internist ends intubation after three days and the patient dies shortly afterwards. The doctor asks the ethics committee for a retrospective ethical review to clarify the following questions: Was it right to make a 'compromise' because the patient had a chance of recovery, or did I improperly persuade him to be intubated?

The two case studies are representative of many ethics consultations in those ethical issues at the end of life make up the largest proportion of the cases discussed. It also becomes clear that the 'sense of possibility' of all those involved is often required in everyday clinical practice. In the latter example, for example, a discussion about the patient's motives and not just his consent to or refusal of artificial ventilation would probably have been informative: Did he have an aversion to intubation, a fear of long-term ventilation or did he want to die now – after a long road of fighting his cancer?

## 3.5 Quality of Health Care Ethics Committees: Requirements and Criticism

Questions about the quality of HECs have existed from the time they were founded until today. The very question of which quality standards should be used and how quality can be measured using empirical methods is the subject of a separate discourse.<sup>49</sup> Nevertheless, some points of criticism are obvious: neither in the USA nor in Germany is it mandatory for an ethics committee to have a specialist in ethics, and there are also no requirements

<sup>&</sup>lt;sup>47</sup> A continuous positive airway pressure (CPAP) ventilation supports the patient's own breathing. It is less invasive respetive "artificial" than a intubation.

<sup>&</sup>lt;sup>48</sup> According to Musil 2014, 16-17.

<sup>&</sup>lt;sup>49</sup> Marckmann et al., 2015, AG "Ethikberatung im Gesundheitswesen" on criteria for ethics committees for research involving human subjects Bobbert and Scherzinger, 2017.

for the members with regard to the interdisciplinary composition of the group and ethical expertise or further training.

In their two national overview studies on HECs in the USA, Fox et al. surveyed formal aspects such as workload, financial support, type of information collection and protocol management. One of Fox et al.'s 2022 survey findings is that there is still a lack of ethics education and training for members. The AMA's requirement that ethics consultants have 'appropriate expertise or training – for example, familiarity with the relevant professional literature, training in clinical/philosophical ethics, or competence in conflict resolution – and relevant experience to fulfill their role effectively' is therefore obviously not fulfilled.

Because in the USA, in addition to counselling by HECs, individuals from medicine, nursing, social work or hospital chaplaincy often carry out ethical case consultations,<sup>52</sup> the American Society for Bioethics and Humanities (ASBH) has been developing guidelines for individual counsellors since 1998, which are constantly being revised.<sup>53</sup> The ASBH is the primary society of bioethicists and scholars in the medical humanities and the organizational home for individuals who perform clinical ethics consultation in the United States, as well as for many bioethics professionals from outside the United States. In 1998, ASBH published the first time 'Core Competencies for Health Care Ethics Consultation', which outlined the knowledge base and skill set that consultants should possess to conduct ethics consultation.

The ASBH recommendations are partly formal in that they require relevant courses of study and further training, but the process of ethics counselling is explained in more detail. Accordingly, the following applies to ethics counselors:

- 'Introduce and clarify relevant ethical concepts and normative guidance.
- Identify ethically acceptable options and provide an ethically grounded rationale for each option.
- Facilitate mutual understanding of relevant facts, values, and preferences.

<sup>&</sup>lt;sup>50</sup> Fox et al., 2007; Fox et al., 2022.

<sup>&</sup>lt;sup>51</sup> AMA, 2022, ch. 10.7.1.

<sup>&</sup>lt;sup>52</sup> Fox et al., 2007, esp. pp. 17–18; Fox et al., 2022, esp. 11–14.

<sup>&</sup>lt;sup>53</sup> ASBH, 1998; 2011; 2024.

- Support ethically appropriate decision-making while respecting differing points of view, values, cultures, religions, and moral commitments of those involved.
- Synthesize the relevant medical and values-based information into an ethical analysis and assessment.
- Make ethical recommendations as appropriate.'54

In 2018, ASBH developed a certification course for anyone with a bachelor's degree or higher who had at least 400 hours of clinical ethics consultation experience.<sup>55</sup>

In Germany, too, the further training of the HEC members is not specifically regulated and therefore takes place in different ways, often self-taught or via individually selected further training courses. However, the professional association 'Academy for Ethics in Medicine (AEM)', which fulfils a similar function to the ASBH regarding recommendations for HECs, has developed a curriculum for the further training of ethics consultants, which specifies the minimum theoretical and practical skills that persons working in ethics consulting should have. <sup>56</sup>

The ethical-reflective competences of ethics counsellors are aimed at, among other things:

The person knows the meaning of 'morality' and 'ethics', can distinguish between normative and descriptive statements and reflect on the binding nature of normative statements. The person can distinguish between ethical norms and legal norms and recognize the relevance of each for the solution of normative questions. The person is familiar with various ethical justification approaches (including deontological, consequentialist, virtue ethical, relational ethical and principled ethical approaches). The person is aware of their strengths and weaknesses and can utilize their potential for answering ethical questions.<sup>57</sup> Organizational skills are also required: 'Ethics consultants need application-oriented organizational knowledge in order to advise and moderate ethical conflicts in institutions and services of the health care system.'

An earlier AEM recommendation from 2010 focused less on well-founded ethical and normative judgements and more on a factual consensus

<sup>55</sup> Baker, 2022, p. 9.

<sup>57</sup> AEM, 2019, pp. 6–7.

<sup>&</sup>lt;sup>54</sup> ASBH, 2024, p. 4.

<sup>&</sup>lt;sup>56</sup> AEM, 2019.

<sup>&</sup>lt;sup>58</sup> AEM, 2019, p. 7 (author's translation).

between members of different professional groups and on specific values of the respective institutions: Ethics counselling in healthcare institutions should be geared towards the following objectives, among others:

- 'The implementation of general moral values (e.g. human dignity, autonomy, responsibility, care, trust) and specific values of the respective organization, which are embodied in mission statements and profession-specific traditions, among other things, in reflected actions,
- to seek solutions to conflicts between different individual and/or institutional values and moral concepts and to arrive at and implement viable decisions through joint reflection.
- Ultimately, the aim is to make decision-making processes transparent regarding their ethical aspects and to align them with morally acceptable criteria, i.e. to make 'good decisions' in 'good decision-making processes'.'59

In the USA, as in Germany, individual ethics counsellors and ethics committee chairs and members can take continuing education courses on a voluntary basis. However, this is not a prerequisite for participation in an ethics committee. There are obviously no formal requirements, such as a qualification in clinical ethics from philosophy or theology, or specific ethics training courses to ensure that ethical reflection takes place in the narrower sense. In addition, the objectives vary in terms of content: Apart from raising awareness of ethical problems, which is mentioned in all professional ethics recommendations, the naming of objectives varies in terms of the quality of the results of ethics counselling: In some cases, the requirement is merely to take into account different perspectives, values and moral concepts, while in others a well-founded ethical judgement is required.

As far as the quality of results is concerned, it is of interest to a HEC how the members position themselves on a metaethical level: In the face of an ethically reformulated problem, are different information and moral perspectives merely brought together, but the question of which interests and moral concepts are justified or unjustified is not discussed? Or is a consensus sought that expresses the moral concepts of the majority of the group members of the ethics committee or the treatment team on the ward, but is not substantiated by argument? Or is an ethical judgement or at least a

<sup>&</sup>lt;sup>59</sup> AEM, 2010, p. 250 (author's translation).

preferential judgement made that is based on generalizable ethical norms and a reasonably comprehensible argument? In the latter case, the ethical and legal norms to which the ethics committee considers itself bound when making an ethical and normative judgement would still be variable.

Overall, it remains an open question whether a HEC affirms and 'applies' the moral concepts currently prevailing in the respective composition or in society and thus limits the critical potential of an ethics committee to questions of consistency – or whether critical potential is introduced via ethical-normative standards that questions prevailing moral concepts or confirms them with good reason. In ethics as a scientific discipline, it is certainly debatable whether moral judgements can be justified with reasonably comprehensible arguments or whether this is considered impossible (cf. the metaethical positions of cognitivism or non-cognitivism). Irrespective of this, however, it should be noted in general and regarding the importance of ethics committees for legal compliance that a HEC can contribute more or less reflexive or critical potential.

Apart from this, there is no doubt that the preliminary stages of ethical reflection are positive for every HEC: By presenting a problem or a conflict to a larger group in order to address the specific moral aspects, it is firstly possible to enrich it with relevant further information and perspectives, secondly to ask critical questions (in various respects), and thirdly to activate the "sense of possibility" — i.e. the joint search for alternative courses of action. A multiple-eye principle instead of an individual decision by an attending physician that is not open to discussion can therefore offer advantages from an ethical point of view.

## 4. Health Care Ethics Committees and Compliance from a Legal Perspective

In accordance with their evolved self-image, HECs have positioned themselves, in terms of their relationship to the law, primarily in relation to the unchanged medical responsibility and the right to self-determination as well as other fundamental legal rights of the patient (4.1). If we now look at the 'HEC' structure from the outside, from the perspective of compliance as 'regulated self-regulation', additional legal perspectives emerge, which are explained in sections 4.4 to 4.6.

#### 4.1. Ethics and Law in Health Care Ethics Committees

HECs must operate within the framework of the law when providing ethical advice and developing guidelines. Where the law opens up room for manoeuvre, ethics counselling can provide valuable assistance. Particularly in the conflict-prone field of limiting therapy at the end of life, the law gives doctors room for decisions by allowing them to choose between different options in order to do justice to the individual case. The right of patients to be allowed to die without being kept alive for a very long time with intensive care is often violated in practice because a doctor does not dare to discontinue life-sustaining treatment that has become ineffective due to inaccurate knowledge of criminal law. Only those who know the room for manoeuvre can make full use of it.

Professional ethics recommendations issued by the AMA in 2022 and by the BÄK in 2006 and 2019 repeatedly emphasize that ethical case consultation does not remove the decision-making authority and responsibility of the individual practitioner: doctors must decide independently and freely. Nor should any pressure be exerted; rather, the results of ethics committees or other forms of clinical ethics counselling are merely advisory in nature and do not have to be followed by the patients and treating physicians. The recommendation drawn up should support the person authorized and responsible to make a decision, but not undermine existing decision-making powers or conceal responsibility. This applies in particular to the attending physician. In case consultations in which anonymity cannot be completely guaranteed, all those involved in a case consultation should be bound to confidentiality by the clinic management, unless they are already subject to a legal and professional duty of confidentiality.

#### 4.2 Compliance in Law

The legal development of compliance originated in Anglo-American law in the 1930s as the idea of regulated self-regulation. <sup>65</sup> It seemed more appropriate for companies to develop their own regulations for their specific

<sup>60</sup> BÄK, 2006, p. A 1706.

<sup>61</sup> Rothärmel, 2010, p. 178.

<sup>62</sup> AMA, 2022, ch. 10.7 (a).

<sup>&</sup>lt;sup>63</sup> BÄK, 2019, p. A 3 (author's translation).

<sup>&</sup>lt;sup>64</sup> BÄK, 2006; AMA, 2022, ch. 10.7 (b).

<sup>&</sup>lt;sup>65</sup> Hauschka, Moosmayer and Lösler, 2016, § 1.

area than for legislators to pass regulations that were not appropriate. Common law, which is based not only on statutes but also on authoritative judicial judgements in precedent cases, predominates in the USA and throughout the Anglo-Saxon-speaking world. For common law it was and is easier to integrate non-codified company-specific or sector-specific regulations into the law than it is for the civil law of continental European countries, i.e. including Germany. Civil law is based on the codified law of the respective legislators and in which the judiciary is bound by the legal code. In this respect, it is not surprising that the legal relevance of HECs has played a greater role in the USA from the very beginning. For Germany and other nations with a civil law, the question of the legal relevance of HECs has hardly been worked out.

In law, the term compliance refers to adherence to rules in the form of law and legislation, as well as internal company guidelines to prevent violations of the law. In relation to companies, this also includes operational measures that are intended to ensure the lawful behaviour of all company employees. The term compliance originally comes from the Anglo-American legal system in the sense of self-regulation in order to fulfil the responsibility of companies to prevent legal violations. As it would go beyond the scope of this article to go into the international legal discussion on compliance in detail, only literature on compliance from the German legal area is referred to below.

### 4.3 Compliance in Medicine and Psychology: A Distinction

To avoid misunderstandings in the interdisciplinary dialogue, it is important to be aware of the different disciplinary uses of compliance and to differentiate these from compliance in law.

When it comes to the doctor-patient relationship in medicine, compliance (more recently also referred to as adherence or persistence) means following the doctor's therapeutic instructions in order to ensure the agreed therapy plan and the success of the therapy. The term compliance has now established itself as a technical term for therapeutic co-operation and motivation when using professional healthcare services in clinical or psychotherapeutic contexts. Factors of non-compliance in the doctor-patient relationship are analyzed, or it is asked whether it is a case of deviation or 'reasoned decision making'. The term, which has now been

\_

<sup>&</sup>lt;sup>66</sup> Schoppmeyer, 2020.

<sup>&</sup>lt;sup>67</sup> Brody, 2010.

used in medicine for 70 years, has been criticized for being understood as 'obedience to therapy', as this does not correspond to respect for patient autonomy.

In medical physiology, compliance is a measure of the elasticity of body structures, e.g. pulmonary compliance for the elasticity of the lungs, vascular or cardiac compliance for the elasticity of blood vessels and the heart wall, and bladder compliance for the elasticity of the urinary bladder wall.<sup>68</sup>

In psychology compliance is a type of social influence that occurs when a person changes her behaviour in response to a direct request of others. <sup>69</sup> Psychologists examine, how reciprocity, commitment and consistency, authority, social validation or social proof, and liking and similarity are used to change people's behaviors.

# 4.4 Health Care Ethics Committees ensuring Legal Compliance: A Classic Form of Compliance

To date, there is no legal definition of compliance in German law. Only the German Corporate Governance Code (DCGC)<sup>70</sup> contains a basic definition: 'The Management Board is responsible for ensuring compliance with legal provisions and internal guidelines and works towards their observance within the company (compliance). The internal control system and the risk management system also include a compliance management system geared towards the company's risk situation.'71 'Employees should be given the opportunity to report legal violations within the company in a protected manner; third parties should also be given this opportunity.'72 'This CG Code contains principles, recommendations and suggestions for the management and supervision of German listed companies on the stock exchange that are recognized nationally and internationally as standards of governance. '73 good and responsible corporate 'The Code's recommendations and suggestions may serve as a guide for companies that are not listed on the capital market.'74 'The Code emphasizes the obligation of the Management Board and Supervisory Board to ensure the continued

<sup>&</sup>lt;sup>68</sup> Schoppmeyer, 2020.

<sup>&</sup>lt;sup>69</sup> Guadagno, 2017, see p. 107.

<sup>&</sup>lt;sup>70</sup> DCGK, 2022.

<sup>&</sup>lt;sup>71</sup> DCGK, 2022, A.I. Grundsatz 5 (author's translation).

<sup>&</sup>lt;sup>72</sup> DCKG, 2022, A.I.A.4 (author's translation).

<sup>&</sup>lt;sup>73</sup> DCGK, 2022, p. 2 (author's translation).

<sup>&</sup>lt;sup>74</sup> DCGK, 2022, p. 3 (author's translation).

existence of the company and its sustainable value creation (corporate interest) in accordance with the principles of the social market economy, taking into account the interests of shareholders, employees and other groups associated with the company (stakeholders). These principles require not only legality, but also ethically sound, responsible behaviour (model of the honourable businessman).<sup>75</sup>

A member from the legal profession can also participate in a HEC, but the discipline of law does not necessarily have to be represented. In Germany, lawyers are rarely members of an ethics committee, whereas in the USA they are somewhat more common. The recommendations in the USA and Germany for the further education and training of ethics advisors and members of ethics committees do not provide for further legal training. This means that legal expertise is often not represented on HECs.

The lack of knowledge or misunderstandings of doctors in Germany described by the medical law expert Sonja Rothärmel with regard to the criminal law provisions on the termination of treatment (and thus the distinction between passive and active euthanasia), the pregnancy conflict, prenatal diagnostics, the duty of confidentiality or the use of medicines in children should be remedied through legal information or further training. Ethics committees or ethics counselling do not provide this per se, as legal knowledge and further training are not provided as standard. Rothärmel therefore states that the 'urgent need for qualified further training in medical criminal law should not be forgotten'77. This is still not the case in Germany today.

However, ethics counselling can be included in the (criminal) legal assessment of medical or nursing actions. It does not relieve the attending physicians and employees from other healthcare professions in the hospital of their legal responsibility. However, doctors who make use of professional ethics counselling or advice from the HEC show that they have fulfilled their duty to make a responsible decision in a difficult situation. The documentation of ethical counselling can also help to demonstrate compliance with the duty of care.<sup>78</sup>

If a HEC can be understood as 'good practice', compliance with "good practice", i.e. the consultation of an ethics committee as a recognized

<sup>&</sup>lt;sup>75</sup> DCGK, 2022, p. 2 (author's translation).

<sup>&</sup>lt;sup>76</sup> Rothärmel, 2010, pp. 181–183.

<sup>&</sup>lt;sup>77</sup> Rothärmel, 2010, p. 184 (author's translation).

<sup>&</sup>lt;sup>78</sup> Rothärmel, 2010, 183.

ethical procedure, could – in the course of increasing legalization – counteract or even rule out accusations of negligent, i.e. careless behaviour in the future. Good practice would therefore gain direct legal relevance through indeterminate legal terms such as negligence. The utilization of the ethics committee as "good practice" could also be a mitigating factor under criminal and fine law. However, the consultation of a HEC as "good practice" would not imply that the attending physician would have to follow the specific advice of the ethics committee. He or she could also deviate from this for good reason. Furthermore, as the AMA and the BÄK repeatedly emphasize, ethics consultation does not protect the individual doctor from punishment, as the doctor bears personal responsibility for the medical and legal correctness of the treatment decisions for the patient within his or her area of responsibility. Furthermore, the ethics counsellor is not liable for his or her counselling, e.g. within the limits of the German Legal Counselling Act. <sup>81</sup>

Beyond the legal framework, a HEC can be seen as an instrument of compliance, provided it follows ethical criteria that correspond to the applicable law. In Germany, deontological ethical approaches in the Kantian tradition, which are based on moral rights and duties, such as the moral philosophical approach of Alan Gewirth (1978), but also the classic medical ethics approach of Beauchamp and Childress (2019), which is based on the prima facie principles of beneficence, non-maleficence, respect for autonomy and justice with regard to doctors and patients, correspond to the current law.<sup>82</sup> In this respect, room for manoeuvre can be interpreted in terms of the law with recourse to such ethical approaches. However, as soon as ethical approaches and criteria are used that do not conform to the applicable legal framework, such as utilitarian or autonomy-centred approaches, e.g. the preferential utilitarian approach of Peter Singer (2011) or the libertarian approach of Tristram Engelhardt (1995), ethical judgements of a HEC based on these approaches may even jeopardise legal conformity.83

<sup>&</sup>lt;sup>79</sup> Dannecker, 2025, ch. 2c.

<sup>80</sup> Dannecker, 2025, ch. 2d.

<sup>81</sup> Rothärmel, 2010, p. 184.

<sup>82</sup> Gewirth, 1978; Beauchamp and Childress, 2019.

<sup>83</sup> Singer, 2011; Engelhardt, 1995.

## 4.5 Health Care Ethics Committees for the Prevention of Legal Violations: Sanction Compliance

HECs can also have a preventive effect. From a legal perspective, compliance involves preventing violations of the law in a company in order to avoid sanctions and claims for damages as well as negative publicity associated with damage to the company's reputation. An ethics committee could prevent individual wrong decisions by doctors or other persons in positions of responsibility by supporting individuals. An ethics committee would thus have a preventative effect as a structure.

A hospital and its attending physicians and other healthcare professionals must respect patients' informed consent, duties of health care and life protection and other fundamental rights, which is not always possible in everyday clinical practice. If problematic cases or difficult decision-making situations are recognized and discussed in good time with the help of the 'clinical ethics consultation structure, this can have a preventive function. Liability risks caused by deviant behaviour on the part of hospital employees can be reduced by HECs, i.e. they may contribute to a reduction in the likelihood of harm. A HEC can therefore be regarded and used as a structure that counteracts deviant behaviour. However, criminal convictions of doctors are quite rare in Germany.<sup>84</sup> Liability proceedings against doctors and hospitals also occur less frequently in Germany than in the USA.

Soon after the first ethics committees were established in Germany, the medical law expert Rothärmel wrote: 'Ethics counselling in hospitals is preventive legal advice. It can make legal counselling in preliminary proceedings superfluous by preventing the preliminary proceedings themselves. If conflicts are resolved in the hospital and relatives and patients are taken seriously, the filing of charges or compensation in medical malpractice proceedings is usually avoided. Good communication and mediation can therefore significantly reduce the forensic risk in hospital.'85 And she continues: 'It is not only the relatives of a patient who can experience relief through ethics counselling, but also all hospital staff. Ethics counselling is risk management, because a conflict that has been satisfactorily resolved in the hospital is not taken to court. This saves everyone involved considerable psychological and financial strain and also

<sup>84</sup> Rothärmel, 2010, pp. 180–181.

<sup>85</sup> Rothärmel, 2010, p. 179 (author's translation).

saves the hospital from bad press.'<sup>86</sup> Rothärmel points out a further advantage: 'Ethics consultation that works well also sensitizes employees to the perception of conflicts, promotes communication within the team, and between departments, and can thus also contribute to improving the culture of error in the hospital.'<sup>87</sup>

In other words, ethics committees can therefore contribute to compliance as 'company self-regulation'<sup>88</sup>.

## 4.6 Health Care Ethics Committees as Instrument for Good and Responsible Behaviour: Compliance Culture

In German law, the English term compliance is also associated with acting in accordance with a company's rules that are not directly legally binding. <sup>89</sup> Corporate compliance or governance encompasses the entirety of measures for good and responsible decision-making and behaviour in a company. The aim is to ensure appropriate ethical and legal responsibility for protected legal interests within a company. Experience has shown that usual delegation structures alone are not sufficient. According to the German defence lawyer Thomas Knierim, numerous individual legal requirements have led companies to develop models for 'ethical corporate management and control', which are reflected in today's compliance discussion. <sup>90</sup> In addition to legal compliance, the aim of compliance is to develop principles of behaviour, guidelines, management and control measures that are both an obligation and a framework for an 'ethically superior corporate culture' <sup>91</sup>.

The criminal law expert Gerhard Dannecker also speaks of a compliance culture in connection with behavioural psychological considerations on compliance: 'Compliance culture refers to the value system of company employees in terms of the extent to which compliance with the law and adherence to rules is accepted, respected and supported as a value by all employees. This is associated with the expectation that all company employees, including managers, behave with moral integrity and do not allow themselves to be corrupted.'92 In addition to legal conformity

<sup>86</sup> Rothhärmel, 2010, p. 180 (author's translation).

<sup>87</sup> Rothärmel, 2010, p. 179 (author's translation).

<sup>88</sup> Dannecker, 2023, p. 131 (author's translation).

<sup>&</sup>lt;sup>89</sup> Rotsch, 2024, esp. pp. 73–75; Knierim, 2025, esp. pp. 389–396.

<sup>90</sup> Knierim, 2025, p. 390.

<sup>&</sup>lt;sup>91</sup> Knierim, 2025, p. 391.

<sup>&</sup>lt;sup>92</sup> Dannecker, 2023, p. 139 (author's translation).

and prevention, compliance can also be understood as adherence to compliance rules that are followed out of insight and conviction.<sup>93</sup>

By providing advice, an ethics committee aims to mediate between different perspectives and, if necessary, to persuade by argument. By providing repeated support in difficult cases, it can establish a culture of discussion and shared ethical goals. Further training for all hospital staff – the third task of HECs – can serve to broaden consensus with regard to the implementation of legal requirements and ethical criteria.

If a hospital wants to ensure in a particularly strong way that moral and legal patient rights are respected and the well-being of patients is paramount, this can be regarded as the organization's value system, which should be respected and lived by all employees in everyday life. A HEC promotes the addressing and discussion of difficult constellations in this regard, while ethical training events for all professional groups in the hospital focus on specific questions relating to the hospital's value system.

Lastly, guidelines developed by ethics committees, for example on the question of when cardiovascular resuscitation should no longer be performed or on the question of what to do when a patient is dying or has died in hospital, can to a certain extent become 'good practice', i.e. a sensible way of achieving certain goals.

### 5. Limits and Positive Aspects of Health Care Ethics Committees in **Regard to Compliance**

## 5.1 Limits to the Integration of Health Care Ethics Committees in Compliance Structures

In 2017, the Fraud Section of the US. Department of Justice published a guideline entitled 'Evaluation of Corporate Compliance Programs'. 94 According to this guideline, which attaches great importance to the qualification, equipment, integration and autonomy of the compliance function, the public prosecutor's office assesses the effectiveness of compliance systems when deciding on a mitigation option as part of the imposition of sanctions.

If these criteria are used to evaluate HECs in relation to any compliance functions, the lack of qualifications described above takes central stage: the ethical qualifications of the members of a HEC and also of

<sup>&</sup>lt;sup>93</sup> Dannecker, 2023, p. 138.

<sup>&</sup>lt;sup>94</sup> According to Dannecker, 2023, p. 146.

the individual advisors are often not guaranteed, although they have been required since the ethics committees were established. Fox et al. report from the USA in 2022 that respondents from larger hospitals did not consider the financial support for ethics counselling to be sufficient. In Germany, some large university hospitals do have qualified ethics experts, but the financial resources for HECs and the further training of their members are usually very limited. Overall, the quality problem has not been solved. The lack of qualifications is usually linked to a lack of financial resources, for example to hire a suitably qualified ethicist, company-funded training for members of ethics committees during working hours and usually only modest budgets that do not allow more than one training event per year to be offered to all hospital employees.

In addition, further legal training in connection with ethics committees and ethics counsellors is not regularly provided for. In its statement on 'Ethics Counselling in Clinical Medicine', the BÄK only mentions in 2006 that employees of clinical ethics counselling should receive appropriate further training in clinical ethics and in medical law issues, but not in the statement on Non-Clinical Ethics Counselling from 2019. Similarly, medical law content is not represented in the curriculum of the professional association 'Ethics in Medicine'. <sup>96</sup> Consequently, the structure of the ethics committee can contribute little to the traditional understanding of compliance as adherence to legal requirements. However, the structure of HEC, because it promotes the identification of problems of an ethical and, indirectly, partly legal nature, at least opens up an area of awareness and opportunity for discussion.

The autonomy of the compliance function is given in Germany insofar as a HEC must be able to advise and decide independently with regard to the task of individual case counselling and the task of training employees. In the USA, HECs are sometimes more closely integrated into the hospital structure if they are obliged to make the principles that the institution defines the basis of their recommendations.<sup>97</sup>

With regard to HECs, it can be added to the criteria of the 2017 US guidelines on Corporate Compliance that the pluralism of ethical theories and the fact that different ethical norms and considerations can be justified and used for practical judgements depending on the ethical approach poses a

<sup>&</sup>lt;sup>95</sup> Fox et al. 2022, p. 12.

<sup>&</sup>lt;sup>96</sup> AEM, 2019.

<sup>&</sup>lt;sup>97</sup> AMA, 2022, ch. 10.7. (g), (h).

difficulty. On the one hand, the outcome of the deliberations of ethics committees is open and can fill a legal space for action; on the other hand, quite different outcomes are conceivable, at least in theory.

## 5.2 Positive Aspects of Integrating Health Care Ethics Committees into Compliance Structures

In addition to the formal criteria of the above-mentioned guidelines on Corporate Compliance, three formal aspects can be identified as positive aspects for the issue of compliance:

Firstly, a HEC must function well, i.e. be known in the hospital and accepted in its mode of operation. If an ethics committee is rarely or never called upon, it is ineffective as a structure. If it is called too often, it may not be able to function or may need to communicate a mandate more clearly. The two national overview studies on ethics committees in the USA by Fox et al. (2007; 2022) therefore rightly analyze the workload of ethics committees. There are no current empirical studies for Germany: in contrast to the early decades of their establishment, when there were many reports on individual HEC and rough overviews of the status of their dissemination, it remains to be seen whether HECs are represented throughout hospitals today, how often they are called upon, which problem constellations are discussed and which medical specialties are most frequently affected. The latest survey from Germany, dating from 2014, reports, that mainly large and middle-sized hospitals offered ethics consultation, more than two thirds via HEC. 98 Overall, it can also be stated that publications on the theory and practice of ethics committees in German-speaking countries have declined sharply. Thus, actual information about dissemination und functioning of HECs is necessary.

Secondly, an ethics committee includes competences for constructive conflict resolution. An ethics committee is often called upon to deal with conflicts within the team or between the team and the patient and their relatives because there is hardly any other structure for addressing them in the hospital. It is true that the chairpersons or the committee as a whole must analyze what type of conflict is involved. If, for example, it is a question of communication, division of labour or labour law, where no ethical aspects are in dispute, an ethics committee will not deal with it, but will nevertheless have contributed to clarification. In Germany, the BÄK already emphasized the need to distance itself from the employee representation,

\_

<sup>98</sup> Schochow 2014.

internal complaints management and professional supervision in its recommendations from 2006.<sup>99</sup> However, if the ethics committee reformulates and analyzes a conflict as ethically relevant, it takes further steps towards clarification.

Thirdly, a functioning ethics committee can contribute to deescalation and finding solutions through its expertise in assigning or analyzing and ethically discussing conflicts between healthcare employees and patients and their families. In this way, ethics committees can also contribute to compliance in the sense of 'corporate self-regulation', which also has an impact on the prevention of legal disputes.

Fourthly, in the USA as in Germany, advice from an ethics committee can show that a doctor who has taken advantage of structured ethics counselling wanted to fulfil their duty to make responsible decisions in a difficult situation. This heightened duty of care can have the effect of preventing or mitigating punishment.

Fifthly, morally controversial issues in healthcare are often linked to legal issues. Ethics committees have the effect of making ethical and legally relevant issues visible and, with their "multiple-eye principle", offer a space for discussion and reflection in which a defined group of hospital employees, who also come from different professional groups, participate. Beyond the HEC, the discussion can result in further actions by those involved in the HEC and even institutional changes – not least through the task of developing guidelines, even if this is rarely carried out by HECs. In this respect, the HEC can contribute to the further development of compliance in hospitals.

#### 6. Conclusion

Overall, HECs are certainly most interesting in their task of advising on difficult treatment cases as an instrument of compliance. A HEC is a structure that can ensure that all ethically relevant aspects that serve the patient's well-being can be considered in a difficult treatment case through a multi-eye principle and multi-professionalism. They therefore represent 'good practice' in the language of compliance. However, the ethics committee structure should be clearly committed to the ethical goal of safeguarding the patient's well-being and guaranteeing respect for the patient's fundamental rights. Since the well-being of patients corresponds to

-

<sup>&</sup>lt;sup>99</sup> BÄK, 2006, p. A 1704.

their fundamental moral and legal rights, an ethics committee, which represents a special competence in the hospital because it is composed of members of numerous professional groups and medical specialties, could be used to guarantee respect for the relevant patient rights and serve as a tool of compliance in this clearly defined sense.

#### **Bibliography**

- [1] Alexander, S. (1962) 'They decide who lives, who dies', *Life Magazine*, 53(20), pp. 102–125.
- [2] Annas, G., Grodin, M. (2016) 'Hospital Ethics Committees, Consultants, and Courts', AMA Journal of Ethics, 18 (5), pp. 554–559; https://doi.org/10.1001/journalofethics.2016.18.5.sect1-1605.
- [3] Aulisio M. P. (2014) 'Clinical Ethics. I. Development, Role, and Methodologies', in Jennings, B. (ed.) *Bioethics. Vol. 2.* 4th ed. Farmington Hills, MI: Macmillan, pp. 596–602.
- [4] Aulisio, M. P. (2016) 'Why Did Hospital Ethics Committees Emerge in the US?', *AMA Journal of Ethics*, 18(5), pp. 546–553; https://doi.org/10.1001/journalofethics.2016.18.5.mhst1-1605.
- [5] Baker, R. (2022) 'A Brief Introduction to the History of Clinical Ethics', in Wasson, K., Kuczewski, M. (eds.) *Thorny Issues in Clinical Ethics Consultation. North American and European Perspectives.* Cham: Springer, pp. 3–12; https://doi.org/10.1007/978-3-030-91916-0\_1.
- [6] Beauchamp, T. L., Childress, J. F. (2019) *Principles of Biomedical Ethics*. 8th ed. Oxford: Oxford University Press.
- [7] Bobbert, M. (2009) 'Klinische Ethikberatung Ein hermeneutischnormatives Modell', in Baumann-Hölzle, R., Arn, C. (eds.) *Handbuch Ethik im Gesundheitswesen. Bd. 3: Ethiktransfer in Organisationen.* Basel: EMH und Schwabe AG, pp. 187–202.
- [8] Bockenheimer-Lucius, G., May, Arnd T. (2007) 'Ethikberatung Ethikkomitee in Einrichtungen der stationären Altenhilfe (EKA). Eckpunkte für ein Curriculum', *Ethik in der Medizin*, 19(4), pp. 331–339; https://doi.org/10.1007/s00481-007-0530-6.

- [9] Brody, H. (2010) 'The Physician-Patient Relationship' in Wedding, D., Stuber, M. L. (eds.) *Behaviour and Medicine*. 5th ed. Cambridge: Hogrefe, 187-198.
- [10] Bundesärztekammer (BÄK) (2006) 'Zentrale Kommission zur Wahrung ethischer Grundsätze in der Medizin und ihren Grenzgebieten bei der Bundesärztekammer (ZEKO), Ethikberatung in der klinischen Medizin', *Deutsches Ärzteblatt*, 103(24), pp. A1703–1707.
- [11] Bundesärztekammer (BÄK) (2019) 'Stellungnahme der Zentralen Kommission zur Wahrung ethischer Grundsätze in der Medizin und ihren Grenzgebieten (Zentrale Ethikkommission), Außerklinische Ethikberatung', *Deutsches Ärzteblatt*, 117(12), pp. A1–A8; https://doi.org/10.3238/baek\_sn\_aeb\_2019.
- [12] Dannecker, G. (2023) 'Compliance Domestic and International Good Practices: Tendenz zur Verrechtlichung ethischer und unternehmensinterner Regeln', in Beisel, H., Laue, C., Meier, B.-D. (eds.) Die Kriminalwissenschaften als Teil der Humanwissenschaften. Festschrift für Dieter Dölling zum 70. Geburtstag. Baden-Baden: Nomos, pp. 131–155.
- [13] Dannecker, G (2025) 'Compliance as Strategy to Avoid Criminal, Administrative, and Civil Sanctions', *European Integration Studies*, 21(1) (in print).
- [14] Deutscher Evangelischer Krankenhausverband e.V. und Katholischer Krankenhausverband Deutschlands e.V. (1997) *Ethik-Komitee im Krankenhaus. Erfahrungsberichte zur Einrichtung von Klinischen Ethik-Komitees.* Stuttgart: Selbstverlag.
- [15] Dörries, A., Simon, A., Marckmann, G. (2015) 'Ethikberatung im Krankenhaus Sachstand und kritischer Ausblick', *Ethik in der Medizin*, 27(3), pp. 249–253; https://doi.org/10.1007/s00481-015-0361-9.

- [16] Engelhardt, T. Jr. (1995) *The Foundation of Bioethics*. 2nd ed. Oxford: Oxford University Press.
- [17] Fox, E., Danis, M., Tarzian, A. J., Duke, C. C. (2022) 'Ethics Consultation in U.S. Hospitals: A National Follow-Up Study', *The American Journal for Bioethics*, 22(4), pp. 5–18; https://doi.org/10.1080/15265161.2021.1893547.
- [18] Fox, E., Myers, S., Pearlman, R. A. (2007) 'Ethics Consultation in United States Hospitals: A National Survey', *American Journal of Bioethics*, 72, pp. 13–25; https://doi.org/10.1080/15265160601109085
- [19] Frewer, A, Fahr, U., Rascher, W. (eds.) (2008) Klinische Ethikkomitees. Chancen, Risiken und Nebenwirkungen. Würzburg: Königshausen & Neumann.
- [20] Gerald N., Alfred S., Vollmann, J. (eds.) (2010) Klinische Ethikberatung. Ein Praxisbuch für Krankenhäuser und Einrichtungen der Altenpflege. 2nd ed. Stuttgart: Kohlhammer.
- [21] Gewirth, A. (1978) *Reason and Morality*. Chicago: University of Chicago Press.
- [22] Guadagno, R. E. (2017) 'Compliance', in Harkins, S. G., Williams, K. D., Burger, J. M. (eds.) *Oxford Handbook of Social Influence*. Oxford: Oxford University Press, pp. 107–127; https://doi.org/10.1093/oxfordhb/9780199859870.013.4.
- [23] Hajibabaee, F., Soodabeh, J., Mohammad, A. C., Pooneh, S., Patricia, R. (2016) 'Hospital/Clinical Ethics Committees' Notion: an Overview', *Journal of Medical Ethics and History of Medicine*, 9(17), pp. 1–9.
- [24] Hauschka, C. E., Moosmayer, K., Lösler, T. (eds.) (2016) *Corporate Compliance. Handbuch der Haftungsvermeidung in Unternehmen.* 3rd. ed. München: Beck.

- [25] Hester, M. D., Schonfeld, T. L. (2022) *Guidance for Healthcare Ethics Committees*. 2nd ed. Cambridge: Cambridge University Press; https://doi.org/10.1017/9781108788250.
- [26] Kettner, M. (2008) 'Autorität und Organisationsformen Klinischer Ethikkomitees', in Frewer, A., Fahr, U., Rascher, W. (eds.) *Klinische Ethikkomitees. Chancen, Risiken und Nebenwirkungen.* Würzburg: Königshausen und Neumann, pp. 15–28.
- [27] Knierim, T. C. (2025) 'Compliance', in Wabnitz, H.-B., Janovsky, T., Schmitt, L. (eds.) *Handbuch Wirtschafts- und Steuerrecht*. München: Beck, pp. 387–434.
- [28] KTQ GmbH: Kooperation für Transparenz und Qualität im Krankenhaus (2004) KTQ-Katalog. Düsseldorf: KTQ-GmbH.
- [29] May, A. T. (2010) 'Ethikberatung Formen und Modelle', in Heinemann, W., Maio, G. (eds.) *Ethik in Strukturen bringen*. Freiburg/Br: Herder, pp. 80–102.
- [30] Musil, R. (2014) Der Mann ohne Eigenschaften. Erstes und zweites Buch. Hamburg: Rowohlt.
- [31] Farber Post, L., Blustein, J. (2021) *Handbook for Health Care Ethics Committees*. 3rd ed. Baltimore: John Hopkins University Press.
- [32] Rothärmel, S. (2010) 'Rechtsfragen Klinischer Ethikberatung', in Dorries, A. et al. (eds.) Klinische Ethikberatung. Ein Praxisbuch für Krankenhäuser und Einrichtungen der Altenpflege. Stuttgart: Kohlhammer, pp. 178–185.
- [33] Rotsch, T. (2024) 'Criminal Compliance', in Achenbach, H., Ransiek, A., Rönnau, T. (eds.) *Handbuch Wirtschaftsstrafrecht*. 6th ed. Heidelberg: C.F. Müller, pp. 61–128.

- [34] Scherzinger, G., Bobbert, M. (2017) 'Evaluation of Research Ethics Committees: Criteria for the Ethical Quality of the Review Process', *Accountability in Research*, 12(3), pp. 152–176; https://doi.org/10.1080/08989621.2016.1273778.
- [35] Schochow, M., Schnell, D., Steger, F. (2019) 'Implementation of Clinical Ethics Consultation in German Hospitals', *Science and Engineering Ethics*, 25, pp. 985-991; https://doi.org/10.1007/s11948-015-9709-2.
- [36] Schoppmeyer, M. (2020) ,Compliance [Physiologie]', in *Pschyrembel online*, Berlin: de Gryuter. [Online]. Available at: Pschyrembel Online | Compliance [Physiologie] (Accessed: 8 March 2025).
- [37] Singer, P. (2011) *Practical Ethics*. 3rd ed. Cambridge: Cambridge University Press.
- [38] Steinkamp, N., Gordijn, B. (2005) *Ethik in der Klinik. Ein Arbeitsbuch*. 2nd. ed. Neuwied-Köln/München: Luchterhand.
- [39] Ten Have, H., do Céo Patrão Neves, M. (2021) 'Clinical Ethics Consultation', in Ten Have, H., do Céo Patrão Neves, M (eds.) *Dictionary of Global Ethics*, Cham: Springer; https://doi.org/10.1007/978-3-030-54161-3\_129.
- [40] Tong, R. (1991) 'The Epistemology and Ethics of Consensus: Uses and Misuses of 'Ethical' Expertise', *Journal of Medicine and Philosophy*, 16(4), pp. 409–426; https://doi.org/10.1093/jmp/16.4.409.
- [41] Wasson, K., Kuczewski, M. (eds.) (2022) Thorny Issues in Clinical Ethics Consultation. North American and European Perspectives. Cham: Springer; https://doi.org/10.1007/978-3-030-91916-0.
- [42] Wirtz, M. A. (eds.) (2025) *Dorsch. Lexikon der Psychologie*, Lemma: Compliance. Bern: Hogrefe. [Online]. Available at: https://dorsch.hogrefe.com/stichwort/compliance (Accessed: 16 February 2025).

- [43] Akademie für Ethik in der Medizin e.V. (AEM) Vorstand (2019) *Curriculum Ethikberatung im Gesundheitswesen*. [Online]. Available at: https://www.aemonline.de/fileadmin/user\_upload/Curriculum\_Ethikberatung\_im\_\_Ges undheitswesen\_2019-06-24.pdf (Accessed: 04 March 2025).
- [44] Akademie für Ethik in der Medizin e.V. (AEM) Vorstand (2010) "Ethikberatung im Krankenhaus Standards für Ethikberatung in Einrichtungen des Gesundheitswesens", *Ethik in der Medizin*, 22(2), pp. 149–153; https://doi.org/10.1007/s00481-010-0053-4.
- [45] American Medical Association (AMA) (2022) Code of Medical Ethics. 2nd ed.
- [46] American Medical Association (AMA) (2022) *Code of Medical Ethics*. 10.7 Ethics Committees in Healthcare Institutions. [Online]. Available at: https://policysearch.ama-assn.org/policyfinder/detail/faith?uri=%2FAMADoc%2FEthics.xml-E-10.7.xml (Accessed: 05 March 2025).
- [47] American Society for Bioethics and Humanities (1998) Core Competencies for Health Care Ethics Consultation. Glenview, Ill: ASBH.
- [48] American Society for Bioethics and Humanities (2011) Core Competencies for Health Care Ethics Consultation. 2nd ed., Glenview, Ill: ASBH.
- [49] American Society for Bioethics and Humanities (2024) *Core Competencies for Health Care Ethics*. 3rd ed., Glenview, Ill: ASBH.
- [50] Arbeitsgruppe ,Ethikberatung im Gesundheitswesen' der Akademie für Ethik in der Medizin (AEM) (2013) ,Empfehlungen zur Evaluation von Ethikberatung in Einrichtungen des Gesundheitswesens', *Ethik in der Medizin*, 25(2), pp. 149–156; https://doi.org/10.1007/s00481-012-0230-8.

- [51] President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research (1983) *Deciding to Forego Life-Sustaining Treatment. Washington.* D.C: U.S. Government Printing Office. (Im Anhang: Modellentwurf für die Satzung zukünftig einzurichtender Ethikkomitees.)
- [52] Regierungskommission (2022) Deutscher Corporate Governance Codex (DCGK) in der Fassung vom 28.04. 2022 [Online]. Available at:

  https://www.dcgk.de//files/dcgk/usercontent/de/download/kodex/2206
  27\_Deutscher\_Corporate\_Governance\_Kodex\_2022.pdf (Accessed: 3 March 2025).
- [53] World Medical Association (1964 respective 2024) *Declaration of Helsinki Ethical Principles for Medical Research Involving Human Participants*. Geneva. [Online]. Available at: (Accessed: 16 February 2025).