

Clinical ethics protocols in the clinical ethics committees of Madrid

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ABSTRACT

Introduction Currently, The nature and scope of Clinical Ethics Protocols (CEPs) in Madrid (Spain) are not well understood.

Objectives The main objective is to describe the features of 'guideline/recommendation' type CEPs that have been or are being developed by existing Clinical Ethics Committees (CECs) in Madrid. Secondary objectives include characterisation of those CECs that have been the most prolific in reference to CEP creation and implementation and identification of any trends in future CEP development.

Methods We collected CEPs produced and in process by CECs accredited in the public hospitals in Madrid, Spain, from 1996 to 2008.

Results CECs developed 30 CEPs, with 10 more in process. The most common topic is refusal of treatment (seven CEPs developed; two in process). If CEPs addressing terminal illness, Do-Not-Resuscitate orders and advance directives are placed into a separate 'ethical problems at the end of life' category, this CEP subject emerges as the most common (eight developed; four in process). There is a relationship between the age of the CEC and the development of CEPs (the oldest CECs have developed more CEPs). CECs now seem to be more likely to engage in CEP development.

Conclusions The CECs in Madrid, Spain, have developed a significant number of CEPs (30 in total and 10 in process) and there is a trend towards continued development. The most frequent topics are ethical problems at the end of life and refusal of treatment by the patient.

INTRODUCTION

Clinical Ethics Protocols (CEPs) are documents intended to regulate complex and frequent ethical conflicts in clinical practice.¹ Examples of CEPs include Do-Not-Resuscitate (DNR) orders,² recommendations on palliative care treatments³ or guidelines regarding refusal of treatment.⁴ CEPs, by detailing clear courses of action, may influence the handling of certain ethical problems, prevention of litigious claims⁵ and even in legislation (as in cases of organ donation in which laws require CEP compliance).⁶

CEPs can be formulated by various bodies, including medical associations ('non-institutional' CEPs)⁷ or institutions ('institutional' CEPs).⁸ One of the main aims of Clinical Ethics Committees (CECs), which are committees addressing ethical issues in health institutions, is the development of CEPs as well as their subsequent implementation and evaluation.⁹

Types of CEPs

CEPs can be categorised into the following subtypes: guidelines or recommendations, policies or models. CEPs of the 'guideline' type¹⁰ suggest principles of conduct or recommended procedures that are acceptable from an ethical standpoint, but ultimately do not mandate compliance by the medical practitioner. In contrast, 'policy'-type CEPs¹¹ (eg, governing voluntary patient discharge) are regarded as normative, with adherence being the expectation; thus, they serve as instruments for institutional authorities to ensure compliance with certain goals, and consequently, often possess a particular regulatory language. 'Model'-type¹² CEPs provide health institutions with blueprints and/or methods in order to develop their own guidelines.

This study concentrates exclusively on the 'guideline/recommendation' CEPs, which best resolve particular ethical conflicts of everyday clinical practice.

Role and function of the 'guideline/recommendation' CEPs in practice

CEPs are ethical guidelines or standards that health-care agents can use to make ultimate decisions regarding care.¹³ In practice, CEPs proffer the best available options towards decision making, delineate particular steps that should be taken and identify responsible agents for each action.¹⁴ For instance, a guideline on Jehovah's Witnesses and refusal of treatment might clarify which particular cases warrant transfusions and specify responsibilities of each involved party (ie, physician, patient, family member, legal counsel, etc).

Clinicians review CEP recommendations and apply them to the specific case in question as they feel appropriate. While clinicians are not formally obligated to follow recommendations, the institution highly encourages them to provide justification in cases where decisions deviate from CEP opinion.

Objectives

The main objective of this study is to describe the features of 'guideline/recommendation' type of CEPs that have been or are being developed by existing CECs of Spanish hospitals in the specific region of Madrid. Other objectives include characterisation of those CECs that have been the most prolific in reference to CEP creation and implementation and identification of any trends in future CEP development.

METHODS

We collected all the CEPs of the 'guideline/recommendation' type created by CECs of the 13 public

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hospitals in Madrid, Spain, from CEC inception until 2008. Data collection was performed in the Spanish public hospital system of Madrid for several reasons. First, the public health system is the most utilised, given universal health coverage of the citizens of the region, and therefore, affords a large cross-section of the population that can be analysed easily in the context of CEPs. Second, while private hospitals in other regions of Spain may also possess CECs, all accredited CECs in Madrid exist in the exclusive domain of the public hospital system.

Not all hospitals possess an accredited CEC; therefore, we first identified the existence of CECs within the hospital infrastructure. In order to garner all CEPs created by their respective CECs, we contacted each committee directly and independently. All of the contacted CECs agreed to cooperate with our request for study, each delivering to us a copy of each of their CEPs. The compilation of all CEPs for study occurred between 2006 and 2007. CEPs that were received range in scope from fully

established protocols to those still in the process of active development over 1 year (2008).

RESULTS

Description of the CEPs

Table 1 describes the CEPs developed as well as those that still are in development (a total of 40). The date of development (in parentheses) corresponds to the date on which the CEP was finally approved by the CEC.

CECs operating in Madrid have developed 30 CEPs, with another 10 CEPs in active development (figure 1). The most common subject of the CEPs is patient refusal of treatment, specifically addressing the management of patients who are Jehovah's Witnesses, with seven completed CEPs and two others in process. The frequency of other CEPs is as follows: regarding the terminally ill, three completed CEPs and one in process; DNR orders, three completed CEPs and two in process; regarding the use of advance directives, two completed

Table 1 CEPs developed by accredited CECs in the public hospitals of Madrid and those in process at the time of the study

Hospital	Year of CEC accreditation*	CEP subject and date of development	Number and subject of CEPs in process
H. 12 de Octubre	1996	Total: 4 1. Jehovah's Witnesses and elective surgery (1997). 2. Patient capacity and decision to leave hospital. 3. Living donors and liver transplant (1999). 4. Use of mechanical restraints (2003, prepared by the Quality Unit).	Total: 0
H. La Paz	1995	Total: 2 1. Recommendations for informed consent (1998). 2. Jehovah's Witnesses and refusal of treatment (2005).	Total: 0
Clínica Puerta de Hierro	1995	Total: 5 1. Information to patients (1996, 2004). 2. Domestic abuse (2006). 3. Jehovah's Witnesses and refusal of treatment (2004). 4. Management of terminal patients (2005). 5. DNR orders (2005).	Total: 1 1. Use of mechanical restraints.
H. Ramón y Cajal	2002	Total: 1 1. Management of terminal patients (2004).	Total: 1 1. Jehovah's Witnesses and refusal of treatment.
H. Clínico San Carlos	1998	Total: 6 1. DNR orders (1999). 2. Institutions of palliative care protocols (1999). 3. Determinations of therapeutic intervention levels of care (1999). 4. Patient information regarding nursing procedures (1999). 5. Use of informed consent documents (2003). 6. Patient capacity and refusal of treatment (2004)	Total: 3 1. Use of mechanical restraints. 2. Domestic abuse. 3. DNR orders (update of the prior protocol).
Fundación Hospital Alcorcón	2005	Total: 0	Total: 0
H. de La Princesa	1995	Total: 2 1. Use of advance directives (2000). 2. Information to professionals about CEC functions and procedures (1996, 2006).	Total: 0
H. Gregorio Marañón	2005	Total: 21. Patient privacy and confidentiality (1999, 2005). 2. Jehovah's Witnesses and refusal of treatment (2004).	Total: 0
H. de Getafe	1995	Total: 6 1. Jehovah's Witnesses and refusal of treatment (1999). 2. DNR orders (2003). 3. Use of advance directives (2003). 4. Identification of patient values and beliefs (2003). 5. Sedation protocols (2003). 6. Living organ donors and transplantation (2005).	Total: 2 1. Institution of palliative care protocols. 2. Access to elective genetic diagnostic services.
H. de Móstoles	1995	Total: 2 1. Jehovah's Witnesses and refusal of treatment (2003). 2. Patient capacity assessment (2003).	Total: 2 1. DNR orders. 2. Use of advance directives.
H. Príncipe de Asturias	2005	Total: 0	Total: 1 1. Jehovah's Witnesses and refusal of treatment.

*Indicates the year of accreditation of the CEC by the Regional Ministry of Health of Madrid, Spain. CEC, Clinical Ethics Committee; CEP, Clinical Ethics Protocol; DNR, Do-Not-Resuscitate.

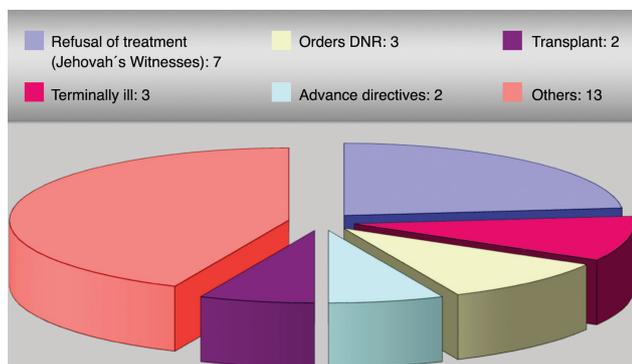


Figure 1 Subjects of Clinical Ethics Protocols created by accredited Clinical Ethics Committees in Madrid, Spain (since inception to 2007).

CEPs and one in process; transplant, two completed CEPs and zero in process; mechanical restraints, one completed CEP and two in process; and domestic abuse, one completed CEP and one in process.

If we place CEPs regarding the terminally ill, DNR orders and advance directives into a discrete 'end-of-life ethical issues' category, this CEP category would, in fact, emerge as the most common, with eight completed CEPs and four in process of active development. Apart from those discussed, there are 11 other CEPs governing the following subjects: patient capacity to leave the hospital, informed consent for procedures, access to patient clinical information, determinations of level of care based on therapeutic intervention, information (to professionals) about the functions and procedures of the CEC itself, patient privacy and confidentiality, patient values and belief identification, sedation protocols and patient capacity assessment. There is one CEP in process dealing with access to elective genetic testing services.

Seven institutional CECs were accredited between 1995 and 2000 and four between 2000 and 2007. The seven hospitals with the oldest CECs developed 27 CEPs, an overall average of four CEPs per CEC. The four youngest CECs have developed three CEPs, less than one CEP per CEC.

Temporal CEP development

The first CEP was elaborated by a CEC in 1996. It is noteworthy that the highest period of CEP productivity (17 CEPs, more than half of all CEPs created, with another 10 CEPs in process—see figure 2) occurred during 2003–2007, while the period 1996–2002 demonstrates development of only 13 CEPs.

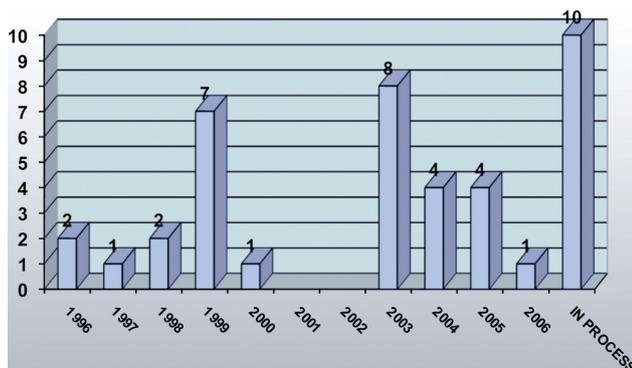


Figure 2 Clinical Ethics Protocol creation on a yearly basis from 1996 to 2008.

DISCUSSION

Eleven of the 13 hospitals involved in the study had accredited CECs and these 11 committees created 30 CEPs. The most recurrent subjects were end-of-life issues and the patient refusal of treatment, specifically by patients who are Jehovah's Witnesses. The attention given to these subjects, especially end-of-life issues, is consistent with findings in other western European countries^{15 16} and in the USA,^{17 18} indicating that the main subjects treated in Spanish CEPs are similar to those found in these countries' CEPs.

There is a relationship between the age of the CEC and CEP development (ie, the oldest CECs have developed more CEPs). It is possible that a longer time in existence affords a CEC with a heightened ability to produce CEPs, based not only on more overall time to produce but also experience that both lead to improved efficiency, growth and breadth of the personnel assigned to such development. The elaboration of a CEP shows that the members of the CEC have capacity of reflection, organisation and proper education, as well as an acknowledgement of the deliberative method that is required.¹⁹ In addition, it reflects CEC participation in, and awareness of, the dynamics of the hospital, allowing for problems at the medical centre to become more familiar and easily addressed.²⁰

More than half of the CECs were developed in the last 5 years of the study, with another 10 more in process. These data suggest that CECs in Madrid during the current era are more likely to engage in CEP development, perhaps indicating a trend of growing awareness of the need to establish protocolised procedures^{21 22} that help navigate the frequently encountered and heretofore nebulous territory of ethical conflict in the healthcare institutions.^{23 24}

Some limitations of this study are that it is restricted to Madrid and that both the production of the CEPs and their respective subjects may have been influenced by the development of the field of bioethics itself in Spain. Future studies should compare the structure and themes governed by CEPs between different regions of Spain and even other countries. Another important area to examine is the impact of CEPs on the environment (institutional or otherwise) in which they were devised, something rarely evaluated and therefore still poorly understood. It would be revealing to investigate the relationship between CEP development and ultimate ethical decisions that are made as well as any consequent changes in local, regional, or national legislation.

In conclusion, characterisation of the 40 CEPs, either already developed or in active development by CECs in Madrid, shows a proclivity towards end-of-life issues and patient refusal of treatment, particularly concerning Jehovah's Witnesses. The data also allow us to consider the existence of a trend towards continued expansion of CEP, especially regarding these specific issues.

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Competing interests None.

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