THE BIOETHICAL PRINCIPLISM MODEL APPLIED IN PAIN MANAGEMENT

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ABSTRACT

An integrative literature review was developed with the purpose to analyze the scientific production regarding the relationships between pain and the principles of bioethics (autonomy, beneficence, nonmaleficence and justice). Controlled descriptors were used in three international data sources (LILACS, SciELO, MEDLINE), in April of 2012, totaling 14 publications categorized by pain and autonomy, pain and beneficence, pain and nonmaleficence, pain and justice. The adequate relief of pain is a human right and a moral issue directly related with the bioethical principlism standard model (beneficence, non-maleficence, autonomy and justice). However, many professionals overlook the pain of their patients, ignoring their ethical role when facing suffering. It was concluded that principlism has been neglected in the care of patients in pain, showing the need for new practices to change this setting.


RESUMO

Trata-se de revisão integrativa da literatura, com o objetivo de analisar a produção científica referente às relações entre a dor e os princípios da bioética: autonomia, beneficência, não maleficência e justiça. Foram utilizados descritores controlados em três bases de dados internacionais (LILACS, SciELO, MEDLINE), em abril de 2012, resultando em 14 publicações, distribuídas nas categorias Dor e autonomia, Dor e beneficência, Dor e não maleficência, Dor e justiça. O alívio adequado da dor é um direito humano e uma questão moral que se relaciona diretamente com a bioética principialista. Entretanto, muitos profissionais negligenciam a dor de seus pacientes, desconsiderando seu papel ético frente ao sofrimento. Concluiu-se que o principlismo tem sido negligenciado no atendimento aos pacientes com dor, evidenciando a necessidade de novas práticas para mudança desse panorama.


Título: O modelo bioético principalista aplicado no manejo da dor.

RESUMEN

Se realizó una revisión de la literatura para analizar la producción científica relacionadas con el dolor y los principios de la bioética (autonomía, beneficencia, no maleficencia y justicia). Se utilizaron descriptores controlados en tres fuentes de datos internacionales (LILACS, SciELO, MEDLINE), en abril de 2012, totalizando 14 publicaciones, distribuidas en las clasess: el dolor y la autonomía, el dolor y la beneficencia, el dolor y no maleficencia, el dolor y la justicia. El adecuado alivio del dolor es un derecho humano y un problema moral relacionado directamente con el principialismo bioético (beneficencia, no maleficencia, autonomía y justicia). Sin embargo, muchos profesionales negligencian el dolor de sus pacientes, ignorando su papel ético frente al sufrimiento. Se concluyó que el principialismo ha sido descuidado en la atención de los pacientes con dolor evidenciando la necesidad de nuevas prácticas para cambiar este panorama.


Título: El principialismo bioético modelo aplicado en el tratamiento del dolor.
INTRODUCTION

Pain is a symptom that affects thousands of people worldwide and may bring on losses for those who experience it\(^1\). The adequate treatment of this experience must be multimodal and comprise drug and non-drug measures. However, despite the advances in knowledge and new technologies, several obstacles make it difficult to relieve pain early and satisfactorily\(^1\). Any pain must be relieved, and when the treatment focuses on the chronic pain, which compromises physical and/or emotional integrity, generates biopsychosocial damage, affects directly human health and becomes the disease itself, efforts must be made in order to achieve the best result, since adequate pain relief is a human right and a moral issue\(^2\). Moreover, treating pain neglectfully is a violation to the Universal Declaration of Human Rights\(^3\) and the Brazilian Federal Constitution\(^4\).

The relief of the pain experience permeates the moral structure and the ethical principles that originated these legal devices and has a significant relationship with bioethics, whose focus resides on ethical questions regarding human life (thus, regarding health) using principlism, that is, the principles of beneficence, nonmaleficence, autonomy and justice to guide its discussions and reflections\(^5\)\(^-\)\(^7\).

The bioethical principlism model\(^8\) is the most frequently adopted theoretical bioethical framework in Brazil, in which autonomy is defined as the patient’s right to choose over his/her own life and the health professional’s duty to respect this autonomy; beneficence, as the principle that every medical action must promote the wellbeing and the participation of the other, requiring some balance between the benefits and possible damages of a certain action; nonmaleficence, as the professional’s duty to cause no harm or damage to the patient; and, justice, as the duty to distribute health resources impartially.

At the moment when a health professional promotes pain relief, the beneficence principle is served; on the other hand, if not treated, it contributes to bring on physical and psychological damages, hurting the principle of nonmaleficence. Similarly, in cases in which a pain complaint is ignored or the procedure to relieve pain is refused, the autonomy of the patient and the self-determination of health care is contradicted. Among all these principles, justice constitutes a greater challenge in the treatment of pain, since the access to the health services and treatments available is still unequal, due to socioeconomic inequalities\(^9\).

Hence, this study was developed to answer the following question: “Which relationships between pain and the bioethical principles (autonomy, beneficence, nonmaleficence and justice) are approached in the studies found in the Brazilian and the international scientific production?”

The importance or the noncompliance with the ethical role of the health professional in face of the patient in pain, and the difficulties of conduct based on bioethical principles in the daily practice are relevant points that justify the development of this study, whose purpose was to analyze the Brazilian and the international scientific production regarding the relationships between pain and the bioethical principles: autonomy, beneficence, nonmaleficence and justice.

METHODOLOGY

The integrative literature review is a broad research method that allows the inclusion of both experimental and non-experimental studies, and has the purpose to review concepts, theories and evidences, allowing a synthesis of several published studies and general conclusions regarding the studied theme\(^10\)\(^-\)\(^12\). This study was developed in April of 2012 and its methodology was elaborated based on the proposal of other authors\(^11\) (Figure 1).

The search for studies was performed in the databases: Latin-American and Caribbean Center on Health Sciences Information (LILACS), Medical Literature Analysis and Retrieval System Online (MEDLINE) and Scientific Electronic Library Online (SciELO). The following health sciences descriptors were crossed (DeCS – 2011 edition): pain and ethics; pain and bioethics; pain and morals and similar descriptors in English. Inclusion criteria comprised studies that had been published between January of 2001 and April of 2012 (period after the establishment of the bioethical principles in Brazil, and the consolidation of the principlism bioethics in health care practices in the national and the international scope), in Portuguese, English or Spanish; and that approached the relationships between pain and at least one of the bioethical principles (autonomy, beneficence, nonmaleficence

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Definition of the study question
Selection of the controlled descriptors and databases for literature search (SciELO, LILACS, MEDLINE)
Establishment of inclusion and exclusion criteria
Search in databases (n=1091) and selection of abstracts (n=22)
Search in the full studies of the selected abstracts (using bibliographic commutation)
Reading and re-reading of the studies focused on the study question
Selection of studies for this review (n=14)
Synthesis of the studies by completing the data collection instrument
Presentation of the results

Figure 1 - Flowchart of the methodological strategy used. Goiânia, GO, 2012.

and justice). Exclusion criteria applied to studies without an abstract available for analysis in the databases used and published in other languages (French and German).

The crossing of descriptors in LILACS resulted in 74 studies, in SciELO in 23, and in MEDLINE, in 994. Considering the inclusion and exclusion criteria, seven abstracts were selected in LILACS, one in SciELO and 14 in MEDLINE, whose full studies were obtained with the help of the bibliographical commutation sector of the Ministry of Health. In the continuation, the relationship between the study issue and the purpose of the present study was evaluated, and this analysis resulted in the selection of three studies in LILACS, none in SciELO and 11 in MEDLINE, totaling 14 studies. As instrument proposed for the data collection of integrative reviews was used[13], which contemplated items regarding the identification of the study, the study institution, the type of study (health area to which the publication belongs), methodological characteristics and evaluation of the methodological rigor. Data were extracted through exhaustive reading and re-reading of the studies and, later, organized into a database in the Microsoft Excel 2007 program.

Data were analyzed through the re-reading of the data inserted in the database and comparison with the theoretical framework of this study. Data regarding the year, country and institution of the published study were explored using absolute frequency and grouped into categories. Afterwards, the methodological characteristics of the studies were analyzed, classifying them in seven levels of evidence[14]: level 1: meta-analysis of multiple controlled studies; level 2: individual studies with experimental design; level 3: studies with quasi-experimental, cohort or case control design; level 4: studies with non-experimental design, including qualitative and case studies; level 5: reports of cases of data obtained systematically, with verifiable quality, or data from program evaluations; and level 6: opinion of respected authorities based on clinical competence or opinion of boards of experts[14]. The studies that did not comply with the requisites mentioned were classified as studies “without evidence”.

The results regarding the relationships between pain and the bioethical principles were grouped in four categories: pain and autonomy, pain and beneficence, pain and nonmaleficence, pain and justice.
RESULTS

The results regarding the analysis of the 14 studies included in this review were summarized in Table 1. A greater number of publications (four) was observed in 2002, followed by 2008 and 2009, with two publications in each year; and 2001, 2003, 2004, 2006, 2007 and 2010 with one publication each. Regarding the origin countries of these productions, nine studies were developed in the United States, two in Chile, and one in Spain, Switzerland and Brazil. Six studies involved participants from hospital institutions, six were originated in universities and three in both universities and hospitals. Two studies did not inform the origin location. Five publications belonged to the nursing area, seven to medicine, one to pharmacy, and one did not provide the knowledge area. Regarding the language, one publication was written in Portuguese, three in Spanish and ten in English.

The methodological characteristics of the studies allowed to classify one of the publications\(^{[27]}\) in the level four of evidence; two\(^{[19, 24]}\) in the level five (case report); three\(^{[20, 25, 26]}\) in the level six (opinions and reflections of experts); and eight publications as “without evidence”, since they were non-systematic literature reviews.

DISCUSSION

The results pointed out the four bioethical principles involved in the treatment of pain and their relevance. These principles were discussed in the categories: pain and autonomy, pain and beneficence, pain and nonmaleficence and pain and justice.

Pain and autonomy

Autonomy is considered the primordial principle in face of an ethical dilemma\(^{[15]}\). A study devel-

<table>
<thead>
<tr>
<th>Authors</th>
<th>Title</th>
<th>Synthesis of the main results</th>
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<tbody>
<tr>
<td>Ballas SK(^{[15]})</td>
<td>Ethical issues in the management of sickle cell pain</td>
<td>Approached the importance to establish a therapeutic plan together with the patient to assure his/her autonomy. It mentioned briefly the principles of beneficence, nonmaleficence and justice.</td>
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<tr>
<td>Swenson CJ(^{[16]})</td>
<td>Ethical issues in pain management</td>
<td>Discussed the knowledge of the nurse regarding the pain experience of the patient being intimately connected to the ability of promoting autonomy and beneficence. It also approached the importance of avoiding unnecessary and potentially painful nursing procedures.</td>
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<tr>
<td>LaDuke S(^{[27]})</td>
<td>Ethical issues in pain management</td>
<td>Suggested that nurses must make questions, including regarding the analgesic review and sedation of the patient in pain, being their duty to promote broadly the implementation of informed consent forms for patients in pain treatment, thus, promoting autonomy.</td>
</tr>
<tr>
<td>Carvalho AV(^{[18]})</td>
<td><em>Etica y dolor</em></td>
<td>Approached the need for balance between the risks and benefits of analgesic therapies and the fact that the autonomy of the patient must be observed through the application of informed consent forms.</td>
</tr>
<tr>
<td>Cohen MJM, Jasser S, Herron PD, Margolis CG(^{[19]})</td>
<td>Ethical perspectives: opioid treatment of chronic pain in the context of addiction</td>
<td>Approached the explanation of the pros and cons for using opioids, as well as orientations regarding the low risk of abuse and dependence of these medications as fundamental steps for preserving the autonomy of the patient. It also suggested that constant monitoring is necessary in order to prevent disadvantages for patients under treatment with opioids and history of dependence.</td>
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<tr>
<th>Author(s)</th>
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<tr>
<td>Cahana A(20)</td>
<td>Why withholding a prescription is unethical: a bioethical analysis of a far too familiar case</td>
<td>Brought to light how important it is for the professional to comply with the prescriptions of opioids, since allowing the permanence of pain means causing injury to the patient. By withholding a prescription, the principle of beneficence is neglected. Moreover, the study showed that the distribution of drugs prescribed for pain must be assured, contributing to the principle of justice.</td>
</tr>
<tr>
<td>Company ES, Abasolo MCM(21)</td>
<td>Consideraciones bioéticas en el tratamiento del dolor</td>
<td>The authors stated that the lack of attention towards pain in public health care services firstly constitutes an ethical issue of magnitude, hurting the principle of justice. Moreover, untreated pain generates comorbidities, contradicting the principle of nonmaleficence.</td>
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<tr>
<td>Coop LA(22)</td>
<td>An ethical responsibility for pain management</td>
<td>Brought to light the need to be attentive to the pain of the patient and not to neglect it, since it may cause damage to this individual, who must be heard and have his/her pain treated comprehensively, assuring autonomy, beneficence and nonmaleficence.</td>
</tr>
<tr>
<td>Ortiz A(23)</td>
<td>Ética y manejo del dolor en instituciones de salud</td>
<td>The author argued that all the options available for treating pain must be presented to the patient, so that, aware, he/she may exert autonomy.</td>
</tr>
<tr>
<td>Zalon ML, Constantino RE, Andrews KL(24)</td>
<td>The right to pain treatment: a reminder for nurses</td>
<td>The authors emphasized how important it is for nurses to inform patients regarding their pain treatment and to defend them to other professionals who may not be complying with the bioethical principles.</td>
</tr>
<tr>
<td>Niebrój LT, Jadamus-Niebrój D, Giordano J(25)</td>
<td>Toward a moral grounding of pain medicine: consideration of neuroscience, reverence, beneficence, and autonomy</td>
<td>Discussed the right to the treatment and relief of pain, favoring the principle of beneficence. The respect to the multidimensionality of the patient’s interests and his/her autonomy are ways of practicing beneficence.</td>
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<tr>
<td>Mancuso T, Burns J(26)</td>
<td>Ethical concerns in the management of pain in the neonate</td>
<td>Ethical concerns in the management of pain in the neonate Approached ethical dilemmas in the treatment of pain in newborns. For instance, certain anaesthetics and sedatives may be associated with neurodegeneration in developing brains, however, the non-relief of pain or its inadequate relief may cause harmful effects in these subjects. It emphasized the importance of keeping the parents aware of the situation.</td>
</tr>
<tr>
<td>Chirstoffel MM, Cunha JM, Sant Anna ASF, Garcia RR(27)</td>
<td><strong>Princípios éticos da equipe de enfermagem ao cuidar da dor do recém-nascido</strong></td>
<td>Showed that, providing comfort and reducing stressors responsible for starting or strengthening pain in newborns are ways of practicing beneficence. Similarly, not puncturing the newborn for countless times until venous access is found, allowing the participation of the parents in the treatment and humanizing care are ways of practicing nonmaleficence, autonomy and justice.</td>
</tr>
<tr>
<td>Ballantyne JC, Fleisher LA(28)</td>
<td>Ethical issues in opioid prescribing for chronic pain</td>
<td>Discussed the bioethical dilemmas in the use of opioids, and the importance of respecting the autonomy of the patient in order to judge the treatment he/she wants to receive.</td>
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**Table 1** – Distribution of the selected studies (n=14), according to authors, title of the publication and synthesis of the main results. Goiânia, GO, 2012.
oped in a teaching hospital in São Paulo, SP, showed that 88.89% (n=27) of the nurses believed that professional, patient and family must participate in the process of making decisions and be informed as for their right to autonomy\[20].

Regarding pain, the most frequently approached dilemma in the studies\[16-20,25-29\] involves the treatment of this experience with opioids or the fact that professionals underprescribe, refuse to prescribe, or do not provide medication for patients who are in pain, or wait for the intensification of pain to then prescribe opioids, indicating professional negligence in face of the pain experience. Opioids must be used respecting the pain ladder of the World Health Organization, that is, mild opioids (codeine and tramal) for moderate pain and strong opioids (morphine, oxycodone, methadone) for strong pain\[30\].

Regarding the non-treatment or inadequate treatment of pain, it was observed that the autonomy of the patient is seriously compromised when he/she is not given the right to choose among the options of treatment available or clarified regarding the pain experience and its management, preventing his/her active participation in the treatment\[19,22\]. In this aspect, there is still paternalism among health professionals when they neglect the autonomy of the patient, proposing therapies based on their own presuppositions of adequacy, ignoring the opinion of those who experience pain\[17,31\].

The autonomy of the patient is disrespected when the nurse waits for him/her to report an increased intensity of pain, and to beg for relief in order to receive the prescribed analgesics. At this time, unfortunately, the patient is no longer able to make choices on his/her own\[20,22\]. In addition to this, when there is the involvement of children and older adults, who are legal dependents of other people and unable to communicate what they are feeling, autonomy must be shared with the family members and/or legal guardians. Inadequate pain treatment may generate comorbidities, such as anxiety and depression, which also interfere in the autonomy of the patient. Hence, health professionals cannot rely on moments of vulnerability to make decisions without the participation of the patient or the person responsible for him/her\[17,21\].

Regarding the treatment with opioid analgesics, there are still unfounded fears as for the physical and psychological dependence of those who use it. Some professionals restrict the use of opioids based on the principle of nonmaleficence, given the risks of respiratory depression and reduction of the level of consciousness. Regarding this topic, one of the studies\[20\] approached the case of a pharmacist who refused to provide a brain cancer patient with an opioid that had been prescribed by his physician, causing significant harm to the patient due to the dissatisfactory pain relief. Respecting the autonomy of the patient is important, since they are the only ones with authority over their pain\[19-20\].

The studies of this review presented a list of proposals outlined in the principle of autonomy, so that nurses and other health professionals act properly in face of pain, such as: explaining the pros and cons of using opioids to patients, informing them regarding the low risk of abuse and dependence\[22\]; keeping informed regarding the pain physiology, the use of analgesics and non-drug treatment\[26\]; establishing a therapeutic plan for pain in association with the patient\[16,19\]; discussing with the patient a free and informed consent form as for the possible methods or analgesics that may be used for his/her pain treatment, its costs and possible adverse effects\[15,28\]; adopting the concept that pain is what the patient says it is, and that it exists when the patient says it does\[16\]; and learning the beliefs and wishes of the patient in face of his/her pain\[22\].

### Pain and beneficence

Beneficence aims at the use of the necessary resources to relieve pain, however, the subject must agree with the presented proposal\[22\].

Two studies approached beneficence in the care of pain in newborns\[26-27\]. Performing actions that provide the newborn with comfort and reduce stressor agents that may cause or strengthen pain are ways of practicing beneficence. The non-nutritional suction is an example of this; however, one of the studies reported that, as some professionals forget and depreciate the strategy, they act with negligence and do not provide this comfort to the newborn before, during and after a pain experience.

The belief that only the act of indicating an analgesic is enough as an exercise of beneficence is still present in the practice of some professionals; nevertheless, this bioethical principle must go far beyond that, since the real wellbeing of the patient and efficacy of the pain treatment requires its management to be made by a multiprofessional team, in an interdisciplinary way. In this sense, studies\[17,24\] discussed the difficulties found by nurses to ques-
tion physicians regarding the review of conducts related to the analgesia and sedation of patients and, when they do so, these professionals often refuse to discuss the question. Moreover, many nurses prefer not to risk their professional relationships with the physician in exchange for the benefits that their questions could bring to the patient(17).

Generally, the simple fact of not treating pain or allowing the patient to keep suffering due to inadequate pain relief characterizes negligence, since, automatically, any benefit is being denied to the patient(23). Hence, if a physician indicates an opioid analgesic to someone who is suffering some sort of pain and this subject agrees to use it, it must be done. In cases in which risks and efficacy are close, professionals must perform a careful assessment of the etiology of pain and the conditions of the patient, having in mind that true beneficence cannot be effectively practiced without autonomy, since the interpretation of the subject regarding the best option of treatment may not be the same as that of the health team(25).

Therefore, some authors of this review suggested that, in order to practice beneficence with the patient in pain, it is necessary to defend the wellbeing of the patient to other health professionals who may not comply with the bioethical principles(17); to learn the most effective strategies for pain measurement and treatment(24); and to consider the multidimensionality of the patient’s demands regarding his/her pain(24).

Pain and nonmaleficence

Untreated pain may generate comorbidities, such as depression, insomnia and anxiety, besides being extremely disabling. Hence, ignoring pain means doing harm(23).

Nonmaleficence becomes a real dilemma when opioids must be used by individuals who have already suffered dependence on chemical substances. These people must be constantly assessed and the professional, in association with the patient, must establish very clear limits regarding the availability and use of these analgesics. In these cases, it is important to monitor these patients’ blood for traces of abuse of alcohol or other drugs, and to encourage their participation in groups such as the alcoholics anonymous. In light of these facts, the patient who does not respond to other treatments, and has the chance to benefit from the use of opioids, must not be untreated, even with a history of chemical dependence(20).

Another dilemma, involving the use of opioids and the principle of nonmaleficence, concerns the use of morphine, which may have a small margin of safety and lead to the reduction of conscious and respiratory function, which is considered, by some authors, to be an abbreviation of life, that is, an indirect active euthanasia. Pain relief must support the patient’s wellbeing and allow him/her to keep living with the best quality of life. Given the benefits of the therapeutic dose of morphine in acute and chronic pain (oncologic or not), and respecting the intensity levels of the analgesic ladder of the World Health Organization, the professional must have sufficient knowledge to propose to the patient or to his/her legal guardians the best option for pain relief with the lowest risk for adverse effects(19,30,32).

A study(27) approached the fact that, in the clinical practice, many newborns have their pain neglected due to the non-compliance with the bioethical principles. For instance, it is possible to mention a situation in which the professional insists on performing a technique, without considering the suffering it will cause(17,26-27). Nonmaleficence may be applied, for instance, by not causing unnecessary pain to the patient, choosing not to administer medication via the intramuscular route in a situation when the oral route could be used with analgesic equivalence(16).

In face of so many dilemmas and a reduced number of practical suggestions for the compliance with this bioethical principle regarding pain, one of the studies suggested nursing to turn to the ethics committees to expose their problems and discuss the most ethical path to follow in the care of patients in pain(17).

Pain and justice

The studies showed that there is lack of justice in the absence of equal access to pain treatment(15,17,24-25). Justice has been neglected when those who can seek major pain treatment centers receive adequate treatment; whereas others, who are less favored, have this access denied(15,25). Many of these patients turn to the services offered by the Unified Health System (SUS, as per its acronym in Portuguese), however, in the basic health care network and in the hospitals, even professionals...
perceive inequalities in access, resulting from the lack of structure, assuming that individuals who are less positioned socially have a shorter waiting time for treatment\(^{(33)}\).

For the authors who approached this theme, this is the most complex principle to apply in the practice, since offering justice in pain treatment consists of humanizing and providing access to the pain treatment centers, to opioid medications\(^{(17,24-25)}\) and to other forms of treatment, besides the drug therapy. Nevertheless, social disparity does not allow this access to less favored social classes and, moreover, the government of most countries does not strive to change this panorama.

In the facts, health professionals must be attentive to this sphere of justice in the treatment of pain, observing, mainly, the most vulnerable groups, such as children and older adults\(^{(33)}\).

The principle of justice must be considered, especially, by the State, since it is their duty to offer sufficient resources so that everyone has access to health care, that is, so that everyone has access to the necessary measures for relieving pain. In the practice, however, in order to achieve this, pain management must constitute, effectively, a public health subject in all countries.

CONCLUSION

The analysis of the scientific production regarding the pain experience and the bioethical principles allowed to verify that health professionals face several ethical dilemmas in their daily clinical practice, and that principlism has been neglected in the care of patients in pain.

The autonomy of the patients is disrespected when they are not given the right to be clarified regarding pain and its treatment, to be introduced to the free and informed consent form for the use of opioids, and to participate in the elaboration and establishment of the therapeutic plan. Beneficence is neglected when pain is not relieved and unethical conduct are not questioned, or when professionals disregard the multidimensionality of patients’ demands regarding their pain. Nonmaleficence, which brings along many dilemmas as for the risk-benefit of using opioids and the application of unnecessary painful procedures, indicates the role of ethics committees, which may offer support for professionals to discuss their actions. Finally, justice, which constitutes a principle that must be applied in the care practice, as it concerns the equal distribution of access to the treatment of pain, shows the social disparity and lack of public health policies aimed at the management of this experience as main barriers for its execution.

In the light of this, the authors emphasize the need for studies to intensify the discussion of this theme and to seek subsidies for the establishment of practices that allow to broaden the knowledge of professionals, patients and families regarding pain; to include the theme as a transversal content in the curricular structure of the courses in the area, creating opportunities for information on the subject and subsidizing the elaboration of public health policies that assure, to the less favored, access to major pain treatment centers and effective treatments for the relief of this experience.

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