*Core Curriculum for Professional Education in Pain*, edited by J. Edmond Charlton, IASP Press, Seattle, © 2005.

# 6

# Ethical Standards in Pain Management and Research

I. General

Know the basic ethical standards in pain management and research (United Nations Office of the High Commissioner for Human Rights 1948; International Association for the Study of Pain 1983, 1995; American Medical Association, Council on Ethical and Judicial Affairs 2001; National Comprehensive Cancer Network 2001; Council for International Organizations of Medical Sciences 2002; Institute of Medicine 2002; World Medical Association 2004).

A. Philosophical concepts

1. Understand the concepts of subjective experience of pain and objective assessment of pain, and ways these confusions have contributed to problems in research and practice (Vrancken 1989; Rollin 1990; Max 1992; Cunningham 1993; Rich 2000).
2. Understand the distinction between the concepts of pain and suffering, and ways this distinction may or may not give scientific and moral status to the emotional component of pain (Roy 1992; Shapiro 1995).
3. Be aware of ways in which scientific and clinical attention to individual and group differences in the intensity and meaning of pain may conflict with the scientific ideal of predictable, universal causes and markers of pain (Vrancken 1989; Rich 2000).

B. Ethical obligations

1. Be aware of the importance of individual cultures, basic human rights and responsibilities, and the need for constant review of current practices (Council for International Organizations of Medical Sciences 2002).
2. Understand that witnesses to patients' suffering of unnecessary pain have a moral responsibility to those patients, even if the witnesses are not clinically responsible for that pain (Hilberg 1992). Understand the potential moral difficulties associated with professionals' development of emotional distance from patients in pain (Shapiro and Ferrell 1992; Cunningham 1993; Shapiro 1995; Rich 2000).
3. Understand that any pain above moderate levels can be physically and psychologically harmful. Preventing or alleviating such pain is not merely a matter of charity or doing good (beneficence), but carries a duty to prevent harm (nonmaleficence) (Melzack 1988; Carr 1993; Walco et al. 1994).
4. Be aware that patients in pain may be at great risk for injury to their dignity, as well as to their autonomy; patients whose pain has been ignored, especially iatrogenic pain, may experience their pain in the same way as do victims of torture (Randall and Lutz 1991). International declarations proscribe torture or other degrading treatment (United Nations Office of the High Commissioner for Human Rights 1948).
5. Understand the principle of justice as it may apply to all individuals and groups of patients in areas of pain prevention, assessment, and treatment (Foley 1995). Defending current practice merely by pointing to historical or current standard practice may be a form of false justice (Cunningham 1993; Walco et al. 1994; International Association for the Study of Pain 1995).

II. Clinical care

A. Professional power and responsibility

1. Be aware of the power professionals may have over patients and families, including physical, bureaucratic, psychological, informational, political, and economic. Understand the moral sensitivity required to use this power in a supportive manner, rather than an indifferent or abusive one (Roy 1992; Shapiro and Ferrell 1992; Porter 1994).
2. Know whether determinations of concepts, such as appropriate pain behavior, patients' tolerance levels, and advantages and disadvantages of treatment alternatives, speak primarily to the needs of patients and their families or primarily to the needs of clinicians (Roy 1992; Qiu 1993; Walco et al. 1994; Shapiro 1995).
3. Be aware of the ways in which the social history of attitudes about pain and the medical history of assessment, treatment, and value of pain can affect current lay and professional attitudes about patients with pain (Vrancken 1989; Macrae et al. 1992; Max 1992; Cunningham 1993; Porter 1994; Walco et al. 1994).
4. Understand the difference between informed consent in clinical treatment and in research, as well as the moral importance of both. Be aware of effective ways to involve patients and their families in the pain assessment and treatment process (National Comprehensive Cancer Network 2001; McGrath et al. 1994).

B. Vulnerable groups

1. Understand the full range of conditions (e.g., dementia, developmental disabilities, severe head injury, stroke) that can lead to limitations in ability to communicate due to cognitive impairment (Hadjistavropoulos et al. 2001; Breau et al. 2004). Understand the use of nonverbal methods to assess pain (Melding 1992; Shapiro and Ferrell 1992; Cunningham 1993; Shapiro 1995).
2. Understand the vulnerability of patients with diseases such as cancer or conditions such as burns, where there has been a historical, professional acceptance of severe, unremitting pain (Max 1992). Know the difference between psychological dependence, physical dependence, and tolerance. Understand common fears and confusions about opioid pain control (Walco et al. 1994; see Chapter 44).
3. Understand the vulnerability of dying patients or others with serious conditions, who prefer death over life because their pain is not adequately controlled. Be aware that the acceptability of physician-assisted suicide may be related to lack of knowledge and availability of effective means of pain control (Foley 1995). Understand the ethical principle of "double effect," as it applies to pain control (it is acceptable to provide medication for pain control, which has as a secondary effect hastening death, when the primary intention is to provide adequate pain control that can be provided in no other manner) (American Medical Association 2001).
4. Understand the vulnerability of chronic pain patients, especially as it may be related to the mystery and complexity of the condition, and the clinician's wish for simple diagnoses and treatment (Vrancken 1989; Melding 1992; Roy 1992; Shapiro 1995).
5. Understand the vulnerability of patients who live in locations where laws or economic factors restrict the availability and use of effective treatments, even to patients in need.

C. Quality assurance

1. Be aware of the moral responsibility for providing appropriate pain care, and the consequent need for an interdisciplinary, system-wide approach that acknowledges the physiological and psychological complexity of pain (Max 1992). This responsibility applies to institutions as well as to units and individuals.
2. Understand that standards of care change and will need constant and regular review. This review must involve changes in moral awareness and commitment, as well as changes in the technical education of professionals.

III. Research

A. Statements of research ethics

1. Know the standards provided in international, national, and professional statements of biomedical research ethics, including instances where standards conflict with one another (McNeill 1993; International Association for the Study of Pain 1995; Council for International Organizations of Medical Sciences 2002; World Medical Association 2004).
2. Understand that laws or rules, traditions, and resources within particular societies and medical cultures may make these standards only partly applicable, or difficult to apply (Council for International Organizations of Medical Sciences 2002; Qiu 2004).

B. Research design, review, and implementation

1. Understand that ethical research requires sound methods, but sound methods do not guarantee ethical research. Researchers are responsible for the well-being of subjects even when subjects or their proxies have given consent (McGrath 1993; Rothman and Michels 1994; International Association for the Study of Pain 1995; Council for International Organizations of Medical Sciences 2002; World Medical Association 2004).
2. Understand philosophical arguments for and against randomized, controlled trials, including the use of placebo controls, when effective forms of pain prevention or control are already scientifically proven (Rothman and Michels 1994).
3. Understand the ethical issues in specific areas of research such as at the extremes of age and in palliative and intensive care. Know that these are legitimate areas for research but that scrupulous care must be taken at all times of the needs of the patient.
4. Be aware that the requirement not to exceed the subject's tolerance limit applies equally to situations of experimentally induced pain and to situations of research about pain that is consequent to disease, injury, or medical procedures (International Association for the Study of Pain 1995).
5. Understand benefits, appropriate use, standard methodologies, and ethical concerns of qualitative research about pain.
6. Know that clinical trials should be registered with a public trials registry before patient enrolment (De Angelis et al 2004).
7. Be aware that the complex nature of pain and the common use of interdisciplinary teams for clinical practice do not contradict the ethical requirement that particular research projects be carried out only by appropriately qualified persons.
8. Be aware that independent review is always necessary. Ethical review committees must ensure that research permission is never adversely affected by factors such as reputation of proposed principal investigators, traditional medical acceptability of certain levels of pain in subjects, funding needs of the research institution, or lack of adequate subject representation on the committee.
9. Be aware of potential problems of unfair profit or scientific bias due to the priorities of the research funding source, whether that source is institutional, commercial, private nonprofit, or government (McNeill 1993; Council for International Organizations of Medical Sciences 2002).

C. Informed consent (Council for International Organizations of Medical Sciences 2002)

1. Understand informed consent. This must be legally competent, voluntary, informed, and with understanding (International Association for the Study of Pain 1995).
2. Be aware that, in some countries, the dignity and autonomy of the subject, which researchers protect with informed consent, cannot be separated from that of the family or community (Qiu 2004).
3. Be aware that those groups of persons who are vulnerable in the clinical context may also be vulnerable in the research context because they cannot give voluntary consent. Additional groups might include prisoners, the mentally ill, students, research center employees, or those who generally have limited access to health care.
4. Be aware that some groups, such as children or pregnant women, are vulnerable to unfair exclusion from pain research.

5. Understand that some groups may be exploitable, in addition to or instead of vulnerable, because they can be misused. Subjects in externally sponsored research projects may be at special risk (Qiu 2004).
6. Know that patients or their proxies need full information about any proposed research including benefits, risks, costs, and side effects. This information must include options for pain reduction or control. Those taking part in any study must consider all factors from both the patient's and the professional view, giving equal weight to both. The patient or their proxy must be made aware that it is possible to opt out of the study without penalty (Rothman and Michels 1994; International Association for the Study of Pain 1995).

D. Animals (International Association for the Study of Pain 1983; see Chapter 5)

1. Know the ethical standards for animal pain research.
2. Know the standards for sound animal pain research, including attention to the animals' physiological and mental health.

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