



Presidenza del Consiglio dei Ministri
NATIONAL BIOETHICS COMMITTEE

PAIN THERAPY: BIOETHICAL GUIDELINES

30th of March 2001

INTRODUCTION

Since October 2000, the National Bioethics Committee launched, due to solicitations by the President of the Council, Prof. Giuliano Amato, a reflection on the theme of dying life, a topic that assumes fundamental bioethical relevance, as death invests our existence and it represents the ultimate horizon of our lives.

The NBC had already tackled in the past the issues relative to the end of human life by publishing various documents, including the Definition and Detection of Human Death (15th of February 1991), NBC's Opinion on the Draft Resolution for the Care of Terminally Ill Patients (6th of September 1991), and Bioethical Issues Relative to the End of Human Life (14th of July 1995).

In the time elapsed between those documents, as well as the explicit request by the Prime Minister and the presentation of bills that have brought the issue before Parliament, our country has matured a new awareness and discussions of the "culture of death". Different attitudes also matured internationally with regards to pain therapy, "persistent vegetative state", "advanced statements" also called "life testaments" and euthanasia.

The NBC has seen fit to proceed on these issues starting with pain therapy, intended as cure and care aimed at controlling physical pain and giving the patient psychological-social support, due to the oversights found in the healthcare system and in medical practice. We place in this context the new law on the prescription of opioids promised by Minister Veronesi, which led to new reflections.

The issue of pain therapy was analysed by a NBC's group coordinated by Prof. Sandro Spinsanti and made up by Giovanni Berlinguer, Luisella Battaglia, Francesco Busnelli, Mauro Ceruti, Isabella Maria Coghi, Francesco D'Agostino, Gilda Ferrando, Eugenio Lecaldano, Adriana Loreti Beghè, Demetrio Neri, Anna Oliverio Ferraris, Angelo Fiori, Aldo Pagni, Livia Pomodoro, Giuseppe Savagnone, Elio Sgreccia, Tullia Zevi. The group met systematically until February, with the contribution of Dr. Maria Caporale, from the NBC's scientific secretariat, and drew up a draft with the collaboration of a variety of experts, who I thank on behalf of the Committee. I extend a special thanks to Prof. Michele Gallucci, Prof. Marco Visentin, Prof. Nicola D'Andrea, who respectively contributed to drawing up paragraphs *Pain in the Terminal Phase of Life*, *Post-surgery Pain*, *Pain in Children*. The group also used the coordinated contributions, in Milan, of Prof. Mauro Ceruti, Professor of Genetic Epistemology. The text was discussed in then Plenary Meeting of the NBC and after corrections suggested in that context, was approved unanimously in the following meeting of the 30th of March 2001.

Rome, 30th March 2001

The President
Prof. Giovanni Berlinguer

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Premise

Pain has always accompanied human life, has a variety of meanings and, until recent times, humanity has not known effective means to eliminate or reduce it. For example, in the Old Testament God talks to the Woman who sinned with these words: "I will greatly increase your pains in childbearing; with pain you will give birth to children", and in the Koran the lack of faith is chastised with "painful punishments". The same notion characterises the barbaric phase of human justice, to the point that the term "penalty" gained the double meaning of pain and conviction. This idea of punishment has also impregnated the common attitude of people. It has gained ground, however, in modern times, another interpretation according to which pain is not a punishment to be passively accepted, but it is the connotation that accompanies bad and distinguishes it from good: it must not, therefore, be suffered, but it must be intended as a warning signal to be switched off as soon as it has fulfilled its task.

The biological analysis of the phenomenon often leads to similar conclusions. Pain is at the same time a physiological mechanism, as it signals damage and danger, and a pathological one, when it transforms into illness. It protects the woman who gives birth, stopping the foetus' push before it becomes devastating for the surrounding tissue. It marks the boundary between the organism's bearable effort and what would kill it. It feels the onset of an illness, wherever it is, when it is still latent or incipient. It manifests itself more during the night, when the other senses that can signal danger are dormant. Pain becomes pathology when it goes beyond its physiological role. It then becomes counterproductive, preventing the mother-to-be to help her child to be born. It exacerbates cardiac arrests, increasing blood pressure and putting the circulatory system under a strain that can be fatal. It makes many chronic illnesses unbearable, well beyond their somatic manifestations, taking away from those who suffer the ability to react and, even, the will to live.

In addition, there is no pain without a psychological integration of this phenomenon that affects its intensity. The expectation of pain magnifies an event that is simply feared. On the contrary, there is the removal of pain, which we see during a fight, even when there are serious injuries. There is the pain that accompanies suffering not in the body, but in the mind wounded by traumatising events, like the loss of a loved one or feeling impotent or useless, like endogenous depression. After all, suffering is always a psychological experience, even when it comes from the body. The term pain applies to physical as well as psychological suffering. It is in any case appropriate, for practical reasons, to distinguish and discuss separately physical pain linked to a clearly identified organic damage, and mental one, which has instead mainly a psychological connotation.

This document intends to reaffirm that the fight against pain, intended in the sense of illness of the body and mind, is part of the primary duties of medicine and society.

1. The value of the fight against pain

Between what is possible and right to do to eliminate and control physical pain and what is done in practice, there is a striking difference. Today we have

adequate knowledge relative to the physiology of pain. And most of all we have many methods of intervention – invasive and non-invasive, neurosurgical and psychological, as well as the whole range of pharmacological therapies – that allow to fight pain in many cases.

To this ability is attributed in our culture a highly positive value. To the cultural and ethical legitimacy recognised to fighting pain, responds the inclusion of actions aimed to this end as one of the priorities of the public healthcare service. The National Healthcare Plan for the period 1998-2000, which presents itself as a “pact of solidarity for health”, identifies the care of people in the terminal phase of life amongst the objectives to be pursued. Within the fourth objective – “To safeguard the protection of vulnerable subjects” – the Plan indicates the care of people affected by irreversible progressive diseases, for which there are no effective treatments. Within the pact of solidarity, public healthcare is committed to providing these people “care aimed at controlling pain, preventing and treating infections, physiotherapy and psychosocial support”. Amongst the actions to favour, the Plan identifies giving pharmaceutical care at home with the help of hospital pharmacies and the expansion of interventions of palliative and pain relief measures.

We must remember that the fight against pain belongs to the entire history of medicine. Anaesthesia with ether and chloroform was developed in the middle of the XIX century, further goals were achieved with the use of cocaine, morphine and their derivatives. Subsequently, more effective drugs against pain were created and the cure of this symptom was seen as a priority and as an illness in itself.

Psychotherapy, psycho-prophylaxis in childbirth, acupuncture and other techniques have been also useful in eliminating the fear and anxiety linked to it.

Yet the fight against pain is burdened in Italy with many shortcomings. Compared to the indicators established by the WHO to assess if a country is in fact implementing an effective analgesia – consumption of opioids, especially morphine – Italy occupies one of the last places in Europe, also because of regulations that, introduced at the time in order to limit the use and abuse of drugs, have hampered the prescription and use of effective analgesic drugs (especially opioids), until the substantial changes introduced by the recent law n. 12 of the 8th of February 2001, “Regulations to facilitate the use of opioids analgesic drugs in pain therapy”.

Medicine’s imbalanced focus towards the objectives of care and healing compared to palliation and alleviating pain and the suffering caused by the pathologies, is a very widespread phenomenon worldwide. The Hastings Center Report – The Aims of Medicine: New Priorities, 1997 – notes that “alleviating pain and suffering is one of the doctor’s most ancient duties and a traditional objective of medicine. So that, in the whole world of contemporary medicine, it does not adequately fulfil this task. For many years, several studies have shown that doctors intend to and pursue the attenuation of pain with varying degrees of efficiency. Inadequate or improper interventions to mitigate pain are still very common”.

2. The evolution of deontological codes

Bioethical guidelines and the new moral perspectives of medicine largely influenced medical thought, inspiring important changes in the deontological code of the medical profession. To this, also contributed the opinions expressed on several occasions by the National Bioethics Committee in the

published documents, amongst which: NBC's Opinion on the Draft Resolution for the Care of Terminally Ill Patients (6th September 1991), Bioethics and Training in the Healthcare System (6th September 1991), Information and Consent to Medical Procedures (20th of June 1992), Bioethical Issues Relative to the End of Human Life (14th Of July 1995).

The evolution of the code on the issue of pain therapy has developed starting with the code of medical deontology approved by the National Federation of the Order of Physicians and Dentists on the 15th of July 1989. Art. 39, chapter V, anticipates the doctor's duty, "in case of illness with certain unfavourable prognosis that has reached the terminal phase", to respect the patient's will, as its work must be limited to "moral assistance and therapy aimed at avoiding unnecessary suffering, providing the appropriate treatments and preserving as much as possible the quality of a dying life".

This concept was taken up with greater force in Art. 15 of the edition of the Deontological Code of the 24th of June 1995: "The treatments resulting in a decrease in the patient's physical or psychological strength can be implemented upon verification of medical needs, and only in order to provide a real clinical benefit to the patient or alleviate his/her suffering".

Significant progress has been made with the last edition of October 1998. Chapter V, after the premise that "The doctor, even at the request of the patient, must not carry out or help with treatments aimed at causing death" (art. 36), tackles the issue of care for the incurably ill: "In the event of an illness with a prognosis of certain death that has reached the terminal phase, the doctor must limit his/her work to moral care and therapy aimed at saving unnecessary suffering, providing the patient with appropriate treatments to protect, as far as possible, the quality of life. In the event of a compromised state of consciousness, the doctor must continue the life support therapy as long as it is believed to be reasonably useful" (Art. 37).

Art. 14 forbids diagnostic-therapeutic persistence, whilst art. 15 admits that "the treatments resulting in a decrease in the vital strength can be carried out in order to give the patient an advantage and alleviate his/her suffering".

Under Art. 20, paragraph II, "The doctor cannot abandon the terminally ill patient but must continue to assist him/her even for the sole purpose of easing his/her physical and psychological suffering".

In conclusion, the Italian deontological code made an irreversible choice, respecting the will of the patient, excluding therapies disproportionate to the need and protection of the dignity of the individual, who should be given relief from pain. The current deontological code of the nursing profession is inspired to the same principles with important changes occurring in the evolution of the codes: whilst the 1977 version indicated the nurse's duty as that of helping the patient to "bear the pain", in the recent 1999 version it is indicated as the duty "of taking steps to alleviate the symptoms, in particular if preventable" of the illness (art. 4-14), amongst which pain has a prevalent role.

3. Legal guidelines

In this context the NBC deems appropriate to propose a recommendation so that medical and nursing practice is in line with the need to give an effective response to the patients afflicted with pain, in particular the pain that accompanies the terminal phase of life.

In this context, so that pain therapy becomes a concrete and widespread reality, legal, clinical, educational guidelines are necessary.

The law that makes it easier to prescribe morphine and other drugs containing opioids, in force after the publication of the Gazzetta Ufficiale of the 6th of March 2001, has mainly had the function of abolishing certain constraints put in place by previous regulations (in particular 1990 DPR 709, in which were put together the regulations for the use of analgesics and the repressive action towards the illegal market of abused substances). The provisions of the law must now be made operative, in particular by involving the doctors. As already required by some associations involved in palliative care, in an open letter to the Ministry of Health in February 1998, it would be highly desirable, even in the absence of specific guidance in the recent law, that the ownership of the ministerial prescriptions became common to all GPs.

From the point of view of healthcare planning, to overcome the current shortcomings, it will be necessary to focus on putting pain therapy amongst the “essential and standardized levels of care” (as provided by Law No. 229/1999 – healthcare reform). It is about healthcare services that everyone has the right to receive, as they are useful, scientifically proven and compatible with the financing system in place. The State-Regions Conference will have to operatively define such guidelines and update them continuously. Since 2001 the National Healthcare Service is substantially different – as healthcare is remanded to the Regions through federalism – then it is possible to introduce unacceptable inequalities in the provision of therapeutic services. Already today, unfortunately, the National Health Service is characterised by such inequalities both between regions and social classes. It is ethically unacceptable to add inequalities in the access to pain therapy, which must be ensured to all patients, free of charge.

4. Aspects of pain therapy

Pain control has a different relevance in the various clinical situations. Apart from the frequent indication in the terminal phase of the illness and in other situations of chronic diseases, degenerative or not, it is important to keep in mind also other clinical conditions, less extreme. As well as the pain that accompanies the end of life, we will consider acute post-surgery pain, the pain of childbirth and pain in children.

Pain in the terminal phase of life

The suffering at the end of life is psychological, social, spiritual, as well as physical; for this reason the pain is defined as “total”. Pain often increases in amount and intensity as death approaches. The appropriate response is palliative care, the first goal of which is pain relief, which, even if it is not the most frequent of the most serious of the symptoms in the terminally ill patient, is the one we can cure better. Unfortunately, although we have the appropriate resources, patients often continue to experience avoidable and unwanted pain; indeed, they perceive themselves as victims of a double suffering: they suffer the effects of pain on the body, on themselves and on their social life, and in addition they suffer the inquisitive and incredulous look of those who, sometimes, consider their pain unreal, exaggerated, excessively manifested.

At least three causes, to explain the prejudice and lack of attention towards these patients, have been analysed. The first is the value given to being resigned to suffering. Delaying the prescription of pain therapy until severe suffering in the patient can be due not only to the ignorance of the fundamental principles of pain treatment, but also to the idea of administering

or taking drugs only when the pain is unbearable, which implies that suffering has some positive value. This recognition cannot happen, in any case, with a unilateral decision by the doctor.

The second cause is the dissimilarity in the estimate of the intensity of pain by many professionals, compared to that declared by the patient. The third cause is linked to the lack of integration in the healthcare system of everything that cures the symptom, even though it does not cure the illness, and to the idea that only positive results in terms of recovery or illness control can be seen as actually medical, also from the point of view of a financial commitment.

There is a general tendency, which regards the majority of hospitals, to delegate pain therapy to specific competences – almost always anaesthetists. It follows a considerable difficulty in organising the answers to specific requests of therapy and the progressive decrease in the responsibility of all the other doctors, as further proof of the frequent absence of overall commitment in the healthcare organisation. This last tendency can also be related to the choice of “defensive” attitudes that can be used by doctors to avoid possible medical-legal consequences caused by the choice of administering analgesic drugs with potentially dangerous side effects.

Terminally ill patients must be able to benefit from pain relief treatments now easily available, effective and inexpensive, which have quick and predictable effects. Only in case they fail, there can be invasive treatments that block the passage of the feeling of pain along the nervous pathways with surgical, electrical or anaesthetic procedures. The main objections to invasive methods are the fact that they can cause further pain, the disproportion compared to the objective pursued, the high cost. It is also necessary to carry out an in-depth bioethical reflection on the request of treatments even when they don't give the rapid response of the drug – like relaxation, massage, posture rehabilitation – or on other non-conventional interventions, the effect of which could be perceived by terminally ill patients as beneficial.

The natural history of malignant tumours, AIDS and many cardiovascular, respiratory and nervous system diseases often evolve into a terminal phase. However, a good end of life care is possible and a painful death is avoidable. It is necessary to disseminate the culture of palliative care and hospices. When any prospect of recovery must be excluded and the life of the patient approaches its end, the main objective of medicine becomes the global care of the patient, amongst which the priority is pain therapy.

Post-surgery pain

Analgesic therapy in the post-surgery phase is part of the “Pain-free hospital” project, which comes from the realisation that the pain following surgery is often neglected in healthcare facilities.

In the post-surgery phase, pain is a situation of great physical discomfort for the patient, even though limited in time. Relief for this pain is often given too sparingly. In addition, it is left to generic prescriptions that often don't take into considerations the individual situation, whilst today it is possible to have a personalised control on pain thanks to the intravenous infusion.

Although it is estimated that pain can be abolished, or at least reduced to a tolerable intensity, recent statistical data show that in Italian hospitals about 50% of patients suffer uncontrolled pain.

Projects to achieve the “pain-free hospital” have been elaborated in various European and American countries and consist in the gradual

transformation of existing hospitals in facilities with an effective system to monitor and treat pain, rather than in the creation of ad hoc hospitals. A national project has been developed in France where, as part of the 1998-2000 plan to fight pain, the Ministry of Health issued directives to all hospitals to put in place detailed measures to combat pain (www.sante.gouv.fr/douleur/2-lutte/34_980307.htm).

Recently, the Italian Ministry of Health has also put together a Committee with the task of studying the methods to achieve the "pain-free hospital", which is hoped will herald the launch of a similar project in Italy as well.

An international project "towards the pain-free hospital" is currently coordinated by the "Ensemble contre la douleur" (www.sans-douleur.ch) in various European countries and in Canada. In Italy, after the first experiences carried out at the hospital in Vicenza and in two oncologic facilities in Milan (National Cancer Institute and European Oncology Institute), last year a first group of hospitals in various regions started carrying out the project in a uniform and coordinated manner (see the Italian page in www.sans-douleur.ch).

It must be clarified that this type of project has a rather long development period, as it is about changing attitudes ingrained in medical practice. It must also be articulated in a variety of phases: statistics, staff training, development of protocols of activity, performance review.

Pain in childbirth

With regards to the problem of pain in childbirth, the NBC comes back, in order to expand them, to the reflections made in the previous document *Pregnancy and Childbirth from a Bioethical Point of View* (April 1998). At that time, the NBC pointed out that, despite the theoretical clarifications, found also in the doctrine of the Catholic Church, which excluded an ethical link between childbirth and pain in women, has not been properly reflected in practice, which continues to be far from the promoted "painless childbirth". In the 1998 document, we simply reported the comparison between two lines of thought, without the medical and bioethical considerations underlying them: on the one hand, there are those who believe that pain in childbirth is an inseparable component of childbirth (which can be attenuated with interventions of preparation to childbirth), on the other, those who feel that a true humanisation of birth cannot happen in the presence of suffering and pain, so that they hope for the use of modern obstetric analgesia currently penalised by an insufficient organisation in hospitals.

Given the specificity of this document on childbirth analgesia and seen as the literature on this topic reports increasingly more data, it was decided to expand the reflections on this issue. In reality, the compatibility of these analgesic techniques with a natural and spontaneous birth, the effectiveness of pain relief with epidural analgesia, the increased number of women who choose to give birth in this way (70% in the United Kingdom and in France against our 15-20%), the rationalisation of the methods, the level of safety they offer for the mother and the newborn (the risks are mainly due to incorrect practice) allow us to consider this type of analgesia applicable, effective and acceptable despite the risks proper of medicine and consequent applications, not excluding organisational ones, which we hope will be resolved.

The cultural processes taking place amongst women are directed on the one hand towards the medicalization of a natural act like childbirth, and, on the

other, towards avoiding pain with analgesic interventions. The decision about which route to take must be reserved for each individual woman on the basis of correct information on the advantages, risks and the possibility of the two solutions.

The pain of childbirth has completely peculiar characteristics because it occurs in a healthy organism, has its duration, after which it goes back to well-being and the gratification of the birth takes over. Faced with the choice of how to give birth, there are women who prefer to go along with the natural process of birth in its entirety, accepting also its painful part. Within this choice, we stress that, if it is true that pain control can make the labour and delivery more manageable for the woman and her experience easier to remember, express and share, it is also true that this pain can have a highly positive connotation. It is in fact a particular pain: it has vital elements, components of passion, long-standing cultural meanings.

As it is clear that there are different and justified possibilities of choice, with regards to the method of delivery, it is recommended that those giving birth, before choosing the way in which they intend to bring their child into the world, are not only informed but also properly sensitised on the scope of their options, their risks and their practicality.

For many women, in any case, the pain of childbirth is a major obstacle to overcome, a passage that absorbs a lot of energy, limiting the possibility of a more focused and serene participation to the event, participation that is the ultimate aim, to be realised in a variety of ways.

Analgesia (as any preparation to childbirth), to best achieve its end, should however be part of a programme of pregnancy that proposes a global view of being born and not be an isolated event, “scarcely informed”, which is suggested in the delivery room.

With this broader view, recurring to pain relief in childbirth would not be an alternative to a natural birth, but a means that medicine offers to make a free choice and achieve with pain relief a higher level of awareness and participation to the event.

The realisation of this project requires an organisation at different levels.

What is currently done is to leave to the good will of the facilities in its various parts: in fact, there isn't, for this type of care, any financial incentive either for the hospitals or for the anaesthetists. The services cover the essential activities in terms of number of personnel, where it would be necessary, in order to have a 24/7 pain relief service, a full time service of Obstetric anaesthesia. The woman's right to choose an effective pain relief should be included amongst those guaranteed free of charge in the “essential levels of care”.

Pain in children

The medicine of the past often ignored or underestimated pain in the newborn. Some publications on the neurological development of the foetus or the newborn, which appeared in scientific journals in the 40s and 50s, concluded that the neonatal response to pain stimuli is not cortical and that therefore the feeling of pain was not perceived. Even more founded was the idea that newborns had no memory of the painful experiences, and that actually their system of adaptation was such that “insensitivity” would protect them from the intense suffering of birth. The result of this idea was, in the past, a care

practice that did not provide the administration of analgesics during invasive practices, including surgery.

Fundamental studies on neonatal pain brought to the recommendation, by the American Academy of Paediatrics, that all invasive and painful procedures on newborns, including preterm ones, and on children, should be carried out after pain relief and appropriate analgesia. A documentation of an inadequate treatment of pain in children led to the creation, in other countries, of operative units and services dedicated specifically to the needs of children. These services are managed in an interdisciplinary manner: paediatrics, anaesthesia, nurses and psychologists.

In international literature some important scientific acquisitions have emerged, and they must direct care: in the newborn the neuroanatomic and neuroendocrine system are sufficiently mature to perceive any pain; the exposition to intense painful sensations can favour the onset of neonatal morbidity; children who have had painful experiences during the neonatal period would be more stressed when experiencing painful events in future years; it is necessary to be able to understand and evaluate those behaviours deriving from painful sensations in the newborn; the absence of evident answers to painful stimuli (including crying and anxiety) does not necessarily show the absence of the perception of pain. It is now accepted that incomplete analgesia can cause negative effects on the long-term behaviour. In addition, it appears that comfortable interventions towards preterm newborns in intensive care units reduce the stress and favour a better clinical outcome.

The knowledge of the behaviours and the physiological changes in the child caused by pain are also essential in order to recognise it. The general approach to the control of pain in the child should involve: 1) knowing that the newborn feels pain (what hurts an adult hurts a newborn); 2) paying attention to behaviours that can be indicators of discomfort; 3) minimising the harmful stimuli (painful procedures, actions); 4) using local anaesthesia for the procedures, like thoracic drainage, epidural, spinal cord aspiration.

5. Formative guidelines

The cultural change about pain control requires interventions both from healthcare operators, as well as the whole of the population. Healthcare professionals must know and take into account the patient's point of view – his/her values, preferences, idea of life and health – in clinical decisions. The quantity of the commitment to pain relief, considered in relation to the limitations that it can involve for the conscience and the duration of life, must be assessed in light of the idea of “quality of life”, which each individual has the right to determine for him/herself. To support the awareness and responsibility towards the request for pain relief is an essential aspect of promoting human rights, also in conditions of illness and need. Pain therapy, in other words, is an integral part of what a person can and must expect from medicine and healthcare services.

From this point of view, the right to have an effective therapy of pain relief is only one element of a wider strategy, which it is necessary to promote. To give voice to pain, making it the object of communication in the context of the clinical relationship, is a fundamental strategy of pain relief. Even religious and mythical explanations of pain, which all cultures have elaborated, and the examples on which to model our behaviour with regards to pain, can complete

the action of the drugs. The medical response to pain is integrated with the cultural response, of which is part.