

## **Editorial:**

### **ETHICAL CONCERNS REGARDING CLINICAL EXPERIMENTS ON PATIENTS WHO ARE NOT ABLE TO CONSENT**

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In 1985, Dr. Alain Milhaud of Nord Hospital in Amiens had performed an experimental blood transfusion on a patient in a coma, without notifying his family. He withdrew one liter of blood from a man in a coma, then reinjected it into the bloodstream two minutes via a pelvic bone. The experiment was aimed at showing that quick, massive transfusions on patients without an available vein are possible. Milhaud said that the experiment was "willfully provocative", intended to open debate on the issue of using patients in deep comas as living laboratories. Professor Pierre Huguenard, of Henri-Mondor Hospital in suburban Creteil, calling the experiment at Amiens "wretched" (1). Some doctors supporting experiments on the comatose, and quoted anonymously by Le Monde, in 1988, contended that such patients were perfect "biological models" for studies of new drug therapies (1).

Later on, in 1988, the same doctor, A. Milhaud from Amiens, did a forensic expertize, on a patient in vegetative state, injecting Nitrous Oxide, aimed to study the cyanosis phenomena (2). In 1988, dr Mihaud, and other colleagues (H Cavaillet, Maurice Cara, H Laborit, G Lazortes, P Milliez, D Patte) drafted their living will. It was the first living will draft and debated in France. "I hereby declare allowing to be performed on me, by experts in clinical research and physicians, diagnostic tests for general and therapeutic interest... where after an accident I find myself in a chronic vegetative state" (2).

After 8 months, in 1988, France has adopted a law, *Law Huriet-Sérusclat*, on the biomedical research, and this law became a reference in the field of clinical trials.

Ethical Committee Rapport (1987) provides: "Tests without therapeutic finality on incompetents, people in chronic vegetative state and inmates are prohibited". This legislation from 1988 was revised in 1994, and provides: No

biomedical research can be performed on a brain dead person without his consent expressed directly or by the testimony of his family. (Art. L.209-18-1). Ans Public Health Law Code (2004) states that: "No biomedical research can be performed on a deceased, in a state of brain death, without his/her expressed consent (directly) during his lifetime or by the his/her family".

### **Ethical Issues on experiments on patients on vegetative state**

1. What are the reasons of these kinds of tests? Why doctors performed these researches on vegetative state patients?

Because they considered the patients in a vegetative state like a 'living laboratories', they treated them as objects, not anymore as a human being, subject of rights. The fact that they drafted even their living will say they agree to be used on research show that they really thought that patients in vegetative state are not able anymore to feel pain, to suffering and their life is totally compromised, perfect resources for studies and research.

The question, if patients in a vegetative state are or not person remains. There are always very important 'struggles', especially in Italy, every time when a patient in such a condition appear in a public debate. The last very discussed case was in 2009, in Italy, Eluana Englaro case (3). In the last time, after many debates, Catholics sustained that patients in vegetative state are patients with severe disabilities and they are subjects of rights, they must to be treated and cared. The fundament is art. 5 of the UN Convention on the Rights of Persons with Disabilities (2006), which provides 'equality and non-discrimination' and "prohibit all discrimination on the basis of disability and guarantee to persons with disabilities equal and effective legal protection against discrimination on all grounds" (4).

2. Does this doctor respect the principles of research ethics?

The Belmont Rapport (1979) on Ethical Principles and Guidelines for the Protection of Human Subjects of Research provides that physicians must to respect these 3 principles:

1. Respect for Persons
2. Beneficence
3. Justice

Dr. Milhaud instead didn't respect anyone. He treated the patients like objects, not like persons: no informed consent, no information. The experiments weren't for the good of these patients. And they were discriminate because of their condition, of coma and vegetative state.

3. Why is important for us to reflect about these experiments?

Because there were many changes in the last 50 years in biomedical field, in our cultural thinking, in ethics and rights. Such as:

1. Changes in the rapport doctor and patients, an increased distance between doctor and his patients.
2. Decrease in the respect for science and questioning medical authority, because of many scandals and abuses in the last decades.
3. Mobilization of citizens' movements, which in the name of human rights, denouncing medical abuse.

And now, we must to reconsider the relationship with the science, the research, the medical profession, ethics and rights and to propose solutions in order to avoid abuses and experiments without any respect for people and for humanity.

And the most important thing in this field is that for the good of humanity, doctor must to have confidence in their patients and patients must to trust their doctors.

This new issue of Studia Universitatis Babeş-Bolyai – Bioethica is a mix of topics from different medical research area: dental medicine, medical student's issues, patient's rights, organ transplantations, and ecological economy. All papers present complex issues and approaches related to different area of thinking Ethics. As a conclusion we can say that Ethics is always very challenging and new.

## BIBLIOGRAPHY

1. AP News Archive, <http://www.apnewsarchive.com/1985/Doctors-React-to-Disclosure-of-Experiment-on-Coma-Patient/id-c23674d47b77e22eb6e07508df46901e>, last accessed on 06/22/2014
2. Milhaud, Alain (1988). Testament de vie. Un combat éthique.
3. Day, Michael (2009-02-08). "Italy faces constitutional crisis over coma woman". London: Guardian. <http://www.theguardian.com/world/2009/feb/08/englaro-italy-vatican>, last accessed on 06/24/2014
4. United Nations Convention on the Rights of Person with disabilities (2006), <http://www.un.org/disabilities/convention/conventionfull.shtml>, last accessed on 06/24/2014
5. The Belmont Rapport (1979) on Ethical Principles and Guidelines for the Protection of Human Subjects of Research. <http://www.hhs.gov/ohrp/humansubjects/guidance/belmont.html>. last accessed on 06/24/2014