EXTREMELY PREMATURE NEONATES, PERSISTENT VEGETATIVE STATE, ARTIFICIAL NUTRITION: ITALIAN POLITICAL POWER CLASHES WITH MEDICAL AUTONOMY

Recently, escalating controversy has been generated in Italy concerning end-of-life dilemmas.

As a result, some recent health policies adopted by the Italian government in compliance with the official point of view of the Roman Catholic Church have rejected published scientific evidence.

This article shows three examples of this situation where doctor's autonomy in Italy is undermined by political power.

THE "ELUANA ENGLARO CASE"

For sixteen years, Ms. Englaro was in a permanent vegetative state *(PVS)* due to a car accident. Before this event, Ms. Englaro had explicitly and repeatly told her parents that if she had to face a *PVS*, they should let her die without providing any vital life support. However, when Ms. Englaro's tragedy occurred, the opposite occurred. After the initial treatments in the Intensive Care Unit she was transferred to a long term care facility where today she is still being cared for.

Her father has been involved for 16 years in legal proceedings to get the State to respect his daughter's wishes, by requesting the withdrawal of artificial nutrition *(AN)*. In Italy, authoritative exponents of the Roman Catholic Church insist that *AN* is not considered as medical therapy. This is in complete contrast with the definition of *AN* by Medical Associations [1]. However, the Italian High Court ruling for Ms. Englaro affirmed that, *"There is no doubt that the artificial feeding by nasogastric tube constitutes a medical treatment".* [2]

Recently the same Court decided that Ms. Englaro's wishes, as represented by her father, should be respected [3].

In reply, the Minister of Health signed an official document preventing public and private Italian hospitals from withdrawing *AN* from Ms. Englaro [4].

Nevertheless, a medical team (one intensivist, ten nurses) withdrew *AN* from Ms. Englaro on February 6, 2009 and she died on February 9.

At the moment a judicial inquiry is set up into the same medical team.

THE CASE OF PERSISTENT VEGETATIVE STATE GLOSSARY

The last example is represented by a *"Glossary"* regarding the *PVS*, produced by a medical working group, appointed and chaired by the Vice-Minister of Health [5] and coordinated by a neurologist, President of the World Federation of Catholic Physician's Associations.

The main issue of the *Glossary* is the question of the reversibility of *PVS*. Three documents edited by the *Multi-Society Task Force on PVS* (USA, 1994) [6, 7], including the *Royal College of Physicians of London* (2003) [8] and the *American Academy of Neurology* (2006), represent the world leaders on this issue [9]. All these documents stipulate end points of: i) 12 months from the onset of post-traumatic *PVS*; ii) 6 months for post-anoxic. These limits today are internationally accepted as a cut-off for *PVS* definition. On the other hand, it is evident that the prognostic evaluation must be decided case-by-case; and the first document edited by the 1994 Task Force stated that setting time limits gave only a probabilistic value.

Based on this sentence, the *Glossary* drafters concluded that irreversibility from PVS could not be determined. They overlooked the epistemological nature of medicine, in that medical choices must be based on the highest degree of probability and on the minimum degree of uncertainty in terms of scientific evidence for each specific illness balanced together with the patient's best interests.

THE CASE OF NEONATES OF LOW GESTATIONAL AGE

138 physicians and 3 Scientific Boards signed an open letter [10] that was handed to the Minister of Health opposing a document [11] on the clinical treatment of neonates of extremely low gestational age *(ELGA neonates)* released from the Ministry itself. This document was formulated by the highest level of Italian Health Institution *(Consiglio Superiore Sanità – CSS)* and proposed that gestational age *(GA)* is not a valid parameter for evaluation of prematurity. It maintained that it was mandatory to sustain life of *ELGA neonates* regardless of "no chances of survival" ($\leq 22^{0+6}$ weeks *GA*), or those at risk of having severe and multiple disabilities related to prematurity (23^{0+6}, 24^{0+6} *GA*).

Contrary to the contents of the *CSS* document, there are two exhaustive studies and fifteen guidelines from Perinatal Scientific Societies of nine countries, including Italy, and recommendations from two International Scientific Societies [12, 13], giving conflicting advice. Therefore, the *CSS* document was instead recommended as a guideline for clinical practice[14]. In addition, a document [15] from the Italian neonatologists and obstetricians-gynaecologists task-force *(Carta di Firenze)* was rejected by the Minister of Health. This is the first time in the history of Medicine in the Italian republic, that politicians chose to intervene in a medical matter.

CONCLUSION

In regard to *ELGA neonates*, *PVS* and *AN*, all governmental documents have manipulated the scientific evidence with ideological assumptions, strictly adopting the official perspective

of the Catholic Church. In this way a great confusion has been created amongst scientific, bioethical, religious and political domains [16].

Furthermore, Italian Doctors involved in *PVS* patient and *ELGA neonates* management and *AN* treatments are confronted with institutional rules making their tasks more difficult in balancing clinical decisions based on best scientific evidence with ethical principles.

This approach constitutes the core of a doctor's professionalism. There must be restraints from any influence of ideological conditionings, religious or not. The correct approach should also permit them to confront and understand the difficult responsibilities arising from the ever increasing complexity of clinical practice in a society where different ethical systems coexist.

GIUSEPPE R. GRISTINA, MD **Department of Emergency** **Rome Trauma Center** **S.Camillo-Forlanini Hospital – Rome**	**DAVIDE MAZZON, MD** **Director of Anaesthesia Division and ICU - Director of Surgical Department** **S. Martino Hospital – Belluno**	**MARIA SERENELLA PIGNOTTI, MD** **Neonatal Intensive Care Unit** **Florence Children Hospital "Meyer"** **Florence University – School of Medicine**
GAETANO IAPICHINO, MD **Professor of Anaesthesia and Intensive Care** **Milan University – School of Medicine**	**IDA ROSA SALVO, MD** **Director of Anaesthesia Division and ICU** **Children Hospital "V. Buzzi" of Milan**	**VIRGINIO BONITO, MD** **Neurology Division** **Bergamo Hospital**
FRANCESCO PROCACCIO, MD **Director of Anaesthesia Division and Neurosurgical ICU – Verona Hospital** **Verona University – School of Medicine**	**LUCIANO ORSI, MD** **Coordinator of Long Term Care Facilities** **Crema**	**MANRICO GIANOLIO, MD** **Department of Emergency** **Turin Trauma Center – CTO Hospital Turin**
MARCELLO ORZALESI, MD **Previous Professor of Paediatrics** **Rome University – School of Medicine**	**ALDO PAGNI, MD** **Past President Italian Medical Association**	**DEMETRIO NERI, PhD** **full professor of Bioethics** **Messina University**

RELEVANT EXPERIENCE/EXPERTISE OF THE AUTHORS

Giuseppe R. Gristina, MD
Doctor G.R.Gristina is the 2007 – 2010 Coordinator of Bioethic Board of Italian Society of Anaesthesia, Analgesia, Resuscitation and Intensive Care (S.I.A.A.R.T.I.)
geigris@fastwebnet.it

Davide Mazzon, MD
Doctor D.Mazzon is the Past Coordinator of Bioethic Board of Italian Society of Anaesthesia, Analgesia, Resuscitation and Intensive Care (S.I.A.A.R.T.I.)
davide.mazzon@ulss.belluno.it

Manrico Gianolio, MD
Doctor M.Gianolio is the President of Italian Resuscitation Council
manricogianolio@alice.it

Maria Serenella Pignotti, MD
Doctor M.S.Pignotti is the promoter and the first Author of Italian Guidelines about Extremely Low Gestational Age neonates treatment ("Carta di Firenze", see references)
m.pignotti@meyer.it

Gaetano Iapichino, MD
Professor G.Iapichino is the past President of Italian Society of Parenteral and Enteral Nutrition (S.I.N.P.E.) and European Society for Clinical Nutrition and Metabolism (E.S.P.E.N.)
g.iapichino@unimi.it

Ida Rosa Salvo, MD
Doctor I.R.Salvo is the past President of Italian Society of Paediatric and Neonatal Anaesthesia and Intensive Care
ida.salvo@icp.mi.it

Virginio Bonito, MD
Doctor V.Bonito is the Past Coordinator of Bioethical Board for Palliative Care of Italian Society Neurology (S.I.N.)
virginiobonito@hotmail.com

Francesco Procaccio, MD
Doctor F.Procaccio is the President of European Society of Transplant Coordinators
francesco.procaccio@azosp.vr.it

Luciano Orsi, MD
Doctor L.Orsi is a Member of Bioethic Board of Italian Society of Anaesthesia Analgesia Resuscitation and Intensive Care (S.I.A.A.R.T.I.) and Board Member of *Consulta di Bioetica* – Milan
orsiluciano@gmail.com

Marcello Orzalesi, MD
Professor M.Orzalesi is the Past Director of Neonatal Intensive Care Unit – Children Hospital "Bambino Gesù" – Rome
morzalesi@interfree.it

Aldo Pagni, MD
Doctor A.Pagni is the Past President of Italian Medical Association
aldopagni@mdtech.it

Demetrio Neri, PhD
Professor D.Neri is a member of the National Italian Bioethics Committee
demetrioneri@tin.it

REFERENCES

[1] **SINPE – Linee guida SINPE per la Nutrizione Artificiale Ospedaliera 2002 Rivista Italiana di Nutrizione Parenterale ed Enterale / 2002;S5: S1 - S171 http://www.sinpe.it/Linee_Guida_NAD_ministeriali.pdf**

[2] **Corte Suprema di Cassazione – R.G.N. 21748/2007 – 16/10/2007**

[3] **Corte Suprema di Cassazione – R.G.N. 20817/2008 – 11/11/2008**

[4] **http://www.ministerosalute.it/dettaglio/phPrimoPianoNew.jsp?id=209**

[5] **http://www.ministerosalute.it/imgs/C_17_minpag_609_documenti_documento_0_fileAllegatoDoc.pdf**

[6] **Multi-Society Task Force on PVS – Medical aspects of the persistent vegetative state – 1/2 parts. NEJM 1994; 330:1499 -1508**

[7] **Multi-Society Task Force on PVS – Medical aspects of the persistent vegetative state – 2/2 parts. NEJM 1994; 330:1572 - 1579**

[8] **Royal College of Physicians of London. The Vegetative State. Guidance on Diagnosis and Management. 2003.**

[9] **E.F.M.Wijdicks A.Hijdra, G.B.Young et Al Practice paramenter: Prediction of outcome in comatose survivors after cardiopulmonary resuscitation (EB review): Report of the quality standars subcommittee of the American Academy of Neurology. Neurology 2006; 67: 203 – 210**

[10] **Lettera Aperta, Bioetica 2008; 2: 237 – 245**

[11] **http://www.ministerosalute.it/imgs/C_17_comunicati_1567_testo.rtf**

[12] **Pignotti MS, Donzelli G, Perinatal Care at the Threshold of Viability: An International Comparison of Practical Guidelines for the Treatment of Extremely Preterm Births. Pediatrics 2008; 121:193-198**

[13] **Pignotti MS The extremely preterm births. Recommendations for treatment in European countries. Arch. Dis. Child. Fetal Neonatal Ed. published 1 August 2008, 10.1136/adc.2008.140871**

[14] **http://www.ministerosalute.it/imgs/C_17_comunicati_1589_testo.rtf**

[15] **Cure perinatali nelle età gestazionali estremamente basse (22-25 settimane) GYNECO/AOGOI 2007,3:20-23**

[16] **Redemption for the Pope? Lancet 2009;373:1054**