

Analysis of Italian regulations on pathways of care for patients in a vegetative or minimally conscious state

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Summary

Different rehabilitation models for persons diagnosed with disorders of consciousness have been proposed in Europe during the last decade. In Italy, the Ministry of Health has defined a national health-care model, although, to date, there is a lack of information on how this has been implemented at regional level. The INCARICO project collected information on different regional regulations, analysing ethical aspects and mapping care facilities (numbers of beds and medical units) in eleven regional territories.

The researchers found a total of 106 laws; differences emerged both between regions and *versus* the national model, showing that patients with the same diagnosis may follow different pathways of care. An ongoing cultural shift from a treatment-oriented medical approach towards a care-oriented integrated biopsychosocial approach was found in all the welfare and healthcare systems analysed. Future studies are needed to explore the relationship between health-care systems and the quality of services provided.

KEY WORDS: *disorders of consciousness, ethics, law, vegetative state, welfare.*

Dear Editor,

Recently, a group of professionals and researchers from eleven Italian regions and two federations of non-governmental organizations of caregivers of patients with disorders of consciousness (DOC) collaborated in the INCARICO project. INCARICO was a study supported by a grant from the "Centro per la Prevenzione ed il con-

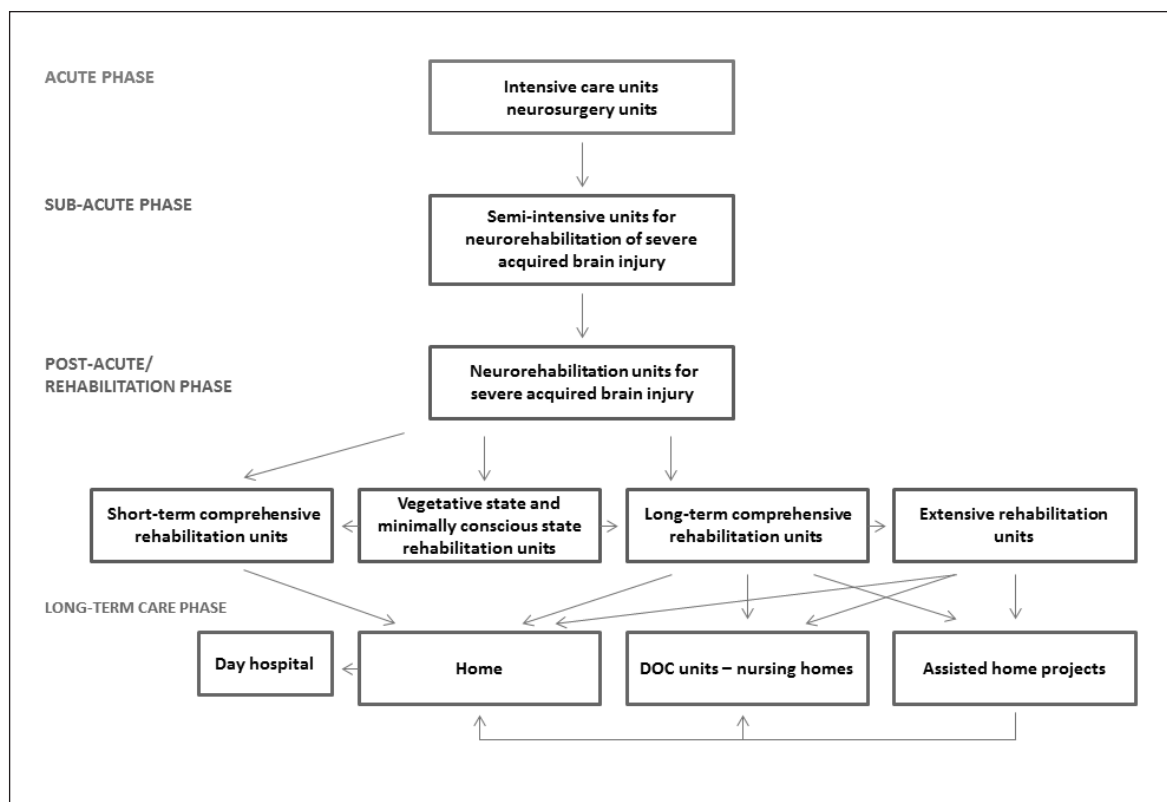


Figure 1 - The Italian care pathway model for persons with disorders of consciousness.

trollo delle Malattie - CCM” and coordinated by the Carlo Besta Neurological Institute IRCCS Foundation (Milan, Italy). The aims of this research were twofold: first, to analyse the care pathways existing in Italy for patients with DOC after a severe brain injury, and second, to identify the ethical and cultural underpinnings of the national care pathway model for persons with DOC proposed by the Italian Ministry of Health (MoH). The vegetative state (VS) and minimally conscious state (MCS) come under the umbrella term DOC. These are states in which the manifestation of consciousness has been affected by damage to the brain, and they are characterised by severe cognitive-motor disability, a high level of comorbidities and absence of, or only limited, interactions with environmental stimuli (The Multi-Society Task Force on PVS, 1994; The Royal College of Physicians, 2003; Leonardi et al., 2013). Healthcare planning for persons with DOC is complex, due the number of hospital services and facilities required to care for them, often for several years. In order to better understand these complex care situations, we investigated which European countries have provided guidelines on health planning for these patients. We found that while some have well-defined clinical management guidelines in place (Federación Española de Daño Cerebral FEDACE, 2011; Italian Ministry of Health, 2011; Royal College of Physicians, 2014), clear health planning recommendations are lacking. Various factors can influence the organisation of healthcare pathways; these include the increasing incidence of VS and MCS

diagnoses in recent decades, which implies an increased need for medical units and hospital beds, and the possibility of late recovery of consciousness (Estraneo et al., 2014). Indeed, due to the presence of severe motor (and cognitive) disabilities, musculoskeletal complications and a high number of comorbidities, unresponsive patients with a severe acquired brain injury (i.e. due to trauma or other cranioencephalic causes, such as cerebral hypoxia and haemorrhage), resulting in coma and disabling sensorimotor impairments (Turner-Stokes and Wade, 2004; Società Italiana di Medicina Fisica e Riabilitativa-SIMFER, 2016), need early and appropriate rehabilitation treatment, beginning in the acute setting and continuing for a long time. Moreover, if patients with severe acquired brain injury are transferred to post-acute rehabilitation units before their conditions (medical and neurological) have been stabilised, they may need to be transferred back to an intensive care unit (ICU) or neurosurgical ward, and will possibly have a worse final outcome (Formisano et al., 2016). All these aspects are considered in a healthcare pathway for persons with DOC, however, to the best of our knowledge, few European countries (Ministère de la Santé et de la Protection Sociale, Secrétariat d'Etat aux personnes handicapées, 2009; Italian Ministry of Health, 2011) have developed clearly defined care pathways taking into account the post-acute and long-term care phases. In Italy, the pathway of care model tailored for patients with severe brain injury and DOC (hereinafter, NPCM-

DOC) was developed by the MoH. Figure 1 schematizes its different stages. In detail, patients with a severe brain injury may be transferred directly to an emergency department and then admitted to ICUs or neurosurgery units. In this Italian model, this phase is followed by a sub-acute phase in which patients who are clinically unstable but do not require continuous intensive care may be admitted to sub-acute units in order to start early rehabilitation. This phase should not last more than 30 days. The first part of the post-acute phase is dealt with by neurorehabilitation units, each with 8-10 beds and staffed by professionals with expertise in the clinical management of severe brain injuries (De Tanti et al., 2015). Thereafter, the Italian NPCM-DOC establishes that an integrated network (Taricco et al., 2001) should provide specific care pathways for patients who recover cognitive and motor abilities quickly (short-term intensive rehabilitation programmes, with hospital stays lasting weeks) and for slow-to recover patients (long-term comprehensive rehabilitation, with hospital stays lasting months).

Finally, the Italian model indicates solutions for patients who show a long-term unresponsive state (care in nursing homes, tailored nursing facilities with certified experience in the management of these conditions, and/or in apartments for groups of patients assisted by health and social workers, or at home under the responsibility of a multidisciplinary team and patients' families). In this way, the national model regulates the entire care pathway from the acute phase through to the long-term chronic care phase. The NPCM-DOC was officially presented in 2009 and modified in 2011 (Italian Ministry of Health, 2011), and the MoH asked all twenty Italian regions to ratify it through specific agreements between government and regional authorities.

Care pathways involve several transfers between healthcare and other facilities; however, there is a lack of information on the way in which the different Italian regions have organised their services (numbers of beds and medical units) in order to "tick each box" in the NPCM-DOC diagram. This is particularly important considering recent reports (Donabedian, 2005; Mitchell et al., 2014) indicating that there is a strong relationship between the number of healthcare structures and the quality of health services.

During the INCARICO project, all the participating centres consulted regional public legislation databases and also collected data on the numbers of units and beds available in their territories (in line with regional pathways of care for persons with VS and/or MCS). In a subgroup of regions (Lombardy, Apulia and Veneto), they also looked for regulations and legislation specifically referring to children and adolescents. All regional laws collected were then analysed and compared in order to identify relevant ethical issues.

The INCARICO researchers found that almost all the regions involved in the study had ratified the NPCM-DOC, either through a specific law or by incorporating its principles into other, more general legislation. The total number of laws relating to patients with DOC found by the INCARICO researchers was 106 (ranging from a minimum of three to a maximum of 18 per region); of these, 5 concerned both ratification and management aspects and only 4 specifically concerned children and adolescents with a VS/MCS diagnosis.

The high number of laws found probably reflects the difficulty in implementing a truly common pathway of care at national level, which in turn is probably due to regional differences in welfare and healthcare systems. We may cite, for example, the introduction of sub-acute units in some regions — Calabria, Campania, Apulia, Sicily and Umbria have regional laws establishing specific sub-acute units for patients with DOC — but not in others, probably because the latter have alternative solutions (e.g. regional agreements between ICUs and rehabilitation units for the clinical management of patients, a sufficient number of beds in rehabilitation facilities to avoid waiting lists, etc.).

Differences, between regions, in the numbers of units and beds available for the specific phase of the model were found in almost all its phases. With regard to the post-acute phase, analysis of the total number of beds in relation to the regional population — the ratio is expressed as a percentage — showed that the regions with the lowest availability of beds were Campania (0.00078%), Piedmont (0.00249%) and Calabria (0.002451), whereas Lombardy (0.07613%), Apulia (0.04742%) and Veneto (0.04711%) had the highest percentages. As for the long-term care phase, Apulia was not found to have any dedicated units for the long-term care of patients in a VS/MCS, while Lazio seemed to have no "ad hoc legislation or pathway of care for persons with DOC", only for general categories, i.e. severe acquired brain injury and severe disabilities. Moreover, only Emilia Romagna and Lombardy have a sufficient number of specific beds in long-term care facilities, in line with the national recommendation of 30/40 beds/1,000,000 people (0.003/4%). The descriptive results of this research showed that Calabria, Campania and Piedmont adopt a *centralising* model for the post-acute rehabilitation phase, in which all patients are hospitalised in a small number of centres (<10 units), whereas other regions, such as Veneto, Apulia and Lombardy, have a more diffuse distribution of units and beds. Given that the healthcare system should guarantee minimum durations of the different rehabilitation phases, the implications of these regional differences should be carefully analysed. For example, three regions with comparable population sizes, namely Sicily, Emilia Romagna and Veneto, showed marked differences in the distribution of units for patients diagnosed with VS/MCS. If we consider this, together with the fact that hospitalisation turnover in regions with lower numbers of units and beds will differ from that in other regions where more beds are available, it seems unlikely, given the probably similar incidence of DOC diagnoses across the regions, that a common standard of rehabilitation interventions can be achieved. Further studies should explore the relationship between the distribution of rehabilitation centres and clinical outcome measures or the management of health costs. Considering all the clinical covariates, is the model important for patient outcome? Moreover, do the different models have different costs for the national health system? These are questions that still await answers.

Another point emerging from the research relates to the long-term care phase. The absence or small number of beds for long-term care in some regions could result in prolonged hospitalisations in rehabilitation settings, or in patients being discharged home prematurely, without

tailored support and assistance, and, relatives may often have to care for them at home. In such cases, it is possible that the low number of beds available in dedicated nursing facilities could be related to a “social effect”, considering that the regions with the lowest numbers of beds for long-term care were in southern Italy, where families are typically larger than in the North of the country. It could be that families in southern regions are more prepared to care for patients at home and that health policies in some of these regions are more geared at providing services at home rather than creating new long-term care units. However, this issue raises several questions, such as, for example, the ethical debate over the “possibility” of a patient being cared for at home by his/her caregiver *versus* the “obligation” on the latter to do so due to a lack of healthcare facilities and centres (resulting in short hospital stays). This is a crucial point that demands serious reflection, also considering the risk of a greater economic burden on families in Italian regions with limited economic resources.

The results also indicated that only Veneto has nursing homes with dedicated beds for children in a VS or MCS, suggesting that this is an aspect requiring greater attention in the future.

Finally, the issue of what should characterise the care of persons in a VS/MCS has been an ongoing part of bioethics debate over the past 30 years. Various ethical and legal issues related to the management of persons with DOC have been identified, and they concern clinical and long-term care, clinical research, and the withdrawal or withholding of life-sustaining treatments (Knight, 2008). Nonetheless, a thorough investigation of the impact of ethical recommendations and policy development on national and regional models of healthcare delivery to persons with DOC is still lacking and would be warranted, given that these patients may be considered “people with a low level of functioning and a high need of environmental factors”, applying the definition of disability used in the International Classification of Functioning, Disability and Health (ICF) (World Health Organization, 2001).

The ethical analysis of current legislation carried out in the INCARICO study revealed that although, at the time of the data collection, one region had not yet formally ratified NPCM-DOC through an *ad hoc* resolution, all the regions included in the analysis had started acting on the MoH recommendations.

In short, national and regional authorities in Italy, accepting the NPCM-DOC, the ICF, and the international recommendations provided by the Convention on the Rights of Persons with Disabilities (CRPD) (United Nations, 2008), have started promoting a care pathway for patients with DOC that recognises them not just as patients with severe brain injury, but also as persons with extreme disability.

From the perspective of the relationship between laws and ethics, three specific theoretical assumptions are embedded in the Italian care model (NPCM-DOC) and implemented through the country’s regional laws. The first is that the biopsychosocial approach, according to which disability is seen as an interaction between the physical, psychological and social components of a person’s functioning, should supersede a purely medical approach to the management of persons with DOC. The second is that healthcare and social services should, to-

gether, promote equity of access to services, and respect for the dignity and rights of people with severe disabilities. In this regard, an anthropological framework that identifies every human being, whatever his capacities and health status, as a person whose rights shall be recognised and promoted through state action (Pessina, 1999) is needed in order to substantiate the recommendations in this field.

Third, in the context of health planning, regional and local authorities should recognise the management of persons with DOC as a paradigm of state action in addressing the needs of persons with severe disabilities. In this sense, persons with DOC, whose condition is characterised by a lack of autonomy and complete dependence, can be seen as a call for social justice based on the ethics of care.

More precisely, the concept of care needs to be understood as a focal point of the restructuring of healthcare and social services (Tronto, 1993). The vulnerability and dependence of persons with DOC impose, on the state, a duty to provide them, and their families and caregivers, with appropriate clinical and social care. This concept is reflected in an ongoing cultural shift from a medical (treatment-based) approach to the management of persons with DOC towards an integrated biopsychosocial one (World Health Organization, 2001), based on the integration of healthcare facilities and social services at regional and local level. Within this context, care is, at once, both a goal that institutions should pursue and a means of political action. Care itself is defined as a means to promote human dignity by addressing and responding to the vulnerability that characterises all human beings (Gastmans, 2013). Designing a care pathway for persons with DOC implies promoting equity and justice for all those involved, families and caregivers (Kittay, 1999) above all. Therefore, we regard further state action in addressing the needs of persons with DOC as the ultimate goal of the restructuring of health planning in Italy, and of the revision of the applicable national legislation.

Notwithstanding the intrinsic limitations of this observational project, the results presented in this letter [the full version of the final INCARICO report is available at the following link: http://www.ccm-network.it/imgs/C_27_MAIN_page_920_listaFile_List11_itemName_1_file.pdf] highlight that there are quite considerable differences in health planning between the Italian regional models analysed, despite the existence of a common national pathway of care for patients with DOC that has been accepted by all the regional authorities. We hope that researchers and readers of *Functional Neurology* may consider conducting or fostering future research to determine whether similar differences exist in other European countries.

Moreover, we hope that future studies will be developed, analysing how different policies impact on the clinical outcomes of patients with a diagnosis of VS/MCS, in order to improve health service quality for them and their caregivers.

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Conflict of interest

The Authors declare no conflict of interest for this study.

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