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Commentary

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American and European Guidelines on Disorders of Consciousness: Ethical Challenges of Implementation

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THE RECENTLY published Guidelines on Disorders of Consciousness (DoCs) by the European Academy of Neurology (EAN)[1] and by the American Academy of Neurology (AAN) in collaboration with the American Congress of Rehabilitation Medicine (ACRM) and the National Institute on Disability, Independent Living, and Rehabilitation Research (NIDILRR)[2] stand as the most ambitious international attempts to provide clear and standardized recommendations to clinicians working with patients with DoCs. They offer an updated, timely, and wide-ranging list of recommendations for the diagnosis, prognosis, and clinical care of affected patients.

However, while commendable, the guidelines pose a number of questions,[3,4] including some related to the practical implementation of their recommendations. For example, both documents rightly consider that the integration of behavioral and instrumental assessments is the best strategy to improve diagnostic accuracy and quality of care. Yet, the operationalization of this recommendation in actual clinical settings, where the necessary technology, for example, functional magnetic resonance image (fMRI), might not be available or convenient to use, remains an open issue. The potential unavailability of the required technology or of the necessary expertise for use in some contexts might undermine the reliability, practical value, and ethical impact of some recommendations. These are not minor concerns because the practical inapplicability of specific recommendations has clear ethical implications: it might directly impact patients' well-being, their right to the best possible care, the communication between clinicians and family members, and overall shared decision-making and unintentionally lead to unequal and unfair treatment of some patients.

In this commentary, we propose a responsibility-oriented strategy to address some of the practical and normative barriers to implementation. We begin by summarizing the main points of the 2 guidelines. Next, we outline a Distributed Responsibility Model (DRM) based on a distributed multilevel understanding of responsibility as a means to better understand and address barriers to the implementation of the recommendations. While we do not aim at elaborating an in-depth analysis of all the relevant factors, we hope to set the stage for a more inclusive and comprehensive discussion that involves diverse relevant stakeholders (ie, clinicians, researchers, and hospital managers, among others).

THE GUIDELINES

The European guidelines by the EAN have 2 main aims: to provide state-of-the-art evidence regarding the diagnosis of DoCs on the basis of relevant data from 3 complementary sources–bedside examination, functional neuroimaging, and electroencephalography (EEG)–and to offer relevant clinical recommendations.[1]

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representing 10 European countries, the guidelines were methodologically developed as a review of relevant scientific evidence for the evaluation of DoCs using standard bibliographic measures. They explicitly refer to sleep analysis and passive/resting state paradigms as possible approaches for better detection of conscious activity and point to the relevance of multicenter collaboration to achieve better diagnosis. They propose the use of passive stimulation to formulate a more reliable diagnosis, a promising strategy to overcome the risk of false-negative results that may arise from classical active stimulation. Furthermore, because the increasing complexity of both diagnostic and therapeutic strategies makes it unlikely that they will be adequately managed by independent groups, they call for multicenter collaboration.

The guidelines released by the AAN in collaboration with the ACRM and the NIDILRR aim to update the 1995 AAN practice parameter on persistent vegetative state (PVS) and the 2002 consensus definition of the minimally conscious state (MCS), as well as to provide care recommendations for patients with prolonged DoCs.[2,5] Methodologically, they are based on a systematic review of the evidence, care principles, and inferences. In contrast to the European guidelines, the American guidelines show a significant attention to patients' and families' needs, calling for educating and counseling family members about patients' diagnosis, prognosis, and treatment. Focusing on patients with prolonged DoCs (lasting more than 28 days), they propose that the term "permanent VS" be replaced by "chronic VS/UWS" after a specified period of time. They also point to the importance of specialized settings managed by teams of rehabilitation specialists to improve the chances of recovery and highlight the importance of detecting pain and suffering in patients with DoCs, a clinical and ethical issue that is still debated both among clinicians and ethicists,[6] and ultimately recommend treatment when there is a reasonable suspicion of their presence. Furthermore, in contrast to the European document, the American guidelines include a distinction between adult and child populations and their relevant characteristics/needs.

Despite the differences in emphasis, the 2 documents converge in their main, final recommendation: the need for implementing a multimodal assessment of residual consciousness, specifically through the combination of bedside examination, functional neuroimaging, and EEG. This is key not only from the clinical and technical points of view but significantly also from an ethical perspective.[3] Misdiagnosis is one of the main challenges of contemporary treatment of DoCs,[7–9] and refinement in detection of residual consciousness is crucial for more accurate diagnosis, prognosis, and appropriate therapy.

MULTILEVEL AND DISTRIBUTED RESPONSIBILITY FOR IMPLEMENTING MULTIMODAL ASSESSMENT

While there is consensus that a multimodal assessment of residual consciousness is crucial for advancing in the diagnosis of DoCs, it is evident that this is not an easy task. It requires several preliminary conditions such as the ability of the hospital to cover the relevant costs and, importantly, the possession of the necessary technology and expertise to undertake this assessment. Therefore, the recommendation to carry out such an evaluation raises at least one issue: its practical feasibility. Not all hospitals have the relevant technologies, for example, fMRI, available, unless they are part of or connected to specific research centers.

As a preliminary step to a comprehensive analysis of this issue, we propose that the discussion be framed in terms of *distributed responsibility.* Accordingly, we introduce the DRM for identifying and assessing responsibility at the practical level.

Generally, responsibility is understood in terms of the specific obligations that come with particular societal or professional roles.[10] In some cases discharging one's role-related obligations may be enough, while in others responsibility may include moral obligations as well. Here, we are not concerned with moral blameworthiness but rather with the issue of accountability. Who should be considered accountable when it comes to implementing the guidelines main recommendations?

The notion of distributed responsibility is intended to shift the emphasis away from specific individuals at a specific point in time (eg, clinicians at the time of admission to the emergency department, or neurologists performing behavioral test at the bedside, such as the Coma Recovery Scale Revised) and proposes, instead, a modular understanding of responsibility where more agents share professional and/or moral obligations across time and where specific responsibilities are assigned depending on the different fields of action. The DRM basically consists of a multilevel mapping of responsibility intended to empower each actor. This makes possible 2 things in particular: clear assignment of autonomy to each agent in relation to his/her specific field of action, and clarification of the mutual interaction among different actors and their fields of action. In this way, while each node of the distribution is as autonomous as possible, it is their mutual connection that is key for assessing responsibility. Importantly, responsibilities are discrete and differentiated, but not separated.

Thus, the structure of the DRM is not top-down or hierarchical, but rather multilevel. To the extent that the DRM allows a transparent assignment of responsibility (making clear who should do what in which context),

the DRM has the potential for promoting trust between the different agents involved in the process.

The guidelines considered in this article do not explicitly frame the implementation of recommendations in terms of responsibility in general and distributed responsibility in particular. This, we believe, is a problem: in situations of scarce resources and financial and technological constraints, rather than leaving the issue open and implicitly putting the burden of responsibility on some specific groups of people, for example, clinicians, a model of distributed responsibility that focuses on several actors at different levels appears to be more productive for operationalizing guidelines on DoCs.* The identification and further clarity regarding who is responsible for what might help monitor the implementation process, making failures at different levels easier to identify and ultimately shaping effective corrective interventions. The identification of possible failures is possible because according to the DRM responsibilities are assigned to particular agents in specific contexts, even if some responsibilities are partly shared.

INSTITUTIONAL RESPONSIBILITY IN MULTIMODAL ASSESSMENT OF DoCs

In the context of the implementation of the guidelines on DoCs, the application of the DRM results in the identification of 3 main levels of responsibility: (*a*) institutional, (*b*) clinical, and (*c*) interpersonal. This multilevel framework of responsibility is consistent with the network approach to healthcare for patients with DoCs described in the Mohonk Report to the US Congress some years ago.[11] To overcome fragmentation of clinical care, the Mohonk Report proposes a mosaic of care, with clearly identified roles for specific agents and respective connections.

According to the DRM, at the institutional level, responsibility refers to the set of obligations that the institution/organization has to set the conditions for the operationalization of the recommendations issued by the guidelines. Of course, an institution does not operate on its own: it is operated by individuals (eg, hospital directors, administrators, managers) who are committed to carrying out the obligations determined by the institution's moral vision. Such a vision, however, should include obligations related to a number of aspects that directly affect the implementation of the guidelines. They can be listed under 4 main categories: resources, research and healthcare, nosology, and caregivers (ie, families and/or surrogates) counseling.

With regard to resources, there are at least 3 background conditions arguably under institutional responsibility that are key for operationalizing the guidelines' recommendations: the institution's financial resources (on which the existence of the relevant technology depends), skilled and experienced medical personnel, and adequate infrastructures (ie, adequate technologies and facilities).

Another aspect that appears to be under institutional responsibility concerns research and healthcare, particularly their respective interaction. More specifically, it seems key to overcome the research/care dichotomization (or binary distinction). This would facilitate a reliable translation of aggregate statistical results into personalized medical procedures and lead to a better regulation of the disclosure of individual information emerging from research to patients' caregivers. Because the relevance to the individual patient of the statistical information emerging from research is not obvious, especially for lay people, clarifying it is crucial in order to both maximize its clinical impact and minimize misleading communication and hyped interpretations. Moreover, a more interconnected view of research and care would make it possible to define clear, standardized, and validated procedures for multimodal assessment of consciousness and facilitate large studies on patients with DoCs, possibly through multicenter collaborations. In fact, institutions appear to play a key role in making possible the standardization of medical procedures such as the translation of research outputs into clinical procedures and the clear definition and operationalization of criteria for diagnostic, prognostic, and therapeutic common approaches.

A third factor that mainly falls under institutional responsibility is the definition of nosological standards and criteria, that is, consensus-based recommendations about the diagnostic classification of patients with DoCs that will allow a reliable diagnosis. In this respect, the institutional responsibility concerning the nosology of DoCs includes at least 3 aspects: rethinking the nosology of DoCs, particularly in light of their relatively dynamic character; facilitating the monitoring of consciousness recovery, for example, setting up adequate time frames; and facilitating the clinical operationalization of the nosology of DoCs, for example, encouraging the application of relevant guidelines and their revision in accordance to emerging scientific results.

Finally, institutions arguably have a responsibility related to caregivers' counseling. Particularly, institutional regulation is crucial in order to facilitate the

*We are aware that other relevant kinds and levels of responsibility might also be identified. For instance, a social level of responsibility as expressed in social biases against the socioeconomic status of the patients. However, we here focus on those we think are the most directly relevant levels that can impact on the operationalization of guidelines' recommendations. Also, the identification of specific levels of responsibility and relative actors does not imply that they are completely separated and independent from each other: a net distinction among them is for the sake of clarity, while we are aware that in practice things are more complicated and intertwined.

involvement of patients' caregivers in both diagnosis and therapy, making clinical assessment and related terminology consistent with needs of patients' caregivers. This might be achieved by identifying and overcoming possible communication, for example, linguistic, barriers, and planning procedures and making available infrastructures for making sure that caregivers' decisions reflect patients' values.

CLINICAL RESPONSIBILITY IN MULTIMODAL ASSESSMENT OF DoCs

At the clinical level, responsibility refers to the obligation that clinical staff generally have to perform specific functions so as to meet the requirements of their role. These obligations might be framed with reference to at least 3 aspects that directly affect the implementation of the guidelines: assessment of DoCs, interpretation of the data about residual consciousness emerging from the performed assessment, and communication.

A multimodal approach to the assessment of patients with DoCs, which is widely recommended nowadays, requires that the clinician improves the use of ancillary methods (eg, fMRI and EEG), which appear as necessary complement of traditional behavioral assessment. Of course, this clinicians' responsibility intersects with an already mentioned institutional responsibility: even if the clinician is aware of and able to use neurotechnological diagnostic tools, the required technology must be available in the institution. Also, the clinician should consider the impact of the necessary therapeutic procedures and the condition of the individual patient whose residual consciousness is being assessed, that is, give adequate attention to the particular condition of the patient in question. Finally, a multimodal approach to the assessment of patients with DoCs requires implementing adequate procedures for monitoring patients (eg, repeating the assessment as necessary, and taking care of background conditions in order to avoid noise as well as false-positive/negative results).

The clinicians' responsibility concerning the interpretation of data about the patient's residual consciousness basically refers to their methodological approach. More specifically, it entails a caution when inferring evidence of the absence of consciousness from the absence of evidence; acknowledgment of the limitation of both diagnosis and prognosis; recognition of the limits of actual nosological distinctions; awareness of the lack of strong statistical assessment of prognostic value of covert awareness detection; and awareness of the risk of both type I (false-positive) and type II (false-negative) errors, which respectively depend on the limited sensitivity and the limited specificity of available diagnostic tools.

Concerning communication, clinicians importantly share the responsibility for planning and implementing adequate communication protocols, particularly for maximizing the involvement of patients' caregivers. It is important that clinicians especially acknowledge the risk of misinterpretation of results from both the caregivers and the clinicians themselves. Another risk to take care of is that of biased interpretation in both the caregivers and the clinicians themselves. Particular attention should be given to avoiding the risk of false hope about recovery or any hyped interpretation and related misplaced expectation by the caregivers. Finally, it is recommendable to think about adequate procedures for handling possible disagreement among family members and/or between caregivers and clinicians.

INTERPERSONAL RESPONSIBILITY IN MULTIMODAL ASSESSMENT OF DoCs

Beyond specific institutional and clinical responsibilities, at the interpersonal level, some duties are best seen as resulting from the demands of the involvement of different stakeholders (ie, institutions, clinicians, and families/surrogates) with individual patients. They include obligations to be informed about and, when possible, use the necessary technology to enhance medical decision-making. This also requires recognition that a multimodal assessment might restore the patients' capacity to exercise their right to self-determination, for example, through neuroimaging-based forms of communication (ie, direct impact on patients); that a multimodal assessment might impact surrogate decision-making, for example, through new evidence about residual consciousness (ie, direct impact on caregivers); and that a multimodal assessment might impact medical assessment of patients' best interest, for example, through new evidence of residual emotional processing (ie, direct impact on medical staff).

CONCLUSION

The operationalization and implementation of some of the recommendations provided by the European and American guidelines on DoCs would benefit from more reflection on the notion of responsibility and the use of the DRM. A multilevel and distributed understanding of responsibility is, we propose, potentially useful in maximizing the impact of the relevant guidelines on clinical practice. Detecting who is responsible for what and at what level of the implementation process is crucial in order to make recommendations effective and to translate them in ordinary practice.

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