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Towards Uniform Insurer Coverage for Functional MRI following Severe Brain Injury

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Abstract

Functional magnetic resonance imaging (fMRI) now promises to improve diagnostic and prognostic accuracy for patients with disorders of consciousness, and accordingly has been endorsed by professional society guidelines, including those of the American Academy of Neurology (AAN), American College of Rehabilitation Medicine (ACRM), National Institute on Disability, Independent Living, and Rehabilitation Research (NIDILRR), and the European Academy of Neurology (EAN). Despite multiple professional society endorsements of fMRI in evaluating patients with disorders of consciousness following severe brain injury, insurers have yet to issue clear guidance regarding coverage of fMRI for this indication. Lack of insurer coverage may be a rate-limiting barrier to accessing this technique, which could uncover essential diagnostic and prognostic information for patients and their families. The emerging clinical and ethical case for harmonized insurer recognition and reimbursement of fMRI for vulnerable persons following severe brain injury with disorders of consciousness is explained and critically evaluated.

Keywords

neuroethics; disorders of consciousness; functional MRI; equity; health policy

Clinicians who care for patients following severe brain injury often face critical uncertainties in accurately measuring patients' levels of consciousness and determining the likelihood and cadence of functional recovery. Such uncertainties generate vexing dilemmas surrounding continuation or cessation of life-sustaining therapies, approaches to analgesia, prognostication, and stewardship of resources, especially in resource-limited settings. The potential for misguided management decisions for a patient with severe brain injury increases with the level of uncertainty about that patient's state of consciousness and rehabilitation potential, especially when such uncertainty is avoided or unseen.[1–3] A patient mistakenly assumed to be unconscious despite harboring covert awareness may

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be at increased risk of harm if therapies are withheld on the basis of misplaced futility judgements; conversely, a person whose likelihood of recovery is overestimated is prone to goal-discordant interventions, potentially prolonging suffering in a current or future state that might be considered by that person to be unacceptable.

Functional magnetic resonance imaging (fMRI) is among a host of novel techniques that now promise to improve diagnostic and prognostic accuracy for patients with disorders of consciousness and has accordingly been recently endorsed by professional society guidelines (including the Disorders of Consciousness Guidelines of the American Academy of Neurology, American College of Rehabilitation Medicine and European Academy of Neurology) (Table 1).[4,5] Other advanced techniques include quantitative resting-state, stimulus-based and task-based electroencephalography (EEG), transcranial magnetic stimulation-EEG (TMS-EEG), and positron emission tomography (PET). Here we focus specifically on fMRI due to distinctive challenges associated with radiology reimbursement,[6–8] however many of the considerations explored may extend to other advanced imaging and electrophysiologic techniques for evaluating patients with disorders of consciousness. The challenges described are rooted in the United States experience but may also extend to other regions.

Practice parameters by the American College of Radiology (ACR), the American Society of Neuroradiology (ASNR), and the Society for Pediatric Radiology (SPR), recognize the emerging roles of fMRI in clinical practice.[9–11] Published professional society parameters and guidelines generally inform the medicolegal standard of care. In the United States, a 2003 Court opinion detailed that “published standards or guidelines of specialty medical organizations are useful in determining the duty owed or the standard of care applicable in a given situation” (Stanley v. McCarver, Arizona Appellate, 2003).[12–14]

Despite multiple professional society endorsements of fMRI in evaluating patients with disorders of consciousness following severe brain injury,[4,5] insurers have yet to issue clear guidance regarding coverage of fMRI for this indication. In this United States, this paucity of payer guidance is not due to lack of CPT (Current Procedural Terminology) codes, the set of descriptive codes devised and updated by the American Medical Association that standardizes reporting and processing of medical procedures in the United States.[15] Indeed, three distinct CPT codes related to the fMRI procedure are available for use (70554, 70555, 96020), allowing for billing of both the neurofunctional and imaging components for fMRI (Table 2). When rendering coverage determinations, insurers have historically recognized fMRI as meeting the definition of medical necessity for pre-operative localization of eloquent cortex,[16,17] and it is now crucial that insurers take steps to uniformly recognize fMRI as meeting the definition of medical necessity for aiding in the detection of consciousness in patients with severe brain injury, as these results could substantially inform care and alter treatment trajectories in both adults and children.[18–23] Apart from enabling clinicians to reliably offer guideline-consistent care, we envision that the impact of harmonized insurer recognition of this indication will be felt in at least four key domains:

1. improved accuracy of neurological diagnosis by enabling detection of covert consciousness in behaviorally unresponsive persons following brain

injury, including patients in apparent coma or vegetative state / unresponsive wakefulness syndrome

2. more accurate neuroprognostic estimates for persons with disorders of consciousness
3. enhanced goal-concordance of treatment strategies and neurorehabilitation services
4. informing surrogate decision making and rational resource use

Improving Diagnostic Accuracy

Without the appropriate use of advanced diagnostic techniques, patients with covert consciousness (i.e., awareness of self or environment that evades detection on behavioral assessment)[25] will be necessarily underdiagnosed. Indeed, the 2020 European Academy of Neurology guideline specifies that "[a] patient should be diagnosed with the highest level of consciousness detected through fMRI, advanced EEG or behavioral exam." It logically follows from this that the diagnostic workup of any behaviorally unresponsive patient remains fundamentally incomplete in the absence of fMRI and advanced EEG. Ascertaining the highest detectable level of consciousness requires implementation of the tools capable of detecting consciousness. Thus, clinicians tasked with determining a patient's level of consciousness and explaining the presumed neurological state to caregivers may no longer rely solely on the physical examination when credibly evaluating the state of consciousness in a patient who is behaviorally unresponsive. While findings of behavioral responsiveness on physical examination may be sufficient to rule in a state of consciousness, absence of overt behavioral findings cannot rule out the possibility of preserved, albeit covert, states of consciousness.[24,25] By analogy, a cardiologist might use the physical exam to screen for signs of heart failure by studying jugular venous pulsations, vital signs, peripheral edema, and abnormal heart sounds, yet these findings may not be determinative of the state of cardiac (dys)function, which might only come to light following dynamic echocardiographic imaging or cardiac MRI permitting more direct visualization of heart function.[26] Whereas advanced cardiac testing could reveal covert (perhaps subclinical) *dysfunction* that might not be evident on the physical exam with signs such as jugular venous distention, pathologic S3 or pedal edema, a volitional prompt on fMRI could reveal *function* not evident on the bedside exam; both may reveal covert functionality but in opposite directions.

In our experience, among the most ubiquitous and pressing questions family members ask following severe acute brain injury in a loved one is "*are they in there?*" or "*can they hear/see/understand me?*" To the extent that clinicians' responses to these questions inform decisions surrounding goals of care or withdrawal of life sustaining treatment, it is imperative that such judgements about the likely level of consciousness are grounded in the most rigorous available multimodal assessments, including fMRI. As in other areas of medicine, harmonized insurance coverage is a necessary step to ensure appropriate access and administration. Without routine reimbursement, medical technologies are unlikely to be regularly utilized, even if they carry demonstrable clinical benefit, especially if deployment would impose inordinate out-of-pocket costs for patients and families.[27]

The catalytic role of insurer coverage on diffusion of technological innovations in medicine has been well described. For example, state health insurance mandates requiring coverage of imaging-based techniques including mammography for breast cancer screening and updates to Centers for Medicare & Medicaid Services (CMS) reimbursement structures have been major drivers of medical technology adoption in breast cancer evaluation, even at times dwarfing evidence of clinical effectiveness in driving utilization.[28–31] Bringing real-world clinical practice into alignment with the aspirational diagnostic standard of care emanating from professional society guidelines will thus require payers to conscientiously update reimbursement structures to routinely cover use of fMRI for the detection of consciousness in patients following severe brain injury.

Enhancing Neuroprognostication

Apart from the role of fMRI in detecting consciousness and clarifying a current diagnosis, signatures of intact brain network connectivity and discovery of covert consciousness revealed through fMRI may also shed light on a patent's potential for recovery in the future.[32–34] Such findings may forestall inappropriate or premature withdrawal of life-sustaining treatments in patients whose physical examination might suggest a more dire outcome, and might guide the provision of multidisciplinary rehabilitative therapies to foster functional recovery. Insofar as a patient's potential for functional recovery can crucially inform what is in the patient's best interests, routine access to and reimbursement for fMRI in patients following severe brain injury may be considered a fundamental human rights issue.[35]

Goal-Concordance

Ethical principles of patient autonomy, beneficence, and non-maleficence demand that treatments align with what is known about patient preferences and goals.[36] Risk of goal-discordant care is heightened if likely outcomes of treatment approaches are uncertain or overlooked. To the extent that fMRI could reduce this cone of uncertainty by clarifying a patient's current state of consciousness and likelihood of recovery, goal-concordant, responsible care will be safeguarded through its utilization.[2]

Informing Decision Making and Rational Resource Use

Apart from enhanced goal-concordance of treatment strategies, we anticipate that regular use of fMRI could help surrogates make more informed decisions which may lead to more rational use of resources. As explored, improving diagnostic and prognostic accuracy through fMRI as part of a multimodal assessment could lead to appropriate continuation of life-sustaining therapy or forestall inappropriate withdrawal of life sustaining treatment. If understood in advance, the heavy burden of life-sustaining medical treatment for a patient who would remain in a dependent state that they would not have wanted could hypothetically be avoided, and conversely, years of independence and return to work for a patient who is supported in recovery due to discovery of positive predictive signals could be safeguarded.[37,38] Uncertainty in diagnosis and prognosis, especially in life-or-death settings, could weigh heavily on clinicians and potentially contribute to medical

errors, driving provider distress and burnout.[39,40] By reducing uncertainty and improving the fidelity of diagnosis and prognosis of patients with severe brain injury, it would be reasonable to expect that clinician and caregiver satisfaction may be enhanced, as preliminary qualitative research suggests.[41] This key externality should be additionally considered when undertaking cost-benefit analyses. Additional cost-effectiveness could also be pursued by developing and expanding access to alternate and potentially less expensive modalities to assess consciousness such as EEG or other interfaces.[42–44]

FDA Approval and Insurer Coverage

One might argue that a paucity of FDA approved tools for analyzing fMRI data pertaining to the presence or absence of consciousness and likelihood of recovery justifies a lack of explicit insurer coverage for this indication, even if the devices used (i.e., MRI machines) for data acquisition are FDA approved. However, it is not clear that the paucity of FDA approved tools for data analysis is what underpins the lack of insurer coverage, as the relevant CPT codes are for the exam (data acquisition) and physician interpretation, and do not include post-processing. Furthermore, there is a long history in medicine of using diagnostic, prognostic and therapeutic tools that are not specifically FDA-approved for the indications towards which they are directed if there is demonstrable clinical benefit.[45,46] For example, insurers routinely approve coverage of amantadine for patients with traumatic disorders of consciousness due to its evidence of efficacy[47] and standard of care,[4] despite its lack of specific FDA-approval for this indication. Moreover, FDA has recently granted 510(k) approval to several clinical fMRI data analysis tools.[48–50] Many of the tools and pipelines currently used in clinical practice for analyzing fMRI data for patients with disorders of consciousness are developed internally based on local clinical expertise and are not marketed, although this might change as this field develops. It should also be noted that FDA itself specifies that “FDA does not have the authority to [r]egulate a physician’s or nurse’s practice[; m]ake recommendations for individual doctors, clinics, or home care agencies[; or c]onduct or provide a rating system on any regulated medical devices.”[51] Further dialogue with payers is necessary to clarify the role of FDA approval in coverage decisions.[52,53] Additional harmonization of stimulus paradigms and processing algorithms could also be useful to establishing more uniform insurance coverage and practice patterns across institutions.

Ought Implies Can: Aligning Practice and Policy to Improve DoC Care

While we recognize that factors beyond insurer reimbursement bear on clinical adoption of fMRI for patients with disorders of consciousness (including availability of imaging acquisition and processing hardware and software; local expertise for interpretation; and other factors), uniform insurer recognition of fMRI as meeting the definition of medical necessity for aiding in the detection of consciousness in patients with severe brain injury is an essential step to catalyze diffusion in real-world clinical practice. Without insurer coverage, clinicians will be unable to reliably offer AAN/ACRM/NIDILRR and EAN guideline-consistent care through provision of fMRI to behaviorally unresponsive patients, and medical centers will not be optimally incentivized to procure the requisite technology and expertise. The impact of harmonized insurer recognition and coverage portends

improved accuracy of neurological diagnosis; more accurate neuroprognostication; enhanced goal-concordance of treatment approaches; and improved stewardship of limited resources. To ensure that these potential benefits are captured and sustained, it is incumbent on insurers to take steps to promote equitable access through fair and consistent reimbursement across the care continuum.

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Table 1.

Professional society guidelines supporting clinical use of fMRI in patients with disorders of consciousness, selected text.

Professional Society	Relevant Guideline	Year
American Academy of Neurology (AAN) / American College of Rehabilitation Medicine (ACRM) / National Institute on Disability, Independent Living, and Rehabilitation Research (NIDILRR)	"Clinicians may assess for the presence of higher level activation of the auditory association cortex using BOLD fMRI in response to a familiar voice speaking the patient's name to assist in prognostication regarding 12-month (post-scan) recovery of consciousness for patients in traumatic VS/UWS one to 60 months post injury" (Recommendation 5e).	2018
	"In situations where there is continued ambiguity regarding evidence of conscious awareness despite serial neurobehavioral assessments, or where confounders to a valid clinical diagnostic assessment are identified, clinicians may use multimodal evaluations incorporating specialized functional imaging or electrophysiologic studies to assess for evidence of awareness not identified on neurobehavioral assessment that might prompt consideration of an alternate diagnosis" (Recommendation 2e).	2018
	"In situations where there is no behavioral evidence of consciousness on clinical examination but functional neuroimaging or electrophysiologic testing suggests the possibility of preserved conscious awareness, frequent neurobehavioral reevaluations may be conducted to identify emerging signs of conscious awareness and decisions to reduce the intensity of rehabilitation treatment may be delayed for those individuals receiving active rehabilitation management, with the length of time over which these are done determined by an agreement between the treating clinician and the health care proxy given the lack of evidence to provide guidance" (Recommendation 2f).	2018
European Academy of Neurology (EAN)	"Recommendation: If a standard clinical (structural) MRI is indicated, it is suggested that a resting state fMRI sequence is added as part of multimodal assessment (low evidence, weak recommendation). Resting state fMRI can also provide valuable information in sedated patients but sedation and movement artefacts might confound results" (PICO 2, p.747)	2020
	"Recommendation: As stated in PICO 2, it is suggested to add a resting state fMRI sequence as part of multimodal assessment whenever a standard (structural) MRI is indicated; however, the default mode network is just one of several resting state fMRI networks that may be used to complement the behavioral assessment in patients with DoC (low evidence, weak recommendation). Other networks to consider include the auditory, salience, executive and fronto-parietal." (PICO 3, p.747)	2020
	"Recommendation: It is suggested that active fMRI paradigms should be considered as part of multimodal assessment in patients without command following at the bedside (moderate evidence, weak recommendation). Active fMRI paradigms allow identification of a specific and important group of patients who can follow commands despite appearing completely unresponsive at the bedside (i.e. cognitive motor dissociation). Beware that sedation and cognitive impairment such as language disorders might confound results, and – importantly – absence of command following is not proof of absence of consciousness. It follows that active fMRI paradigms have a high specificity but very low sensitivity for the detection of covert consciousness." (PICO 5, p. 748)	2020
	"Standardized clinical rating scales such as the CRS-R and the FOUR, including careful inspection of voluntary eye movements, EEG-based techniques and functional neuroimaging (fMRI, PET) should be integrated into a composite reference standard. This means that a given patient should be diagnosed with the highest level of consciousness as revealed by any of the three approaches (clinical, EEG, neuroimaging)."	
Norwegian Neurological Society	"Noen pasienter i klinisk vegetativ status, som siden har oppnådd en viss bedring, har fått påvist økt opptak i relevante områder i hjernen på funksjonell MR og PET når de har fått beskjed om tenke på noe spesielt. Funksjonell MR kan derfor i framtiden tenkes å bli et supplement I diagnostikk/ prognoseavklaring"[54] [Some patients in clinical vegetative status, who have since achieved a certain improvement, have been shown to have increased uptake in relevant areas of the brain on functional MRI and PET when they have been told to think of something special. Functional MRI can therefore be considered to be a future supplement in diagnostics / prognostic clarification.]	2021

Table 2.

Selected CPT codes with potential application to evaluation of patients with disorders of consciousness. Associated RVUs are detailed in the regularly updated Medicare Physician Fee Schedule.[25]

CPT	Description per CPT code set[24]
70554	Functional MRI brain, including test selection and administration of repetitive body part movement and/or visual stimulation, not requiring physician or psychologist administration
70555	Functional MRI brain, requiring physician or psychologist administration of entire neurofunctional testing
96020	Functional brain mapping; neurofunctional testing selection and administration during noninvasive imaging functional brain mapping, with review of test results and report.
96116	Neurobehavioral status exam, first hour, including report preparation
96121	Neurobehavioral status exam, each additional hour, including report preparation
95957	EEG digital analysis