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National Network of Depression Centers' Recommendations on Harmonizing Clinical Documentation of Electroconvulsive Therapy

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Abstract: Electroconvulsive therapy (ECT) is a highly therapeutic and cost-effective treatment for severe and/or treatment-resistant major depression. However, because of the varied clinical practices, there is a great deal of heterogeneity in how ECT is delivered and documented. This represents both an opportunity to study how differences in implementation influence clinical outcomes and a challenge for carrying out coordinated quality improvement and research efforts across multiple ECT centers. The National Network of Depression Centers, a consortium of 26+ US academic medical centers of excellence providing care for patients with mood disorders, formed a task group with the goals of promoting best clinical practices for the delivery of ECT and to facilitate large-scale, multisite quality improvement and research to advance more effective and safe use of this treatment modality. The National Network of Depression Centers Task Group on ECT set out to define best practices for harmonizing the clinical documentation of ECT across treatment centers to promote clinical interoperability and facilitate a nationwide collaboration that would enable multisite quality improvement and longitudinal research in real-world settings. This article reports on the work of this effort. It focuses on the use of ECT for major depressive disorder, which accounts for the majority of ECT referrals in most countries. However, most of the recommendations on clinical documentation proposed herein will be applicable to the use of ECT for any of its indications.

Key Words: electroconvulsive therapy, electronic medical record, clinical documentation, harmonization, depression

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BACKGROUND

Electroconvulsive therapy (ECT) has been shown to be a highly therapeutic and cost-effective treatment for severe and/or

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treatment-resistant major depression.[1,2] Treatment guidelines in the United States and around the world typically recommend ECT for patients with depression who have not benefited from adequate trials of medication and psychotherapy; when rapid clinical improvement is required; in severe clinical cases who exhibit inadequate oral intake, high suicide risk, high levels of distress, psychosis, and catatonia; or who have previously demonstrated a positive clinical response to ECT.[3–10] Several important guidelines are also available with recommendations on best practices for the effective use of ECT.[11–14] Nevertheless, clinical outcomes with ECT vary considerably, and prior studies have suggested that some of the variability may be due to differences in delivery practices, including ECT documentation across programs.[15–17]

A majority of patients with major depression show a substantive clinical response to acute treatment with ECT, but up to one-half do not experience a full remission, and between one-third to one-half may experience relapse, even with maintenance therapies.[3,18] In addition, ECT has been associated with cognitive adverse effects, including anterograde and retrograde amnesia, that, although typically short term in nature, may discourage its greater use.[3,19,20] The therapeutic mechanisms of action of ECT are still not fully understood, and identifying molecular or other biological markers that can predict which patients would benefit most from ECT or in whom ECT should be avoided because of the risk of adverse effects would yield tremendous clinical benefits.[21] As a result, there is a need for more research to advance our understanding of this critical tool in treating depression, but such research is often challenged by the clinical heterogeneity of the disorder, small sample sizes, limited characterization of samples, and limited longitudinal follow-up.[22]

The National Network of Depression Centers (NNDC), a consortium of 26+ geographically distributed US academic medical centers of excellence providing care for patients with mood disorders, formed a task group with the goals of promoting best clinical practices for the delivery of ECT and to facilitate large-scale, multisite research to advance more effective and safe use of this fast-acting treatment modality. Because of the varied clinical practices in ECT, there is a great deal of heterogeneity in how it is delivered and documented, even among leading academic medical centers. This situation represents both an opportunity to study how differences in implementation influence clinical outcomes and a challenge for carrying out coordinated quality improvement and research across multiple ECT centers.

The NNDC ECT Task Group set out to define standards for the clinical documentation of ECT to promote interoperability and the exchange of clinical information to better inform treatment decisions and, at the same time, facilitate a nationwide collaboration that can carry out multisite quality improvement and longitudinal research in real-world settings, which overcomes the limitations of small sample sizes and short follow-up periods that often plague efforts to study ECT. This article reports on the work of this effort. It does not make clinical recommendations on the delivery of ECT but rather reports on recommendations for standardizing the clinical documentation of ECT—including what clinical data should be collected and how it should be recorded—to facilitate improvement in the care of patients treated with ECT. Our focus in this report is on the use of ECT for major depressive disorder, which accounts for the majority of ECT referrals in most countries. However, most of our recommendations on clinical documentation will be applicable to the use of ECT for any of its indications.

METHODS

A total of 19 leading ECT centers across the country from the NNDC Task Group participated in this effort. These centers included the following: Johns Hopkins University, Duke University, University of Michigan, Emory University, McLean Hospital, University of Pennsylvania, Indiana University, Stanford University, Penn State University, Ohio State University, University of Iowa, University of Florida, University of Louisville, University of Massachusetts, University of Texas, Houston, Cornell University, Pine Rest Christian Mental Health Services, the Mayo Clinic, and the Lindner Center of Hope. Other NNDC centers did not participate because they do not have sufficiently active ECT programs and/or lead investigators who participate regularly in the Task Group's ongoing activities. More information about the NNDC and criteria for joining it can be found on its Web site: https://nndc.org/.

We conducted an inventory of these NNDC centers to determine which electronic health record (EHR) platform they use and the data elements they capture in structured form and/or procedure notes during the administration of ECT. More than two-thirds of the centers use Epic Systems Corporation's EHR (Verona, Wisconsin); thus, for these centers, we further consulted the ECT Flowsheets and Procedure Note templates available in the Epic Community Library. Although we recognize that important additional information related to ECT is documented by the nursing staff and anesthesia teams, for the purpose of this initial effort, we focused on clinical data typically documented by the psychiatrist overseeing the delivery of ECT at the time of a given treatment. We also inventoried the patient- and/or clinician-rated outcome measures on depressive symptoms and cognitive function, as well as other domains of illness or functioning, that are collected by the centers during the course of ECT administration to monitor efficacy and adverse effects. We documented both which instruments are used and the time frames around treatment when they are administered.

A working committee of experts from the Task Group including representatives from Johns Hopkins University, Duke University, and the University of Michigan reviewed the results of the inventory. After a series of conference calls over a 6-month period, the working committee proposed recommendations for a set of core data elements and outcome measures that should be captured by ECT centers. These recommendations are guided by the 2 motivating goals of the effort: (1) to promote best clinical practice and facilitate ease of adoption and (2) to enable multisite quality improvement and research efforts. A draft recommendation was reviewed by the full Task Group on subsequent monthly conference calls, and comments were gathered. The working committee iteratively finalized its recommendations taking into account all feedback until a consensus by the full Task Group on what should be included in the final recommendations was achieved. The final recommendations are reported here, and Flowsheet and Procedure Note templates that implement these recommendations in Epic, one of the most widely used EHR, will also be provided through the Epic Community Library for ECT centers that wish to use them.

RESULTS

ECT Clinical Documentation

A total of 19 NNDC ECT centers participated in the inventory and Task Group discussions. The inventory and ensuing discussions focused separately on 2 key components: the clinical documentation of ECT by psychiatrists, and patient- and/or clinician-rated outcome assessments related to safety and efficacy. The inventory of documentation practices revealed broad but incomplete agreement on what clinical information is important to capture and greater differences in how this information should be captured.

At all centers, psychiatrists document the delivery of ECT in the EHR with a procedure note that captures the relevant details of the procedure in text form. In addition, a total of 12 centers further document some of these details in a structured form within the

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EHR (such as a Flowsheet used in Epic), which captures information in data fields that can be readily extracted. In some centers, these and others fields in the EHR are automatically extracted to help autofill the procedure note. Two centers capture details on structured paper forms. Regardless of the method, the information captured by the clinical documentation across centers generally covers details about the treatment date, treatment type (e.g., acute, maintenance, etc.), ECT device, stimulus electrode placement, electrical stimulus parameters, electroencephalogram (EEG) seizure duration and quality, ECT intraprocedural medications, and any clinically significant complications.

Based on a review of the inventory and several rounds of discussions, the Task Group reached consensus on a minimum set of core data elements that should be captured at every ECT treatment session. The recommendations should be considered flexible, so centers who want to capture additional information beyond these basic core data elements should do so as they deem appropriate. In making these recommendations, the Task Group was guided by 3 overarching principles: (1) data entry should be minimally burdensome to promote adoption; (2) the captured data should be as structured as possible with minimal free text to promote standardization and facilitate downstream use of the data for clinical and research purposes; and (3) for categorical data elements, mutually exclusive and exhaustive entries should be defined that are straightforward to select and minimize ambiguity. The final core data elements are shown in Table 1.

Several points about the recommended core data elements merit further discussion. First, although some of the recommended data elements may be captured in other ways in the EHR, the Task Group decided it is still desirable to capture these explicitly for the ECT clinical documentation, whether they are reentered manually or automatically pulled from elsewhere in the EHR. These include information on the patient status (i.e., inpatient vs outpatient), as well as on the primary indication for which the patient was referred to ECT. The Task Group decided on a list of relevant indications that, although not exhaustive, captures what is considered most salient for ECT. These include major depressive disorder, bipolar disorder (depression), bipolar disorder (mania), bipolar disorder (other), schizophrenia, schizoaffective disorder, other psychosis, catatonia, stereotypic movement disorder, or other (with text field for additions). The Task Group discussed also information on important psychiatric and medical comorbidities that may influence ECT treatment outcomes but decided against its inclusion as a core data element. Instead, centers may choose to add this information and/or document relevant comorbidites in the procedure note.

Second, there was a discussion about how best to capture ECT series type. Of the 18 centers that explicitly documented ECT series type, many (n = 8) distinguished between acute (or index) and maintenance, whereas most (n = 10) further distinguished continuation treatment (sometimes referred to as tapering). The final recommendation was to capture treatment type as

TABLE 1. NNDC Recommended Core* Data Elements†,‡

Data Element	Data Type
Patient status	CAT: inpatient, outpatient
Primary indication	CAT: major depressive disorder, bipolar disorder (depression), bipolar disorder (mania), bipolar disorder (other), schizophrenia, schizoaffective disorder, other psychosis, catatonia, stereotypic movement disorder, other-textfield
Series type	CAT: acute, maintenance
Treatment no.	INT: 1-N
ECT procedure date	Date: MM/DD/YYYY
ECT procedure time	Time: XX:XX AM/PM
ECT provider	CAT: user-defined options
ECT device model	CAT: MECTA5000Q, MECTA5000M, MECTASIGMA, Thymatron-4, other-textfield
Electrode placement	CAT: RUL, BT, BF, LART, other-textfield
Pulse width	INT: milliseconds
Pulse frequency	INT: hertz
Stimulus duration	INT: seconds
Pulse amplitude	INT: amperes
ECT dose charge	INT: millicoulomb (derived)
EEG seizure duration	INT: seconds
Seizure quality	(Site choice)

*Shown are the recommended core data elements that at a minimum should be documented by a treating psychiatrist at each treatment. Centers may capture additional data elements as they deem appropriate.

†These core data elements may be expanded in the future, as feedback is provided by the wider ECT community on other data that are deemed important to include in the standards. This may include motor seizure duration, which, as discussed in the text, is recommended as optional for now. Other potential standardized data elements for future consideration may include anesthesia medications, other notable psychotropic medications, social determinants of health, illegal drug use, concomitant medications, medical complications, and others.

‡If more than 1 stimulus is administered at a given treatment, then the following core data elements should be documented for each subsequent stimulus: electrode placement, pulse width, pulse frequency, stimulus duration, pulse amplitude, ECT dose charge, EEG seizure duration, and seizure quality. If it is not feasible to document this additional information, then the data elements for the last stimulus should be documented. Similarly, in the cases where seizure titration is used for dosing, then these data elements should be completed based on the final parameter settings.

BF indicates bifrontal; BT, bitemporal; CAT, categorical (note for categorical data elements, centers may use alternative labels for the controlled selections if they are easily mapped to the labels recommended here—eg, "In" for "inpatient" and "Out" for "outpatient"); INT, integer; LART, left anterior right temporal; RUL, right unilateral.

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either acute or maintenance, where acute designates successive treatments to achieve a clinical response during clinically acute episodes of illness (typically involving 6–12 treatments administered 2–3 times per week). By contrast, maintenance ECT refers to successive treatments (typically administered at least 1 week apart) to consolidate a positive response to acute treatment and prolong the period of remission. This definition of maintenance ECT encompasses the so-called continuation series, where an acute series may be tapered over a period of up to several months. The Task Group further determined that if a center prefers to distinguish between the continuation and maintenance series, it may choose to do so because this will not preclude the possibility of harmonizing data with centers that adhere to the core definition.

Third, data elements for ECT device and electrode placement include an option for "other" with the ability to specify in free text. Although this option creates the possibility for the inclusion of unstructured information, it was deemed important to allow flexibility for the introduction of new ECT devices and approaches for electrode placement that are less common than right unilateral or bitemporal placements or that may be developed in the future.

Fourth, a minimal set of the key electrical stimulus parameters (ie, pulse width, pulse frequency, stimulus duration, and pulse amplitude) is included to ensure sufficient understanding of the dosage delivered by the various ECT devices currently in use. These data are readily available with all present US ECT devices. The ability to calculate the ECT charge dose from the other 4 parameters is included to minimize redundant data entry.

Fifth, although some centers routinely capture data on ECT-related medications (such as anesthetic agents, muscle relaxants, etc) and/or ECT-related complications, it was decided not to include these as core data elements in the ECT clinical documentation. The rationale was that these data, especially on medications, are typically documented in a structured manner elsewhere in the EHR, and it was unclear how to capture this potentially redundant information in the ECT clinical documentation in a harmonized way that satisfies all the needs of different participating centers. Moreover, similar to medical and/or psychiatric comorbidities discussed previously, centers may choose to add this information and/or document it in the procedure note.

Finally, there was a considerable discussion about how best to document seizure duration and seizure quality given considerable differences in practice on whether and how this information should be captured. Seizure quality is defined here as aspects of ictal EEG seizure expression, not limited to seizure duration, which may affect clinical response.[23] The precise time of onset of the ictal EEG seizure is not reliably determinable, given that EEG chart output signals are not available on US ECT devices until immediately after the electrical stimulus ends (at which point, chart recorded EEG activity appears and timing of the activity begins on the chart printout). In this regard. 18 of 19 surveyed centers reported using the stimulus endpoint time as a de facto ictal EEG seizure onset for purposes of estimating EEG seizure duration. Although all 19 surveyed centers capture EEG seizure duration, 15 centers also routinely document motor seizure duration, 1 center documents it only if there is some question about seizure quality, and 3 centers do not document it. Of the 15 centers that routinely document motor seizure duration, 10 use the cuff method typically with the blood pressure cuff on the right lower leg.[13] Of these 10 centers, 5 measure the duration based solely on the ictal motor activity distal to the cuff, whereas the other 5 measure the duration based on the last visible movement observed anywhere in the body. The other 5 centers who document motor seizure duration do not specify basing their determinations on the cuff method. Of the 19 centers surveyed, 10 routinely document seizure quality, 4 do so only if indicated, and 5 do not document it. Of 14 centers who document seizure quality in some form, 8 use a structured scale (typically a 3-point scale such as good/fair/poor or a 2-point scale such as adequate/inadequate), 2 use metrics reported by their ECT device, and 4 rely on free text to provide qualitative statements.

Although there was a unanimous consensus on the importance of documenting EEG seizure duration and seizure quality, there was less consensus on *how* to document seizure quality. This lack of consensus is consistent with the lack of agreement within the field of ECT in general on how to measure seizure quality.[24] The Task Group decided to recommend that seizure quality should be included as a core data element, but defer to the centers how they choose to document it provided they do so in a structured format after each treatment. There was greater disagreement about the importance of capturing motor seizure duration. Because consensus was not achieved, the Task Group decided not to include motor seizure duration as a core data element but leave it as an optional field. Again, the Task Group emphasized that if centers opt to include this data element, they should do so in a way that is definable. The Task Group agreed that it will be crucial to gather more information and compare how seizure quality and motor seizure duration are used in academic and community clinical settings, which can be used to drive future consensus.

ECT Patient Outcomes

Although all surveyed centers routinely assess patient outcomes when treating patients with depression, there is a wide diversity in the outcome measures used and the frequency with which they are administered and documented. Centers most often capture and document measures of depressive symptoms, cognitive function, and general overall severity of illness. Both clinician- and patient-rated measures are used. For depressive symptoms, the most commonly used measures across the surveyed centers include clinician-rated measures such as the Montgomery-Asberg Depression Rating Scale[25] (n = 8) or the Hamilton Rating Scale for Depression[26] (n = 3), or patient-rated measures such as the Patient Health Questionnaire-9[27] (n = 9), self-report version of the Quick Inventory of Depressive Symptomatology[28] (n = 3), or Beck Depression Inventory—Second Edition[29] (n = 3). Some centers use more than 1 of these assessments. The Clinical Global Impression—Severity/Improvement Scale,[30] a quick and simple to use clinician-rated global assessment of illness severity and treatment efficacy, is also used by 2 centers.

The Task Group recommended that ECT practitioners should routinely collect and document standardized and structured measures of depressive symptoms and/or overall clinical status to better monitor the efficacy of treatment. The measures should have well-established psychometric properties and may be clinician or patient rated, although clinician rated is preferred, especially early during acute treatment when patients may have limited insight into the illness and/or inability to provide a meaningful response. Although not always clinically feasible, the measures should be collected and documented weekly during an acute treatment series and monthly, or less, depending on the frequency of treatment, during the maintenance series.

In line with best practice guidelines, the Task Group also recommended that cognitive function be assessed throughout the course of treatment to effectively monitor for the emergence of adverse cognitive effects.[13] Although the most concerning adverse cognitive effects reported with ECT have been related to memory function, the US Food and Drug Administration in its 2018 reclassification of ECT devices recommended monitoring of attention, memory, and executive function.[31] Some brief cognitive screening measures may meet this recommendation, such as the second edition of the Mini-Mental State Examination (MMSE-2)[32] or the Montreal Cognitive Assessment.[33]

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To date, the MMSE-2, a copyrighted fee for use instrument, has no published data on its use in patients treated with ECT. The MoCA has been found to be useful in measuring cognitive function in patients treated with ECT.[34] The MoCA is a copyrighted instrument, can be administered via paper-and-pencil or computer, and requires completion of a training session (with associated fees).[33,35] Most surveyed centers use the first edition of the MMSE or the MoCA and supplement or substitute them with structured, although unstandardized questions related to memory directed by the ECT clinicians to the patient and/or family to assess cognitive function throughout the treatment series.

Recently, a new standardized, rapidly administered instrument, the Electro-Convulsive Therapy Cognitive Assessment (ECCA) was developed specifically to measure ECT-associated cognitive adverse effects.[36] This instrument is available via open access to ECT practitioners (https://fuquacenter.org/ecca/). The Task Group agreed that further research is needed in the development of structured cognitive tests that are specific and sensitive to the cognitive adverse effects of ECT and can be administered in an ECT treatment setting.

The Task Group recommended that, when operationally feasible, a standardized measure of cognitive function (e.g., MMSE-2, MOCA, ECCA) should be administered and documented before, after, and at least once (or more if indicated) during an acute treatment series, and as indicated throughout the maintenance ECT series. At a minimum, the Task Group agreed that some type of structured global cognitive function measure should be administered and documented at those time points.

DISCUSSION

Electroconvulsive therapy is an effective and important therapeutic modality for clinical management of severe and/or difficult to treat depression and other indications. However, there is considerable variability in ECT delivery practices and treatment outcomes across centers, and more needs to be understood about its mechanisms of action and who would most benefit from treatment to help guide treatment decisions. The NNDC formed a Task Group of academic neurostimulation treatment centers around the country to begin working together to address these challenges in an ECT-centered approach. To achieve the goal of a greater collaboration, the Task Group has developed recommendations for standardizing the clinical documentation of ECT delivery and assessment of outcomes, including what clinical data should be collected and how it should be recorded, to advance best practices for ECT treatment and facilitate multisite research on ECT in real-world settings. We envision that our core recommendations on clinical documentation will be applicable to the use of ECT for any of its indications, whereas those recommendations related to certain outcome measures (as discussed previously) will be specific to major depressive disorder.

The work reported herein builds on an earlier effort by some members of our Task Group,[37] and it is envisioned as a next step toward standardizing clinical documentation and data collection across ECT centers. We anticipate continuing to refine these recommendations in the future with the inclusion of additional data elements that emerge as important (Table 1). For example, future efforts to refine these recommendations will need to consider how to incorporate more standardized measures of seizure quality for greater comparability across centers, or if there is value in expanding the core data elements to include motor seizure duration, as well as social determinants of health, medical comorbidities, ECT-related medications, or other factors that might influence ECT outcomes and are potentially documented in other parts of the EHR. It will be important to incorporate feedback from the broader community of ECT centers beyond those represented in the NNDC Task Group, which are primarily situated in large academic research medical institutions, to accommodate more diverse clinical settings in the recommended standards. This report is intended to initiate discussions with the broader community to elicit such feedback and establish a foundation for future consensus on updated recommendations.

There have also been similar efforts in other countries to establish networks of ECT centers that seek to collect harmonized clinical data for quality assurance and research initiatives at scale. A leader in this area is the Scottish ECT Accreditation Network (https://www.sean.org.uk/index.htm).[38] The Scottish ECT Accreditation Network provides an accreditation system for ECT clinics across Scotland that includes national standards for data collection on a common set of minimum information meeting clinical needs. In an effort that most closely parallels ours, The Clinical Alliance and Research in ECT Network, including ECT centers from Australia as well as Spain and Singapore, has established a framework for working together on clinical and research initiatives by routinely collecting a common set of demographic and clinical variables and outcome measures across centers.[39] The core set of variables it collects largely overlaps with our current recommendations, with perhaps the inclusion of additional variables beyond our current scope. It also is more prescriptive in the outcomes assessments to be collected and their frequency, whereas we propose to accommodate greater flexibility with local practices. Most recently, an emerging network of 31 ECT centers in Quebec, Canada, reported on a survey of data collection systems and data recorded across the centers.[17] It did not make any specific recommendations, but it is preparing to establish an integrated ECT provincial data collection system for a regional ECT registry that can support clinical research and quality improvement efforts of ECT practice in Quebec. The Scandinavian countries of Sweden and Denmark also have large national registries of patients treated with ECT. In Sweden, The Swedish National Quality Register for ECT[40] was established in 2011 as a nationwide quality register that supports quality assurance and research. In Denmark, data on patients treated with ECT are collected in the Danish National Patient Registry, and a recent survey of practices, including documentation across ECT centers, was recently published.[41]

The recommendations we propose here are meant to provide a foundation for a nationwide network of centers to work together on multisite quality improvement and facilitate research projects that advance ECT treatment of patients with mood disorders in the United States. This network has already been leveraged to support a large-scale multisite study in collaboration with the Psychiatric Genomics Consortium and centers around the world as part of the Genetics of ECT International Consortium to examine the genetic architecture of severe and/or treatment-resistant depression and identify genetic variants that may help predict who are good candidates for ECT.[42,43] This is the first of what the Task Group hopes are many similar efforts that allow the study of ECT on a scale that was not previously possible.

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