Aids to Programming: Paper Documentation

The following pages are sample forms for documenting clinical responses to Deep Brain Stimulation (DBS) programming.

There are two aspects to the forms, diagnosis and DBS target site. As indications and targets expand, additional rating forms can be developed. For example, evidence indicates that DBS of the subthalamic nucleus (STN) and the globus pallidus interna (GPi) can treat dystonia.

The forms contain columns for the electrode configuration, DBS stimulation parameters, common side effects specific to the DBS target, and clinical ratings specific to the disease. A column in the side effect section is entitled "Other" (**Figure 1**). Unlisted side effects can be numbered in this column at the appropriate row and be described in elsewhere in a numbered note.

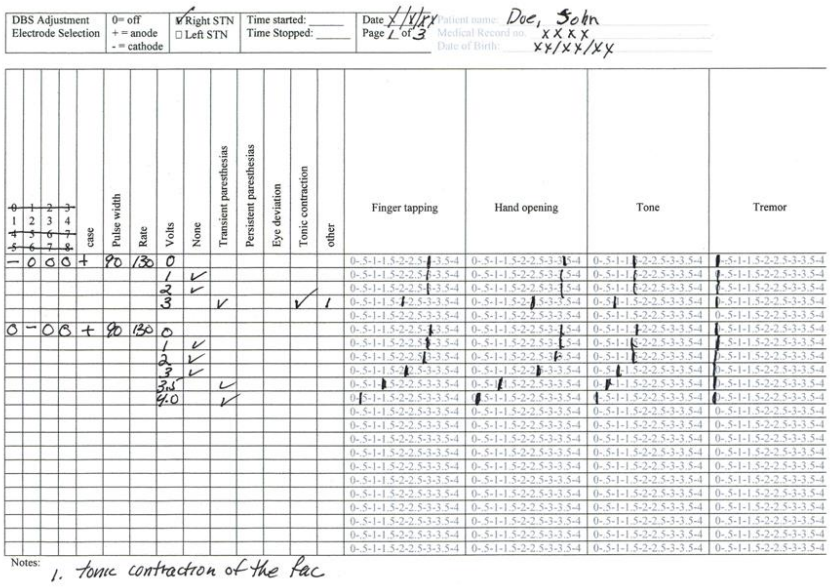

Figure 1. An example of documenting STN DBS in a patient with Parkinson's disease. The first five columns indicated the active contact

configuration. Note that there are five sets of possible configurations depending on the naming convention. The naming configurations not relevant to this particular patient's IPG have been struck. The next three columns indicate the stimulation parameters. The next six columns indicate the common side effects to STN DBS. There is one column labeled "other". This allows you to document any other side effects. Typically a footnote number is entered into the column for as many other side effects and the other side effects are described in the "Notes" section at the bottom. The next four columns identify four main symptoms and signs responding to STN DBS. The grading system for each symptoms and signs are listed below. A vertical hash mark is made to grade the clinical response. As can be seen, the initial electrode configuration produced limiting side effects. One the configuration was changed, there was a progressive improvement in the patient's symptoms and signs. However, the optimal voltage was greater than the battery voltage of the patient's IPG and consequently, another electrode parameter should be attempted, such as an increase in the DBS frequency.

Parkinson's Disease

The majority of Parkinson's disease patients undergo either STN or globus pallidus interna DBS. Forms specifically for documenting stimulation to the STN and globus pallidus interna are given below. Clinical assessments for patients with Parkinson's disease are based on subtests of the motor examination of the Unified Parkinson Disease Rating Scales, part III (Fahn et al. 1987). Guides to the quantification are:

Finger tapping (rapidly tapping index finger to the thumb)

0 = Normal.

1 = Mild slowing or reduction in amplitude.

2 = Moderately impaired. Definite and early fatiguing. May have occasional arrests in movement.

3 = Severely impaired. Frequent hesitation in initiating movements or arrests in ongoing movement.

4 = Can barely perform the task.

Hand opening (and closing)

0 = Normal.

1 = Mild slowing or reduction in amplitude.

2 = Moderately impaired. Definite and early fatiguing. May have occasional arrests in movement.

3 = Severely impaired. Frequent hesitation in initiating movements or arrests in ongoing movement.

4 = Can barely perform the task.

Tone (resistance to passive flexion and extension of a joint, typically at the elbow)

0 = Absent.

1 = Slight or detectable only when activated by mirror or other movements.

2 = Mild to moderate.

3 = Marked, but full range of motion easily achieved.

4 = Severe, range of motion achieved with difficulty.

Tremor at rest

0 = Absent.

1 = Slight and infrequently present.

2 = Mild in amplitude and persistent. Or moderate in amplitude, but only intermittently present.

3 = Moderate in amplitude and present most of the time.

4 = Marked in amplitude and present most of the time.

Other symptoms that often are tested include: Postural stability, postural reflexes, and gait

0 = Normal

1 = Walks slowly, may shuffle with short steps, but no festination (hastening steps) or propulsion.

2 = Walks with difficulty, but requires little or no assistance; may have some festination, short steps, or propulsion.

3 = Severe disturbance of gait, requiring assistance.

4 = Cannot walk at all, even with assistance.

Electronic forms for documenting DBS adjustments for GPi and STN can be downloaded from http:// www.greenvilleneuromodulationcenter.com/ DBS_ Programming_ forms/

Cerebellar Outflow Tremor or Essential tremor

The below rating scales for evaluating patients undergoing ventral intermediate nucleus of the thalamic (Vim), STN or GPi DBS to treat tremor are based on the Clinical Tremor Rating Scales (Fahn et al. 1993):

Resting Tremor: assessed in the upper extremities with the hands resting on the lap

Postural tremor: assessed with the upper extremities held extended in front of the patient

Action tremor: assessed with the upper extremities held extended in front of the patient and then the index finger is brought to the patient's nose and to the examiner's finger held in front of the patient in an alternating fashion.

Cup task: the patient reaches to a cup held in front of the subject, grasps the cup and brings the cup to the patient's lips as if to drink from the cup.

The degree of tremor is rated as:

0 = no tremor

1 = barely perceptible or intermittent tremor

2 = tremor amplitude less than 2 cm

3 = tremor amplitude of 2 to 4 cm

4 = tremor greater than 4 cm or the patient was unable to perform the task

Electronic forms for documenting DBS adjustments for GPi, STN and Vim can be downloaded from http:// www.greenvilleneuromodulationcenter.com/ DBS_ Programming_ forms/

The federal Food and Drug Administration (FDA) has *not* approved DBS for treating tremor secondary to causes other than Parkinson's disease and essential tremor. However, considerable evidence suggests that globus pallidus interna DBS is safe and effective (Montgomery 2008), and it is considered standard and accepted "off-label" treatment when using FDA-approved IPGs for other conditions.

Dystonia

The majority of patients with dystonia undergo globus pallidus interna DBS, although the use of STN DBS is increasing. Below are forms specific to documenting such treatment. Clinical assessments for patients with Parkinson's disease are based on subtests of the motor examination of the Unified Dystonia Rating Scales (Dystonia Study Group 1997). The forms are designed to document dystonia that affects up to four different muscle groups. These forms are specifically modified by the user for each patient according to the type of dystonia being treated. Guides to the quantifying the dystonia are given below. Patients can be assessed at rest, as in cervical dystonia, or while attempting a specific task, such as reaching for a cup. To assess the degree of abnormality, visualize the normal or neutral position and the normal range of motion of the body part, then estimate the degree of departure from normal or neutral position as a percentage of the normal range of motion about that body part.

0 = none

1 = mild: movements of affected muscle group < 25% of possible normal range

2 = moderate: movements of affected muscle group 25% but < 50% of possible normal range

3= severe: movements of affected muscle group 50% but < 75% of possible normal range

4 = extreme: movements of affected muscle group > 75% of possible normal range

There are special cases that are graded differently as follows.

Larynx

0 = none

1 = mild: barely detectable hoarseness or choked voice or occasional voice breaks

2 = moderate: obvious hoarseness or choked voice or frequent voice breaks

3 = severe: marked hoarseness or choked voice or continuous voice breaks

4 = extreme: unable to vocalize

Eyes and upper face

0 = none

1 = mild: increased blinking or slight forehead wrinkling (< 25% maximal intensity)

2 = moderate: eye closure without squeezing or pronounced forehead wrinkling (> 25% but < 50% maximal intensity)

3 = severe: eye closure with squeezing, able to open eyes within 10 seconds or marked forehead wrinkling (> 50% but < 75% maximal intensity)

4 = eye closure with squeezing, unable to open eyes within 10 seconds or intense forehead wrinkling (> 75% maximal intensity)

Lower face

0 = none

1 = mild: grimacing of lower face with minimal distortion of mouth (< 25% maximal)

2 = moderate: grimacing of lower face with moderate distortion of mouth (> 25% but < 50% maximal)

3 = severe: marked grimacing with severe distortion of mouth (> 50% but < 75% maximal)

4 = extreme: intense grimacing with extreme distortion of mouth (> 75% maximal)

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Dyskinesia

Most patients with dyskinesia undergo globus pallidus interna DBS. The forms are specific to globus pallidus interna and allow recording treatment for dyskinesia that affects up to four different muscle groups. Guides to the quantification of the dyskinesia are given below. Patients can be assessed while performing a specific task, depending on the muscle group being assessed, such as reaching for a cup for the hand and arm.

0 = no dyskinesia

1 = minimal severity, no interference with volitional task

2 = dyskinesia may impair performance but the task can be completed without significant difficulty

3 = dyskinesia significantly impairs performance of the task which can be completed only with great difficulty

4 = dyskinesia prevents the patient from performing the task

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The federal Food and Drug Administration (FDA) has *not* approved DBS for the treatment of dyskinesia. However, considerable evidence suggests that globus pallidus interna DBS is safe and effective (Montgomery 2004b), and it is considered to be a standard and accepted “off-label” use when using FDA devices approved for other conditions.

Tourette's Syndrome

Most patients with Tourette's syndrome undergo globus pallidus interna DBS. The forms below are specific to globus pallidus interna and allow recording treatment for Tourette's syndrome that affects up to four different tics. The user can modify the columns depending on the patient's specific manifestations. Guides to the quantification of the tics are below.

0 = no tics

1 = < 3 tics per minute of observation

2 = 3 to 6 tics per minute of observation

3 = 7 to 10 tics per minute of observation

4 = > 10 tics per minute of observation

Electronic forms for documenting DBS adjustments for GPi, STN and Vim can be downloaded from http:// www.greenvilleneuromodulationcenter.com/ DBS_ Programming_ forms/

The federal Food and Drug Administration (FDA) has *not* approved DBS for treating Tourette's syndrome. However, considerable evidence suggests that globus pallidus interna DBS is safe and effective for Tourette's syndrome, as with other hyperkinetic disorders (Montgomery 2004), and it is considered standard and accepted "off-label" use when using FDA devices approved for other conditions.

References:

1. Dystonia Study Group (DSG) Unified Dystonia Rating Scale (UDRS) DSG consensus conference 1997
2. Fahn S, Elton RL, UPDRS program members. Unified Parkinsons Disease Rating Scale. In: Fahn S , Marsden CD , Goldstein M , Calne DB , editors. Recent developments in Parkinsons disease, vol 2. Florham Park, NJ: Macmillan Healthcare Information; 1987. p 153-163.
3. Fahn S, Tolosa E, Marin . Clinical Rating Scale for Tremor. In: Jankovic J, Tolosa E, eds. Parkinson's disease and movement disorders. 2nd ed. Baltimore:Williams & Wilkins, 1993:271–280.
4. Montgomery, E. B. Jr. (2004b). "Deep brain stimulation for hyperkinetic disorders." Neurosurgical Focus 17: E1.
5. Montgomery , E. B. Jr. (2008). Thalamic stimulation for other tremors. Deep Brain Stimulation for Neurological and Psychiatric Disorders. D. Tarsy, J. Vitek, P. A. Starr and M. S. Okun, Humana Press: 215-228.