Neurostimulation Therapy for Epilepsy for Advanced Practice Providers (APPs)

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This document is intended as an educational tool for APPs and is not meant to guide individual practice or to supersede decisions of individual practitioners.

Introduction: Use of neurostimulation devices has become commonplace in Epilepsy Centers. APPs are frequently involved in the clinical management of the three currently FDA approved devices for epilepsy which include: Vagus Nerve Stimulation (VNS), Responsive Neurostimulation (RNS), and Deep Brain Stimulation (DBS).

Each device is considered an ***adjunctive therapy*** for medically refractory focal epilepsy when surgical resection or ablation of the seizure focus is not feasible. The goal of therapy is to reduce the frequency and severity of disabling seizures.

Patient Education

- When reviewing neurostimulation devices with your patients one educational strategy is to discuss that devices lack the systemic side effects seen with medications (somnolence, mood changes, bone health, risk of birth defects and effects on liver, kidney, and hematologic function).
- Prepare your patient for the journey:
  - Set realistic expectations. These devices may or may not improve seizure control, and medication reduction may not be possible.
  - After implant, patients must be seen in person within a few weeks for post-op check and to begin programming. Further in-person visits will be needed at appropriate intervals in order to optimize device therapy. Devices cannot be programmed remotely and should only be managed by appointments with providers who routinely program these devices.
  - Patients will most likely need to remain on antiseizure medications. Remind patients that device therapy is an adjunctive therapy and not a cure. Patients will need to remain on stable doses of anti-seizure medications (ASMs), without reduction, until at least some improvement has been seen after starting device therapy. It is unlikely that the patient will be able to discontinue all ASMs.
  - Try not to change ASMs during optimization period. Changes will make it difficult to determine whether medication changes or device changes are responsible for any clinical worsening or improvements.
  - Encourage patients to continue using their seizure diary and bring it to their visits. Devices do not record clinical events and do not take the place of seizure diaries.

- Patients will need to have regular surgical battery replacements depending on parameters programmed. After several years, the battery of all these devices will require surgical replacement, if the patient wishes device therapy to be continued. Typical battery life is between 3-10 years, depending on programming and type of device.
- Review potential limitations with patient: Make patient aware that some procedures are contraindicated following implant of the devices (e.g. diathermy, TMS, local radiation), and tests requiring strong magnetic fields (e.g. MRI, MEG) may not be possible, or, if possible, require turning the device off before, and on again after, the procedure.

Programming Visits

- Programming visits must be in person. Programming cannot be done remotely. Electrocorticograms recorded by the RNS can be checked remotely, if the patient uploads data regularly.
- Guidelines are provided by device companies and are available for reference, but therapy should be individualized in close collaboration with the epileptologist.
- VNS, RNS, and DBS are not the same, and programming settings for optimization will differ among each of these devices.
- A common treatment strategy is to start with low treatment parameters and titrate over time slowly, but this can vary. Be aware that optimization may be reached at low stimulation.
- Be methodical in programming changes and allow stimulation parameters a chance to work. Do not react to every seizure with a programming change. Longer times at a single setting may result in a benefit, and efficacy may improve over time with no changes in parameters.
- Each device company has qualified field representatives to guide, teach, and educate. Don't hesitate to contact them or company support lines for help. Field representatives are often helpful to guide, educate, and participate in initial programming visits, if desired. With more complex programming goals, it may be helpful to have field representatives come to visits. Preferences for representatives in the clinic may vary among institutions and providers.
- Contact departments performing any other specific procedures with the patient (e.g., radiology, OB/GYN, surgery, dental).

Helpful Links

- **Programming and Safety Reference Links (2022)**
  - **Liva Nova, VNS**
    - Product Training
    - Safety Information
  - **NeuroPace, RNS**
    - Protocol
    - Manual
  - **Medtronic, DBS**
    - About
    - Safety Warnings

Comparison Chart of VNS, RNS, DBS

	VNS	RNS	DBS
FDA approved for seizure type	Focal *	Focal *	Focal *
Localization necessary	No	Yes	No
Target of stimulation	Left vagus nerve	Intracranial, based on target	Anterior nucleus of the thalamus
Implanted Pulse Generator (IPG) site	Usually subclavicular, may be variable	Skull	Subclavicular
Lead site	Left neck	Intracranial, based on target	Anterior nucleus of the thalamus
Reversible	Yes	Yes	Yes
Response type	Open Loop Closed Loop (Heart rate detection)	Closed Loop	Open Loop
Recording capability: chronic ECoG capability	No	Yes	No
Effects on cognition and mood	Positive in some cases	Positive in some cases	Unclear
Side effect during stimulation	Yes, effect on voice is common	Typically, no	No
MRI compatible **	Yes, under certain conditions	Model 300 - No Model 320 - Yes, under certain conditions	Yes, under certain conditions
Approved for use in children	Yes, for >4 years old	No, 18 years and older	No, 18 years and older
Efficacy improves over time	Yes	Yes	Yes

Table Footnotes

***** These devices sometimes have been used by licensed independent practitioners “off-label” for other types of seizures.

** **Device-Specific MRI Guidelines (2022)**

- **LivaNova, VNS**
- **NeuroPace, RNS**
- **Medtronic, DBS**

Reference

Touma L, Dansereau B, Chan AY, et al. Neurostimulation in people with drug-resistant epilepsy: Systematic review and meta-analysis from the ILAE Surgical Therapies Commission. *Epilepsia. 2022;63(6):1314-1329. doi:10.1111/epi.17243*
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