

Study Title: Best Management of Muscle Relaxation with Rocuronium Using Objective Monitoring and Reversal with Neostigmine or Sugammadex

NCT03958201

Document title: Protocol

Date of the document: 5/8/2019

## PROTOCOL

This study implements a standardized protocol for NMBD (neuromuscular blocking drug) management that is currently used by some providers at UWMC and HMC to help prevent residual paralysis in surgical patients. While this protocol is within the scope of routine care that an anesthesiologist could follow in his/her clinical practice, it is not consistently used throughout HMC. This protocol follows clinical best practices for NMBD management in a surgical population and adheres to the recommendations from the P&T committee on reversal drug choice and recommendations from the Department of Anesthesiology and Pain Medicine on neostigmine dosing. While this protocol is in line with best practices, we are continuing to systematically evaluate it in the setting of prospective research. All drugs will be administered for clinical care only. This research does not add additional medications. The study will take place at HMC and will follow a standardized research protocol for the timing, dosing, and monitoring surrounding muscle relaxants and reversal, and makes use of objective TOF monitors. If a patient agrees to participate in this study, the following research protocol will occur:

### Before Surgery:

1. **TOF measurements before surgery:** A study investigator will perform the routine clinical train-of-four measurements with an objective monitor at baseline after the clinical induction of general anesthesia but before the administration of the NMBD. Information will be recorded for research purposes. Research staff will leave the operating room after obtaining the baseline measurement and will return to the operating room at the end of the surgical procedure, to be available for TOF ratio measurements at the time of extubation.
2. **Dose calculation of initial NMBD:** A study investigator will assist the anesthesia provider with calculation of the recommended intubating dose of rocuronium (an NMBD). The dose will be calculated per this research protocol based on Ideal Body Weight (IBW) which is calculated as follows:
  - a. For women 45.5 kg plus 2.3 kg/inch over 5 feet of height
  - b. For men 50 kg plus 2.3 kg/inch over 5 feet of height.
  - c. For routine intubations, the recommended dose for intubation will be a maximum of Rocuronium 0.6 mg/kg.
  - d. The intubating dose will be reduced by 15% for females
  - e. Higher intubating dose may be used at the discretion of the anesthesia provider

### During Surgery:

3. **Additional dose calculation of NMBD:** Each additional dose of rocuronium will be 25% of the recommended intubating dose and will be administered when the TOF count has returned to at least 2, the aim is to maintain an intraoperative TOF count of 1-2 unless the anesthesia provider has deemed deep paralysis to be necessary in which case a TOF count of 0 will be maintained. An attempt will be made to avoid administration of rocuronium during the last 30 minutes of the procedure. If the surgeon requests muscle relaxation during the final stage of surgery, consideration should be given to providing relaxation by using non-NMBDs such as propofol which is an option an anesthesiologist has in their clinical practice.

After Surgery: Patients will receive reversal drugs for their routine care that will help reverse the effects of their muscle relaxant. In this study, the decision of reversal drug use will follow institutional guidelines. The timing and dose calculation of the reversal drug will follow the research protocol as follows:

4. **Timing of neostigmine or sugammadex:** Based on the results of the clinical pre-reversal TOF assessment, reversal with neostigmine will be administered only if the objective TOF-ratio is between 40%-90%. If the block is deeper than this, then sugammadex will be used for reversal (This is per institutional guidance on choice of reversal drug).
5. **Dose calculation of neostigmine and sugammadex:** For this study, the dose of neostigmine will be calculated based on the IBW. The dose of sugammadex will be calculated based on patients' actual body weight.  
\*For all subjects enrolled in this study, we will follow a dose schedule which is based on clinical TOF monitoring and is in accordance with institutional recommendations for dosing of neostigmine.
6. **Timing of extubation:** The patient's trachea will not be extubated before routine objective monitoring confirms recovery to a TOF-ratio  $\geq 90\%$ . However, in the case that objective monitoring cannot be obtained by the provider then the following will happen:
  - a. For subjects who receive neostigmine for their routine care , it is recommended that the patient's trachea will not be extubated earlier than 10 minutes after the administration of this drug.
  - b. For subjects who receive sugammadex for routine care, it is recommended that the patient's trachea will not be extubated earlier than 3 minutes after drug administration.
7. **TOF measurements after surgery (extubation):** The TOF-ratio will be measured by a study investigator or provider at the time of extubation. Information will be recorded for research purposes. If we miss obtaining research measurements at the time of extubation, we will obtain TOF measurements on the patient's arrival to the PACU.
8. **Collection of data from EMR:** We will collect information from the patient's medical record including the intraoperative TOF counts, ASA class, surgical procedure, times of the surgical procedure, time and dose of administered medications, and the patient's temperature in the operating room and PACU.