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|   | | CLACKAMAS & WASHINGTON COUNTY EMERGENCY MEDICAL SERVICES | | |
| EMS Clinical Notification | | | | |
| EFFECTIVE DATE: 19 July 2023 | NUMBER: 071923-OPS | TYPE: Clinical Guideline | REPLACES: None | PAGE: 1 OF 1 |
| ENTER NAME/TITLE HERE (signature on line below): DR. RITU SAHNI, MD, MPH, FAEMS | | TITLE: IMMEDIATE SUSPENSION OF PACT | | |

Good afternoon!

All enrollments in the Prehospital Airway Control Trial (PACT) are to be suspended immediately.

What happened?

- All Exception from Informed Consent (EFIC) trials, such as PACT, have a Data Safety Monitoring Board (DSMB) that is independent of the study investigators. They review the study data at regular, scheduled intervals to ensure that performing the trial is safe for our patients. After a regularly scheduled review, the DSMB asked that the trial be suspended.

Does this mean that there was a problem?

- Not necessarily. It could mean that one of the two arms of the study significantly outperformed the other OR it could mean that the two arms were so close that we could run the study for much longer than planned and still not see a difference. We will follow up as soon as we know.

What does this mean clinically?

- Our protocols allow for placement of either an iGel or an ET tube when managing the trauma airway. At this time, it will be clinician judgement as to which airway they prefer. This means that clinicians may still utilize the iGel first line if that is their preference.

Should we get rid of all our PACT stuff?

- No. It is possible that this is just a pause to give the DSMB more time to evaluate the data. They may take a deeper look and then determine that the study is safe to resume.



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