

Clinician Notification regarding preliminary data from a prospective, randomized, [multi-platform](#) trial of therapeutic anticoagulation in hospitalized patients with COVID-19

The purpose of this communication is to acknowledge the unpublished clinical trial data and provide interim guidance to clinicians considering therapeutic anticoagulation for inpatients hospitalized with COVID-19 - NIH news release [here](#).

In brief, these preliminary trial findings **report superiority of therapeutic anticoagulation over prophylactic dose anticoagulation among "moderately ill" patients** (not requiring either ICU level care or organ support, defined as HFNC >30LPM, invasive or non-invasive mechanical ventilation, vasopressors, or ECMO) **hospitalized with symptoms of COVID-19** based on a pre-defined primary composite 21-day endpoint of organ-support free days and mortality. The difference in mortality between groups, while favoring the therapeutic arm, may have been underpowered. The risk of major bleeding was low in both prophylactic and therapeutic arms (<2%). **Importantly, among "severely ill" patients**, defined as requiring ICU-level care and/or organ support, **the data support inferiority of therapeutic anticoagulation and potential for increased harm including increased bleeding risk.**

While the Committee does not feel that these preliminary findings support a change of formal recommendations before the full data are available and published, **this notification serves to inform providers:**

1. Permissive use of therapeutic heparin-based anticoagulation (LMWH or VTE dosed UFH) can be considered in non-ICU patients hospitalized for symptoms of COVID-19 (either respiratory or GI) that meet the following criteria, which match the inclusion criteria used in the trial:

- Within 72 hours of admission and likely to remain inpatient for 3 days (elevated D-Dimer and/or need for oxygen therapy were considered though not strict inclusions for the trial, and the apparent benefit was independent of the low and high D-Dimer groups)
- Requiring less than 30 LPM respiratory support via HFNC or LFNC
- Not requiring ICU-level care or likely to imminently transfer to the ICU
- No anticipated imminent death (e.g., acute care patients on comfort level care)
- No contraindication to anticoagulation, including but not limited to:
 - o Known bleeding within the last 30 days requiring emergency room presentation or hospitalization
 - o Known history of an inherited or active acquired bleeding disorder
 - o Known history of heparin induced thrombocytopenia
 - o Recent ischemic stroke
 - o Platelet count < 50 x 10⁹/L
 - o Hemoglobin < 8 g/dL
- Not on dual antiplatelet therapy

2. If a patient is on pre-existing therapeutic anticoagulation, continuation of this treatment if not contraindicated is recommended.

3. The current trial data do not yet provide guidance on whether therapeutic anticoagulation should be continued for non-ICU-level patients escalated to the ICU or ICU-level organ support. Clinician determination is recommended.

4. There is currently no data to support continuation of therapeutic anticoagulation beyond 14 days of therapy or upon discharge from the hospital, whichever comes first.