

2. Please propose a nomenclature and scale for bleeding severity. This scale ideally should be one that helps identify patients who are candidates for novel device treatment and helps determine whether the novel device treatment was successful or not. (i.e. Mild / Moderate / Severe)

Truncal Bleeding (not extracavitary)

Group 1

- Patients in battlefield get tourniquets, removed at trauma centers, venous
- Distinguish arterial moderate /severe – still tourniquets applied
- Challenges – is this a surgical patient or not?

Group 2

- Concern without clear IFU – exposure to unnecessary risks
- Best way to identify internal bleeding was hypotension (but not exclusive to bleeding and with many caveats)
- Other potential causes
- Internal bleeding – knowing due to bleeding
- Prehospital setting – hard to determine truncal bleeding (different from biologic study)

Group 3

- Surface and visible bleeding and internal
- External: assessed on system relevant to all people (medic and surgeon get same score)
- Internal: bleeding scores, e.g., ADC scores
- Look at data and registries – not a lot of time dependence, infrequently linked with outcomes – need this for evidence based scale

Group 4

- Utility – clinical trial setting, stratification purposes helpful in clinic; determine device use based on experience, not scale.
- How translate scale into clinical environment?

Group 5

- Extracavitary – don't need scoring system, if wait at POI - treat, therefore intervene before score determination
- Mild/moderate (not important to consider)
- Experience can differentiate, both inexperience and experience can identify life-threatening hemorrhage
- Standard vital signs and how they look
- Extracavitary – undetectable BP – at high end, don't care

Group 6

- Mild, moderate, severe – class I,II,III shock
- Mild – I or II
- Class 4 – everyone recognizes and needs interventions and will use products
- Class III shock – not necessarily use products, triage
- 2,3,4 non-trauma in class III shock – put in device because of timeline to treatment/transport
- ABC score
- Tactical “score”: Weak, absent, etc.
- Possibly data with molecular info?