

Validation of the Quantra Hemostasis Analyzer during Aeromedical Flight

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Acknowledgements

- Catherine McGaughey MS
- Daniel Grabo MD
- Alison Wilson MD
- No conflicts to report

Disclosures

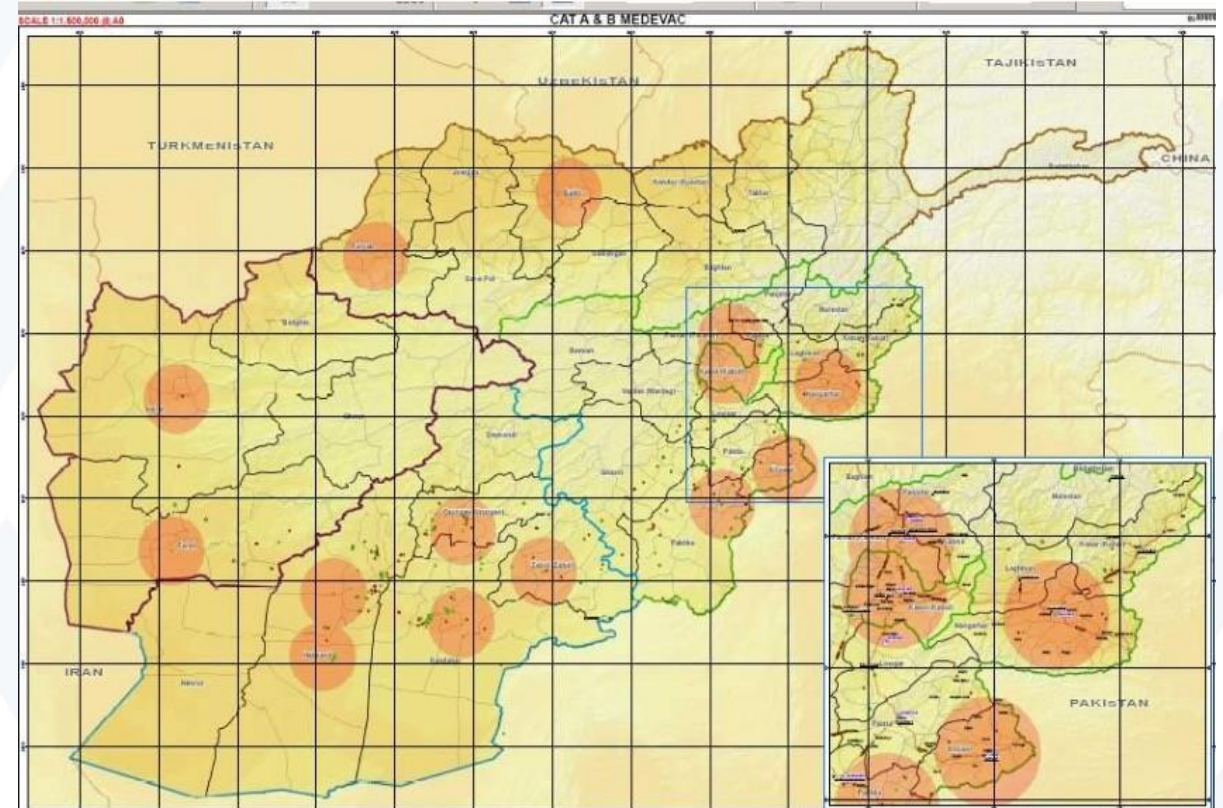
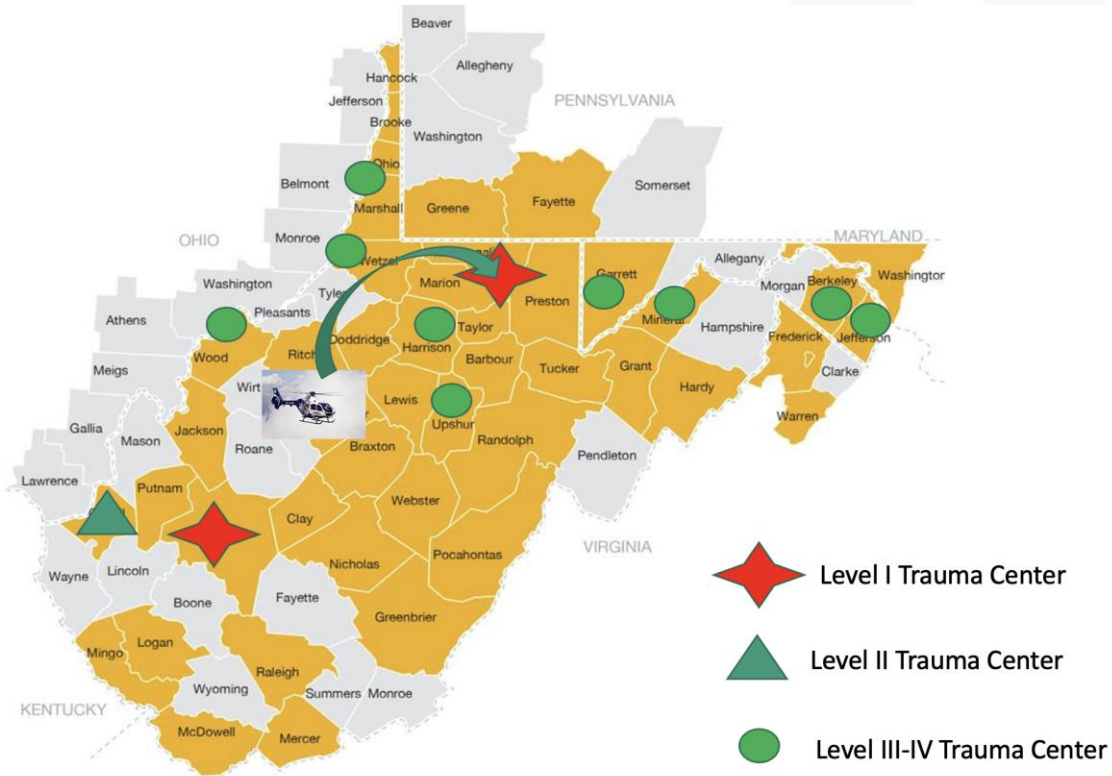
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 - Provided two Quanta analyzers and disposables for the study period
 - Study design was the responsibility of the investigators
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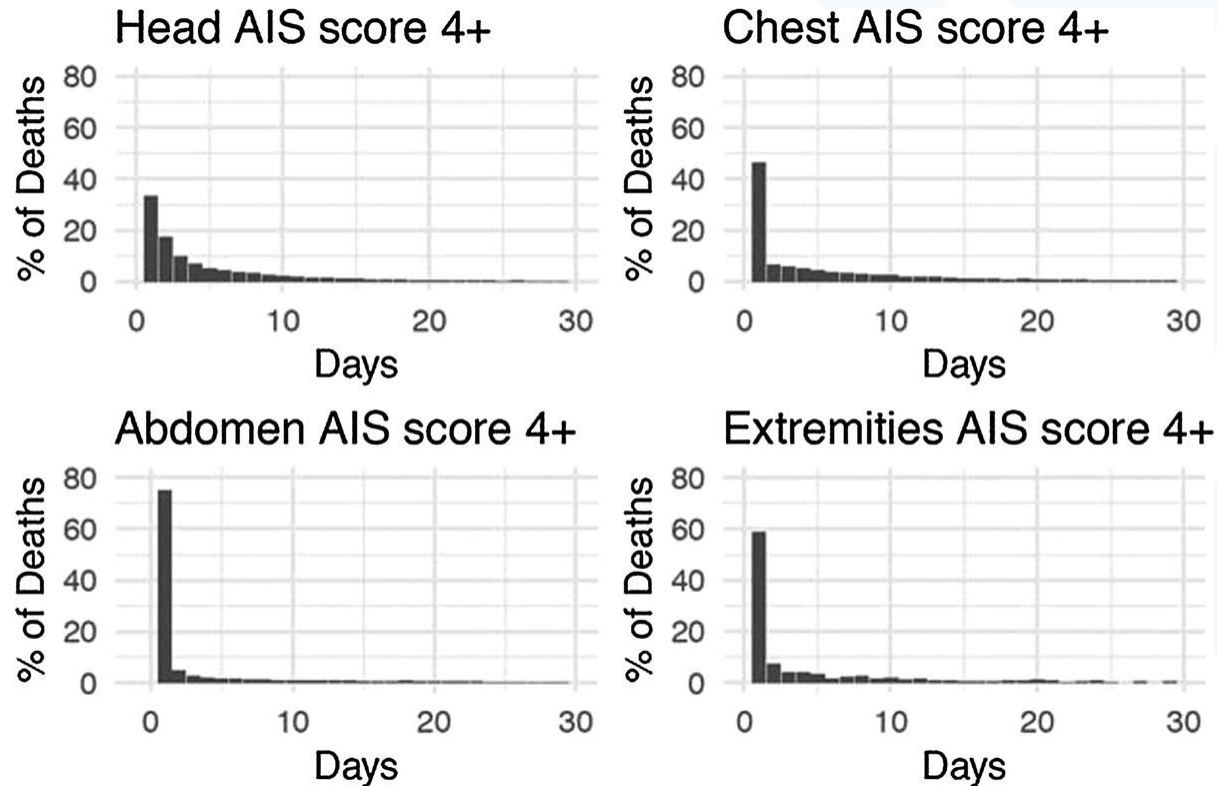
Challenges in Rural and Austere Care



Challenges in Rural and Austere Care



- Hemorrhage remains leading cause of mortality
- Resource limited environments have worse outcomes



The Golden Hour



The time following a traumatic injury when prompt medical treatment has the highest likelihood to prevent death

The contemporary timing of trauma deaths

Bardes, James M.; Inaba, Kenji; Schellenberg, Morgan; Grabo, Daniel; Strumwasser, Aaron; Matsushima, Kazuhide; Clark, Damon; Brown, Niquelle; Demetriades, Demetrios

Journal of Trauma and Acute Care Surgery 84(6):893-899, June 2018.

January 2016

The Effect of a Golden Hour Policy on the Morbidity and Mortality of Combat Casualties

Russ S. Kotwal, MD, MPH^{1,2,3}; [Jeffrey T. Howard, PhD¹](#); Jean A. Orman, ScD, MPH¹; [et al](#)

» [Author Affiliations](#) | [Article Information](#)

JAMA Surg. 2016;151(1):15-24. doi:10.1001/jamasurg.2015.3104

- 2009 mandate to reduce time between combat injury and definitive care
- Decreased mortality

- How do we overcome time and distance?
 - Take high level care closer to the point on injury
 - Increase blood product availability in the field
 - Addressing coagulopathy early

Viscoelastic Testing

- Real time evaluation of the entire clotting cascade
 - Factors
 - Platelets
 - Fibrinogen
 - Thrombolysis

Viscoelastic testing

- Traditionally hospital-based testing
- Shown to:
 - Improves outcomes
 - Decrease total blood product usage

Gonzalez E, Moore EE, Moore HB, Chapman MP, Chin TL, Ghasabyan A, Wohlauser M V., Barnett CC, Bensard DD, Biffi WL, et al. Goal-directed Hemostatic Resuscitation of Trauma-induced Coagulopathy. *Ann Surg.* 2016 Jun;263(6):1051–9.

JOINT TRAUMA SYSTEM CLINICAL PRACTICE GUIDELINE (JTS CPG)



Damage Control Resuscitation (CPG ID: 18)

This CPG provides evidence-based guidance to minimize variation in resuscitation practices and improve the care of massively hemorrhaging, severely injured casualties.

Blood product transfusion

Cryoprecipitate is available in hospital settings and should be added to the component mix to create a 1:1:1:1 ratio of products in order to adequately supply fibrinogen and other clotting factors (Factors VIII, XIII, and vWF).

When operationally necessary due to component shortages, WB from walking blood banks can be life-saving. For additional information, refer to the JTS CPG titled Whole Blood Transfusion.⁴⁹

Continual reassessment of the casualty status is needed during and between transfusions. As the patient stabilizes, component ratios should be replaced by 'goal-directed' therapy guided by laboratory evaluation, including PT/INR, Activated Partial Thromboplastin Time (aPTT), and viscoelastic testing (ROTEM® or TEG if available).



ROTEM



Quantra



TEG 5000



TEG6s

- Limited real-world data on use in a helicopter
 - TEG6s
 - Found not to be accurate
 - *Limited by lack of vibration mitigation*



Emergency Medicine Australasia (2020) 32, 786–792



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ORIGINAL RESEARCH

Viscoelastic haemostatic assays in aeromedical transport

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Investigation and validation of the TEG6s during rotary wing aeromedical flight

Bardes, James MD; Grabo, Daniel MD; Shmookler, Aaron MD; Wen, Sijin PhD; Wilson, Alison MD

[Author Information](#) ✓

Journal of Trauma and Acute Care Surgery 97(2S):p S113-S118, August 2024. | DOI:

10.1097/TA.0000000000004335 ©

- With simple vibration mitigation TEG6s appears accurate



Quantra Device

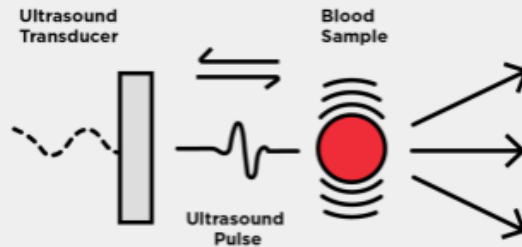


Quantra

Sonic Estimation of Elasticity via Resonance (SEER)

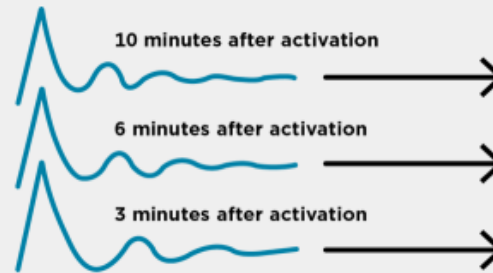
The Quantra[®] System is based on a patented technology called SEER (Sonic Estimation of Elasticity via Resonance) Sonorheometry.

SEER uses state-of-the-art ultrasound technology to measure clot stiffness (shear modulus of elasticity) over time using ultrasound-induced resonance.



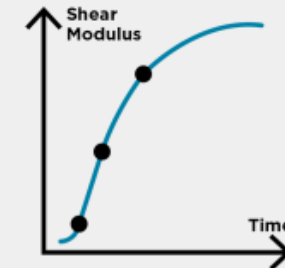
Data Acquisition

Ultrasound pulses are sent into the blood sample to induce resonance, causing the sample to oscillate.



Displacement Estimation

As the blood coagulates over time and its stiffness increases, the frequency of oscillation will also increase.



Clot Time and Clot Stiffness Measurement

Clot times and clot stiffness values are measured from the evolving shear modulus.

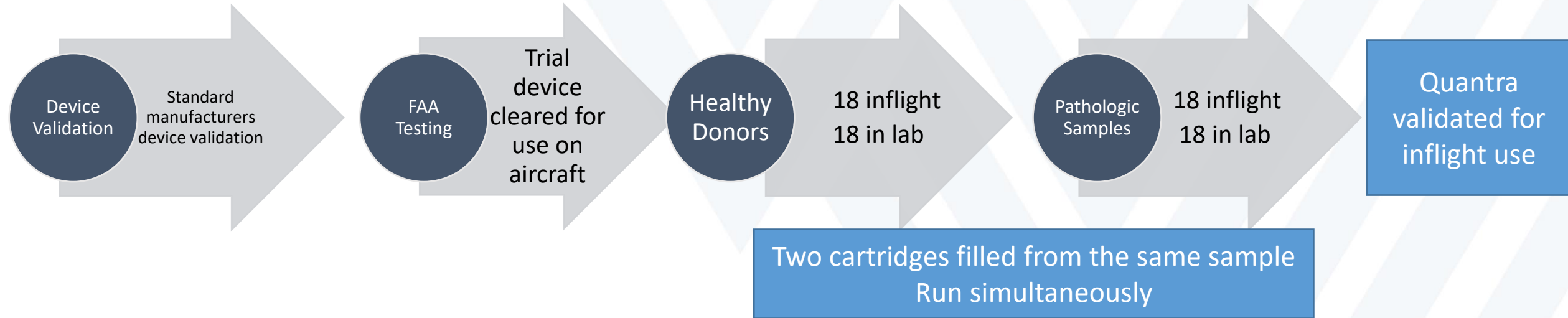
Quantra

- Rapid analysis of all portion of the clotting cascade
- Shown to identify TIC



Study design

Investigator initiated; industry supported



- Airbus EC-135H





Inflight Validation- Phase 1

- Samples of healthy donor blood
- Volunteers were consented
- Exclusions:
 - Subjects prescribed any blood thinners, antiplatelet medications
 - NSAIDS within 12 hours
- Blood was drawn per manufacturers instructions

Inflight Validation- Phase 2

- Samples from patients expected to have pathologic findings
 - Heparin drips, ECMO, liver failure
- Volunteers were consented
- Blood drawn in same fashion

In-Flight Use

- Helicopter sample started once level flight achieved
- Crews recorded altitude, barometric pressure, and flight events
- Results recorded at landing

Analysis

- Two-sided paired t-test to evaluate means
- Fisher exact test to compare categorical values

Results

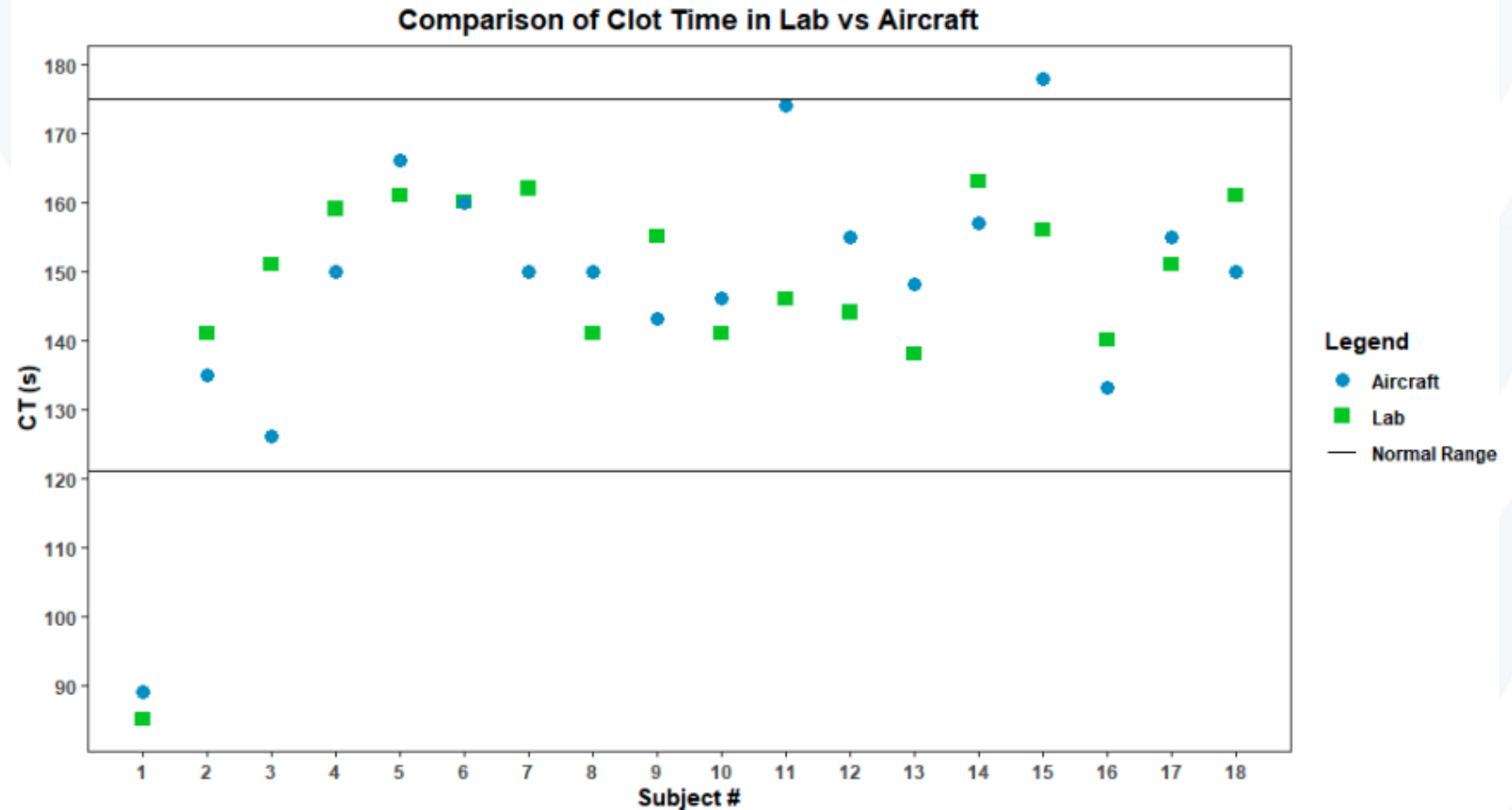
- Phase 1
 - 18 subjects
 - Evenly distributed by sex
 - Mean age 35 ± 10 years

- 20 samples to get 18 results in phase 1
- 1 showed error and had to reboot
 - Heavy turbulence
- 1 issue with barcode scanner



Clot time

- Mean (seconds)
 - Aircraft 147 ± 18
 - Lab 148 ± 20
 - $P=0.86$



- Clot time results classified as normal vs abnormal
 - 17/18 lab tests were labeled as normal
 - 16/18 aircraft tests were labeled normal
- 2 of these were for the same sample
- The isolated aircraft sample would not have resulted in transfusion

Clot Stiffness

- Mean (hPa)
Lab 24 ± 6
Aircraft 25 ± 6
 $P=0.2$

Platelet contribution

- Mean PCS (hPa)

Lab 21

Aircraft 22

P=0.3

Fibrinogen contribution

- Mean FCS (hPa)

Lab 2.5

Aircraft 2.4

P=0.2

Lysis

- Flight times were not long enough to allow reporting
- Mean flight time 17 minutes

Discussion

- Initial testing of the Quantra in an aeromedical environment appears promising
- Cartridge based system was successfully used by flight crews once in level flight

- For normal samples
- No significant difference in lab or aircraft values

- Additional samples are still needed for phase 2 of this study to validate pathology identification
- Currently limited sample size

- Longer flight times to determine CLS (Lysis) accuracy
- Investigate adverse flight conditions

Goal of Prehospital Use

- Long Term Benefits
 - Viscoelastic guided blood resuscitation
 - Data driven decisions about TXA
 - Provide actionable test results on arrival to the hospital

Thank you

- HemoSonics Inc
- Healthnet Aeromedical
 - Base 6
 - Clinton Burley
 - Josh Gillespie



Questions

