

Changing Practice Without RCTs: When to Pull the Trigger with New Therapies

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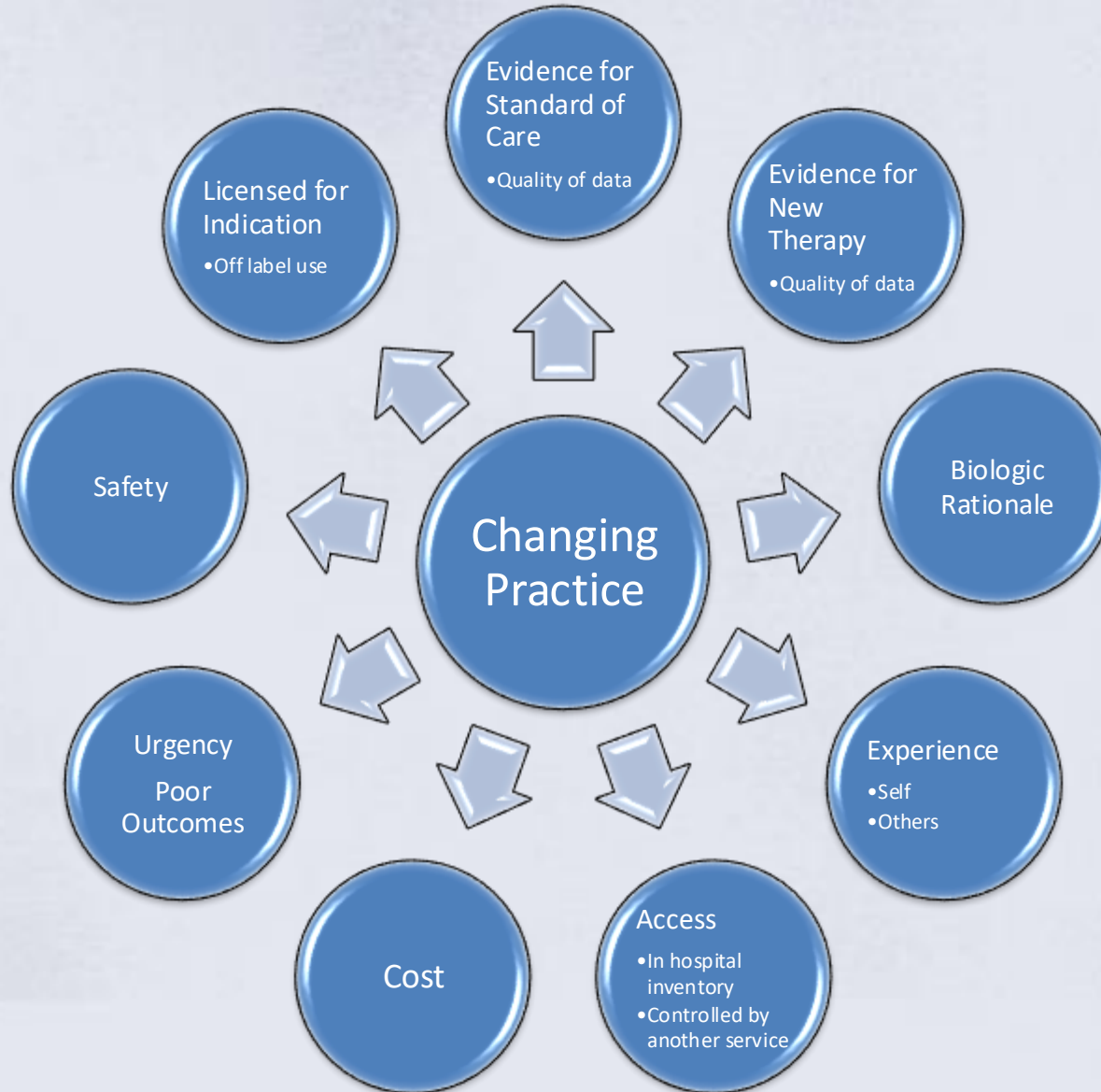
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Background

- Plasma for septic shock RCT presentation
 - Why do we need a trial for change?
 - We must have an RCT to make this change!

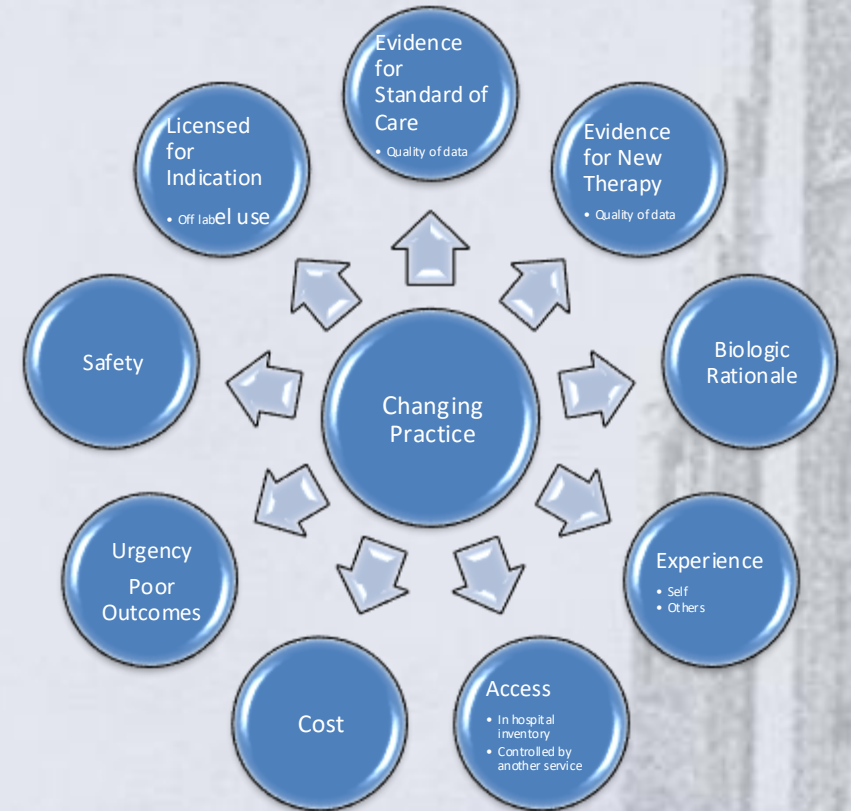


Considerations for Changing Practice in Critically Ill



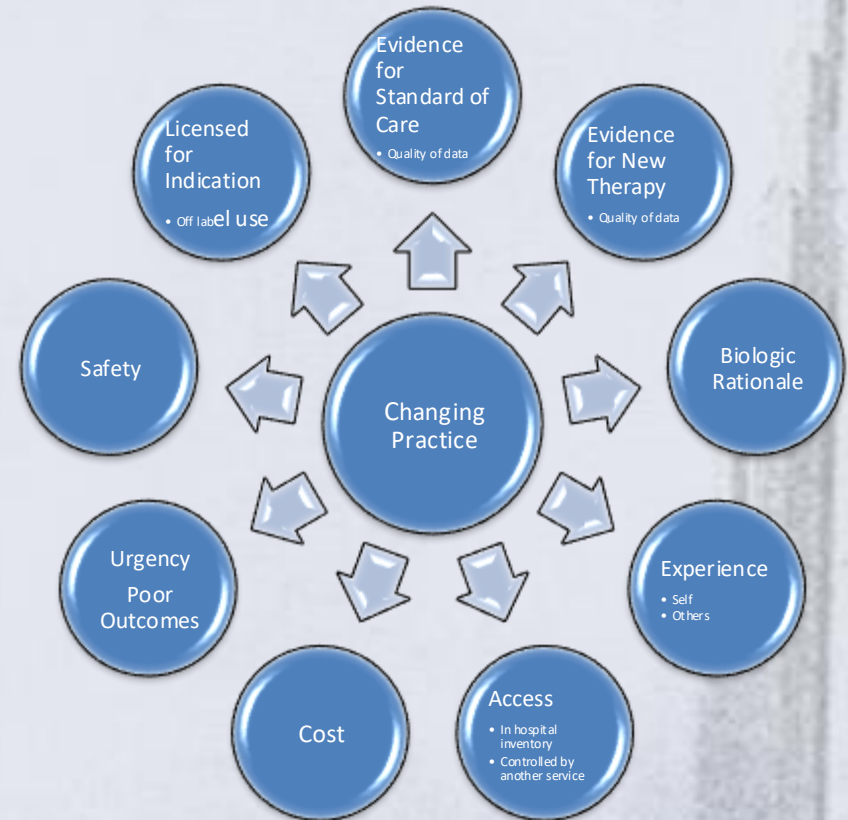
Practice Change with Hemostatic Resuscitation

- Threshold to change in context of
 - Quality of data: High or low
 - Safety of new therapy: high risk or low risk
 - Biologic rationale for new therapy
 - Urgency due to poor outcomes
 - Access to product
 - Cost



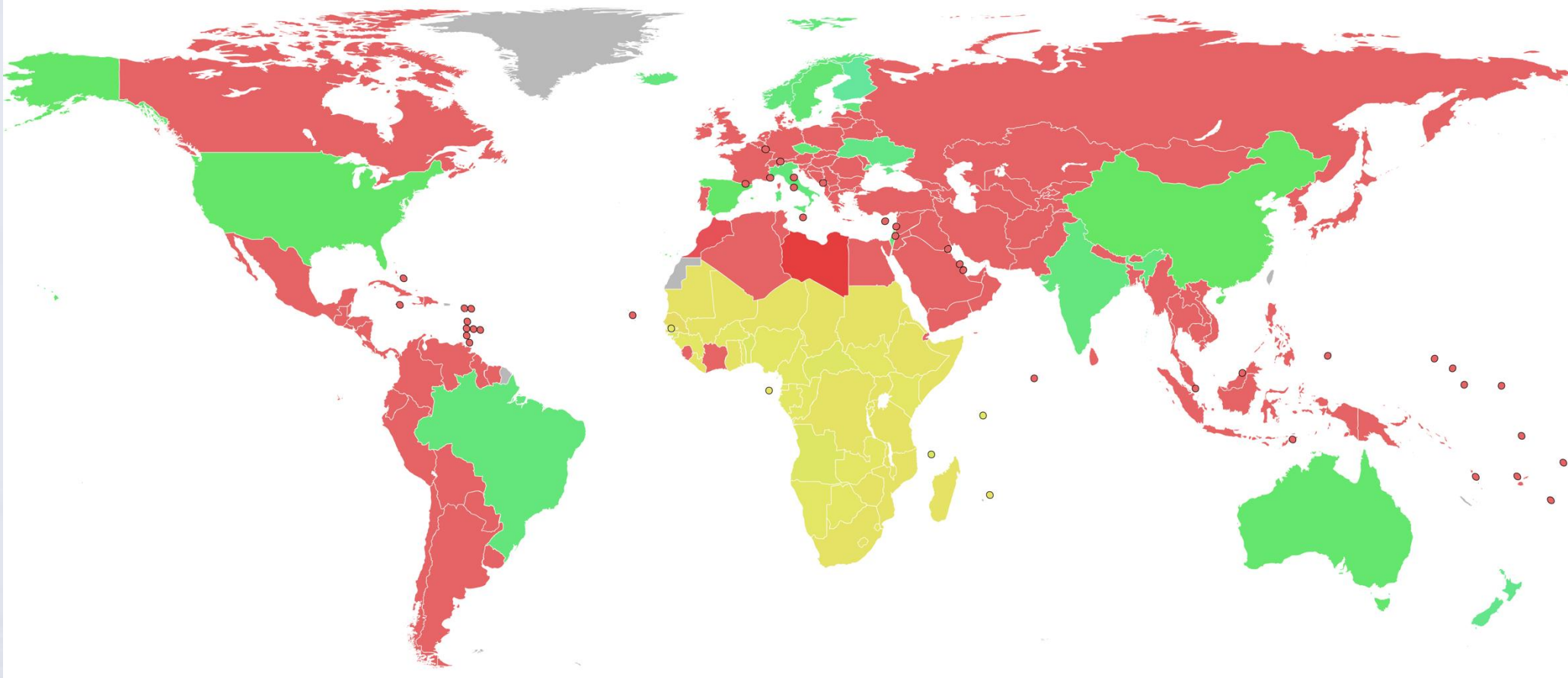
Inconsistency in Transfusion Medicine with Practice Change for Hemostatic Resuscitation

- No RCTs for change to
 - Components for severe bleeding
 - 5 day Thawed Plasma
 - Leukoreduction
- RCTs needed to use LTOWB
 - Perspective of many globally



Global Use of Whole Blood

- Norway
- USA
- Czech republic
- Ukraine
- Israel
- Brazil
- Spain
- Estonia
- Finland
- Sweden
- Greenland
- India
- China
- Australia and Italy
– (soon)
- Sub Saharan Africa



Green Whole Blood Red Components



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RCTs Needed for Practice Change?

- Affirmative Position

“Practice change without RCTs will cause more harm than good”

- Negative Position

“We are not against RCTs, only magical thinking about them”

COMMENTARY



Why Randomized Controlled Trials Are Needed to Accept New Practices: 2 Medical Worldviews
Mayo Clin Proc. ■ October 2013;88(10):1046-1050 Vinay Prasad, MD

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Understanding and misunderstanding randomized controlled trials

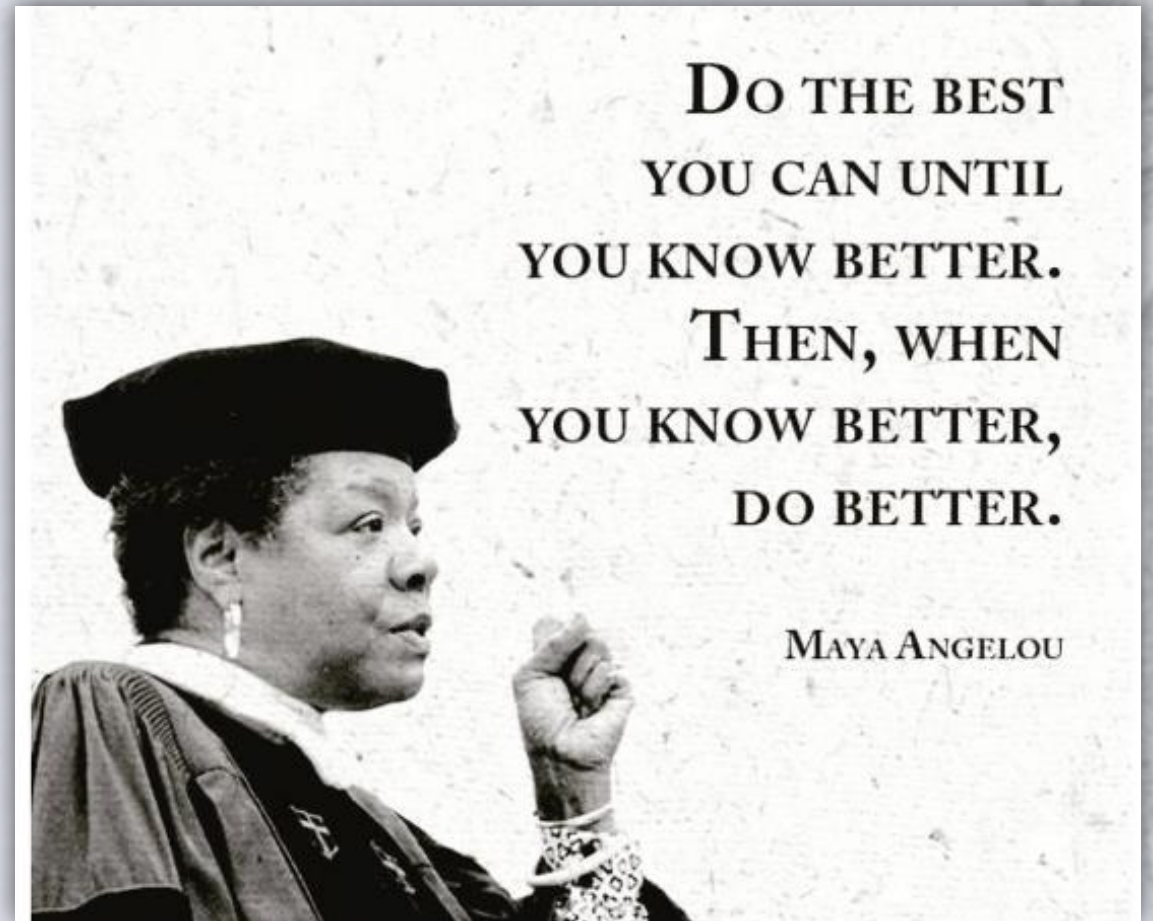
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^d Durham University, England
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Practice Change

- Each decision to change is distinct
- RCT is not required for every change
- Change practice and perform RCTs in parallel



Implementation Science

- To start a new therapy - Make it easier (facilitators) to use it
 - Thawed and dried plasma
 - Intercept treated cryoprecipitate, rapid reconstituted factor concentrates
- To stop old therapy- Make it harder (barriers) to use it
 - Crystalloids
 - Large volume blood sample tubes



Practice Change

- Changing practice requires
 - Learning of new practice and
 - Unlearning of old/outdated knowledge
- More difficult to stop continuing old practices



Practice Change

- Practice change disturbs the status quo equilibrium
- Establishing a new equilibrium can be a struggle
- Struggle involves interpretation of evidence and tensions of change within a health system

- Example: RhD+ LTOWB

Gupta DM. Physician's experience of changing clinical practice. A struggle to learn. *Implement Sci.* 2017;12:28



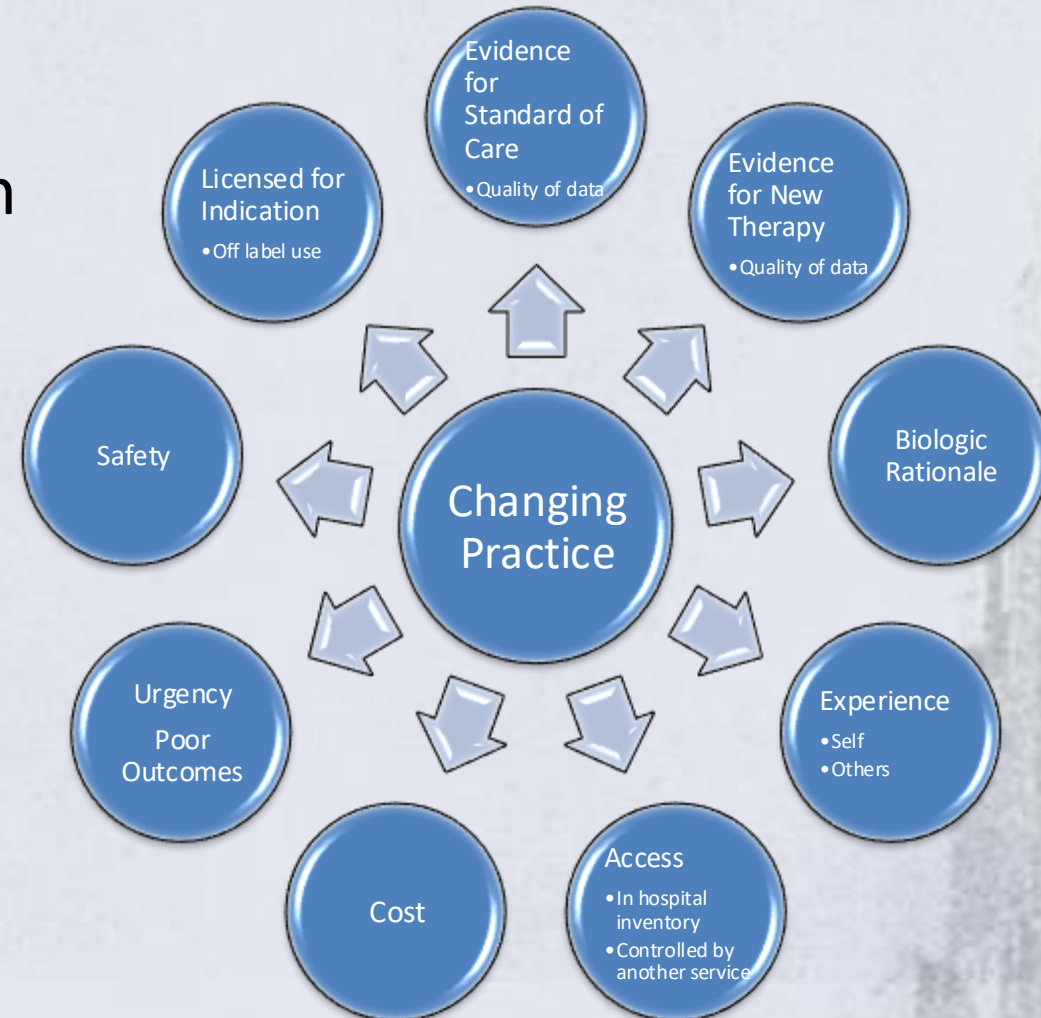
Practice Change

- Change introduces uncertainty in context of perceived certainty.
- Barriers for change are higher:
 - Change initiated from outside the field
 - How message is delivered promoting change matters
- Change requires acknowledging and accepting previous practice was not optimal.
 - Hard pill to swallow for many



Why the Difference in Adoption of LTOWB?

- Pittsburgh/San Antonio vs Boston
- Norway vs Germany



Panel Discussion

- Recent hemostatic resuscitation changes in your health system and what drove this change?
- Changes not made that should occur?
- Hemostatic resuscitation principles that do require an RCT prior to change ?
 - Dried plasma
 - Fibrinogen sources
 - Calcium
 - Whole blood

