Thrombase Aspiration in Myocardial Infarction (TASTE) Case Example: Learning from an Embedded Registry Trial

Embedding trials into health care delivery is possible. CTTI spoke with individuals from five different trials in which certain elements of the trial were embedded into clinical practice. We provide an example of one trial, the TASTE trial, below.

**TRIAL OVERVIEW**

- Randomized, controlled, open-labeled
- Number of sites: ~29 (hospitals across Denmark, Sweden, and Iceland)
- Number of patients enrolled: 7244
- Ages eligible for study: Adult, Older Adult
- Intervention: Device (thrombus aspiration vs catheter)
- Primary outcome/endpoint: all-cause mortality [ Time Frame: 30 days ]
  - Death from any cause is registered via national registries during the first 30 days after study inclusion.

**EMBEDDED TRIAL ELEMENTS**

- **Patient Identification and Randomization**: Identified, randomized, and followed patients via national registry database
- **Data Acquisition**: Aligned trial outcomes and endpoints to data captured within routine care and registry database (appreciating the level of structured data existing and needed)
- **Evidence Integration**: Results of a diverse, representative population made available in close to real time and rapidly translated into clinical practice

**WORDS OF WISDOM**

- Think through the clinical process of patients.
- Do not burden sites with extra visits. Make it simple on the investigators. Use only what's already used in routine clinical care.
- Clearly communicate to patients what is expected of them and what they're accepting to do.

Innovation Through Collaboration

http://www.ctti-clinicaltrials.org
Patients should have the right to be offered randomization. If you don't get exposed to or offered randomization for a trial, that's a limitation of care.

<table>
<thead>
<tr>
<th>CHALLENGES</th>
<th>SOLUTIONS</th>
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<tbody>
<tr>
<td><strong>Technology Infrastructure</strong></td>
<td>Different legal entities and regulations required having a separate database for research purposes from that created for everyday healthcare or registry purposes</td>
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<td><strong>Data</strong></td>
<td>A tension existed between outcomes that align with clinical care, such as all-cause mortality, and the need for more complex outcomes to answer specific research questions (and was adjudication needed)</td>
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<td><strong>Culture</strong></td>
<td>Some physicians expressed a lack of comfort with randomization as they are used to deciding themselves what is best for their patients</td>
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<td><strong>Process</strong></td>
<td>Regulators were hesitant to accept cluster randomizations</td>
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**REFERENCES:**