

Implementation Strategies for Early Feasibility Studies

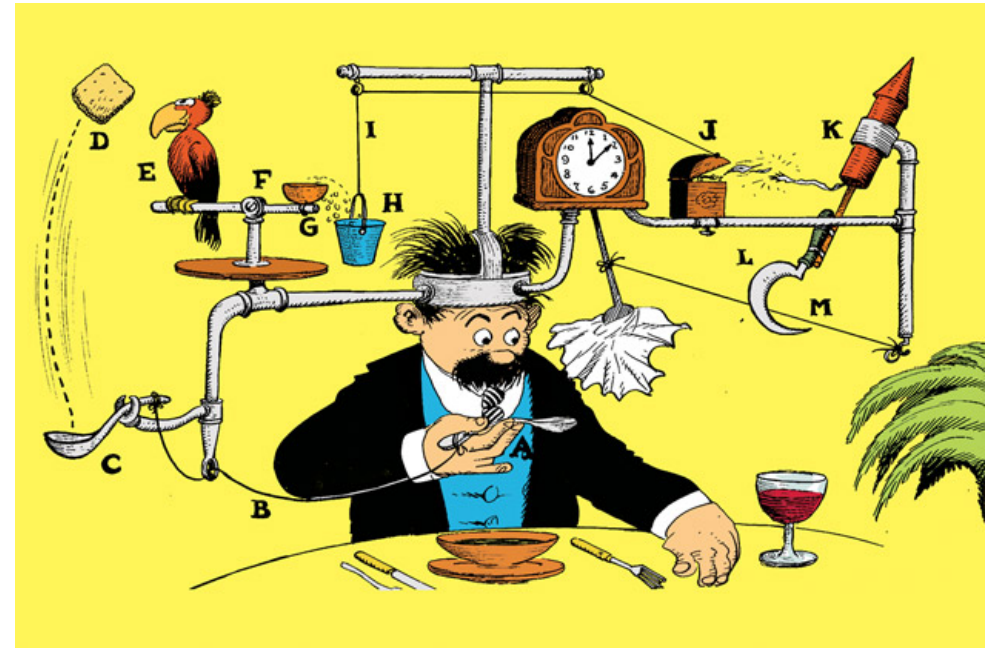
Topic 3: Procedural and clinical follow-up issues

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Clinical Perspective on EFS

- EFS: New procedures intended for diseases not previously treated or at least not treated in this way
- Devices often still in evolution
- Procedure not well established and may require flexibility/creativity
- Require organizational focus and additional resources



Rube Goldberg: Professor Butts and the Self-Operating Napkin

Communication with patient and family

- Honest communication focusing on unknowns is critical to establishing trust and appropriate expectations
- Beyond simple device safety and efficacy, important unknowns may include:
 - Duration of procedure and hospitalization
 - Impact of unanticipated complications
 - Need for additional tests and/or procedures
- Clear commitment to follow-up requirements

Procedure Scheduling and Coordination

- Not just the patient and operator!
- Additional necessary personnel
 - Cardiac imagers, anesthesiologists
 - Industry personnel, proctors
 - Case example: Only 1 Proctor worldwide, requires month notice
- Device availability
 - Case example: “In short, it is held up in customs in Memphis and we will not have the device in time”

Monday	Tuesday	Wednesday	Thursday	Friday
2 Busy	3 Busy Election Day	4 Busy	5 Busy	6 Busy
9 Busy	10 Busy	11 Busy	12 Busy	13 Busy
16 Busy	17 Busy	18 Busy Veterans Day	19 Busy	20 Busy
23 Busy	24 Busy	25 Busy	26 Busy Thanksgiving Day	27 Busy Election Day Begins at Sundown
30 Busy	31 Busy How Far Is It to Grandma's House?			

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Additional Procedure Scheduling Concerns

- Training requirements
 - Bench and animal models
 - Refresher training if cases infrequent
 - **Case examples:**
 - Animal training on 3 separate occasions
 - Team to Israel for training
- Final Device and Case Review
 - Same week, night before, morning of?



When the day of the Case finally arrives!

- Patient may require admission prior
 - **Case Example: ICU admission and Swan**
- Very unpredictable, may take longer than expected
- Issues related to device availability, uncommon equipment requirement, ergonomics, etc
- Number of observers
 - **Case Example: Sponsor requested ~ 10 people**
- Unusual Requests
 - **Case Example: Videotaping initial cases?**



Clinical Follow-up Issues (In-Hospital)

- Duration of hospitalization, ICU stay may not be predictable
- Significant post-procedure burden on coordinators
 - More intensive follow-up, imaging studies, labs, etc.
- Financial implications
 - Case Example: Tricuspid case >30 day ICU stay, not reimbursed
- Sponsor expectations
 - Case Example: Request for daily progress updates for all patients

Clinical Follow-up Issues (long-term)

- EFS tend to be small studies and therefore more sensitive to loss of follow-up
 - **Case examples:**
 - Israel patient withdrawn from study
 - Texas patient successfully followed in NY
- May require more frequent or more intensive follow-up
 - Frequent visits
 - Additional imaging procedures
- Role for home visits, telehealth, etc?



Follow-up Plan

- ~~Send invitation~~
- ~~1st Reminder~~
- ~~2nd Reminder~~
- ~~1st Call~~
- ~~2nd Call~~
- Send silly cartoon
- Beg
- Hire goons
- Release hounds

Conclusions

- EFS are complex: new procedures for new diseases using devices that may still be in evolution
- Multiple challenges related to procedure scheduling, personnel availability, training requirements, costs
- Intra-procedural issues often require flexibility and creativity.
 - Minimize observers to those absolutely necessary
- Complete follow-up is critical and requires appropriate resources and strong commitment from both investigators and patients