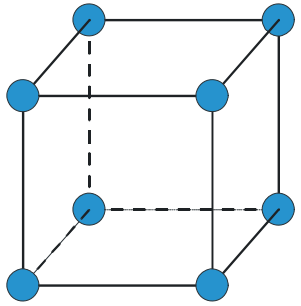
Webinar September 19, 2007



Factorial Design Planning Process

Shari Kraber

Stat-Ease, Inc.

shari@statease.com

Pat Whitcomb

Stat-Ease, Inc.

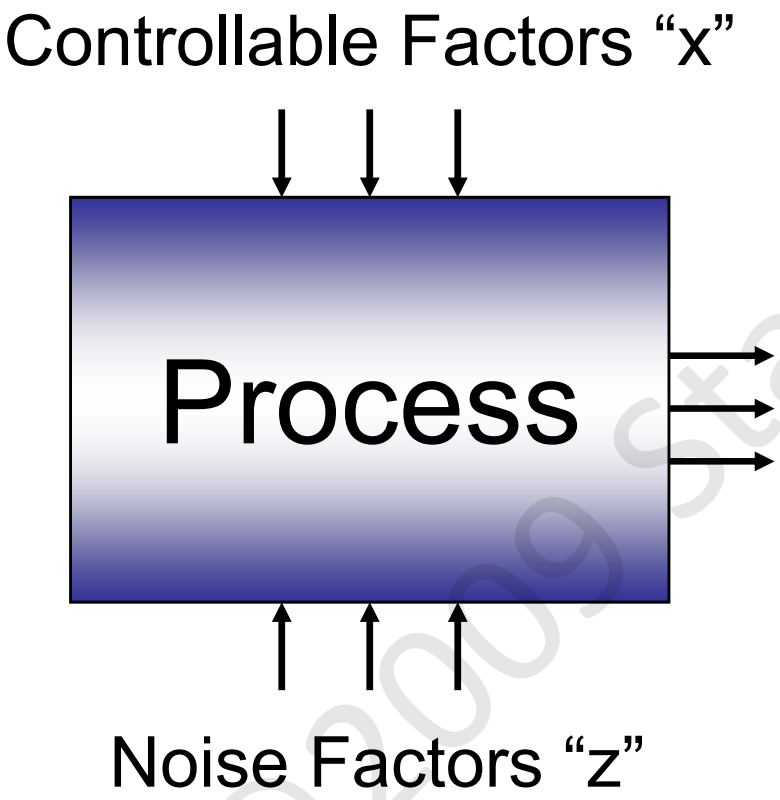
pat@statease.com

Factorial Design Planning Process

Our talk has three parts:

1. **Broad brush description of the DOE planning process**
2. Illustrate key points via an example
3. Summary

Design of Experiments

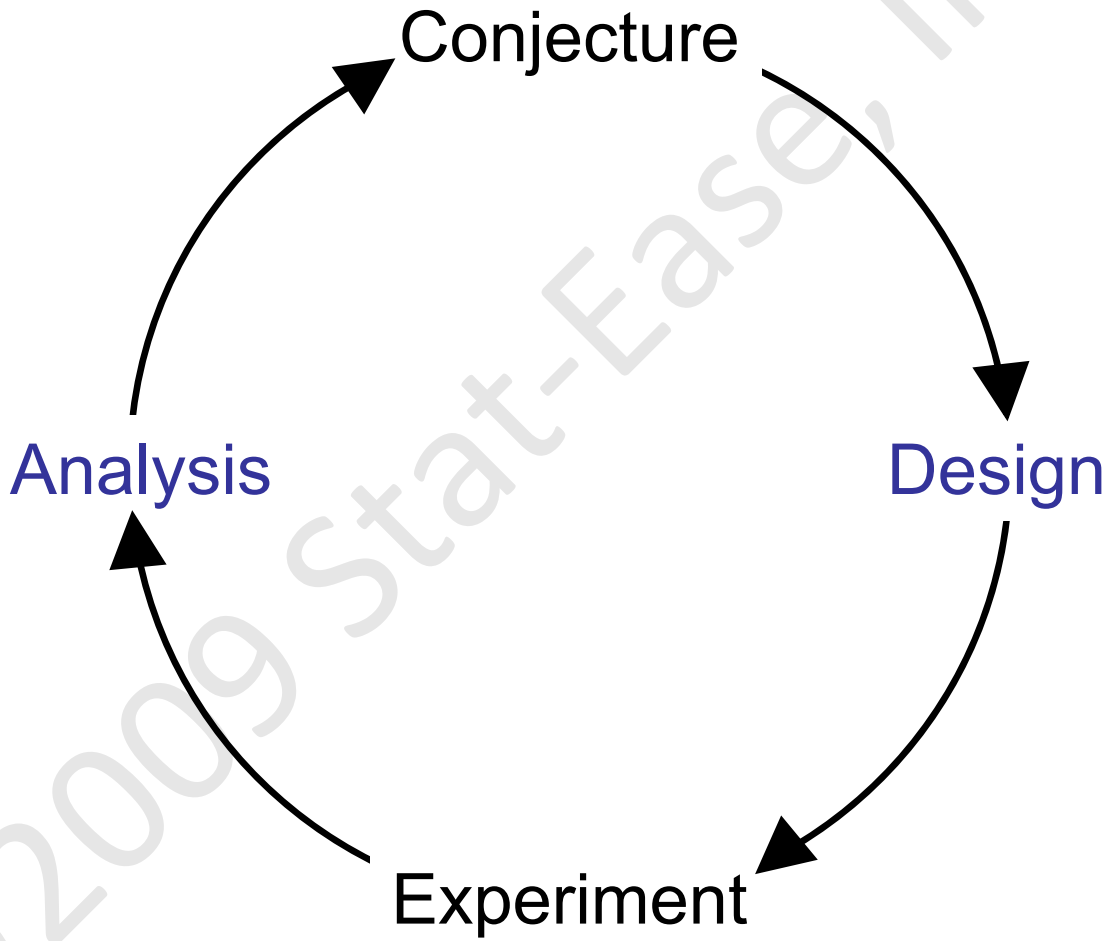


DOE (Design of Experiments) is:

“A systematic series of tests, in which purposeful changes are made to input factors,

so that you may identify causes for significant changes in the output responses.”

Iterative Experimentation



Expend no more than 25% of budget on the 1st cycle.

Factorial Design Planning Process *(1 of 2)*

1. Identify opportunity and define objective.
2. State objective in terms of measurable responses.
   a. Define the change (Δy) that is important to detect for each response.
   b. Estimate experimental error (σ) for each response.
   c. Use the signal to noise ratio ($\Delta y/\sigma$) to estimate power.
3. Select the input factors to study. (*Remember that the factor levels chosen determine the size of Δy.*)

Factorial Design Planning Process *(2 of 2)*

4. Select a design and:
   - Evaluate aliases (fractional factorials and/or blocked designs); generally use two-factor interaction (2FI) model.
   - Evaluate power (desire power > 80% for effects of interest); generally use main effects (ME) model (for robust design use only 1 ME).
   - Examine the design layout to ensure all the factor combinations are safe to run and are likely to result in meaningful information (no disasters).

Factorial Design Planning Process

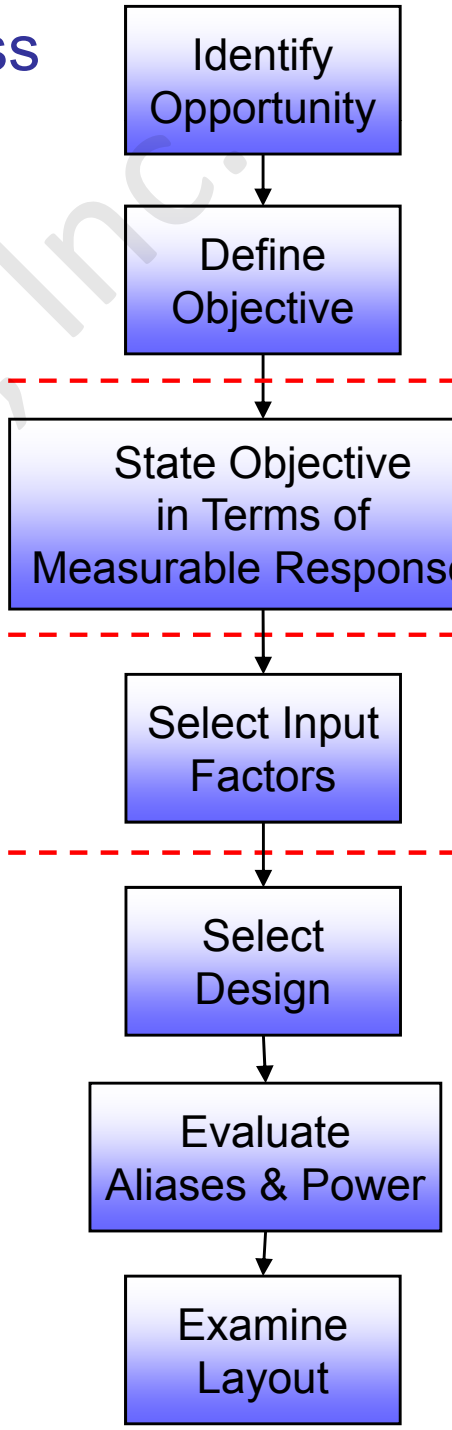
Tools:

- Brainstorming *(fishbone)*
- Consensus

- Outputs Voting Form
- Outputs, Δy, σ, %Contribution

- Factors Voting Form
- DOE inputs, levels, operating range
- Other inputs

- Select an appropriate factorial design
- Evaluate aliases *(fractional factorials and/or blocked designs)*
- Evaluate power
- Examine the design layout



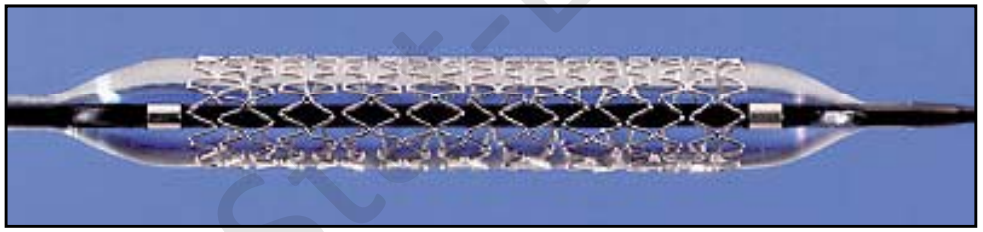
Factorial Design Planning Process

Our talk has three parts:

1. Broad brush description of the DOE planning process
2. **Illustrate key points via an example**
3. Summary

Stent Delivery System

A stent is a wire mesh tube used to prop open an artery that's recently been cleared using angioplasty. The stent is collapsed to a small diameter over a balloon catheter. It's then moved into the area of the blockage.



When the balloon is inflated, the stent expands, locks in place and forms a scaffold. This holds the artery open. The stent stays in the artery permanently, holding it open to improve blood flow to the heart muscle.

Stent Delivery System

1. Identify opportunity and define objective.
   Relate stent deliverability and safety to process factors.

Guidelines for Brainstorming a Designed Experiment

Team Make Up: "Experts"
"Semi-Experts" or Peripheral Experts
Technicians or Operators
"Customers"

Scheduling: Two meetings no more than 2 days apart.
First day spend approximately 1 to 2 hours discussing Goal, Objective, Outputs and Inputs.
Second day spend approximately 2 to 4 hours developing DOE.

Stent Delivery System

2. State objective in terms of measurable responses.
   Deliverability is quantified by Trackability and Pushability; safety is quantified by Burst pressure. Want to estimate 2FI model, this requires a resolution V (or higher) design.
   a. Define the change (Δy) that is important to detect for each response.
   b. Estimate experimental error (σ) for each response.
   c. Use the signal to noise ratio ($\Delta y/\sigma$) to estimate power.

Outputs Voting Form

Objective as Measurable Responses

Evaluation of Outputs Voting Form											
Response Output (y)	Type of Response (V) Variable (D) Destructive (A) Attribute	Team Member's Ranking of Importance of the Responses 1: low rank; 5: high rank								Average	Standard Deviation
		M1	M2	M3	M4	M5	M6	M7	M8		

Stent Delivery System

2. Typical of responses in actual DOE:

Response	Unit of Measure	Specification or Target	Practical Difference Δ	Std Dev σ	%MC*
Y_1: Burst	psig	Maximize	6	8	27%
Y_2: Push	g/cm	Maximize	15	30	75%
Y_3: Track	g*cm	Minimize	10	6	19%

* % measurement contribution

Stent Delivery System

3. Select the input factors to study. (*Remember that the factor levels chosen determine the size of Δy.*)

   Typical factors include:

   - Lengths and diameters of various components, e.g. tip, balloon, catheter, etc.
   - Materials used for the components.
   - Assembly parameters, e.g. weld locations, how the balloon is folded, etc.
   - Stent geometry, wall thickness, how it is crimped on the balloon, etc.