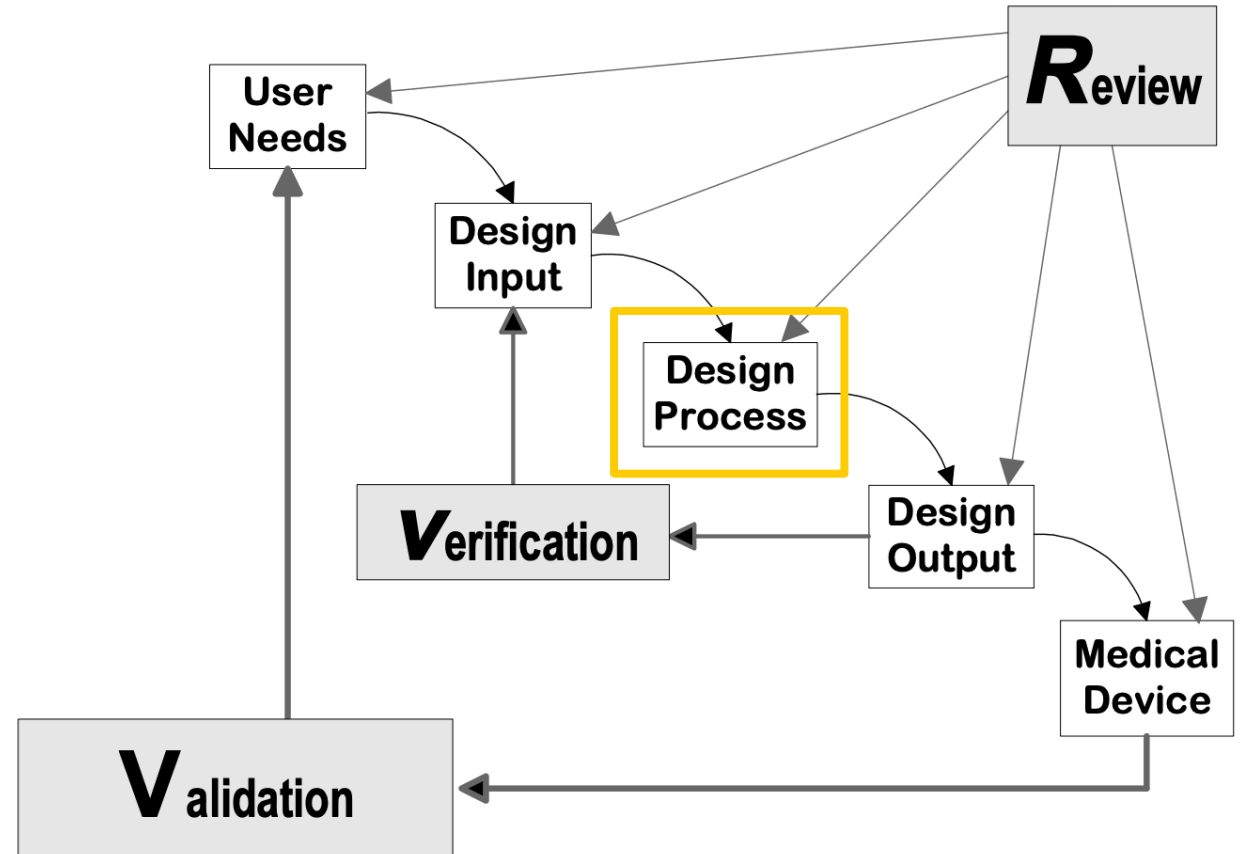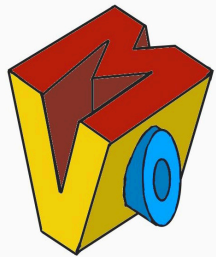# Plan for Jan 28th

- Assignment 2 reminder
- Brainstorming!
- Concept Evaluation
  - Pugh Matrices
- *Break*
- Project work time
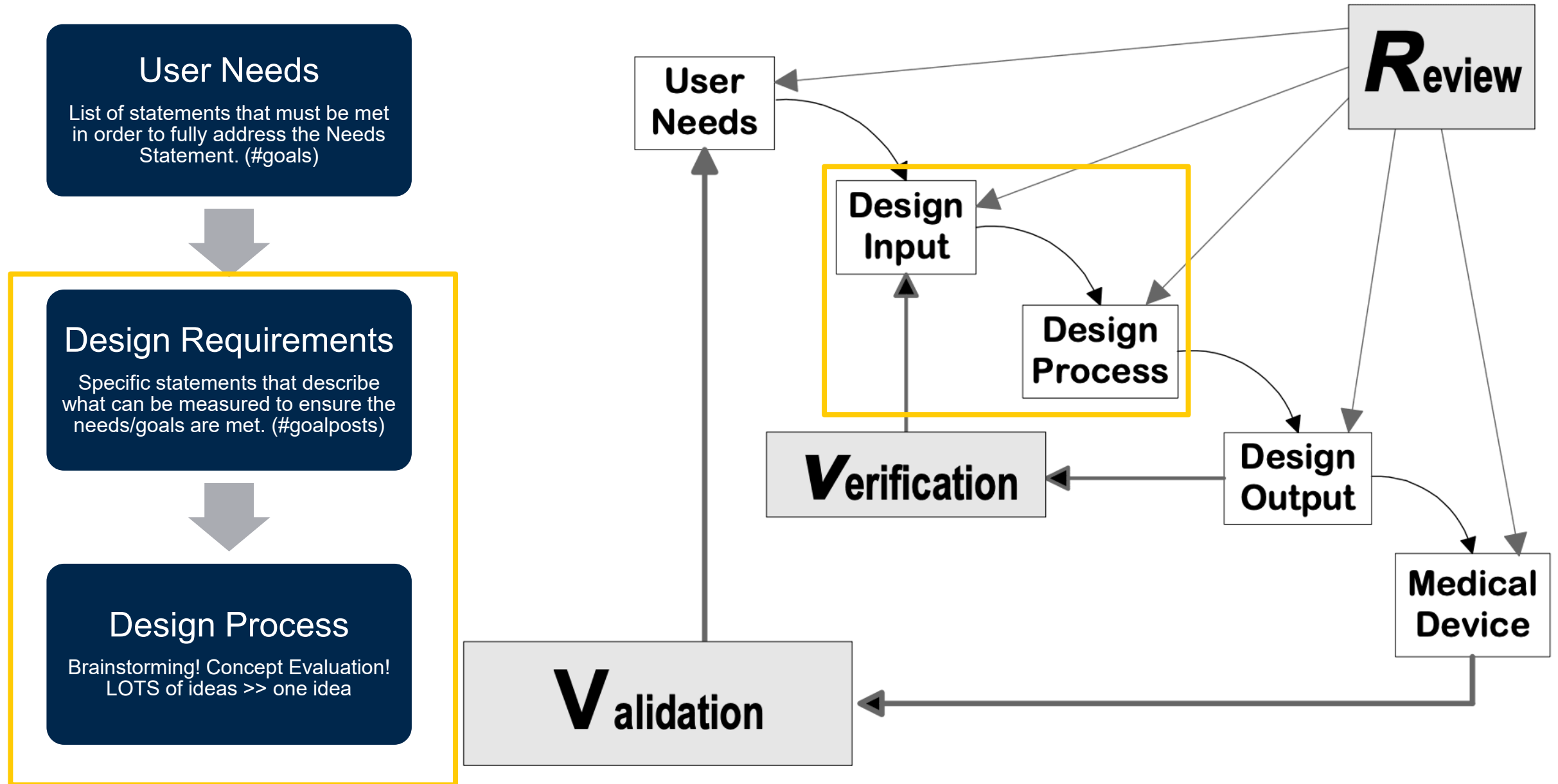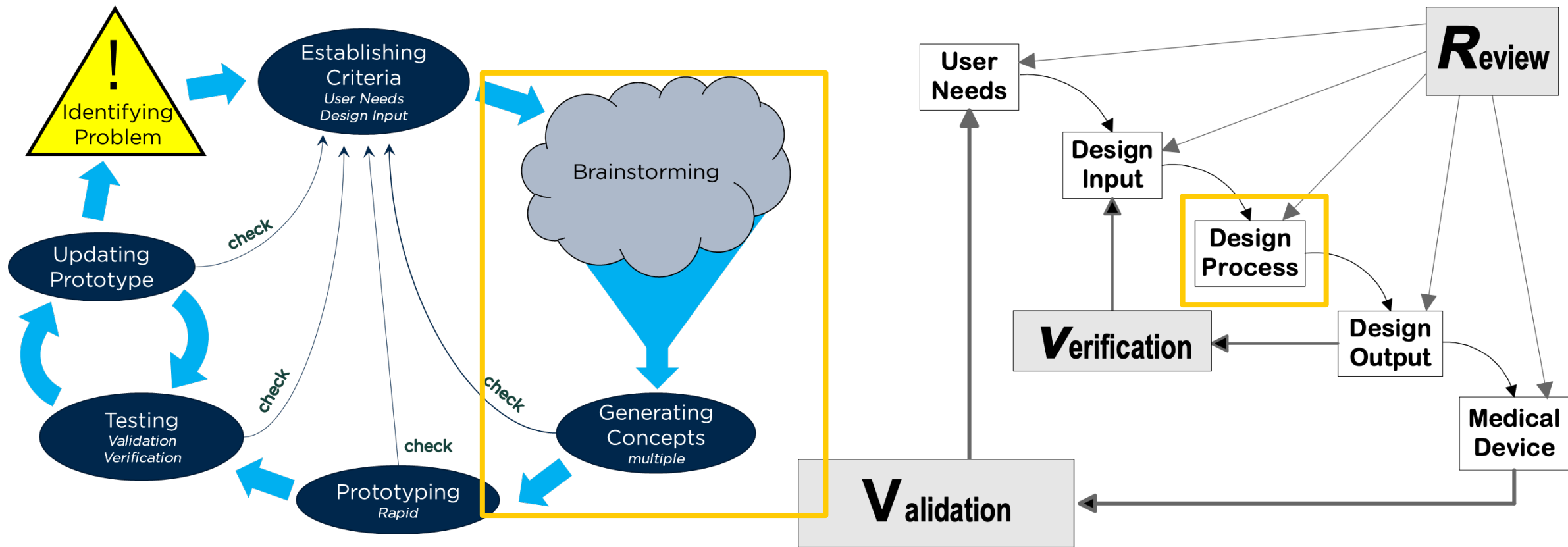 - Brainstorming AND Design Requirements.
  - Help initial decision if needed

Assignment #2: Design Inputs Draft

There will be a few Requirements that are therapeutic dependent!

IF you are uncertain right now, use brainstorming tools to help you decide

2.1.1g	Safety	Anti-restenosis agent is present in safe concentrations	Local concentration of the therapeutic in the blood/arterial tissue does not exceed identified toxic concentration at any time in _____ days.	(Hint: Lit Review with toxic thresholds; *in vitro* data may also be helpful here, as may more systemic parameters such as MTD. Also see note below on possibility for "further experimentation")
2.1.1h	Effectiveness	Anti-restenosis agent is present in effective concentrations	Local concentration of the therapeutic in the blood/arterial tissue remains above identified minimum concentration at all times in _____ days.	(Hint: investigate parameters such as EC50; note that for this section and the above, it is possible that values will be unavailable via literature review alone and will require further experimentation. If this is the case, document the search procedures and lack of acceptable results)

User Needs

List of statements that must be met in order to fully address the Needs Statement. (#goals)

Design Requirements

Specific statements that describe what can be measured to ensure the needs/goals are met. (#goalposts)

Design Process

Brainstorming! Concept Evaluation! LOTS of ideas >> one idea

User Needs

*R*eview

Design Input

Design Process

*V*erification

Design Output

Medical Device
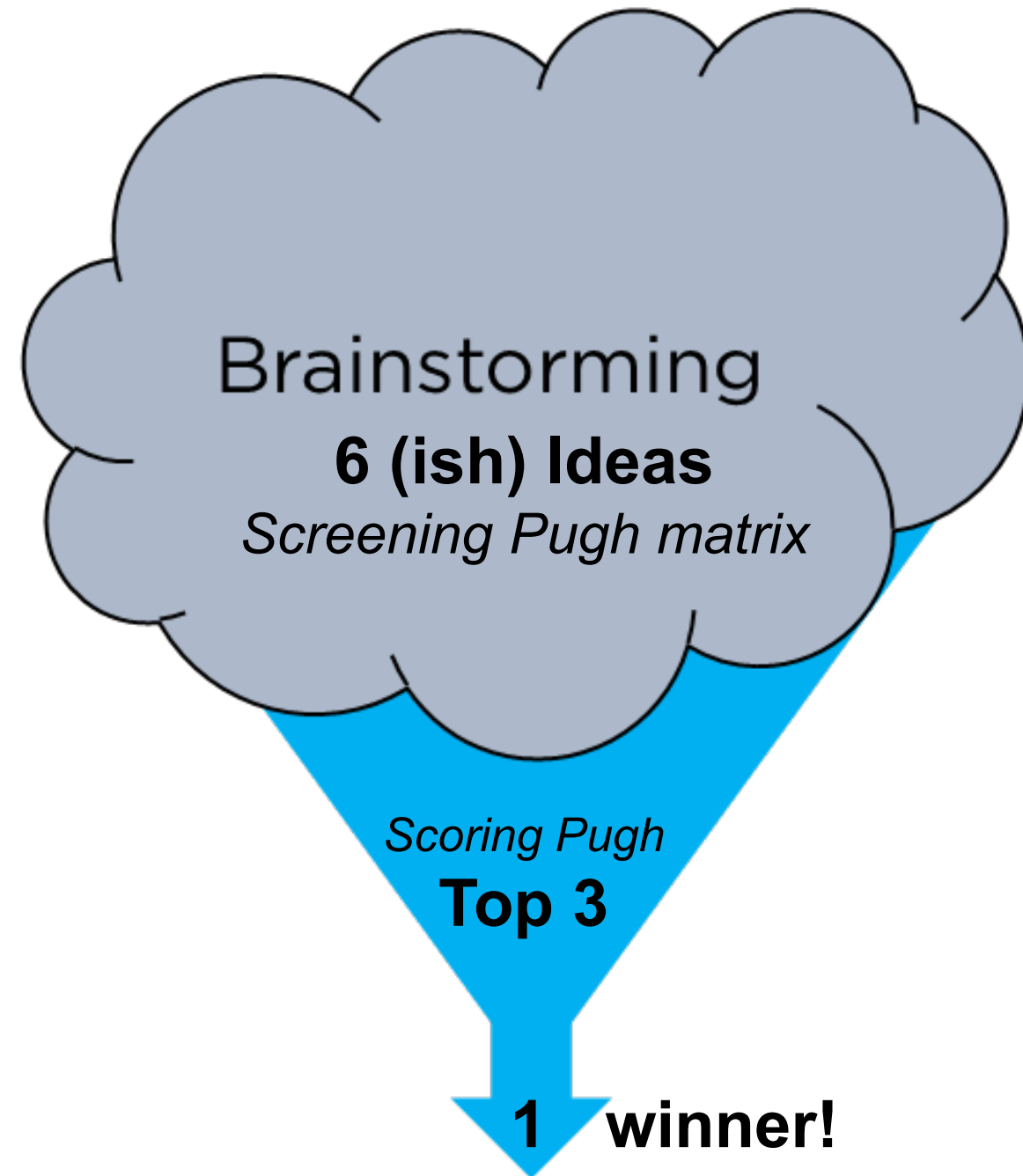
*V*alidation

4

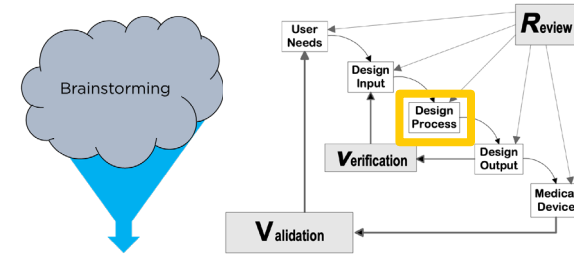# Ideation and Concept Generation

You already know a general idea of what you're making

Ideation will be related to decisions on subcomponents:

Therapeutic (?)
Materials
Geometries
Coating methods

Brainstorming

6 (ish) Ideas
Screening Pugh matrix

Scoring Pugh
Top 3

1 **winner!**

Some general ground rules

Defer Judgment – Don't dismiss any ideas

Encourage Wild Ideas – Think "outside the box"

Build on the Ideas of Others - No "buts," only "ands"

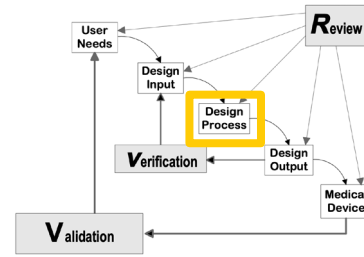**Go for Quantity** – Aim for >6 ideas by the end of this step

One Conversation at a Time – Let people have their say

Stay Focused on the Topic – Keep the discussion on target

Be Visual – Use drawings to stimulate ideas

Next Lecture!

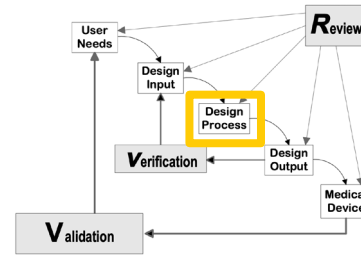# Evaluate your ideas with a *Pugh Matrix*

- Compare All Concepts to the Gold Standard or Baseline product
  - Each criteria you are comparing
    - Design Requirements or User Needs
    - Uncover DRs or UNs you missed?
- You concept is either:
  - Better (+)
  - Worse (-)
  - Or the same (0)
- You may need multiple Pugh Matrices
  - Comparing different materials for an aspect of your design
  - Comparing different styles of devices

Evaluation Chart	Sketch 1	Sketch 2	Sketch 3	Sketch 4	Sketch 5	Sketch 6	D
Easy to assemble 7	0	0	0	+		0	+	A
Easy to disassemble 7	0	0	0	+	+	+		T
Safe for operator 10	0	0	0	0	0	0	U
Low vibration 5	+	−	+		0	0	0	M
Portable 4	−	0	0	0	0	+	
No sharp edges 6	+	0	+	−	−	0	
Retails for less than competition 9	+	+	+	+	+	+	
Convert energy efficiently 10	−	0	0	0	0	0	
No flying debris 8	0	0	0	0	0	0	
Low pollution 3	0	0	0	0	0	0	
Low replacement part cost 7	+	0	0	+	+	+	
Low noise 4	0	+	+	0	0	+	
Strong material 6	0	0	0	0	0	−	
Low energy dissipation 8	+	0	0	−	0	−	
Aesthetically appealing 5	−	0	−	0	0	+	
Total +	5	2	4	4	5	7	
Total −	3	1	1	2	1	2	
Overall total	2	1	3	2	4	5	
Weighted total	16	8	19	16	22	29	

Figure 8.11 Evaluation table for the machine shop kit.
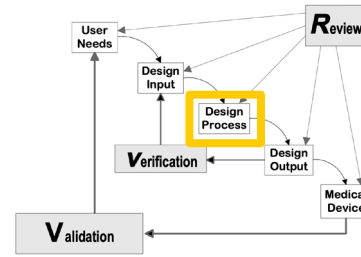
A **Screening** Pugh Matrix

Evaluation Chart	Sketch 1	Sketch 2	Sketch 3	Sketch 4	Sketch 5	Sketch 6	D
Easy to assemble 7	0	0	0	+	0	+	A
Easy to disassemble 7	0	0	0	+	+	+	T
Safe for operator 10	0	0	0	0	0	0	U
Low vibration 5	+	—	+	0	0	0	M
Portable 4	—	0	0	0	0	+	
No sharp edges 6	+	0	+	—	—	0	
Retails for less than competition 9	+	+	+	+	+	+	
Convert energy efficiently 10	—	0	0	0	0	0	
No flying debris 8	0	0	0	0	0	0	
Low pollution 3	0	0	0	0	0	0	
Low replacement part cost 7	+	0	0	+	+	+	
Low noise 4	0	+	+	0	0	+	
Strong material 6	0	0	0	0	0	—	
Low energy dissipation 8	+	0	0	—	0	—	
Aesthetically appealing 5	—	0	—	0	0	+	
Total +	5	2	4	4	5	7	
Total —	3	1	1	2	1	2	
Overall total	2	1	3	2	4	5	
Weighted total	16	8	19	16	22	29	

Figure 8.11   Evaluation table for the machine shop kit.

f: Haik, Engineering Design Process, Thomson Press, 2003

- Ratings of +, 0, -

- Eliminate low fidelity solutions

  - Ideas that don't compete with other ideas

  - Better to have brainstormed and cut than to never have brainstormed at all

- Reduce solutions by 50-70%

- When quantitative data difficult to acquire

8

A **Scoring** Pugh Matrix

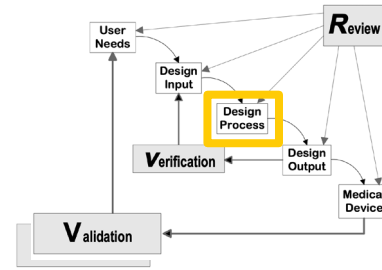| DESIGN Constraints and Objectives	Weight (%)	Glass bottle with twist-off cap	Aluminum can with pull-tab	Polyethylene bottle with twist-off cap	Mylar bag with straw
C: No sharp edges		✖	✖		
C: No toxin release					
C: Preserves quality					
O: Environmentally benign	33			0.9 × 33% 29.7%	0.1 × 33% 3.3%
O: Easy to distribute	09			0.5 × 9% 4.5%	0.6 × 9% 5.4%
O: Preserves taste	22			0.9 × 22% 19.8%	1.0 × 22% 22%
O: Appeals to parents	18			0.8 × 18% 14.4%	0.5 × 18% 9.0%
O: Permits marketing flexibility	04			0.5 × 4% 2.0%	0.5 × 4% 2.0%
O: Generates brand identity	13			0.2 × 13% 2.6%	1.0 × 13% 13%
TOTALS	99			73.0%	54.7%

FIGURE 5.4   A numerical evaluation matrix for the beverage container design problem. This chart reflects BJIC's values in terms of the weights assigned to each objective, as given in the pairwise comparison chart of Figure 3.4 (b).

- Numerical scale scoring

- *May* include complex weighting systems
  - We'll use a slightly less complex style in our classes

- Use in later stage of concept evaluation

- Identify top concepts from small pool of solutions

- More likely to include long term, non-critical requirements

Ref: Dym and Little, Engineering Design, 2nd ed.

Pugh Matrix online template

AND

Companion document with your reasoning
- Why is criteria important?
- How did you pick your baseline?
- Why did a device receive the score it did?

Will need this *logic* for Prelim. Design Review
Will need this *writing* for your final report

Biomedical Example of Pugh matrix decision making

Current system is inconvenient
- Not retractable
- Difficult to perform additional diagnosis or treatments
   - → extra time and cost
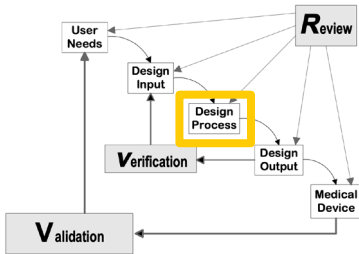
Need to create a retractable capsule deployment device

Pugh matrix: Retractable capsule deployment device

Criteria	Current Design	Elastic Ring Holder	Multiple Loops	Bent Finger Holder	Weight
Safety	0	–1	0	–1	x3
Retractability	0	+1	+1	+1	x3
Component failure	0	–1	0	0	x3
Feasibility	0	+2	+2	0	x3
Holding capsule	0	0	0	0	x2
Release capsule	0	0	–2	0	x2
Bulkiness	0	+1	+1	+1	x2
Capsule stability	0	0	–2	0	x2
Cost	0	0	0	0	x1
Ease of Use	0	0	–1	0	x1
Visibility	0	+1	+1	+1	x1
Totals:	**0**	**+6**	**+3**	**+3**	

Much better: +2

Better: +1

Equal: 0

Worse: -1

Much worse: -2

Ref: Haik, Engineering Design Process, Thomson Press, 2003

Pugh matrix: Retractable capsule deployment device

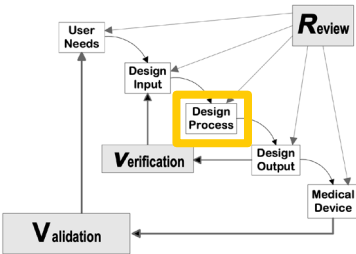| Criteria	Current Design	Elastic Ring Holder	Multiple Loops	Bent Finger Holder	Weight
Safety	0	–1	0	–1	x3
Retractability	0	+1	+1	+1	x3
Component failure	0	–1	0	0	x3
Feasibility	0	+2	+2	0	x3
Holding capsule	0	0	0	0	x2
Release capsule	0	0	–2	0	x2
Bulkiness	0	+1	+1	+1	x2
Capsule stability	0	0	–2	0	x2
Cost	0	0	0	0	x1
Ease of Use	0	0	–1	0	x1
Visibility	0	+1	+1	+1	x1
Totals:	**0**	**+6**	**+3**	**+3**	

Much better: +2

Better: +1

Equal: 0

Worse: -1

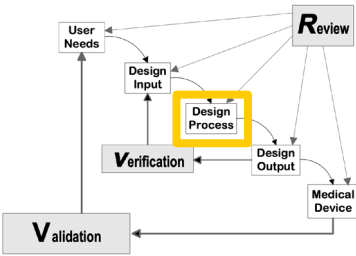Much worse: -2

Ref: Haik, Engineering Design Process, Thomson Press, 2003

Pugh matrix: Retractable capsule deployment device
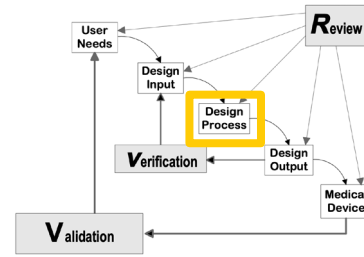
Criteria	Current Design	Elastic Ring Holder	Multiple Loops	Bent Finger Holder	Weight
Safety	0	–1	0	–1	x3
Retractability	0	+1	+1	+1	x3
Component failure	0	–1	0	0	x3
Feasibility	0	+2	+2	0	x3
Holding capsule	0	0	0	0	x2
Release capsule	0	0	–2	0	x2
Bulkiness	0	+1	+1	+1	x2
Capsule stability	0	0	–2	0	x2
Cost	0	0	0	0	x1
Ease of Use	0	0	–1	0	x1
Visibility	0	+1	+1	+1	x1
Totals:	**0**	**+6**	**+3**	**+3**	

Much better: +2

Better: +1

Equal: 0

Worse: -1

Much worse: -2

Ref: Haik, Engineering Design Process, Thomson Press, 2003

Pugh matrix: Retractable capsule deployment device

No current design?

Use the gold standard or most "popular" available option As your baseline

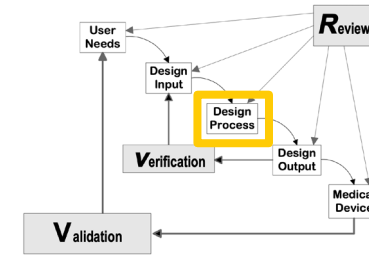| Criteria	Current Design	Elastic Ring Holder	Multiple Loops	Bent Finger Holder	Weight
Safety	0	–1	0	–1	x3
Retractability	0	+1	+1	+1	x3
Component failure	0	–1	0	0	x3
Feasibility	0	+2	+2	0	x3
Holding capsule	0	0	0	0	x2
Release capsule	0	0	–2	0	x2
Bulkiness	0	+1	+1	+1	x2
Capsule stability	0	0	–2	0	x2
Cost	0	0	0	0	x1
Ease of Use	0	0	–1	0	x1
Visibility	0	+1	+1	+1	x1
Totals:	**0**	**+6**	**+3**	**+3**	

Much better: +2

Better: +1

Equal: 0

Worse: -1

Much worse: -2

How do you reduce bias for your favorite idea?

Literature Review
Research
Standards
Patents

Expert Input
Engineering managers
External Consultants

Usability Testing
Time on task
Mistakes made
Almost errors & recoveries

Criteria	Current Design	Elastic Ring Holder	Multiple Loops	Bent Finger Holder	Weight
Safety	0	-1	0	-1	x3
Retractability	0	+1	+1	+1	x3
Component failure	0	-1	0	0	x3
Feasibility	0	+2	+2	0	x3
Holding capsule	0	0	0	0	x2
Release capsule	0	0	-2	0	x2
Bulkiness	0	+1	+1	+1	x2
Capsule stability	0	0	-2	0	x2
Cost	0	0	0	0	x1
Ease of Use	0	0	-1	0	x1
Visibility	0	+1	+1	+1	x1
Totals:	**0**	**+6**	**+3**	**+3**	

Engineering Analysis
Mathematical models
Estimations
Simulations (COMSOL!)

Functional Testing
Materials testing
Compression & tensile
Crash testing

Have someone else score your idea
Write strong justifications when possible

Ref: Haik, Engineering Design Process, Thomson Press, 2003

Just like Design Requirements
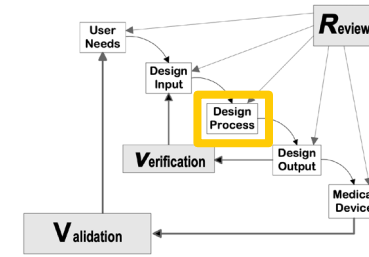## *Pugh needs written justifications*

Table 5. Pugh Matrix of device ideas compared to the current gold standard of hypopen auto injector.

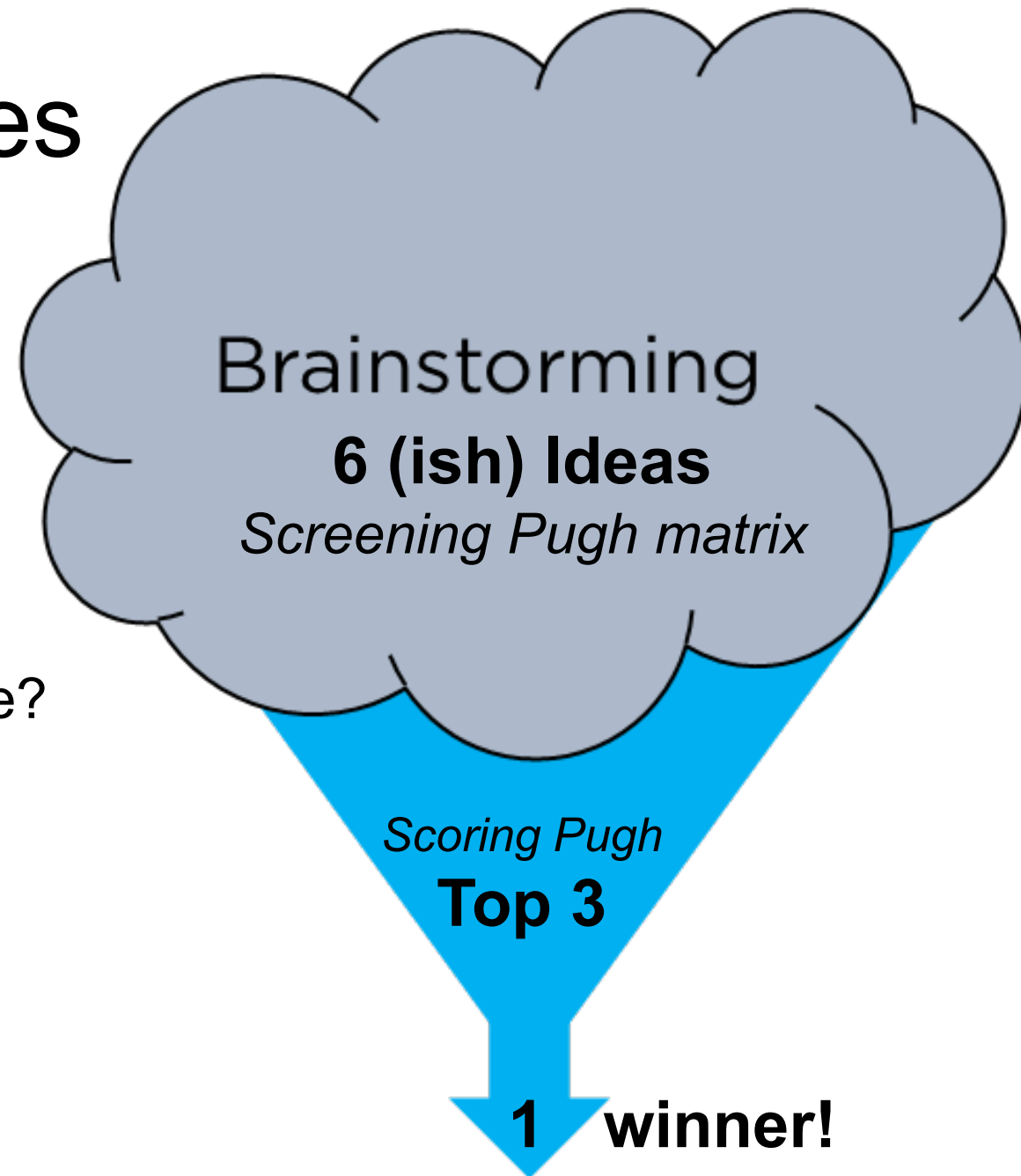| Criteria	CGM Sensor Injector	Dermal Patch	Improved Autoinjector	Integrated Glucagon Pump	CGM Receiver Autoinjector	Gold Standard: Autoinjector	Weight
Usability	2	2	1	1	2	0	3
Efficacy	0	-2	1	0	1	0	3
Detection	2	0	0	1*	2	0	3
Safety	-1	1	0	-2	0	0	3
Portability	1	1	0	1	1	0	2
Affordability	0	1	-1	1	0	0	2
Storage	0	-1	0	0	0	0	1
Durability	0	-1	1	1	1	0	3
Sum	11	3	7	7	20		
Ranking	2	4	3	3	1		

Usability. The success rate at which devices are administered correctly by untrained bystanders and the speed with which an untrained bystander can assemble and give the treatment. If the device cannot be correctly delivered to the patient because it is too complex and multi step it has no use. The speed of administration is important in an emergency because after 15 minutes, the side effects of hypoglycemia can become serious [21]. We must assume the bystander won't see the diabetic until some time after the episode has started time is vital. Because of this, we weighted usability as a 3 because it is one of the most important traits of an emergency medical treatment. Each of our designs had a large focus on usability and would be easier for bystanders to administer. Based on our prototyping sessions and stakeholder interviews, we placed CGM devices and dermal patches highest because of their success rates being at 95% and having administration times around 30 seconds. The normal autoinjector in the prototyping session also had a much lower success rate of 40% and took longer on average than the other two devices, which is why it was rated lower. The glucagon pump and improved autoinjector are improvements on the HypoPen, but are not as bystander friendly.

^ Prior BME 450 example, anonymized – expectations for 350 may be different, see PDR and DHF rubric when they are available

- **Preliminary Design Review**
  - Presentation
  - Only need visuals & verbal
- **For your Design History File**
  - end of semester Report
  - Need figure AND written
- **Recommended:**
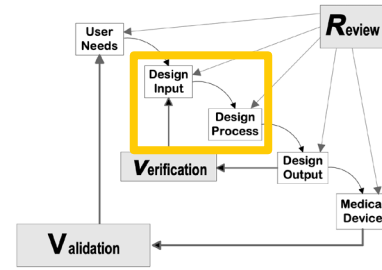 - Keep companion document for now

You do not need to add your Pugh to your Inputs assignment

17

During Solidworks classes

- Brainstorm choices for
  - Materials
  - Geometries
  - Coating methods
- **Make multiple or "mini" Pughs**
  - Materials for different sections of device?
  - Coating methods
- For **Preliminary Design Review** we want to see your **Material(s) Pugh!**
- For Final **Design History File**
  - Write your **justifications** in **narrative**

Brainstorming

6 (ish) Ideas
Screening Pugh matrix

Scoring Pugh
Top 3

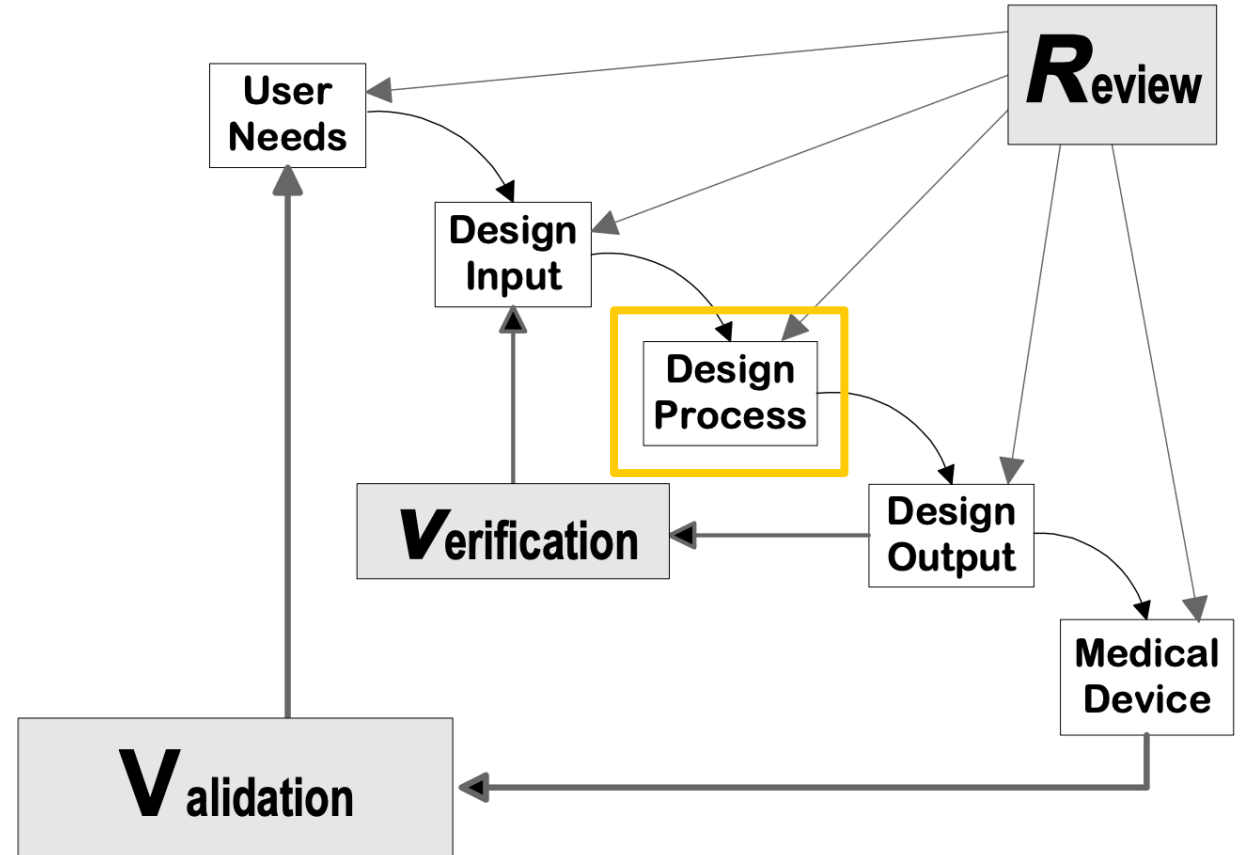**1** winner!

Pugh Troubleshooting Tips

- You can use a screening matrix if you need to OR
- Skip to scoring matrix with a few top candidates
- Choose evaluation criteria
  - Could be based on User Needs OR
  - Other things you found impactful
    - Amount of available research could be one!
- Weight the importance of each criteria
  - Be aware of over-weighting.
  - 1-2-3 is usually sufficient.
- Reconsider what you're evaluating
  - All 2's across the board?
    - Is there bias?
  - All 0's across the board?
    - Is criteria not powerful/informative enough?
      - If so, remove!
  - Be careful not to overcorrect – have reason!

Table 5. Pugh Matrix of device ideas compared to the current gold standard of hypopen auto injector.

Criteria	CGM Sensor Injector	Dermal Patch	Improved Autoinjector	Integrated Glucagon Pump	CGM Receiver Autoinjector	Gold Standard: Autoinjector	Weight
Usability	2	2	1	1	2	0	3
Efficacy	0	-2	1	0	1	0	3
Detection	2	0	0	1*	2	0	3
Safety	-1	1	0	-2	0	0	3
Portability	1	1	0	1	1	0	2
Affordability	0	1	-1	1	0	0	2
Storage	0	-1	0	0	0	0	1
Durability	0	-1	1	1	1	0	3
Sum	11	3	7	7	20		
Ranking	**2**	**4**	**3**	**3**	**1**		

Plan for today

- Assignment 2 reminder
- Brainstorming!
- Concept Evaluation
  - Pugh Matrices
- *Break*
- Project work time
  - Optional In-Class activity
  - Brainstorming AND Design Requirements.
  - Help initial decision if needed

Take a 5-minute Break!

Versailles, France – August 2025

Next time: Art materials will be provided!
(but feel free to bring your own pencils, paper, erasers)
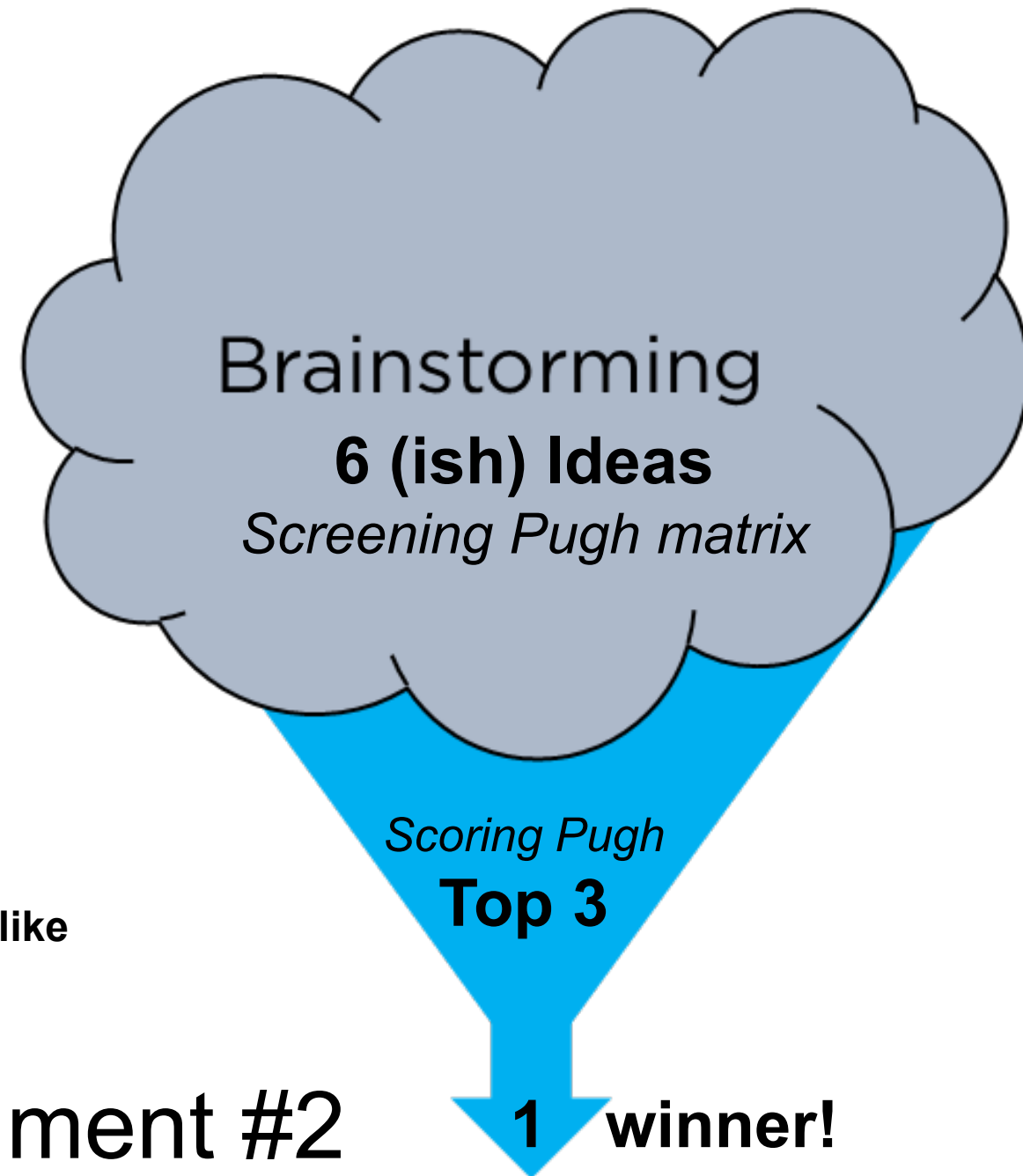
- Intro to Visual Communication
- Sketch!
  - 5 – 2 – 30!
- Draw!
  - Paper and a Straight Edge
  - Basic Shapes
  - 1- and 2-point perspective
  - Isometric
- Spatial Vis App Overview, *if time*

Break will be halfway through, but can be variable location in topics

Today's Project Work Time (Optional In-class activity)

- *If needed* Brainstorm choices for
  - Therapeutics
- **Research/collect**
  - **Safety and Efficacy information**
    - **Toxic doses vs. effective doses**
    - **How toxic is it?**
    - **How well researched is it?**
    - **Oral or local dosing?**
      - **Check units**
      - **Conceptualize what your delivery looks like**

Otherwise, work on Assignment #2

Brainstorming

6 (ish) Ideas
Screening Pugh matrix

Scoring Pugh
Top 3

1 winner!