Medical Device Innovation through Biodesign Process

Adarsh Somayaji ED15B001

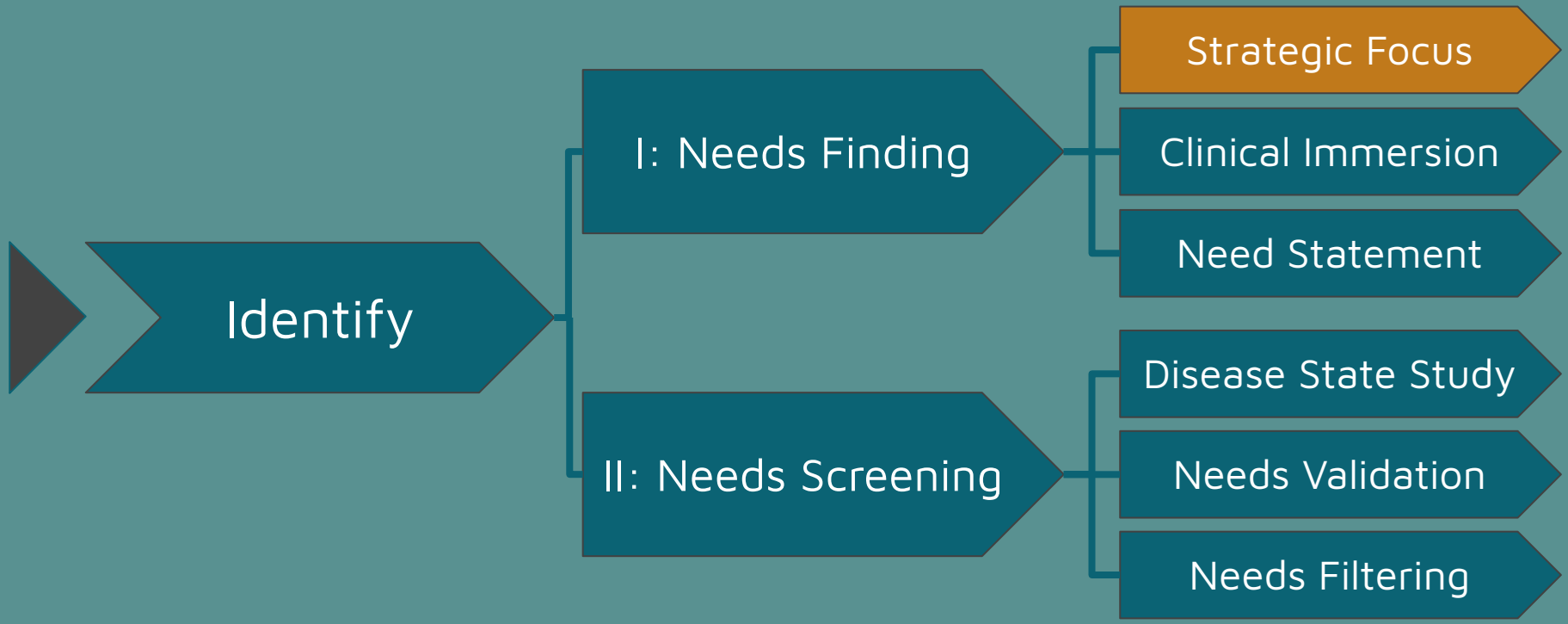
Company: Shira MedTech Pvt. Ltd.
Mentors: Anand Parikh, Prasann Jain

Scope of the Project

- To identify problems in a clinical environment that can be solved through technology
- To research on & validate the scope of the problems
- To shortlist problems & ideate on solution concepts for the same
- To develop a proof of concept prototype for the best solution

What is Biodesign?

Biodesign is an innovation model that begins with careful identification of a clinical need and moves in a stepwise approach through inventing & planning the implementation of a marketable solution


Identify
I: Needs Finding
Strategic Focus
Clinical Immersion
Need Statement
II: Needs Screening
Disease State Study
Needs Validation
Needs Filtering

Strategic Focus

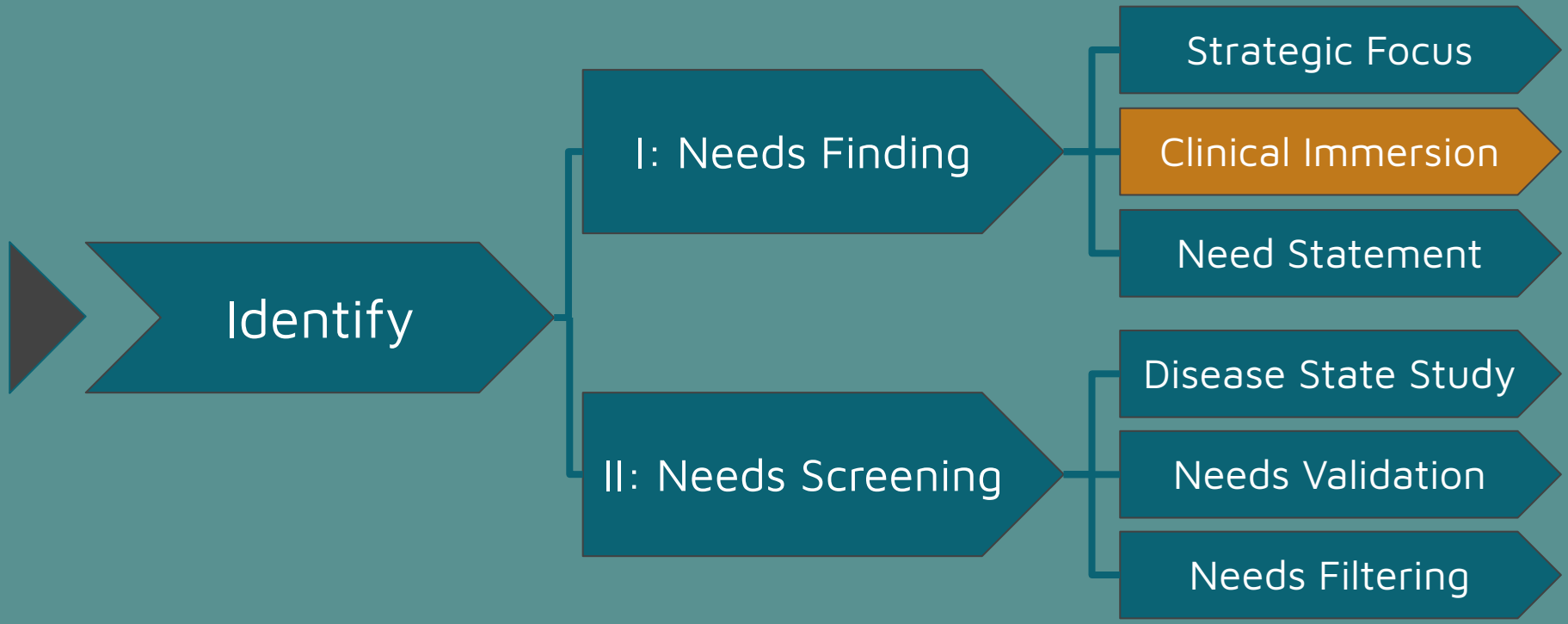
The following departments were chosen as a part of our strategic focus:

- Emergency Medicine
- General Surgery
- Gastro-Intestinal Surgery

Phase I - Dec

- Plastic Surgery
- Nephrology & Urosurgery
- Neurosurgery

Phase II - Jan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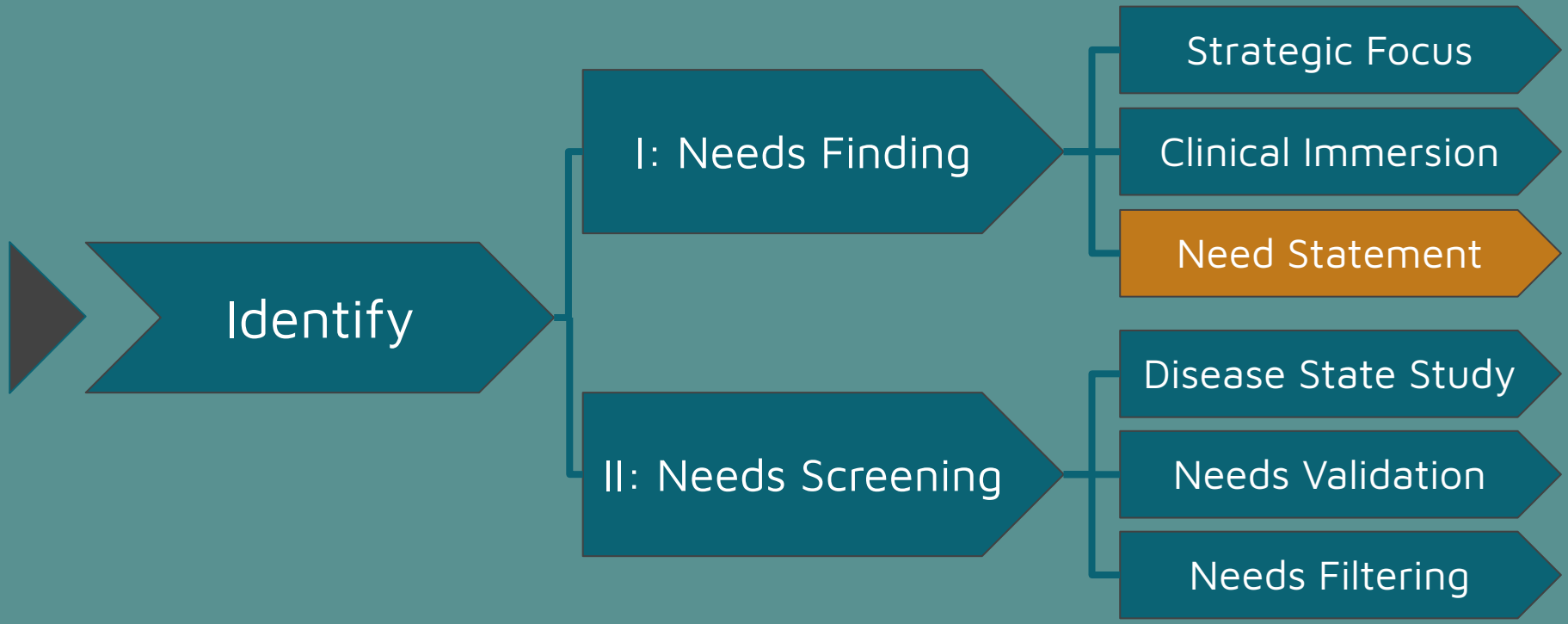
Clinical Immersion

Procedures Observed

~160

- All observations documented with time stamps
- Interactions with junior & senior doctors to understand the procedural pain points

Defective CBD stents extracted after an ERCP procedure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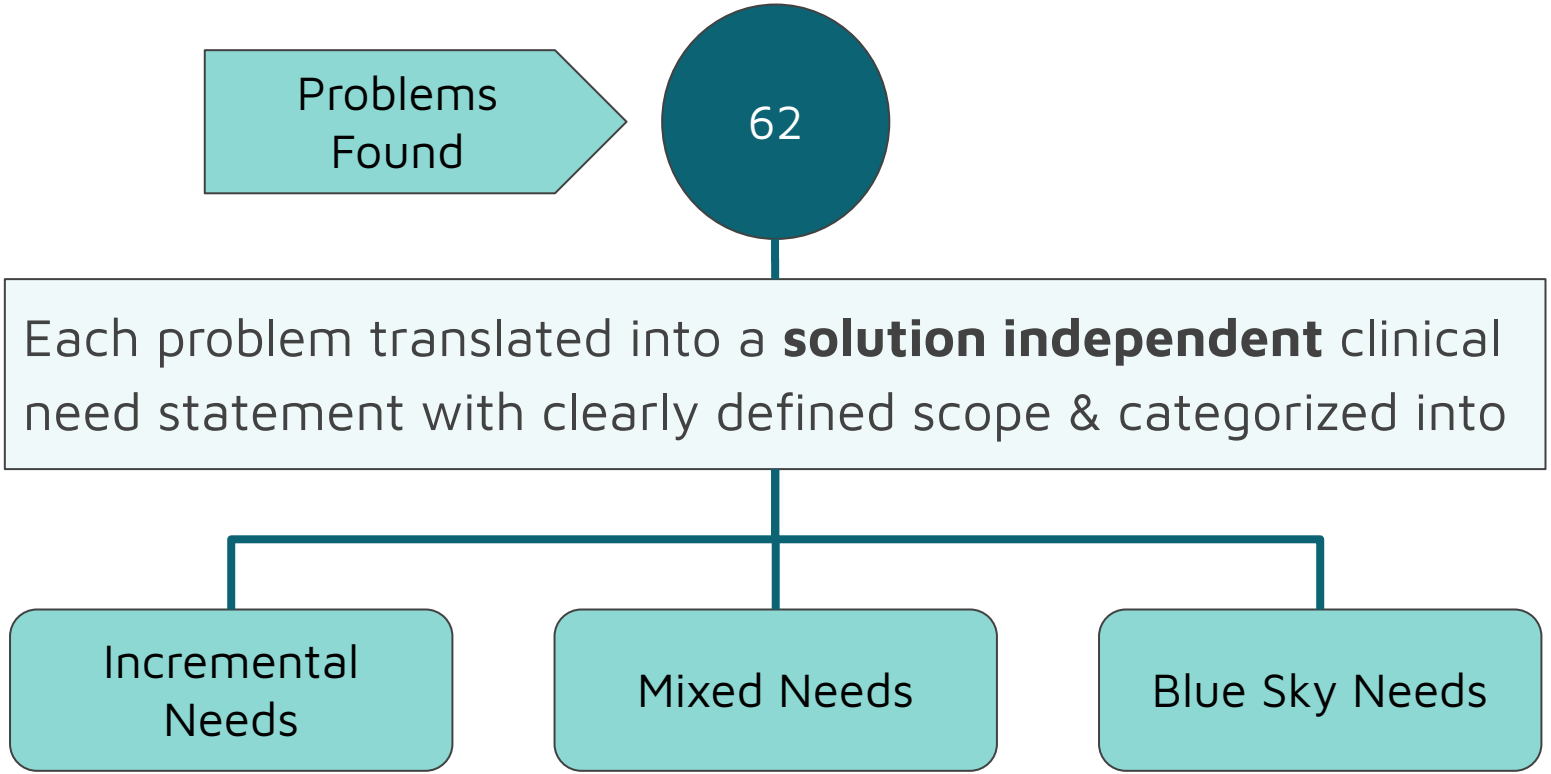
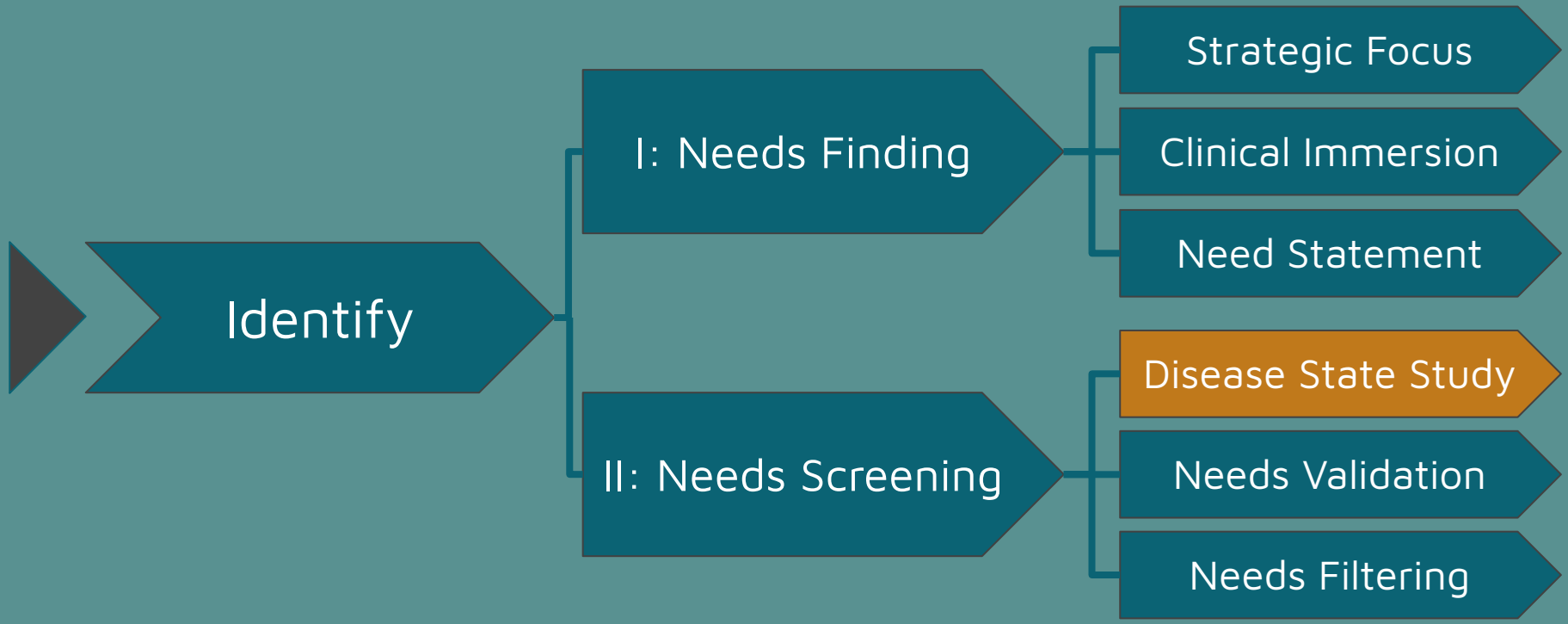
Need Statement Development

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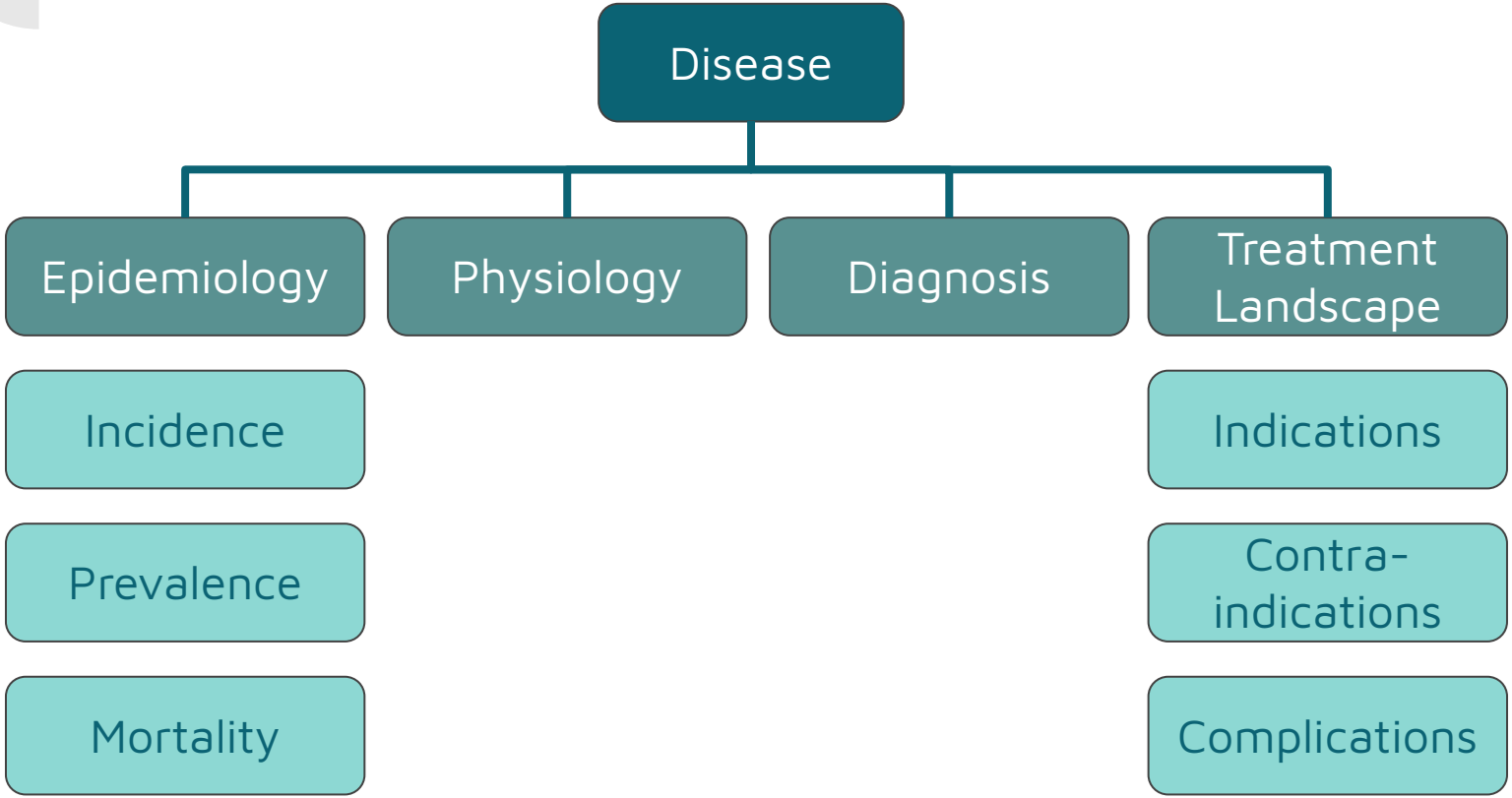
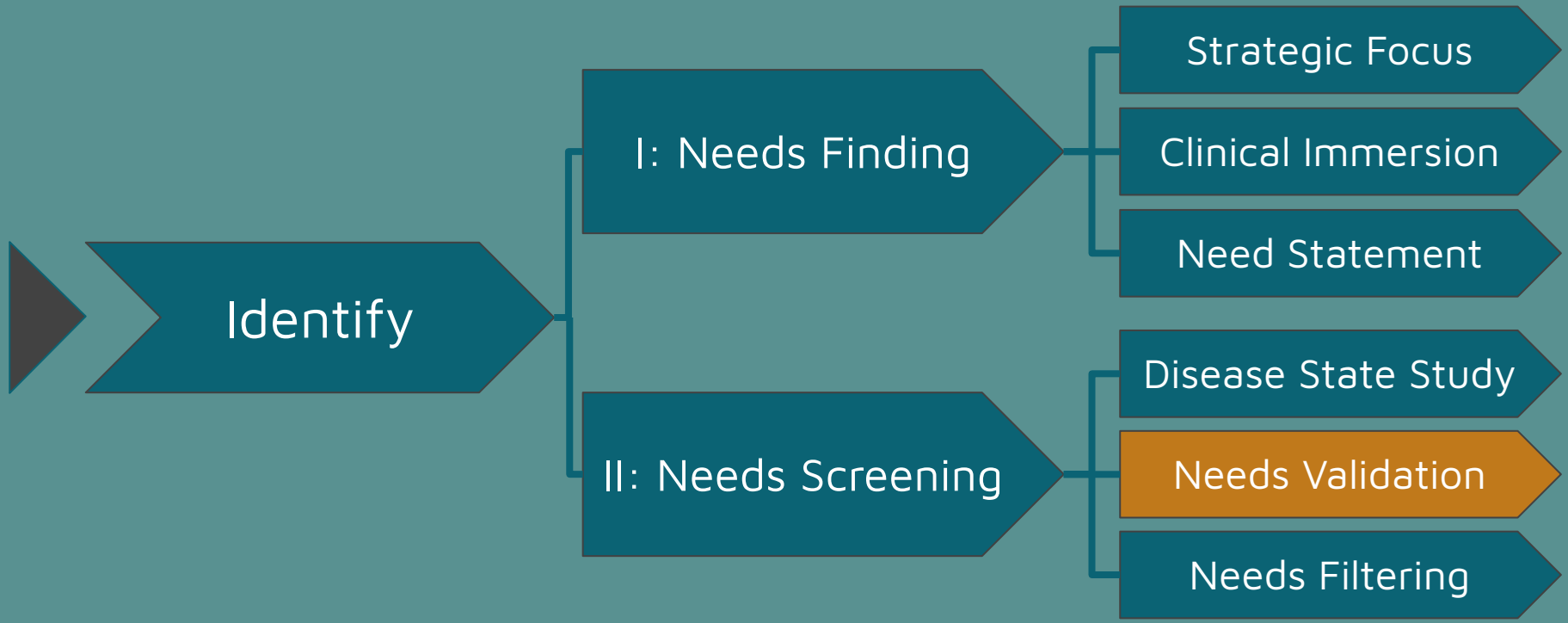
Disease State Study

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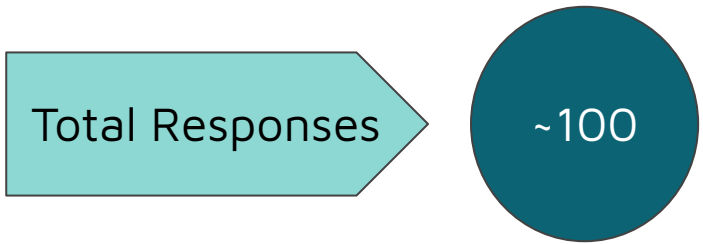
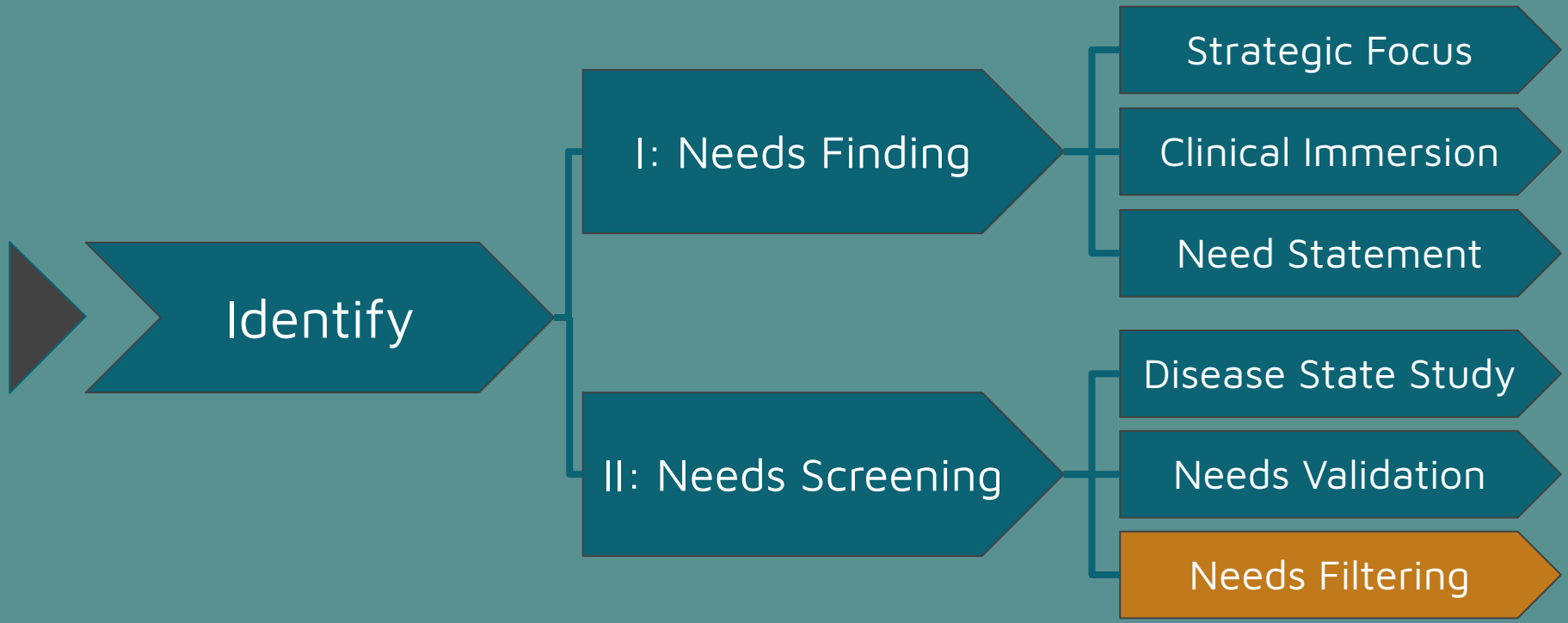
Needs Validation

- Questionnaire circulated amongst doctors from different departments
- Doctors asked to rate each need statement based on 2 parameters
  - Patient/Provider Impact
  - Treatment Landscape

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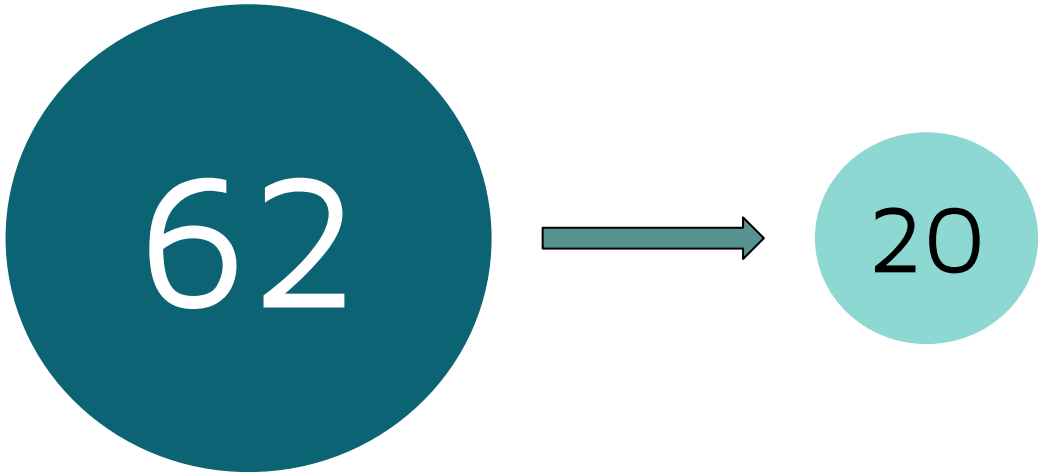
Needs Filtering - Filter 1

The feedback scores from the questionnaire as we was used as a primary filter for the need statements



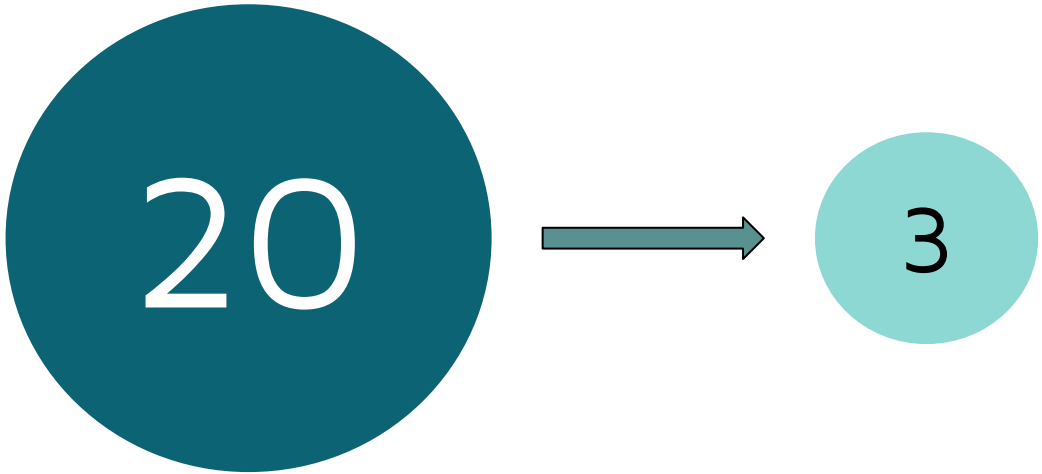
Market Analysis

Market Analysis involved analysis of the following for each need statement

- Epidemiology data to estimate market size & to segment the market
- Existing products to find gaps in user requirements & device specifications
- Opportunities & threats for developing solutions

Needs Filtering - Filter 2

Data from the market analysis & disease state studies was used to further filter the needs



Final Needs

A way to prevent blockage of Endo-Tracheal Tubes due to accumulation of secretions while reducing frequency of routine interventions

A way to provide prone ventilation to ARDS patients while accommodating for CPR

A way to prevent needle prick related failures of Arteriovenous Fistulas for patients on dialysis

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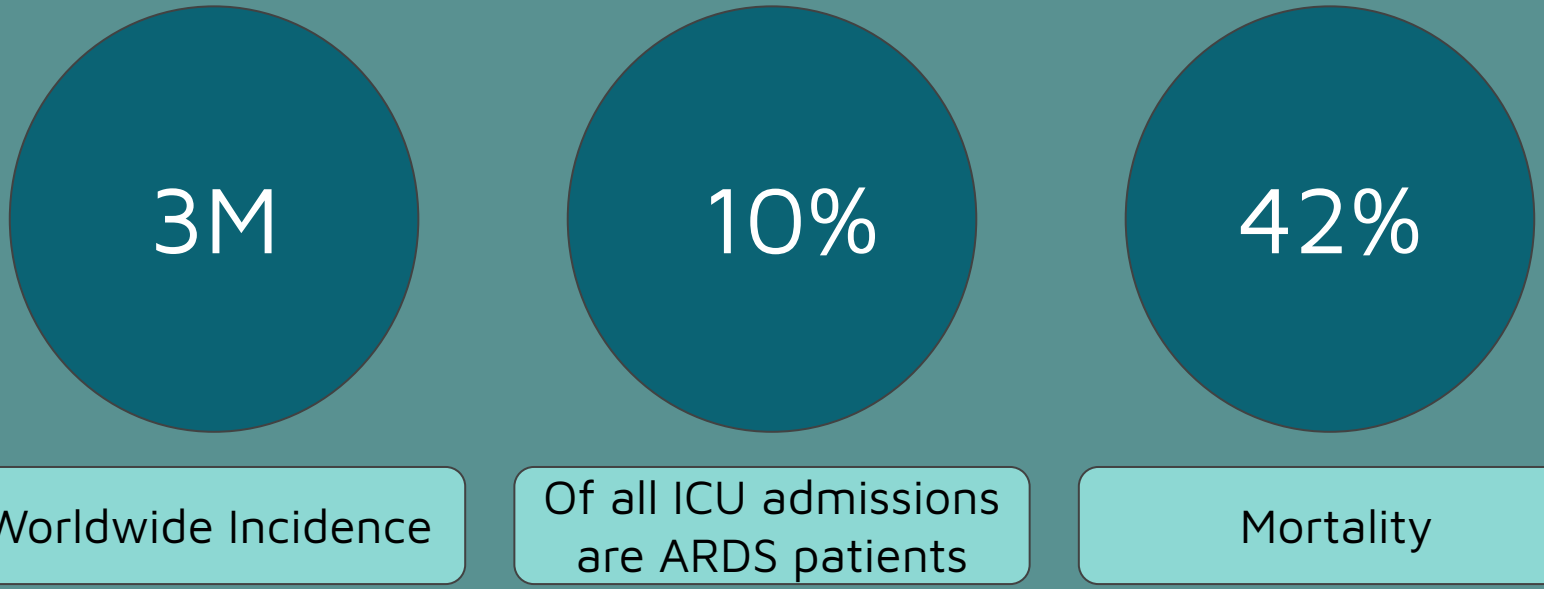
A way to prevent needle prick related failures of Arteriovenous Fistulas

ARDS Pathophysiology

- ARDS: Acute Respiratory Distress Syndrome
- Inflammation of lung tissue leading to collapse of air sacs & accumulation of fluid in the lung
- Triggered by a variety of factors such as sepsis, bacterial or viral lung infections, inhalation of vomit or water, pancreatitis, pneumonia etc.

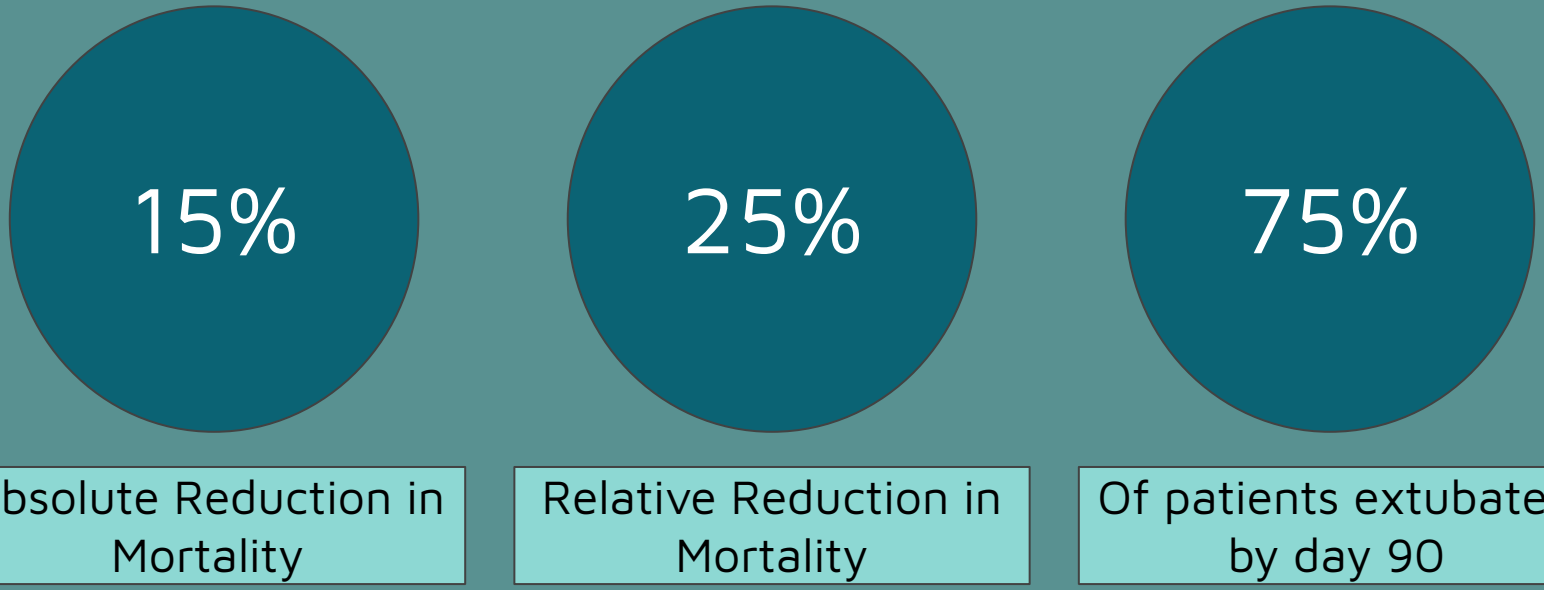
ARDS: The Numbers



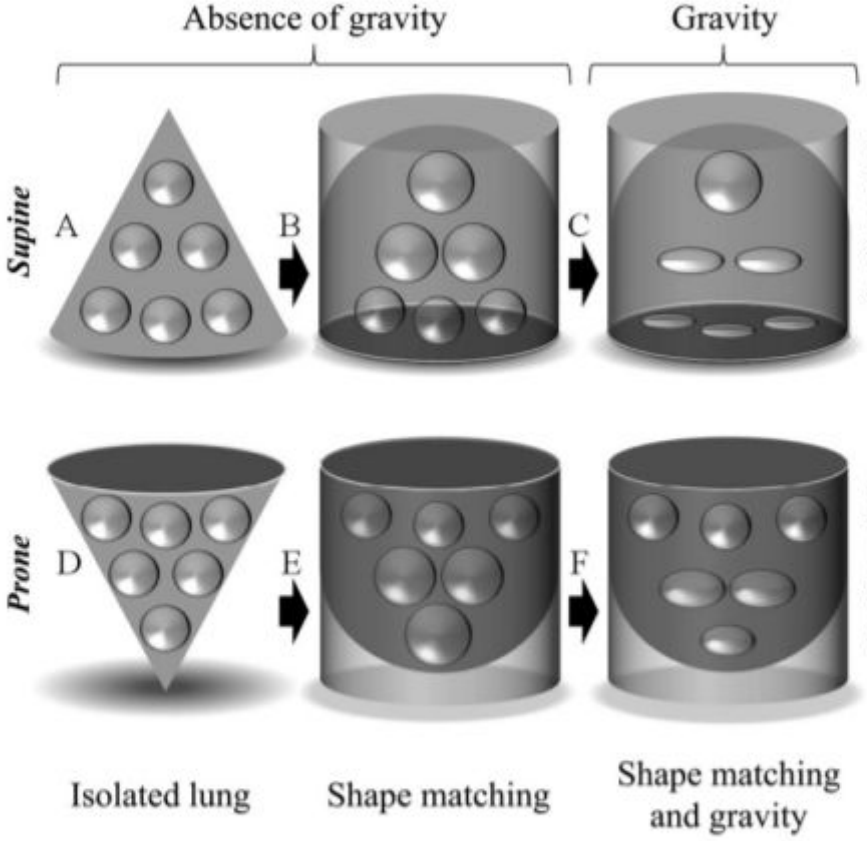
ARDS Treatment Landscape

- All ARDS patients are on mechanical ventilation while doctors treat root cause of ARDS
- Two methods of mechanical ventilation
  - Supine Ventilation
  - Prone Ventilation
    - Better for the patient as it is shown to result in improved oxygenation & lower chances of ventilator induced lung injury

Prone Ventilation: The Numbers



Prone Ventilation Physiology



2 effects balance each other in prone position

- Gravity
- Shape Matching

Issues with Prone Ventilation

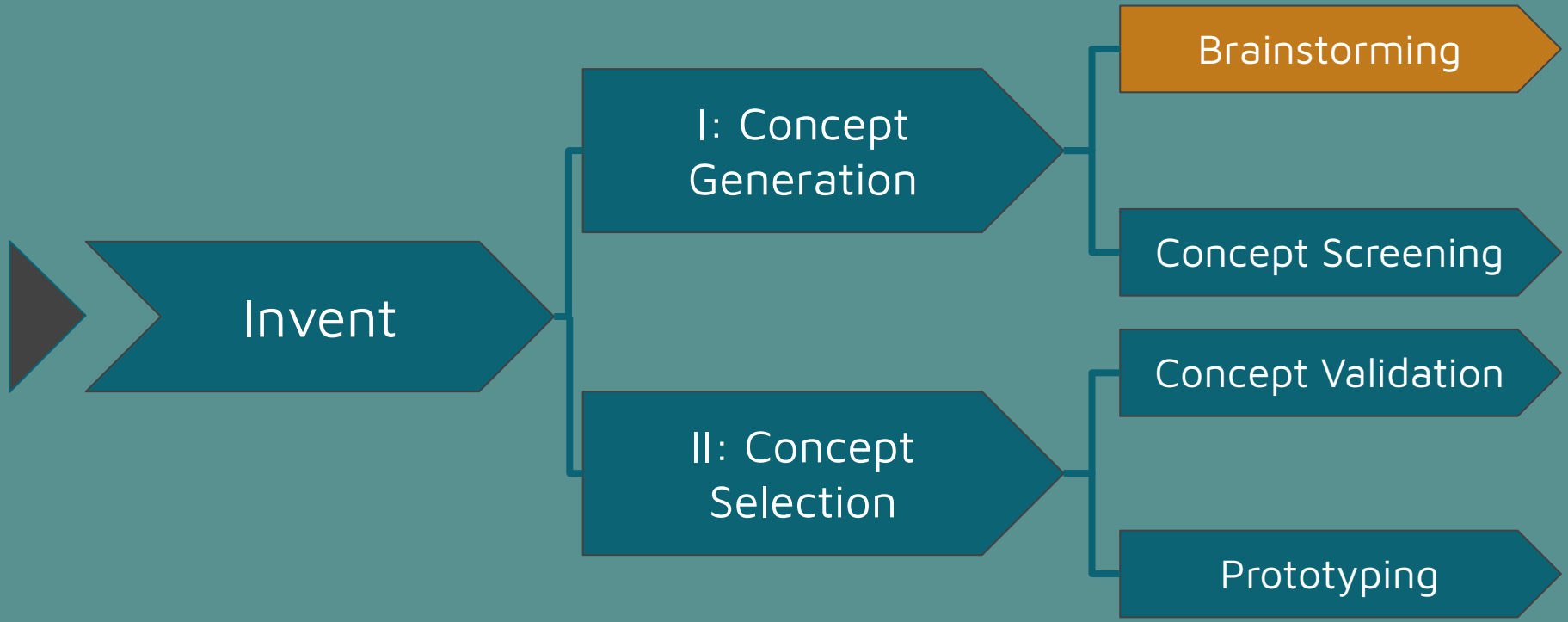
- Needs 6-8 **trained** personnel
- Difficult to provide CPR
- Detachment of tubings & lines
- Physical trauma to the patient while performing the procedure
- Difficult to examine patient in prone position
- Difficult to feed & suction patient
- Pressure sores & corneal Injuries

Need Criteria for MVP

Need Criteria - Must Haves
Prevention of physical trauma to patient
Provision for CPR
Accommodation of tracheostomy tubes
Prevention of dislodgement of attachments

Need Criteria for MVP

Need Criteria - Good to Haves
Reduction in effort in performing procedure
Reduction in time taken in performing procedure
Cost Effectiveness
Prevention of pressure sores
Prevention of Corneal injuries


Invent
I: Concept Generation
II: Concept Selection
Brainstorming
Concept Screening
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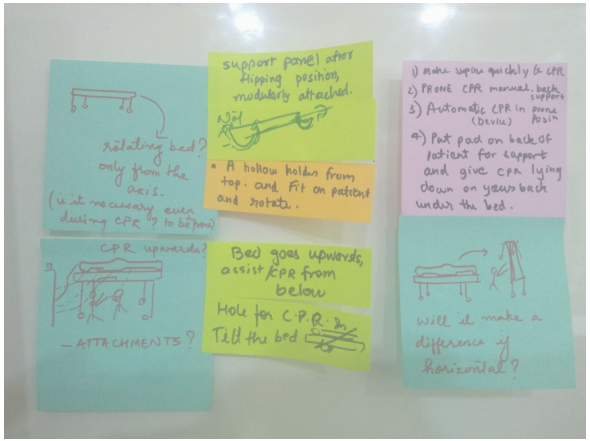
Prototyping

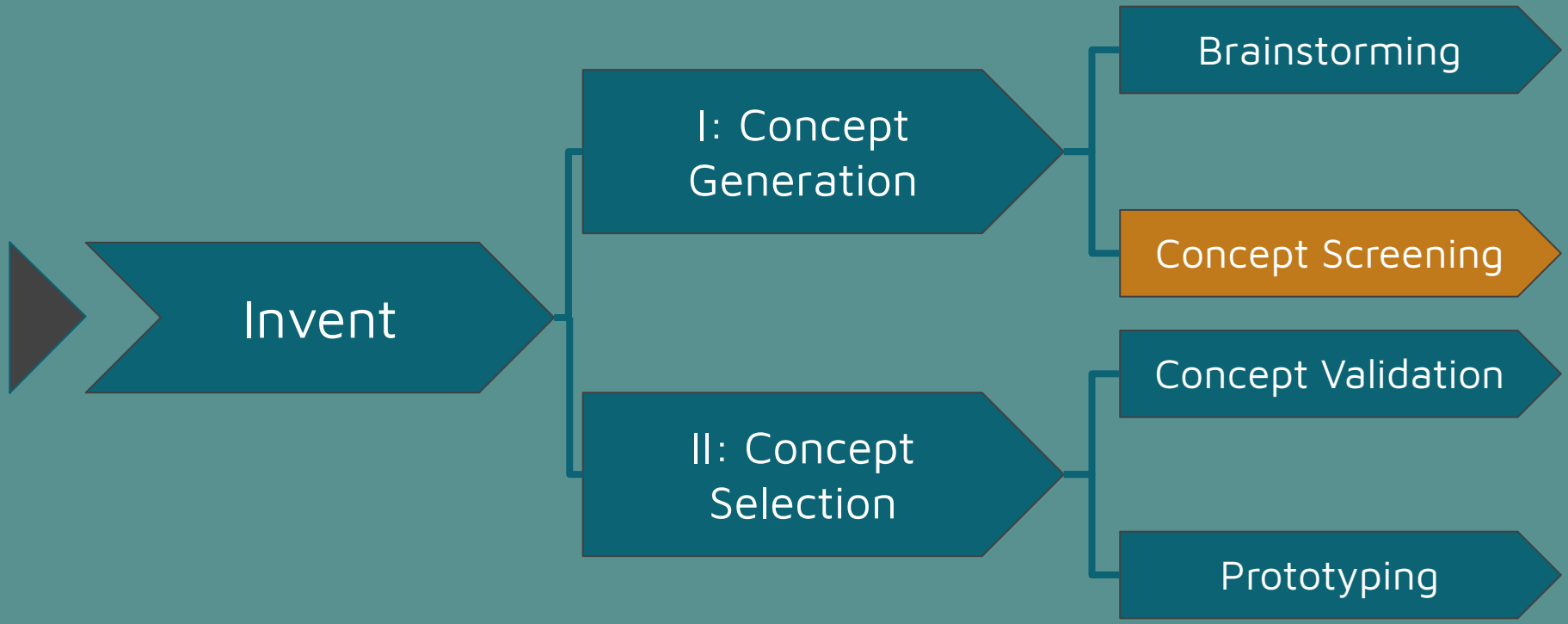
Ideation & Brainstorming

Brainstorming Rules:

- Defer Judgement
- Encourage Wild Ideas
- Build on Ideas of Others
- Go for Quantity
- One Conversation at a Time
- Stay Focused
- Be Visual



3 sessions → 132 ideas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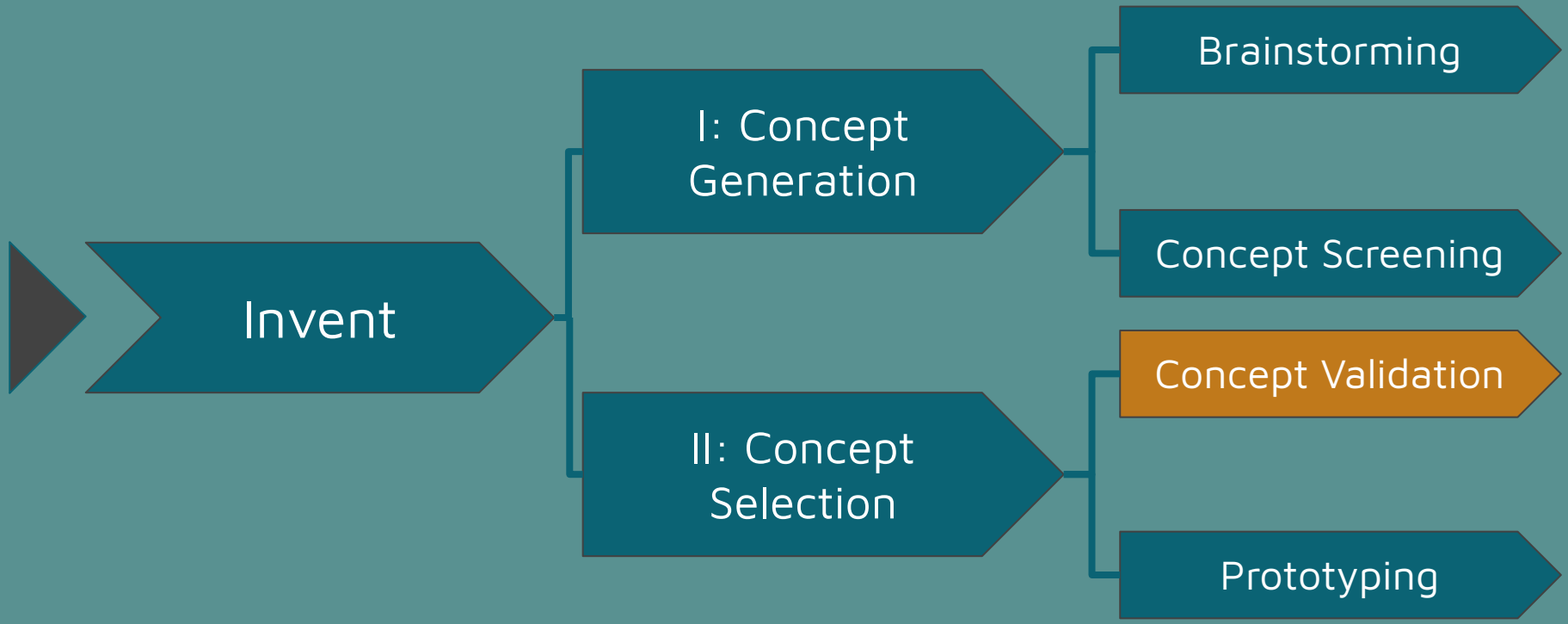
Concept Screening

- Grouping & Organization of Ideas
- Filtering out infeasible concepts
- Concept Mapping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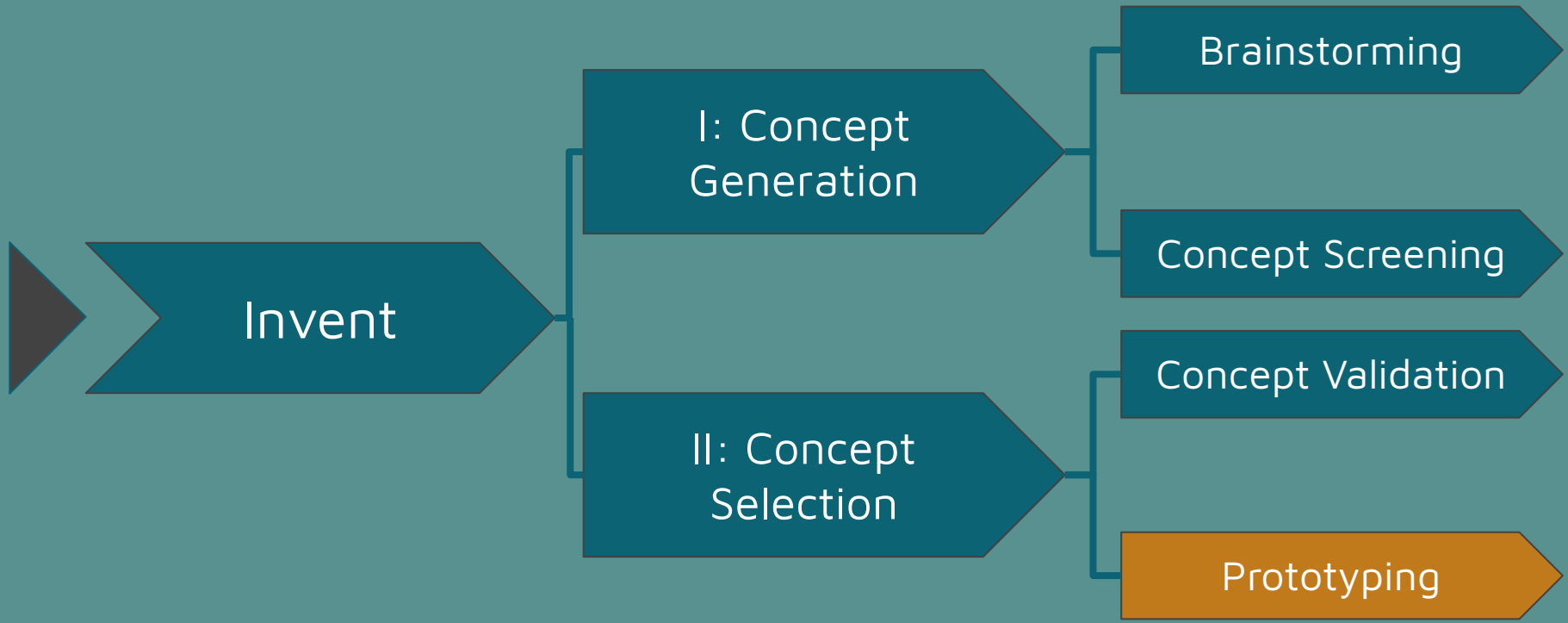
Concepts Validation

- Toy models made of lego, clay etc were developed for each main concept
- Models shown to ~15 intensivists at different hospitals for feedback
- New constraints of hospital economics found & applied to shortlist the best concept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References

1. Zenios, S., Makower, J., Yock, P., "Biodesign: The process of innovating medical technologies", Cambridge University Press 2010
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3. Mancebo, J., Fernández, R., Blanch, L., et al. "A Multicenter Trial of Prolonged Prone Ventilation in Severe Acute Respiratory Distress Syndrome", American Journal of Respiratory and Critical Care Medicine, 173(11), 1233–1239
4. Gattinoni, L., Taccone, P., Carlesso, E., and Marini, J.J., "Prone Position in Acute Respiratory Distress Syndrome. Rationale, Indications, and Limits" American Journal of Respiratory and Critical Care Medicine, 188(11)
5. http://ardsglobal.org/acute-respiratory-distress-syndrome/

Thank You!