Milestone 1 – Cover Page

Team Number: 36

Please list full names and MacID's of all *present* Team Members

Full Name:	MacID:
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Milestone 1 (stage 1) – Client visit Questions worksheet

Team Number: 36

As a team, prepare a preliminary **list of questions** to ask your client. Enter questions in the space below.

Preliminary List of Questions:

- *What procedures / mechanisms are currently in place?*
- *What are some of the downsides of the current procedure?*
- *What aspect of the current design needs to be improved?*
- *What is the most difficult part of the current procedure?*

Document any questions that come up *during* the client visit in the space below.

Additional Questions:

- ROP Introduction
- What is the size of the syringe?
- Is this a one time injection process?
- Should this process be administered directly through the eye?
- What degree can a baby move during the administration?
- Is delivery constant or varies in patients?
- Side effect?
- Alternatives?
- What finger is prefered for suppressing the eye?
- How do we check if the blood vessels are getting better?

- What changes in the past have applied to this surgery?

Milestone 1 (Stage 2) – Documentation of Discussion

Team Number: 36

As a team, document your discussions with the client during their visit.

What procedures / mechanisms are currently in place?

- Apply topical anaesthetic
  - For pain management
- Placement of sterile eyelid speculum to hold eye open
  - Numbing drops are added to prevent movement of the eye, yet movement is still a possibility
- Prepare area with antiseptic/antibiotic
- Determine injection site with calipers
- Bring thumb up to depress syringe plunger, injecting 0.25 mL medication
- It essentially reduces the size of blood vessels blocking the retina
- Procedure takes about 5 minutes
  - Risk increases with additional time, in general
  - Numbing drops last 20 min

What are some of the downsides of the current procedure?

- Could lead to clouding of the lens or retinal detachment
- Margin of error for premature babies is nearly 0
  - It is OK if you tilt the needle during the procedure, but not so much that you hit another part of the eye
  - Even if doctors can realize quickly when a mistake is made, it is difficult to correct such mistake

What aspect of the current design needs to be improved?

- Auto inject mechanism, instead of bringing thumb to the top of the syringe. A “stop” and “start” button

What’s the most difficult part of the current procedure?

- Since a tiny needle is used, the injection has to be 100% accurate, a 1mm difference can cause complications

ROP Introduction:

- A potentially blinding eye disorder that affects babies with birth weight < 1200g or gestational age at birth < 30 weeks
- The smaller a baby is at birth, the more likely it is for them to develop ROP

What is the size of the syringe:

- 4 - 6 mm needle length
- 0.50 mL or 1.00 mL volume
- 0.25 mL of anti-VEGF drug

Is this a one time injection process:

- Yes, one injection is enough for the blood vessel to regress
- After the surgery, the baby has to have a check-up every 40 weeks

Should this process be administered directly through the eye?

- Yes!
- Must be administered to the eye vessel, and an injection is the best way to get anti-VEGF to reach the retina

What degree can a baby move during the administration?

- Numbing drops are injected to prevent movement of the eye and other nurses within the surgery will also constrain the movement of the baby.

Is delivery constant or varies in patients?

- Tends to remain constant, as this administration only treats infants having significant ROP

Side effect?

- Most side effects do not relate to drugs, rather, it relates to the process of injection.
- If the injection goes too deep into the eye, it can go to the wrong structure.

Alternatives?

- Laser
    - BUT laser only prevents further harm, it doesn't get rid of the disease
    - It also causes scarring which results in areas in which you can no longer see
- Automated device.
    - Still, it should have a similar shape of a syringe

What finger is prefered for suppressing the eye?

- Index finger

How do we check if the blood vessels are getting better?

- Use of Binocular indirect ophthalmoscope (BIO)

What changes in the past have applied to this surgery?

- Type of anti-VEGF changes within the history.

Milestone 1 (stage 3) – Customer Requirements

Team Number: 36

As a team, develop a list of customer requirements that detail what the proposed solution should do and achieve. For each requirement, categorize in parentheses as an objective, constraint or function. As a reminder, requirements ***can be*** *more than one* of the three.

List your customer requirements in this field. Bullet-point format is acceptable. Requirements can be written as either a brief sentence or 2-4 words, whichever is most appropriate. For each requirement, indicate (in parentheses) whether it is an objective, function, or constraint.

Objectives:

- Should improve accuracy of injection
- Should be lightweight
- Should be easy to use
- Should be comfortable to hold

Constraints:

- Must be sterile
- Must conform to safety standards
- Must administer medicine (anti-VEGF)
- Must fit within known size constraints determined by premature baby anatomy

Functions:

- Must puncture the eye
- Must deliver the drug to the location of vessels
- Must safely store medicine (anti-VEGF) prior to the surgery

Milestone 1 (stage 4) – Need Statement

Team Number: 36

Write your Need Statement in the space below. Recall that your need statement should:

→ Have a clearly defined problem (what is the need?)
→ Indicate your client (who has the need?)
→ Have a clearly defined outcome (what do you hope to solve and why is it important?)

NEED STATEMENT:	Pediatric opthamologists require a device to improve precision and reduce human errors during intravitreal ROP injection, since slight errors in needle placement can cause severe complications.