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## Neonatal Intraocular Injection and Delivery System

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Neonatal Intraocular Injection Device Executive Summary

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Department of Biomedical Engineering

**Honors Research Project**

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# Neonatal Intraocular Injection Device

## Executive Summary

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Biomedical Engineering, University of Akron  
April 25, 2023

### I. Introduction

Currently, ophthalmologists use diabetic insulin needle syringes to introduce medication to the neonate eyeball. They estimate the injection location with hand-held calipers. This may allow the medicine to be misplaced and introduce preventable errors.

Major issues identified by the client revolve around two problems: 1. The delivery of the correct volume of medicine, and 2. Delivery to the correct location in the neonatal eye. The amount of medicine being injected can be as little as 10  $\mu\text{L}$ , an extremely small volume. Small syringes with volumes between 0.3 and 1 mL are the item doctors use to obtain such precision, but this can still be improved. The location of injection for this drug and procedure involves measurements less than a millimeter, opening another region for error. The injection site is to be 2-4 millimeters from the limbus posteriorly on the eyeball. This unique distance must be measured prior to injection to ensure accurate delivery. Current methods for obtaining this measurement are poor and can cause misplacement.

The syringes used in this procedure now are the Monoject 0.3 mL insulin syringe and the BD 1 mL tuberculin syringe [1]. These products do not offer the best volume precision and hinder needle placement by being rather small. Additionally, they are used in combination with calipers which can be cumbersome.

A handful of technologies exist for helping the placement of the needle during injection [2]. The InVitria Injection Assistant situates on top of the iris and has a slot to guide the needle [3]. However, this slot is for 3.5 millimeters from the limbus and is not adjustable. Other devices act as an eye speculum and guide at once. The Rapid Access Vitreal Injection Guide (RAVI Guide) holds the eyelid back while also providing a hole to guide the injection [4]. The injection distance again is not adjustable and does not provide optimal precision.

The necessity for these injections stems from a condition that develops in some premature neonates called retinopathy of prematurity (ROP). This disease manifests in the retina of one or both eyes and entails extreme vascular growth [5]. This is because, during the last 12 weeks of pregnancy, the eyes and retina of the neonate develop rapidly. When born prematurely, this rapid development may not be stopped. ROP has stages ranging from abnormal vessel growth (stage 1) to complete retinal detachment (stage 5). The condition can cause permanent blindness and other vision issues, especially if left untreated.

### II. User Needs

The user needs relate mostly to the delivery of the correct volume of medication and the procedure of measuring and injecting the correct location. The syringe shall clearly label and deliver accurate volumes of medicine between 0.02 mL and 0.2 mL while still being disposable. The additional device for measuring distance should help minimize adverse effects by guiding the needle more consistently and steadily without hindering the vision of the needle. This device shall also be easily controlled by those trained and should offer an adjustable aspect. Lastly, the combination of device and syringe needs to be affordable compared to the current solutions.

### III. Design Inputs

Quality Functional Deployment or QFD is a method of organizing user needs and requirements into quantifiable plans to implement the voice of the customer into the finished medical device. The user needs discussed above were shown to the clinical advisor and were rated on a scale of 1 to 5, where 5 was the most important user requirement

and 1 was the least important user requirement. QFD Phase 1 was also the time when potential competitors were evaluated in terms of how they could meet the customer requirements.

Each customer requirement was individually evaluated for all needed and foreseeable engineering requirements. The engineering requirements were either direct conversion from the customer requirements in which the unit for a requirement was changed, additional anticipated requirements, or ISO standards. Each engineering requirement had an associated target or limit value, in which the difficulty of achieving the values was evaluated.

The concept failure modes effect analysis (FMEA) was developed for a preliminary risk assessment for the device. Most of the failure modes centered around the needle and syringe during the concept FMEA. An example was the syringe-needle interface posed a concern about the potential for the parts to disconnect. This would risk an inaccurate dispense of the drug or the needle could fall out of the device and risk injuring the patient or doctor. Another risk was the incorrect dosing of medication. Since the amount of the drug was such a small amount there is a risk that the measurement markings on the syringe could be inaccurate or unable to be read.

Several standards are applicable to this device system, especially for the syringe and needle. These include standards for sterile single-use hypodermic syringes (ISO 7886-1), single-use hypodermic needles (ISO 6009), and syringe-needle interfaces (ISO 80369-7). Another applicable standard is the biological evaluation of medical devices that encounter the human body (ISO 10993-1).

#### IV. Design Process

Over the duration of the brainstorming sessions, two sketches and various concept solutions were purposed on how to find a solution. Some initial ideas were having a measuring attachment that would be secured over the patient's ear or the bridge of their nose. However, due to the variability in the size of the patients and the risk of the device securement relying on balance, it was concluded that those two would not be viable options. Another solution was the concept of having a long measuring stick that would be cut to the injection length and placed on the eye. The measuring stick would mimic a zip tie where you could pull through the length needed for the procedure and then cut. The needle would then be placed on the other end of the zip tie. Some concern with this design was the unknown material, the physician's ability to see where the material ended, and if the material would slide around on the eye.

Another concept design developed was having a measuring component attached to the side of the syringe with a probe that would extend next to the needle and measure the distance of where the injection should be. Moving the measuring component to the side would still allow the doctor to see the eye during the procedure. The device in contact with the eye would raise fewer concerns for adverse reactions to the material.

Each prospective device design was evaluated for its ability to accurately perform the desired task, as well as safety, manufacturability, cost, and ease of effective operation. The concept designs were compared to each other and how well they conformed to the identified criteria using a comparative matrix. The matrix used the customer requirements and engineering requirements as criteria, and each concept design was evaluated for its ability to satisfy each requirement on a scale of 1 to 5, where 5 is the high ability to satisfy the requirement and 1 is the inability to satisfy the requirement. The last concept solution was chosen for its high performance in each category, especially those deemed most critical, compared to the other two potential designs.

Phase 2 of the QFD evaluated the relationships between customer requirements and functional requirements. These relationships were evaluated on the scale of a strong relationship (9) to a weak relationship (1), and corresponding correlations were also evaluated to see how each requirement was linked to other requirements. This analysis allowed for the concept solutions to be more thoroughly evaluated, as the most important characteristics of the end device and allowed the interplay between each characteristic. This allowed critical functions to take precedence in evaluating each design and allowed for the best design to be picked using objective and clear criteria.

The precision syringe in our design fulfills engineering requirements regarding the volumes of medicine. For example, the syringe can inject 0.02-0.2 mL, clearly labels the total volume, can be operated with one hand, is Luer-lock compatible, and its diameter is that of a 1 mL-sized syringe. The final product will also be disposable and competitively priced. The needles to be used with the syringe are 30 gauge and half an inch in length. The novel part

of the device measures the distance from the edge of the limbus to the injection site. The device will be produced for injectable distances of 2, 3, and 4 mm.

## V.Design Outputs

Through the process of evaluating concept designs and choosing the most suitable design for the application to mitigate risks and maximize performance efficacy, it was necessitated that the frontrunning concept design be more thoroughly designed and evaluated. This process involved the selection of key parts and assemblies contributing to the overall design. There were 2 subassemblies selected, a syringe and a measuring guide. The syringe subassembly consisted of the individual parts of a syringe body, plunger cap, plunger rod, plunger head, and Luer-locking needle. The measuring guide subassembly consists of the measuring guide, measuring guide stick, and measuring guide cap.

Following formal identification of the key components and assemblies required for the design, 3D modeling of each component was performed using SolidWorks software. Each component was individually modeled using appropriate dimensions and specifications gathered from the customer requirements, engineering requirements, and relevant ISO standards. An assembly was created by mating the parts together as they would be on the final fabricated device to ensure that the design was appropriately dimensioned for each part. Drawings of individual parts and the completed assembly were created, including appropriate dimensioning and labels, for documentation and replicability purposes. The 3D models were directly used for 3D printing a functioning prototype for verification purposes using a resin printer, aside from the plunger rod and needle.

A bill of materials (BOM) was created to keep an inventory of all materials and purchased components required for project fabrication and verification. The BOM includes 2 syringes from McMaster-Carr and 1 box of 100 needles from Knixxo for design reference, understanding of device design feasibility, and verification testing. The BOM additionally includes 1 12-inch steel rod from McMaster-Carr for use in the fabricated prototype as a plunger rod to be used for verification testing. The BOM includes a cost reference, with itemizations for the \$145.45 spent of the \$500.00 project budget.

## VI.Design Verification

The design verification will have additional verification tests, but two tests have been planned and one test has been performed. The first verification test is the volume test, and it is to test the first engineering requirement. The second verification test was the measurement test and was utilized to determine the injection distance of the needle (d) from the limbus of the eye to be 2 mm. The method of verification was an inspection by measurement. The distance (d) from the measurement test was found to be 1.98 mm. The acceptance criteria for the distance were  $1.90 \text{ mm} \leq d \leq 2.10 \text{ mm}$ . Since the inspection distance was within the range of acceptance then the design met the engineering requirement.

## VII.Medical Device

The final medical device was 3D printed so the validation tests could be conducted regarding the accuracy and integrity of the device. After a few iterations, the device was tested using a mock clinical procedure.

## VIII.Validation

A validation plan was created and carried out to assess how the medical device compared to the customer's requirements. There was a total of seven customer requirements validated through the methods of test, inspection, and analysis. There were three customer requirements that were unable to be validated and this was justified through the literature found and documented in the validation protocol document. For example, according to manufacturing policies, the desired size of the syringe necessary for the procedure could not be made from plastic as a requirement stated and must be made of glass for precision purposes. There were two tests performed through the analysis method to assess affordability and disposability. The main form of validation used was inspection by the clinical mentor, Dr. Hertle. This was performed by recording a video demonstration of the medical device and receiving feedback from the mentor. The requirements validated through this method focused on how the device was operated

and how accurately the device can guide the needle without obstructing the view of the user. Feedback from the mentor stated that the requirements given were accomplished, meaning the validation test passed.

#### IX. Risk Mitigation Process

The risk assessment process allowed us to evaluate which parts of our design raised extra concern. Overall, in accordance with the risk priority number (RPN), all potential failure modes fell under an acceptable range except three that were under the investigate section with an RPN value of 32. These were investigated further, and actions were taken to mitigate these risks. All these risks further investigated were related to the measuring device. These were the possibility of the angle of the measuring device being inaccurate, the measuring device forcefully contacting the patient's eye, and the measuring device breaking. The mitigation process for these concerns included verification testing for the angle of the measuring device and creating a protocol for doctors to follow during the procedure to decrease these risks.

#### X. Summary Feasibility Discussion

The device ultimately satisfied the needs identified at the beginning of the project. Despite the scope of the device changing throughout development, the measuring guide satisfied the need of clinicians to have a device that can more easily and accurately guide a needle to the correct injection site than current solutions and remain cost-effective. Through device validation and testing, confidence was gained in this device as a solution to real-world medical needs to enhance current practices and reduce user error in clinical contexts. The device is most likely to be adopted by systems and individuals to augment current solutions to improve patient outcomes. The product would become available for sale following manufacturing, marketing, safety testing, and patenting processes, but the current fabrications and research predict future success in all areas of the process of putting the product on the market.

#### XI. Discussion, Lessons, and Conclusion

One major problem during this process was learning that part of the original design was not feasible. Originally, the design encompassed a measuring device and syringe, however, we learned during the beginning of the second semester that a plastic syringe was unable to be manufactured precisely at the dimensions that were required. This prompted some reworking of the FMEA, user needs, and a lot of work put into the design of the syringe had gone to waste. This also meant there needed to be changes to the measuring device to fit a standard glass syringe instead of the syringe that was created by the team.

#### XII. Future Work

The project could be more broadly applied to guide intraocular injections to treat multiple different conditions and age ranges. The device can be adjusted simply by calculating a new angle for the probe to alter the distance between the tip of the needle and the probe. The sizes of 3 and 4 mm were easily implemented into the design. This would greatly increase the potential market for this device. Improvements to the manufacturing of the device can be made. Currently, the 3D print of the device contains some minor flaws. Changing to a manufacturing setting with dies and molds would eliminate most of the flaws associated with the quality of the device.

#### XIII. Individual Roles and Responsibilities

As a group, each member made individual contributions to continue accomplishing the tasks needed to complete the project. The professor assigned a project manager position for each team and for ours, that role was assigned to Marie Kosco. Marie has made impactful contributions to the team by organizing meeting dates and communicating tasks that needed to be completed with the group. She spearheaded the creation and completion of the QFD, has been the spokesperson when speaking to our clinical mentor, and described the goals and objectives detailed in this report. Marie was crucial when it came to brainstorming a prototype and creating the following 3D models. She also handled most of the validation plan and execution. Jackson Carrell's individual contributions can prominently be seen in the background research we had to conduct to have the knowledge necessary to complete our project. He did a wonderful job finding information relevant to the device we are creating and continues to have this knowledge in his back pocket during the brainstorming sessions we started having during our design process.

Jackson also helped with creating a prototype and the necessary 3D models. The last role for Jackson was aiding with a small portion of the validation plan. Cory Ramsey has assisted in the development of our project in meaningful ways. He contacted and conducted an interview with one of our stakeholders, created the risk assessment and mitigation pathways for the device, and consistently updated our work logs. He will continue to contribute by updating the work logs, creating a prototype, and other tasks deemed necessary. Nina Treacher has contributed to the project in various ways. She ran the competitive analysis for the device, set up and maintains the faculty mentor position for the project, and made significant contributions to the FMEA. She continued to contribute to the group by working on phase 2 of the QFD, keeping the faculty mentor in the loop, and completing other tasks assigned by the project mentor. Nina also helped lead the risk mitigation process. Our project is very collaborative, and all members have assisted and contributed to the whole project, creating a group environment that will continue to be productive in the spring semester. Future contributions are subject to change depending on the route our project takes during the design process.

#### XIV. Professional and Ethical Responsibilities

To engineer a device for use in a professional or medical setting, the utmost emphasis must be placed upon the professional and ethical responsibilities of the engineers involved in the design and fabrication process. It is essential that due diligence is carried out for all steps of the engineering process, from research to fabrication. A medical device is inherently designed to interface with a human for the benefit of the health of the individual. As a result, serious consideration must be given to the potential risks, failure modes, use cases, and ways the design could harm an individual beyond the ways a design could be used to solve a clinical problem in a perfect-use scenario. The ethical and professional duties of the engineer are thus to prevent risk where possible while improving upon current procedures in a safe, effective, and proven manner by course of intensive, focused research and honest publication of results.

#### XV. Acknowledgements

The team would like to thank the clinical mentor, Dr. Hertle, the faculty mentor, Dr. Nguyen, as well as Steve Patterson, and Professor Elijah Wreh for their guidance and expertise with the project.